Oracle® Life Sciences Clinical One Platform

Sponsor and CRO User Guide

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Primary Author: Oracle Life Sciences Documentation Team

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Preface

This preface contains the following sections:

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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I'm a new user. Where do I start?

- Get sign-in information
  To start working, you must be provisioned in Oracle Life Sciences Identity and Access Management Service, and you must obtain the product URL from your organization's delegated administrator.
- Learn how to navigate in Oracle Clinical One Platform
  Learn how to access the study settings to configure your study, view existing study versions and their designs, and access your study in different modes.
- Operate a clinical study in Oracle Clinical One Platform
  Understand the stages of a study flow and how different users collaborate to build a study and manage data in Oracle Clinical One Platform.
- Get trained as you work
  When you navigate to a new page, you're prompted to complete the training assigned to you for the page. After you complete the training, you can start working on the page. Training is assigned according to your roles, so all training is relevant to your work.

Get sign-in information

To start working, you must be provisioned in Oracle Life Sciences Identity and Access Management Service, and you must obtain the product URL from your organization's delegated administrator.

What you need to start working

You need to have all necessary roles from Oracle Life Sciences IAMS and from Oracle Clinical One Platform assigned to your account before you can work in Oracle Clinical One Platform. If you're responsible for user management and study design, see the *Add Users Guide* for details on provisioning yourself and others.

User name and password

After the delegated administrator creates your account in Oracle Life Sciences IAMS, you receive up to two email messages with account activation instructions.

For step-by-step instructions, see Oracle Life Sciences SSO account notification.

Product URL

The URL is sent to your delegated administrator, who is responsible for sharing it with all Oracle Clinical One Platform users at your company.

Bookmark the URL that was given to you, not the URL that appears in your browser after you open the application. If your browser doesn't let you bookmark a typed URL, you can always bookmark the URL that appears after you open the application and then edit the URL of the bookmark to use the URL that was given to you.

Learn how to navigate in Oracle Clinical One Platform

Learn how to access the study settings to configure your study, view existing study versions and their designs, and access your study in different modes.

- Open the study settings
  Open the study settings to update general information about your study, as well as to set up facilities, manage users and study roles and define Source Data Verification (SDV) strategies, and other settings.
- Open the study in Draft mode
  Open a study in Draft mode to configure or update a study version's design.
- Open the design of a study version
  View the study versions available in the different modes and get details about the visit schedule, forms, treatment arms, randomization, and kits configured in the study design of a given study version.
- Access your study in a specific mode
  You can operate a study in different modes depending on what you want to achieve. Use *Testing* mode to test and verify a study version with mock data, *Training* mode to train users that will operate your study using mock data, and operate your study in *Production* mode to manage real data.
- What keyboard shortcuts can I use?
  Oracle Clinical One Platform supports the following keyboard shortcuts provided by Oracle JET.

Open the study settings

Open the study settings to update general information about your study, as well as to set up facilities, manage users and study roles and define Source Data Verification (SDV) strategies, and other settings.

To have access to a study's settings you must make sure that the following prerequisites are complete:

- You must be provisioned with the appropriate permissions, either as a global user or at the study level.
- The study version that you are working in must be moved to either the Testing, Approved or Archived container. This ensures that the study's settings are available for you to navigate and configure.

1. On the Home page, locate your study.
2. Click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

The setting page opens with the following tabs available:

- **General**
- **Sites & Labs**
- **Depots**
- **Users**
- **Study Roles**

- **Codelist**
- **Study Settings**
- **Supply Settings**
- **Device Settings**
- **Source Data Verification**
- **Signature Configuration**
- **Archives Settings**

> **Note:**
>
> Depending on your role and permissions within the study, some of these tabs may or may not be available to you.
> **Can't see what you are looking for?** Reach out to your user administrator to revise your permissions.

To go back to the home page, click **Home** in the upper right corner of the screen.

Open the study in Draft mode

Open a study in Draft mode to configure or update a study version's design.

1. On the Home page, locate your study.
2. Click the pencil button () on the study you want to edit.

   The *Draft*, *Testing*, *Approved* and *Archived* containers are displayed below the study name.

   > **Note:**
   >
   > If you cannot see the Edit Study icon (), reach out to your user administrator to revise your role and permissions within the study.

3. In Draft, open an existing draft version or create a new one:
   - **Open an existing draft study version**: locate and click the existing study version in the Draft container to open it.
   - **Create a new draft version**: click **Create Study Version**.

     > **Note:**
     >
     > If you already have a draft version of the study, **Create Study Version** is not available below Draft. To create a new version of the study, you must first drag the Draft version of the study to either Testing or Archived.

The new draft version is a copy of the latest version of the study. The latest version of the study has the highest fourth number (for instance, 4 in 1.0.0.4). When you create a new draft version of a study, this number increases by 1. For example, 1.0.0.1 becomes 1.0.0.2.

The study version's design is then available to make updates as required.
To go back to the home page, click **Home** in the upper right corner of the screen.

Open the design of a study version

View the study versions available in the different modes and get details about the visit schedule, forms, treatment arms, randomization, and kits configured in the study design of a given study version.

> **Note:**
>
> Opening the study design of a *Testing*, *Approved* or *Archived* version can only be done in read-only mode. You cannot edit any design details. Updates to the study design can only be made to a *Draft* study version. See Open the study in Draft mode.

1. On the Home page, locate your study.
2. Click the pencil button () on the given study.

   The *Draft*, *Testing*, *Approved* and *Archived* containers are displayed below the study name. Study versions associated to a given mode are listed in the respective container. Do this when you want to verify that there is a study version associated to the Testing or Production (*Approved*) mode.

   > **Note:**
   >
   > If you cannot see the pencil button (), reach out to your user administrator to revise your role and permissions within the study.

3. To open a study's design in read-only mode, click a study version under *Testing*, *Approved* or *Archived* containers.

Access your study in a specific mode

You can operate a study in different modes depending on what you want to achieve. Use *Testing* mode to test and verify a study version with mock data, *Training* mode to train users that will operate your study using mock data, and operate your study in *Production* mode to manage real data.

1. On the Home page, locate your study.
2. Determine in which mode you need to work:

Option	Steps
Testing	Click the Testing mode icon () for a given study.

Option	Steps
Training	Click the Training mode icon () for a given study.
Production	Click a study's ID. ***Tip**: By clicking on the study row, next to the study ID, a dashboard displays on the right side pane where you can view a summary of **Open/ Answered Queries**, **Shipments in Transit**, and **Total Subjects**. Clicking on any of these fields will take you to a designated page to get more details.*

What keyboard shortcuts can I use?

Oracle Clinical One Platform supports the following keyboard shortcuts provided by Oracle JET.

Table 1-1 Keyboard shortcuts

Action	Key
Move focus from outside a table to the first column header, or from the first column header to the next focusable element outside a table.	Tab
Move focus from an actionable row in a table to the next focusable element within the row, or from the last focusable element within a row to the first focusable element in the row.	Tab
Move focus from the first row in a table to the first column header, or from a row in a table to the previous focusable element outside of the table.	Shift + Tab
Move focus from an actionable row in a table to the previous focusable element within the row, or from the first focusable element in a row to the last focusable element in the row.	Shift + Tab
Move focus to the next row in a table.	Down Arrow
Select the row and move focus to the next row in a table.	Shift + Down Arrow
Move focus from a row to the previous row in a table, or from the first row to the column header.	Up Arrow
Select the row and move focus to the previous row in a table.	Shift + Up Arrow
Move focus to the first row in a table.	Home
Move focus to the last row in a table.	End
Select a row in a table.	Space

Operate a clinical study in Oracle Clinical One Platform

Understand the stages of a study flow and how different users collaborate to build a study and manage data in Oracle Clinical One Platform.

> **Note:**
>
> Some of these tasks may not be required depending on your study's objective. Reach out to your Oracle point of contact for more details about the tasks specific to set up and manage your study.

Create a study and manage users

> **Tip:**
>
> It is not necessary that you create all users in order to start building your study. However, you may want to consider creating your custom study roles at global level before creating the study, so they are included when the study is created.

See Before you configure a study and refer to the *Add Users Guide* to get more details about user management.

Tasks	Users who typically do this
• Create user accounts in Oracle Life Sciences Identity and Access Management Service(IAMS) • Provision product roles	• Delegated administrator in Oracle Life Sciences Identity and Access Management Service (IAMS)
• Create and manage global users in Oracle Clinical One Platform • Create study roles at global level	• Product Administrator as either: – Study Creator (global role) – Global User Manager (global role)
• Create a study • Activate your study	• Study Creator (global role)
• Create and manage system-level codelists	• Code List Manager (global role)
• Create a study-level study role • Specify data classifications for study roles • Add users to your study	• Product Administrator as either: – Study Creator (global role) – Global User Manager (global role) • User Administrator

Design a study

See Design a study.

Tasks	Users who typically do this
• Create and manage study-level code lists • Create forms • Create visits and events • Add a form to a visit • Define the visit schedule • Create treatment arms • Create the randomization design • Create kit types • Define the dispensation schedule	• Study Designer

Configure a study for Testing mode

> **Note:**
>
> First, you configure your study in Testing mode to verify that the study's settings match your protocol requirements. Once your study version is verified and approved, you can proceed to configure your study in Production and Training modes.

Table 1-2 Set up facilities and define settings

Tasks	Users who typically do this
• Make a study version available in Testing mode	• Production Administrator • Oracle Designer • Study Creator (global role) • Study Designer
• Specify study settings • Add regions for region-blocked randomization • Specify settings for Source Data Verification • Create a Source Data Verification strategy	• Study Manager
• Add depots • Add sites • Specify supply settings • Create a resupply strategy	• Clinical Supply Manager
• Add site and depot users and make sure users are assigned to the correct sites and depots • Create labs	• User and Site Administrator

For more details, see Set up facilities and Define settings.

Table 1-3 Manage randomization and supplies

Tasks	Users who typically do this
• Generate a randomization list	• Production Administrator • Statistician
• Generate a kit list • Create manufacturing and blinded lots to manage expiration dates • Create label groups and assign kits to them	• Clinical Supply Manager

For more details, see Manage randomization and Manage supplies.

Make your study live in Testing mode and verify it

For more details, see Make a study live and Verify a study in Testing mode.

Tasks	Users who typically do this
• Specify and review settings before verifying a study • Assign a resupply strategy to depots • Activate depots	• Clinical Supply Manager

Tasks	Users who typically do this
• Assign a study version to a site • Select a resupply strategy for a site • Activate sites	• Site Administrator
• Specify a ship date for automatically generated shipments or release kits to sites or depots	• Clinical Supply Manager
• Verify a study **Note:** To verify a study you must add subjects, collect data, manage kits and shipments and run reports. For more information, refer to the Work during the study conduct period chapter and the *Site User Guide*.	Adding subjects and collecting data require permissions associated with: • Site User The rest of the tasks require permissions associated with: • Clinical Supply Manager • Other sponsor users

Create and manage custom rules

For more details, see Create and manage custom rules.

Tasks	Users who typically do this
• Create rules in Testing mode • Prepare your rule for testing • Test and approve rules • Publish a rule	• Rules Designer

Configure a study for Production and Training mode

Note:

- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.

Table 1-4 Set up facilities and define settings

Tasks	Users who typically do this
• Make a study version available in Production	• Production Administrator

Table 1-4 (Cont.) Set up facilities and define settings

Tasks	Users who typically do this
• Specify study settings • Add regions for region-blocked randomization • Specify settings for Source Data Verification • Create a Source Data Verification strategy	• Study Manager
• Add depots • Add sites • Specify supply settings • Create a resupply strategy	• Clinical Supply Manager
• Add site and depot users and make sure users are assigned to the correct sites and depots • Create labs	• User and Site Administrator

For more details, see Set up facilities and Define settings.

Table 1-5 Manage randomization and supplies

Tasks	Users who typically do this
• Generate a randomization list	• Production Administrator • Statistician
• Generate a kit list • Create manufacturing and blinded lots to manage expiration dates • Create label groups and assign kits to them	• Clinical Supply Manager

For more details, see Manage randomization and Manage supplies.

Make your study live in Production and Training modes

For more details, see Make a study live.

Tasks	Users who typically do this
• Assign a study version to a site • Select a resupply strategy for a site • Activate sites	• Site Administrator
• Assign a resupply strategy to depots • Activate depots • Specify a ship date for automatically generated shipments or release kits to sites or depots	• Clinical Supply Manager

Work during the study conduct period

Table 1-6 Manage training of your study team

Tasks	Users who typically do this
• Assign and track In-product training	• Training Manager
• Get trained as you work • Practice data entry in Training mode	• Sponsor Users • Site Users

Table 1-7 Conduct the study

Tasks	Users who typically do this
• Add subjects • Receive shipments • Enter data and dispense kits • Manage investigational product	• Site User
• Manage shipments • Manage kits at the site and study level	• Clinical Supply Manager
• Monitor subjects and sites • Create and manage queries • Archive a study version, decommission and recommission a study	• Sponsor Users
• Run and download a report, data extract, or archive	• Sponsor Users • Site Users
• Analyze data and share your insights with Oracle Clinical One Analytics	• Data Manager • Other sponsor users

For more information, see Work during the study conduct period, the *Site User Guide* and the *Analytics User Guide*.

Table 1-8 Update the study's design during the study conduct period

Tasks	Users who typically do this
• Create a new Draft version of a study to update the Approved version • Manage study versions during the study conduct period • Update forms and visit schedule during the study conduct period	• Study Designer
• Update randomization and kit types definitions during the study conduct period	• Study Designer • Statistician • Clinical Supply Manager
• Update subject settings during the study conduct period	• Study Manager

For more details, see Updates during the study conduct period.

Get trained as you work

When you navigate to a new page, you're prompted to complete the training assigned to you for the page. After you complete the training, you can start working on the page. Training is assigned according to your roles, so all training is relevant to your work.

After you complete all assigned training, you'll receive a notification with a list of all completed training.

You can rewatch videos, too

- In the upper-right corner, click your name, and select **Help**. The training videos assigned to you for that page appear.

And there's a place to practice

- Work in Practice data entry in Training mode, where any data saved doesn't affect a production study.

2

Before you configure a study

Before you dive into configuring the settings and strategies required for your study, you must ensure that your users, roles, and code lists are correctly set up in the application. While most of these tasks can be performed or revisited at any time during the study development, we recommend you prioritize these tasks before you configure any study settings.

- Create a study
  When you're ready to start building a study, you can create the study and add users to it. Don't forget to add yourself, or you won't be able to work. Follow the same steps to create a rollover study.
- Activate a study
  As a study creator, after creating your study in the application, you must create a Change Request in Oracle Life Sciences Support Cloud to activate the study.
- Customize the welcome letter
  All users who are added to a study receive a welcome letter. Customize that welcome letter to detail aspects of the study.
- Manage users
  Add and manage users in your study and at global level in Oracle Clinical One Platform.
- Design a study

Create a study

When you're ready to start building a study, you can create the study and add users to it. Don't forget to add yourself, or you won't be able to work. Follow the same steps to create a rollover study.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click **Create Study**.
2. Fill in the fields and click **Save**. To view tips for completing a field, click into the field or choose an option.

Field or setting	Description
Study Title	Enter the title of the protocol.
Study ID	Enter a unique value, such as a protocol acronym and protocol number.
Study Phase	From the drop-down, select the phase of your study.
Therapeutic Area	From the drop-down, select the therapeutic area of your protocol.

Field or setting	Description
Open Label / Blinded	From the drop-down, select the type of study you want to create, whether it is: • Open Label • Blinded • Blinded and Open Label • Observational Your selection does not determine whether unblinding information is revealed.
System Code List	From the drop-down, select the system code list group that you want your study to use. For more information, see Assign a system code list group to your study.
Study GUID	Click **Copy GUID** if you need to use the study GUID in setting up an integration with Oracle Central Coding, for example.
Company	Enter the company name to help you identify and associate a study with a company, if you plan to use the filter.

The new study is added to the Home page. By default, the study contains a study version of 1.0.0.1 with a status of Draft.

3. Give the study team access to the study so that they can start working in it. For instructions, see Create study user accounts.
4. To complete the study setup in the Oracle Cloud, you must activate your study.

> **Note:**
>
> If you don't submit a support ticket, errors will occur when you try to perform some tasks.

If you want to open a study or create a new Draft version, see Open a study's design or Create a new Draft version of a study to update the Approved version.

Related Topics

- Activate a study
  As a study creator, after creating your study in the application, you must create a Change Request in Oracle Life Sciences Support Cloud to activate the study.
- Create and use study company filters
  As a CRO, filter and order all studies when working with multiple sponsors. In addition, you can use the study company filter to categorize studies using other criteria such as therapeutic area.
- Customize the welcome letter
  All users who are added to a study receive a welcome letter. Customize that welcome letter to detail aspects of the study.

Activate a study

As a study creator, after creating your study in the application, you must create a Change Request in Oracle Life Sciences Support Cloud to activate the study.

Only after a study is activated in the Oracle Cloud, can the study team begin their work in the study. If you do not submit this Change Request, errors will occur when any user attempts to perform a task in the study.

> **Note:**
>
> The study designer can start designing the study at any time, even before this ticket is entered and resolved.

- Make sure you have a single sign-on account and that you specified a password for your Support Cloud account. For more information, see Specify a password for Support Cloud.

  Create a study in Oracle Clinical One Platform. For step-by-step instructions, see Create a study.

Create a Change Request:

1. Determine whether the study has been activated and a database has been created for it.
   - If you signed a contract for one study, the study database is already set up, the study is activate, and you can start testing it at any time.
   - If you signed a capacity contract, the study database is set up for the first study. For all other studies, you must create a Change Request in Support Cloud so that the database can be created. After the ticket is resolved, the study is active and you can start testing it.
2. To navigate to the Oracle Life Sciences Support Cloud.
3. In the upper-right corner of the screen, click **Create Request**.
4. On the newly loaded page, click **Complete a new installation**.
5. Fill-in the following fields:

Field	Description
Summary	In this field, enter *Clinical One Study Provisioning <study> for <ShortOrgId>-clinicalone.oraclecloud.com*. ***Note**: Replace <study> and <ShortOrgId> with the exact values as created in the Service Activation Request (SAR).*
Severity	Select **High**.
Description	In this field, enter *Please provision a Clinical One Study for customer <customer> and study <study>.* ***Note**: Replace <study> with the exact value as created in the Service Activation Request (SAR). Use copy and paste to get the study name from the SAR to prevent any typos or discrepancies.*

Field	Description
Category	Select the following options, one by one: • **Change - Cloud Environment** • **Application** • **Setup**
Oracle Internal	Select **No**.
Customer	Select the organization that you are a part of.
Product	Select **Clinical One**.
Business Service	Select **Clinical One - <customer name>**.
Environment	Select **Prod / Live**.
Implementation Window	Typically, you would select **As Soon As Possible**.
Date Required By	Select a specific date by which the study must be activated.
Action	Select either **Study Provisioning** or **Capacity**.
Tick if sFTP path is not applicable for this request	Select the checkbox for this option.

6. If required, click **Choose file** and attach a file from your computer that would help with identifying the study that must be activated,

   This is an optional step.

7. In the Additional Contacts field, include the email addresses of other team members or Oracle representatives who must be aware of the updates related to your study's activation.

   This is an optional step.

8. After receiving the email that your study has been activated, inform the study team that the study designer can start testing the study at any time.

> **Note:**
>
> Within 1 or 2 business days of submitting the ticket, look for an email from Oracle HSGBU Support (oracle_hsgbu_support@custhelp.com) with a subject of *Support Incident <incident number>* has been closed.

Customize the welcome letter

All users who are added to a study receive a welcome letter. Customize that welcome letter to detail aspects of the study.

Depending on your permission and the type of information you want to share with your team, you can identify the correct role at the level at which you work.

Permissions

- **Global level:**The *Study Creator* is the only role who has the permission to edit the welcome letter content (for all studies at your organization) and an individual study.
- **Study level:**The *Production Admin*, *Study Manager* and the *Rules Designer* are the roles who have the permissions to edit the welcome letter content.

For all other users, the fields are read-only.

Use the welcome letter to notify users of relevant information. Include the company's name, the study ID, the sponsor's name, the help center, or training information. You can customize the welcome letter at any time during the study conduct period. Only newly added users to the study can see the changes you apply to the welcome letter.

1. To customize the welcome letter you can choose either one of the following options:
   - **Global level:** From the home page, go to the **Global Settings** page and navigate to the **General** tab.
   - **Study level:** Open the study settings for the given study and go to the **General** tab.
2. Locate the Welcome Email Body Text box and edit the welcome letter.

   > **Tip:**
   >
   > Use the full Company name instead of the short organization ID.

3. Click **Apply Changes**.

Manage users

Add and manage users in your study and at global level in Oracle Clinical One Platform.

Refer to the *Add Users Guide* for a detailed list of tasks and prerequisites necessary to add and manage users in Oracle Clinical One Platform.

Design a study

Before you can perform any of the tasks described in the *Sponsor and CRO User Guide*, you must create a study and design it based on your protocol requirements. For a complete list of tasks performed in study design, see the *Study Designer User Guide*.

3

Create and manage your organization's library

In your organization's library, you can manage different types of code lists and code list groups for all studies at your organization, as well as library studies and objects that you can import into your live studies.

- About library studies
  A library study is meant to store your company's standards in study design objects, such as forms or custom Javascript rules. Objects that you create in a library study remain stored in your organization's library and you can import them into your live studies at any time. You can also import object from a live study into a library study.
- Copy a library study
  You can copy a Production study into your organization's library and copy a library study into your own Production study. Copying a Production study into your library creates a new study on the Library Studies page.
- Create and design a library study
  You create a library study to include study design objects that you can test, approve, and then re-use in other studies.
- Create and manage code lists
- Create and manage library objects
- Create and manage institutions, vendors, and contacts

About library studies

A library study is meant to store your company's standards in study design objects, such as forms or custom Javascript rules. Objects that you create in a library study remain stored in your organization's library and you can import them into your live studies at any time. You can also import object from a live study into a library study.

> **Note:**
>
> To view and manage library studies, you must be assigned certain global roles. For more information, see Roles for global users.

The basics of a library

To make the most of a library study, you must understand its structure, how to navigate to it, and how to manage objects. A library can contain multiple library studies, and a library study can contain multiple objects. A library exists at the organization level and you can use it to store multiple library studies and multiple objects that can be used in other live studies at your organization. In a library you can also store your system default code lists, and custom code lists.

The following details are important to remember for every element of a library study:

Element	Description
Library study	***Note**: The Approved container is not required to be used in a library study. For more details, see Known Issue **35239676** on My Oracle Support (MOS).* A library study works and is displayed similarly to an actual study on your homepage. A library study can be versioned and moved through all four different containers: Draft, Testing, Approved, and Archived, but only within the library. • In the library study version located in the **Draft** container, you can create or import your library objects. • In the **Testing** container you can test out the objects to see how site staff will see it and use it in a live study. • While the **Approved** container is available in a library and you can move a study version there, you can only access the library study's design while being placed in the Approved category. • The **Archived** container displays all of the object versions you chose to retire and no longer use in the library study.
Objects	***Note**: All objects in a library must have a unique title and version in order for you to update their status to Published.* You can have objects in more than one library study, as well as versions of the same object in multiple library studies. For example, you can have a Demography form version 1.0 in library study A and you can create as many versions of that form within library study A. When you create an object in a library study, that object is displayed in the overall library, as well. For example, you create a Demography form in library study A. That demography form appears on the Library landing page, as well. While you can only edit the details of that form within a library study, you can manage some of the form's attributes or update its status within the overall library. A library object has a unique system-generated object ID and every new version of an object will have a unique ID assigned to it.

The life cycle of an object

> **Note:**
>
> You cannot delete a library object from a library study when that object is imported and used in another library study at your organization. You can only delete a library object once that object is no longer used in another library study or is imported to a Production study. The same rule applies to deleting an entire library study - you can only delete a library study when none of its objects are being used in another library study at your organization.

Once you create an object in your library, there are several actions that you can perform with that object that impact its status. For more information on objects statuses, see Library object statuses and icons.

Library studies and custom JavaScript rules

You can create and manage custom JavaScript rules in a library study just as you would do it in an actual study. In a library study, you can create, modify, test, approve, and eventually publish custom rules. When you add an object with custom rules from a library study to a live study, keep in mind the following recommendations:

- Prior to deleting a question, verify that there are no rules on the question. If the question contains rules, delete the rule prior to deleting the question.
- When you import a library form with custom rules into a live study, all rules associated with that form get a status of Invalid in the live study. A rule designer must manually test, approve, and publish those rules again. Additionally, a rule designer must ensure that all variables and targets are set up correctly for the new study.

Copy a library study

You can copy a Production study into your organization's library and copy a library study into your own Production study. Copying a Production study into your library creates a new study on the Library Studies page.

> **Note:**
>
> You can only delete a library study when there are no forms in it that are used in other library studies. Deleting a library study removes all of its records.

1. Depending on what you want to do, follow the appropriate group of steps:
   - To copy a Production study into your organization's library, on the Home page, locate the study that you want to copy, click the **Study Settings** icon (), and select **Copy Study**.
   - To copy a library study into another Production study, on the Home page, click **Library** and locate the library study that you want to copy. Click the **Study Settings** icon (), and select **Copy Study**.

2. On the Copy Study dialog, fill in the fields, and click **Copy**.

> **Note:**
>
> The following fields will contain the same values that were selected for the study you're attempting to copy. You can choose to change these fields when copying the selected study:
>
> - **Study Phase**
> - **Therapeutic Area**
> - **Open Label/ Blinded**
> - **System Code List**
> - **Company**

Field	Description
Study Type	• Select **Production Study** if you want to copy the selected study into a live study. • Select **Library Study** if you want to copy the selected study into your organization's library.
Study Title	Enter the new study's title. This title has to be different than the study title you are copying. A study's title must be unique in the application. For a Production study, you can enter the title of the protocol. For a library study, you can use a title that is relevant to your library study based on information related to the study's therapeutic area, indication, or phase. Your library study's title can be related to a Clinical Research Organization (CRO).
Study ID	Enter a unique value that is relevant to the study you are creating, whether it's a Production study or a library study.
Study Phase	Use the value that is already selected or, from the drop-down, select another phase for the study you're copying.
Therapeutic Area	From the drop-down, select a different therapeutic area of your protocol or library, or leave the therapeutic area that is already selected.
Open Label/ Blinded	Use the value that is already selected or, from the drop-down, select the type of study you want to create, whether it is: • Open Label • Blinded • Blinded and Open Label • Observational Your selection does not determine whether unblinding information is revealed.
System Code List	Use the value that is already selected or, from the drop-down, select another system code list group that you want your study to use.

Field	Description
Company	If you want to change the associated company, select another company name from the drop-down or remove it.

3. An Information message may appear stating that copying this study may take longer than expected. Click **Close** or **View Homepage** to view or access your newly copied study.
4. If an error occurs during the process of copying a study, a warning message is displayed next to the study. You can click **Cancel** to quit the copying process or click **Try Again** to try copying the study again.

Related Topics

- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Create and design a library study

You create a library study to include study design objects that you can test, approve, and then re-use in other studies.

Before you begin, learn more about the specifics and limitations of a library study. For more information, see About library studies.

To create and design a library study version, follow these steps:

1. On the homepage, click **Library**.
2. In the upper-left corner of the page, click **View Library Studies**.
3. On the Library Studies page, click **Create Library Study**.
4. On the Create Library Study dialog, fill-in the fields and click **Save**.

> **Note:**
>
> After clicking **Save**, an Information message may appear stating that creating this study may take longer. Click **OK** and follow the progress icon on the Library Studies page to see when your library study is saved. While the study is saved, a message is displayed on the study that states: "Creating Study...".

Field	Description
Study Title	Enter the title of your library study. You can use a title that is relevant to your library study based on information related to the study's therapeutic area, indication, or phase. Make sure that the title is unique in the application.
Study ID	Enter a unique value that is relevant to your library study.
Study Phase	From the drop-down, select the phase of your study.
Therapeutic Area	From the drop-down, select the therapeutic area of your library study.
Open Label/ Blinded	From the drop-down, select the type of study you want to create, whether it is: • Open Label • Blinded • Blinded and Open Label • Observational Your selection does not determine whether unblinding information is revealed.
System Code List	From the drop-down, select the system code list group that you want your study to use. For more information, see Assign a system code list group to your study.
Company	Select the company name to help you identify and associate a library study with a company, if you plan to use the filter.

The new study is added to the Library Studies page. By default, the library study contains a study version of 1.0.0.1 with a status of Draft.

5. A library study must contain several other design elements, as well as study configurations. These are required for you to properly test the objects that you create in a library study. For step-by-step instructions on how to design and configure a library study, see the following:

Task	Notes
1. Create a study role for one study.	As an alternative, you can also use the Oracle predefined study roles already present in your library study. A user administrator must perform this task.
2. Add a user to a study.	A user administrator must perform this task. ***Note**: At a minimum, you should add a study designer who can create library objects in your library study's design.*
3. Create a custom code list	A study designer must perform this task.
4. Create visits and define the visit schedule.	A study designer must perform this task.
5. Create objects or import objects.	A study designer with the global roles *Change Library Objects* and *Manage Library Objects* must perform this task.
5. Create and manage custom rules.	A rules designer must perform this task.
8. Add a site to a study.	A site administrator must perform this task.
9.Specify study, enrollment, and visits settings.	A study manager must perform this task.
10. Specify settings for Source Data Verification.	This step is optional. If you choose to specify settings for a source data verification strategy, you'll have to create the actual strategy, too. For step-by-step instructions, see Create a source data verification strategy and assign it to a site. A study manager must perform this task.

After going through all of these steps, your study will be ready for use. You can start creating or importing objects, as well as testing, approving, and publishing them in your library.

Related Topics

- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.

- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Create and manage code lists

- About your code list library
- Understand the prerequisites for importing a code list
  Before you import a custom code list in the application, make sure you follow the prerequisites and understand the limitations of importing a custom code list.
- Create a system code list group for all studies
  You can create a system code list group so that all studies at your organization can make use of the code lists within that group for their various study needs.
- Create and use study company filters
  As a CRO, filter and order all studies when working with multiple sponsors. In addition, you can use the study company filter to categorize studies using other criteria such as therapeutic area.
- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).
- Import a custom code list
  Import a custom code list to populate it with the appropriate code values.
- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).
- Browse the list of system default code lists
  Oracle is offering you a set of predefined system default code lists that you can edit and re-use in any of your studies at your organization. Certain code lists in this system default group can be fully edited, while for others you can only edit specific elements.

About your code list library

Every organization has an associated library of code lists. That library contains system default code lists and custom code lists, all organized by groups. A library of code lists functions at two different levels: in a global library available for all studies at your organization and in a study library for an individual study.Code lists that exist in the global library can be re-used in a single study, as well. For example, a Reason For Change code list that exists on the Library page (in the global library) can also be seen in the individual study library, on the Code list tab.

However, a code list that only exists in the context of an individual study (in the study library) cannot be used for other studies at the organization.

The taxonomy of code lists

To make sense of the types of code lists that you can use, you must first understand the different levels of a code list. The following elements comprise a code list and exist in Oracle Clinical One Platform.

> **Note:**
>
> System default and custom code lists that exist on the Library page will be displayed on the Code list tab for an individual study, as well.

Type	Description
Code list groups	Code list groups contain the actual code lists. On the Library page and on the Code List tab, you can find two types of code list groups: • **System default code lists:** these are predefined Oracle code lists that you cannot create from scratch or delete, but you can edit certain elements for them. • **System code lists**: these are system code lists that you can create using the existing system-default code lists. • **Custom code lists:** these are code lists that you can create and manage from scratch, and that can only be used for form design.
Codes or values	Each code list contains several code values. For example, a Lab Normals Tag code list may contain several code values related to local lab normals that can be used in a study. ***Note**: For lab forms, duplicate code list labels are currently not supported. The code list values are case insensitive, therefore, the code list value must be a unique name.*

About the global library and system default code lists

As a global code list manager, you can access the global code list library from the Library page located on the application's homepage. In the global library, you can find the system default code lists, as well as any code lists that you choose to create here and make available for all studies at your organization.

When it comes to system default code lists and custom code lists located in the global library, consider the following:

- In a default system code list group, you cannot create new code lists or delete existing code lists. You can only edit some of the existing code lists. Certain code lists can be fully edited, while for others, you can only edit certain values.
  For example, you cannot delete an existing Geography default code list, but you can hide a value if you do not wish for it to appear in the study for a user's selection.
- Apart from the system default code list group, you can create your own system code list group. That customized system code list group can be re-used in other studies, as well.

For example, you may choose to create an Oncology system code list group that can then be used in future oncology studies at your organization.

- System code lists can be created in all languages available in the application. Upon selecting a code list, you can view its elements by switching between language tabs in the library. Based on your language preference set in the application, the code list is created in your preferred language. If you want to create code lists in other languages, you must add their translated code values on the other language tabs.
  For example, you may create a code list category in Japanese (while your preferred language is set to Japanese). When you create or modify a custom code list or when you modify a system code list, the additional language tabs are pre-populated with those changes. For other languages, all you have to do is translate the Value text for every code value in a code list. In this example, if you don't enter any code values on the English tab, the Japanese code values will display as you specify them on Japanese tab.

About the study library and study-level code lists

As a study designer, you can access an individual study's code list library from the Code list tab, in a study's settings. When a code list manager creates a new system code list group or edits an existing system code list in the global library (for all studies at your organization), these updates are also displayed for you in the individual study library. Updates to a custom code list group (on the Library page) are not displayed in an individual study.

In your individual study library you can find the system default code lists, system or custom code list groups (created in the global library), as well as any custom code lists that you choose to create in the study library only. If you create or edit a new code list in your individual study library, these updates are not reflected in the global library of code lists.

For example, if you edit an existing system default code list in a specific pediatric study, those updated values cannot be reused in other pediatric studies at your organization because they only exist in the study library of that specific study. Or, if you create a custom code list in a specific oncology study, that newly created code list cannot be used in forms for other oncology studies at your organization.

In short, if you create or update a code list on the Code lists tab (for a study) none of those updates will be displayed on the Library page.

Related Topics

- Browse the list of system default code lists
  Oracle is offering you a set of predefined system default code lists that you can edit and re-use in any of your studies at your organization. Certain code lists in this system default group can be fully edited, while for others you can only edit specific elements.
- Create a system code list group for all studies
  You can create a system code list group so that all studies at your organization can make use of the code lists within that group for their various study needs.
- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).
- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.

- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).

Understand the prerequisites for importing a code list

Before you import a custom code list in the application, make sure you follow the prerequisites and understand the limitations of importing a custom code list.

- When you import a code list, make sure the title of the file is unique.
- You cannot overwrite or re-import an existing code list.
- You can choose any name for the custom code list that you want to import. When you choose to export an existing custom code list, the file will be named using the following naming conventions:
  - For a custom code list imported at a study level:
    StudyName_CodeListName_ddMMMyyyy
  - For a custom code list imported at a global level (for all studies):
    CodeListName_ddMMMyyyy
- The file that you choose to import must contain a maximum of 1000 rows and a minimum of 1 row. While a custom code list's general details cannot be imported (such as the title or the description), it's important that you include the expected columns in your imported file. Those columns are: Order, Value, Label, Code, and LOINC (used for the Lab Normals Test element).
- Once you have imported your code list, you can only edit all of its fields in the application (such as order, value, label, or code) until you save your code list. Once you save an imported code list, you can only edit its code, label, and order values.
- Anytime you import a custom code list that doesn't pass all of the application's validations, the application will notify you of the errors found in the file.

Create a system code list group for all studies

You can create a system code list group so that all studies at your organization can make use of the code lists within that group for their various study needs.

To learn more about study code lists, see About your code list library.

Before working with this feature, consider the following:

- To create a system code list group on the Library page, you must be assigned the *Code List Manager* global role.
- A system code list group's name must be unique in the system. Upon creating a system code list group, its name is assigned as a machine-generated ID which you can update either at the time of creating the code list group or later.

> **Caution:**
>
> A system code list group is different from the system default code list group. When you create a new system code list group, all of the code lists from the default system code list group are displayed in this newly created group. You cannot add new code lists to a system code list group. You can only edit certain elements of some system-level code lists. To learn more about system default code lists, see Browse the list of system default code lists.

1. On the home page, click **Library**.
2. On the Library Studies page, click **View Library**.
3. On the Code List tab, click **Add System Code List**.

   A new system code list group is created on the right side-panel.
4. To rename a system code list group, click the Menu icon ( ) and select **Rename Group**. Enter the new system code list group in the text field.
5. From the newly created system code list group, select a code list.
6. On the right side of the page, click the **Edit** icon ( ) and edit a code list's details.

> **Note:**
>
> Depending on the details that you are allowed to edit for a specific system code list, you can edit any of the following fields below.

Field or column	Description
Code List Title	Edit the title of your code list. For example, enter **Specimen Type**.
Code List Description	Enter a relevant and helpful description for your code list. For example, enter **The names and descriptions of biological specimen**.
Order	Modify the numbers assigned to a code value to re-order code values in a code list. Use numbers from 1 to 2,147,483,647.
Value	Enter a value in your code list. For example, enter **Plasma**. You cannot remove a code value that exists in a system code list by default or remove a code value after a code list has been saved.
Label	Enter the label for the value in your code list. A label can be identical with the value. For example, enter **Plasma**.
Code	Enter a code corresponding to the code value A code can contain numbers and letters.

7. To add another row and complete its fields, click the **Add icon** ( ).
8. Depending on your language preference, select a language tab, and enter the translated text for the **Value** and **Label** columns.

When you modify a system code list, the additional language tabs are pre-populated with those changes. For other languages, all you have to do is translate the Value and Label text for every code value in a code list.

9. Click **Save**.

Related Topics

- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).
- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).

Create and use study company filters

As a CRO, filter and order all studies when working with multiple sponsors. In addition, you can use the study company filter to categorize studies using other criteria such as therapeutic area.

Only Global User Managers and Study Creators can create and manage the study company filter.

Study filters only display the studies that a user is assigned to. For example, a study designer can only see the studies that they are assigned to for a specific company.

Company code lists are part of the Custom Code Lists group and they can be created for the English language, as well as other languages available in the application.

To use the study company filters:

NOT_SUPPORTEDCreate or edit a company code list

> **Note:**
>
> For more detailed guidelines, see Create a custom code list and Manage a code list for all or one study.

1. On the homepage, click **Library**.
2. On the Library Studies page, click **View Library**.
3. Make sure you're on the Code List tab.
4. Expand the Custom Code List group and select the **Companies** code list.
5. On the right side of the page, fill in the table rows with the appropriate data for the companies associated with your CRO.

6. Set up a custom code list for each company you work with and fill in the following fields in order for the filter to apply:

Field	Description
Value	Enter the company name to help you identify companies later in the filter.
Description	Briefly describe the scope of the company or the nature of the studies it works with. ***Note**: This can help you connect what study belongs to which company.*
Code	Set up a unique code to help you identify the company across the board.

NOT_SUPPORTEDAssociate a company to a study

1. After setting up the code list, click **Home** to go back to the homepage.
2. Open the study's settings and go to the **General** tab.
3. From the **Company** drop-down, select one or multiple companies to assign to your study.
4. Click **Apply Changes**.

NOT_SUPPORTEDApply the study company filters

1. Click **Home** to return to the homepage.
2. Along the top of the page, from the **Filter by Company** drop-down, select a company to view all studies associated with it. This label could be empty if you made no company selection.

> **Tip:**
>
> To clear all of your filters, select and delete the inserted code-lists in the **search bar**.

Related Topics

- About your code list library

Create a custom code list

You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).

If you chose to create a custom code list only in a study's library (on the Code Lists tab), that newly created code list can only be used within the context of that specific study. If you chose to create or update a custom code list in the global library (on the Library page), that newly created code list can be used across all studies at your organization.
To learn more about code lists, see About your code list library.

To learn more about the system default code lists that you can re-use in your study, see Browse the list of system default code lists.

To create a code list (whether custom or system) on the Library page (at a global level), you must be assigned the *Code List Manager* global role. To create a custom code list on a study's Code list tab (for an individual study), you must be assigned the *Manage Study Code Lists* permission, as a *Study Designer*.

> **Caution:**
>
> A custom code list can only be used in designing forms or for study filters.

> **Note:**
>
> When updating a custom code list that is used as part of a system code list group (for example, the EDCYearRange custom code list) you hide the existing values and update its labels. The new code values that you then specify must have the same labels as the labels that you previously marked as hidden. This way, the system can properly use the updated values in the study.

1. Depending on where you want to create your custom code list, do one of the following:

   > **Tip:**
   >
   > You can also create or update a custom code list by accessing a form in Draft mode, and clicking **Code List** next to a question in that form.

   - To create a custom code list group for all studies at your organization, on the Home page, click **Library**. On the Library Studies page, click **View Library** and make sure you're on the Code List tab.
   - To create a custom code list group for a single study at your organization, open a study's settings and select the Code Lists tab.
2. Expand the Custom Code Lists group and click **Add Custom Code List**.
3. On the right side of the page, fill in the following fields:

Field	Description
Code List Title	Enter a title for your code list. For example, *Specimen Type*. ***Note**: Code lists do not appear in the **Annotated Case Report Forms** or **Study Design** standard reports if the code list title (entered in all uppercase) matches the reference code of the question where the code list is to be applied.* *To avoid this, do not enter the code list title in all uppercase or assign a unique title.*
Code List Description	Enter a relevant and helpful description for your code list. For example, *The names and descriptions of biological specimen*.

Field	Description
Select a Lab Normals Tag (Optional)	If applicable, select a lab normals tag for your custom code list. Choose any of the following options: • Test • Unit • Gender • Race • Normal Text Result • Fasting

4. Fill in the row for each code value that you want to include in your code list:

Field	Description
Order	To order values in a code list, enter a number from 1 to 2,147,483,647.
Value	Enter a value to be used in the system database that your custom code list must contain. For example, *Plasma*.
Label	Enter the label for the value in your code list. A label can be identical with the value. For example, you could also enter *Plasma* for this field. ***Note**: When you apply a code list to a question with multiple options for an answer, it is the value in the Label field that is displayed for site users in a form.*
Code	Enter a code corresponding to the code value A code can contain numbers and letters.
LOINC	This column is only displayed if you've previously selected Test for the Lab Normals Tag. Enter a specific LOINC code for your code value. This field is not mandatory, there are no character restrictions for special characters, although you cannot exceed 255 characters.

5. To add another row and complete its fields, click the **Add icon** ( ).
6. Depending on your language preference, select a language tab, and enter the translated text for the **Label** column.

> **Note:**
>
> The **Value** column always displays in English.

When you create or modify a custom code list, the additional language tabs are pre-populated with those changes. For other languages, all you have to do is translate the Label text for every code value in a code list.

7. Click **Save**.

Related Topics

- Create a code list

- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).
- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Import a custom code list
  Import a custom code list to populate it with the appropriate code values.
- Create a code list in study design
- Edit a code list in study design
- Add a code list to a question in study design

Import a custom code list

Import a custom code list to populate it with the appropriate code values.

> **Caution:**
>
> Before you import a custom code list, you must be aware of the prerequisites for performing this task. See Understand the prerequisites for importing a code list.

> **Tip:**
>
> Importing a code list can be easier if you use the application's template. To download an importing template and fill it in with data, click **Download Template**.

1. Depending on where you want to create your custom code list, do one of the following:

   > **Note:**
   >
   > You can also create or update a custom code list by accessing a form in Draft mode, and clicking **Code List** next to a question in that form.

   - To create a custom code list group for all studies at your organization, on the Home page, click **Library**. On the Library Studies page, click **View Library** and make sure you're on the Code List tab.
   - To create a custom code list group for a single study at your organization, open your study's settings and select the Code Lists tab.
2. Expand the Custom Code Lists group and click **Add Custom Code List**.
3. On the right side of the page, fill in the following fields:

Field	Description
Code List Title	Enter a title for your code list. For example, enter **Specimen Type**.
Code List Description	Enter a relevant and helpful description for your code list. For example, enter **The names and descriptions of biological specimen**.
Select a Lab Normals Tag (Optional)	If applicable, select a lab normals tag for your custom code list. Choose any of the following options: • Test • Unit • Gender • Race • Normal Text Result • Fasting

4. Click **Import Code List**.
5. On the Import Code List dialog, click **Upload a file** or drag the file from your computer, and drop it onto the highlighted space.
6. Click **Done** or **Cancel**.

   While the file is imported, you can click **Cancel** to cancel the importing process.
7. Once the file is imported, click **Done** to finish or **Remove** to remove the newly imported code list from the application.
8. To export an imported custom code list, select the code list, and click **Download**. Then select **XLSX**.

Assign a system code list group to your study

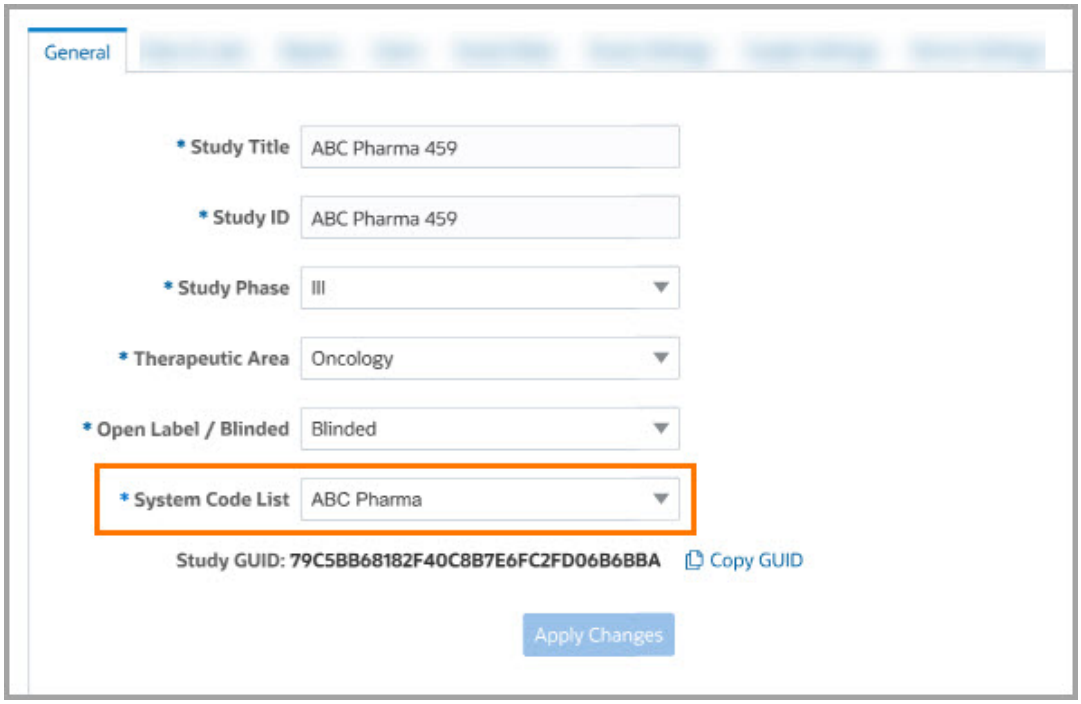
For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.

To learn more about study code lists, see About your code list library.

To assign a system code list group to a study, you must be assigned either the *Code List Manager* or the *Study Creator* global role.

1. Open the study settings.
2. On the the **General** tab, from the System Code List drop-down, select a system code list group that your study must use.
3. Click **Apply Changes**.

Figure 3-1 How a sponsor user assigns a code list



Related Topics

- Browse the list of system default code lists
  Oracle is offering you a set of predefined system default code lists that you can edit and re-use in any of your studies at your organization. Certain code lists in this system default group can be fully edited, while for others you can only edit specific elements.
- Create a system code list group for all studies
  You can create a system code list group so that all studies at your organization can make use of the code lists within that group for their various study needs.
- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).
- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).

Manage a code list for all or one study

You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).

To learn more about study code lists, see About your code list library.

To learn more about the system default code lists that you can re-use in your study, see Browse the list of system default code lists.

To manage a code list (whether custom or system) on the Library page (at a global level), you must be assigned the *Code List Manager* global role. To manage and update a code list on a study's Code list tab (for an individual study), you must be assigned the *Manage Study Code Lists* permission, as a *Study Designer*.

> **Note:**
>
> After you update a system default code list, the updates become effective in all studies that are assigned that specific code list group. In a study, when you update a system default code list, the updates become effective in all versions of that study, whether they're in Draft, Testing, or Approved.

1. Depending on where you want to create your custom code list, do one of the following:
   - To edit a custom code list group for all studies at your organization, on the Home page, click **Library**. On the Library Studies page, click **View Library**, and make sure you're on the Code List tab.
   - To edit a custom code list group for a single study at your organization, open a study's settings and select the Code Lists tab.
2. From the **Sort by** dropdown, select one of the following options to sort your code list groups:
   - **Last Modified** to sort code list groups based on when the latest changes in a code list group have occurred.
   - **Code Name (A-Z)** to sort code list groups in an ascending alphabetical order.
   - **Code Name (Z-A)** to sort code list groups in a descending alphabetical order.
3. To narrow down your search, you can also type a code list group's name in the Search for codelist search bar.
4. Expand a code list group.
5. Select one of the code lists that you want to edit or copy.
6. Depending on your language preference, select a language tab.
7. To create a new codelist from an existing one, on the right side of the page, click the **Copy icon**( ), enter a new title for the copied code list in the New Code List Title field, and click **Copy**.

   > **Note:**
   >
   > Do not copy EHR code lists; doing so can create issues with EHR mappings during an Oracle Clinical One Platform upgrade.

8. To edit an existing codelist, on the right side of the page, click the **Edit icon** ( ) and edit a code list's details.
9. To add another row and complete its fields for a new code value, click the **Add icon** ( ).
10. To remove a row that you added to the code list, click the **Delete icon** ( ).

> **Note:**
>
> Once a code list has been saved, you cannot delete that code list or any values from it. You can only hide values from a code list.

11. To hide a row from a code list, click the **Hide icon** ( ).
12. To rename a code list group, click the **Menu icon** ( ) and type the new name in the code list group title.
13. Click **Save**.

Related Topics

- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).
- Create and use study company filters
  As a CRO, filter and order all studies when working with multiple sponsors. In addition, you can use the study company filter to categorize studies using other criteria such as therapeutic area.

Browse the list of system default code lists

Oracle is offering you a set of predefined system default code lists that you can edit and re-use in any of your studies at your organization. Certain code lists in this system default group can be fully edited, while for others you can only edit specific elements.

There are several code lists that contain a code value called **Other** that is not specifically displayed on the Code List tab, on the Library page, as well as in a study's settings on the Code Lists tab. Instead, this code value is only displayed once it is assigned to a study and a user performs any data collection-related activities in Testing, Production, or Training mode.

You should not add an extra code value with the **Other** label to any of the following code lists:

- Screen Failure Reason
- Subject Transfer Reason
- Undo Withdraw Reason
- Undo Screen Fail Reason
- Withdraw Reason

> **Note:**
>
> The default code lists mentioned in the list above can also be found in the table below. The rest of the default code lists listed in the table below don't contain a code value called **Other**.

Code list name	Update the label of the code list	Add values to the code list	Hide values from the code list	Description and editable elements
Affidavit	Yes	Yes	Yes	Contains a description of the affidavit text that a Principal Investigator must sign when signing a subject's data.
Data Flags	Yes	No	No	Contains all data flag values that can be used to apply to a question.
Device Type	Yes	No	No	Contains all code values for device types that can be used in a study.
Geography Code (Country)	Yes	Yes	Yes	Contains all code values for all countries.
Kit Replace Reason (Kit Replacement Reason)	Yes	No	No	Contains code values for reasons to replace a kit.
Request Manual Shipment Reason	Yes	Yes	Yes	Contains code values for reasons to request a manual shipment.
Screen Failure Reason	Yes	Yes	Yes	Contains code values for reasons a subject might fail screening.
Skip Visit Reason	Yes	Yes	Yes	Contains code values for all of the reasons specified for skipping a visit.
Subject Event Type	Yes	No	No	Contains code values for all subject events.
Subject State Type	Yes	No	No	Contains code values for all subject states.
Subject Transfer Reason	Yes	Yes	Yes	Contains code values for reasons to transfer a subject from one site to another.

Code list name	Update the label of the code list	Add values to the code list	Hide values from the code list	Description and editable elements
Tag for Oracle Central Coding	Yes	No	No	Contains code values for all tags utilized in Oracle Central Coding integrations.
Undo Randomization Reason	Not in Use	Not in Use	Not in Use	Contains code values for reasons a site user might undo a subject's randomization.
Undo Screen Fail Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might undo a subject's screen failure.
Undo Skip Visit Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might undo the skipping of a visit.
Undo Study Complete Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might undo a subject's completion visit.
Undo Withdraw Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might undo a subject's withdrawal from the study.
Update Data Element Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might update a field in a form.
Update Kit Settings Reason	Yes	Yes	No	Contains code values for reasons why kit settings might be updated.
Update Visit Date Reason	Yes	Yes	No	Contains code values for reasons why a site user might update a visit's date.
Withdraw Reason	Yes	Yes	Yes	Contains code values for reasons why a site user might withdraw a subject from the study.

Code list name	Update the label of the code list	Add values to the code list	Hide values from the code list	Description and editable elements
Study General Settings Open Label Blinded	Yes	Yes	Yes	Contains code values for all options that can be specified for the Open Label/ Blinded field on the General tab in a study.
Study General Settings Study Phase	Yes	Yes	Yes	Contains code values for all options that can be specified for the Study Phase field on the General tab in a study.
Study General Settings Therapeutic Area	Yes	Yes	Yes	Contains code values for all options that can be specified for the Therapeutic Area field on the General tab in a study.

Related Topics

- About your code list library
- Create a system code list group for all studies
  You can create a system code list group so that all studies at your organization can make use of the code lists within that group for their various study needs.
- Assign a system code list group to your study
  For a system code list to become effective in a study at your organization, you must assign it to that study. You can assign a system code list to a study at any point during the study's development (whether the study is in Draft, Testing, or Approved) and without creating a new version of a study.
- Create a custom code list
  You can create or import a custom code list in the global library (for all studies at your organization) or you can create or import a custom code list in an individual study's library (for a single study at your organization).
- Manage a code list for all or one study
  You can manage a code list whether it is part of a system group that you created yourself, the system default group, or a custom code list group. Managing a code list can be done both in the global library (for all studies at your organization) or in the study library (for a single study).

Create and manage library objects

- About pooling kits in a study
  With pooled kits and shipments, you can create a centralized supply management for your investigational product. Learn more about the specifics and limitations of this feature in the application.

- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Create and edit a kit object
  You can create a pooled kit object in a library study and then import it into a Production study.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Edit a kit's object attributes
  Once you create a kit object, you can edit its details or update its status.
- Leave and manage comments
  You can leave comments in the Study Design (Draft) mode and Testing mode of any Production study, as well as in any library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.
- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.

About pooling kits in a study

With pooled kits and shipments, you can create a centralized supply management for your investigational product. Learn more about the specifics and limitations of this feature in the application.

Details about designing and configuring a pooled kit

Consider the following when designing a pooled kit type:

- An existing kit type cannot be changed to a pooled kit type. If you need to design a pooled kit, you have to create that kit from scratch.
- If your study contains pooled kits and non-pooled kits, the system ships kits separately: pooled kits are shipped in one shipment, while non-pooled kits are shipped in another system. To make sure that your study preserves its blind, single kit ordering is not allowed when your study contains pooled kits.

- A kit's pooling ID must be unique in each study. You can have multiple kits with pooling IDs in a study, as long as those IDs are always unique.

For more information on how to create a pooled kit, see Create and edit a kit object.

Details about pooled kits in the study's inventory

Consider the following when creating shipments or kit lists in a study that has pooled kits:

- The sidebar on the Shipments tab only displays the details of a shipment containing pooled kits after the kit receipt is received by a depot user or the clinical supply manager.
- For pooled kits, label group assignments are not restricting you when it comes to shipping of these kits. For example, even though pooled kits may be labeled for a specific country, you can still choose to ship those kits to different countries, depending on how you've set up your resupply strategy. Because kits are managed in a centralized manner, you have more control over where you ship them.
- When it comes to kit lists, you should know that any pooled kits in your study are grouped in a system-generated kit list automatically named *Pooled*. Any other pooled kits you may create in an ongoing study will get included in that system-generated kit list.
- You cannot deactivate a kit list containing pooled kits.
- For all of the kit types that are not pooled, you can upload or generate a separate kit list. In this other kit list, you cannot include or import pooled kits. If all kits in your study are pooled, you cannot upload or generate a kit list for your study.

Details about lots and shipments

Consider the following when it comes to lots or manufacturing batches in your study:

- You can only ship pooled kits through a supply integration. For example, if you want to generate a manual shipment containing pooled kits, that shipment is sent through an integration. If you want to start drug pooling for your studies, work with your Oracle point of contact to find the best solution for integrating your study with a supply vendor. In the meantime, remember the following details about shipping pooled kits:
  - A pooled shipment's ship date can only be updated through an integration. As a clinical supply manager or depot user, you can still manually specify a tracking number for a pooled shipment or cancel it.
  - As part of an integration, a stock report runs daily and updates the quantities in the lot. The counts of kits assigned to a lot are managed through the daily integration of this stock report.
  - When you ship pooled kits through a supply integration, the new Material ID field and the Lot Number value are associated to kits. These values are integrated into the stock report that runs daily and updates the quantities in lots created in your study.
  - Each material ID can be associated with multiple countries and multiple kit types, but each unique material ID can only be assigned to one kit type. Each material ID can contain multiple lots, and each lot is assigned to only one material ID.
  - When generating shipments through a resupply strategy (whether it's the first shipment, a manual shipment requested by site, or the resupply shipment created automatically), the system selects the lowest batch expiry date (first to expire to last to expire) and the lowest material ID (lowest to highest). Moreover, the system ensures that each material ID corresponds to one country and one kit type.
  - Resupply shipments are generated from lots that have a full count of kits. If no lots can ship the full count of kits requested, the resupply shipment cannot be honored and sent to the sites.

  - The system reconciles the count of kits after each shipment request (manual and resupply), ensuring that the inventory is accurately updated.
- Values for the DNS (Do Not Ship) Days and DNC (Do Not Count) Days are calculated using the Manufacturing Lot Expiry Date specified in a study's supply settings the first time the country is added to the lot. You can only update this value in the User Interface (UI), not through an integration.
- A clinical supply manager or depot user cannot add or remove kits from a pooled shipment.
- Depot-to-depot shipments that contain pooled kits are also managed outside of the application.

Details about pooled kits and supply integrations

The following supply integrations are not sending data on pooled kits:

- Almac Global Depot Network
- Catalent Clinical Supply Services
- Fisher Clinical Services
- SmartSupplies PMD

> **Note:**
>
> The related topics below display the workflow of creating a pooled kit. As stated above, to ship pooled kits, you must work with your Oracle point of contact to configure the appropriate integration in your study.

Related Topics

- Create and edit a kit object
  You can create a pooled kit object in a library study and then import it into a Production study.
- Edit a kit's object attributes
  Once you create a kit object, you can edit its details or update its status.
- Import a pooled kit type
- Supply settings fields
  This reference provides you with the fields and their descriptions when specifying supply settings for a study.
- Create a manual shipment
  Create a manual shipment if a source depot is in need of supplies or if a site anticipates an enrollment surge, such as for a clinic day, and requires additional supply. You shouldn't need to create a manual shipment for any other situations. This procedure also applies to rollover studies.
- Add and remove kits in a shipment
  You typically add and remove kits in a shipment when something happens to a kit that was selected for the shipment. For example, when a kit is damaged before it is packed, you can replace it with another kit of the same type. This procedure also applies to rollover studies.

- Specify a ship date and tracking number for a shipment
  You must specify a ship date and tracking number for every shipment, with one exception: If the study uses an integration with Almac or Fisher Clinical Services for shipments, you should not perform these steps. This procedure also applies to rollover studies.

Create and edit a form object

You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.

> **Note:**
>
> Want to create a kit object? See Create and edit a kit object.

If you want to import an existing object into your library study, see Import a form object.

Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

To create a form object in your library study, follow these steps:

1. On the Home page, click **Library**.
2. In the upper-right corner of the page, click **View Library Studies**.
3. On the Library Studies page, click the Edit Study icon () on the study you want to edit.

   > **Tip:**
   >
   > If your library contains many library studies, in the upper-right corner of the Library Studies page, type your study's title in the search bar and press **Enter** on your keyboard. You can also filter through your library studies by its associated company.

4. Below Draft, click the library study version.
5. On the Forms tab, you can do one of the following: click **Create Form**.
   - Click **Create Form** to build a new form object from scratch.
   - Locate an existing form, select **Duplicate** from the **Action** drop-down.
6. Fill-in the details of the form and add questions.

   For step-by-step instructions, see Forms.
7. Click **Save** or **Save & Close**.
8. On the Forms tab, do one of the following:
   - Click **Action** and select **Visit Assignment**.
     On the Assign Form to Visit or Event dialog, select the visits that you want this form to be assigned to.
   - Double-click a visit. On the Visit dialog, click **Add a Form** or the **Add icon** (**+**) to add a new form to the visit.

9. Click **Save**.

Once you create an object, that object is included in a library study with a status of **Draft**.

> **Tip:**
>
> Want to make it easier for you to find a form you created in the Draft version of a library study? On the **Forms** tab, click **Filter** and determine whether you want to filter forms based on their objects status (such as Draft, Published, or Ready for testing) or filter forms based on their associated tags.

Related Topics

- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Create and edit a kit object

You can create a pooled kit object in a library study and then import it into a Production study.

> **Note:**
>
> Want to create a form object? See Create and edit a form object.

You cannot assign a pooled kit type to a visit in a library study. However, you can add a pooled kit object to a live study, and assign that kit to a visit in the live study.

Before you begin, consider the following:

- Learn more about the specific features of a library study. For more information, see About library studies.
- Understand the specifics of a pooled kit and its lifecycle in a study. For more information, see About pooling kits in a study.

To create a kit object in your library study, follow these steps:

1. On the Homepage, click **Library**.

2. Click **Kit Types**.
3. On the Kit Types tab, click **Create New Kit Type**.
4. On the Create New Kit Type dialog, fill-in the following fields, and click **Create**.

Field	Description
Pooling ID	Enter a pooling identifier for the kit, such as A.
Description	Enter the name of the product and its dosage amount. If the kit type is unblinded, make sure the description is appropriate for blinded users.
Storage Temperature	Choose the storage temperature requirements for kits of this type (ambient, refrigerated, or frozen). If you're not sure, work with the clinical supply manager.
Type	Choose the packaging of the product. This selection determines the image that appears for the kit type.
Unit Per Kit	Enter the number of units in the kit, such as the number of pills in a bottle.

The newly created kit appears in the Kit Types table with a status of **Draft**. Each pooled kit is displayed along with its details: the pooling ID, its description, its type, the unit per kit, the required storage temperature, and the kit object's status.
Next up, you can publish a kit object. To do that, all you have to do is update its status appropriately. For more information, see Edit a kit's object attributes.

Related Topics

- Edit a kit's object attributes
  Once you create a kit object, you can edit its details or update its status.
- Import a pooled kit type

Edit a form object's attributes

Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.

> **Note:**
>
> Want to edit a kit object? See Edit a kit's object attributes.

Within the context of a library study, you can view all of the form objects that you created, as well as their version numbers, statuses, tags, and titles. Besides updating a form object's details within the context of a study (for example, you can update a question's label in a form), you can also update a form object's attributes and even its status.

A form object's audit trail is displayed in the Object History side panel. In there, you can view an object's status updates, the UTC date and time of the status update, the user who performed that update, as well as the version number of the object.

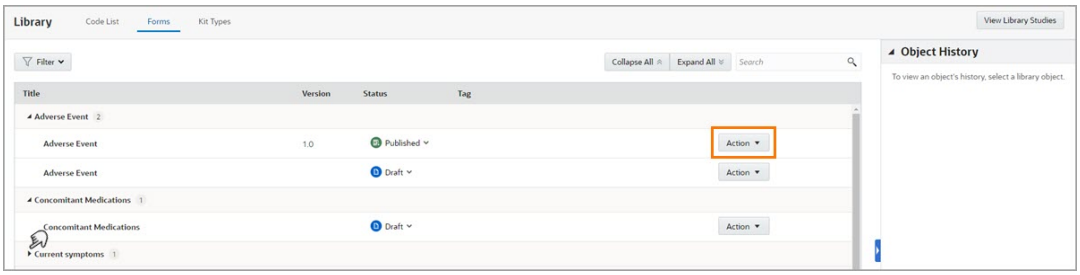
Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

To edit the attributes of an object, you must first create that object or import it in a library study. For step-by-step instructions, see the following:

- Create and edit a form object
- Import a form object

To edit a form object's attributes, follow these steps:

1. Depending on where you're currently located, do one of the following:
   - If you're located on the main Library page, click the **Forms** tab.
   - If you're located on the Library Studies page, click **View Library**, and then click the **Forms** tab.
2. On the Forms tab, look for the form object that you want to edit. Do one of the following:
   - To filter your objects, click **Filter** and select one or more options from each drop-down to get the best combination of filters for the object that you're looking for. Depending on the object, you can filter by **Status**, **Study Name**, **Tags**.
   - To search for a specific form object, in the search bar, type the object's title and press **Enter** on your keyboard.
   - If your library study contains many objects, you can click **Collapse All** to only display the titles of the objects and make the navigation easier. If you want to view all details of your objects, including the **Action** button, click **Expand All**.
3. Click the arrow ( ) to the left of the form object that you want to edit to expand the form object's details.



4. Click **Action**.
5. From the Action drop-down, select **Edit Attributes**.
6. On the Edit Attributes dialog, edit the following fields, as needed:

> **Tip:**
>
> You can easily update an object's status from the Status drop-down. Select either one of the options displayed in the drop-down, whether it's **Publish**, **Mark as Ready to Test**, **Reject**, or **Archive**, and view the object's updated status on the Object History side panel on the right.

   - **Description**: Enter a new description. This field is optional, although we recommend you always enter a description that is relevant to other library users.
   - **Tags**: If required, remove or update an object's tags.
7. Click **Save Changes**.

Related Topics

- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Edit a kit's object attributes

Once you create a kit object, you can edit its details or update its status.

> **Note:**
>
> Want to edit a form object? See Edit a form object's attributes.

Within the context of a library study, you can view all of the kit objects that you created, their details, their history, as well as update their status.

A kit object's audit trail is displayed to the right of the screen. In there, you can view an object's status updates, the UTC date and time of the status update, and the user who performed that update.

Before you begin, you must first create the kit object. For more information, see Create and edit a kit object.

To edit a kit object's attributes, follow these steps:

1. Depending on where you're currently located, do one of the following:
   - If you're located on the main Library page, click the **Kit Types** tab.
   - If you're located on the Library Studies page, click **View Library**, and then click the **Kit Types** tab.
2. On the Kit Types tab, look for the kit object that you want to edit. Do one of the following:
   - To filter your objects, click **Filter** and select one or more options for each filter to get the best combination for the object that you're looking for. Depending on the object, you can filter by **Status** (Draft, Approved, Published, or Archived) and **Type** (Blister Pack, Bottle, Device, and many more). By default, the Status filter is set to display kit objects with a status of Draft, Approved, and Published.
   - To search for a specific kit object, in the search bar, type the object's description or pooling ID, and press **Enter** on your keyboard.
3. For the kit object that you want to edit, click **Action**.
4. From the Action drop-down, select either one of the following options:

Option	Description
Edit	You can edit a kit object's description, storage temperature, type, and unit per kit specification only when that kit object has a status of **Draft**. Select to edit a kit object's details on the Edit Kit Type dialog and then click **Save**.
Delete	In the Confirmation dialog, click **Delete** again to remove the kit object from the library.
View History	On the right side of the screen, a kit object's complete history is displayed.
Approve	Select to update a kit object's status to **Approved**. The kit object is now ready for publishing.
Archive	Select to update a kit object's status to **Archived**.
Publish	This option only appears after you approved a kit object. Select to update a kit's status to Published. The kit object is now ready to be improted into a Production study.
Mark as Draft	This option only appears after you approve a kit object. Select this option to update a kit object's status back to **Draft**. You can then edit a kit's details.

Related Topics

- About pooling kits in a study
  With pooled kits and shipments, you can create a centralized supply management for your investigational product. Learn more about the specifics and limitations of this feature in the application.
- Import a pooled kit type

Leave and manage comments

You can leave comments in the Study Design (Draft) mode and Testing mode of any Production study, as well as in any library study.

For step-by-step instructions, see Leave and manage comments in the *Study Designer User Guide*.

Import a form object

You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.

> **Note:**
>
> You can only import forms as library objects.

If you want to create a brand new object, see Create and edit a form object.

Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

To import a form object into your library study, follow these steps:

1. On the Home page, click **Library**.
2. In the upper-right corner of the page, click **View Library Studies**.
3. On the Library Studies page, click the Edit Study icon () on the library study you want to edit.
4. Below Draft, click the library study version.
5. Select the **Import Forms** tab.
6. Below **Import forms from**, select **Production Study** if you want to import an object from a Production study.

> **Tip:**
>
> - In the **Search Forms** field, type the title of a specific form to search for it.
> - To import multiple forms at the same time, press the CTRL key and select each form that you want to import.

   a. From the **Studies** drop-down, select a live study.
   b. From the section below, select one or multiple forms.
   c. Click **Import Form to Current Study**.

7. Select **Library** if you want to import an object from a library study:

> **Note:**
>
> You can only import an object that has a status of **Published**.

   a. Click **Filter** and choose whether to filter your library forms by Study Name or associated tags.
   b. From the table, select a form.
   c. Click **Import Form to Current Study**.

An imported object is included in a library study with an automatically assigned status of **Draft**.

Related Topics

- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.

- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Version a form object

Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

> **Note:**
>
> In a library study, you can only version forms. You cannot version kit types.

Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

To version a form object, you must first create that object or import it in a library study. For step-by-step instructions, see the following:

- Create and edit a form object
- Import a form object

To version a form object in a library study version, follow these steps:

1. On the Library Studies page, click the Edit Study icon () on the study where you want to version an object.
2. Below Draft, do one of the following:
   - If you already have a study version located in Draft, determine whether you want to move it to the Testing or Archived container.
   - If there is no existing study version in Draft, click **Create Study Version**.
3. Click the draft study version.
4. On the Forms tab, click the form that you want to version.
5. Click **Action** and select **Create New Draft**.

   This option is available only for for a form object that is already in a state of **Published**.
6. Make the required change in your form, whether you want to update any labels or create, or remove any questions.
7. On the Details side panel, in the **Description** field, update the object's description with the changes you performed.

8. Click **Save** or **Save & Close**.

> **Note:**
>
> All versions of the same form object are easier to view on the **Forms** tab on the main **Library** page. If you're located in a library study or on the Library Studies page, click **View Library**, and then click the **Forms** tab. You can see all form objects created in your library, as well as their versions and statuses.

Related Topics

- Test and approve an object
  Once you create or import an object in your library study, it's time to test and approve it.
- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.

Test and approve an object

Once you create or import an object in your library study, it's time to test and approve it.

> **Note:**
>
> While testing a form object is a more complex process, testing a kit is easier. All you have to do is create the kit object, define its details, approve and publish the object, and then import it into your Production study.

Before you begin, learn more about the specifics and limitations of a library study. For more information, see About library studies.

> **Tip:**
>
> - During the testing phase, you can write down your findings using the Comments feature. That way, you can go back to them later and determine how an object's status should be updated next.
> - Can't find your back to the Library Studies page? Click the **Library Studies** breadcrumb link in the top-left corner of the page. This takes you to the Library Studies page where you can see all library studies at your organization. Also, click the **View Library** button in the same location to go to the main Library page where you can view code lists, forms, and kit types.

To test and approve an object, you must perform the following prerequisite steps:

- Specify study, enrollment, and visits settings
- Add a site to a study
- Create and edit a form object or import a form object.
- Update a form object's status to Ready for Test

To test and approve a form object, follow these steps:

1. On the Library Studies page, click the Edit Study icon () on the study you want to edit.
2. Below Draft, grab the draft library study version and drag it into the Testing container.
3. Next, you must update the study version that is assigned to your sites. For step-by-step instructions, see Update the study version that is assigned to a site.
4. Click the Testing Mode icon () for the given study.

   On the Subjects page of the library study, you can see the subjects table and the Library Objects side panel to the right of the screen.
5. On the Subjects page, start by adding your subjects. Click **Add Subject**
6. On the Subjects page of the library study, use the filters above the subjects table to filter your view:
   - **Site**: By default, this option is set to the first created site in the library study. If needed, select another site from the drop-down.
   - **Status**: By default, this option is set to **All subjects**. From the drop-down, select other subject statuses that you want to filter through.
   - **Review**: By default, this option is set to **All reviews**. From the drop-down, select other review labels that you want to filter through.
   - **Search for Subject**: In this text field, type the subject number you're looking for and press **Enter** on your keyboard.
7. Click a visit and identify the object that you want to test and approve. For example, if you want to test and approve a form, you have the following options:
   - On the Library Objects side panel, type the title of the form that you want to test and approve in the search bar, and press **Enter** on your keyboard.
   - Click **Filter** and select a tag associated with the form that you're looking for.
   - Click **Visit** and select a visit associated with the form that you're looking for.

- Select any of the following options to filter objects:
  - **All** displays all forms associated with the visit that you're in irrespective of their status.
  - **Draft** displays all forms with a status of Draft.
  - **Testing** displays all forms that have been already marked as Ready to Test.
  - **Approved** displays all forms that have already been approved for publishing.
  - **Published** displays all forms that have already been published.
  - **Rejected** displays all forms that were rejected during testing.
  - **Archived** displays all forms that were archived.

8. Start testing an object that you just marked for testing.

   For example, if you need to test a form, start by filling in the form and determine whether the object meets your testing criteria.

9. After successfully testing an object, on the Library Objects side panel, click **Approve** next to that object.

After you approve an object, the Approved status and icon is displayed next to it on the **Forms** tab on the **Library** page. You can also view a form object's status on the Forms tab of a draft study version.

Related Topics

- Publish an object in a library
  Only after you've approved an object, can you publish it in a library.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Publish an object in a library

Only after you've approved an object, can you publish it in a library.

This is the last step in the life cycle of an object version. After an object is created with a status of Draft, it can then be marked for testing, tested, approved, and ultimately published. After publishing an object, you can then add that object to a live study and further test it.

Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

To publish an object, you must first test and approve that object. For step-by-step instructions, see Test and approve an object.

To publish an approved object, follow these steps:

1. To publish a form, follow these steps:
   a. Depending on which page you want to update the form's status, do one of the following:
      - Go to the Library main page and click the **Forms** tab. Locate the form that you want to publish and, on the Status column, select **Publish**.
      - Go to the Library Studies page, click the Edit Study icon () on the study you want to edit, access the study version in Draft and update a form's status on the Forms tab.
      - Click the Testing Mode icon () for the given study and, on the Library Objects side panel, select the **Approved** status filter. Click **Publish** next to the form that you want to publish.
   b. On the Publish Objects dialog, complete the following fields:
      - **Description**: Enter a relevant description for the object that you're about to publish. This field is optional.
      - **Version Number**: Enter the appropriate version number for the object you're about to publish. This field is mandatory and the version number must be unique for the object that you're publishing across the entire library.
      - **Tags**: Select the appropriate tags to associate them with the object you want to publish.
   c. Click **Publish**.
2. To publish a kit type, follow these steps:
   a. On the Library main page, click the **Kit Types** tab.
   b. Locate the kit that you want to publish in the table.
   c. Click **Action** and select **Publish** from the drop-down.

Related Topics

- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Add an object to a live study
  After you test, approve, and publish an object in a library study, you can add that object to a live study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Add an object to a live study

After you test, approve, and publish an object in a library study, you can add that object to a live study.

To add an object to a live study, you must import it into the draft version of your live study. Then, you'll have to update the live study version to ensure that the newly imported object appears for subjects during the study conduct period.

Before you begin, learn more about the specifics and limitations of a library study. For more information, see About library studies.

1. Open the study in Draft mode.
2. To add a form object to a live study, follow the steps below:
   a. On the Data Collection page, click **All Forms**.
   b. Below Import forms from, choose one of the following:

> **Tip:**
>
> In the **Search Form** field, type the title of a specific form to search for it.

Options	Steps
If you choose **Production**	i. From the **Studies** drop-down, select a live study. By default, the current study you're accessing is selected. ii. Choose a filter to filter your studies by. iii. From the section below, select a form. iv. Click **Add Form to Current Study**.
If you choose **Library**	***Note**: You can only import an object that has a status of **Published**.* i. Click **Filter**. ii. From the **Study Name** drop-down, select **All Studies** or a specific library study. iii. From the table, select the form you want to import. iv. Click **Add Form to Current Study**.

3. To add a kit object to a live study, follow the steps below:
   a. On the Study Supplies page, click **Kits**.
   b. On the Kits tab, click **Import Kit Type**.
   c. Locate the kit object that you want to import and click **Import**.
   d. In the Import Kit dialog, verify and modify any required fields.
   e. Click **Import**.

   For more information, see Import a pooled kit type.

The newly imported object is displayed in its appropriate location in your live study.

Related Topics

- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Test an object in a live study
  After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.
- Create and edit a kit object
  You can create a pooled kit object in a library study and then import it into a Production study.
- Edit a kit's object attributes
  Once you create a kit object, you can edit its details or update its status.

Test an object in a live study

After you import an object in the draft version of a live study, you must test the newly imported object, and make it available in Production mode.

Before you begin, learn more about the specific features of a library study. For more information, see About library studies.

Before you can test an object in a live study, you must make sure it was imported. For step-by-step instructions, see Add an object to a live study.

1. Start by navigating to the **Sites & Labs** tab and update the assigned study version for Testing sites.

   For step-by-step instructions, see Assign a study version to a site.
2. On the homepage, move the updated study version from the Draft container to the Testing container.

   For step-by-step instructions, see Make a study version available in Testing mode.
3. Access your study in Testing and begin testing the imported object.

   For step-by-step instructions on how to access a study in a specific mode, see Access your study in any mode.

   For guidelines on how to test a study, see Verify a study.
4. Make sure you archive the approved version of the study that you no longer want to use.

   For step-by-step instructions, see Archive an Approved version of a study.
5. After you've completed the verification of your imported object, you must move the updated study version from the Testing container to the Approved container.

For step-by-step instructions, see Make a study version available in Production.

6. Lastly, navigate to the **Sites & Labs** tab again and update the assigned study version for Production sites.

Related Topics

- Create and edit a form object
  You can choose to import a form object from an existing live study or a library study, or you can create a brand new form object. You can only create a form object in the Draft version of your library study.
- Import a form object
  You can choose to either create a form object from scratch or import a form object from a live study or another library study. You can only import an object in the Draft version of your library study.
- Edit a form object's attributes
  Once you create or import a form object, you can edit its attributes in a library, such as the description or its associated tags.
- Version a form object
  Once you create a form object and you publish it in your library, you can version it multiple times within the same library study.

Create and manage institutions, vendors, and contacts

- Understand site, depot, and lab management
  Learn more about the terminology and workflows in managing your sites, depots, and labs at both the study and global levels.
- Create an organization (institution)
  Sponsor users can add and manage institutions for all studies at their organization.
- Create a vendor (depot)
  Sponsor users can add and manage a depot as a vendor in their study at the global level.
- Create a vendor (lab)
  Sponsor users can create a lab as a vendor at the global level.
- Create a contact at your organization
  At a global level, you can create and manage contacts for institutions associated with your organization's studies.
- Specify a reusable address for your organization and contacts
  At the global level, when you create an institution (site) or a vendor (depot or lab), you must define a primary address for these organizations.
- Set up a site at the global level
  For you to set up a site at the global level, you must associate an existing contact with an institution and assign those .
- Edit a contact's details
  You can edit a contact's details at anytime throughout a study's lifecycle. Any changes you make to a contact's details appear in the studies that the contact is associated with, as well.
- Edit an organization's details
  Sponsor and CRO users can update and manage an organization's information, whether an institution (site) or a vendor (depot, lab).

- Manage associations for a contact
  You can manage a contact's associated institutions. Any changes you make to a contact's associated institutions will be reflected in the studies where these sites are assigned.
- Update the status of a contact
  You can only change a contact's status at the global level. Every contact status update has impact on the associations that exist between that contact and existing institutions.
- Deactivate a contact and transfer studies
  If you want to associate a contact with a different institution and site, you must first deactivate that contact.
- Delete a contact
  You can only delete a contact if it's never been used in a study. If a contact is used in a study, you can only retire it.
- Delete an organization
  If necessary, an organization can be deleted by a sponsor or CRO user.
- Retire a site at a global level
  When you retire an organization (a site) at the global level, you need to first make sure the organization is not used in an active study. If the organization is used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.
- Retire a depot at a global level
  When you retire a vendor at the global level, you need to first make sure the organization is not used in an active study. If the organization is used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.
- Retire a lab at a global level
  When retiring a vendor at the global level, you need to first make sure the organization is not being used in an active study. If the organization is being used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.
- Transfer active organizations
  Global users with the *Manage Contacts and Organizations* role can transfer organizations which are associated with active studies.
- Transfer active contacts
  Global users with the *Manage Contacts and Organizations* role can transfer contacts which are associated with active studies.

Understand site, depot, and lab management

Learn more about the terminology and workflows in managing your sites, depots, and labs at both the study and global levels.

Required roles to work with this feature

This feature may impact all users who work with sites, depots, labs, or administrate a study in general. Users responsible for managing organizations and their contacts at the global level should be assigned the following roles:

- Global user managers
- Site administrators
- Study managers

- Clinical supply managers
- Manage contacts and organizations
- View contacts and organizations

Defining and using a primary address

> **Note:**
>
> Keep in mind that at least one address is required and must be selected as the main primary address.

Creating a primary address allows you to manage a recurring address throughout your studies in one place, ultimately reducing the amount of places you update it. Because this address is the first entered in the system for your study, it becomes the default primary address. When specifying details in any **Addresses** section, you have the ability to copy the primary address into other address fields, such as Billing or Shipping.

For more details and field descriptions for primary addresses, see Specify a reusable address for your organization and contacts.

Manage your study's contacts and organizations

When managing your contacts and organizations at the global and study levels, you should know the following:

- All sites and depots are created at a global level, but can still be added at the study level, as well. Their addresses and associations with specific contacts and studies are maintained only at the global level.
- Depots or lab facilities can be created at the study level. Furthermore, you can associate a local lab with a site at the study level.
- You are not required to transfer or retire existing studies when a contact's or organization's status has been updated to *Restricted* or *Retired*.
- **When managing an institution**:
  - If a study level site or depot is retired and the global level institution or depot is retired, the study level site or depot cannot be activated until the global institution or depot is activated.
  - Retiring an institution at the global level only allows for a site at the study level to be transferred or retired. Furthermore, a depot or lab cannot be transferred or retired regardless of their associations.
  - If an institution has a contact associated with it, its site can be transferred or retired.
  - Existing associations remain tied to the retired or restricted institution.
- **When managing a vendor (lab)**:
  - Transferring a lab migrates the study level sites to the new vendor that has been selected from other available vendor labs.
  - Retiring a lab at the global level does not allow the lab to be used for future sites. The existing sites at the study level continue to be tied to the now retired lab and its data.
  - Existing associations at the global level remain tied to the retired or restricted lab.
- **When managing a vendor (depot)**:

- Transferring a depot migrates the study level sites to the new vendor that has been selected from other available vendor depots.
- Depots are only able to be transferred to another depot when retired from the global level. Retiring a depot at the study level only retires it from the study, and it cannot be transferred to another depot.
- Existing associations at the global level remain tied to the retired or restricted depot.

Understand this feature's terminology

Term	Description	Details
Primary Address	The main primary address that is associated with the contact or organization that you create.	Any updates made to a contact's primary address does not impact any of their other associated addresses (billing address, shipping address,secondary address), even when these other addresses are the same as the primary one. Other addresses associated with a contact must be manually updated.

Term	Description	Details
Contact	**Investigator**: An individual responsible for or partaking in conducting a clinical study at a site.	• A single contact can be associated with multiple institutions. • For every contact that you create, you must specify any required information and their addresses. A contact can have multiple types of addresses such as a primary address, billing address, shipping address, or an alternate address. *A contact's address(es) can be deleted if not being used at the study level.* • A contact can be deleted if it has never been used in a study. • You can add the date of retirement or death when marking an investigator as *Retired* or *Deceased*. *An investigator is not selectable in a study if they have been marked as* ***Retired*** *or* ***Deceased****.* • Any updates made to a contact's existing data at the global level will automatically update at the study level. For step-by-step instructions on contact management, see: • Create a contact at your organization • Edit a contact's details • Manage associations for a contact • Delete a contact

Term	Description	Details
Organization	**Institution**: A facility in which a clinical study is developed and conducted at. • **Hospital**: An environment that provides medical services assisting in clinical studies. • **Teaching Hospital**: A hospital that is affiliated with a medical school. • **Medical Clinic**: A medical facility that provides outpatient services. • **Other**: A facility outside of the others listed. **Vendor**: A company or organization that provides services to sponsors of clinical studies. • **Lab**: – **Local**: A lab facility that may be present at the site or a nearby location. – **Central**: A lab facility that processes data and specializes in testing. For step-by-step instructions on creating lab type of vendor, see Create a vendor (lab). • **Depot**: A facility that manages and distributes supplies, such as medications, during a clinical study. For step-by-step instructions on how to create a depot type of vendor, see Create a vendor (depot).	• For every organization that you create, you must specify any required information, as well as their addresses. An organization can have multiple types of addresses, such as a primary address, billing address, shipping address, or an alternate address. *An organization's address(es) can be deleted if not being used at the study level.* • For an institution, you can also create departments to better organize the hierarchy and workflows at that specific organization. • When creating an institution, you can associate a contact with that institution, and then assign that institution to a study and a specific study mode at your organization. This creates a site that becomes available in the studies. For step-by-step instructions on organization management, see: • Create an organization (institution) • Edit an organization's details • Delete an organization

Term	Description	Details
Statuses for contacts and organizations	For more information on what each status entails, and step-by-step instructions on how to update the status of a contact or organization, see Update the status of a contact.	• When a status other than *Active* is selected for a contact or organization, the system ensures that no active studies are associated with the contact or organization. If you update the status of a contact or organization that is associated with an active study, see Transfer active contacts or Transfer active organizations. • Contacts and organizations cannot be set to *Restricted* if they have not been used in a prior study. Furthermore, if a contact or organization has been set to *Restricted*, it cannot be selected in a study until it has been set back to *Active*.

Create an organization (institution)

Sponsor users can add and manage institutions for all studies at their organization.

Sponsor and CRO users assigned the *Manage Contacts and Organizations* global role can create and manage their study's organizations.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select **Create Organization**.
3. Select **Create Institution**.
4. In the Create Organization: Institution dialog, complete the following fields and click **Next**.

> **Note:**
>
> Mandatory fields are marked with an asterisk (*) in the User Interface (UI). If you do not fill in those fields, you cannot proceed to the next step.

Field	Description
Category	From the drop-down, select the appropriate category for the institution you are creating: • Hospital • Teaching Hospital • Medical Clinic • Other

Field	Description
Parent Institution ID	Select the ID of the parent institution from the drop-down. **Note:** If no parent institution is available, this field is not displayed.
Institution Name	Enter the name of the institution. ***Caution**: Avoid using a backslash (/) character when naming an institution (site). If a site's name is used in a custom rule, special characters might prevent a custom rule from running.*
Institution ID	Enter the institution's ID number.
Time Zone	From the drop-down, select the appropriate time zone of the institution that you're creating. For example, select UTC +5 New York. If you use the Oracle Siebel Clinical Trial Management System (CTMS)—Site integration to create institutions and a time zone was not specified in the source CTMS system, Oracle Clinical One Platform defaults the setting to UTC. ***Note**: The same does not occur if you use the Site API to create institutions.*
Web URL	Enter the institution's valid web URL.
Mark as SMO	Select the checkbox if you would like to add the institution as a Site Management Organization.
Integration ID	*For integration teams:* If applicable, enter an integration ID.
Tax ID	Enter the institution's Tax Identification Number (TIN).
VAT Number	Enter the institution's Value Added Tax identification number.
Master Service Agreement	Select the checkbox to include the Master Service Agreement with the established terms and conditions for the institution.
From	Select the date in which in the Master Service Agreement is applied.
To	Select the end date in which the Master Service Agreement is applied.
Status	***Note**: The institution's status is set to Active by default.* From the drop-down select a status for the institution: • Choose **Active** only when the institution is ready to begin the study conduct period. • Choose **Restricted** only when the institution can no longer be active in a study at your organization.

Field	Description
Mode	Select one of the following modes in which you are adding this institution: • Testing • Training • Production

5. In the **Addresses** section, click **Add Address** and define the required addresses for your institution.

   For step-by-step instructions, see Specify a reusable address for your organization and contacts.

6. Click **Save & Add Department**.

7. In the Departments section, click **Add a Department**, and fill-in the fields to define a department for your institution:

Field	Description
Department Name	Enter the name of the department.
Address Line 1	Enter the first line of the department's address, typically, the building street number, street name, and any additional unit number.
Address Line 2	Enter an optional or secondary address line that is associated.
Phone	Enter the phone number of the department you're creating.
Email Address	Enter the associated email address to the department you are creating.

8. Click **Finish**, then click **Close**.

Related Topics

- Create a contact at your organization
  At a global level, you can create and manage contacts for institutions associated with your organization's studies.
- Set up a site at the global level
  For you to set up a site at the global level, you must associate an existing contact with an institution and assign those .
- Edit an organization's details
  Sponsor and CRO users can update and manage an organization's information, whether an institution (site) or a vendor (depot, lab).
- Delete an organization
  If necessary, an organization can be deleted by a sponsor or CRO user.
- Add a site to a study
  A site is created at a global level as an institution, making it available for use by multiple studies at your organization. Furthermore, as a site manager, you can add sites to your study and configure more details for the institution and the site staff.
- Retire a site at a study level
  Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.

- Retire a site at a global level
  When you retire an organization (a site) at the global level, you need to first make sure the organization is not used in an active study. If the organization is used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.

Create a vendor (depot)

Sponsor users can add and manage a depot as a vendor in their study at the global level.

Sponsor and CRO users assigned the *Manage Contacts and Organizations* global role can create and manage their study's organizations.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select **Create Organization**.
3. Select **Create Vendor**.
4. In the Create Organization: Vendor dialog, complete the following fields and click **Next**:

> **Note:**
>
> Mandatory fields are marked with an asterisk (*) in the User Interface (UI). If you do not fill in those fields, you cannot proceed to the next step.

Field	Descriptions
Vendor Type	Select **Depot** from the drop-down menu.
Depot Name	Enter the name of the depot you would like to add.
Depot ID	Enter the depot's ID number.
Time Zone	From the drop-down, select the appropriate time zone of the vendor that you're creating. For example, select UTC +5 New York.
Web URL	Enter the vendor's valid web URL.
Plant ID	Enter an ID for the manufacturing facility where the investigational product is manufactured.
Shipping Point	Enter the location from where the investigational product is shipped in kit form. This location can be another depot that is part of the study.
Tax ID	Enter the vendor's Tax Identification Number (TIN).
VAT Number	Enter the institution's Value Added Tax identification number.
DEA	Enter the Drug Enforcement Agency (DEA) Registration Number.
DEA Expiration	From the drop-down, select the expiration date of the DEA number.

Field	Descriptions
Status	***Note**: The vendor's status is set to **Active** by default.* From the drop-down, select a status for the lab vendor: • Choose **Active** only when the depot vendor is ready to begin the study conduct period. • Choose **Restricted** only when the depot vendor can no longer be active in a study at your organization.
Mode	Select one of the following modes in which you are adding this vendor: • Testing • Training • Production

5. Click **Next**.
6. In the **Addresses** section, click **Add Address** and define the required addresses for your institution, then click **Create**. For step-by-step instructions, see Specify a reusable address for your organization and contacts.
7. Click **Finish**, then select **Close**.

Create a vendor (lab)

Sponsor users can create a lab as a vendor at the global level.

Sponsor and CRO users assigned the *Manage Contacts and Organizations* global role can create and manage their study's organizations.

> **Caution:**
>
> We recommend you do not retire a lab that is actively used in a live study. Retired lab vendors may still appear for site users when they click the Select Lab drop-down in a lab form.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select **Create Organization**.
3. In the newly displayed dialog, select **Create a Vendor**.
4. In the Create Organization: Vendor dialog, complete the following fields and click **Next**:

> **Note:**
>
> Mandatory fields are marked with an asterisk (*) in the User Interface (UI). If you do not fill in those fields, you cannot proceed to the next step.

Field	Descriptions
Vendor Type	Select **Lab** from the drop-down menu.
Lab Name	Enter the name of the lab you would like to add.

Field	Descriptions
Category	From the drop-down, select one of the following categories for the lab you are creating: • **Local**: A lab facility that may be present at the site or nearby location. • **Central**: A lab facility that processes data and specializes in testing.
Lab ID	Enter the lab's ID number. For example, US0001.
Time Zone	From the drop-down, select the appropriate time zone of the vendor that you're creating. For example, select UTC +5 New York.
Web URL	Enter the vendor's valid web URL.
Tax ID	Enter the vendor's Tax Identification Number (TIN).
VAT Number	Enter the institution's Value Added Tax identification number.
Status	***Note**: The vendor's status is set to **Active** by default.* From the drop-down, select a status for the lab vendor: • Choose **Active** only when the lab vendor is ready to begin the study conduct period. • Choose **Restricted** only when the lab vendor can no longer be active in a study at your organization.
Mode	Select one of the following modes in which you are adding this vendor: • Testing • Training • Production

5. In the **Addresses** section, click **Add Address** and define details of the lab's primary address. For more information, see Specify a reusable address for your organization and contacts.
6. Click **Finish** and then **Close**.

Related Topics

- Add a lab to a study
  You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- Assign a local lab to a site
  Site managers or other sponsor users can assign a local laboratory to a site.
- Define lab normals
  Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- Create and manage institutions, vendors, and contacts

Create a contact at your organization

At a global level, you can create and manage contacts for institutions associated with your organization's studies.

You have the option of configuring multiple addresses for a contact: a primary address and a billing address. If you want to create multiple contacts that have the same primary address, you can first set up a primary address. For more information, see Specify a reusable address for your organization and contacts.

1. On the Home page, click **Global Settings**.
2. Click the **Contacts** tab.
3. On the **Contacts** tab, click **Create Contact**.
4. On the Create Contact: Investigator dialog, fill-in the following fields, and click **Next**.

> **Note:**
>
> All mandatory fields are marked with a blue asterisk in the application's UI.

Field	Description
Prefix	From the drop-down, select the prefix of the contact that you are creating.
First Name	Enter the first name of the contact that you are creating.
Middle Name	Enter the middle name of the contact that you are creating.
Last Name	Enter the last name of the contact that you are creating.
Suffix	If applicable, from the drop-down, select the contact's suffix.
Email	Enter the contact's email address.
Degree	Enter the contact's associated degree. For example, indicate whether they're Doctor of Philosophy (Ph. D).
Investigator ID	Enter the contact's associated ID. You can use both numbers and letters. For example, enter US0001. Keep in mind that the Investigator ID must be unique across all contacts at your organizations.
Time Zone	From the drop-down, select the appropriate time zone of the contact that you're creating. For example, select UTC +5 New York.
Tax ID	Enter the contact's Tax Identification Number (TIN).
Primary Specialty	From the drop-down, select the contact's primary medical specialty.
Sub Specialty	If applicable, from the drop-down, select the contact's sub-specialty.
License Research Number	Enter the contact's licensed research number.
Exemption Number	Enter the contact's exemption number.

Field	Description
Medical Identifier	Enter the contact's medical identifier. You can use both numbers and letters. For example, enter DB54390.
NPI	Enter the contact's National Provider Identifier (NPI). This is a unique identification number for covered health care providers. You can use both numbers and letters. For example, enter 207XS0106X.
DEA	Enter the Drug Enforcement Agency (DEA) Registration Number.
DEA Expiration	From the drop-down, select the expiration date of the DEA number.
Status	From the drop-down, select a status for the contact: • Choose **Active** only when the contact is ready to work at a site during the study conduct period. Only active contacts can enter data for a site (institution). • Choose **Restricted** only when the contact can no longer be associated with a site or enter data at an active site.
Mode	From the drop-down, select one or multiple study modes: Testing, Training, or Production.

5. In the **Addresses** section, complete the following fields, and click **Create**.Repeat this step for the Primary Address and the Billing Address.

> **Note:**
>
> If applicable, when you configure a contact's billing address, you can select **Same as the Primary Address** .

> **Tip:**
>
> In the Address Search bar, type the name of an existing address, contact ID, or name to pre-populate certain fields.

Field	Description
Address Line 1	Enter the primary address that is associated with the contact that you're creating.
Address Line 2	Enter an optional and secondary address that is associated with the contact that you're creating.
City	Enter the city that is associated with the contact that you're creating.
Country	From the drop-down, select the country that is associated with the contact that you're creating.
State	If applicable, from the drop-down, select the state that is associated with the contact that you're creating.

Field	Description
ZIP/Postal Code	Enter the ZIP or postal code associated with the contact's primary address.
Phone	Enter the phone number of the contact that you're creating.
Alternative Phone	If needed, enter an alternative phone number of the contact that you're creating.
Fax	If needed, enter the fax number associated with the contact that you're creating. This could be the organization's fax number.
Email Address	This field includes the email address you previously specified for the contact that you're creating.

Specify a reusable address for your organization and contacts

At the global level, when you create an institution (site) or a vendor (depot or lab), you must define a primary address for these organizations.

These addresses can then be re-used by other sponsor users to add sites, depots, or labs to their specific studies. At a minimum, an institution or a vendor must have a primary address. You can choose to create other types of addresses, such as a shipping address, a billing address, or an alternate address.

> **Note:**
>
> A primary address is mandatory and must be the first entered address.

You must be assigned the *Manage Contacts and Organizations* global role to define an address for contacts and organizations at the global level.

After entering the information for your new contact or organization, complete the following fields in the **Addresses** section:

Field	Description
Address Type	From the drop-down, select one of the following types of addresses you would like to associate with this contact or organization: • **Primary**: Enter the main primary address that is associated with the contact or organization you're creating. • **Billing**: Enter the billing address associated with the contact or organization you are adding. • **Shipping**: Enter a shipping address to where you would like to receive your study's kits. A single shipping address can be associated for all kit types, or a different shipping address can be assigned for each kit type. ***Note**: If no shipping address is specified, the primary address entered is used as the shipping address.* • **Alternate**: Enter an optional or secondary address that is associated with the contact or organization you're creating.
Address Line 1	Enter the first line of the address you are adding, typically, the building street number, street name, and any additional unit number.
Address Line 2	Enter an optional or secondary address line that is associated.
City	Enter the city that is associated with the contact or organization you're creating.
Country	Select the country that is associated with the contact or organization you're creating.
State	Select the state that is associated with the contact or organization you're creating.
Postal / Zip Code	Enter the ZIP or postal code associated with the contact or organization primary address.
Phone	Enter the phone number of the contact or organization you're creating.
Alternative Phone	If needed, enter an alternative phone number of the contact or organization you're creating.
Fax	If needed, enter the fax number associated with the contact or organization you're creating. This could be the contact or organization's fax number.
Email Address	Enter the associated email address to the contact or organization you are creating.

Set up a site at the global level

For you to set up a site at the global level, you must associate an existing contact with an institution and assign those .

To complete this task, you must first create a contact and an institution. For more information, see:

- Create a contact at your organization
- Create an organization (institution)

Before you set up a site at the global level, consider the following:

- A single contact can be associated with multiple institutions.
- To associate a contact with an institution, both of them must be assigned to the same study modes: Testing, Training, or Production.
  For example, if a contact is assigned to a study in all three modes but the institution is only assigned to a study in Production and Testing mode, then the association would only be possible between the contact and the institution in Production and Testing modes.
- When you search for the correct institution to associate with a contact, you can filter all institutions by Mode, Country, or by searching for the institution's name.

1. On the Home page, click **Global Settings**.
2. On the **Contacts** tab, select the contact that you want to associate with an institution.
3. On the right side of the screen, click **Associate Institution**.
4. On the Add Associations dialog, from the **All Institutions** left section, select the checkbox icon () for one or multiple institutions.
5. Click **Save**.

   All of the associated institutions appear in the **All Institutions** section. Each associated institution indicates in how many active studies it is being used, as well.
6. In the Associated Institutions section, select an institution.
7. Click the **Menu icon** () and select **Assign Site to Study**.
8. In the Assign Site to Study dialog, from the drop-down, select a study to assign the site to.
9. Select one of the three study modes where you want your site to be assigned to: **Testing**, **Training**, or **Production**.
10. For the selected mode, enter the site's ID in the newly-displayed field.
11. Click **Assign**.

Edit a contact's details

You can edit a contact's details at anytime throughout a study's lifecycle. Any changes you make to a contact's details appear in the studies that the contact is associated with, as well.

1. On the Home page, click **Global Settings**.
2. Click the **Contacts** tab.
3. Select a contact, and click **Manage Contacts**.
4. From the **Manage Contacts** drop-down, select **Edit Contact**.
5. In the Edit Contact: Investigator dialog, in the **Info** section, edit a contact's details.

> **Note:**
>
> During this step, you can update a contact's status. For more information, see Update the status of a contact.

6. Click **Next**.
7. In the Addresses section, you can edit a contact's addresses.

8. Click **Save**.
9. Click **Close**.

Edit an organization's details

Sponsor and CRO users can update and manage an organization's information, whether an institution (site) or a vendor (depot, lab).

Before you work with this feature

Be aware of the following before updating an organization's details:

- To modify an organization's details, you must be assigned the global role of *Manage Contacts and Organizations*.
- If you select a status other than *Active*, the system ensures no active studies are associated with the organization. If you update the status of an organization associated with an active study, see Change the status of a contact.
- You can only add a Mode to an organization actively used in a study or with current associations.
- You can only delete an address that is not used in an active study or site.
- You cannot remove an association until the study or sites have been retired or transferred. For more information, see Retire a site at a global level.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, locate the institution or vendor you want to edit.
3. From the **Manage Organizations** drop-down, select **Edit Organization**.
4. Make applicable updates on the **Info** section, then click **Next**.
5. If necessary, update the address details, then click **Save** or **Save & Edit Department**.

   For information about departments, see Create an organization (Institution).

Related Topics

- Transfer active organizations
  Global users with the *Manage Contacts and Organizations* role can transfer organizations which are associated with active studies.
- Delete an organization
  If necessary, an organization can be deleted by a sponsor or CRO user.

Manage associations for a contact

You can manage a contact's associated institutions. Any changes you make to a contact's associated institutions will be reflected in the studies where these sites are assigned.

Before managing a contact's association, consider the following:

- You can only manage a contact's associations with other institutions when that contact or institution are inactive. For example:
  - If contact A is associated with institution B in Production mode, you can assign contact A to Testing mode, as well. However, you cannot unassign contact A from Production mode since an active institution is associated with contact A in that specific mode.
  - If contact B is associated with institution C in Training mode, and you want to associate the two elements in Testing mode as well, you must assign both contact B and

institution C to Testing mode. Only after that can you associate the two of them. Moreover, you will not be able to unassign contact B or institution C from Training mode while they are still associated.

  - If contact Z is assigned to all three modes (Testing, Training, and Production) and is associated with institution Y in Testing mode, you can't unassign contact Z from Testing mode. To do that, you must first remove the association between contact Z and institution Y in Testing mode.

- Any updates you make to a contact's primary address will not impact any of their other associated addresses (billing address, secondary address), even when these other addresses are the same as the primary one. You must manually update a contact's other addresses.
- You can only delete an address when it is not associated with an active site assigned to an active study.
- If you want to remove the association between a contact and an institution, you must first retire the site.

1. On the Home page, click **Global Settings**.
2. Click the **Contacts** tab.
3. On the **Contacts** tab, select a contact, and click **Manage Contact**.
4. From the **Manage Contacts** drop-down, select **Manage Associations**.
5. In the **Associated Institution** section, select an institution, click the **Menu** icon ( ), and select either one:
   - **Assign Site to Study**: in the Assign Site to Study dialog, you can change the study and the modes associated with this specific contact and its associated institutions.
   - **Remove Association** this removes the association between the contact that you're editing and the institution that you previously selected.

Update the status of a contact

You can only change a contact's status at the global level. Every contact status update has impact on the associations that exist between that contact and existing institutions.

When updating a contact's status, you have several options. Typically, you update a contact's status when that contact is no longer required in the studies that it is assigned to. See the significance and impact of each status update below.

Status	Description
Restricted	This status indicates that the contact is associated with an institution but they are not active yet.
Active	This status indicates that the contact is active at the global level and is associated with an institution or more.
Retired	This status indicates that the contact is inactive and can no longer be associated with an institution. Moreover, no institutions are associated with this contact.
Disbarred	This status indicates that the contact no longer has the right to practice their profession, therefore they cannot be a part of the organization anymore. Their associated sites must be transferred, as well.

Status	Description
Deceased	This status indicates that the contact passed away and therefore its associates sites can no longer be associated with them.

1. On the Home page, click **Global Settings**.
2. Make sure you're on the **Contacts** tab.
3. On the **Contacts** tab, select a contact, and click **Manage Contacts**.
4. From the **Manage Contacts** drop-down, select **Edit**.
5. In the Edit Contact dialog, in the **Info** section, select a new status from the **Status** drop-down.
6. Click **Next**.
7. If you chose to set a contact's status to *Disbarred* or *Deceased*, you must transfer any active sites associated with them, as well. For step-by-step instructions, see Deactivate a contact and transfer studies.

Deactivate a contact and transfer studies

If you want to associate a contact with a different institution and site, you must first deactivate that contact.

1. On the Home page, click **Global Settings**.
2. Make sure you're on the **Contacts** tab.
3. On the **Contacts** tab, select a contact, and click **Manage Contacts**.
4. From the **Manage Contacts** drop-down, select **Edit**.
5. In the Edit Contact dialog, in the **Info** section, select **Retired** from the **Status** drop-down.

   A Confirmation dialog is displayed. The dialog indicates that there are active studies associated with this contact.
6. In the Confirmation dialog, select any of the following options on what to do with the active sites associated with the contact that you want to deactivate:
   - **Retire all**: selecting this option effectively retires all sites.
   - **Transfer all to one**: Upon selecting this option, a drop-down appears. From the drop-down, select which contact you want to transfer the active sites to.
   - **Select for each**: Upon selecting this option, a table appears. From the table, for each of the displayed sites, select either **Retire** to retire the site or **Transfer** to transfer the site to another contact. You can also select **No Change** if you wish to not do anything with a specific site.
7. Click **Save**.

A deactivated contact is displayed with an information tool tip indicating the date when the contact was deactivated. Additionally, all of their associated institutions are displayed with a status of *Unavailable* in the **Associated Institution** section.

Delete a contact

You can only delete a contact if it's never been used in a study. If a contact is used in a study, you can only retire it.

To delete a contact, you must first retire it and remove any associations with any sites in a study. For more information, see Update the status of a contact.

1. On the Home page, click **Global Settings**.
2. Make sure you're on the **Contacts** tab.
3. On the **Contacts** tab, select a contact, and click **Manage Contact**.
4. From the **Manage Contacts** drop-down, select **Delete Contact**.
5. In the Confirmation dialog, from the **Reason to Delete** drop-down, select a reason for removing this contact.
6. Click **Delete**.

Delete an organization

If necessary, an organization can be deleted by a sponsor or CRO user.

Before you work with this feature

Be aware of the following before deleting an organization:

- You must be assigned the *Manage Contacts and Organizations* global role to edit or delete an organization.
- An organization can only be deleted if it has never been associated to or used in a study.

1. On the Home page, click **Global Settings**.
2. Click the **Organizations** tab.
3. Locate and select the organization you would like to delete.
4. Click the **Manage Organizations** drop-down and select **Delete Organization**.
5. In the Confirmation dialog, select a **Reason to Delete**.
6. Click **Delete**.

Retire a site at a global level

When you retire an organization (a site) at the global level, you need to first make sure the organization is not used in an active study. If the organization is used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.

If you choose to transfer a site to another contact, you must select a contact to associate it to from the newly displayed drop-down.

> **Tip:**
>
> Do you want to retire a site only for a specific study? For step-by-step instructions, see Retire a site at a study level.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select the institution that you want to retire.
3. Click **Manage Organizations** and select **Edit Organization**.

> **Note:**
>
> If you want to retire a site at the global level, you can also click **Manage Study Sites**. The Transfer Organization dialog appears and you can choose whether to retire the site or cancel.

4. In the Edit Organization: Institution dialog, click **Status**.
5. From the **Status** drop-down, select **Retired** and click **Next**.

   A Transfer Organization dialog is displayed. The dialog indicates if there are active sites associated with this institution.
6. In the dialog, select any of the following options on what to do with the active institutions or vendors associated with the site that you want to retire:
   - **Retire all**: selecting this option effectively retires all vendors or other institutions associated with this site.
   - **Transfer all to one**: Upon selecting this option, a drop-down appears. From the drop-down, select which contact you want to transfer the active vendors or institutions to.
   - **Select for each**: Upon selecting this option, a table appears. From the table, for each of the displayed sites, select either **Retire** to retire the institution or vendor or **Transfer** to transfer the institution or vendor to another contact. You can also select **No Change** if you wish to not do anything with a specific site.
7. Click **Confirm**.

Retire a depot at a global level

When you retire a vendor at the global level, you need to first make sure the organization is not used in an active study. If the organization is used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.

If you choose to transfer a vendor to another contact, you must select a contact to associate it to from the newly displayed drop-down.

> **Tip:**
>
> Do you want to retire a depot only for a specific study? For step-by-step instructions, see Retire a depot at the study level.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select the institution that you want to retire.
3. Click **Manage Organizations** and select **Edit Organization**.
4. In the Edit Organization: Vendor dialog, click **Status**.
5. From the **Status** drop-down, select **Retired** and click **Next**.

A Transfer Organization dialog is displayed. The dialog indicates if there are active depots associated with this vendor and that all active depots must be transferred or retired to change the status of this vendor.

6. In the dialog, select any of the following options on what to do with the active vendors associated with the vendor that you want to retire:
   - **Retire all**: selecting this option effectively retires all vendors or other institutions associated with this vendor.
   - **Transfer all to one**: Upon selecting this option, a drop-down appears. From the drop-down, select which contact you want to transfer the active vendors or institutions to.
   - **Select for each**: Upon selecting this option, a table appears. From the table, for each of the displayed depots, select either **Retire** to retire the institution or vendor or **Transfer** to transfer the institution or vendor to another contact. You can also select **No Change** if you wish to not do anything with a specific depot.
7. Click **Confirm**.

Related Topics

- Create a vendor (depot)
  Sponsor users can add and manage a depot as a vendor in their study at the global level.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Transfer active organizations
  Global users with the *Manage Contacts and Organizations* role can transfer organizations which are associated with active studies.
- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.

Retire a lab at a global level

When retiring a vendor at the global level, you need to first make sure the organization is not being used in an active study. If the organization is being used in an active study, the system guides you to transfer the associated vendors (depots, labs) to other contacts and institutions.

If you choose to transfer a vendor to another contact, you must select a contact to associate it to the newly displayed drop-down.

1. On the Home page, click **Global Settings**.
2. On the **Organizations** tab, select the institution that you want to retire.
3. Click **Manage Organizations** and select **Edit Organization**.
4. In the Edit Organization: Vendor dialog, click **Status**.
5. From the **Status** drop-down, select **Retired** and click **Next**.

   A Transfer Organization dialog is displayed. The dialog indicates if there are active labs associated with this vendor and that all active labs must be transferred or retired to change the status of this vendor.

6. In the dialog, select any of the following options on what to do with the active vendors associated with the vendor that you want to retire:
   - **Retire all**: selecting this option effectively retires all vendors or other institutions associated with this vendor.
   - **Transfer all to one**: Upon selecting this option, a drop-down appears. From the drop-down, select which contact you want to transfer the active vendors or institutions to.
   - **Select for each**: Upon selecting this option, a table appears. From the table, for each of the displayed depots, select either **Retire** to retire the institution or vendor or **Transfer** to transfer the institution or vendor to another contact. You can also select **No Change** if you wish to not do anything with a specific depot.
7. Click **Confirm**.

Related Topics

- Understand site, depot, and lab management
  Learn more about the terminology and workflows in managing your sites, depots, and labs at both the study and global levels.
- Create a vendor (lab)
  Sponsor users can create a lab as a vendor at the global level.

Transfer active organizations

Global users with the *Manage Contacts and Organizations* role can transfer organizations which are associated with active studies.

> **Caution:**
>
> We recommend you do not retire a lab that is actively used in a live study. Retired lab vendors may still appear for site users when they click the Select Lab drop-down in a lab form.

1. On the Home page, click **Global Settings**.
2. At the top of the settings panel, navigate to the **Organizations** tab.
3. Using the check boxes on the left, select the organization you wish to transfer.

> **Note:**
>
> Organizations which are associated with active studies can only be transferred one at a time.

4. Click **Manage Organizations** and select one of the following, accordingly:
   - **Manage Study Sites**
   - **Manage Study Depots**
   - **Manage Study Labs**
5. You will be prompted to choose one of the following options:
   - **Retire all**: retires all active sites associated with the organization.

- **Transfer all to one**: all active sites associated with the organization are transferred to a new study.
- **Select for each**: allows you to select what happens to each site associated with the organization.

6. Select **Confirm**.

Transfer active contacts

Global users with the *Manage Contacts and Organizations* role can transfer contacts which are associated with active studies.

1. On the Home page, click **Global Settings**.
2. At the top of the settings panel, navigate to the **Contacts** tab.
3. Using the check boxes on the left, select the contact you wish to transfer.

> **Note:**
>
> Contacts which are associated with active studies can only be transferred one at a time.

4. Click **Manage Contacts** and select **Manage Study Sites**.
5. You will be prompted to choose one of the following options:
   - **Retire all**: retires all active sites associated with the contact.
   - **Transfer all to one**: all active sites associated with the contact are transferred to a new study.
   - **Select for each**: allows you to select what happens to each site associated with the contact.
6. Select **Confirm**.

4

Configure a study

After your study design is ready and the appropriate study version is placed in Testing or Approved containers, you can configure your study.

- Define settings for *Testing mode* first, so you can test and verify a study version using mock data.
- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Make a study version available
  Make a study version available in Testing mode to begin configuring your study after the study design is ready. Move a study version to Approved after the study design and configuration have been verified and you're ready to make the study live.
- Set up facilities
  During this phase, you must set up the facilities involved in your study, such as sites, depots and labs. We recommend to use mock facilities in Testing mode to avoid confusions when receiving notifications.
- Define settings
  Once you have created and configured facilities in your study, study managers and clinical supply managers must specify the study's settings.
- Manage randomization
  Once you are done setting up sites, depots, labs, and other study settings, a clinical supply manager and other sponsor users can begin configuring settings for the randomization processes of a study.
- Manage supplies
  After defining randomization, clinical supply managers can define how to manage supplies in the study, including lists, lots and other features.
- Make a study live
  After all required elements of a study are created, it's time to put all of the pieces together. During this phase, a study team member must assign the appropriate study version to sites, activate sites, and complete many more settings to make a study version live in a specific mode.
- Verify a study in Testing mode
  After all settings and elements of a study are configured in Testing mode, you must verify that the study design is matching the protocol to proceed with the Production mode configuration. During this phase you must also check the user workflow and make sure everything follows a logical order.
- Create and manage custom rules
  Oracle Clinical One Platform provides a user interface for creating custom rules using JavaScript. Rules are applied in all modes when published, but you can only create, test, edit, approve and publish them in Testing mode.

- Manage dispensation exceptions
  While study designers can configure the Do Not Dispense (DND) Days in a study's visit schedule, a sponsor user (typically a clinical supply manager) can configure DND exceptions for a country or site to better control dispensation in a study. Exceptions can be made for all visits where dispensation occurs.
- Enable a study for Electronic Health Record (EHR) data import
  Enable EHR data import for a study so site users can import EHR data into Oracle Clinical One Platform forms, which can save site users time and improve data quality by reducing data entry mistakes.

Make a study version available

Make a study version available in Testing mode to begin configuring your study after the study design is ready. Move a study version to Approved after the study design and configuration have been verified and you're ready to make the study live.

For step-by-step instructions, see the following topics in the *Study Designer User Guide*:

- Make a study version available in Testing mode
- Make a study version available in Production

Set up facilities

During this phase, you must set up the facilities involved in your study, such as sites, depots and labs. We recommend to use mock facilities in Testing mode to avoid confusions when receiving notifications.

- Define settings for *Testing mode* first, so you can test and verify a study version using mock data.
- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Add a depot for a study
  With depots created at your organization, you can select a depot's details to associate it with your study, too.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Add a site to a study
  A site is created at a global level as an institution, making it available for use by multiple studies at your organization. Furthermore, as a site manager, you can add sites to your study and configure more details for the institution and the site staff.
- Edit a site at the study level
  You can modify certain details of a site at the study level.
- Delete a site at the study level
  If necessary, a study level site can be deleted by a sponsor or CRO user.

- Manage site permissions
  You can limit the activities a site user can perform, such as adding new subjects, screening and randomizing subjects or dispensing kits.
- Manage screening and randomization limits by site
  Study managers can set screening and randomization limits for each site individually.
- Add a lab to a study
  You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- Define lab normals
  Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- How are lab normal updates reflected in existing lab forms?
  If you update lab normal values during a study's conduct period, these updates are reflected in all started lab forms, including existing ones, whether complete or not.
- Assign a local lab to a site
  Site managers or other sponsor users can assign a local laboratory to a site.
- Make sure users are assigned to the correct sites and depots
  Sometimes users are created before sites and depots are set up. If your study followed that workflow, make sure you assign everyone to the appropriate sites and depots after the sites and depots are created.

Add a depot for a study

With depots created at your organization, you can select a depot's details to associate it with your study, too.

> **Note:**
>
> To complete this task, a global user must first create a depot at your organization's level. For more information, see Create a vendor (depot).

Before you create a depot, consider the following:

- We recommend creating mock depots to use in Testing mode and creating real depots to use in Production and Training modes. For instance, an action taken by a user who works in Testing mode might result in a notification, and the receiving user might be confused if the same depots were used for both testing and production.
- If your study uses tertiary depots that receive kits for destruction but don't ship kits, create the depots the same way that you create depots that ship kits. Make sure you specify the countries that can ship kits to the depot for destruction. When you release kits to depots, don't release kits to the tertiary depots. For more information, see Release kits to sites or depots.

1. Open the study settings.
2. Below the study name, click the **Depots** tab.
3. Along the top of the page, select a study mode:
   - **Production Mode**

- **Testing Mode**
- **Training Mode**

4. Click **Create Depot**.
5. In the Create Depot dialog, in the **Info** section, complete the following fields, and click **Next**.

Field	Description
Search Depot	From the drop-down, select a depot. You can search for a depot by its name or adress (city or state). The Search Depot drop-down includes all depots (vendors) that were created at a global level and they're available to add to studies at your organization.
Depot ID	Enter a short identifier for the depot, such as a number. By default, this field displays the depot's ID specified at the global level, but you can change it at a study level. ***Note**: You can only update a depot's ID if the depot you're about to create has a status of **New**.*
Status	By default, the depot's status is set to **New**. You can change it during this process.
Mode	Choose one or more modes that the depot is available in. By default, this field is set to the mode specified at a global level, but you can change it for your study.
Drug Destruction Capable	By default, this setting is set to **No**. Choose **Yes** if the depot is responsible for receiving kits sent back from sites and destroying them.

6. In the **Addresses** section, click **Add Address** to add subsequent addresses associated with your depot (such as a billing address, an alternate address, or a shipping address).

> **Tip:**
>
> For any subsequent addresses you want to add, you can select **Same as Main Primary Address** for the rest of the fields to get automatically completed with the details of the primary address.

7. Click **Next**, then choose the kit types that the depot distributes and specify the supplying depot and the notification threshold.

Field	Description
Kit Type and Description	Select the kit type that the depot can distribute. A depot can also distribute pooled kits but only to other sites, not to another depot.
Supplying Depot	From the drop-down, select the supplying depot that supplies the depot that you are now creating with kits. You can choose not to select a supplying depot, so the depot that you are creating does not receive shipments from another depot.

Field	Description
Inventory Kit Level Alert	Enter a number that represents the lowest number of kits that generate a notification for low supplies at a depot. ***Note**: Clinical supply managers and other users with the appropriate permissions will receive a notification about the depot running low on supplies when reaching this limit. For more information, see Low kit depot notification.*

8. Click **Next** and select the countries that the depot can supply. From the left column, select one or more countries, and click the arrow icon () to move your selection to the **Selected Countries/ States** column.
9. Click **Next** and select the checkboxes for the countries that must use this depot as their primary supplier.
10. Click **Finish** twice.

Next, you can assign a resupply strategy to a depot and activate a depot. For step-by-step instructions, see Assign a resupply strategy to a depot.

Related Topics

- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.
- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Create and manage institutions, vendors, and contacts
- Site, depot, labs, and source data verification FAQs

Edit a depot at a study level

You can modify certain details of a depot at the study level

Before you work with this feature

Be aware of the following before editing a depot's details:

- Once the depot's status has been updated to *Active*, you cannot update the a depot's ID.
- The entered Shipment Address cannot be deleted until the Shipping Address is changed.

1. Open the study settings.
2. Click the **Depots** tab.
3. Locate and select the depot that you want to manage.
4. Click the **Manage Depots** drop-down and select **Edit**.
5. In the Edit Depot dialog, in the **Info** section, edit the depot's details, and click **Next**.

   At the study level, you can only edit a depot's status and update whether the depot can perform drug destruction activities or not.
6. In the Addresses section, edit an existing address or add a new one for the depot, then click **Next**.
7. In the **Kit Types** section, you can edit the kit types that the depot can deliver, their supplying depot, or the threshold for the Inventory Kit Level alert.
8. Click **Next** and in the **Countries & States** section, you can edit the countries that the depot can supply, as well as the countries and states that the depot is the primary supplier for.
9. Click **Finish** twice.

Related Topics

- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.
- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Create and manage institutions, vendors, and contacts

- Site, depot, labs, and source data verification FAQs

Delete a depot at a study level

If necessary, a study-level depot can be deleted by a sponsor or CRO user.

> **Note:**
>
> A depot can only be deleted when it is in a status of *New*. Once a depot is set to *Active*, it can only be retired.

1. Open the study settings.
2. Click the **Depots** tab.
3. Locate and select the depot that you want to manage.
4. Click the **Manage Depots** drop-down and select **Delete**.
5. In the Confirmation dialog, click **Yes**.

Related Topics

- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.
- Create and manage institutions, vendors, and contacts
- Site, depot, labs, and source data verification FAQs

Add a site to a study

A site is created at a global level as an institution, making it available for use by multiple studies at your organization. Furthermore, as a site manager, you can add sites to your study and configure more details for the institution and the site staff.

Consider the following before you proceed with this task:

- We recommend creating mock sites for Testing mode and using real sites for Production and Training mode. Creating sites with the same names in all modes could confuse users. For instance, an action taken by a user working in testing mode may result in a notification, and the receiving user might be confused about whether the study uses the same sites for testing and production.
- You can, but we don't recommend activating sites before assigning them a study version. This way, you avoid creating shipments before the study is in production.
- In a rollover study, sites must have the same name as in the original study.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Along the top, select a specific mode:
   - **Production Sites**
   - **Testing Sites**
   - **Training Sites**

   > **Tip:**
   >
   > You can select your site to be available in additional modes later in the Create Site wizard.

4. Click **Create Site**.
5. In the **Info** section, complete the following fields, then click **Next**.

Field	Description
Search for Site	From the drop-down, select a site. The Search for Site drop-down includes all sites (institutions) that were created at a global level and they're available to add to studies at your organization.
Site ID	Enter a short identifier for the site, such as a number. This value is included in the subject numbers of all subjects at the site.
Status	Choose New for a site that hasn't started the study conduct period, and change to Active only when the site is ready to start the study conduct period. Only Active sites can enter data. Choose Retired for sites that are no longer collecting data.
Mode	The mode in which the site was created at the global level is selected by default.
Drug Destruction Capable	Choose Yes if kit destruction occurs at the site. Choose No if kit destruction should not be done at the site.
Return Depot	From the drop-down, select the depot where kits should be returned from the site.
Time Zone	The timezone that was selected for the site at the global level is displayed here. This field is read-only and cannot be modified at the study level.
Site Permissions	Select the permissions you would like to assign to the site

6. In the **Address** section, click **Add Address** and select **Primary Address**, then expand the section.
7. From the **Site Address** drop-down, select an existing primary address configured at the global level for this site.

8. You can also add a Shipping Address, a Billing Address, or an Alternate Address if needed. For more information, see Specify a reusable address for your organization and contacts.
9. After adding the necessary addresses, click **Next**.
10. In the **Kits** section, select the types of kits you want to associate with your site. In the Send column, select a shipping address for each kit type.
    - If your study settings were configured to include locally sourced kits, the **Locally Sourced** option is available in each kit's **Select Shipping Address** drop-down menu.
    - If kits were not defined for your study, you must select **Send All Kits To** and specify a shipping address.
11. Click **Save**.

To complete the process of site configuration:

- Create a source data verification strategy and assign it to a site
- Assign a study version to a site
- Select a resupply strategy for a site
- Once the study set up is complete for the given mode, Activate a site.

Related Topics

- Activate a site
  To make a study version live, activate a site. Make a study live in Production mode only after the site has contractually agreed to the protocol and regional regulatory requirements are in place. A site that has been activated can never be deleted, but it can be retired. This procedure also applies to rollover studies.
- Edit a site at the study level
  You can modify certain details of a site at the study level.
- Retire a site at a study level
  Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.
- Delete a site at the study level
  If necessary, a study level site can be deleted by a sponsor or CRO user.
- Site, depot, labs, and source data verification FAQs
- Create and manage institutions, vendors, and contacts

Edit a site at the study level

You can modify certain details of a site at the study level.

Before you work with this feature

Be aware of the following before editing a site's details:

- You cannot update a site's ID when it has an *Active* status.
- You can only delete a Shipping Address if the address is previously changed.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Locate and select the site that you want to edit.

4. Click the **Manage Sites** drop-down and select **Edit**.
5. In the Edit site dialog, edit the site's details in the **Info** section, then click next.

   At the study level, you can only edit the **Status**, **Drug Destruction Capable**, **Return Depot**, and **Site Permissions** settings.
6. In the **Addresses** section, edits to site information at the study level are limited to the following. Make any necessary updates, then click **Next**.

> **Note:**
>
> Edits to details, such as the Postal Code, City, State, and Country, are made at the global level. For more information, see Edit an organization's details.

Table 4-1 Address types and available edits

Address type	What is editable
Primary Address	The settings **Same as Main Primary Address** and **Shipping Address** can be edited.
Shipping Address	In addition to the settings **Same as Main Primary Address** and **Shipping Address**, you can edit **Attention** and **Instructions**.
Billing Address	The settings **Same as Main Primary Address** and **Shipping Address** can be edited.
Alternate Address	The settings **Same as Main Primary Address** and **Shipping Address** can be edited.

For more information about address types, see Specify a reusable address for your organizations and contacts.

7. In the **Kits** section, you can edit the shipping addresses for the defined kits, then click **Save**.

Related Topics

- Add a site to a study
  A site is created at a global level as an institution, making it available for use by multiple studies at your organization. Furthermore, as a site manager, you can add sites to your study and configure more details for the institution and the site staff.
- Activate a site
  To make a study version live, activate a site. Make a study live in Production mode only after the site has contractually agreed to the protocol and regional regulatory requirements are in place. A site that has been activated can never be deleted, but it can be retired. This procedure also applies to rollover studies.
- Delete a site at the study level
  If necessary, a study level site can be deleted by a sponsor or CRO user.
- Retire a site at a study level
  Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.
- Create and manage institutions, vendors, and contacts
- Site, depot, labs, and source data verification FAQs

Delete a site at the study level

If necessary, a study level site can be deleted by a sponsor or CRO user.

> **Note:**
>
> A site can only be deleted when it is in a status of *New*. Once a site is set to *Active*, it can only be retired.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Locate and select the site that you want to manage.
4. Click the **Manage Sites** drop-down and select **Delete**.
5. In the Confirmation dialog, click **Yes**.

Related Topics

- Activate a site
  To make a study version live, activate a site. Make a study live in Production mode only after the site has contractually agreed to the protocol and regional regulatory requirements are in place. A site that has been activated can never be deleted, but it can be retired. This procedure also applies to rollover studies.
- Edit a site at the study level
  You can modify certain details of a site at the study level.
- Retire a site at a study level
  Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.
- Site, depot, labs, and source data verification FAQs
- Create and manage institutions, vendors, and contacts

Manage site permissions

You can limit the activities a site user can perform, such as adding new subjects, screening and randomizing subjects or dispensing kits.

During the study conduct period, you might need to stop the enrollment of new subjects and limit screening, randomization and dispensation, at one or multiple sites at once. For instance, if you need to have a balance between subjects enrolled at different sites and you notice that one site is approaching its limit for randomized subjects, you can prevent site users at that site from adding more subjects, screening, or randomizing them. Or, if one of the sites in your study requires additional protocol training, you might need to suspend dispensing to all subjects.

1. On the Home page, click the study settings button ( ) for the study you want to monitor, and select **Open Settings**.
2. Below the study name, navigate to the **Sites & Labs** tab.
3. On the left, select **Production Sites**, **Testing Sites** or **Training Sites**.

4. Choose one or multiple sites and from the **Manage Sites** drop-down select **Edit**.
5. Go to **Site permissions** and, depending on your study protocol, click the check boxes to activate or deactivate one or more of the following permissions:
   - **Add Subjects**: Enable or prevent site users from adding subjects at one or multiple sites
   - **Screen Subjects**: Enable or prevent site users from screening subjects at one or multiple sites
   - **Randomize Subjects**: Enable or prevent site users from randomizing subject at one or multiple sites
   - **Dispense to Subjects**: Enable or prevent site users from dispensing kits, devices or performing dose changes for subjects at one or multiple sites
6. In the lower left, click **Save**.

Note on the main Sites & Labs screen, that for each permission that is turned off a new icon appears next to the given site.

Manage screening and randomization limits by site

Study managers can set screening and randomization limits for each site individually.

When managing screening and randomization limits, users can either set site limits for the total of sites at once or for individual sites. SeeSpecify study, visit, limit, and cohort settings for more information on setting total limits.

Users must consider the status of the site when setting limits. For example, active sites can have limits, but retired site cannot, However, subjects from retired sites will still count toward the overall limit for study totals.

1. Open the study's settings.
2. Select the **Sites & Labs**tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Turn on the **Show Limits** toggle, in the upper right corner of the screen, to show the limits columns.

> **Note:**
>
> When toggle is **off**, no specific limits are considered for sites.

5. Enter a number for the **Screening Limit** and **Randomized Limit** in the appropriate column and for each site as required.

> **Note:**
>
> The column for randomization limits is not available if you have not defined randomization in any study version for the given mode. To add a randomization list, see Generate a randomization list.

6. Click **Apply Changes**.

Add a lab to a study

You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.

> **Note:**
>
> To complete this task, a global user must first create a lab at your organization's level. For more information, see Create a vendor (lab).

To perform this task, you must be assigned the *Create and Add Labs to a Site* permission.

You create laboratories in the context of a site. Creating a lab in the context of the site automatically associates that lab with the respective site. You cannot create or assign a lab to a retired site. Moreover, you cannot remove a lab that is used for a site (whether the site is active or retired).

We recommend creating mock laboratories to use in Testing mode and actual laboratories to use in Production and Training modes.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Along the top, select a specific mode:
   - **Production Sites**
   - **Testing Sites**
   - **Training Sites**
4. Locate the site that you want to create a lab for.
5. In the Labs column, click **View Labs** next to the site that you want to create a lab for.
6. Click **Add Lab**.
7. In the Add Lab dialog, fill in the fields and click **Next**.

Field	Description
Search Lab	From the drop-down, select a lab. This drop-down includes the labs that were created at a global level.
Lab ID	Enter a short name or ID for the local lab. A lab ID may contain other characters such as numbers or special characters.

8. In the **Addresses** section, click **Add Address** and select the type of address you want to associate with this lab.

   For more information, see Specify a primary address.

9. Click **Create**.

10. Click **Close**.

Along the top, click **Assign/ Manage Labs**, to either assign another lab to the site you're currently in, edit a selected lab, or remove it.

Related Topics

- Assign a local lab to a site
  Site managers or other sponsor users can assign a local laboratory to a site.
- Define lab normals
  Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.

Define lab normals

Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.

Lab normals are typically numeric values or predefined options that you need to set for lab units, low and high data ranges, normal text results, and so forth. You must define lab normals for every lab test collected for a subject. For example, if you need to collect results for a creatinine test, you must define lab normal ranges, including the lab unit, low range and high range, as well as the gender, age, and effective date for that lab test.

Lab normals are defined within the context of a laboratory. Values used for lab tests, lab units, normal text values, gender, and race are all defined by the study designer. When you define lab normals, these values appear in the drop-down for each column.

Want to see how to perform this task? Watch the video below.

Video

> **Note:**
>
> Before you begin defining lab normals, consider the following notes:
>
> - If a lab normal is not relevant in your study, you can leave it empty. In turn, that empty lab normal row is displayed as a grayed out form table cell in the lab form.
> - If you have to specify age-dependent lab normal ranges, make sure there is no overlap between the age ranges that you enter in the **Age From** and **Age To** columns. For example, if you have to specify lab normal ranges for two different age groups (2-5 and 5-12 years), then you must specify them as follows:
>   - For the first age group, enter 2 in the **Age From** field and 5 in the **Age To** field.
>   - For the second age group, enter 6 in the **Age From** field and 12 in the **Age To** field.

1. Open the study settings.

2. On the **Sites & Labs** tab, select a specific mode:
   - **Production Sites**
   - **Testing Sites**
   - **Training Sites**
3. Locate the site for which you are creating or managing the laboratory.
4. On the Labs column, next to the site, click **View Labs**.
5. Click the name of the laboratory for which you need to define the lab normals.
6. On the left, in the Lab Tests column, select each test, and fill-in the following fields as needed:

Lab Normal	Description
Lab Unit	Select the unit of measure used for collecting and measuring data for the lab test. For example, select U/L or ng/mL for a creatine kinase (CK) test.
Low Range	Enter the lower limit of the reference range for the lab test. For example, 24 for a creatine kinase (CK) test.
High Range	Enter the upper limit of the reference range for the lab test. For example, 174 for a creatine kinase (CK) test.
Normal Text Result	Select the value that can be used as a reference for a lab test. For example, **Negative** for an HPV test. ***Note**: For a lab test, you can either define values for the low range and high range or the normal test results. You cannot define both types of lab normals.*
Fasting	Select the value that can be used as a reference for a subject's fasting status: • **Yes** • **No** • **All** By default, the **All** option is selected for each lab test. These options are defined as part of a code list (at a study level or at a global level), so the options displayed for the Fasting lab normal can be different in your study. For example, you might see **Fasting** and **Not Fasting**. **Caution:** Keep the **Fasting** and **Collection Date** fields visible and required. Avoid turning the toggle on for the **Hidden** or the turning the toggle**Required**off from the Detail pane. This change will make the subject tag uneditable to all users and prevent lab selection and form completion.

Lab Normal	Description
Gender	Select the gender that the laboratory normals apply to for a the lab test. For example, for a creatine kinase (CK) test you can select **Male** if the values for a lab unit and low range are defined according to laboratory normals typical to men. You can select **All** if the lab normals apply to all genders or if your study doesn't collect data on gender. ***Note**: A site user can only select one option for the Gender lab normal.*
Age From	Enter a number for the minimum age included in the age range for a lab test.
Age From Units	Select the unit of measure for a subject's age.
Age To	Enter a number for the maximum age included in the age range for a lab test.
Age to Units	Select the unit of measure for a subject's age.
Race	Select the race that the laboratory normals apply to for the lab test. You can select **All** if the lab normals apply to all races or if your study doesn't collect data on race. ***Note**: A site user can only select one option for the Race lab normal.*
Effective Date	Enter the date from which the lab normal range became effective at the laboratory. If a second normal range with matching unit, age, gender, and race values is entered with a later effective date, those values are used for any visit date on or after the new effective date. The effective date is compared to the sample collection date or the visit date, if the sample collection date is not being used in a lab form.

7. Save your changes:
   - Click **Save**, if you want to make any other changes to the lab normals.
   - Click **Save & Close** to complete this task.

Related Topics

- Add a lab to a study
  You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- Assign a local lab to a site
  Site managers or other sponsor users can assign a local laboratory to a site.
- How are lab normal updates reflected in existing lab forms?
  If you update lab normal values during a study's conduct period, these updates are reflected in all started lab forms, including existing ones, whether complete or not.
- Tag questions on age, gender, and race
- What should I do if my study cannot collect data on a subject's race?

How are lab normal updates reflected in existing lab forms?

If you update lab normal values during a study's conduct period, these updates are reflected in all started lab forms, including existing ones, whether complete or not.

Automatic updates for lab normal ranges in lab forms do not impact a question's Signed or Verified status. Lab normal updates are still pushed to lab forms even if data is locked.

If you work with local labs, upon updating and saving a lab's normal ranges from the **Sites & Labs** tab, your updates are automatically refreshed in the existing lab forms five minutes after your last update was saved. For example, if you save an update to the lab normal ranges at 05:00 PM, the system begins processing the update at 05:05 PM, and the changes may take additional time to appear in all impacted lab forms, depending on the volume of updates. You can view an audit trail of that lab normal update on the Answer & Visit History sidebar.

Impact on reports

You can view which lab form rows had their lab normals updated throughout the study in the following reports:

- In the Subject Data report, the **Type of Change** column indicates that a lab normal value was updated. The **User Name** column displays"system user" indicating that this update was performed automatically by the system in the lab form.
- In the Subject Data Extract, the latest updates for lab normals are displayed in the applicable columns.
- In the Lab Normal Range Report you can view all details related to how lab normal values were updated, which user performed the update, and when they made the update.

Impact on custom JavaScript rules

If any of the lab normal updates that are performed in your study impact any custom JavaScript rules, here's what you should know:

- If a lab normal range is updated, any custom rules that reference the normal range values re-run based on the custom rule's logic. For example, if a data manager updates the lab normal range for a Creatinine test, and you have a calculation rule that references the Creatinine test field in a lab form, that calculation rule is re-run.
- If the re-running of a custom rule for a lab normal range value results in an error, the target field is highlighted in the lab form and indicates that there's an error.

Related Topics

- Create a vendor (lab)
  Sponsor users can create a lab as a vendor at the global level.
- Add a lab to a study
  You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- Define lab normals
  Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- Assign a local lab to a site
  Site managers or other sponsor users can assign a local laboratory to a site.

Assign a local lab to a site

Site managers or other sponsor users can assign a local laboratory to a site.

Local labs are created at the global level and then manually assigned to a site. Sponsor users assigned the *Manage Contacts and Organizations* global role can assign additional labs to the same sites, allowing site users to indicate which local lab they are collecting data from.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Locate the site that you want to assign a lab to.
4. Click **Assign Lab**.
5. In the Assign Labs dialog, select the lab you would like to assign.
6. Click **Assign**.

Related Topics

- Create a vendor (lab)
  Sponsor users can create a lab as a vendor at the global level.
- Add a lab to a study
  You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- Define lab normals
  Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- How are lab normal updates reflected in existing lab forms?
  If you update lab normal values during a study's conduct period, these updates are reflected in all started lab forms, including existing ones, whether complete or not.

Make sure users are assigned to the correct sites and depots

Sometimes users are created before sites and depots are set up. If your study followed that workflow, make sure you assign everyone to the appropriate sites and depots after the sites and depots are created.

> **Note:**
>
> For a site user to enroll and dispense kits to subjects in a rollover study, they need to be assigned the same permissions, the same sites, and depots in both the original and the rollover study.

1. Open the study settings.
2. Click the **Users** tab.
3. To see the roles and sites assigned to a user, select the user, and expand **Assigned Study Roles** and **Assigned Sites** on the right side pane.

4. To edit a user's roles or sites, or to see the user's assigned depots, select a user, and from the **Manage Users** drop-down, select **Edit**.
5. In the Edit User dialog, verify that the user has the correct study roles for Production, Training, and Testing modes. Make updates as required.
6. Click **Next** and verify user is assigned to the correct sites and depots. Make updates as required.
7. Click **Finish**.

Repeat for every user who will work in Production, Training, and Testing modes.

Define settings

Once you have created and configured facilities in your study, study managers and clinical supply managers must specify the study's settings.

- Define settings for *Testing mode* first, so you can test and verify a study version using mock data.
- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Add a locally sourced kit
  Define locally sourced kits for your study's countries.
- Add a region
  You need to add regions to your study to be able to successfully randomize subjects. This procedure can also apply to rollover studies.
- Specify study, enrollment, and visits settings
  Typically, a study manager specifies these settings. They can configure settings for all modes simultaneously. We recommend you set and verify these settings in Testing mode first. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.`
- Specify enrollment settings for minimization cohorts
  When specifying the enrollment settings, if your study includes a minimization design , the system displays the cohorts in sections by each minimization design. Typically, a study manager specifies these settings. This procedure also applies to rollover studies.
- Create or edit custom enrollment limits
  Study managers can create custom enrollment limits to restrict subject enrollment based on specific criteria. Custom enrollment limits can be defined in all three modes: Testing, Training, and Production.
- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.

- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- Specify supply settings
  Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.
- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.
- Create or edit a dose hold
  As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.
- Create and manage a partial dispensation
  Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.
- Create a min/max resupply strategy
  You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.
- Create a predictive resupply strategy
  You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.
- Create a blinded group of kits
  Create blinded groups if you don't allow single kit ordering, and if the kits in your study use different packaging. Blinded groups determine the kit or kits that are added to a single-kit shipment to protect the study blind. This procedure also applies to rollover studies.
- About signature configurations
  Learn more about creating signature configurations.
- Create a signature configuration
  As a study administrator, create a signature configuration to allow sites to sign off at the form and or visit level using custom affidavits.
- Manage signature configurations at the casebook level
  Define a signature configuration at the casebook level.
- Configure the connection to Oracle mHealth Connector so you can dispense devices
  When a study dispenses IoT-enabled devices managed with Oracle mHealth Connector, you must establish a connection with Oracle mHealth Connector so that data collected from the devices can be sent to the appropriate application. To establish a connection, you enter a user name, password, and URLs for Oracle mHealth Connector. This procedure can also apply to rollover studies, according to how the rollover study is designed.

Add a locally sourced kit

Define locally sourced kits for your study's countries.

Depending on your study's restrictions and requirements, you can configure locally sourced kits for your study.

> **Note:**
>
> A kit type must be set to Unblinded at the time it is created in order for it to be available to be locally sourced. For more information on defining kit types, see Define the kits for investigational products.

To add a locally sourced kit:

1. Open the study settings.
2. Below the study name, click the **Supply Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. In the **Locally Sourced Kit Settings** section, select **Add Kit**.
5. In the Add Locally Sourced Kit dialog, complete the following fields:

Field	Description
Kit Type	Select the type of kit that can be locally sourced.
Locally Sourced Countries	Choose the countries the selected kit type can be sourced from.
Sourced by Site Countries	Choose the countries whose kits can be locally sourced.

> **Note:**
>
> A country can only be added to either **Locally Sourced Countries** or **Sourced by Site Countries**, but not added to both.

6. Click **Add**.

Add a region

You need to add regions to your study to be able to successfully randomize subjects. This procedure can also apply to rollover studies.

Do I have to do this? Only if you're using region-blocked randomization.

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Click the **Study Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. In the Randomization Regions section on the right side pane, click **Create Region**.
5. In the Create Region dialog, enter a title for the region, such as **Asia Pacific** or **Eastern Europe**.
6. Select and expand the country to include in the region.

   If you want to define a region to include states only, expand a country to view its provinces and select those to be included in the region.

   > **Note:**
   >
   > The same country is available to select in multiple regions but country states are only available to be added into one region.

   The country provinces are displayed.
7. Move the countries or provinces to the Selected States section by clicking the arrow icon (»).
8. Select any of the following:
   - **Save & Add Another** to save and create another region.
   - **Add** to create the region and close the Create Region dialog.

   The regions are now displayed in the Selected States section along with their countries and states or provinces.
9. Create additional regions as needed for all modes.

Specify study, enrollment, and visits settings

Typically, a study manager specifies these settings. They can configure settings for all modes simultaneously. We recommend you set and verify these settings in Testing mode first. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.`

> **Tip:**
>
> These settings can be modified anytime and apply to all study versions. For guidance on editing the settings, see Updates during the study conduct period.

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Below the study name, click the **Study Settings** tab.
3. Along the topic, select a specific study mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Fill in the fields below **Study Settings**.

> **Tip:**
>
> To view tips for completing a field, click into the field or choose an option.

Setting	Description
Allow Subjects to be Manually Added	• Choose **Yes** to let site users manually add subjects to your study. • Choose **No** to prevent site users from manually adding any subjects to your study.
Replace Subject Number with Randomization Number	This setting is only visible when the permission *Manage Subject Number Configuration* is added to a study role. If the setting is grayed out, a subject has already been screened or enrolled in that mode. • Choose **Yes** to automatically replace the subject number with the randomization number. ***Note**: The setting cannot be changed after the first subject has been screened or enrolled.* For more information about this setting, see Study impact when replacing a subject number with the randomization number.
Blind Randomization Number	• Choose **Yes** to hide subject randomization numbers in the system's user interface (UI) for your study. *Blinded Randomization Number* displays in place of the randomization number. • Choose **No** to display subject randomization numbers in the UI for your study. ***Note**: Setting the **Blind Randomization Number** option to **Yes**, disables the **Replace Subject Number with Randomization Number** option.*
Allow Site to Select Subject Number	• Choose **Yes** to let site users select subject numbers. • Choose **No** if subject numbers should be automatically assigned.
Include Hyphen Between Site and Subject Number	• Choose **Yes** to separate the site ID and subject number with a hyphen (for example, 001-001). • Choose **No** for no hyphen (for example, 001001).
Leading Zeros in First Subject Number	Enter the number of zeros to include at the beginning of the first subject number. Note that the number of leading zeros decreases as the number of digits in the subject number increases. For example, if you enter 3, the first subject number might be 0001, the 99th subject might be 0099, and the 100th subject might be 0100.

Setting	Description
First Subject Number	Enter the number assigned to the first subject in either the study (if subject numbering is sequential in the study) or at each site (if subject numbering is sequential at each site). ***Note**: This setting is only available when **Allow Site to Select Subject Number** is set to **No**.*
Subject Numbering	• Select **Sequential in Study** if subject numbers are sequential across all sites in the study (for example, subject 1 is at Site A, subject 2 is at Site B, and subject 3 is at Site A). • Select **Sequential at Sites** if subject numbers are sequential at each sites (for example, Sites A and B both have subjects 1, 2, 3, and so on). ***Note**: This setting is only available when **Allow Site to Select Subject Number** is set to **No**.*
Subject Number Format	Specify the characters allowed at each position of the subject number, moving from left to right. For instance, you can use the expression [0-9] to indicate that in the first position only a single digit between 0 and 9 is allowed. For more details on how to define a subject number format, see What are my options for defining a subject's number format? ***Note**: This setting is only available when **Allow Site to Select Subject Number** is set to **Yes**.*
Withdraw Subjects After Code Break	Choose **Yes** if subjects are withdrawn from the study after a code break. A code break is the unblinding of a subject's treatment arm.
Hide the Visit Window Projection	• Choose **Yes** to hide the time frame for scheduled visits under the visit title on the Subjects page. • *Choose **No** to display the time frame for scheduled visits.* ***Note**: This setting is set to **No** by default.*
Screen Failed Subjects	• Select **Allow Screen Fail before Screened** to allow manual screen failure if subjects have not yet been screened. • Select **Allow Withdrawal** to allow subjects that have failed screening to withdraw from the study. • Select **Allow Completion** to allow subjects that have failed screening to complete the study. ***Note**: **Allow Withdrawal** and **Allow Completion** are deselected by default.*
Allow Withdrawal for Subjects before Enrollment	Select the checkbox to allow subjects to withdraw from the study before they've been enrolled.
Display signature elements for site staff and sponsors	Select **Yes** to allow the Signature widget () and Signature Request side panel to appear in the user interface for the corresponding study mode. ***Note**: This option is set to **No** by default and cannot be changed back to **No** once you have selected **Yes**.*
Code data for new and screen failed subjects	***Note**: This setting can be changed at any time. It is set to **Yes** by default.* • Select **Yes** to allow all verbatim terms to be sent to Oracle Central Coding. • Select **No** to allow new verbatim terms to be sent to Oracle Central Coding once a subject's status is changed to *Enrolled* or *Active*.

5. Fill in the fields below **Enrollment Settings**:

> **Tip:**
>
> You don't need to specify limits for every field and in fact probably don't want to. Setting limits on many levels can sometimes result in randomization errors that are difficult to troubleshoot. You can change limits at any time.

a. Locate the row with the type of limit that you want to set and turn the toggles on and off as required:

- **Study Total**: Specify limits for the entire study.
- **Site Total**: Specify limits for sites. All sites are subject to the same limit.
- **Country**: Specify limits that every country is subject to; or create country-specific limits. To specify country-specific limits, click Add Countries, select your countries, and then enter limits for them.
- **Cohorts**: Specify a limit for each cohort. Want to know how to open and close a cohort?

> **Note:**
>
> Only the studies that use a randomization type that requires cohorts will display this field.

b. For each row, select the checkboxes in the column First Screened Notification or First Randomized Notification, to activate the alerts respectively.

> **Note:**
>
> Activating the notifications is not enough. Users need to have the appropriate permissions assigned to receive these notifications. For more information, see Subject notifications.

c. For each activated row, fill in the values for:

> **Note:**
>
> Notifications sre sent only to those site and sponsor users with permission to receive it. For more information on how to activate the notifications, see First subject screened in study notification and First subject randomized in study notification.

Setting	Description
First screened notification	Select the check-box if you want to receive information about the first screened subjects for either a study or a site.
First randomized notification	Select the check-box if you want to receive information about the first randomized subject for either a study or a site.

Setting	Description
Screening Limits	Enter the maximum number of subjects who can be screened. Screen failures count toward this limit. After this limit is reached, sites can't add any more subjects. • If you want to limit only randomization, for example, you can leave the Screening limit fields blank. • If you want to add screening limits individually by site, click **View Sites** to go to the **Sites & Labs** tab. For more information, see Manage screening and randomization limits by site. ***Note**: Limits defined on the Sites & Labs tab will override values set in this table.*
Randomization Limits	Enter the maximum number of subjects who can be randomized. After this limit is reached, no subjects can be randomized (even subjects who were already added to the study). • If you want to limit only randomization, for example, you can leave the Screening limit fields blank. • If you want to add screening limits individually by site, click **View Sites** to go to the **Sites & Labs** tab. For more information, see Manage screening and randomization limits by site. ***Note**: Limits defined on the Sites & Labs tab will override values set in this table.*
Notification %	Enter the percentage of subjects in the limit who can be either screened or randomized before a notification occurs. The notification percentage that you specify applies to both the screening and randomization limits. You can adjust this value throughout the study conduct period so that you receive updates about the number of screened and randomized subjects. ***Note**: Subjects from all study versions for a particular study count toward the limits.*

d. If your study includes a minimization design with cohorts, specify enrollment settings for minimization cohorts that have been created in study design.

6. Fill in the fields below **Visit Settings**:

Setting	Description
Site Enters Visit Dates	Select the types of visits for which site users can select either the current date or an earlier date as the visit start date. • If this setting is checked for a visit, a site user can enter a visit date prior to entering visit data in the form. When data is entered (outside of the Visit Start Date field), the system does not automatically update the visit date to the current date. • If this setting is not checked, a site user cannot enter a visit date prior to entering visit data in the form. When data is entered, the system automatically updates the visit date to the current date.

Setting	Description
Site Edits Visit Date	Select the visits for which site users can edit the visit start date after the form has been saved. The visit schedule is based upon the visit date, and if site users enter data prior to the visit date, the visit schedule might not be calculated as expected. If you expect that site users will enter data for a visit prior to the visit date, consider allowing them to edit the visit date. Otherwise, the visit start date that is recorded might not be accurate. ***Tip***: • *For screening visits, this setting is useful when sites enter data for the screening visit on a later day than when the site user clicked Screen for the subject.* • *For dispensation visits, this setting is useful when a site must click Dispense prior to the subject coming in for a visit, such as if a pharmacist must prepare the product in advance for the subject.*
Visit Date Must Be On or After Randomization	Select if the visit date for the randomization visit must be on or after the date when the site user clicked the Randomize button for the subject. ***Tip***: • *This setting is useful for when a site starts the randomization visit before the visit date. For instance, if a site user starts entering data for a form on Monday, the visit date is set to Monday. However, if the subject doesn't come in until Wednesday, and the site user doesn't click Randomize for the subject until Wednesday, Oracle Clinical One Platform requires the site user to update the Visit Start Date to Wednesday.* • *This setting is also useful if a site has to complete a randomization visit prior to the subject arriving for a visit, such as for when a compound must be prepared for the subject.*
Visit Date Must Be On or After Dispensation	Select if the visit date for the type of visit must be on or after the date when the site user clicked the Dispense button for the subject. ***Tip***: • *This setting is useful for when a site starts the dispensation visit before the visit date. For instance, if a site user starts entering data for a form on Monday, the visit date is set to Monday. However, if the subject doesn't come in until Wednesday, and the site user doesn't click Dispense for the subject until Wednesday, Oracle Clinical One Platform requires the site user to update the Visit Start Date to Wednesday.* • *This setting is also useful if a site has to complete a dispensation visit prior to the subject arriving for a visit, such as for when a compound must be prepared for the subject.*
Visit Can Be Skipped	Select to allow site users to mark a visit as skipped when a subject doesn't come in for a scheduled visit. If site users skip a dispensation visit, they won't be able to dispense for the visit unless they undo the skip and complete the required fields on the forms in the visit. Site users can always skip optional visits and can never skip the following visits: • Screening and randomization. • A required visit that occurs before the screening visit. • Any visit for which data has been entered.

Setting	Description
Send Visit Notification	Select to allow study team members and site users to receive notifications for subjects completing their screening, non-dispensation, optional, and unscheduled visits. • Select **Success and Failure** to make sure they receive both types of notifications. • Select **Failure Only** to be notified only when the visit presents errors. ***Tip**: This setting is useful for all study team members who should know if subjects have successfully completed their visits, if they couldn't be screened, or if they couldn't successfully go through their visit.*

7. In the upper right, click **Apply Changes**, then select an option:
   - Select the option to apply to the given mode.
   - Select **Apply to All Modes** to use the study settings in all 3 modes.

- Study impact when replacing a subject number with the randomization number
  See how your study is impacted when you replace a subject number with a randomization number.

Related Topics

- Add a region
  You need to add regions to your study to be able to successfully randomize subjects. This procedure can also apply to rollover studies.
- Specify enrollment settings for minimization cohorts
  When specifying the enrollment settings, if your study includes a minimization design , the system displays the cohorts in sections by each minimization design. Typically, a study manager specifies these settings. This procedure also applies to rollover studies.
- Create or edit custom enrollment limits
  Study managers can create custom enrollment limits to restrict subject enrollment based on specific criteria. Custom enrollment limits can be defined in all three modes: Testing, Training, and Production.

Study impact when replacing a subject number with the randomization number

See how your study is impacted when you replace a subject number with a randomization number.

When the setting **Replace Subject Number with Randomization Number** is enabled, subjects are still assigned a subject number after being screened or enrolled.

After randomizing a subject, the randomization number replaces the subject number throughout the study, and the original subject number is referred to as the Screening Number.

The table below provides information about how the setting impacts your study.

Table 4-2 Details about the impact to your studies

Impacted area	Details
User interface	• The new subject number is displayed in the user interface anywhere the original subject number was displayed, including all dialog windows. • When sorting subjects on the all-subjects screen, the system uses the Screening Number (the original subject number assigned after screening or enrollment). This ensures sorting reflects the order in which subjects were added to the study. • When searching for subjects on the all-subjects screen, users can search using Screening Number (the original subject number assigned after screening or enrollment) or the new subject number (assigned after randomization).
Randomization lists	If the randomization number is updated in the Randomization List after the number was assigned to a subject, the updated value overwrites the randomization number (subject number) in the study. ***Note**: While in Testing mode, Oracle Clinical One Platform restricts the use of duplicate subject numbers. To ensure accurate testing and avoid issues, do not import the same randomization list after randomization testing has started. This ensures the system does not attempt to use the same randomization number twice*.
Re-randomization	The new subject number, assigned after initial randomization, is not updated if a subject is re-randomized.
Randomized in error	Replacing the subject number with the randomization number only occurs once per subject. The one exception is if a subject is randomized in error. • The randomization number, assigned in error, remains associated with the subject until it is updated to **Randomized in Error** in the Randomization List. • When that is done, the subject number is reverted to the subject number assigned after screening or enrollment. • If the subject is randomized in the future, the randomization number replaces the subject number. ***Note**: If a randomization number is manually assigned to a subject randomized in error, the subject number is not updated. For more information, see Manually assign a randomization number to a subject*.

Table 4-2 (Cont.) Details about the impact to your studies

Impacted area	Details
Update Subject Number(s) permission	Selecting **Update Subject Number(s)** from the **Manage Subjects** drop-down on the All Subjects screen results in an update to the Screening Number, not the new Subject Number.
The Subject Number Format setting	The **Subject Number Format** setting on the **Study Settings** tab does not apply to the randomization number assigned to a subject; it only applies to the initial number assigned to a subject after screening or enrollment, which is also reflected in the Screening Number.
Notifications	• Notifications include the current subject number displayed in the user interface. • Notifications sent as a part of or after randomization include the new subject number. For more information about notifications, see the Notifications and Permissions Guide.

Table 4-2 (Cont.) Details about the impact to your studies

Impacted area	Details
Standard reports	For more information about standard reports, see the Reporting Guide. Once the subject number is changed, the new subject number is associated with all data, including data collected before the change. The following reports are uniquely impacted: • Subject Data report – The report output includes a column to capture the Screening Number, populated with the original subject number assigned after screening or enrollment. – After randomization, the **Subject Number** column displays the randomization number, and the **Screening Number** column remains unchanged. • Study Design report – The setting that controls this functionality is not available in design mode, sometimes called draft mode, and, therefore, is not included in the report when generated in design mode. – The setting appears in the report output for the three other modes (Testing, Training, and Production) if the permission that controls the setting is added to any study role. • Subject Events Report – Before randomization, the **Current Subject Number** and **Screening Number** columns display the subject number assigned after screening or enrollment. The **Previous Subject Number** column also displays N/A. – After randomization, data is displayed in the following ways: * **Current Subject Number** column displays the randomization number. * The original subject number (assigned after screening or enrollment) is displayed in the **Screening Number** column. * And the **Previous Subject Number** column displays N/A. ***Note**: If the Screening Number is edited, the new number appears in the **Screening Number** column, and the previous Screening Number is displayed in the **Previous Subject Number** column.* – The report contains an entry to record the activity. The **Event Type** and **Reason** columns are populated with *Randomization Number assigned to subject number*.

Table 4-2 (Cont.) Details about the impact to your studies

Impacted area	Details
Subject Data Extracts	The Subject Data Extract includes three columns containing data related to the subject number. • **USUBJID**: Also referred to as the subject GUID. This is a unique value across all studies and does not change if the subject number does. • **SUBJID**: This is a unique value within a study and contains the original subject number or the new subject number after randomization. • **SCRNID**: This is the Screening Number, the original subject number assigned after screening or enrollment. – The Screening Number is displayed even if the setting is not enabled. – The value is updated if the **Update Subject Number(s)** option is used under **Manage Subjects** on the subject listings page. For more information, see Subject Data Extract.
Oracle Clinical One Analytics	For the following datasets, the Subject folder contains a SCREENING_NUMBER data element. This is a static element that always displays a subject's original screening number. • Blinded Kits dataset • Blinded Subject Events dataset • Queries dataset • Subject dataset • Subject Form Items dataset • Subject Forms dataset • Unblinded Kits dataset • Unblinded Subject Event dataset After you randomize a subject: • The SUBJECT_NUMBER data element displays the randomization number. • The PREVIOUS_SUBJECT_NUMBER data element displays the subject number assigned to a subject before randomization. • The SCREENING_NUMBER data element remains unchanged, as it always displays the original screening number for a subject. For more information about Analytics, see Get started with Oracle Clinical One Analytics
Oracle Life Sciences Data Management Workbench (DMW)	• The integration between Oracle Clinical One Platform and DMW continues to work. This is because the subject GUID, which does not change if the subject number does, is the unique identifier used when exchanging data between the two systems. • However, even though the integration continues to work, the updated subject number is not currently present in DMW. Integrating the updated subject number is planned for a future release.

Table 4-2 (Cont.) Details about the impact to your studies

Impacted area	Details
Oracle CRF Submit archives and reports	• Requests that use **Now** for the **As of Date** include the new subject number once a subject is randomized. • Requests that use an **As of Date** before randomization reflect the initial Subject Number assigned after screening or enrollment, and a date used after randomization reflects the new subject number. • The **Subject ID** column in the Download Log report may contain a single subject's original and new subject numbers. This is because the report is an audit history for downloads of PDFs and reports, which can occur before and after randomization. For more information about Oracle CRF Submit, see Oracle CRF Submit archives and reports
Oracle Clinical One Digital Gateway configured integrations	***Note**: Review this section in future releases to see additionally supported Oracle Clinical One Digital Gateway configured integrations*. Oracle Clinical One Platform can send the updated subject number to an integrated third-party system. Make sure the other system is capable of processing such an update. If not, you may want to reconsider enabling this setting. **Supported integrations** • Oracle Clinical One Platform to Oracle InForm – In addition to the new setting being enabled, a configuration update is required to take advantage of this feature. Work with your Oracle Services Consultant to apply the necessary updates.
Oracle Central Coding	This feature is not supported in Oracle Central Coding. Verbatim terms, present in Oracle Central Coding, entered before and after randomization, remain associated with the original subject number assigned after screening or enrollment.
Subject migration	The APIs that migrate subjects populate the database with the original subject number (assigned after screening or enrollment) and the new subject number (assigned after randomization).

Specify enrollment settings for minimization cohorts

When specifying the enrollment settings, if your study includes a minimization design , the system displays the cohorts in sections by each minimization design. Typically, a study manager specifies these settings. This procedure also applies to rollover studies.

Each minimization design contains a number of cohorts defined when creating the randomization. Minimization cohorts are organized underneath each minimization design listed

in this section. For example, a minimization design called "Minimization 1:1" will have a corresponding section of cohorts on this screen called "Minimization 1:1 Cohorts".

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Below the study name, click the **Study Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Within the Enrollment Settings section, locate the cohorts and expand each to fill in the fields:
   a. For each of the displayed cohorts, turn on the toggle to open the enrollment of subjects based for that cohort. Turn the toggle off to close the enrollment for that minimization cohort.
   b. In the **Enrollment and Randomization Limits** column, enter the maximum number of subjects who can be randomized.

      After this limit is reached, no subjects in this cohort can be randomized (even subjects who were already added to the study). The system then proceeds to randomize subjects from the next cohort included in the minimization.
   c. In the **Notifications** column, enter the percentage of subjects in the limit who can be randomized before a notification occurs.

      You can adjust this value throughout the study conduct period so that you receive updates about the number of screened and randomized subjects.
5. In the upper right, click **Apply Changes**, then select an option:
   - Select the option to apply to the given mode.
   - Select **Apply to All Modes** to use the study settings in all 3 modes.

Related Topics

- Add a region
  You need to add regions to your study to be able to successfully randomize subjects. This procedure can also apply to rollover studies.
- Specify study, enrollment, and visits settings
  Typically, a study manager specifies these settings. They can configure settings for all modes simultaneously. We recommend you set and verify these settings in Testing mode first. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.`
- Create or edit custom enrollment limits
  Study managers can create custom enrollment limits to restrict subject enrollment based on specific criteria. Custom enrollment limits can be defined in all three modes: Testing, Training, and Production.
- Upload a randomization list for minimization
  Create a randomization list for minimization in Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

- Define the minimization

Create or edit custom enrollment limits

Study managers can create custom enrollment limits to restrict subject enrollment based on specific criteria. Custom enrollment limits can be defined in all three modes: Testing, Training, and Production.

To make sure you create relevant and appropriate custom enrollment limits in your study, you must work with your study designer to make sure the following elements are defined in a study's design:

- You must include a screening visit in your study. Moreover, you must assign forms to that visit.
- You must include questions with multiple options for an answer, as well as age questions.
- Work with your study designer to make sure that multiple-choice questions, such as checkboxes and drop-down questions, have a Select Exactly One or Answer Must Be validation rules defined.
- Questions on a subject's age must be defined as the specific age type of question.

A custom enrollment group may need to be modified during the study conduct period. For example, if a question used as enrollment criteria is removed or modified, that question is highlighted when you attempt to edit the custom enrollment group. Review the changes and if you still need to use that question for your enrollment criteria, work with your study designer.

1. Open the study settings.
2. Below the study name, click the **Study Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Scroll down to the Custom Enrollment Settings.
5. Depending on whether this is your first time creating a custom enrollment limit or not, you can:
   - Click **Add Custom Enrollment Group** to create your first enrollment group.
   - Click the **Edit icon** () to edit an existing enrollment group.
6. On the Create Custom Enrollment Group dialog, enter the details for the following fields:

Field	Description
Group Title	Enter the name of the enrollment group, such as High Risk.
Subject Limit	Insert the maximum number of subjects permitted for the enrollment group.
Notification	Enter the percentage of enrollments that generates the Study Limits notification.
Description	(Optional) Provide additional information about the enrollment group that does not fit in the title.

7. Click **Select a Visit**.

The system displays all scheduled visits at or before the Screening visit.

8. From the drop-down, select the appropriate visit, branch, or cycle.
9. Click **Select a Form** and select a form to display its questions.
10. Drag the desired question and drop it onto the Group Criteria section.

    Repeat this step for every question you want to use as enrollment criteria.
11. Configure the settings of each question for your group criteria.

    For example, for a question with multiple choices, select the exact answer options that must be used as enrollment criteria. Or, for the age question, define the age range of subjects that can be enrolled.
12. Click **Save** or **Save & Add Another**.

    The system adds the custom enrollment group to the table.

Related Topics

- Add a region
  You need to add regions to your study to be able to successfully randomize subjects. This procedure can also apply to rollover studies.
- Specify study, enrollment, and visits settings
  Typically, a study manager specifies these settings. They can configure settings for all modes simultaneously. We recommend you set and verify these settings in Testing mode first. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.`
- Specify enrollment settings for minimization cohorts
  When specifying the enrollment settings, if your study includes a minimization design , the system displays the cohorts in sections by each minimization design. Typically, a study manager specifies these settings. This procedure also applies to rollover studies.
- Create or edit custom enrollment limits
  Study managers can create custom enrollment limits to restrict subject enrollment based on specific criteria. Custom enrollment limits can be defined in all three modes: Testing, Training, and Production.

Understand source data verification

Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.

> **Note:**
>
> You can verify any type of visible question in a form, except for the Visit Date field.

Your study may require different levels of SDV for the study's data. Oracle Clinical One Platform allows you to configure your study for different requirements:

- No SDV required
- Full SDV required
- Targeted SDV required

If your study uses Targeted SDV, you additionally set up an SDV strategy and question-level SDV settings that allow you to configure SDV at a more granular level, covering a variety of specific use cases.

> **Tip:**
>
> The SDV settings can be updated at any time. This includes changes to make the study require a full, targeted or no SDV. For targeted SDV you can also change the SDV strategy associated with a site and the question-level SDV settings, but these changes are not retroactive and are only applied on new data. For more details, see How do changes in Source Data Verification settings impact a study?.

Workflow for defining SDV in your study

Depending on the level of SDV required in your study, the process to configure SDV may involve the following tasks:

Task	Description
Specify settings for Source Data Verification	As a study manager, you start with defining general SDV settings at the study level, on the **Source Data Verification** tab. This is where you define whether your study requires: • No SDV • Full SDV • Targeted SDV If your study requires no SDV or full SDV, this is all you have to do to complete the study's SDV configuration.
Create a source data verification strategy and assign it to a site	**Only if your study uses targeted SDV**, must you create an SDV strategy and assign it to a site. In the SDV strategy you define the amount of subjects that are required to be verified, and whether this verification is needed for all questions or only for a specific set of questions (defined in form design). ***Note:*** *You can create an SDV strategy regardless of the level of SDV used in your study, but it will only become effective for a given site once the strategy is assigned to the site and only in studies using targeted SDV.*
Configure source data verification settings for a question	**Only if your study uses targeted SDV**, should you work with your study designer to configure question-level SDV settings in form design and define which questions require verification. Study designers can define questions as *critical variables* that need to be verified for the targeted SDV subject pool (randomly determined as per the numbers set in the SDV strategy) and also questions that need to be verified for all subjects. These settings are applied according to the SDV strategy. If your SDV strategy dictates verification is needed for specific questions (if it uses the **SDV for All Subjects & Critical Variables** option), you must complete this step. ***Note:*** *You can define question-level SDV settings regardless of the level of SDV used in your study, but these will only become effective in studies using targeted SDV and once an SDV strategy is assigned to sites.*

SDV configuration for different use cases

When no SDV is required in a study

In some cases, your study may not require any level of SDV. For example, when you use Oracle Clinical One Platform primarily for randomization and trial supply management. In this use case, the study manager configures the study-level SDV settings to not allow SDV. Given that SDV is not allowed, any SDV strategy or question-level SDV settings are not applied, so

you don't need to define them. As a result, the Clinical Research Associate (CRA) doesn't need to verify any data in the study.

> **Note:**
>
> When SDV is turned off in a study, the **Verify Data** button to perform SDV is not available, even if the user has the appropriate permissions to verify data.

SDV settings (in the SDV tab of the study settings)	SDV strategy	Question-level SDV settings (in form design)
• Allow SDV in Study: **No**	*Not required.*	*Not required.*

When full SDV is required in a study

If your study requires verification of all data entered for all subjects, without exception, you need to configure a full SDV. To enable a full SDV, the study manager configures study-level SDV settings for it. In this use case, CRAs must verify all questions (that are not *Read-only*) for all subjects, so the study manager doesn't need to create any specific SDV strategies, nor is the study designer required to select any specific questions for data verification.

SDV settings (in the SDV tab of the study settings)	SDV strategy	Question-level SDV settings (in form design)
• Allow SDV in Study: **Yes** • Amount of SDV: **100%** • Include Screen Failures: – Select **Yes** to consider screen failed subjects for data verification. – Select **No** to make screen failed subjects to not require any data verification.	*Not required.*	*Not required.*

When targeted SDV is required in a study

If your study requires partial SDV, for a targeted amount of subjects or for specific questions only, you need to configure a targeted SDV. A targeted SDV involves the three tasks described in the workflow section: specify study-level settings for SDV, create an SDV strategy and assign it to a site, and configure question-level SDV settings.

1. The study manager must configure a **Targeted SDV** in the study-level SDV settings. Additionally, with the **Include Screen Failures** and the **Allow SDV Overrides** settings, you can control the SDV definition at a more granular level.
2. Next, study managers must define an SDV strategy and assign it to sites. This is required to determine the amount of subjects that will require verification and the amount of data that needs to be verified for the subjects that require SDV.

The numbers set in the SDV strategy associated to a site define the targeted SDV subject pool, which consists of the selected subjects that will require verification for that site. For each set of subjects in the SDV strategy, you must specify the SDV type: whether they require verification for all data (**100% SDV**) or only for a specific set of questions (**SDV for All Subjects & Critical Variables**).

3. To complement SDV strategies, study designers can define question-level SDV settings in form design to mark specific questions for SDV. This is required if your SDV strategy uses the **SDV for All Subjects & Critical Variables** option, but you can also define questions that require verification for all subjects (even for those not selected for the targeted SDV subject pool), regardless of the SDV type used in the SDV strategy.

> **Caution:**
>
> Unblinded data may be inferred by blinded users during the verification process, even when a question is hidden. Take this into consideration when defining SDV settings and when specifying the questions that require SDV.

CRAs will then be required to verify the questions for the subjects according to these SDV settings.

- If **100% SDV** is selected for any of the subject subsets in the SDV strategy (defined initial subjects or percentage of remaining subjects), CRAs must verify all answered questions for those subjects. Read-only questions are excluded.
- If **SDV for All Subjects & Critical Variables** is selected for any of the subject subsets in the SDV strategy (defined initial subjects or percentage of remaining subjects), CRAs must only verify the questions marked by study designers with the given toggles.
- For all remaining subjects that were not selected for SDV, CRAs must only verify the questions marked by study designers with the **SDV for All Subjects** toggle.
- Only if your study settings **Allow SDV Overrides**, will CRAs have the ability to also verify non-required questions. These include questions that were not marked with the SDV toggles by study designers, and questions for subjects that were not selected for the SDV subject pool, as per the SDV strategy (including screen failed subjects when excluded from SDV).

> **Note:**
>
> Questions set as critical variables in form design, are marked with a bullseye icon( ) for subjects not selected for the targeted SDV subject pool.

SDV settings (in the SDV tab of the study settings)	SDV strategy	Question-level SDV settings (in form design)
• Allow SDV in Study: **Yes** • Amount of SDV: **Targeted SDV** • Include Screen Failures: – Select **Yes** to consider screen failed subjects for data verification. – Select **No** to exclude screen failed subjects from the targeted SDV subject pool. • Allow SDV Overrides: – Select **Yes** to allow CRAs to verify all data for all subjects. – Select **No** to restrict CRAs to only verify SDV required questions.	*Required.* Refer to Create a source data verification strategy and assign it to a site to set up an SDV strategy that meets your study's needs. Besides creating the SDV strategy, you must assign it to sites for it to be applied.	*If your SDV strategy uses **SDV for All Subjects & Critical Variables**, question-level SDV settings are required.* You have the option to activate the following toggles for the questions that require SDV: • **SDV for All Subjects** for questions that must be verified for all subjects (regardless of whether they were seleted for the targeted SDV subject pool). • **Critical Variables (Targeted SDV)** for questions that must be verified only for the selected subjects as per the SDV strategy.

Related Topics

- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.
- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.

- How are subjects selected for targeted source data verification?
  If your study only requires partial source data verification (SDV), then you might opt for configuring targeted SDV and create a partial SDV strategy. This configuration defines a specific number of subjects randomly selected at a site and the specific questions that a Clinical Research Associate (CRA) must verify.
- Configure source data verification settings for a question

Specify settings for Source Data Verification

Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.

> **Tip:**
>
> Even when these settings can be defined for all modes simultaneously, we recommend you set and verify these settings in Testing mode first.

For more details and use cases, see Understand source data verification.

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Below the study name, click the **Source Data Verification** tab.
3. Select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**

   > **Note:**
   >
   > You can specify Production and Training settings only after you make a study version available in Production.
4. Fill in the fields. To view tips for completing a field, choose an option:

Setting	Description
Allow SDV in Study	• Select **Yes** if it is mandatory for Clinical Research Associates (CRAs) to perform source data verification in the study. • Select **No** if source data verification isn't required in this study

Setting	Description
Amount of SDV	• Select **100%** if CRAs should perform source data verification on all started visits, forms, and questions at a site. • Select **Targeted SDV** if CRAs should only perform source data verification for a certain number of subjects at a site. If you choose to enable Targeted SDV in your study, remember that you should also create an SDV strategy that defines the total number of initial subjects and the percentage of remaining subjects whose data should be verified. See Create a source data verification strategy and assign it to a site.
Include Screen Failures	• Select **Yes** to make screen failed subjects eligible for SDV. For 100% SDV studies, this means SDV is also required for screen failed subjects. For targeted SDV studies means screen failed subjects can be part of the selected SDV subject pool, both for the counts of initial and remaining subjects. • Select **No** to make SDV not required for screen failed subjects. For targeted SDV studies this would mean screen failed subjects can not be selected for the SDV subject pool, neither for the initial nor the remaining subjects counts. In this case, subjects will only become eligible for the SDV pool once they are Enrolled or Randomized. For more information see How are subjects selected for targeted source data verification?.
Include Read Only Questions	*This setting is currently disabled and reserved for a future release.* This is set to **No** by default and means SDV is not required for read-only items.
Allow SDV Overrides	*This setting is only available if you previously selected* **Targeted SDV** *for the Amount of SDV setting.* • Select **Yes** if CRAs should be allowed to additionally perform SDV on questions that don't require SDV. These are for not selected subjects, screen failed subjects (when excluded) and for questions that aren't marked by a study designer as **SDV for All Subjects**. ***Note:*** *When overrides are allowed, for subjects that are not selected for the targeted SDV subject pool, critical variables are made optional to SDV and can be idenfied with a bullseye icon* () • Select **No** if SDV should be allowed only on questions that require verification (according to the SDV settings and strategy).

5. In the upper right, click **Apply Changes**, then select an option:
   - Select the option to apply to the given mode.
   - Select **Apply to All Modes** to use the study settings in all 3 modes.

Specify or update these settings for other modes in your study as required.

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.

- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.
- How are subjects selected for targeted source data verification?
  If your study only requires partial source data verification (SDV), then you might opt for configuring targeted SDV and create a partial SDV strategy. This configuration defines a specific number of subjects randomly selected at a site and the specific questions that a Clinical Research Associate (CRA) must verify.
- Configure source data verification settings for a querstion in form design

Create a source data verification strategy and assign it to a site

If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.

To set SDV in your study as partial targeted SDV, see Specify settings for Source Data Verification.

The numbers set in the SDV strategy associated to a site define the criteria for the targeted SDV subject pool. These are the selected subjects that will require verification for that site. Depending on whether screen failed subjects are included or not (as determined by the study's general SDV settings), the **Initial Subjects** are selected as they are screened or added to the site, until the defined number is reached. From there on, subjects are randomly selected among the **Remaining Subjects** until the required percentage is met.

For more information and use cases see Understand source data verification.

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Below the study name, click the **Source Data Verification** tab.
3. On the right side pane, click **Create SDV Strategy**.
4. On the Create Source Data Verification Strategy dialog, fill in the following fields and select **Create**.

Field	Description
SDV Strategy Title	Enter the name of the source data verification strategy. If you create multiple source data verification strategies, consider using names that will indicate the type of SDV performed for each strategy.

Field	Description
Initial Subjects	Enter the total amount of initial subjects that Clinical Research Associates (CRAs) should verify for a site. For example, enter `5` if you want a CRA to verify the data collected for the first 5 added or enrolled subjects at a site. ***Note:*** *Depending on whether screen failed subjects are included or not (as per the study's general SDV settings), initial subjects are selected differently.* • *When the **Include Screen Failures** setting is set to **Yes**, the SDV pool considers subjects for data verification as soon as they have been added to the site.* • *When the **Include Screen Failures** setting is set to **No**, the SDV subject pool doesn't consider subjects for data verification until their status is **Enrolled** or **Randomized**. Subjects are evaluated in the order that they are added to a site and a subject is not skipped for data verification unless it gets a status of **Screen Failed**, even if a subject added later is enrolled first.*
Remaining Subjects	Enter the percentage of remaining subjects that CRAs should verify at a site. These are randomly selected after the number of initial subjects is reached and until the specified percentage is reached. The system continuously adjusts to match and maintain the percentage of selected subjects as the total number of subjects increases. For example, enter `10` to randomly select 10% of the remaining subjects at a site (after the initial subjects selection) whose data must be verified by a CRA. ***Note****: Depending on whether screen failed subjects are included or not (as per the study's general SDV settings), the total count of subjects, used to calculate the percentage of remaining subjects to be selected, may be different.* • *When the **Include Screen Failures** setting is set to **Yes** screen failed subjects are considered in the total subject count.* • *When the **Include Screen Failures** setting is set to **No**, newly added subjects, screen failed subjects, and subjects whose screening is in progress are excluded from the total count of subjects.* *For more details on how subjects are randomly selected for verification in the system, see* How are subjects selected for targeted source data verification?
SDV Type	For each set of subjects (initial and remaining subjects), you must specify the SDV type: • Select **100% SDV** if a CRA should perform SDV on all questions in started forms and visits of all the selected subjects, whether they are initial or remaining subjects at a site. • Select **SDV for All Subjects & Critical Variables** if a CRA should perform SDV only on questions marked as **SDV for all Subjects** and **Critical Variables (Targeted SDV)** by a study designer. Work with your study designer and refer to Configure source data verification settings for a question.

5. Associate a source data verification strategy with a site:
   a. Navigate to the **Sites & Labs** tab.
   b. On the top left, select a specific mode:
      - **Production Sites**
      - **Testing Sites**

- **Training Sites**

c. From the SDV Strategy drop-down for each site, select a source data verification strategy.

d. In the upper right, click **Apply Changes**.

Make sure you create SDV strategies and assign them to sites for other modes in your study, as applicable.

> **Tip:**
>
> Click the **Edit** icon () next to an SDV strategy to edit it.

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.
- How are subjects selected for targeted source data verification?
  If your study only requires partial source data verification (SDV), then you might opt for configuring targeted SDV and create a partial SDV strategy. This configuration defines a specific number of subjects randomly selected at a site and the specific questions that a Clinical Research Associate (CRA) must verify.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.
- Configure source data verification settings for a querstion (in form design)

Specify supply settings

Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.

> **Note:**
>
> We recommend you set and verify these settings in Testing mode first. Specify supply settings for Production mode once you have verified that the study design and settings are working as expected in Testing, then make Training mode settings match.

Want to see how to perform this task? Watch the video below.

Video

1. Open the study settings.
2. Below the study name, click the **Supply Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Fill in the fields.

   To view tips for completing a field, click into the field or choose an option to reveal a tool tip. Refer to Supply settings fields for fields descriptions.
5. In the upper right, click **Apply Changes**.

- If your study allows sites to perform partial dispensation, Create and manage a partial dispensation.
- If your study allows sites to perform does holds, Create or edit a dose hold.

Specify these settings for other modes in your study, if you haven't already and when required.

- Supply settings fields
  This reference provides you with the fields and their descriptions when specifying supply settings for a study.

Related Topics

- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.
- Create or edit a dose hold
  As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.

- Create and manage a partial dispensation
  Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.
- Create a min/max resupply strategy
  You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.
- Create a predictive resupply strategy
  You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.
- Inventory management and dispensation FAQs (for clinical supply managers)
- Create a new Draft version of a study to update the Approved version

Supply settings fields

This reference provides you with the fields and their descriptions when specifying supply settings for a study.

Schedule Settings

Field	Description
Days to Run Inventory	Choose the days of the week when the resupply process runs for every site.
Time to Run Inventory	Choose the time when the resupply process runs.

Inventory Settings

Field	Description
Site Kit Reconciliation Required	Select **Yes** if you want to manage the return or destruction of any unused product from within Oracle Clinical One Platform at a site.
Dispense Kits By	Select whether kits are dispensed by • **Lowest Kit Number & Closest Expiration Date**: this is helpful when you store your kits in a physical space. • **Lowest Sequence Number & Closest Expiration Date**: this is the default method where kit numbers are scrambled.
Depot Kit Reconciliation Required	Choose **Yes** if you want to manage the destruction of any shipments from within Oracle Clinical One Platform at a depot facility.
Randomize Only when All Kits are Available at Site	• Select **Yes** if you want to ensure that randomization is prevented unless all required kit types are available in the site's inventory, in the necessary quantities. • Select **No** to allow the randomization of subjects regardless of a site's inventory. By default, this setting is set to **No**.

Field	Description
Select Kits ***Note**: Available only when **Yes** is selected for **Randomize Only when All Kits are Available at Site.***	Select kit types that must be available at a site to allow for subject randomization. This is a multi-select field with a default of **All**.
Dispense Reusable Kits	• Select **Yes** if you want to let site users conserve and re-dispense a subject's reusable kits. • Select **No** if you want to restrict site users from conserving and re-dispensing reusable kits to subjects.
Dispense only reusable kits from a subject's last dispensation visit	Click the checkbox if you want to set a limit for site users to only see conserved kits from a subject's last dispensation visit. If this setting is enabled, site users only see reusable kits from a subject's latest dispensation visit as opposed to seeing reusable kits from all previous dispensation visits.
Request Sites to Confirm Dispensation	• Select **Yes** if you want to let site users confirm kits are dispensed to each subject during a visit. • Select **No** if you don't want to enable site users to confirm the dispensation of kits during each dispensation visit.

Shipment Settings

Field	Description
Shipment ID Prefix	Choose the prefix to use for every shipment ID. • For shipments sent through the Oracle Clinical One Platform - Fisher Clinical Services integration, only IDs that contain numbers are accepted. To make sure you use the right Shipment ID prefix, select **Use Depot ID** or **None**. If a depot ID contains leading zeros, they do not appear in the Shipment Request file as part of the Shipment ID format for Fisher Clinical Services. • For shipments sent through the Oracle Clinical One Platform - Catalent Clinical Supply Services integration, Shipment ID prefixes must consist only of numbers. To make sure you use the right Shipment ID prefix, select **Use Depot ID** (if depot IDs are defined using numbers only), **Enter Prefix** to use a prefix that consists only of numbers or **None**, if no prefix is used.
Send Initial Shipments	Select whether initial shipments are sent to sites when each site is activated, or after the first subject starts a particular visit, which you choose. Only one initial shipment is ever sent to a site, even if you change this setting in a live study. ***Note**: If you select **First Subject in Visit Number**, the Visit Number drop-down shows only scheduled visits.*
Visit Number	*(Available only when **First Subject in Visit Number** is selected for the previous field)* Select the visit that the first subject must start for initial shipments to be sent to a site.
Single Kit Ordering Allowed	Select **Yes** if a shipment can contain one kit. If the study is blinded, you typically select **No**. ***Note**: Single kit ordering is not supported for pooled kits.*

Field	Description
Blinded Groups Required	*(Available only when single kit ordering isn't allowed)* Select **Yes** if kits have different packaging requirements. Create blinded groups of the kits that ship together to protect the study blind. If you select **No**, specify the kit that is added to single-kit shipments to protect the study blind.
Kits Added to Prevent Unblinding	*(Available only when single kit ordering isn't allowed)* Select how kits are added to a shipment to protect the study blind when single-kit ordering isn't allowed. If you choose to send a specific kit type, the location where you choose the kit type depends on whether you have blinded groups. If you don't have blinded groups, you choose the kit type to add to the shipment on this page. If you have blinded groups, you choose the kit type to add to the shipment when you create a blinded group.
Kit Type	*(Available only when single kit ordering isn't allowed, blinded groups aren't required, and you chose to send a specific kit type to prevent unblinding)* Select the kit type to add to a single-kit shipment to protect the study blind.
Label Groups Required	Select **Yes** if a kit type has more than one label. A label group is a collection of kits that use the same label. ***Note**: If you assigned the label to a depot in error, click **Clear assigned label group** to remove it from the **Kit Settings**.*
Allow for Temperature Excursion	Select **Yes** if any kits are sensitive to temperature excursions. A kit that experiences a temperature excursion cannot be dispensed until data about the excursion has been reviewed.
Allow Single Kit Quarantine	*(Available only when **Yes** is selected for **Allow for Temperature Excursion**)* Select **Yes** if you would like to allow single kits to be quarantined if they experience a temperature excursion.
Shipments Received without a Temperature Monitor Should be	*(Available only when **Yes** is selected for **Allow Temperature Excursions**)* • Select **Quarantined** if you would like kit statuses to update to Quarantined if they are received without a temperature monitoring device. • Select **Allow to Continue to Receipt Process** to let kits received without a temperature monitor to progress through the receipt process.
Temperature Excursion Starting Number	*(Available only when **Yes** is selected for **Allow for Temperature Excursion**)* Provide a starting number for the shipment's tracking number. The number can begin with a value of one digit up to 8 digits that sequentially increment by 1. ***Note**: The starting number cannot begin with 0.*
Multiple Storage Requirements	• Select **Yes** to create shipments according to the storage needs of the kit types. For example, kits requiring refrigeration are shipped separately from kits that require ambient storage. If kit reconciliation is required and kits are shipped to a depot for destruction, shipments are created based on the temperature requirements for the kits. • Select **No** if all kits have the same storage needs.

Field	Description
Notification Schedule	• Select **Daily** to receive the Receive Shipment notification daily, depending on the days resupply is scheduled to run. • Select **Once** to receive the Receive Shipment notification only once.
Notification to Receive Shipment (in days)	Insert the number of days after the ship date when the site user receives a notification to mark a shipment as received. ***Note**: If the ship date isn't defined, raise the date.*
Site Can Request Shipments	• Select **Yes** if sites can order a blinded shipment that you don't have to approve. You define the contents of the shipment in the resupply strategy that you assign to the site. • Select **No** if the clinical supply manager will specify the contents of manual shipments that sites request.

Locally Sourced Kit Settings

For step-by-step instructions on configuring locally sourced kits, see Add a locally sourced kit.

> **Note:**
>
> A country can only be added to either **Locally Sourced Countries** or **Sourced by Site Countries**, but not added to both.

Field	Description
Kit Type	Select the type of kit that can be locally sourced.
Locally Sourced Countries	Select the countries the selected kit type can be sourced from.
Sourced by Site Countries	Select the countries whose kits can be locally sourced.

Understand how dose holds work

Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.

What clinical supply managers must know

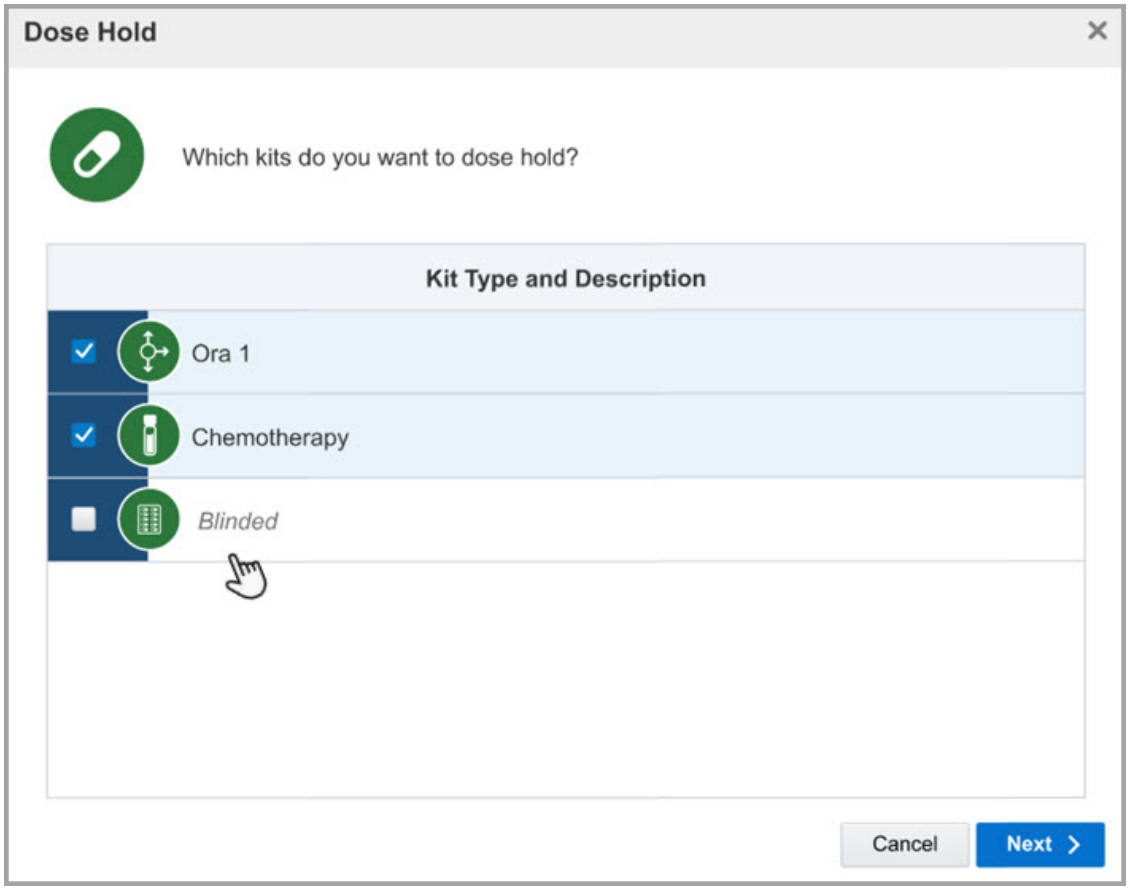
As a clinical supply manager, it is your responsibility to properly configure dose holds for one or all required kit types in a study. How a site user performs a dose hold during the study conduct period depends entirely on what you allow them to do.

Before you begin your work with dose holds, there are several particularities of this feature that you must consider to make sure you approach your task in the right way.

You can choose to create one or more dose holds in your study, in any study mode (Testing, Training, or Production) and properly define the details of each dose hold. For step-by-step instructions on how to create and manage a dose hold, see Create or edit a dose hold.

Consideration	Notes
Kit types	• You cannot define more than one dose hold for the same combination of a visit and kit type. For example, you cannot create two separate dose holds for Kit A, starting with a Week 1 visit. • If you already created a dose hold for an individual kit type titration within a titration group, but also created a dose hold for an entire titration group, the dose hold created for that titration group takes precedence over the dose hold created for the individual kit type. A dose hold created for a titration group is always taken into account, even when a dose hold for an individual kit type is not created separately.
Visits	You cannot create a dose hold for an unscheduled event or a randomization visit. However, you can create a dose hold for an unscheduled visit (that is different from an unscheduled event, such as an Adverse Event). An end visit date can be entered for dose holds.
Frequency of dose holds	When establishing the frequency of dose holds, keep in mind that, in the application, days are considered calendars days and not increments of 24 hours. Days are determined by a site's current time zone.
Avoiding unblinding	If you are creating a dose hold for an Unblinded Pharmacist kit, work with your study designer to make sure there is a matching placebo kit that you can use to configure the dose hold. You must know that kits available for dose holds are displayed using an icon for the site user to match the kit that they want to put on hold. If the kits that can be put on hold are using the same icon (for example, the Blister pack icon), and if multiple blinded kits must be dispensed to a single treatment arm, these similar kits are grouped using one dose hold icon. **See figure below.**

Figure 4-1 How a site user sees blinded kits available for dose holds



What the site staff must know

If you want to learn more about what a site user must do to pause dispensation, see Pause dispensation by placing a dose hold.

Create or edit a dose hold

As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.

To learn more about the end-to-end workflow of creating and applying dose holds, as well as any particularities of this feature, see Understand how dose holds work.

To create dose holds for multiple kit types, you must create one dose hold for each type of kit. For example, you create one dose hold for a kit containing the investigational product and another dose hold for a kit type titration group.

To create or edit a dose hold:

1. Open the study settings.
2. Click the **Supply Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**

- **Testing Settings**
- **Training Settings**

4. Scroll down to the Dose Hold Settings and depending on whether this is the first time you are creating a dose hold or not, you can:

   - Make sure the toggle () is turned on.
   - Click the toggle () to activate the feature.
     By default, the toggle is turned off.

   > **Note:**
   >
   > You cannot set to have partial kit dispensations and dose holds at the same time in your study. If you activate either of the toggles, the other one will be deactivated.

5. Click **Create Dose Hold**.
6. On the Dose Hold dialog, fill-in the fields:

Field	Description
Kit Type or Titration Group	From the drop-down, choose the kit type or titration group that sites can pause dispensation for.
Starting Visit	From the drop-down, choose the visit where site users can begin performing dose holds for the previously specified kit type. ***Note**: On this drop-down, while you may see the randomization visit in your study available for selection, remember that a site user cannot place a dose hold during a randomization visit.*
End Visit	If you set an end visit date, dose holds will not be able to occur past this visit.
Cycle	If you chose a visit from a branch, for the Starting Visit field, a new Cycle field appears. You must choose the cycle where site users can begin the dose holds.
Max per Subject	Enter a whole number (from 1 to 999) for the maximum number of dose holds that site users can perform for the selected kit type. Leaving the field empty sets the maximum number of dose holds to unlimited.
Frequency per Subject	Choose whether there is a limited frequency or timeframe during which the site user can perform a dose hold: • **Unlimited** • **Up to a certain number of sequential dose holds**: enter a whole number from 1 to 999. • **Every certain amount of days**: enter a whole number from 1 to 999.

7. Click **Submit & Create Another** or **Create**.

8. To edit the details of an existing dose hold, click the edit icon ( ) and edit its details on the Create Dose Hold dialog.

9. To stop the functioning of an existing dose hold, click the toggle ( ) next to a dose hold to deactivate it.

Every dose hold that you create is displayed in a table, in the Dose Holds Settings section, along with the dose hold's corresponding details, such as the chosen kit type, the starting visit, as well as the allowed number of dose holds per subject, and the frequency.
Activate and create dose holds for other modes in your study, if you haven't already and when required.

Related Topics

- Specify supply settings
  Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.
- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.
- Create and manage a partial dispensation
  Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.
- Create a min/max resupply strategy
  You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.
- Create a predictive resupply strategy
  You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.
- Inventory management and dispensation FAQs (for clinical supply managers)
- Create a new Draft version of a study to update the Approved version

Create and manage a partial dispensation

Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.

Partial dispensation must be defined for each kit type to allow for its partial dispensation, but it is not necessary that all kit types in a study have matching settings. For studies that allow

titration, the rules for partial dispensation are defined for each of the titration kits, not on the titration definition.

> **Note:**
>
> - For kits with calculated doses, data changes after a partial dispensation will not result in the recalculation of the dose.
> - The DND days requirement considers the initial dispensation date only.

Any dispensation visit, scheduled or unscheduled, will allow partial dispensation for the given kit type, as long as it is within the defined visit range and regardless of whether there was a skipped visit or not.

> **Caution:**
>
> Partial dispensation visits can be left with incomplete dispensations.

1. Open the study settings.
2. Click the **Supply Settings** tab.
3. Along the top, select a mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Scroll down to the Partial Kit Dispensation Settings section and depending on whether this is the first time you are creating a partial dispensation or not, you can do one of the following:

   > **Note:**
   >
   > You cannot have partial kit dispensation and dose holds at the same time in your study. If you activate either one of the toggles, the other one is deactivated.

   By default, the toggle is turned off.

   - Make sure that the toggle () is turned on.
   - Turn on the toggle () to activate the feature.
5. Click **Create Partial Dispensation**.

   If you already have a partial dispensation defined, look for the button with the plus icon **(+)**.
6. On the Create Partial Dispensation dialog, fill in the fields, and click **Create** or **Save & Add Another**.

Field	Description
Kit Type	From the drop-down, choose the kit type that sites can partially dispense. This is a multi-select field, allowing you to equally define partial dispensation for multiple kit types at the same time.
Starting Visit	From the drop-down, choose the visit where site users can begin partial dispensations for the previously specified kit type. ***Note**: You may see the randomization visit in your study available for selection. However, partial dispensation cannot be performed during a randomization visit.*
Starting Visit Cycle	(Available only when selecting a cyclic visit as the starting visit) Choose the cycle where you want the starting visit to apply for the partial dispensation.
Ending Visit	(Optional field) If you set an end visit date, partial dispensations will not be allowed past this visit.
Ending Visit Cycle	(Available only when selecting a cyclic visit as the ending visit) Choose the cycle where you want the ending visit to apply for the partial dispensation.

Every partial dispensation that you create is displayed in a table, in the Partial Kit Dispensation Settings section, along with the corresponding details for each.

7. Manage existing partial dispensations:

   - To edit the details of an existing partial dispensation, click the edit icon ( ) and edit its details on the Create Partial Dispensation dialog.
   - To stop the functioning of an existing partial dispensation, click the toggle ( ) next to the kit type to deactivate it.
   - To delete the partial dispensation, click the trash can icon ( ) and confirm on the confirmation window.

If required, activate and create partial dispensations for other modes in your study..

Related Topics

- Specify supply settings
  Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.
- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.

- Create or edit a dose hold
  As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.
- Create a min/max resupply strategy
  You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.
- Create a predictive resupply strategy
  You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.
- Inventory management and dispensation FAQs (for clinical supply managers)

Create a min/max resupply strategy

You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.

Create min/max resupply strategy for other modes in your study, if you haven't already and when required.

> **Note:**
>
> In the system, resupply runs once a day based on the offset of UTC that you set in the Schedule Settings (under Supply Settings), not the current time zone for your sites.

> **Tip:**
>
> Set resupply to run at 12:01AM to ensure kit status accuracy. Whereas expired kits will not be dispensed, the status of these kits on the inventory page will only be refreshed to "expired" once resupply runs.
>
> For more information on managing expiration dates, see Manage expiration dates with lots.

1. Open the study settings.
2. Below the study name, click the **Supply Settings** tab.
3. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. On the right side pane, expand **Min/Max Resupply**.

5. Click **Create Min/Max Resupply Group**.
6. Fill in the fields and click **Create**. To view tips for completing a field, click into the field.

Field	Description
Min/ Max Resupply Title	Enter the name of the resupply strategy. If you create multiple resupply strategies, consider using names that tell you the sites that use each strategy.
Type	Choose **Site** if this resupply strategy is created to resupply a site. Choose **Depot** if this resupply strategy is created to resupply a source depot.
Kit Type and Description	Select the checkbox next to the kit type that you want to include in this resupply group.
Minimum Buffer	Enter the number of kits that trigger a shipment when the resupply strategy runs. When a single kit type reaches the number specified in the buffer, a shipment is created so that all kit types in the resupply strategy are raised to the maximum buffer at the site or depot.
Kits in First Shipment	***Note**: This field only appears if you previously selected **Site** for the Type setting.* Enter the number of kits of each type that are in the initial shipment. The number should be higher than the minimum buffer so that a new shipment isn't created after the resupply strategy runs the first time. ***Tip**: Use "0" for certain kit types, if you don't want to ship that kit type at site initiation.*
Kits in Manual Shipment	***Note**: This field only appears if you previously selected **Site** for the Type setting.* Enter the number of kits of each type that are included in a manual shipment when you allow sites to request manual blinded shipments. ***Tip**: Use "0" for one or multiple kit types, if you want to set a kit type to be shipped only with a manual order.*

Related Topics

- Specify supply settings
  Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.
- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.
- Create or edit a dose hold
  As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.

- Create and manage a partial dispensation
  Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.
- Create a predictive resupply strategy
  You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.
- Inventory management and dispensation FAQs (for clinical supply managers)
- Create a new Draft version of a study to update the Approved version

Create a predictive resupply strategy

You create a predictive resupply group to resupply a site based on actual enrollment and planned dispensation visits. After running inventory, the application creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for. You also set minimum and maximum levels so that sites have sufficient supply for new subjects.

For titration visits with available dosing changes, the predictive resupply strategy will create shipments with enough kits for site users who need to maintain the same dose for subjects.

> **Note:**
>
> In the system, resupply runs once a day based on the offset of UTC that you set in the Schedule Settings (under Supply Settings), not the current time zone for your sites.

> **Tip:**
>
> Set resupply to run at 12:01AM to ensure kit status accuracy. Whereas expired kits will not be dispensed, the status of these kits on the inventory page will only be refreshed to "expired" once resupply runs.
>
> For more information on managing expiration dates, see Manage expiration dates with lots.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click study settings ( ) on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Supply Settings** tab.
3. Open the study settings.

4. Below the study name, click the **Supply Settings** tab.
5. On the top left, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
6. On the right side pane, expand **Predictive Resupply**.
7. Click **Create Predictive Resupply Group**.
8. Fill in the fields and click **Create**. To view tips for completing a field, click into the field.

Field	Description
Predictive Resupply Title	Enter the name of the resupply strategy. If you create multiple resupply strategies, consider using names that tell you the sites that use each strategy.
Kit Type and Description	Select the checkbox next to the kit type that you want to include in this resupply group.
Trigger Weeks	Enter the number of weeks that the resupply strategy looks at, to determine the supply that is required for subjects who have already been randomized. If additional supply is required, a shipment is created based on the resupply weeks. ***Tip**: Use "0" here and for Resupply Weeks if you don't want the site to be resupplied with a certain kit type or all kit types during the study. Choose this option for resupply strategies that use minimum and maximum buffers.*
Resupply Weeks	Enter the number of weeks that the resupply strategy resupplies for. For example, if you specify 2 trigger weeks and 4 resupply weeks, the resupply strategy determines the supply needed for the next 2 weeks for subjects who have been randomized. If the on-site supply is insufficient for that time, enough supply is sent so that the site can dispense for the next 4 weeks. ***Tip**: Use "0" here and for Trigger Weeks if you don't want the site to be resupplied with a certain kit type or all kit types during the study. Choose this option for resupply strategies that use minimum and maximum buffers.*
Minimum Buffer	Enter the number of kits that trigger a shipment when the resupply strategy runs. When a single kit type reaches the number specified in the buffer, a shipment is created so that all kit types in the resupply strategy are raised to the maximum buffer at the site or depot.

Field	Description
Maximum Buffer	Enter the number of kits that will be present at the site after a resupply shipment arrives. When a single kit type reaches the minimum buffer, a shipment is created so that all kit types in the resupply strategy are raised to the maximum buffer at the site. ***Note**: This number refers to the maximum available kits on site. In case the supply need is greater than the maximum buffer, the system will only ship to the maximum. The quantity of kits is set considering the storage limitations at the sites.*
First Shipment	Enter the number of kits of each type that are in the initial shipment. The number should be higher than the minimum buffer so that a new shipment isn't created after the resupply strategy runs the first time. ***Tip**: Use "0" for certain kit types, if you don't want to ship that kit type at site initiation.*
Manual Shipment	Enter the number of kits of each type that are included in a manual shipment when you allow sites to request manual blinded shipments. ***Tip**: Use "0" for one or multiple kit types, if you want to set a kit type to be shipped only with a manual order.*

Create a predictive resupply strategy for other modes in your study, if you haven't already and when required.

Related Topics

- Specify supply settings
  Typically, a clinical supply manager specifies these settings. These settings apply to all versions of the study and you can edit them at any time. This procedure also applies to rollover studies.
- Understand how dose holds work
  Dose holds are crucial when an investigator needs to pause dispensation and respond appropriately to subjects' experiences concerning their health and well being. To make sure this feature is properly configured in a study, several types of users must do their part in creating and applying a dose hold.
- Create or edit a dose hold
  As a clinical supply manager, you can create a dose hold to enable site staff to pause dispensation for a subject due to safety reasons. A dose hold can be created in all three modes: Testing, Training, or Production.
- Create and manage a partial dispensation
  Define partial dispensation settings so that site users are able to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when the dispensation of multiple kits of the same type is required for the visit and you have at least one kit available of each kit type that must be dispensed.
- Create a min/max resupply strategy
  You create a min/max resupply group to resupply a site or a depot only when their inventory is low. When the application checks inventory, shipments are created as needed to bring the inventory at sites or depots up to the maximum number of kits you specify.
- Inventory management and dispensation FAQs (for clinical supply managers)

- Create a new Draft version of a study to update the Approved version

Create a blinded group of kits

Create blinded groups if you don't allow single kit ordering, and if the kits in your study use different packaging. Blinded groups determine the kit or kits that are added to a single-kit shipment to protect the study blind. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Supply Settings** tab.
3. Open the study settings.
4. Below the study name, click the **Supply Settings** tab.
5. Along the top, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
6. At the bottom of the right side pane, expand **Blinded Groups**.

> **Note:**
>
> If **Blinded Groups** doesn't appear, make sure that *Yes* is selected for Blinded Groups required within the Shipments Settings in the **Supply Settings** tab. Refer to Specify Supply settings for step-by-step help and Supply settings fields for descriptions.

7. Click **Create Blinded Group**.
8. Fill in the fields, and then click **Create**.

> **Tip:**
>
> To view tips for completing a field, click into the field or choose an option.

Field	Description
Title	Enter a title for the blinded group.
Select kits to create blinded group	Select the kit types to include in the blinded group.
Kits added to prevent unblinding	(Available only if you choose to send a kit type to prevent unblinding) Select the kit type that is added to a shipment to protect the study blind. Consider choosing the placebo or the kit with the highest number in the treatment ratio.

Create blinded groups for other modes in your study, if you haven't already and when required.

About signature configurations

Learn more about creating signature configurations.

As a sponsor user, your study may encounter different scenarios where a signature is required, such as signing a Serious Adverse Events form, adjudication forms, completed visits, and forms that capture certain protocol deviations. By creating custom signature configurations, you can allow sites to sign off at the form or visit level for given forms and visits using customized affidavits.

What sponsor users must know

Before you begin your work with signature configurations, consider the following to assure you approach your task properly:

- You must be assigned the *Manage signature settings* permission in order to create and edit signature configurations.

  > **Note:**
  >
  > Only roles with permission to sign will appear in the configuration drop-down list. Template users will not appear in the drop-down list for form and visit level signatures.

- Signature elements on the Study and Subject homepages are hidden by default for existing studies. In the Study Settings, selecting **Yes** for the **Display signature elements for site staff and sponsors** option enables the Signature widget (

) to display in Production mode, while the Signature Request side panel appears in all modes.

  > **Note:**
  >
  > It is not possible to go back and select **No** for the **Display signature elements for site staff and sponsors** option once **Yes** has been selected and saved for the corresponding mode.

- Every form that has been created is available in the Forms list when creating a signature configuration, regardless of whether they have been assigned to a visit or not.
- To add more than one combination of an affidavit and role(s) for a given set of forms or visits, you must create an additional signature configuration for each combination.
- If a new visit is named the same as a deleted visit, both appear as options in the Signature Configuration.
- Modifications made to a signature configuration are applied to unsigned data and data that has never been signed, but does not affect signed data unless it becomes unsigned.
- If more than one role is selected in a signature configuration, a user assigned any of the selected roles can sign and fulfill the signature requirement.

> **Note:**
>
> If two roles are required to sign, then two signature configurations are required.

- When removing signature related permissions from study roles, be aware that if a role is still referenced in a signature configuration they no longer have permission to sign, the **Sign** option will still be available, but they will receive an error when attempting to sign.
- When a role referenced in a signature configuration has been retired, it will not be removed from the signature configuration, but the role will no longer have the ability to sign the data.
- Once a signature's target date has been reached or become overdue, you have the option to trigger an email notification each day until the overdue signature is applied.
  For notification details, see the Signature request notification.

You can choose to create a signature configuration in your study in any mode (Testing, Training, or Production). For step-by-step instructions on how to create a signature configuration, see Create a signature configuration.

Create a signature configuration

As a study administrator, create a signature configuration to allow sites to sign off at the form and or visit level using custom affidavits.

Before performing this task, see About signature configurations to understand the specifics of creating a signature configuration.

To create a signature configuration:

1. Open the study settings.
2. Select the **Signature Configuration** tab.
3. Along the top, select a specific mode:
   - **Production Mode**
   - **Testing Mode**
   - **Training Mode**
4. Click **Create Signature Configuration**.
5. In the Create Signature Configuration dialog, fill in the following fields, and click **Create**.

Field	Description
Title	Enter the title of the signature configuration. For example, Adverse Event Signature.
Required by (One of the Following Roles)	Select one or multiple study roles required for the signature configuration. ***Note**: If more than one role is specified, any user with any of the specified roles can sign.*
Signature Text	Select the affidavit required for this configuration. You can add, edit, or manage affidavits on the Code List tab. For more information, see Create and manage code lists.
Required on	First, select **Form** or **Visit**. Then, select the form or visit that the signature is required on.

Field	Description
Only Required in Following Visits	By default, this toggle is turned off. Turn the toggle on to only include the visits you would like the signature to be required for a specific form. For example, Adverse Event Visit. ***Note**: This configuration is available if only one form is selected and the **Required on** radio button is set to **Forms**.*
Trigger Signature Request with the Response to a Question	By default, this toggle is turned off. Turn the toggle on to choose a specific choice question and a specific response that should trigger a signature request. ***Note**: This configuration is available if only one form is selected and the **Required on** radio button is set to **Forms**.*
Choice Question	Select a specific choice question.
When the Answer is (One of the Following Answers)	Select a specific answer to the choice question that you previously selected. When this answer is selected in a form, it triggers the signature request.
Set Target Date	By default, this toggle is turned off. Turn on the toggle to specify the number of days after the Start or Completion visit, or the selected form or visit.
Target Date	Enter the exact number of days to pass after the Start or Completion visit.
After	Select **Start** or **Completion**.
Send Reminder Through Email	By default, this toggle is turned off. Turn on the toggle to receive to receive email notifications regarding an overdue signature at sites that you are assigned to. ***Note**: You must be assigned the Receive the Pending Signatures Notification permission to receive these email notifications.*

Manage signature configurations at the casebook level

Define a signature configuration at the casebook level.

Users assigned the *Manage signature settings* permission have the ability to define casebook level signature configurations. Be aware that the Casebook Signature dialog displays by default.

1. Open the study settings.
2. Select the **Signature Configuration** tab.
3. Along the top, select a specific mode:
   - **Production Mode**
   - **Testing Mode**
   - **Training Mode**
4. In the Casebook Signature dialog, complete the following fields, and click **Apply Changes**.

Field	Description
Required By	The custom role(s) required for the signature configuration ***Note***: • *If more than one role is specified, any user with any of the specified roles can sign.* • *The Site User Template role is available for casebook signatures.* • *Only users assigned the **Approve and sign data** permission can be selected.*
Set Frequency	Set the toggle to **On** to set a frequency of how often the casebook is required to be signed. ***Note**: Additional signatures are only required when there is unsigned data present in the casebook. Once all data has been signed no additional signatures will be required.*
Every	This field is only available if the **Set Frequency** toggle is set to **On**.
Send Reminder Through Email	Set the toggle to **On** to receive email notifications regarding an overdue signature at sites you are assigned to. ***Note**: You must be assigned the Receive the Pending Signatures Notification permission to receive these email notifications.*

Configure the connection to Oracle mHealth Connector so you can dispense devices

When a study dispenses IoT-enabled devices managed with Oracle mHealth Connector, you must establish a connection with Oracle mHealth Connector so that data collected from the devices can be sent to the appropriate application. To establish a connection, you enter a user name, password, and URLs for Oracle mHealth Connector. This procedure can also apply to rollover studies, according to how the rollover study is designed.

> **Tip:**
>
> While some tasks in a study's settings must be performed one time for each mode, this task needs to be done only one time for an entire study.

The user account for Oracle mHealth Connector is created in Oracle Life Sciences Identity and Access Management Service. The user account must have the **mHealth_External_Web_Services-System_Users_Only** role.

1. Open the study settings.
2. Below the study name, click the **Device Service** tab.
3. Fill in the fields and click **Apply Changes**.

> **Note:**
>
> If you can't see or edit all three URL fields, you might not have the appropriate roles for all three modes. Work with a user administrator to update your roles. All the fields must have values for data collection to work as expected.

Field	Description
User Name	Enter the user name for Oracle mHealth Connector. The user account is typically a service or integration account and isn't used by a user to sign in to Oracle mHealth Connector. If you don't have the user name or password, work with the delegated administrator who is responsible for provisioning users in Oracle Life Sciences Identity and Access Management Service to obtain the user name and password.
Password	Enter the password for the Oracle mHealth Connector user.
Production URL	Paste the URL for the Production instance of Oracle mHealth Connector. Your organization received the URLs when Oracle mHealth Connector was set up. If you don't have the URLs, reach out to your Oracle point of contact.
Testing URL	Paste the URL for the Testing instance of Oracle mHealth Connector.
Training URL	Paste the URL for the Training instance of Oracle mHealth Connector. *Note: Having a study available in Training mode isn't mandatory for setting up the connection to Oracle mHealth Connector, so having a URL for the Training field can be optional.*

Manage randomization

Once you are done setting up sites, depots, labs, and other study settings, a clinical supply manager and other sponsor users can begin configuring settings for the randomization processes of a study.

- Define settings for *Testing mode* first, so you can test and verify a study version using mock data.
- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Generate a randomization list
  Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

- About the randomization list duplicate
  Learn more about duplicating a randomization list.
- Upload a randomization list
  Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.
- Understand the concepts used in minimization
  Minimization can be particularly useful for studies that aim to balance subjects across treatment groups. A key aspect of working this this type of randomization design is understanding the main concepts that it operates with.
- Upload a randomization list for minimization
  Create a randomization list for minimization in Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.
- Assign blocks of randomization numbers to a site, country, or region
  You must assign blocks of randomization numbers to a site, country, or region if you selected a type of randomization with Fixed in its name, and you either generated a randomization list in Oracle Clinical One Platform or uploaded a randomization list that didn't identify sites, countries, or regions for blocks. This procedure also applies to rollover studies.
- Assign a randomization list to a randomization design and study version
  You typically need to assign a randomization list to a randomization design and study version if you created a second randomization list for a randomization design (such as if you added a treatment arm to a study and needed to create another randomization list to support it). This procedure also applies to rollover studies.

Generate a randomization list

Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

> **Tip:**
>
> To prevent potential unblinding, create separate lists for each mode. If a statistician provides only the production list for a study, upload it in Production mode and generate lists for Testing and Training modes.
> We recommend you first create a randomization list in Testing mode before you create one in Training or Production mode.

Do you want to upload a randomization list, instead of generating one? See Upload a randomization list.

You can generate or upload a new randomization list at any time, without creating a new version of a study.

Identify the randomization seed in the Manage Randomization Lists dialog in Study Supplies. Each randomization seed displays as a read-only value in the Randomization lists column under the name of the randomization list it duplicated. If no value is displayed, this means the randomization list was generated without a randomization seed value assigned to it.

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, make sure the **Randomizations** tab is selected.
4. From the **Randomization List** drop-down, select **Generate**.
5. Select the randomization design that you want to generate a randomization list for, and click **Next**.

> **Tip:**
>
> Only the randomization designs that randomize subjects and that are assigned to a visit appear.

6. Fill in the fields, and click **Generate**.

   To view tips for completing a field, click into the field or choose an option.

> **Note:**
>
> You can re-generate an existing randomization list by adding the same design parameters and the same **Randomization Seed**. For more information, see About the randomization list duplication.

Option	Description
Title	Enter a title for your randomization list.
Description	Enter a description for your randomization list.
Mode	Choose the mode that the randomization list is available in.
Multiplier for Blocks	Enter the number used to calculate the size of blocks in the randomization list. The numbers in the treatment ratio are added and multiplied by this number. For example, for a 1:2 ratio, if the multiplier is 4, each block size is 12 (1 + 2 = 3, and 3 x 4 = 12).
Starting Number	Enter the first number in the randomization list.
Length	Enter the length of the randomization list, calculated by the randomization numbers in the list, the number of blocks per strata, or the number of blocks per cohort.
Starting Sequence Number	*Optional.* Enter a starting number for a sequence if you want the randomization to be based on a given sequence. This is to make it double blinded and less predictable. Enter a number from 1 to 99,999,999 and the system will assign the randomization number according to the sequence number, instead of assigning consecutive randomization numbers (1001, 1002, 1003). ***Note**: The randomization list is, by default, arranged in ascending order of sequence numbers.*

Option	Description
Randomization Seed	Fill in this field to generate a list for the first time or reuse the seed to generate a second list as a duplicate of the first list. The number you enter must be from 1 to 99,999,999. ***Warning**: If you skip the seed field and generate a randomization list using the same design, the result will be a new and different randomization list, not a duplicate.* Reproduce any randomization list number as long as all parameters match the initial format. For example, if you initially added 1234 in the Randomization Seed field, use the same 1234 number for the Randomization Seed, as well as the same randomization design in the new list you are generating. ***Caution**: Oracle Clinical One Platform will use the most recent active randomization list to re-randomize the treatment arm.*

7. Click **Finish** once you complete the wizard.

We recommend using dynamic block assignments. However, if you are doing static block assignments with a generated randomization list, you must assign blocks of randomization numbers to each site, country, or region. For more details, see Assign blocks of randomization numbers to a site, country, or region.

Verify if a randomization seed is assigned to a randomization list or if randomization is sorted by sequence number on the Manage Randomization Lists window. Look for the details (if present) in the randomization lists column under the randomization list title.

Related Topics

- Randomization lists and kit lists FAQs
- Assign blocks of randomization numbers to a site, country, or region
  You must assign blocks of randomization numbers to a site, country, or region if you selected a type of randomization with Fixed in its name, and you either generated a randomization list in Oracle Clinical One Platform or uploaded a randomization list that didn't identify sites, countries, or regions for blocks. This procedure also applies to rollover studies.
- Update a randomization list that ran out of numbers during the study conduct period
- Upload a randomization list
  Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

About the randomization list duplicate

Learn more about duplicating a randomization list.

In the study process, you may encounter a scenario where an exact copy of the randomization list is needed after you first generated it for the first time, such as providing evidence for auditing purposes. To generate the randomization list duplicate on demand you must insert a randomization seed in the original list as a starting point. With that seed number and the same parameters as the original list, the system generates a new list that copies the same randomization design with the same outcome. The result allows you to recreate any randomization list consistently, so regulatory agencies can verify that the study was randomized correctly.

What sponsor users must know

Duplicate the randomization list by using the same parameters as in the original with the help of the randomization seed that acts as a vector of the initial randomization list. An algorithm will produce a second list as a duplicate of the first.

For step-by-step guidelines on how to use the randomization seed to duplicate an existing list, see generate a randomization list.

> **WARNING:**
>
> If you skip the randomization seed field and generate a randomization list using the same design, the result will be a new and different randomization list, not a duplicate.

> **Note:**
>
> Every time you generate a randomization list with a seed, Oracle Clinical One Platform associates and maintains the latest active randomization list to re-shuffle the treatment arms in the study. To revert to any previous randomization lists you need to manually unassign the current active list from the study version.

Identify the randomization seed in the Manage Randomization Lists dialog in **Study Supplies**. Each randomization seed displays as a read-only value in the Randomization lists column under the name of the randomization list it duplicated. If no value is displayed, this means the randomization list was generated with a randomization seed value assigned to it.

If you use the Randomization Generator or upload your initial randomization list, the randomization seed number is also not displayed in the Manage Randomization Lists window.

Upload a randomization list

Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

> **Tip:**
>
> To prevent potential unblinding, create separate lists for each mode. If a statistician provides only the production list for a study, upload it in Production mode and generate lists for Testing and Training modes. We recommend you first create a randomization list in Testing mode before you create one in Training or Production mode.
> You can generate a randomization list to see the format Oracle Clinical One Platform uses. For more guidelines on special characters and formatting of lists, see Guidelines for creating a kit or randomization list.

File requirements to upload a randomization list

- The file name must not include any periods, other than the period that appears before the file extension.
- Create a comma-separated values (CSV) file (up to 1 GB) that includes one row for each randomization number with the following corresponding columns:

  - *Randomization number*
  - *Block number*
  - *Treatment ID*
  - *Stratum groups* (required only if you use a stratified randomization design)
  - *Sequence number* (required only if you use randomization by sequence number)
- We recommend using dynamic block assignments. However, if you are doing static block assignments, the list you upload must identify the site to associate with each block.

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, make sure the **Randomizations** tab is selected.
4. From the **Randomization List** drop-down, select **Upload**.
5. Select the randomization design that you want to upload a randomization list for, and click **Next**.
6. Fill in the following fields:
   - **Title**
   - **Description**
   - **Mode**: Choose the mode that the randomization list is available in.
   - **Columns in File Have Headings**: Select if the CSV file you're uploading contains column headings.
7. Click **Choose File**, select your CSV file, then click **Next**.
8. On the **Map Headers** section of the wizard, from the **Mapped to** drop-down, select the corresponding column header that Oracle Clinical One Platform uses to map it to your CSV imported column headers. Then click **Next**.

   If you select the **Sequence number** in the **List Settings** the mapping is mandatory.
9. On the **Map Data Points** section of the wizard, specify the treatment arms, stratum groups, or cohorts in your CSV file that are mapped to the treatment arms, stratum groups, and cohorts you created in Oracle Clinical One Platform, and click **Upload**.
10. Click **Finish** once you complete the wizard.

You can generate or upload a new randomization list at any time, without creating a new version of a study.

Related Topics

- Randomization lists and kit lists FAQs
- Guidelines for creating a kit or randomization list
  If you choose to upload a kit or randomization list into the system, there are certain guidelines related to special characters and file formatting that you should keep in mind before performing this task.
- Update a randomization list that ran out of numbers during the study conduct period
- Assign a randomization list to a randomization design and study version
  You typically need to assign a randomization list to a randomization design and study version if you created a second randomization list for a randomization design (such as if

you added a treatment arm to a study and needed to create another randomization list to support it). This procedure also applies to rollover studies.

Understand the concepts used in minimization

Minimization can be particularly useful for studies that aim to balance subjects across treatment groups. A key aspect of working this this type of randomization design is understanding the main concepts that it operates with.

As a non-random method of treatment allocation in clinical studies, minimization aims to balance treatment groups by subject factors (ensuring that common subject characteristics have a balanced weight across stratum factors). In recent history, it was proven that minimization provides better-balanced treatment groups given its flexibility to integrate more demographic or prognostic factors into its algorithm.

Let's go through the key concepts that define minimization's algorithm. Each main concept is tied to a product area where one of the three involved user roles perform a different task for creating and setting up minimization.

For the purpose of this exercise, we will describe the concepts in the context of an oncology study that uses minimization with five stratum factors: Country, Age, Gender, Race, and Cancer Stage.

Weight

In Oracle Clinical One Platform, weight represents an even number (from 0 to 99) that you must use to define the importance of each minimization stratum factor. How you define the weight of each stratum factor determines how each subject is assigned to a treatment arm and what drug they ultimately receive during the course of a study. In other words, the higher the weight number of a stratum factor is, the higher the priority it has when balancing subjects across treatment groups.

Using a sequential number for defining the weight is not mandatory. Moreover, a study designer typically defines the weight number based on the study protocol and a statistician's recommendations.

For example, as a study designer, you define the Weight number of a Cancer Stage minimization stratum factor as the highest among a list of other stratum factors, such as Country, Age, Gender, and Race.

Two new subjects of similar age, gender, and country are enrolled into the study. To balance out treatment groups, the two subjects will be assigned to two different treatment arms based on the severity of their illness (the Cancer Stage stratum factor).

For step-by-step instructions on how to define a minimization design, see Define the minimization.

Probability factor

When it comes to minimization, the probability factor is a measure or an estimate of the possibility one subject may have to be assigned to a certain treatment arm and receive a certain type of drug during the course of a study. This probability is measured on a scale from zero (impossibility) to one (certainty).

In Oracle Clinical One Platform, the probability factor is a decimal number included in a randomization list. The probability factor must be between 0 and 1 (exclusively) and can only have up to a maximum of six decimal places.

For example, in an oncology study, as a clinical supply manager, you can define the probability factor of a first subject being assigned to Treatment Arm A as 0.728, based on the associated stratum factors. Then, as you go further down the randomization list, you can alternate between a number closer to 1 (certainty) and a number closer to 0 (impossibility) for the probability factor associated with each subject and randomization number.

> **Note:**
>
> In general (and especially if your study contains three treatment arms), we recommend a randomly assigned probability factor, not an alternating one.

For step-by-step instructions on how to upload a randomization list, see Upload a randomization list for minimization.

Minimization cohorts

Minimization cohorts represent the groups of subjects that are created in the system based on stratum factors defined by a study designer.

In Oracle Clinical One Platform, minimization cohorts are associated with each minimization design they belong to. Minimization cohorts can be enabled for enrollment and randomization of subjects in the study.

For example, in an oncology study, as a study manager, you can enable all minimization cohorts for enrollment and randomization (Country, Age, Gender, Race, and Cancer Stage) and then define a Randomization Limit of 50 and a Notification Limit of 50%. That way, every time the limit of 25 subjects is reached in each minimization cohort, the study manager (or any other assigned study team member) receives a notification about this reaching this limit.

For step-by-step instructions on how to configure settings for minimization cohorts, see Specify enrollment settings for minimization cohorts.

Upload a randomization list for minimization

Create a randomization list for minimization in Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

> **Tip:**
>
> To prevent potential unblinding, create separate lists for each mode. If a statistician provides only the production list for a study, upload it in Production mode and generate lists for Testing and Training modes.
> We recommend you first create a randomization list in Testing mode before you create one in Training or Production mode.

Typically, minimization does not use a randomization list and the assignment of treatment arms is done dynamically based on the balance of subjects across the defined parameters. However, you can still upload (but not generate) a randomization list and her is how you can do it.

File requirements to upload a randomization list:

Create a comma-separated values (CSV) file (up to 1 GB) that includes one row for each randomization number with corresponding columns for:

- *Randomization number*
- *Probability factor*

The probability factor defines a probability score for each randomization number and must be a decimal value between 0 and 1, exclusive.

For guidelines on special characters and formatting of lists, see Guidelines for creating a kit or randomization list.

> **Note:**
>
> The file name must not include any periods, other than the period that appears before the file extension.

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, make sure the **Randomizations** tab is selected.
4. From the **Randomization List** drop-down, select **Upload**.
5. Select the randomization design that you want to upload a randomization list for, and click **Next**.
6. Fill in the fields the following fields:
   - **Title**
   - **Description**
   - **Mode**: Choose the mode that the randomization list is available in.
   - **Columns in File Have Headings**: Select if the CSV file you're uploading contains headings.
7. Click **Choose File** and select your CSV file, then click **Next**.
8. On the third page of the wizard, specify the type of data in each column (Randomization Number and Probability Factor) of your CSV file by mapping it to the column headers that Oracle Clinical One Platform uses, and click **Upload**.

   > **Note:**
   >
   > Make sure the Probability Factor is a decimal number between 0 and 1, exclusively.

9. Click **Finish** once you complete the wizard.

Related Topics

- Randomization lists and kit lists FAQs

- Guidelines for creating a kit or randomization list
  If you choose to upload a kit or randomization list into the system, there are certain guidelines related to special characters and file formatting that you should keep in mind before performing this task.
- Update a randomization list that ran out of numbers during the study conduct period
- Define the minimization

Assign blocks of randomization numbers to a site, country, or region

You must assign blocks of randomization numbers to a site, country, or region if you selected a type of randomization with Fixed in its name, and you either generated a randomization list in Oracle Clinical One Platform or uploaded a randomization list that didn't identify sites, countries, or regions for blocks. This procedure also applies to rollover studies.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Randomizations** tab.
4. If the study has more than one randomization list, select the appropriate list from the **Randomizations List** drop-down.
5. To the right of the **Randomization List** drop-down, click **Block Assignment**.
6. To assign blocks to a site, country or region you have two options:
   - For each block number, select a site, country, or region from the drop-down list.
   - To assign multiple consecutive blocks to the same site, country or region, in the upper left corner of the block assignment window search for the number range you need, click **Assigned to** and choose a site/country/region from the drop-down.

   > **Note:**
   >
   > You can also search for block numbers based on specific status. For instance, you can filter for unused blocks, so that you don't reassign a block that has been partially used.

7. Click **Save**.

Assign blocks of randomization numbers to a site for other modes in your study, if you haven't already and when required.

Assign a randomization list to a randomization design and study version

You typically need to assign a randomization list to a randomization design and study version if you created a second randomization list for a randomization design (such as if you added a treatment arm to a study and needed to create another randomization list to support it). This procedure also applies to rollover studies.

You can perform this action in all three modes: Testing, Training and Production.

Want to see how to perform this task? Watch the video below.

Video

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, make sure the **Randomizations** tab is selected.
4. From the **Randomization List** drop-down, select **Manage**.
5. Along the top in the dialog, select either:
   - **Production Lists**
   - **Testing Lists**
   - **Training Lists**
6. In the table, find the randomization list you need to use in a study version, and make sure that it is associated with both the appropriate randomization design and the study version that is being used for the mode you selected.
7. To assign a randomization list to an additional study version or randomization design:
   a. If needed, delete an existing association.

      Remember that each combination of study version and randomization design can be associated with only one randomization list for a given mode.

   b. In the Study Version column for the randomization list, click **+Add Study Version**.
   c. Fill in the fields. To view tips for completing a field, click into the field.

Study Version	Select the study version that will use the randomization list.
Randomization List	Click into the field, and select the randomization list to use in the selected study version.

> **Note:**
>
> Even if two randomization designs have the same stratum factors, a randomization list that was generated for one randomization design cannot be associated with the other randomization design.

   d. Click **Add**.
8. Click **Close**.

Tips:

- Click the pencil button () to the right of an assignment to change the randomization designs that are associated with a study version and randomization list. If the pencil is grayed out, the study version has been archived, so you can no longer make any changes (though you can delete the association entirely).

Manage supplies

After defining randomization, clinical supply managers can define how to manage supplies in the study, including lists, lots and other features.

- Define settings for *Testing mode* first, so you can test and verify a study version using mock data.
- Configure settings for *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Generate a kit list
  You can generate a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.
- Upload a kit list
  You can upload a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.
- Deactivate a kit list in Testing mode
  Deactivate a kit list if you ever uploaded a kit list in error and don't want to upload or generate a new kit list with different kit or sequence numbers. This procedure applies to rollover studies, as well.
- About manufacturing and blinded lots
  In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.
- Manage expiration dates with lots
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Assign kits to a manufacturing lot
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Combine manufacturing lots into a blinded lot
  Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot for one of two reasons: (1) to monitor batches of kits while protecting the study blind, or (2) to organize kits in multiple groupings. This procedure also applies to rollover studies.
- Create label groups
  A label group contains kits with the same label and ensures that kits are shipped to countries with the appropriate labels. Create label groups only if a country has special label requirements and you want to verify the complete end-to-end business process. This procedure also applies to rollover studies.

Generate a kit list

You can generate a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.

When you generate a kit list in Testing mode, the kits specified in that kit list are displayed in the study's inventory with a status of **Available**. When you generate a kit list in Production mode, the kits specified in that list are displayed in the study's inventory with a status of **Not in Use**.

> **Note:**
>
> You cannot generate or upload a kit list for pooled kits. The system generates a pooled kit list by default. Pooled kits can only be shipped through an integration. For more information, see About pooling kits in a study.

> **Tip:**
>
> To prevent potential unblinding, create separate lists for each mode. If a statistician provides only the production list for a study, upload it in Production mode and generate lists for Testing and Training modes.
> Make sure you verify the list for Testing mode before creating the lists for Production and Training modes.

To upload a kit list, instead of generating one, see Upload a kit list.

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, click the **Kits** tab.
4. From the **Kit List** drop-down, select **Generate**.
5. Fill in the fields and click **Next**.

> **Tip:**
>
> To view tips for completing a field, click into the field or choose an option.

Field	Description
Title	Type the appropriate description for your kit list.
Description	Type a description that is relevant to the kit list.
Mode	From the drop-down, select the mode that the kit list should be available in: Testing, Training, or Production.
First Kit Number	Enter the first number in the kit list. Each kit is randomly assigned to a kit number.
First Sequence Number	Enter the first sequence number for the kits in the kit list.
Generate Barcodes	Click this checkbox if you want to generate barcodes for kits in the study.
Barcodes	(Available only if you selected the **Generate Barcodes** checkbox) • Select **Use Kit Numbers** to use kit numbers for generating barcodes. • Select **Generate New Numbers** to generate brand new barcodes.

6. On the Select Kit Types section, select the kit types that should be mapped in the kit list and, in the **Quantity** field, enter the number of kits of each to include.
7. Click **Generate**.
8. Click **Export** and select **CSV** to first export your generated kit list.
9. Click **Finish**.

Related Topics

- Randomization lists and kit lists FAQs
- Why are barcodes useful in a study?
  Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.
- Update a kit list that ran out of numbers during the study conduct period
- Upload a kit list
  You can upload a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.

Upload a kit list

You can upload a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.

> **Note:**
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> You cannot generate or upload a kit list for pooled kits. The system generates a pooled kit list by default. Pooled kits can only be shipped through an integration. For more information, see About pooling kits in a study.

> **Tip:**
>
> To prevent potential unblinding, create separate lists for each mode. If a statistician provides only the production list for a study, upload it in Production mode and generate lists for Testing and Training modes.
> Make sure you verify the list for Testing mode before creating the lists for Production and Training modes.

File requirements to upload a randomization list:

Create a comma-separated values (CSV) file (up to 1 GB) that includes one row for each kit with corresponding columns for:

- *Kit numbers*
- *Sequence numbers*
- *Kit descriptions*
- *Kit IDs*

The file name must not include any periods, other than the period that appears before the file extension. For more guidelines on special characters and formatting of lists, see Guidelines for creating a kit or randomization list.

Do you want to generate a kit list, instead of uploading one? See Generate a kit list.

1. Access the study version for a given mode as described in Open the design of a study version.
2. Along the top, click **Study Supplies**.
3. Below the study name, click the **Kits** tab.
4. From the **Kit List** drop-down, select **Upload**.
5. Fill in the fields, upload your kit list, and click **Next**.

Field	Description
Title	Type the appropriate description for your kit list.
Description	Type a description that is relevant to the kit list.
Mode	From the drop-down, select the mode that the kit list should be available in: Testing, Training, or Production.
File Upload	Click **Choose File** to upload your kit list as a CSV file.
Columns in File Have Headings	Select if the CSV file you're uploading contains headings.

6. Map each header in your kit list and click **Next**.

Field	Description
Kit Number	From the Mapped To drop-down, select the appropriate option to map with the Kit Number header. This column indicates the number of each kit.
Sequence Number	From the Mapped To drop-down, select the appropriate option to map with the Sequence Number header. This column indicates the exact sequence number of each kit.
Kit Type	From the Mapped To drop-down, select the appropriate option to map with the Kit Type header. This column indicates the kit type of each kit.
Kit Type Description	From the Mapped To drop-down, select the appropriate option to map with the Kit Type Description header. This column indicates a kit type's description as entered in the system by a study designer.
Barcode	From the Mapped To drop-down, select the appropriate option to map with the Barcode header. Depending on what type of barcodes you are using, this column may indicate the kit number of each kit or a specific barcode number.

Field	Description
Block Number	From the Mapped To drop-down, select the appropriate option to map with the Block Number header. This column indicates the exact block number to which a kit belongs.

7. Specify the kit types in your CSV file that are mapped to the kit types you created in Oracle Clinical One Platform and click **Upload**.
8. Click **Finish**.

Related Topics

- Randomization lists and kit lists FAQs
- Why are barcodes useful in a study?
  Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.
- Update a kit list that ran out of numbers during the study conduct period
- Generate a kit list
  You can generate a new kit list at any time, without creating a new version of a study. Create a kit list for Production and Training modes when you're ready to make the study live.

Deactivate a kit list in Testing mode

Deactivate a kit list if you ever uploaded a kit list in error and don't want to upload or generate a new kit list with different kit or sequence numbers. This procedure applies to rollover studies, as well.

> **Note:**
>
> It may take longer than you would expect for a larger kit list to be deactivated in the system. For example, a kit list that contains over 50.000 rows may take up to 4 minutes to get deactivated.

Learn more about kit lists in the FAQs.

Want to see how to perform this task? Watch the video below.

Video

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. To deactivate a kit list, click the **Deactivate Kit List** button.
5. From the drop-down, select the kit list that you want to deactivate.
6. On the Confirmation dialog, read the message and either click **Deactivate** or **Cancel**.

You'll receive a Kit List Deactivated notification once the deactivation process is done. Once the kit list is deactivated, you can re-upload the same kit list under a new name.
Tips:

- Remember to re-upload your kit list under a different name, otherwise the system will warn you about the duplicate name of the kit list.
- You can deactivate as many kit lists as you have to.
- If a kit list is deactivated and some of the kits are also part of a shipment, those kits will be removed from the shipment.
- If any kits that are part of a deactivated list have already been dispensed to a subject, they will still be visible in a subject's dispensation history.

About manufacturing and blinded lots

In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.

Manufacturing lots

You must use this type of lot in every study. Kits in a manufacturing lot share an expiration date, and you must create at least one manufacturing lot in each study mode (Testing, Training, and Production) so that you can assign an expiration date to kits in Oracle Clinical One Platform.

Blinded lots

Create a blinded lot in Testing mode if the study or organization requires them and you want to verify the complete end-to-end business process.

Creating blinded lots is optional. You may choose to combine one or more manufacturing lots into a blinded lot for the following reasons:

- To monitor batches of kits while protecting the study blind.
- To organize kits in multiple groupings.

Create a blinded lot in Production mode if the study or organization requires blinded lot numbers. You can also create a blinded lot in Training mode if you want users to be able to practice the end-to-end business process.

Related Topics

- Manage expiration dates with lots
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Assign kits to a manufacturing lot
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Combine manufacturing lots into a blinded lot
  Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot for one of two reasons: (1) to monitor batches of kits while protecting the study blind, or (2) to organize kits in multiple groupings. This procedure also applies to rollover studies.
- Create label groups
  A label group contains kits with the same label and ensures that kits are shipped to countries with the appropriate labels. Create label groups only if a country has special label requirements and you want to verify the complete end-to-end business process. This procedure also applies to rollover studies.

- How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?
  A few settings help you manage the expiration dates of kits.

Manage expiration dates with lots

A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.

To understand which type of lot to create, see About manufacturing and blinded lots.

Want to see how to perform this task? Watch the video below.

Video

1. **Task 1. Create a manufacturing lot.**
   a. Access your study in a specific mode.
   b. Along the top, click **Supplies**.
   c. Below the study name, click the **Inventory** tab.
   d. On the right, make sure that **Lots** is expanded.
   e. From the **Create Lot** drop-down, select **Manufacturing Lot**.
   f. Fill in the fields and click **Create**.

> **Note:**
>
> Custom country settings defined for a blinded lot override the default settings you may have specified for a manufacturing lot.

Field	Description
Manufacturing Lot Title	Enter a unique name for the manufacturing lot.
Short Name	Enter an alternative manufacturing lot label. For example, you might enter a short name if your organization's labeling conventions differ from the lot name supplied by the depot.
Expiration Date	Choose the expiration date for the kits in the manufacturing lot. If you're creating a manufacturing lot for devices that don't expire, you can choose a date that is very far in the future.
Do Not Ship (DNS) Days	Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site.
Do Not Count (DNC) Days	Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory.

   g. Assign kits to the manufacturing lot to manage their expiration dates.
2. **Task 2. (Optional) Create a blinded lot**.

a. Access your study in a specific mode

b. Along the top, click **Supplies**.

c. Below the study name, click the **Inventory** tab.

d. On the right, make sure that **Lots** is expanded.

e. From the **Create Lot** drop-down, select **Blinded Lot** and fill in the fields.

Field	Description
Blinded Lot Title	Enter a unique name for the blinded lot.
Short Name	Enter a short name for the blinded lot. This field is useful when multiple depots use the same lot and have different naming conventions. One depot can use the title, and another can use the short name.
Expiration	Choose the expiration date for the blinded lot. The date must be on or before the earliest expiration date of the manufacturing lots in the blinded lot.
Release for Depot to Depot	By default, this toggle is turned off. Turn the toggle on to allow your study team to ship kits at depots through a depot-to-depot shipment before kits are released at the sites. If there are any country-specific restrictions, a depot-to-depot shipment will be delivered at the depot without taking those country-specific settings into account.
Do Not Count/ Do Not Ship Settings	Specify a number in each column: • **Do Not Count (DNC) Days**: Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory. • **Do Not Ship (DNS) Days**: Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site. • **Select countries**: In the Do Not Count / Do Not Ship Settings section, click **Select countries**, and select the countries you want to specify custom DNC and DNS values for. Click the plus icon (+) to add a new row where you can customize these values for a different country. ***Note:*** *Custom country settings override any default settings you may have specified.*

f. If you know the manufacturing lots that you want to combine into the blinded lot, select the manufacturing lots. Otherwise, combine manufacturing lots into the blinded lot later.

g. Click **Create**.

Remember that you can update the expiration date for a manufacturing lot or a blinded lot at any time. After a lot expires, its kits are no longer distributed to sites or dispensed to subjects.

Related Topics

- About manufacturing and blinded lots
  In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.
- Assign kits to a manufacturing lot
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Combine manufacturing lots into a blinded lot
  Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot for one of two reasons: (1) to monitor batches of kits while protecting the study blind, or (2) to organize kits in multiple groupings. This procedure also applies to rollover studies.
- Create label groups
  A label group contains kits with the same label and ensures that kits are shipped to countries with the appropriate labels. Create label groups only if a country has special label requirements and you want to verify the complete end-to-end business process. This procedure also applies to rollover studies.
- How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?
  A few settings help you manage the expiration dates of kits.

Assign kits to a manufacturing lot

A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.

You typically assign kits to a manufacturing lot before a study goes live and as needed during the study conduct period, such as when a new batch is released.
What do I do first? Before you can work with kits in any mode, you need to generate or upload a kit list.

Want to see how to perform this task? Watch the video below.

Video

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. Click a kit type.
5. Above the kit list, from the **Lots** drop-down, click **Unassigned** so you see only kits that aren't assigned to any lots.

> **Tip:**
>
> You can narrow your view further using the filters above the kit list:
>
> - If the kits in the lot are at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down. If the kits aren't at a site or depot, click **Unassigned**.
> - Below Number Range, click **Kit** or **Sequence**, and enter the range of kit or sequence numbers for the kits in the lot.

6. In the list, select the kits to include in the manufacturing lot.
7. From the **Add to Lot** drop-down, located to the right of the filters, select the manufacturing lot.
8. In the confirmation window, select a reason for the change, and click **Yes**.
9. Above the kit list, use the filters to check your work:
   a. In the upper right, click **Clear Filters**.
   b. Above the kit list, from the **Lots** drop-down, select the manufacturing lot that you assigned the kits to.

Related Topics

- About manufacturing and blinded lots
  In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.
- Manage expiration dates with lots
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Combine manufacturing lots into a blinded lot
  Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot for one of two reasons: (1) to monitor batches of kits while protecting the study blind, or (2) to organize kits in multiple groupings. This procedure also applies to rollover studies.
- Create label groups
  A label group contains kits with the same label and ensures that kits are shipped to countries with the appropriate labels. Create label groups only if a country has special label requirements and you want to verify the complete end-to-end business process. This procedure also applies to rollover studies.
- How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?
  A few settings help you manage the expiration dates of kits.

Combine manufacturing lots into a blinded lot

Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot for one of two reasons: (1) to monitor batches of kits while protecting the study blind, or (2) to organize kits in multiple groupings. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. On the right, expand **Lots**.
5. Drag one or more manufacturing lot to the blinded lot that you want to combine them in.

> **Tip:**
>
> You can add manufacturing lots to a blinded lot at creation as explained in Manage expiration dates with lots.

Related Topics

- About manufacturing and blinded lots
  In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.
- Manage expiration dates with lots
  A kit can't be dispensed unless it has an expiration date, and you assign an expiration date to a kit by associating the kit with a manufacturing lot. This procedure also applies to rollover studies.
- Assign kits to a manufacturing lot
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Want to see how to perform this task? Watch the video below.

Video

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. In the lower right, expand **Label Groups**.
5. Click **Create Label Group**, and fill in the fields.

To view tips for completing a field, click into the field.

6. Select the countries to include in the label group by either double-clicking them or clicking the arrow buttons, and then click **Create**.

Assign kits to a label group:

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. Click a kit type.
5. Above the kit list, use the filters to return the kits you want to assign to the label group:
   a. Below Location, click **Depots**, and select the depot that is supplying kits for the country from the **All Depots** drop-down.
   b. Above the kit list, from the **Status** drop-down, select **Available**.
   c. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
6. In the list, select the kits to include in the label group.
7. On the right side pane, make sure **Kit Settings** is expanded and, from the **Label Group** drop-down, select the label group.

> **Tip:**
>
> To remove the group label, click **Clear assigned label group** from drop-down, if you assigned the label to a depot in error.

8. Click **Update Kits**.
9. In the confirmation window, select a reason for change and click **Yes**.
10. Repeat this procedure for every kit type included in the label group.

> **Tip:**
>
> To repeat for different kit types, click **Back**, and select a different kit type from the kit type list.

Related Topics

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- How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?
  A few settings help you manage the expiration dates of kits.

Make a study live

After all required elements of a study are created, it's time to put all of the pieces together. During this phase, a study team member must assign the appropriate study version to sites, activate sites, and complete many more settings to make a study version live in a specific mode.

- Make a study version live in *Testing mode* first, so you can test it and verify it using mock data.
- Make a study version live in *Production mode* once you have verified that the study design and settings are working as expected.
- Configure *Training mode* settings to match those defined for Production mode, so that users who operate your study can get properly trained with the real study configuration using mock data.
- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Assign a study version to a site
  To make a study version live in any mode, you must perform these steps and then activate a site. If the site you need to activate hasn't been created yet, you must first add the site. This procedure also applies to rollover studies.
- Select a resupply strategy for a site
  You must select a resupply strategy for a site so that automatic shipments can be generated. This procedure also applies to rollover studies.
- Open and close a cohort
  All cohorts are closed by default in a cohort study. Open at least one cohort before the study goes live, or sites won't be able to randomize subjects. After the limit is reached for a cohort, sites can't randomize subjects until you open the next cohort or increase the limit. This procedure also applies to rollover studies.

- Activate a site
  To make a study version live, activate a site. Make a study live in Production mode only after the site has contractually agreed to the protocol and regional regulatory requirements are in place. A site that has been activated can never be deleted, but it can be retired. This procedure also applies to rollover studies.

Assign a resupply strategy to a depot

When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.

You can only assign a Min/Max resupply strategy to a receiving depot.

You must first create a supplying depot and a receiving depot in order to assign a resupply strategy to the receiving depot. For step-by-step instructions, see Add a depot for a study.

1. Open the study settings.
2. Click the **Depots** tab.
3. Along the top, select a specific mode:
   - **Production Depots**
   - **Testing Depots**
   - **Training Depots**
4. Locate the depot that you want to assign the resupply strategy to.
5. From the Resupply Strategy drop-down for each depot, select a resupply strategy.

> **Tip:**
>
> You can also click **Create Resupply Strategy** to create a new Min/Max resupply strategy on the spot and assign it to the receiving depot.

Next, activate a depot. For step-by-step instructions, see activate a depot.

Related Topics

- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.

- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Site, depot, labs, and source data verification FAQs

Activate a depot

You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.

> **Note:**
>
> If the depot you need to activate hasn't been created, you must add the depot. For more information, see Add a depot for a study.

1. Open the study settings.
2. Click the **Depots** tab.
3. Along the top, select a specific mode:
   - **Production Depots**
   - **Testing Depots**
   - **Training Depots**
4. Locate a depot that you want to activate.
5. Next, from the **Manage Depots** drop-down, you can select either one of the following options:
   - Select **Edit** and in the Edit Depot dialog, select **Active** from the **Status** drop-down and click **Save** and **Finish**.
   - Select **Activate**.

Activate additional depots as needed. Do the same for other modes when required.

Related Topics

- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.

- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.
- Create and manage institutions, vendors, and contacts
- Site, depot, labs, and source data verification FAQs

Release kits to sites or depots

Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Click the **Study Inventory** tab.
4. Click a kit type.
5. Above the kit list, use the filters to return only the kits you want to release to the site or depot:

   > **Tip:**
   >
   > We recommend releasing many kits in Testing mode so you don't run out while testing.

   a. Below Location, click **Unassigned**.
   b. Above the kit list, from the **Status** drop-down, select **Available**.
   c. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
6. In the list, select the kits to update.
7. On the right side panel, make sure **Kit Settings** is expanded.
8. Do one of the following:
   - From the **Location** drop-down below Kit Settings, select the depot to associate the kits with.

     > **Note:**
     >
     > If you don't see the depot you need, make sure it was created and activated.

   - Alternately, in Testing mode you can release kits directly to sites if you don't want to test the end-to-end distribution. In this case, from the **Location** drop-down, select a site to associate the kits with.
9. Click **Update Kits**.
10. In the confirmation window, select a reason for change and click **Yes**.

> **Tip:**
>
> In the upper right of the kit list, the Total Kits number tells you the number of available kits at the depot.

- You can use the filters to check your work:
  1. On the left, below Location, click **Sites** or **Depots**, and select the site or depot from the **All Sites** or **All Depots** drop-down.
  2. Above the kit list, from the **Status** drop-down, select **Available**.
  3. f necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
- Click **Back** to select a different kit type from the kit type list and repeat for each as required.

Related Topics

- Manage shipments
- What if users have problems working in a live study?
  If users run into problems while working in a live study, these troubleshooting tips will help you get everyone back on track.
- What is the workflow for shipments?
  This workflow applies to shipments when you don't use an integration for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Assign a study version to a site

To make a study version live in any mode, you must perform these steps and then activate a site. If the site you need to activate hasn't been created yet, you must first add the site. This procedure also applies to rollover studies.

> **Note:**
>
> You or your delegate are responsible for ensuring that appropriate regional and local regulatory approvals are in place before allowing a site access to any study versions that may mandate the conduct of specific procedures and investigations on subjects.

> **Tip:**
>
> If you have a lot of sites, use the filters above the table of sites to find the site you're looking for.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Along the top, select a specific mode:
   - **Production Sites**

- **Testing Sites**
- **Training Sites**

4. Locate a site and, from the **Study Version** drop-down, select the study version that the site must use.

   The study version must be under either Testing or Approved on the Home page.

   > **Tip:**
   >
   > Use the **Study Version** drop-down in the column header to apply a study version to all sites.

5. In the upper-right corner, click **Apply Changes**.

Related Topics

-

Select a resupply strategy for a site

You must select a resupply strategy for a site so that automatic shipments can be generated. This procedure also applies to rollover studies.

To complete this task, you must first add a site and assign a study version to that site. For more information, see Add the site and Assign a study version to a site.

> **Tip:**
>
> If you have a lot of sites, use the filters above the table of sites to find the site you're looking for.

1. Open the study settings.
2. Click the **Sites & Labs** tab.
3. Along the top of the page, select a specific mode:
   - **Production Sites**
   - **Testing Sites**
   - **Training Sites**
4. Locate a site and, from the **Resupply Strategy** drop-down, select the resupply strategy that the site must use.

   > **Tip:**
   >
   > Use the **Resupply Strategy** drop-down in the column header to apply a resupply strategy to all sites.

5. Assign resupply strategies to additional sites as required.
6. In the upper right corner, click **Apply Changes**.

Select a resupply strategy for sites in other modes when required.

Open and close a cohort

All cohorts are closed by default in a cohort study. Open at least one cohort before the study goes live, or sites won't be able to randomize subjects. After the limit is reached for a cohort, sites can't randomize subjects until you open the next cohort or increase the limit. This procedure also applies to rollover studies.

If your study uses a minimization cohort, you must first specify the enrollment settings for that cohort. For more information, see Specify enrollment settings for minimization cohorts.

1. Open the study settings.
2. Click the **Study Settings** tab.
3. Along the top of the page, select a specific mode:
   - **Production Settings**
   - **Testing Settings**
   - **Training Settings**
4. Scroll to the **Enrollment Settings** section, and expand **Cohort**.
5. Do one of the following:
   - To **open a cohort**, click the toggle to the left of the cohort name so that the color of the toggle changes from gray to blue and the circle moves from the left to the right ().
   - To **close a cohort**, click the toggle to the left of the cohort name so that the color of the toggle changes from blue to gray and the circle moves from the right to the left ().

Open and close cohorts for other modes when required.

Related Topics

- Upload a randomization list for minimization
  Create a randomization list for minimization in Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.
- Define the minimization
- Specify enrollment settings for minimization cohorts
  When specifying the enrollment settings, if your study includes a minimization design , the system displays the cohorts in sections by each minimization design. Typically, a study manager specifies these settings. This procedure also applies to rollover studies.

Activate a site

To make a study version live, activate a site. Make a study live in Production mode only after the site has contractually agreed to the protocol and regional regulatory requirements are in place. A site that has been activated can never be deleted, but it can be retired. This procedure also applies to rollover studies.

Before you can activate a site, you must perform the following tasks in the specified order:

1. Add the site, including specifying the principal investigator's last name.

2. Assign a study version to a site.
3. Select a resupply strategy for each site.
4. Specify the first subject number for Testing mode in Study Settings.
5. Open the appropriate cohort(s).

- Depending on how supply settings are set up, site activation might initiate a shipment to the site.
- If you activated a site in error, or if a site is no longer active, mark the site as retired. You can activate a retired site at any time.

What if users have problems working in a live study?

> **Note:**
>
> You or your delegate are responsible for ensuring that appropriate regional and local regulatory approvals are in place before allowing a site access to any study versions that may mandate the conduct of specific procedures and investigations on subjects.

1. On the Home page, click the pencil button () on a study, and make sure the correct study version is in the appropriate container:
   - **Testing** for Testing mode.
   - **Approved** for Production and Training modes.
2. Open the study settings.
3. Click the **Sites & Labs** tab.
4. Along the top of the page, select a specific mode:
   - **Production Sites**
   - **Testing Sites**
   - **Training Sites**
5. Locate a site that you want to activate.
6. Next, from the **Manage Sites** drop-down, you can select either one of the following options:
   - Select **Edit** and in the Edit Site dialog, select **Active** from the **Status** drop-down and click **Save** and **Close**.
   - Select **Activate**.

Activate sites in other modes when required.

- Verify a study in Testing mode once you have activated sites and make your study live in *Testing mode*.
- Practice data entry in Training mode once you have activated sites and make your study live in *Training mode*.
- Manage real data and Work during the study conduct period once you have activated sites and make your study live in *Production mode*.

Verify a study in Testing mode

After all settings and elements of a study are configured in Testing mode, you must verify that the study design is matching the protocol to proceed with the Production mode configuration. During this phase you must also check the user workflow and make sure everything follows a logical order.

- Specify and review settings before verifying a study
  It's a good idea to make sure your settings are correct before you start verifying your study. This procedure also applies to rollover studies.
- Verify a study
  When you verify a study, you typically check that a user's flow is logical and usable and that the study design matches the protocol. This procedure also applies to rollover studies.
- What if I have problems trying to verify a study?
  If you run into problems while verifying your study in Testing mode, these troubleshooting tips will help you get back on track.

Specify and review settings before verifying a study

It's a good idea to make sure your settings are correct before you start verifying your study. This procedure also applies to rollover studies.

1. On the Home page, click the pencil button () on a study, and make sure a study version is below either Testing or Approved.
2. Review supply settings for Testing mode:
   a. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
   b. Below the study name, click the **Supply Settings** tab.
   c. On the left, make sure **Testing Settings** is selected.
   d. Fill in the fields. To view tips for completing a field, click into the field or choose an option.

      > **Tip:**
      >
      > You can edit these settings at any time, including during the study conduct period.

   e. In the upper right, click **Apply Changes**.
3. Review the read-only kit types in the study:
   a. On the Home page, click the pencil button () on the study you want to review.
   b. Below Testing, click the study version.
   c. Along the top, click **Study Supplies**.
   d. Below the study name, click the **Kits** tab.
   e. Review the settings for each kit type.

> **Tip:**
>
> To edit the settings, Create a new Draft version of a study to update the Testing version. You can edit the settings in the Draft version of the study.

4. Make sure the dispensation schedule was defined correctly:

   a. On the Home page, click the pencil button () on the study you want to review.

   b. Below Testing, click the study version.

   c. Along the top, click **Study Supplies**.

   d. Below the study name, click the **Kits** tab.

      The visit schedule appears on the right, with the pill icon representing a dispensation visit.

   e. Click a visit to review its details.

      > **Tip:**
      >
      > To change the dispensation schedule, you must Create a new Draft version of a study to update the Testing version.

   f. To review the dispensation settings for a kit type, click the pencil button on a treatment arm, and select the kit type.

Verify a study

When you verify a study, you typically check that a user's flow is logical and usable and that the study design matches the protocol. This procedure also applies to rollover studies.

1. On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.
2. Make sure the correct study version is assigned to active Testing sites and update if required. See Assign a study version to a site.
3. Click the Testing Mode button () on the study you want to verify.
4. Verify the study.

   Consider performing the following verification activities:

Activity	Tips	Where to get more information
Verify data collection: • Verify that a user's flow through forms is logical and usable and that you are collecting the data that you expect. • Run the **Subject Data report** to view the data collected for subjects.	• We recommend randomizing a number of subjects to make sure that randomization and dispensation occur as expected. The number of subjects to randomize depends on your randomization design. For example, if you have a block size of 4, you might want to randomize 8 or more subjects. • We recommend completing all forms in the study for at least one test subject to make sure that the study design meets your expectations. Consider checking that: – The **Site** drop-down in the upper-right corner contains all sites that you expect to see. – Required questions are identified correctly. – The text in the Question Hint panel on the right is useful. – The validation rules work as you expect. – You are capturing data as you expected. – The forms flow as expected. – Site users will have a positive experience entering data.	For information about a site user's activities, see the *Site User Guide*. See how to Run a report and Subject Data report description.
Verify the workflow of kits.	None.	See Manage kits at the site and study level.
Verify that randomization and dispensation occur in accordance with the specifications.	Consider verifying the following information: • The correct randomization numbers are assigned to subjects. • Subjects are dispensed kits in accordance with the dispensation schedule. • If the study uses label groups, kits have appropriate labels for countries.	An unblinded user can View a subject's randomization number in a study you are verifying in Testing mode and can also run the following reports: • **Kit Chain of Custody (Unblinded)** In this report, you can see the kits that were dispensed to subjects. • **Randomization List (Unblinded) report**

- For more information for sponsor users about operating a live study, see Work during the study conduct period.
- For more information for site users about entering data, see Add subjects and enter data.

- What if I have problems trying to verify a study?

Once you have verified your study is in compliance with the study protocol, you are ready to go live. To do this, configure your study settings in Production mode as you did for Testing mode.

Related Topics

- Run a report
- Report descriptions
- View a subject's randomization number
  Unblinded users can view all randomization numbers and the subjects who are assigned to them. This procedure also applies to rollover studies.
- Work during the study conduct period

What if I have problems trying to verify a study?

If you run into problems while verifying your study in Testing mode, these troubleshooting tips will help you get back on track.

Having problems with a live study?

What if I can't work in a study?

1. Ask a user administrator to confirm your effective date range in the study is not in the past or future. For instructions on creating users, see Create study user accounts.
2. Contact Oracle Support.

What if I open a study, and it says I have no sites?

1. Verify that you created sites for Testing mode.
2. Make sure the sites are all activated.
3. Contact Oracle Support.

What if shipments aren't being raised?

1. **If shipments were created in the past and aren’t being created anymore**: Make sure a study version is assigned to the site. If the site uses predictive resupply and doesn’t have a study version assigned to it, the supplies that are needed at the site can’t be predicted, so no shipments are created.
2. Make sure the study has a kit list for Testing mode.
3. Check your depots:
   - Make sure a depot is assigned to send shipments to the country that the site is in.
   - Check that depots are activated.
   - Check that kits are assigned to the depot.
4. **If your study requires label groups**:
   a. Make sure each kit is assigned to a label group.
   b. Make sure that kits of each type are in label groups that are allowed to be sent to the site(s) that are missing shipments.
5. Verify the following information for the manufacturing lots (and blinded lots, if you are using them):

- Expiration dates of all lots are in the future.
- Expiration dates of all lots are late enough that kits can still be dispensed in consideration of the Do Not Ship (DNS) Days value for the manufacturing lot.

6. Check that the site:
   - Has been activated.
   - Has a resupply strategy associated with it.
7. Check the event that triggers the first shipment, either site activation or the first subject who starts a specified visit. A shipment is created only after the selected event occurs.
8. Contact Oracle Support.

What if I can't create shipments in a study I am trying to verify?

1. Check your depots:
   - Make sure a depot is assigned to send shipments to the country in which the site exists.
   - Check that kits are assigned to the depot.
2. Make sure that kits that are assigned to the depot are also assigned to a manufacturing lot.
3. Verify the following information for the manufacturing lots (and blinded lots, if you are using them):
   - Kits of every type are assigned to a lot.
   - Expiration dates of all lots are in the future.
   - Expiration dates of all lots are late enough that kits can still be dispensed in consideration of the Do Not Ship (DNS) Days value for the manufacturing lot.
4. **If your study requires label groups**:
   a. Make sure each kit is assigned to a label group.
   b. Make sure that the kits you're trying to add to the shipment are in label groups that are allowed to be sent to the site you're creating a shipment for.
5. If your study requires label groups, make sure each kit is assigned to a label group.
6. If the study allows single kit ordering, check whether the depot has the right combination of kits. If not, make kits available at the depot.
7. Contact Oracle Support.

What if I can't add subjects in a study I am trying to verify?

1. If you have access to multiple sites, make sure the site you're verifying is selected from the **Site** drop-down, to the right of the Manage Subjects drop-down.
2. Check with an administrator to make sure you have a site user role for Testing mode. For instructions, see Create study user accounts.
3. Check whether the limits for the study have been met, and make sure enrollment isn't closed.
4. Contact Oracle Support.

What if I can't randomize subjects or dispense kits in a study I am trying to verify?

1. Make sure the subject came in within the visit window, if the study doesn't allow dispensation out of window.
2. Ask a user administrator to verify that you are assigned to:
   - A site user role for Testing mode. For instructions, see Create study user accounts.
   - The site you're trying to work with for Testing mode.
3. Make sure the study has:
   - A kit list for Testing mode.
   - A randomization list for Testing mode.
4. Confirm that the randomization list is assigned to the study version that you are verifying.
5. Check that kits are assigned to the site.
6. Verify the following information for the manufacturing lots (and blinded lots, if you are using them):
   - Kits of every type are assigned to lots.
   - Expiration dates of all lots are in the future.
   - Expiration dates of all lots are late enough that kits can still be dispensed in consideration of the DND (Do Not Dispense) value for the visit.
7. Check whether the screening, randomization, and cohort limits have been met. If the cohort limit has been met, make sure that a cohort that hasn't reached its limit is open.
8. If you are randomizing into stratum groups, make sure the stratum groups don't have overlapping ranges.
9. Contact Oracle Support.

Create and manage custom rules

Oracle Clinical One Platform provides a user interface for creating custom rules using JavaScript. Rules are applied in all modes when published, but you can only create, test, edit, approve and publish them in Testing mode.

To further understand the scope and management of custom rules, and to get additional helper function details and rules examples, see Before you begin your rules development.

Manage dispensation exceptions

While study designers can configure the Do Not Dispense (DND) Days in a study's visit schedule, a sponsor user (typically a clinical supply manager) can configure DND exceptions for a country or site to better control dispensation in a study. Exceptions can be made for all visits where dispensation occurs.

- Understand dispensation exceptions
  Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.
- Create a DND exception
  Sponsor users can control kit dispensation based on protocol requirements to ensure patient safety by setting DND exceptions.

- Edit a DND exception
  Make changes to a defined dispensation exception.
- Copy a DND exception
  Copy a previously defined dispensation exception to kits.
- Delete a DND exception
  Delete a defined dispensation exception.

Understand dispensation exceptions

Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.

As a Clinical Supply Manager(CSM), it is your responsibility to dispense products for all scheduled dispensation based on protocol requirements while preserving patient safety. Dispensation exceptions allow you to set an exception for kits with the Do Not Dispense (DND) dispensation logic at both the country and site level.

While study designers can configure the Do Not Dispense (DND) Days in a study's visit schedule, a sponsor user (typically a CSM) can configure DND exceptions for a site or country to better control dispensation during the study conduct period. Exceptions can be made for all visits where dispensation occurs. When removing an exception from a site, the site defaults to the country's DND settings. If you remove an exception from a country, the country returns to the study design's default DND settings.

The DND logic then considers the limit or exceptions for a subject's country or site at the time of dispensation. This is also applied when the subject completes a partial dispensation or when removing the subject from a dose hold visit.

This feature supports sponsor users in scenarios such as a country or a site that requires a longer expiration timeframe for distributing the investigational product to subjects. Similarly, this can be helpful in emergency situations when there is a shortage in supply at the site and an override of the initial distribution setting is necessary.

Before working with dispensation exceptions, you must be assigned with the appropriate permissions.

- The *View Dispensation Exceptions* permission allows you to view dispensation exceptions that have been created.
- The *Create and Manage Dispensation Exceptions* permission allows you to add, edit, copy, and delete DND dispensation logic exceptions.

Reach out to your study user administrator and refer to Descriptions of permissions in Clinical One.

For step-by-step instructions on managing dispensation exceptions, see:

- Create a DND exception
- Edit a DND exception
- Copy a DND exception
- Delete a DND exception

For more information on specifying DND dispensation in study design, see Define the dispensation schedule.

Create a DND exception

Sponsor users can control kit dispensation based on protocol requirements to ensure patient safety by setting DND exceptions.

For more details, see Understand dispensation exceptions.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. In the Dispensation Exceptions side panel, select **Add a DND Exception**.

   The Add a DND Exception dialog appears.
5. In the **Settings** section, choose one or multiple active kits you would like to set an exception for.
6. For the **Location** field, choose one of the following:
   - **All countries**: select this option to create the exception for all countries that have been defined at the time of kit creation.
   - **Country specific**: select this option to create the exception for a particular country.
   - **Site specific**: select this option to create the exception for a particular site.
7. Click **Next**.
8. In the **Exceptions** section, choose which visits you would like to apply the exception to, and enter the amount of days the exception should be set for.
9. Click **Create Exception**.

   The kits with defined exceptions appear in the Dispensation Exceptions side panel.

Related Topics

- Understand dispensation exceptions
  Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.
- Edit a DND exception
  Make changes to a defined dispensation exception.
- Copy a DND exception
  Copy a previously defined dispensation exception to kits.
- Delete a DND exception
  Delete a defined dispensation exception.

Edit a DND exception

Make changes to a defined dispensation exception.

For more details, see Understand dispensation exceptions.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. In the Dispensation Exceptions side panel, locate the exception you would like to edit.

5. Click the menu icon ( ) and select **Edit**.

   The Edit DND Exception dialog appears.

6. Make any desired changes in the **Settings** or **Exceptions** sections.
7. Click **Confirm**.

Related Topics

- Understand dispensation exceptions
  Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.
- Create a DND exception
  Sponsor users can control kit dispensation based on protocol requirements to ensure patient safety by setting DND exceptions.
- Copy a DND exception
  Copy a previously defined dispensation exception to kits.
- Delete a DND exception
  Delete a defined dispensation exception.

Copy a DND exception

Copy a previously defined dispensation exception to kits.

For more details, see Understand dispensation exceptions.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. In the Dispensation Exceptions side panel, locate the exception you would like to copy.
5. Click the **Menu** icon ( ) and select **Copy**.

   The Add a DND Exception dialog appears with the **Settings** section pre-populated with the copied exception's entries.

6. In the **Settings** section, choose one or multiple active kits you would like to apply the copied exception to.
7. For the **Location** field, choose one of the following:
   - **All countries**: select this option to create an exception for all countries that have been defined at the time of kit creation.
   - **Country specific**: select this option to create an exception for a particular country.
   - **Site specific**: select this option to create an exception for a particular site.
8. Click **Next**.

   The **Exceptions** section appears with the **DND (Days)** fields pre-populated with the copied exception's entries.

9. In the **Exceptions** section, choose which visits you would like to apply the copied exceptions to.
10. Click **Create Exception**.

Related Topics

- Understand dispensation exceptions
  Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.
- Create a DND exception
  Sponsor users can control kit dispensation based on protocol requirements to ensure patient safety by setting DND exceptions.
- Edit a DND exception
  Make changes to a defined dispensation exception.
- Delete a DND exception
  Delete a defined dispensation exception.

Delete a DND exception

Delete a defined dispensation exception.

> **Note:**
>
> When removing an exception from a site, the site defaults to the country's DND settings. If you remove an exception from a country, the country returns to the study design's default DND settings.

For more details, see Understand dispensation exceptions.

1. Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.
4. In the Dispensation Exceptions side panel, locate the exception you would like to delete.
5. Click the menu icon ( ) and select **Delete**.

   The Delete Exception dialog informs you that by deleting the exception, you are removing it from the dispensation exceptions list, and it will no longer be applied to the selected kits, countries, and sites.
6. Click **Confirm**.

Related Topics

- Understand dispensation exceptions
  Learn more about setting dispensation (DND) exceptions for kits based on study requirements. Use DND exceptions to adhere to study protocol and ensure patient safety.
- Create a DND exception
  Sponsor users can control kit dispensation based on protocol requirements to ensure patient safety by setting DND exceptions.
- Edit a DND exception
  Make changes to a defined dispensation exception.
- Copy a DND exception
  Copy a previously defined dispensation exception to kits.

Enable a study for Electronic Health Record (EHR) data import

Enable EHR data import for a study so site users can import EHR data into Oracle Clinical One Platform forms, which can save site users time and improve data quality by reducing data entry mistakes.

Once you enable a study,

- The label **Oracle Clinical Connector Enabled** appears on the **General** tab under Study Settings. For more information, see Open the study's settings.
- Study designers see the **EHR Mapping** setting on the **Advanced** side panel, allowing them to map form questions to EHR data elements in an Oracle-managed data dictionary.

What EHR data can be imported?

The Oracle Clinical Connector (OCC) data dictionary contains the values that a study designer selects from when mapping a form question for EHR data import. Oracle maintains the dictionary and updates it with each release when applicable, guaranteeing study designers have access to the most recent mapping options and code lists.

The EHR data categories available for mapping and data import include the following:

- Demographics
- Medical History
- Medications
- Labs
- Vitals
- Procedures

How do I implement EHR data import for a study?

1. The sponsor reaches out to their Oracle point of contact to request Oracle Clinical Connector (OCC) enablement for a study.

   > **Note:**
   >
   > Once enabled, you can test EHR data import using test data. For more information, see Test the EHR data import.

2. The study designer maps form questions to EHR data elements. For more information, see Map form questions for EHR data import.
3. The sponsor associates an EHR connector instance with participating sites. For more information, see Enable and manage your EHR site connections.

   > **Note:**
   >
   > If more connector instances are required for new sites, the sponsor should reach out to their Oracle point of contact.

4. The site user links subjects to their Medical Record Number (MRN). For more information, see Link subjects for EHR data import.

Site users can now import subject EHR data. For more information, see Import EHR data.

Permissions and global roles required to use this feature

The following permissions and global role provide the access needed to use and manage this feature. For more information, see Sponsor and site permissions and Roles for global users.

Permission	Type
Link and Unlink Subject with EHR Patient	Site permission
Manually Update EHR Imported Data	Site permission
Create and Manage sites	Sponsor permission
View EHR Connectors	Global Role

For details about how to enable sites and other useful information, browse the sections below:

- Test the EHR data import
  When OCC is enabled for your study, Oracle provides you with a test connector and subject data that you can import, providing you with the ability to see how the EHR data import feature functions.
- Enable and manage your EHR site connections
  After your sites have consented, you can map them to one of the Oracle-created clinical connectors.
- Actions that impact an EHR-connected site
  Learn about the implications of transferring or retiring an EHR-connected site, and decommissioning an EHR-enabled study.
- EHR standard report and Oracle Clinical One Analytics details
  See where EHR-related details are captured in standard reports and Oracle Clinical One Analytics datasets.

Test the EHR data import

When OCC is enabled for your study, Oracle provides you with a test connector and subject data that you can import, providing you with the ability to see how the EHR data import feature functions.

Prerequisites

You must complete the following tasks before you can import the test data.

- Confirm the label **Oracle Clinical Connector Enabled** appears on the **General** tab under Study Settings. This appears when OCC is enabled for the study. For more information, see Open the study's settings.
- Confirm the required permissions are assigned to connect a site and link the subject.

Permission	Description
Link and Unlink Subject with EHR Patient	Site permission required to link a subject for EHR data import.
Manually Update EHR Imported Data	(Optional) Site permission needed to edit EHR data after import.
Create and Manage sites	Sponsor permission required to enable a site for EHR data import.
View EHR Connectors	(Optional) Global Role needed to view the **EHR Connectors** tab under Global Settings to view a list of Oracle Clinical Connectors.

- On the **Sites & Labs** tab, under Study Settings, create a test site and link it to the **Test HDI Connector** option under the **EHR Connection** drop-down. For more information, see Enable and manage your EHR site connections.
- Create a test study version that includes questions that match some or all of the EHR data items in the tables below to ensure the data imports successfully.
- Create the test subject (**Alex Carter**) in the test site and link them to their Medical Record Number (MRN); for Alex use **29560**. For more information, see Link subjects for Electronic Health Record (EHR) data import.
- You can now import the test subject data. For more information, see Import Electronic Health Record (EHR) data.

Import and validate the test data

Each section below correlates to a form you designed in your test study. After you link the subject, the **Import EHR Data** button becomes available on the subjects page. Upon clicking, the system presents the following data for import into Oracle Clinical One Platform.

Table 4-3 Test data—Demographics

Question	Value
First Name	Alex
Last Name	Carter
Medical Record Number (MRN) to be used for patient linking.	29560
BIRTH_DATE	Oct-1-1995
BIRTH_SEX	Male
ETHNICITY	Hispanic or Latino
RACE	Asian

Table 4-4 Test data—Vitals

Recorded Date & Time	1/20/2025 09:05 CST (20-Jan-2025 3:05 PM UTC)	1/20/2025 09:00 CST (20-Jan-2025 3:00 PM UTC)	1/6/2025 15:05 CST (06-Jan-2025 9:05 PM UTC)	1/6/2025 13:00 CST (06-Jan-2025 7:00 PM UTC)	1/6/2025 11:00 CST (06-Jan-2025 5:00 PM UTC)	1/6/2025 09:10 CST (06-Jan-2025 3:10 PM UTC)	1/6/2025 09:00 CST (06-Jan-2025 3:00 PM UTC)	Units
Body Height	*n/a*	**164.5**	*n/a*	*n/a*	*n/a*	*n/a*	**165**	cm
Body Weight	*n/a*	**58**	*n/a*	*n/a*	*n/a*	*n/a*	**65**	kg
BMI	*n/a*	**21.43**	*n/a*	*n/a*	*n/a*	*n/a*	**23.88**	kg/m2
Body Surface Area	*n/a*	**1.63**	*n/a*	*n/a*	*n/a*	*n/a*	**1.73**	m2
Head Circumference	**54**	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*	cm
Body Temperature	*n/a*	*n/a*	*n/a*	**37.1**	**36.7**	**36.9**	**36.6**	C
Blood Pressure-Systolic	*n/a*	*n/a*	**125**	**118**	*n/a*	**120**	**140**	mmHg

Table 4-4 (Cont.) Test data—Vitals

Recorded Date & Time	1/20/2025 09:05 CST (20-Jan-2025 3:05 PM UTC)	1/20/2025 09:00 CST (20-Jan-2025 3:00 PM UTC)	1/6/2025 15:05 CST (06-Jan-2025 9:05 PM UTC)	1/6/2025 13:00 CST (06-Jan-2025 7:00 PM UTC)	1/6/2025 11:00 CST (06-Jan-2025 5:00 PM UTC)	1/6/2025 09:10 CST (06-Jan-2025 3:10 PM UTC)	1/6/2025 09:00 CST (06-Jan-2025 3:00 PM UTC)	Units
Blood Pressure-Diastolic	*n/a*	*n/a*	**82**	**78**	*n/a*	**80**	**90**	mmHg
Oxygen Saturation	*n/a*	*n/a*	*n/a*	*n/a*	**98**	**95**	*n/a*	**%**

Table 4-5 Test data—Medications

Collection Date & Time	9/24/2024 09:28 CDT (24-Sep-2024 2:28 PM UTC)	9/24/2024 13:27 CDT (24-Sep-2024 6:27 PM UTC)	1/5/2025 09:31 CST (05-Jan-2025 3:31 PM UTC)	1/8/2025 09:33 CST (08-Jan-2025 3:33 PM UTC)	1/6/2025 09:26 CDT (06-Jan-2025 3:26 PM UTC)
Medication Name	metFORMIN (MetFORMIN (Eqv-Fortamet) 1000mg oral tablet, extended release)	metFORMIN (MetFORMIN (Eqv-Fortamet) 1000mg oral tablet, extended release)	Lisinopril (lisinopril 10mg oral tablet)	Simvastatin (Simvastatin 20mg oral tablet)	amoxicillin (amoxicillin 500mg oral capsule)
Dose	1	1	1	1	1
DoseUnits	{tbl}	{tbl}	{tbl}	{tbl}	{capsule}
Frequency	BID	BID	once a day (at bedtime)	once a day (at bedtime)	TID
RouteOfAdministration	Oral	Oral	Oral	Oral	Oral
MedicationStartDate	24-Sep-24	24-Sep-24	05-Jan-25	08-Jan-25	06-Jan-25
MedicationEndDate	*n/a*	15-Oct-24	12-Jan-25	15-Jan-25	16-Jan-25
MedicationStatus	Ordered	Ordered	Ordered	Ordered	Completed

Table 4-6 Test data—Lab Results

Collected Date & Time	1/25/2025 12:05 CST (Jan-25-2025 6:05 PM UTC)	12/12/2024 09:20 CST (12-Dec-2024 3:20 PM UTC)	11/22/2024 10:10 CST (22-Nov-2024 4:10 PM UTC)	9/12/2024 20:50 CDT (13-Sep-2024 1:50 AM UTC)	Units	Reference Range
(Procedures) Glucose Random	*n/a*	*n/a*	*n/a*	**120**	mg/dL	[80-120]
Albumin Lvl	*n/a*	**4.4**	*n/a*	*n/a*	g/dL	[3.5-5.2]

Table 4-6 (Cont.) Test data—Lab Results

Collected Date & Time	**1/25/2025 12:05 CST (Jan-25-2025 6:05 PM UTC)**	**12/12/2024 09:20 CST (12-Dec-2024 3:20 PM UTC)**	**11/22/2024 10:10 CST (22-Nov-2024 4:10 PM UTC)**	**9/12/2024 20:50 CDT (13-Sep-2024 1:50 AM UTC)**	**Units**	**Reference Range**
HDL	**65**	*n/a*	*n/a*	*n/a*	mg/dL	[27-67]
T4 Free	*n/a*	*n/a*	**0.9**	*n/a*	ng/dL	[0.8-1.7]
Collected Date & Time	**9/12/2024 12:20 CDT** (12-Sep-2024 5:20 PM UTC)	**9/12/2024 07:35 CDT** (12-Sep-2024 12:35 PM UTC)	**9/3/2024 09:35 CDT** (03-Sep-2024 2:35 PM UTC)	**6/10/2024 10:08 CDT** (10-Jun-2024 3:08 PM UTC)	**Units**	**Reference Range**
(Procedures) Glucose Random	**135**	**95**	*n/a*	*n/a*	mg/dL	[80-120]
Albumin Lvl	*n/a*	*n/a*	**3.8**	*n/a*	g/dL	[3.5-5.2]
HDL	*n/a*	*n/a*	*n/a*	*n/a*	mg/dL	[27-67]
T4 Free	*n/a*	*n/a*	*n/a*	**1.2**	ng/dL	[0.8-1.7]
Collected Date & Time	**6/6/2024 09:10 CDT** (06-Jun-2024 2:10 PM UTC)	**3/10/2024 11:05 CDT** (10-Mar-2024 4:05 PM UTC)	**1/15/2024 10:13 CST** (15-Jan-2024 4:13 PM UTC)	**7/15/2023 10:05 CDT** (15-Jul-2023 3:05 PM UTC)	**Units**	**Reference Range**
(Procedures) Glucose Random	*n/a*	*n/a*	*n/a*	*n/a*	mg/dL	[80-120]
Albumin Lvl	**4.0**	*n/a*	*n/a*	*n/a*	g/dL	[3.5-5.2]
HDL	*n/a*	**6.2**	*n/a*	**58**	mg/dL	[27-67]
T4 Free	*n/a*	*n/a*	**2.0**	*n/a*	ng/dL	[0.8-1.7]

Table 4-7 Test data—Medical History

Diagnosis, Start Date, Medical History Status, & Confirmation Status	**Diagnosis, Start Date, Medical History Status, & Confirmation Status**	**Diagnosis, Start Date, Medical History Status, & Confirmation Status**	**Diagnosis, Start Date, Medical History Status, & Confirmation Status**	**Diagnosis, Start Date, Medical History Status, & Confirmation Status**	**Diagnosis, Start Date, Medical History Status, & Confirmation Status**
Asthma	Asthma Attack	Hypertension	High Cholesterol	Chronic Pain	Anemia
Sep-2010	Sep-2010	Feb-2012	Oct-2017	Mar-2024	Aug-2024
Active	Inactive	Active	Active	Active	Active
Confirmed	Provisional	Confirmed	Confirmed	Confirmed	Confirmed

Table 4-8 Test data—Procedures

Procedure Name & Start Date	Procedure Name & Start Date	Procedure Name & Start Date	Procedure Name & Start Date	Procedure Name & Start Date	Procedure Name & Start Date
Appendectomy	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	Colonoscopy through stoma; with biopsy, single or multiple	Colonoscopy through stoma; with biopsy, single or multiple	Exploration of spinal fusion
15-Mar-20	17-Mar-20	19-Mar-20	10-May-22	1-Jun-22	12-Oct-24

Enable and manage your EHR site connections

After your sites have consented, you can map them to one of the Oracle-created clinical connectors.

Users assigned to a study role that includes the *Create and Manage Sites* permission can enable, disable, and update the site and connector association on the **Sites & Labs** tab under **Study Settings**.

1. From the home page, Open the study's settings.
2. Go to the **Sites & Labs** tab.
3. Select the mode (Production, Testing, or Training) to establish the EHR site connection.
4. Select the appropriate Oracle Clinical Connector (OCC) option from the **EHR Connection** drop-down for each site. You can link multiple sites to a single connector.

   A complete list of connectors can be viewed under the Health System column on the **EHR Connectors** tab under Global settings. To do this, you must be assigned to the *View EHR Connectors* global role.
5. Select **Apply Changes**.
6. To disable a connector, deselect it from the dropdown, then select **Apply Changes**.

   At any time, you can select the connector again to re-enable the connection.

What if I need to change a connector?

If needed, you can change the connector associated with a site to a different one by selecting a new option from the **EHR Connection** dropdown.

A dialog window informs you if the current connector has active EHR patient links. Select **Confirm** to close the window and complete the change.

> **Note:**
>
> Site users are required to relink subjects before they can import EHR data. The change in the connector does not remove previously imported EHR data for subjects associated with that site.

Actions that impact an EHR-connected site

Learn about the implications of transferring or retiring an EHR-connected site, and decommissioning an EHR-enabled study.

Action	Impact
Transfer active contacts associated with EHR-connected sites	When you transfer a contact, the existing EHR connection is removed for any associated site. This is true if you retire or transfer the sites. For more information, see Transfer active contacts. A dialog window notifies you if the site has existing Subject-Patient links associated with the current connector. You can still transfer the contact if you don't remove the links, but site users are required to relink subjects manually before importing additional EHR data.
Retire an EHR-connected site	When you retire a site, the existing EHR connection information is preserved. If the site is reactivated, the connection is also reactivated. For more information, see Retire a site at a study level.
Decommission an EHR-enabled study	All subject links are removed during the study decommission process. For more information, see Decommission a Production study.
Recommission a previously EHR-enabled study	Recommissioning a study requires you to follow the same steps you used to initially enable it for EHR data import. For more information about recommissioning a study, see Recommission a study.

EHR standard report and Oracle Clinical One Analytics details

See where EHR-related details are captured in standard reports and Oracle Clinical One Analytics datasets.

Impact to reports, extracts, and datasets

Refer to the table below to see where you can find EHR-related details in standard reports:

Report	Description
Annotated Case Report Forms	The **Advanced** column includes **EHR Mapping** and displays the data dictionary mapping values for the parent and child (if applicable). For example, EHRMapping:Birth Sex or EHR Mapping:Labs-Lab Test Name.
Sites and Depots	The **Attribute** column, in the Site Additional Information section, includes **EHREnabled** and displays the EHR Connector (Health System) name under the **Data** column.
Study Design	The **Properties** column, in the Forms section, includes **EHR Mapping** and displays the data dictionary mapping values for the parent and child (if applicable). For example, EHR Mapping:Birth Sex or EHR Mapping:Labs-Lab Test Name.

Report	Description
Subject Data	• **User Name** displays the logged-in user who imported the data. • **Date & Time** indicates when the data was saved. • **Type of Change** indicates if the data was created (initial import) or modified (subsequent imports). • **Value** provides the imported EHR data value. • **Reason for Change Comment** includes the following: – **Data Originator**: Indicates the connector name plus the HDI Record ID. – **Date of Collection**: Displayed as YYYY-MM-DD (if collected). – **OCC Mapped Codes**: Provides the codes from the source EHR system, which are associated with the EHR mapping value selected during form design and the associated imported data value. – **Source Date and Converted Date**: Included if the source date was converted to match the date format defined for the question in the study. For example, the source date YYYY-MM-DD is converted to DD-MMM-YYYY. – **Source Units and Converted Units**: Included if the source unit was converted to match the unit defined for the question in the study. For example, the source unit inch is converted to cm. – **Source Value and Converted Value**: Included if the source precision was converted to match the precision defined for the question in the study. For example, the source value 4.00 is converted to 4.0.
Subject Events	The **Event Type** column includes **Subject-patient Link Created** and **Subject-patient Link Removed**.

Refer to the table below to see where you can find EHR-related details in Oracle Clinical One Analytics datasets:

> **Note:**
>
> For more information, see Dataset descriptions.

Dataset	Description
Blinded Subject Event	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.
Queries	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR. • The **Audit Folder** section includes **EHR_IMPORTED** indicating if a question was populated via an EHR data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.

Dataset	Description
Study Design	• The **Study Folder** section includes **OCC_ENABLED** and displays Yes or No, indicating if a study is enabled for EHR data import. No is displayed if your study is not currently enabled; this includes those studies that previously were. • The **Item Folder** section includes **EHR_MAPPING** and displays the OCC data dictionary mapping value for a question mapped for EHR data import.
Subject	• The **Subject (Required) folder** section includes **EHR_LINK_STATUS** and displays Yes or No, indicating if a subject is currently linked for EHR data import.
Subject Forms	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.
Subject Form Items	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR. • The **Audit Folder** section includes **EHR_IMPORTED**, indicating if a question was populated via an EHR data import. If EHR data import is disabled after the data is imported, EHR_IMPORTED continues to show Yes.
Unblinded Subject Event	• The **Site Folder** section includes **EHR_ENABLED** and displays Yes or No, indicating if a site is currently enabled for EHR data import. No is displayed if EHR has never been enabled for a site or if a site has been disabled for EHR.

5

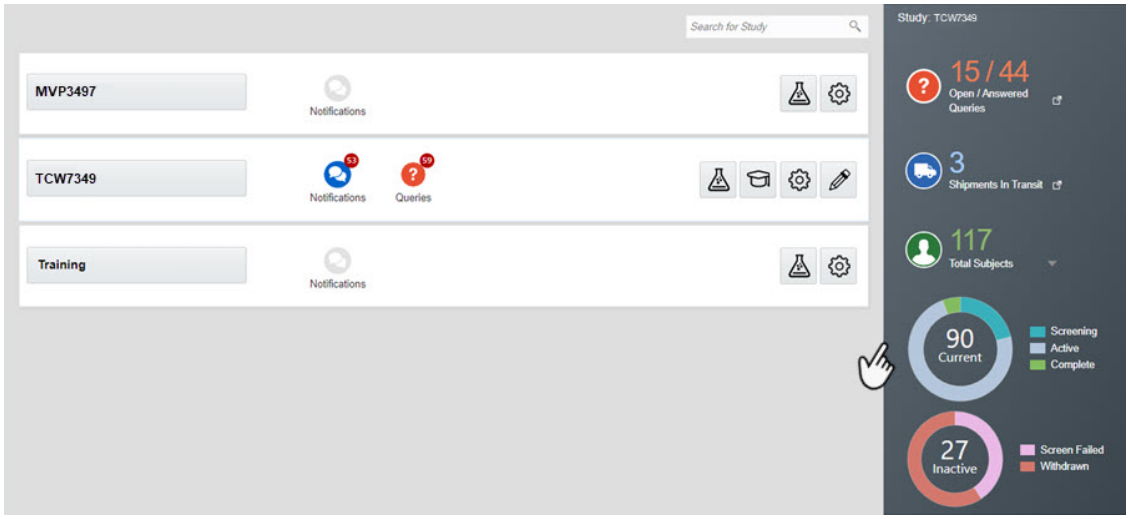
Work during the study conduct period

- Use the study dashboard to get easy access to data
  As a user working with queries, shipments, or subject data, you can see these types of data at a glance in the study dashboard, displayed on the home page of the application.
- Manage shipments
- Manage kits at the site and study level
- View and update randomization numbers
- Monitor subjects and sites
- Create and manage queries
- Perform kit reconciliation
- Run and download a report, data extract, or archive
  As a sponsor user, you can typically run a multitude of standard reports and Oracle CRF Submit archives, as well as extract subject data.

Use the study dashboard to get easy access to data

As a user working with queries, shipments, or subject data, you can see these types of data at a glance in the study dashboard, displayed on the home page of the application.

Figure 5-1 How the study dashboard is displayed on the home page



To view data about each study you're working in, all you need to do is click once on the study row, next to the study ID, and data about your subjects, shipments, or queries instantly becomes available to you.

The data is displayed according to the roles and permissions that you are assigned in the system. For example, if you are a clinical supply manager who must work with shipments and

also create queries in forms, you see data on both shipments and queries displayed on the study dashboard.

Additionally, you only see data for sites that you are assigned to. For example, you only see the total number of subjects enrolled at a site that you are assigned to.

Open/Answered Queries

This section shows the total number of queries with an **Open** and **Answered** status for all the sites that you are assigned to. To see more details about these queries:

1. On the study dashboard, click **Open/Answered Queries**.
   The Subjects tab opens in Production mode.
2. From the Sites drop-down, select a site.
   A list of all opened and answered queries for that site are displayed on the right sidebar.

Total Subjects

This section shows the total number of subjects for all the sites that you are assigned to and acts as a shortcut to the main **Subjects** page. The **Total Subjects** section also includes charts that show how subjects with different statuses are distributed in the study. One chart displays the number of current subjects in a **Screened**, **Active**, **Enrolled**, and **Complete** state, while the second graphic shows the number of inactive subjects in a **Screen Failed** and **Withdrawn** state.

To browse through the list of subjects:

1. Next to the **Total Subjects** icon, click the drop-down arrow.
2. To find out more about a specific subject in the list either select the subject's ID from the drop-down or type the subject's ID in the search field above the subjects list.
   The Subjects tab opens in Production mode, the subject you searched for is already selected, and the Subject History pane is displayed on the right.

Shipments In Transit

This section shows the number of shipments with an **In Transit** status for all the sites that you're assigned to. When you click the **Shipments In Transit** section, the **Shipments** page opens and a list of all shipments is displayed.

Related Topics

- View and monitor queries
  There are different ways to find and monitor queries. You can find queries for all subjects within a site or for a specific subject, and you can view them in the sidebar directly on the Subjects tab or within the visit containing the query. You can also view the history of a single query. This procedure also applies to rollover studies.
- View the shipments sent to sites
  If you're troubleshooting an issue with shipments or inventory, you might need to see the shipments that have been sent to sites. This procedure also applies to rollover studies.
- What actions impact subjects?
  Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?

- What states can a subject have?
  Depending on the protocol, site users can update a subject's state through multiple actions for a number of times during the study. But have you ever wondered what each state really means for the way you manage subjects' data at a site?

Manage shipments

- View the shipments sent to sites
  If you're troubleshooting an issue with shipments or inventory, you might need to see the shipments that have been sent to sites. This procedure also applies to rollover studies.
- Add and remove kits in a shipment
  You typically add and remove kits in a shipment when something happens to a kit that was selected for the shipment. For example, when a kit is damaged before it is packed, you can replace it with another kit of the same type. This procedure also applies to rollover studies.
- View a drug order form
  A drug order form (also known as a DOF, kit order form, or shipment order form) is a document that presents all details of a shipment requested during a clinical study.
- Create a manual shipment
  Create a manual shipment if a source depot is in need of supplies or if a site anticipates an enrollment surge, such as for a clinic day, and requires additional supply. You shouldn't need to create a manual shipment for any other situations. This procedure also applies to rollover studies.
- Specify a ship date and tracking number for a shipment
  You must specify a ship date and tracking number for every shipment, with one exception: If the study uses an integration with Almac or Fisher Clinical Services for shipments, you should not perform these steps. This procedure also applies to rollover studies.
- Mark a shipment as lost
  When a shipment gets lost in transit, you can mark the shipment as lost so that all kits in the shipment are also marked as missing. This procedure also applies to rollover studies.
- Cancel a shipment
  You can cancel a shipment with a status of Pending, Invalid, Confirmed, In Transit, or Pending Destruction. If the study uses an integration with Almac for shipments, you must cancel every shipment with a status of Invalid; otherwise, a new shipment won't be created the next time inventory runs. This procedure also applies to rollover studies.
- Check whether a shipment was marked invalid
  If the study uses an integration with Almac for shipments, you need to check whether a shipment was marked invalid so you can confirm whether the depot received the shipment request. This procedure also applies to rollover studies.
- Receive a shipment with disabled temperature excursions
  Mark kits in a shipment as Missing or Damaged when you choose not to allow temperature excursions in your study.
- Quarantine a shipment with temperature excursions
  Mark shipments in your study as Quarantined when they've experienced temperature excursions.
- Quarantine shipments set to Quarantine with no temperature monitor
  Depending on your study settings, the system will quarantine shipments or ask you to update the status for individual kits.

- Move shipments through the receipt process with no temperature monitors
  If your study is configured to move shipments through the receipt process when there are no temperature monitors included, you will be prompted to mark any damaged or missing kits.
- Release kits or shipments from quarantine
  Mark kits and shipments as Damaged or Available by releasing them from quarantine.

View the shipments sent to sites

If you're troubleshooting an issue with shipments or inventory, you might need to see the shipments that have been sent to sites. This procedure also applies to rollover studies.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the pencil button ( ) on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button ( ) on the study.
   - To work with mock data in Training mode, click the Training Mode button ( ) on the study.
3. Along the top, click **Supplies**.
4. Below the study name, click the **Shipments** tab.
5. The shipments are grouped by the site they're shipped to, in alphabetical order.

> **Tip:**
>
> Use the **Filter by Status** drop-down to view shipments that are in transit or have been received.

Add and remove kits in a shipment

You typically add and remove kits in a shipment when something happens to a kit that was selected for the shipment. For example, when a kit is damaged before it is packed, you can replace it with another kit of the same type. This procedure also applies to rollover studies.

Before adding or removing kits in a shipment consider the notes below:

> **Caution:**
>
> If your study uses an integration with Almac or Fisher Clinical Services for shipments, do not perform the steps below, even if you need to adjust the shipment. Instead, cancel the shipment and either allow the resupply process to create a new shipment the next time inventory runs or create a manual shipment.

> **Note:**
>
> Consider the following:
>
> - You cannot add or remove kits from a shipment containing pool kits (also known as a pooled shipment).
> - If the study doesn't allow shipments with a single kit and you need to remove all but one kit, add replacement kits first, and then remove the other kits. Oracle Clinical One Platform prevents you from removing kits and leaving only a single kit.
> - All non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the User Interface (UI) as lot numbers followed by the quantity.

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment with a status of **Pending**.

   > **Tip:**
   >
   > If a shipment has a status of **In Transit** but hasn't shipped yet, you can remove the shipping date, and the status changes back to **Pending**.

5. To add kits:
   a. On the Shipment Details sidebar, click **Add Kits**.
   b. Under Available Kits, select the kits or lots you want to add to the shipment.
   c. Use the arrow (›) icon to move the selected kits to **Add to the Shipment**.
   d. If you are adding a lot, in the Quantity column, enter the quantity of non-serialized kits.

e. Click **Add**.

6. To remove kits:
   a. On the Shipment Details sidebar, select the kits or lot you want to remove from the shipment.
   b. If you are removing a lot, enter the quantity of non-serialized kits that you want to remove from the shipment.
   c. Click **Remove Kits**.
   d. Select **Yes** to confirm the kits or lots you want to remove from the shipment.
7. Upon adding or removing kits from a shipment, a Confirmation dialog appears asking you if you choose to update the form or not.
   - If you do not wish to update the form, click **Don't Update Form**.
   - If you want to update the form, click **Update Form**.

Related Topics

- Supply settings fields
  This reference provides you with the fields and their descriptions when specifying supply settings for a study.
- Can I modify a Pending Destruction shipment?
  No. But a couple workarounds are available if you need to add kits and all kits are going to the same depot.
- Kit reconciliation FAQs

View a drug order form

A drug order form (also known as a DOF, kit order form, or shipment order form) is a document that presents all details of a shipment requested during a clinical study.

As a sponsor user, you can update the drug order form to reflect the shipment's contents. A depot or site user can then download the drug order form, print it out, add any special instructions for other users in a study, and sign it.

The drug order form is considered a report in Oracle Clinical One Platform studies. Like any standard report, it is auto-purged at 120 days old. For more information, see About standard reports.

> **WARNING:**
>
> You should not **Resend** an auto-purged drug order form, as it will be resent to the depot. This may trigger the depot to send shipments to sites that are not needed. Applicable shipment details for an auto-purged form are still available on the **Shipment Details** right-side panel in the user interface, even after the system deletes a form.

Required permissions

As a clinical supply manager or an unblinded depot user, you can update the a drug order form if you're assigned with the *Update the Shipment Order Form* permission. If you wish to know more about shipment orders in your overall study, generate the Shipment Order Summary report.

Field descriptions

The table below contains descriptions of all fields displayed in a drug order form. The **Special Instructions**, **Signature**, and **Date** fields can only be filled in offline, after you download and print the drug order form.

Field	Description
Study	Indicates the study associated with the drug order form that you downloaded.
Mode	Indicates the study mode in which you downloaded the drug order form. Displayed values can be TEST, ACTIVE, or TRAINING.
Shipment Number	Indicates the shipment number associated with your drug order form.
Date Requested	Indicates the date when the shipment associated with the drug order form has been requested.
(Site/ Center) Number	Indicates the site number associated with the requested shipment.
Investigator (Full Name)	Indicates the name of the Principal Investigator, as specified by a site manager when they created the site.
Ship Care Of (Ship to Name) or Ship to Address)	Indicates the name of the facility where the shipment is supposed to be delivered, as well as the address of the facility. This facility can be a site or another depot within the study.
Telephone (Ship to Phone)	Indicates the facility's associated phone number, whether it's a depot or site facility.
Fax (Ship to Fax)	Indicates the facility's associated fax number, whether it's a depot or a site facility.
Date Expected at Site/ Depot	Indicates the projected date of a shipment's arrival at a site. For a depot-to-depot shipment, this field indicates the projected date of a shipment's arrival at a depot.
Number of Study Medication (Kits/ Bottles/ Boxes)	Indicates the exact number of investigational product kits, specifically for kits, boxes, or bottles.
Depot Email	Indicates the email address of the depot that prepares and delivers this shipment to the site or to another depot. The email address is displayed as it was specified by a clinical supply manager when they created the depot.
Phone	Indicates the phone number of the depot that prepares and delivers this shipment to the site or to another depot. The phone number is displayed as it was specified by a clinical supply manager when they created the depot.
Fax	Indicates the fax number of the depot that prepares and delivers this shipment to the site or to another depot. The fax number is displayed as it was specified by a clinical supply manager when they created the depot.
Special instructions	Indicates any special instructions specified by an unblinded depot user for other depot users within the study or site users. May contain specific details on how to handle packages or the contents of a shipment.

Field	Description
Kit / Lot Numbers	Indicates kit (serialized inventory) or lot (non-serialized inventory) numbers included in a shipment.
Signature	This is the field that a site or depot user is supposed to sign upon receiving and registering a shipment.
Date	This is the field that a site or depot user is supposed to fill-in with the date of the shipment reception.

Create a manual shipment

Create a manual shipment if a source depot is in need of supplies or if a site anticipates an enrollment surge, such as for a clinic day, and requires additional supply. You shouldn't need to create a manual shipment for any other situations. This procedure also applies to rollover studies.

All non-serialized inventory is distributed in bulk, and therefore cannot be individually tracked. Instead, non-serialized kits are added to lots, and display in Oracle Clinical One Platform as lot numbers, followed by the total quantity. You can select a given lot number for kits in your shipment to specifically ship non-serialized kits.

> **Note:**
>
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page appears blank for all non-serialized inventory.

If automatic shipments do not meet a site's needs, either select a more appropriate resupply strategy or create a new resupply strategy and assign it to the site. For step-by-step instructions see:

- Create a predictive resupply strategy
- Create a min/max resupply strategy
- Select a resupply strategy for a site

> **Note:**
>
> Depending on how kits are designed in your study, a kit type may include information about its block size. If you add a number of kits that is lower than its block size, the system adds additional kits to complete the block. For example, if you include 2 vials in a shipment, the system includes 2 additional vials to complete the block of 4 units. Oracle Clinical One Platform also adds kits to the shipment if the study doesn't allow single kit ordering. See Specify supply settings.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the Edit button () on the study, and make sure a study version appears below Approved.
2. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
3. Along the top of the page, click **Supplies**.
4. Below the study name, click the **Shipments** tab.
5. Click **Create Shipment**.
6. On the Create Shipment dialog, fill in the fields. To view tips for completing a field, click into the field or choose an option.

> **Note:**
>
> For a site-to-depot shipment, you can include a maximum of 99 kits. For a depot-to-depot shipment, you can include a maximum of 9999 kits.

Field	Description
Destination	Select whether the destination of this shipment is a site or a depot. • If you select **Site**, then you must select the destination site from the second drop-down. • If you select **Depot**, then you must specify the destination depot (in the **Destination** field) and the source depot (in the **Ship From** field), too.
Kit Type and Description	For a specific kit type, turn on the toggle () to specify that the shipment must include that kit type.
Quantity	Enter the number of kits of this type to include in the shipment. You can only include a quantity of kits that ranges from 1 to 99. ***Tip**: Manual shipments for a single site typically contain less than 100 kits and can be better suited for one-time shipments or for sending small quantities of supplies to sites. If you need to send a larger quantity of kits to one or multiple sites, consider configuring a specific resupply strategy for your study's needs. See* Create a min/max resupply strategy *and* Create a predictive resupply strategy*.*
Lot	From the **Select Lot** drop-down, select a lot to assign the required quantity of kits from that given lot to the shipment. ***Notes**:* • *You can select a lot for serialized, non-serialized, and pooled kits that you want to include in a manual shipment.* • *You cannot include pooled kits in a depot-to-depot shipment.* • *The **Select Lot** drop-down only displays lots specific to every available kit type, along with the lot's expiration date.*

7. Click **Create Shipment**.
8. Click **Close**.

Related Topics

- Inventory management and dispensation FAQs (for clinical supply managers)
- Kit reconciliation FAQs
- Site, depot, labs, and source data verification FAQs

Specify a ship date and tracking number for a shipment

You must specify a ship date and tracking number for every shipment, with one exception: If the study uses an integration with Almac or Fisher Clinical Services for shipments, you should not perform these steps. This procedure also applies to rollover studies.

> **Note:**
>
> A pooled shipment's ship date can only be updated through an integration. As a clinical supply manager or depot user, you can still manually specify a tracking number for a pooled shipment or cancel it.

- If a shipment has a status of In Transit but hasn't shipped yet, you can remove the shipping date, and the status changes back to Pending.
- If the study uses an integration with Almac or Fisher Clinical Services, the integration automatically adds a ship date and tracking number and changes the status of the shipment.
- If the study doesn't use an integration, someone from either the sponsor or depot must specify a ship date so that the status of a shipment changes from Pending to In Transit and so that the site can mark the shipment as received. Site users can't see Pending shipments, but they can see In Transit shipments.

Want to see how to perform this task? Watch the video below.

Video

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.

   Make sure a study version appears below Approved.
2. Along the top, click **Supplies**.
3. On the **Shipments** tab, from the **Filter by Status** drop-down, select **Pending** or **Confirmed**.

   > **Tip:**
   >
   > If a shipment has a status of In Transit in Oracle Clinical One Platform but hasn't shipped yet, you can remove the Ship Date, and the status changes back to Pending.
4. Add a ship date:
   a. Under the **Ship Date** column for the Pending shipment, click the **Click to Add** link.
   b. Select the correct date from the calendar drop-down.

      The status of the shipment changes from Pending to In Transit.
5. Specify tracking information:
   a. If you just added a ship date to the shipment, above the table and to the right, select **In Transit** from the status drop-down.

b. In the Tracking Number column, click the **Click to add** link of the shipment you added a ship date to.

> **Tip:**
>
> You can add tracking information to any shipment at any time. Adding this information is optional.

6. Fill in the fields, and click **Save**.
   - **Tracking Number**: Enter the tracking number of the shipment.
   - **Tracking Link**: Enter the URL for tracking the shipment.

Mark a shipment as lost

When a shipment gets lost in transit, you can mark the shipment as lost so that all kits in the shipment are also marked as missing. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the pencil button () on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button () on the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
3. Along the top, click **Supplies**.
4. Below the study name, click the **Shipments** tab.
5. Select one or more shipments with statuses of In Transit or Confirmed.
6. From the **Edit Shipment** drop-down, select **Mark Shipment Lost**, and click **Confirm**.

   All kits in the shipment are marked as Missing.

Cancel a shipment

You can cancel a shipment with a status of Pending, Invalid, Confirmed, In Transit, or Pending Destruction. If the study uses an integration with Almac for shipments, you must cancel every shipment with a status of Invalid; otherwise, a new shipment won't be created the next time inventory runs. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the pencil button () on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button () on the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
3. Along the top, click **Supplies**.
4. Below the study name, click the **Shipments** tab.
5. Select a shipment with a status of Pending, Invalid, Confirmed, In Transit, or Pending Destruction.

> **Tip:**
>
> You can cancel multiple shipments if they have the same status and if you select the same new status for all the kits.

6. From the **Edit Shipment** drop-down, select **Cancel Shipment**.
7. Select the new status of the kits in the shipment, and click **Confirm**.

   For example, if you canceled your shipment because it had a temperature excursion, you should choose Pre-quarantined. However, if you canceled the shipment because the site did not need the inventory, you should choose Available.

> **Caution:**
>
> You cannot reverse a shipment cancellation. Please ensure that you are canceling the correct shipment before you confirm.

Tips:

- You typically cancel a shipment to control costs and avoid the waste of the investigational product.
- You can cancel both automatically generated shipments and manual shipments.
- As a Clinical Supply Manager, if you learn that a shipment has been canceled in error, do not adjust on-site clinical supplies manually, even if the investigational product has been delivered to the site. Create a new shipment instead, ensuring that its content matches that of the canceled shipment. You can then send the investigational product delivered as part of the canceled shipment back to the depot.

Check whether a shipment was marked invalid

If the study uses an integration with Almac for shipments, you need to check whether a shipment was marked invalid so you can confirm whether the depot received the shipment request. This procedure also applies to rollover studies.

If the depot received the request, the status of the shipment changes to Confirmed. If an issue occurred with the shipment request, the status of the shipment changes to Invalid. You must cancel an invalid shipment so that:

- You can change the status of the kits in the shipment back to Available or another status.
- A new shipment can be created the next time inventory runs.

1. On the Home page, click the pencil button () on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button () on the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
3. Along the top, click **Supplies**.
4. Below the study name, make sure the **Shipments** tab is selected.
5. Locate the shipment in the table. For example:
   - If you know the shipment ID, enter it in the **Search by Shipment ID** field, above the table and to the right, and press **Enter**.
   - If you don't know the shipment ID, find the shipment using the Site and Created Date columns.
6. Check the status of the shipment in the Status column:
   - If the status is **Confirmed**, you don't have to do anything. The depot received the shipment request successfully.
   - If the status is **Invalid**, an issue occurred, such as a system outage, and the depot was unable to process the shipment request.

Next step for an Invalid shipment: Cancel the shipment so the resupply process can create a new shipment the next time inventory runs.

Receive a shipment with disabled temperature excursions

Mark kits in a shipment as Missing or Damaged when you choose not to allow temperature excursions in your study.

If you disallow temperature excursions for your study when defining the supply settings, the system will prompt you to mark any kits that are damaged or missing in the shipment at receipt. For more information on configuring supply settings for a study, see Specify supply settings.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

To mark impacted kits when temperature excursions are deactivated for a study:

1. On the Home page, click the Testing Mode button () on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment.

   The system displays the shipment details.
5. Click **Add Shipment to Inventory**.
6. If any specific kits or kits assigned to a lot are damaged, select the affected kits and click **Next**:
   - **Kits**: Select the damaged kits.
   - **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are damaged.
7. If any specific kits or kits assigned to a lot are missing, select the affected kits and click **Next**:
   - **Kits**: Select the missing kits.
   - **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are missing.
8. Review the information in the Add Shipment to Inventory dialog and click **Finish**.

   The status of the selected kits are updated to Damaged or Missing.

Related Topics

-

Quarantine a shipment with temperature excursions

Mark shipments in your study as Quarantined when they've experienced temperature excursions.

If your study allows for temperature excursions, you can update the status for all the kits and lots in the shipment to *Quarantined* if they have reached a temperature reading outside of the defined range. To learn how to configure temperature excursions in your study, see Specify supply settings.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

To quarantine a shipment with temperature excursions:

1. On the Home page, click the Testing Mode button ( ) on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment.

   The system displays the shipment details.
5. Click **Add Shipment to Inventory**.
6. In the Add Shipment to Inventory dialog, select **Yes, a temperature monitor inside of the shipment went off.**

   > **Note:**
   >
   > Depending on your study settings, the system may skip forward to the Review dialog. In this case, continue to the final step. Otherwise, go to the next step.
7. Choose specific kits or kits assigned to a lot you would like to quarantine, then click **Next**:
   - **Kits**: Select kits for quarantine.
   - **Lot**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits for quarantine.
8. If any specific kits or kits assigned to a lot are damaged, select the affected kits and click **Next**:
   - **Kits**: Select the damaged kits.
   - **Lot**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are damaged.
9. If any specific kits or kits assigned to a lot are missing, select the affected kits and click **Next**:
   - **Kits**: Select the missing kits.
   - **Lot**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are missing.
10. Review the information in the Add Shipment to Inventory dialog and click **Finish**.

    The status of all kits in the shipment, or the selected kits (if marking individual kits is allowed in your study), are updated to Quarantined.

Related Topics

•

Quarantine shipments set to Quarantine with no temperature monitor

Depending on your study settings, the system will quarantine shipments or ask you to update the status for individual kits.

By choosing to quarantine shipments when no temperature monitors are included, the system will automatically update the status of every kit and lot in the shipment to *Quarantined*. To learn more about configuring supply settings for your study, see Specify supply settings.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

To quarantine shipments when no temperature monitors are present:

1. On the Home page, click the Testing Mode button ( ) on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment.

   The system displays the shipment details.
5. Click **Add Shipment to Inventory**.
6. In the Add Shipment to Inventory dialog, select **I didn't find any temperature monitors in the shipment.**

   > **Note:**
   >
   > Depending on your study settings, the system may skip forward to the Review dialog. In this case, continue to the final step. Otherwise, go to the next step.
7. Choose specific kits or kits assigned to a lot that you should quarantine, then click **Next**:
   - **Kits**: Select kits for quarantine.
   - **Lots**: Expand a lot's details, and in the **How many?** field, enter the quantity of non-serialized kits for quarantine.
8. If any specific kits or kits assigned to a lot are damaged, select the affected kits and click **Next**:
   - **Kits**: Select the damaged kits.

- **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are damaged.

9. If any specific kits or kits assigned to a lot are missing, select the affected kits and click **Next**:
   - **Kits**: Select the missing kits.
   - **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are missing.
10. Review the information in the Add Shipment to Inventory dialog and click **Finish**.

    The status of all kits in the shipment, or the selected kits (if marking individual kits is allowed in your study), are updated to *Quarantined*.

Related Topics

-

Move shipments through the receipt process with no temperature monitors

If your study is configured to move shipments through the receipt process when there are no temperature monitors included, you will be prompted to mark any damaged or missing kits.

By allowing shipments to continue the receipt process when no temperature monitors are present, the system asks you to mark any kits that are damaged or missing. For more information on configuring your study's supply settings, see Specify supply settings.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

To move a shipment through the receipt process when no temperature monitors are present:

1. On the Home page, click the Testing Mode button ( ) on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment.

   The system displays the shipment details.
5. Click **Add Shipment to Inventory**.
6. In the Add Shipment to Inventory dialog, select **I didn't find any temperature monitors in the shipment.**

   The system skips the option to select quarantined kits or lots and moves to the next step.
7. If any specific kits or kits assigned to a lot are damaged, select the affected kits and click **Next**:
   - **Kits**: Select the damaged kits.

- **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are damaged.

8. If any specific kits or kits assigned to a lot are missing, select the affected kits and click **Next**:
   - **Kits**: Select the missing kits.
   - **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits that are missing.
9. Review the information in the Add Shipment to Inventory dialog and click **Finish**.

   The status of the selected kits are updated to *Damaged* or *Missing*.

Related Topics

-

Release kits or shipments from quarantine

Mark kits and shipments as Damaged or Available by releasing them from quarantine.

Users assigned the *Release Shipments from Quarantine* permission have the ability to move kits and lots out of quarantine and update their statuses to *Damaged* or *Available*.

> **Note:**
>
> Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

To release individual kits and shipments from quarantine:

1. On the Home page, click the **Testing Mode** icon ( ) on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Shipments** tab.
4. Select a shipment and click **Edit Shipment**.
5. Choose **Release Quarantined Kits**.
6. Select **Yes, I tested one or more kits in the shipment**.
7. Choose the quarantined kits or kits assigned to a lot you'd like to release, and click **Next**.
   - **Kits**: Select the kits you would like to release from quarantine.
   - **Lots**: Expand a the lot's details, and in the **How many?** field, enter the quantity of non-serialized kits you would like to release from quarantine.

   The kits are sorted by Kit/Lot Number and Status in Review, with non-serialized kits represented as lot numbers.
8. Click **Finish**.

The kits or lots are marked as *Damaged* or *Available* in Shipment Details.

Manage kits at the site and study level

- Access the Study Inventory tab
  The Study Inventory tab shows all kits, grouped by kit type. On the right, you can see the total number of kits, the number of dispensed kits, and the number of damaged kits for each kit type.
- Access the Site Inventory tab
  As a Clinical Research Associate (CRA) or clinical supply manager, you may have to perform certain tasks on the Site Inventory tab.
- Access the Depot Inventory tab
  As a blinded depot user or a clinical supply manager, you may have to fulfill some inventory tasks while protecting the study blind. If managing blinded kits at assigned depots is part of your responsibility, then you may need to work on the **Depot Inventory** tab:
- Filter kits in a Study's Inventory tab
  Inventory filters are located at the top of the page. You can use these filters individually or in a combined way.
- Filter kits in a site's inventory
  Inventory filters are located at the top of the page. You can use filters individually or they can be combined.
- Search and filter kits on the Depot Inventory tab
  Inventory filters are located at the top of the page. You can use filters individually or combine them.
- Manage non-serialized inventory
  Understand how non-serialized inventory differs from serialized inventory, and how you can manage it in your study.
- Add non-serialized kits to a lot
  To distribute non-serialized inventory, sponsor users can assign non-serialized kits to lots.
- Monitor site and depot stock levels
  As long as resupply strategies meet sites' enrollment needs, you don't need to monitor product levels. However, you might want to monitor supply levels at the beginning of a study to make sure the resupply strategies meet the sites' needs. This procedure also applies to rollover studies.
- Transfer the product to another location
  You can transfer an investigational product to another site to minimize waste, such as when a site doesn't enroll as anticipated. This procedure also applies to rollover studies.
- Mark kits to test for temperature excursions
  Before quarantining your kits, determine if they have experienced a temperature excursion.
- Quarantine kits
  Mark individual kits as Quarantined if they've experienced a temperature excursion.
- Mark a kit as missing or damaged
  Kits at sites and depots can be marked as missing or damaged. This procedure also applies to rollover studies.
- Reserve kits for a quality check
  Two kit statuses are available when you need to reserve kits for a quality check: Temporarily Unavailable and Not In Use. These two statuses give your organization flexibility for managing kits that are unavailable for distribution. This procedure also applies to rollover studies.

- Update the status of a kit for a site user
  Site users should update the kit status themselves whenever possible. If you're a CRA, and a site user asks you what to do about the status of a kit that is no longer available, instruct them to perform this task. If you're a clinical supply manager who needs to update the status of a kit that should be available in the inventory, follow this procedure.
- Update a kit's barcode
  There may be cases during a study when a clinical supply manager should manually update a kit's barcode. Follow this procedure to know more about a clinical supply manager can do.
- Available inventory statuses for kits
  Kit statuses allow you to manage shipments and inventory in your study. Here's a list of every status a kit might have in Oracle Clinical One Platform and their descriptions.
- Allowed updates for inventory status
  Kits in certain statuses cannot be directly updated to a specific status. This is applicable for regular and non-serialized kits, and for updates done in both the study inventory and site inventory pages.
- What if a site user dispensed a kit in error?
  You next steps depend on what happened.

Access the Study Inventory tab

The Study Inventory tab shows all kits, grouped by kit type. On the right, you can see the total number of kits, the number of dispensed kits, and the number of damaged kits for each kit type.

1. On the Home page, click the pencil button () on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button () on the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
3. Along the top, click **Supplies**.
4. Below the study name, click the **Study Inventory** tab.

Related Topics

- Monitor site and depot stock levels
  As long as resupply strategies meet sites' enrollment needs, you don't need to monitor product levels. However, you might want to monitor supply levels at the beginning of a study to make sure the resupply strategies meet the sites' needs. This procedure also applies to rollover studies.
- Transfer the product to another location
  You can transfer an investigational product to another site to minimize waste, such as when a site doesn't enroll as anticipated. This procedure also applies to rollover studies.
- Mark kits to test for temperature excursions
  Before quarantining your kits, determine if they have experienced a temperature excursion.

- Quarantine kits
  Mark individual kits as Quarantined if they've experienced a temperature excursion.
- Mark a kit as missing or damaged
  Kits at sites and depots can be marked as missing or damaged. This procedure also applies to rollover studies.
- Reserve kits for a quality check
  Two kit statuses are available when you need to reserve kits for a quality check: Temporarily Unavailable and Not In Use. These two statuses give your organization flexibility for managing kits that are unavailable for distribution. This procedure also applies to rollover studies.
- Update a kit's barcode
  There may be cases during a study when a clinical supply manager should manually update a kit's barcode. Follow this procedure to know more about a clinical supply manager can do.

Access the Site Inventory tab

As a Clinical Research Associate (CRA) or clinical supply manager, you may have to perform certain tasks on the Site Inventory tab.

1. Determine where to work:
   - To create real data in Production mode, click the title of the study.
   - To create mock data in Training mode, click the Training Mode button () on the study.
2. Along the top, click **Supplies**.
3. Below the study name, click the **Site Inventory** tab.

Related Topics

- Update the status of a kit for a site user
  Site users should update the kit status themselves whenever possible. If you're a CRA, and a site user asks you what to do about the status of a kit that is no longer available, instruct them to perform this task. If you're a clinical supply manager who needs to update the status of a kit that should be available in the inventory, follow this procedure.

Access the Depot Inventory tab

As a blinded depot user or a clinical supply manager, you may have to fulfill some inventory tasks while protecting the study blind. If managing blinded kits at assigned depots is part of your responsibility, then you may need to work on the **Depot Inventory** tab:

To access or manage the Depot Inventory tab, you must be assigned the **Blinded Depot User** and a **Clinical Supply Manager - Unblinded** study role, or to have the *Blinded Depot User* permission assigned to your role.

1. On the Home page, determine where to work. For more information, see Access your study in a specific mode.
2. Along the top of the page, click **Supplies**.
3. Below the study name, click the **Depot Inventory** tab.

   The tab displays the following columns:

Field	Description
Kit Number/Lot Number	The kit number indicates a unique number assigned to the individual kits (serialized kit distribution). The lot number indicates a unique number assigned to a group of kits (non-serialized kit distribution).
Sequence Number	This column indicates the exact sequence number of each kit.
Block Number	This column indicates the exact block number to which a kit belongs.
Kit Description	This column indicates a kit type's description as entered in the system by a study designer. ***Note**: Blinded Depot Users will see this field as **Blinded** to protect the study.*
Status	This column indicates the states of the kit during the reconciliation process went through as selected by the user: • *Available* • *Damaged* • *Damaged by Subject* • *Destroyed* • *Dispensed* • *Expired* • *In Transit* • *Lost by the Subject* • *Misallocated* • *Missing* • *New* • *Not Dispensed to Subject* • *Not in Use* • *Pending Destruction* • *Pre-Quarantined* • *Quarantined* • *Received for Destruction* • *Returned to Site* • *Temporary Unavailable* For the full description of all statuses a kit undergoes, see Kit status descriptions.
Expiration Date	This column indicates the UTC time and date when the kits in the manufacturing lot expire.
Units per Kit	This column indicates the number of individual consumable units in a kit such as pill count or mg.

Related Topics

- Search and filter kits on the Depot Inventory tab
- Manage kits at the site and study level
- Kit status descriptions

Filter kits in a Study's Inventory tab

Inventory filters are located at the top of the page. You can use these filters individually or in a combined way.

> **Tip:**
>
> Consider the following tips:
>
> - The number of Total Kits at each site includes kits that are In Transit. To filter for Available kits, click the name of a kit type.
> - You can combine the Lots filter with a Location filter for a depot to see kits that can be shipped.

1. Access the Study Inventory tab.
2. Filter kits by kit type, location or lot.

Filter	Description
Kit Type	Select the type of kits you would like to view: • **All**: To view both serialized and non-serialized kits. • **Serialized**: To view serialized kits assigned to that site. • **Non-Serialized**: To view non-serialized kits assigned to that site.
Location	To filter kits by their location, select one of the following options: • **All**: displays all kits at every facility, both site and depot. • **Unassigned**: displays all kits that are currently not associated with any depot or site in your study. • **Sites**: displays all kits that are assigned to a specific site. After selecting this option, you must select one specific site or **All Sites** from the All Sites drop-down. • **Depots**: displays all kits that are assigned to a specific depot. After selecting this option, you must select one specific depot or **All Depots** from the All Depots drop-down.
Lots	To filter kits by the lot that they belong to, select one of the following options: • **All**: displays all kits associated with all lots in your study (whether the lot is blinded or a manufacturing lot). • **Unassigned**: displays all kits that are currently not part of any lots. • **Blinded Lots**: select one blinded lot that is displayed underneath this section. • **Manufacturing Lots**: select one manufacturing lot that is displayed underneath this section.

3. After filtering your kits by location or lot, you can further narrow your view by looking for kits of a specific kit type or a specific kit.

> **Note:**
>
> This filter only appears after you have previously clicked a specific kit type from the list.

Filter	Description
Status	Select one kit status to view kits with that specific status. Or select **All** to view all kits in the inventory no matter their status.
Label Group	Filter your study's inventory by label group to view kits with the same label requirements.
Number Range	***Be aware of the following***: • *You only see the kit or sequence numbers within the range you have defined. Should the study inventory include no kits with sequence or kit numbers within this range, no results are displayed.* • *Leaving either field blank will display no results.* Select one of the following options: • **Kit**: Narrow the list of kit numbers that you want to view by entering a kit number in the two fields for the Kit filter. These fields are only available if the kit list does not contain special UTF-8 characters ("|", "/", "$", "&", "-"). • **Sequence**: Narrow the list of sequence numbers that you want to view by entering sequence numbers in the two fields for the Sequence filter.
Block Number	Filter your study's inventory based on block number. To use this filter, you must first Assign blocks of randomization numbers to a site, country, or region.
Kit Number	Filter your study's inventory based on an individual kit number. Searching by individual kit numbers is only available when your list of kits contains special UTF-8 characters ("|", "/", "$", "&", "-").
Temperature Excursion	Search your study's inventory based on an tracking number for kits that have experienced a temperature excursion. This is valid only for kits marked in the **Quarantined** status. Searching by individual kit numbers is only available when your list of kits contains one (1) digit up to eight (8) digits that sequentially increment by 1. For example, 001, 002, 003, 004, and so on. Starting number cannot begin with 0.

4. Click **Clear Filters** to clear all of your filters.

> **Tip:**
>
> The filters you apply to the kit types also apply to the kit list. If you change or add filters while viewing the kit list, those filters are also applied when you return to the kit types. Click **Clear Filters** in the upper right corner on either page to clear all the filters.

Related Topics

- Monitor site and depot stock levels
  As long as resupply strategies meet sites' enrollment needs, you don't need to monitor product levels. However, you might want to monitor supply levels at the beginning of a study to make sure the resupply strategies meet the sites' needs. This procedure also applies to rollover studies.
- Transfer the product to another location
  You can transfer an investigational product to another site to minimize waste, such as when a site doesn't enroll as anticipated. This procedure also applies to rollover studies.
- Mark kits to test for temperature excursions
  Before quarantining your kits, determine if they have experienced a temperature excursion.
- Quarantine kits
  Mark individual kits as Quarantined if they've experienced a temperature excursion.
- Mark a kit as missing or damaged
  Kits at sites and depots can be marked as missing or damaged. This procedure also applies to rollover studies.
- Reserve kits for a quality check
  Two kit statuses are available when you need to reserve kits for a quality check: Temporarily Unavailable and Not In Use. These two statuses give your organization flexibility for managing kits that are unavailable for distribution. This procedure also applies to rollover studies.
- Update a kit's barcode
  There may be cases during a study when a clinical supply manager should manually update a kit's barcode. Follow this procedure to know more about a clinical supply manager can do.

Filter kits in a site's inventory

Inventory filters are located at the top of the page. You can use filters individually or they can be combined.

> **Note:**
>
> You can only see sites that you are assigned to.

> **Tip:**
>
> For filtered kit lists containing special UTF-8 characters, results are sorted numerically first, then alphabetically.

1. Access the Site Inventory tab
2. Determine which filters you want to use.

Filter	Description
Site	Select the site you want to view kits for.
Kit Types	Select the type of kits you would like to view: • **All**: To view both serialized and non-serialized kits. • **Serialized**: To view serialized kits assigned to that site. • **Non-Serialized**: To view non-serialized kits assigned to that site.
Subject Number	Select the subject number you want to view kits for.
Search by Kit Number	Enter a specific kit number that you want to search for. These fields are only available if the kit list contains special UTF-8 characters such as: a vertical line (|), slash (/), dollar sign ($), ampersand (&), or hyphen (-).
Filter by Status	To view kits by status, select one or more statuses.

3. Click **Clear Filters** to clear all of your filters.

> **Note:**
>
> To clear your selection of kit statuses, click **Clear Filters** under **Filer by Status** .

Related Topics

- Update the status of a kit for a site user
  Site users should update the kit status themselves whenever possible. If you're a CRA, and a site user asks you what to do about the status of a kit that is no longer available, instruct them to perform this task. If you're a clinical supply manager who needs to update the status of a kit that should be available in the inventory, follow this procedure.

Search and filter kits on the Depot Inventory tab

Inventory filters are located at the top of the page. You can use filters individually or combine them.

To access or manage the Depot Inventory tab, you must be assigned the **Blinded Depot User** and a **Clinical Supply Manager - Unblinded** study role, or to have the *Blinded Depot User* permission assigned to your role.

Video

1. Access the Depot Inventory tab
2. From the **Depot** drop-down, select a depot.
3. Determine how you want to search for kits:
   - Select **Kit** and then type the kit number in the **Search Bar**, and press **Enter**.

- Select **Sequence number** and then type the **Sequence number** in the **Search Bar**, and press **Enter**.

4. Determine which filters you want to use to view your depot's supply:

Filter	Description
Kit Type	Select the type of kits you would like to view: • **All**: To view both serialized and non-serialized kits. • **Serialized**: To view serialized kits assigned to that depot. • **Non-Serialized**: To view non-serialized kits assigned to that depot.
Status	Select one kit status to view kits with that specific status from the drop-down. Or select **All** to view all kits in the inventory no matter their status.
Lot	Filter by the **Blinded Lot** or select **Unassigned**.
Shipment ID	Enter a specific ID to narrow the list of sequence numbers that you want to view. Or click **All** to view all shipped kits in the inventory.
Quarantine ID	Enter a specific ID to narrow the list of quarantine numbers that you want to view. Or click **All** to view all quarantined kits in the inventory.
Kit number	Enter a number in the fields **From** and **To** to narrow the search range.
Sequence number	Enter a number in the fields **From** and **To** to narrow the search range.

5. Click **Clear Filters** to clear all of your filters.

Related Topics

- Update the status of a kit for a blinded depot user

Manage non-serialized inventory

Understand how non-serialized inventory differs from serialized inventory, and how you can manage it in your study.

In some cases, your study may call for distributing non-serialized inventory. Non-serialized inventory can be useful in multiple scenarios, such as in studies with a large subject pool, or studies that call for more generalized investigational products. Because non-serialized kits are not tracked, it is easier to perform reconciliation, depending on the type of investigational product.

All non-serialized inventory is distributed in bulk, and therefore cannot be individually tracked. Instead, non-serialized kits are added to lots, and display in Oracle Clinical One Platform as lot numbers, followed by the total quantity.

> **Note:**
>
> Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page appears blank for all non-serialized inventory.

As a clinical supply manager, you are responsible for providing sites the ability to distribute non-serialized inventory to subjects when needed. Consider the following before managing non-serialized kits:

- Sponsor users assigned inventory management permissions have the ability to manage non-serialized inventory and distribution.
- Non-serialized kits *cannot* be individually ordered.
- Non-serialized kits assigned to a lot can be included when creating a manual shipment.
- When specifying resupply settings, a min/max or predictive resupply strategy can be used for non-serialized kits.
- Non-serialized kits can be partially dispensed, locally sourced, and selected for a dose hold.
- Dispensation of reusable kits, site confirmation for dispensation, temperature excursion numbers, site and depot kit reconciliation, are *not* available for non-serialized kits when both serialized and non-serialized kits are present in a study.'
- Related kit status and dispensation notifications provide details for non-serialized inventory when applicable.
  For more information, see the *Notifications and Permissions Guide*.

There are certain kit statuses that are not supported for non-serialized kits. Also, kits in certain statuses cannot be directly updated to the statuses related to particular tasks in inventory management. For more information see Allowed updates for inventory status.

For more information and additional instructions on managing both serialized and non-serialized kits, see Manage kits at the site and study level and Manage shipments.

Add non-serialized kits to a lot

To distribute non-serialized inventory, sponsor users can assign non-serialized kits to lots.

Before you work with this feature

Before adding kits to a lot, it's important to understand the differences between serialized and non-serialized inventory, any restrictions, and how each are managed. For more information, see Manage non-serialized inventory.

1. Access the Study Inventory tab.
2. Select the type of kit you would like to add to a lot.
3. Above the kit list, select **Add to Lot**.
4. In the drop-down, select the lot you would like to assign the non-serialized kits to.
5. In the Add Non-Serialized Kit to Lot dialog, enter the number of kits you would like to add to the lot.
6. Click **Add**.

The non-serialized kits are added with a status of *Not In Use*. To update their status, see Update the status of a kit for a site user.

Monitor site and depot stock levels

As long as resupply strategies meet sites' enrollment needs, you don't need to monitor product levels. However, you might want to monitor supply levels at the beginning of a study to make

sure the resupply strategies meet the sites' needs. This procedure also applies to rollover studies.

The Study Inventory tab shows all kits, grouped by kit type. On the right, you can see the total number of kits, the number of dispensed kits, and the number of damaged kits for each kit type.

Want to see how to perform this task? Watch the video below.

Video

- Make sure depots and sites have sufficient stock before the study conduct period begins.
- If you find that sites are not meeting or are exceeding their enrollment goals, or if the shipping time for shipments is too long, consider adjusting or switching the resupply strategy for the sites. For more information, see Create a predictive resupply strategy or Select a resupply strategy for a site.

1. Access the Study Inventory tab.
2. Filter kits in a Study's Inventory tab.

Related Topics

- Inventory management and dispensation FAQs (for clinical supply managers)

Transfer the product to another location

You can transfer an investigational product to another site to minimize waste, such as when a site doesn't enroll as anticipated. This procedure also applies to rollover studies.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

Want to see how to perform this task? Watch the video below.

Video

1. Access the Study Inventory tab.
2. Click a kit type and filter the kits in your inventory.

   For step-by-step instructions, see Filter kits in a Study's Inventory tab.
3. In the list, select the kits you want to transfer, and make sure **Kit Settings** is expanded on the right.
4. From the **Location** drop-down, select the site to transfer the kits to.

   > **Tip:**
   >
   > To remove the location, click **Clear assigned location** in the **Location** drop-down, if you assigned the kit to a depot in error.
5. Click **Update Kits**.
6. In the confirmation window, select a reason for change and click **Yes**.

7. Above the kit list, use the filters to check your work:
    a. Below Location, click **Sites**, and select the site that you transferred the kits to from the **All Sites** drop-down.
    b. Above the kit list, from the **Status** drop-down, select **Available**.
    c. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Mark kits to test for temperature excursions

Before quarantining your kits, determine if they have experienced a temperature excursion.

If your study allows for temperature excursions, you can mark your kits for testing when you need to determine if any kits in the shipment have experienced a temperature excursion. To learn more on how to configure temperature excursions for a study, see Specify supply settings.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

1. Access the Study Inventory tab.
2. Click the type of kit you'd like to test for a temperature excursion.
3. Above the kit list, use the filters to only see the kits you want to mark for testing.

   For step-by-step instructions, see Filter kits in a Study's Inventory tab.
4. In the list, select the kits you want to mark for testing.
5. Make sure **Kit Settings** is expanded on the right.
6. From the **Status** drop-down, select **Pre-Quarantined**.
7. Click **Update Kits**.
8. In the confirmation window, choose the reason for change and click **Yes**.

> **Note:**
>
> **Repeat these steps for each kit type with a kit that needs to be tested for a temperature excursion.**

Quarantine kits

Mark individual kits as Quarantined if they've experienced a temperature excursion.

If your study allows for temperature excursions and any of the kits have reached a temperature reading outside of the recommended ranges, you can update their statuses to Quarantined. For step-by-step instructions on how to configure temperature excursions in your study, see Specify supply settings.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

1. Access the Study Inventory tab.
2. Select the type of kit you'd like to quarantine.
3. Above the kit list, use the filters to only see the kits you want to update.

   For step-by-step instructions, see Filter kits in a Study's Inventory tab.
4. Update the kits that experienced a temperature excursion:
   a. Select the kits you want to quarantine.
   b. Make sure **Kit Settings** is expanded on the right.
   c. From the **Status** drop-down, select **Quarantine**.
   d. Click **Update Kits**.
   e. In the confirmation window, choose the reason for change and click **Yes**.

Mark a kit as missing or damaged

Kits at sites and depots can be marked as missing or damaged. This procedure also applies to rollover studies.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

Want to see how to perform this task? Watch the video below.

Video

1. Access the Study Inventory tab.
2. Click a kit type.
3. Above the kit list, use the filter to find the kits to update.

   For step-by-step instructions, see Filter kits in a Study's Inventory tab.
4. In the list, select the kits to update.
5. On the right, make sure **Kit Settings** is expanded.
6. Below Kit Settings, from the **Status** drop-down, select **Missing** or **Damaged**.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.
9. Above the kit list, use the filters to check your work:
   a. If the kits are at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

      If the kits aren't at a site or depot, click **Unassigned**.

b. Above the kit list, from the **Status** drop-down, select the status the kit had before it went missing or was damaged.

c. To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

To view the history of a kit, select the kit on the Site Inventory tab, and expand Kit History, on the right.

If you marked a kit in error as Missing or Damaged, you can set the kit back to Available by following the previous steps.

Reserve kits for a quality check

Two kit statuses are available when you need to reserve kits for a quality check: Temporarily Unavailable and Not In Use. These two statuses give your organization flexibility for managing kits that are unavailable for distribution. This procedure also applies to rollover studies.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

Want to see how to perform this task? Watch the video below.

Video

To view the history of a kit, select the kit on the Site Inventory tab, and expand Kit History, on the right.

Task 1 Make kits unavailable for distribution

1. Access the Study Inventory tab.
2. Click a kit type.
3. Above the kit list, use the filter to return only the kits you want to perform a quality check on. Make sure you select the status the kit had before it went missing or was damaged.

   For step-by-step instructions, see Filter kits in a Study's Inventory tab.
4. In the list, select the kits you want to update.
5. On the right, make sure **Kit Settings** is expanded.
6. Below Kit Settings, from the **Status** drop-down, select one of the following:
   - **Not in Use**: if you don't want the kit to be counted in site inventory.

     The kit must currently be marked as Available or Temporarily Unavailable.
   - **Temporarily Unavailable**: if you want the kit to be counted in site inventory.

     The kit must currently be marked as Available, Missing, Pre-Quarantined, Quarantined, or Not in Use.

> **Tip:**
>
> Kits marked as Not in Use or Temporarily Unavailable can't be dispensed or shipped.

7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.
9. Above the kit list, use the filters to check your work:
   - If the kits are at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

     If the kits aren't at a site or depot, click **Unassigned**.
   - Above the kit list, from the **Status** drop-down, select **Not in Use** or **Temporarily Unavailable**.
   - If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Task 2 Update the status of kits after testing them

1. Access the Study Inventory tab.
2. Click a kit type.
3. Above the kit list, use the filter to return only the kits you want to update:
   a. If the kits are at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

      If the kits aren't at a site or depot, click **Unassigned**.
   b. Above the kit list, from the **Status** drop-down, select **Not in Use** or **Temporarily Unavailable**.
   c. To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.
   d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
4. In the list, select the kits to update.
5. On the right, make sure **Kit Settings** is expanded.
6. Below Kit Settings, from the **Status** drop-down, select one of the following:
   - **Available**: if the kits passed the quality check.
   - **Damaged**: if the kits didn't pass the quality check, and are currently marked as Temporarily Unavailable.
   - **Temporarily Unavailable**: if the kits didn't pass the quality check, and are currently marked as Not in Use. After you mark the kits as Temporarily Unavailable, mark them as Damaged by following the previous steps.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.
9. Above the kit list, use the filters to check your work:

a. If the kits are at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

   If the kits aren't at a site or depot, click **Unassigned**.

b. Above the kit list, from the **Status** drop-down, select **Available** or **Damaged**.

c. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Update the status of a kit for a site user

Site users should update the kit status themselves whenever possible. If you're a CRA, and a site user asks you what to do about the status of a kit that is no longer available, instruct them to perform this task. If you're a clinical supply manager who needs to update the status of a kit that should be available in the inventory, follow this procedure.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

If you need to reconcile kits, see Verify returned kits to confirm and correct site reconciliation.

> **Note:**
>
> If titration is part of a study's design, we recommend you never mark a kit as **Not Dispensed to Subject**. This kit status update will interfere with the way dose changes are performed in the system.

1. Access the Site Inventory tab
2. Filter kits in a site's inventory
3. Select the kit.
4. On the right, below Kit Settings, click **Update Kit**.
5. Select the appropriate status from the **Kit Status** drop-down:
   - If a kit went missing or was damaged at the site, mark the kit as **Missing** or **Damaged**.
   - If a kit experienced a temperature excursion, mark the kit as **Pre-quarantined**.
   - If the subject didn't receive the kit, mark the kit as **Not Dispensed to Subject**
   - If a kit (particularly a device) was previously marked as **Not Dispensed to Subject** and you want to make it available for dispensation again, mark the kit as **Available**.
6. Enter a reason, and click **Update Kit**. To view tips for completing a field, click into the field or choose an option.

> **Tip:**
>
> To view the history of a kit, select the kit on the **Site Inventory** tab, and expand Kit History, on the right.

> **Note:**
>
> The history of a kit is not available for non-serialized kits.

Related Topics

- What if a site user dispensed a kit in error?
  You next steps depend on what happened.
- How do I dispense the same device to another subject?

Update a kit's barcode

There may be cases during a study when a clinical supply manager should manually update a kit's barcode. Follow this procedure to know more about a clinical supply manager can do.

If your study uses barcodes and you need to update a kit's barcode, you can perform this task during the study conduct period. If your study doesn't use barcodes, this task isn't mandatory.

Yes. Check with your user administrator to make sure you're assigned the clinical supply manager role and have the *Update Supplies Information After Design Approval* permission.

1. Access the Study Inventory tab.
2. Click a kit type.
3. Below Number Range, click **Kit** and enter the range of kit or sequence numbers for the kits in the lot that you included in the generated kit list with barcodes.
4. Select a kit.
5. On the right, make sure **Barcodes** is expanded.
6. View the barcode of the selected kit or click the pencil icon ( ) to edit the barcode.

   Your changes are automatically saved.

Available inventory statuses for kits

Kit statuses allow you to manage shipments and inventory in your study. Here's a list of every status a kit might have in Oracle Clinical One Platform and their descriptions.

> **Tip:**
>
> Depending on your role and the permissions assigned to it, you can see a kit's changed status at either a site or depot, on the Study Inventory, Site Inventory, or Kit Reconciliation tabs, or in Subject History. Information about all kit statuses in your inventory can also be found in the Kit Inventory (Blinded) and Kit Inventory (Unblinded) reports in Oracle Clinical One Platform.

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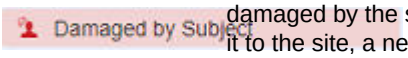
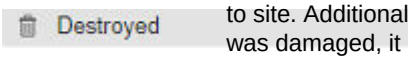
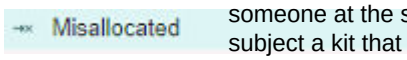
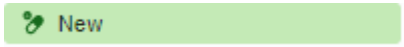
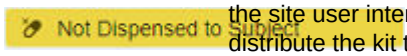
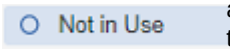
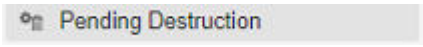
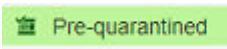
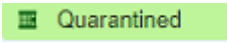
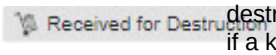
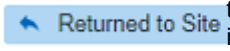
Kit status	Description	How a kit reaches this status
Available 	A kit is ready to be dispensed to subjects at a site, or ready to be shipped from a depot.	A kit's status is updated to Available as follows: • Automatically: when kits are released to a depot for Testing mode, and when a site user marks a shipment as received. • Manually: when a sponsor user releases kits to a depot for Production or Training mode.
Damaged 	A kit was physically deteriorated at a site or depot. For example, a kit might have been damaged as a result of being dropped.	A site user or sponsor user marks the kit as Damaged.
Damaged by Subject 	A kit was physically deteriorated after it was dispensed to the subject. In this case, the subject needs to return it to the site to be destroyed. Usually, if the kit is damaged by the subject, after returning it to the site, a new one is dispensed.	A site user marks the kit as Damaged by Subject.
Destroyed 	A kit was destroyed during the kit reconciliation process. Most kits are destroyed after the subjects return them to site. Additionally, a kit is destroyed if it was damaged, it expired, or wasn't dispensed to a subject at all.	Only Pending Destruction kits can be marked as Destroyed. Typically, before destruction, a Clinical Research Associate (CRA) verifies the kit and marks it as being ready for destruction. The next step depends on the location of the drug destruction facility: • If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to Destroyed. • If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility. After the kit is destroyed, its status is updated to Destroyed.
Dispensed 	A kit was dispensed to a subject during a dispensation visit.	A kit's status automatically changes to Dispensed after a site user dispenses it to a subject.

Kit status	Description	How a kit reaches this status
Expired 	The investigational product exceeded its expiration date.	A site or sponsor user marks a kit as Expired.
In Transit 	A kit is being shipped from a depot to a site.	A shipment request was made by a site or sponsor user for that kit, and the ship date has been provided.
Lost by Subject 	A kit went missing after being dispensed to a subject. Usually, if the kit is lost by a subject, a new one is dispensed to them.	A site user marks the kit as Lost by Subject.
Misallocated 	A kit was dispensed in error. There are several reasons why a kit can be dispensed in error. For example, someone at the site might have given a subject a kit that was different from the kit that Oracle Clinical One Platform said to dispense, and the subject left the site with it; or someone at the site might have entered data in the wrong subject's visit and dispensed a kit.	A site user must dispense a replacement kit before marking the kit as Misallocated. If a site user marks a kit as Misallocated before dispensing a replacement kit, the site user won't be able to dispense a replacement kit. A site user manually updates a kit's status to Misallocated.
Missing 	A kit hasn't been dispensed yet and has gone missing from the site or depot.	A site user or sponsor user manually updates a kit's status to Missing.
New 	The kit has just been uploaded in Production mode, and it's going to be manufactured and made ready for use.	The kit was created in Production mode.
Not Dispensed to Subject 	A dispensed kit was never distributed. A subject might not receive a kit for various reasons. For example, they accidentally left the kit at the site after their visit, or the site user intentionally chose not to distribute the kit to them.	A site user marks the kit as Not Dispensed to Subject. A site user must dispense a replacement kit before marking the kit as Not Dispensed to Subject. If a site user marks a kit as Not Dispensed to Subject before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

Kit status	Description	How a kit reaches this status
Not in Use 	A kit can't be dispensed or shipped. Think of this status as an "emergency brake". Whenever users want to prevent a kit from being dispensed or shipped they mark it as Not in Use. For example, they would use this status if a kit needs to be moved from one depot to another.	• A site user or sponsor user marked a kit as Not in Use. • Kits included in a generated kit list in Production mode first appear in a study's inventory with a status of Not in Use.
Pending Destruction 	A kit is ready to be destroyed.	Typically, the Clinical Research Associate (CRA) verifies the kit and then marks it as Pending Destruction. The user must provide a reason for the status update.
Pre-quarantined 	A kit failed to comply with the shipment or storage requirements. For instance, it could have suffered a temperature or humidity excursion. After the kit is pre-quarantined, a clinical supply manager determines whether the kit can still be dispensed or not. If it can be dispensed, the kit changes its status to Available. If the kit can't be dispensed, the kit's status is updated to Quarantined so that it isn't considered part of the site's inventory anymore.	The sponsor user marks the kits as Pre-quarantined. A pre-quarantined kit is counted in a site's inventory.
Quarantined 	A kit failed to comply with the shipment or storage requirements, and it was damaged as a result. A Quarantined status marks the end of life for a kit. Quarantined kits can no longer be dispensed to subjects, and aren't counted in a site's inventory. Multiple quarantined kits from the same depot might be a sign of issues with a shipping procedure.	A clinical supply manager marks the kit as **Quarantined.**
Received for Destruction 	The site user or Clinical Research Associate (CRA) has shipped the kit to a drug destruction depot and a depot user confirmed they received the kit for destruction at their facility. For instance, if a kit suffered some sort of irreversible damage, the site user might send it back to the depot facility to destroy it.	A depot user confirms a receipt per kit that they have received it at the depot.
Returned to Site 	The subject returned the kit to the site. Subjects are required to bring any used and unused investigational products to their next dispensation visit. For instance, if the subject received three blisters of pills, and at his next dispensation visit they're left with three pills, they're required to return both the empty blisters and remaining pills to the site.	A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.

Kit status	Description	How a kit reaches this status
Temporarily Unavailable	A kit is temporarily on hold and can't be dispensed or shipped.	A site or sponsor user marks the kit as Temporarily Unavailable.

Related Topics

- Allowed updates for inventory status
  Kits in certain statuses cannot be directly updated to a specific status. This is applicable for regular and non-serialized kits, and for updates done in both the study inventory and site inventory pages.

Allowed updates for inventory status

Kits in certain statuses cannot be directly updated to a specific status. This is applicable for regular and non-serialized kits, and for updates done in both the study inventory and site inventory pages.

> **Note:**
>
> Non-serialized kits cannot be updated to any drug reconciliation statuses. These include **Pending Destruction**, **Destroyed** and **Returned to Site**.

For more details about kit statuses, see Available inventory statuses for kits.

The ability to update kit statuses depends on your study role and their assigned permissions. Typically, Clinical Supply Managers (CSM) and depot users are allowed to make additional updates compared to Clinical Research Associates (CRA) and site users. However, regardless of your study role you can be granted with the necessary permissions to make any of the allowed updates to inventory statuses as needed. Contact your study user administrator and refer to Descriptions of permissions in Clinical One.

This document contains the allowed updates for inventory statuses performed by different users:

What if a site user dispensed a kit in error?

You next steps depend on what happened.

What if Oracle Clinical One Platform dispensed a kit, but the subject left the site without it?

1. Tell the site user to dispense a replacement kit to the subject if he or she needs one.

> **Caution:**
>
> A site user must dispense a replacement kit before marking the kit as Not Dispensed to Subject. If a site user marks a kit as Not Dispensed to Subject before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

2. Tell the site user to mark the kit that the subject didn't receive as Not Dispensed to Subject.

What if a site user gave a subject a kit that was different from the kit that Oracle Clinical One Platform said to dispense, and the subject left the site with it?

Perform these steps only if it is determined that the subject can continue with the study.

1. Tell the site user to dispense a replacement kit to the subject.

> **Caution:**
>
> A site user must dispense a replacement kit before marking the kit as Misallocated. If a site user marks a kit as Misallocated before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

2. Mark the kit that the subject left the site with as Misallocated.

   From the **Subject Number** drop-down, tell the site user to select the subject who received the kit.

What if a site user entered data for the wrong subject?

1. Tell the site user to dispense a replacement kit to the subject whose visit the site user mistakenly entered data in.

   For example, if the site user entered data for subject 001-001 in the visit for subject 001-002, the site user should dispense a replacement kit for subject 001-002.

> **Caution:**
>
> A site user must dispense a replacement kit before marking the kit as misallocated. If a site user marks a kit as Misallocated before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

2. Tell the site user to mark the kit that was dispensed as Misallocated.

   From the **Subject Number** drop-down, tell the site user to select the subject who received the kit.

   For example, after the site user dispenses a replacement kit for subject 001-002, tell the site user to mark the kit dispensed in error to subject 001-001 as Misallocated, and select subject 001-001 from the **Subject Number** drop-down.

3. If the subject who received the wrong kit can continue in the study, tell the site user to enter data for the correct subject. For example, the site user should enter the data for subject 001-001 in the visit for subject 001-001. Oracle Clinical One Platform dispenses a kit to the subject; use your organization's procedures to determine whether to exchange the kit in the subject's hands for the kit that Oracle Clinical One Platform dispensed.

What if a site user dispensed a kit without using Oracle Clinical One Platform?
Site users should never dispense a kit without using Oracle Clinical One Platform.

- Tell the site user to mark the kit as Misallocated.

  In the **Subject Number** field, the site user should enter the number of the subject who received the kit.

What if a site user titrated in error?
If a site user titrated up or down in error, there are ways to fix the error from within Oracle Clinical One Platform. The site user's next steps depend on the blinding status of the kits that were dispensed:
Unblinded kits
The site user should work with the clinical research associate and other members of the study team as needed to determine whether they can fix the error by not dispensing one or more kits. For example, consider a subject who is currently consuming 5 mg of an investigational product and wants to stay on the dose. If the site user titrates up in error, the subject might switch to a 7.5 mg dose, consisting of a 5 mg kit and a 2.5 mg kit. Here's what should happen in this situation:

1. The site user and sponsor team determine whether removing one of the kits from the dispensation will solve the error. In this case, removing the 2.5 mg kit does solve the problem. What if the error can't be solved by removing a kit? The error can't be solved from within Oracle Clinical One Platform. The study team must determine the next steps for the subject.
2. The site user and sponsor team identify the kit number of the kit to remove.
3. The site user marks the kit as Not Dispensed to Subject. When a kit is marked as Not Dispensed to Subject, the kit is no longer considered part of the subject's current dose. So when the subject has their next dispensation visit and they choose to maintain their current dose, they'll stay on the 5 mg dose.

Blinded kits
The site user should reach out to their clinical research associate, who should contact the clinical supply manager. The clinical supply manager should look at the kits that were dispensed to see whether they can fix the error by not dispensing one or more kits. For example, consider a subject who is currently consuming 5 mg of an investigational product and wants to stay on the dose. If the site user titrates up in error, the subject might switch to a 7.5 mg dose, consisting of a 5 mg kit and a 2.5 mg kit. Here's what should happen in this situation:

1. The clinical supply manager determines whether removing one of the kits from the dispensation will solve the error. In this case, removing the 2.5 mg kit does solve the problem. What if the error can't be solved by removing a kit? The error can't be solved from within Oracle Clinical One Platform. The study team must determine the next steps for the subject.
2. The clinical supply manager identifies the kit number of the kit to remove and shares the kit number with the CRA, who tells the site user.
3. The site user marks the kit as Not Dispensed to Subject. When a kit is marked as Not Dispensed to Subject, the kit is no longer considered part of the subject's current dose. So when the subject has their next dispensation visit and they choose to maintain their current dose, they'll stay on the 5 mg dose.

Other examples of titration dispensation errors
For example, consider the following situation: a subject who is currently on 75mg of an investigational product wants to maintain the same dose. During one of the visits, a site user

titrates down in error, so the system dispenses 50mg to the subject who wanted to maintain its 75 mg dose.
Titration is based on the latest dispensation for a subject, whether it be a dispensation event that occurred through the visit or a manual dispensation (through the misallocation of a kit). A site user then chooses to perform a manual dispensation (through misallocation) to be able to dispense the right investigational product to the subject.
If a misallocation occurs for a visit in which the kit dispensed is at a higher dosage (75mg) of what was originally dispensed in the system (which was 50mg), the system will check for a matching row within the **Start** column of a titration kit type (in this case, the system is looking at the Start column to contain Kit Type A 50mg + Kit Type B 75mg), when performing the titration during the next visit. If there is no matching row, the dispensation will fail, as expected based on the study's design. The following error message will be displayed: “You cannot dispense a kit to subject <subject_number>. Contact your clinical research associate, and tell them to verify that titration rules have been defined for all kits.”

View and update randomization numbers

- View a subject's randomization number
  Unblinded users can view all randomization numbers and the subjects who are assigned to them. This procedure also applies to rollover studies.
- Manually assign a randomization number to a subject
  If a subject was randomized in error but is still eligible to participate in the study, you can manually assign a randomization number to a subject. You cannot manually assign a randomization number in a study using minimization.
- Mark randomization numbers that were used in error
  If a subject was randomized in error, you must correct the error in the randomization list. For example, a site user might have randomized a subject in Oracle Clinical One Platform without the subject present, but the subject never arrived for the visit. This procedure also applies to rollover studies.

View a subject's randomization number

Unblinded users can view all randomization numbers and the subjects who are assigned to them. This procedure also applies to rollover studies.

1. Access your study in a specific mode
2. Along the top, select **Supplies**.
3. Below the study name, select the **Randomizations** tab.
4. If the study has more than one randomization list, select the appropriate list from the **Randomizations List** drop-down.
5. (Available only if your randomization design blocks by site) From the **Filter by Site** drop-down, select the subject's site.

   The Subject Number column lists the subject who was assigned the randomization number. If the Subject Number column is blank, the randomization number has not been used.
6. Identify the number for a given subject in the **Randomization Number** column.

   If your randomization list is ordered by sequence number, you may also refer to the Sequence Number column.

Related Topics

- Generate a randomization list
  Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.
- Upload a randomization list
  Create a randomization list for Testing mode when you're ready to test data entry and randomization. Create a randomization list for Production and Training mode when you're ready to make the study live.

Manually assign a randomization number to a subject

If a subject was randomized in error but is still eligible to participate in the study, you can manually assign a randomization number to a subject. You cannot manually assign a randomization number in a study using minimization.

Mark the subject's randomization number as randomized in error, and make sure you know the subject number of the subject you are assigning a randomization number to.

1. Access the study version for a given mode as described in Open the design of a study version
2. Along the top, select **Supplies**.
3. Below the study name, select the **Randomizations** tab.
4. If the study has more than one randomization list, select the appropriate list from the **Randomizations List** drop-down.
5. Filter the view of the list appropriately:
   - If you know the randomization number or the sequence number you are assigning to the subject, enter it in the **Search by Number** field above the table.
   - If you don't know the randomization number you are assigning to the subject:
     – (Available only if your randomization design blocks by site) From the **Filter by Site** drop-down, select the subject's site.
     – From the **Filter by Status** drop-down, select **Available** so you see only the randomization numbers that you can assign to subjects.
6. In the table, select the randomization number to assign to the subject.

> **Tip:**
>
> The Treatment Arm and Stratum Groups columns contain treatment details for the randomization number.

7. Below Randomization Settings on the right, from the **Select Status** drop-down, select **Assigned**.
8. From the **Select Subject Number** drop-down, select the subject number.

   The software doesn't prompt you to confirm the change. Make sure you select the correct subject number.
9. In **Reason for Update**, enter a reason for the change, and click **Update**.

The subject is assigned the new randomization number. If you filtered the page to see only Available randomization numbers, you can change the Available filter to Assigned to see the new assignment.

Mark randomization numbers that were used in error

If a subject was randomized in error, you must correct the error in the randomization list. For example, a site user might have randomized a subject in Oracle Clinical One Platform without the subject present, but the subject never arrived for the visit. This procedure also applies to rollover studies.

1. On the Home page, click the pencil button () on the study, and make sure a study version appears below Approved.
2. Determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Testing mode, click the Testing Mode button () on the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
3. Along the top, click **Supplies**.
4. Below the study name, click the **Randomizations** tab.
5. If the study has more than one randomization list, select the appropriate list from the **Randomizations List** drop-down.
6. (Available only if your randomization design blocks by site) From the **Filter by Site** drop-down, select the subject's site.
7. In the Subject Number column of the randomization list, locate the subject that was randomized in error, and select their randomization number.
8. On the right, below Randomization Settings, select **Randomized in Error** from the **Select Status** drop-down.
9. Enter a reason for the change, and click **Update**. To view tips for completing a field, click into the field.
10. Next, you can manually assign a randomization number to the subject, if needed.

> **Tip:**
>
> You'll need the subject's number.

11. If a kit was dispensed to the subject after they were randomized in error, ensure that someone at the site marks the kit as Misallocated.

Monitor subjects and sites

- Filter subjects in a study
  Subject filters are located at the top of the subjects table. You can use these filters individually or in a combined way.

- Find incomplete visits
  A visit is marked as incomplete if the visit window passes or if a subject arrives within the visit window but the site user doesn't complete the required questions associated with the visit. An incomplete visit means that screening, randomization, or dispensation didn't occur. This procedure also applies to rollover studies.
- Lock a subject at the form or visit level
  Sponsor users can lock forms and visits to prevent users from editing subject data.
- Unlock a subject at the form or visit level
  Sponsor users can unlock forms and visits to allow users to modify subject data.
- Lock a subject at the casebook level
  Lock a subject's casebook to prevent users from adding new or updating existing data for that subject.
- Unlock a subject at the casebook level
  Unlock a subject at the casebook level to allow users to add new or update existing data for a subject that has been previously locked.
- Freeze and unfreeze data
  As a data manager or CRA, you can prevent site users from editing case form data, to use it in data extracts and analysis. The only form item that you cannot freeze is the Visit Date field.
- Verify that a site has been activated
  If you're troubleshooting site or inventory issues, you might need to verify that a site has been activated. On the Sites tab, a green icon next to the site name means the site has been activated. This procedure also applies to rollover studies.
- Review the data collected for a subject
  You can review the data entered for a subject and the history of events that have occurred for the subject. This procedure also applies to rollover studies.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- Reveal a subject's treatment arm
  Oracle Clinical One Platform does not automatically withdraw subjects that have been unblinded with a code view. After you reveal a subject's treatment arm, you can perform the code view as many times as necessary to retrieve the unblinding results again. This procedure also applies to rollover studies.
- Transfer a subject
  When a subject is transferred, the subject number doesn't change. The site that the subject is transferred to can view and edit all subject data, including data that the subject's previous site entered. The site that the subject is transferred from can no longer edit any data for the subject. This procedure also applies to rollover studies.
- Verify that a site received a shipment
  If the site received the shipment, but did not register it as received in Oracle Clinical One Platform, the site won't be able to dispense the kits in the shipment, and the site may appear to be out of stock when there are kits available at the site. This procedure also applies to rollover studies.

- What if a site user randomized a subject in error?
  The following workflows provide suggestions for rectifying possible user errors. We recommend confirming that these measures are consistent with your organizational policies and processes.

Filter subjects in a study

Subject filters are located at the top of the subjects table. You can use these filters individually or in a combined way.

> **Note:**
>
> Depending on your study role and site assignments, only certain countries and sites are available when filtering through subjects. For more information, see Best practices for study role assignment.

The filters you select are preserved until you sign out of the application, but they are not preserved if you switch to another study.

For step-by-step instructions, see Filter subjects in a study.

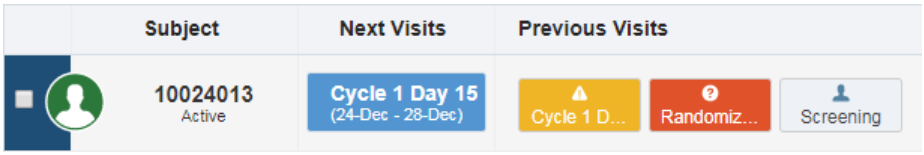
Find incomplete visits

A visit is marked as incomplete if the visit window passes or if a subject arrives within the visit window but the site user doesn't complete the required questions associated with the visit. An incomplete visit means that screening, randomization, or dispensation didn't occur. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Training mode, click the Training Mode button ( ) on the study.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. In the table, a yellow visit with an exclamation point in the Previous Visits column indicates an incomplete visit. An orange visit with a question mark indicates a failed screening visit.



Lock a subject at the form or visit level

Sponsor users can lock forms and visits to prevent users from editing subject data.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission have the ability to lock forms and visits to prevent other users from modifying that subject's data.

> **Note:**
>
> Consider the following:
>
> - If all questions on a form are marked for unlock at the question level, any hidden questions on the form will also be unlocked.
> - Advanced Study Version changes will not be applied to locked data, but will be applied once the data is unlocked.
> - Coding updates and lab normal range updates will still be visible even if the form is locked.
> - There are instances when you might have to manually lock questions that couldn't be automatically locked. To do that, locate the visit that is referenced in the Auto-lock failure notification, identify which questions have the auto-lock rule configured, and lock them in your study. If you want to learn more about the Auto-lock failure notification, see Auto-lock failure notification.

> **Tip:**
>
> If the question's data you would like to lock was previously cleared, it may be necessary to refresh the page to view the **Lock** option in the menu.

To lock a subject's data at the form or visit level, follow these steps:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Locate the visit you want to lock.
5. On the Visit screen, click **Lock Data** and select **Lock**.
6. Choose one of the following:
   - The checkbox next to the question or form that you would like to lock.
   - The checkbox next to **Forms** in the Forms side panel to lock the entire visit.
7. Select one of the following to lock the selected item(s):
   - **Lock**
   - **Lock & Close**
8. In the Lock Data dialog, select **Lock** to confirm you would like to lock the selected data.

A lock icon () appears next to all forms and questions that have been started within the visit.

A lock icon () appears next to the visit.

Related Topics

- Unlock a subject at the form or visit level
  Sponsor users can unlock forms and visits to allow users to modify subject data.

Unlock a subject at the form or visit level

Sponsor users can unlock forms and visits to allow users to modify subject data.

Sponsor users provided with the *Lock Subject Data Entered at a Site* permission have the ability to unlock forms or visits that were locked in order to prevent other users from updating that subject's data.

> **Note:**
>
> If all questions on a form are marked for unlock at the question level, any hidden questions on the form will also be unlocked.

> **Tip:**
>
> If the item's data you would like to unlock has been previously cleared, it may be necessary to refresh the page to view the **Unlock** option in the menu.

Use the following steps to unlock a subject's data at the form or visit level:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Locate the visit you want to unlock.
5. On the Visit screen, click the **Lock Data** drop-down and select **Unlock**.
6. Choose one of the following:
   - The checkbox next to the question or form that you would like to unlock.
   - The checkbox next to **Forms** in the Forms side panel to unlock the entire visit.
7. Select one of the following to unlock the selected item(s):
   - **Unlock**
   - **Unlock & Close**
8. In the Unlock Data dialog, choose an option from the **Reason for Change** drop-down, then select **Unlock**.

An unlock icon () appears next to all forms and questions within the visit.

An unlock icon () appears next to the visit.

Lock a subject at the casebook level

Lock a subject's casebook to prevent users from adding new or updating existing data for that subject.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can lock a subject at the casebook level, preventing other users from modifying that subject's data.
Before locking a subject at the casebook level, be aware that:

- Locking all subjects at a site does *not* prevent additional subjects from being added. On the Sites page, the **Add Subjects** option must be set to Off to disallow users from adding additional subjects.
- Programmable rules do not run against locked subject data.
- While subject locking is in progress, the *Subject Locked* status will not be reflected in the subject's history until the lock action has completed.

Use the following procedure to lock a subject's data at the casebook level:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Locate the subject you want to lock.
5. Click the **Manage Subjects** drop-down and select **Lock Subject**.
6. In the Lock Subject dialog, select **Lock** to confirm you would like to lock the selected subject.

   A lock icon () appears next to the subject and all visits, along with an updated status of *Subject Locked* in the Subject History.

Related Topics

- Unlock a subject at the casebook level
  Unlock a subject at the casebook level to allow users to add new or update existing data for a subject that has been previously locked.

Unlock a subject at the casebook level

Unlock a subject at the casebook level to allow users to add new or update existing data for a subject that has been previously locked.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission can unlock a subject's casebook that was previously locked, even when its forms and visits were partially locked, allowing them to update that subject's data.
Use the following steps to unlock a subject's data at the casebook level:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Locate the subject you want to unlock.
5. Click the **Manage Subjects** drop-down and select **Unlock Subject**.
6. In the Unlock Subject dialog, choose an option from the **Reason for Change** drop-down, then select **Unlock**.

   An unlock icon ( ) appears next to the subject and all visits, along with an updated status of *Subject Unlocked* in the Subject History.

Freeze and unfreeze data

As a data manager or CRA, you can prevent site users from editing case form data, to use it in data extracts and analysis. The only form item that you cannot freeze is the Visit Date field.

You can freeze data at a visit, form, and question level for both complete and incomplete visits. All question types can be frozen, including instances of a repeating form, coding questions, and individual questions in question groups.

> **Note:**
>
> When it comes to repeating forms, you can only freeze data in a repeating form instance when that form instance is completed.

If you or another sponsor user raises a query against a frozen question, that question remains frozen but the query can be answered by a site user at any time. However, site users can only update the question after you unfreeze it. You can only unfreeze data at a question level, one by one.

> **Note:**
>
> When an unfrozen question is updated and the change is submitted, the question automatically refreezes. This auto-refreeze action is attributed to the user who updated the data in the question's audit history.

Want to see how to perform this task? Watch the video below.

Video

1. Access your study in a specific mode.
2. Along the top of the page, select the **Subjects** tab.
3. If you have access to multiple sites for the study, select a site from the Site drop-down.

> **Tip:**
>
> - From the View drop-down, select **Signed & Verified** to filter your search for subjects whose data can be frozen.
> - If you want to unfreeze data, select the **Frozen** option to filter your search for subjects whose data is already frozen.

4. Locate a subject in the table, and click a visit in the **Previous Visit** column.
5. Along the top of the page, click **Freeze Data**.
6. There are two ways for you to freeze data:
   - To freeze all questions in a form, select the checkbox next to that form's name, on the Forms list on the left.
   - To freeze a specific question, select the checkbox next to that question.
7. In the lower-right corner, click **Freeze** or **Freeze & Close**.
8. On the Freeze Data dialog, review the message, and click **Freeze Data**.

   If you don't want to freeze a subject's data, click **Cancel**.
9. **To unfreeze a question:**

   This is applicable only for frozen questions.

   a. Click the menu icon ( ) next to it.
   b. Select **Unfreeze**.
   c. On the Unfreeze Question dialog, select an option from the **Reason for Change** drop-down.
   d. Click **Unfreeze**.

All frozen forms and questions appear with the frozen icon ( ) next to them. The same icon displays for a given subject if all of their data has been verified.

All unfrozen forms and questions appear with the unfrozen icon ( ) next to them.

Related Topics

- What does each icon mean for signing, verifying, or freezing data?
  Each sign, verify, or freezing action has an impact on the study data. Learn more about what each icon means.

Verify that a site has been activated

If you're troubleshooting site or inventory issues, you might need to verify that a site has been activated. On the Sites tab, a green icon next to the site name means the site has been activated. This procedure also applies to rollover studies.

Need to activate a site?

1. On the Home page, click the study settings button ( ) for the study you want to monitor, and select **Open Settings**.

2. Below the study name, click the **Sites** tab.
3. On the left, select **Production Sites** or **Training Sites**.
4. Select a site.
5. From the **Manage Sites** drop-down, select **Edit**.
6. Look at the **Status** field to see if **Active** is selected.

Review the data collected for a subject

You can review the data entered for a subject and the history of events that have occurred for the subject. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Training mode, click the Training Mode button ( ) on the study.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. Find the subject. To filter your view of subjects, enter some or part of the subject number in the **Search** field in the upper right above the table of subjects, and press **Enter**.
5. To review a subject's history, select the subject, and view audit details to the right, below Subject History.
6. To review data entered for a subject, locate a subject in the table, and click a visit in the **Previous Visit** column.
7. Review the data entered for the visit by scrolling down the forms.

> **Tip:**
>
> To view the answer history of any question, click into the answer field, and Answer & Visit History expands on the right.

8. Above the form, select another previous visit to continue reviewing data for this subject.
9. In the upper-left, click **Return to All Subjects** to select another subject to review.

Tips:

- You can also run the Subject Data report to view all data collected for a subject during site visits.
- To view the history for a kit, select a subject, and on the right below Subject History, click the arrow icon ( ) next to Dispensation History. Then, select the kit, and expand Kit History, on the right.

Related Topics

- Run a report

- Subject Data report

Verify a subject's data

If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.

You can verify forms and questions in any started or skipped visit, irrespective of the visit's status in the system, whether it's complete, in progress or incomplete.

> **WARNING:**
>
> If a response to a question is updated on a form or visit that is already verified, that question becomes **Unverified**, as well as the form and visit. In order to complete SDV and return the question, form and visit to a **Verified** status, you have to re-verify that question to validate the latest information.

To understand how the SDV status can change for a form, visit or question, see About Source Data Verification statuses.

Before working in this task, be aware that if SDV is turned off in the study settings, you will not be able to perform SDV. The **Ready to Verify** filter and the button to **Verify Visit Data** won't be available even if you have the appropriate permissions.
For more information about SDV settings and use cases see Understand source data verification.

Also, consider that hidden questions with data classifications may also require verification. Only the users with the appropriate permissions to see the classified data will be able to verify it.

> **Note:**
>
> For users that are not allowed to view classified data, it may happen that a form or visit has a **Verification Required** or **Unverified** status even when they see all data within as verified. This would indicate that the data that is pending verification is classified and another user with the appropriate permissions must do it.

Want to see how to perform this task? Watch the video below.

Video

1. From the Home page, Access your study in a specific mode.
2. If you have access to multiple sites for the study, select a site from the Site drop-down.
3. From the *All reviews* drop-down, select **Ready to Verify** to filter your search for subjects who need to be verified.

   The filter results only display visits that have been started and include at least one question requiring verification (that is not under a status of **Verified**).
4. Locate a subject in the table, and click to open the visit to be verified.
5. Review data entered for the visit by scrolling down the forms. See Review the data collected for a subject.

6. Along the top of the page, click **Verify Visit Data**.
7. There are two ways for you to verify data:
   - If you want to verify a certain question, select the checkbox next to that question.
   - If you want to verify an entire form, select the checkbox next to that form, on the left.
   - If you want to verify all forms and questions from a visit, select the checkbox next to the word **Forms**, on the left.

   > **Note:**
   >
   > When you check the form-level or visit-level verification box:
   >
   > – Only the questions that are visible to the user will be verified. Hidden questions will not be verified.
   >
   > – If overrides are not allowed, only the questions that require verification will get verified.
   >
   > – Read-only questions are never verified.

8. Depending on how the study's targeted source data verification strategy is configured, you may see three types of indicators for questions that need to be verified.
   - **Bold check box:** Verification is required for this question.
   - **Simple check box:** This is only available if study allows SDV overrides and means verification is optional.
   - **Simple check box with a Targeted SDV icon**(): This only displays if study allows SDV overrides and means this is a critical variable question but SDV is optional because the subject is not part of the targeted SDV subject pool.
     Critical variables are only required for subjects selected for the targeted SDV subject pool as per the SDV strategy. You can verify this question if you wish knowing it is a critical variable, even though it is not required for this particular subject.
9. In the lower-right corner, click **Verify** or **Verify & Close**.

All verified questions display with the verified icon () next to them. The same icon appears on the visit tile for a verified visit, in the Answer & Visit History and next to each subject if all of their data has been verified. All verification records in the Visit History are attributed to the user who performed the SDV.

Need more help with icons? See What does each icon mean for signing, verifying, or freezing data?

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.

- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.
- Configure source data verification settings for a question

About Source Data Verification statuses

Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.

For more information about SDV settings and use cases see Understand source data verification.

For studies that use any level of SDV, forms, questions and visits can have SDV related statuses. The following statuses apply:

Status	Description
Verification required	The icon for verification required only displays for started visits (never for a question, form or subject) when at least one of its question has never been verified and requires verification, and as long as there is no data in the visit that is unverified. ***Note:*** *If a started visit is cleared, it returns to a state of new, so the icon for verification required disappears.*
Verified	The item has been verified by the user. You can verify a question, form or visit directly. A form, visit or subject becomes verified when all its questions that require verification are verified and as long there is no data that is unverified. ***Note:*** *When you verify a form or visit directly, only the questions that are visible to the user will be verified. Hidden questions will not be verified. If any hidden question requires verification, the form or visit will not become verified until that hidden question is also verified.*
Unverified	A question was once verified but then updated, so it becomes unverified. A form, visit or subject becomes unverified if at least one of its questions that require verification is unverified.

Each status is identifiable by their respective icons. Visits that do not require SDV are identifiable by the absence of any SDV-related icons. For more information see What does each icon mean for signing, verifying, or freezing data?

During the study conduct period, forms, questions, and visits can change status as a result of certain actions. Records for these actions and changes of status are listed in the **Answer &**

Visit History. Even visits that do not require SDV can acquire an SDV status and display the given icon. Once any of the following actions occur, the status is updated as applicable:

- A question becomes **Verified** after a Clinical Research Associate (CRA) user verifies it.
- Forms, visits and subjects become **Verified** when all their questions that require SDV get verified, as long as there is no unverified data. If there is at least one question in unverified status, the whole form, visit and subject get an **Unverified** status.
  - Visits that don't require verification become **Verified** with just one question being verified, regardless of any unverified data.
  - Hidden questions with data classifications may also require verification. For users that are not allowed to view classified data, it may happen that a form or visit has a **Verification Required** or **Unverified** status even when they see all data within as verified. This would indicate that the data that is pending verification is classified and another user with the appropriate permissions must do it.
- A question becomes **Unverified** if it gets updated after being verified.
- A form or visit can become **Verification required** if a new question requiring verification is added to the visit, after the visit has been verified. This may happen when the following occur:
  - A completely new question is added to the form by the study designer and it is SDV required.
  - An existing question is updated to become SDV required.
  - A parent question is updated and the new answer triggers the display of a dynamic question that is SDV required, or a dynamic form with at least one question that requires verification.
- If you update the **Include Screen Failures** setting from **Yes** to **No**, screen failed subjects get excluded from the SDV subject pool and SDV is no longer required for them. Any data that was previously verified for screen failed subjects remains **Verified**, but any subsequent data changes will not impact the SDV status of the subject.

> **Note:**
>
> Questions marked as **SDV for All Subjects** remain SDV required for screen failed subjects, even when excluded.

- A subject's visits can become **Verification required** if the given subject is selected for the targeted SDV subject pool (Targeted SDV only). This can happen even after the visit has been verified or for visits that didn't have any SDV-required questions.

> **Note:**
>
> Changes to the SDV settings and SDV strategy can impact the number of subjects requiring SDV and how they are selected. For more information, see How are subjects selected for targeted source data verification?

- The number of questions requiring SDV may decrease due to changes in the SDV settings This can change the status of a visit from **Verification Required** to **Verified**.
  For other details on how your study is impacted when SDV settings change, see How do changes in Source Data Verification settings impact a study?

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.
- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.
- Configure source data verification settings for a question

Reveal a subject's treatment arm

Oracle Clinical One Platform does not automatically withdraw subjects that have been unblinded with a code view. After you reveal a subject's treatment arm, you can perform the code view as many times as necessary to retrieve the unblinding results again. This procedure also applies to rollover studies.

Show me how!

1. On the Home page, determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. Find the subject. To filter your view of subjects, enter some or part of the subject number in the **Search** field in the upper right above the table of subjects, and press **Enter**.
5. In the table, select the checkbox to the left of the subject you want to unblind.
6. Above the table of subjects, from the **Manage Subjects** drop-down, select **Code View**.
7. Click **Continue**.
8. Confirm the subject number and study name, and select the checkbox to confirm the code break.

9. Indicate whether an adverse event occurred, and click **Continue**.
10. Review the unblinding results for the subject, and click **Done**.

Transfer a subject

When a subject is transferred, the subject number doesn't change. The site that the subject is transferred to can view and edit all subject data, including data that the subject's previous site entered. The site that the subject is transferred from can no longer edit any data for the subject. This procedure also applies to rollover studies.

Are the subject's kits transferred to the new site? No. The kits either need to be reconciled at the subject's original site, or a clinical supply manager has to transfer the kits to the new site so that the receiving site can reconcile them.

Are queries associated with a subject transferred to the new site, as well? Yes, but only the open queries. If the subject you want to transfer has any open queries associated with it, these will also move to the new site along with the subject. Moreover, the open queries will show up in the reports you run for that new site.

Show me how!

1. On the Home page, determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. Find the subject. To filter your view of subjects, enter some or part of the subject number in the **Search** field in the upper right above the table of subjects, and press **Enter**.
5. In the table, select the checkbox to the left of the subject you want to transfer.
6. Above the table of subjects, from the **Manage Subjects** drop-down, select **Transfer**.
7. Fill in the fields and click **Transfer**. To view tips for completing a field, click into the field or choose an option.

> **Tip:**
>
> Before transferring a subject, clear out all data inputs that connect to the subject's former site. (Subject data or event-related reports are examples that would bound the subject to the former site). If you make edits after transferring the subject to a new site, the edits will show in the new site.

> **Note:**
>
> After transferring a subject, allow the system a 15-minute buffer time to load existing commands before making any other changes to subject data or related reports.

8. Click **Done**.

Verify that a site received a shipment

If the site received the shipment, but did not register it as received in Oracle Clinical One Platform, the site won't be able to dispense the kits in the shipment, and the site may appear to be out of stock when there are kits available at the site. This procedure also applies to rollover studies.

Show me how!

1. On the Home page, determine where to work:
   - To work with real data in Production mode, click the title of the study.
   - To work with mock data in Training mode, click the Training Mode button () on the study.
2. Along the top, click **Supplies**.
3. Below the study name, make sure the **Shipments** tab is selected.
4. From the **Site** drop-down, select a site.
5. From the **Status** drop-down, select **Received**.
6. Review the contents and dates of the shipments the site has received.
7. If you don't see the shipment you're looking for, check if the shipment is still in transit:
   a. From the **Filter by Status** drop-down on the right, select **In Transit**.
   b. If the shipment has a Tracking Number, check whether the shipment has arrived. If there is no Tracking Number, review the shipment's **Ship Date**, and contact the site outside Oracle Clinical One Platform if they should have received the shipment already.

What if a site user randomized a subject in error?

The following workflows provide suggestions for rectifying possible user errors. We recommend confirming that these measures are consistent with your organizational policies and processes.

What if a site user randomized a subject and there is no intention to treat the subject?

- Instruct the site user to withdraw the subject.

What if a site user randomized the wrong subject?
In this scenario, Subject A comes in, and the site user enters Subject A's data into Subject B's visits.

1. Instruct the site user to mark the kit dispensed to the wrong subject (Subject A) as Damaged, and to note what happened in the Reason for Change field.
2. Instruct the site user to go to the correct randomization visit for Subject A, and randomize Subject A.
3. Instruct the site user about the next steps to take for Subject B. The options include:
   - Creating a new subject record for the subject, and then completing the randomization visit.

- Asking an unblinded user, such as the clinical supply manager, to mark the randomization number that was assigned to Subject B as used in error and then manually assign a randomization number to the subject.

What if a site user accidentally randomized a subject before they were ready to randomize?

1. Instruct the site user to mark the kit initially dispensed to the subject as Damaged, and to note what happened in the Reason for Change field.
2. When the subject is ready to be randomized, instruct the site user to verify or update the values on the forms.
3. If the subject is still eligible for randomization, instruct the site user to dispense a replacement kit.

   If the subject is no longer eligible for randomization, tell the site user the next steps for the subject, such as withdrawing the subject.

Create and manage queries

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Understand query statuses
  The status of a query helps users identify whether they need to take action for that query.
- Access the Query List
  The Query List helps you investigate and work with all of the queries you have permission to view.
- Filter the Query List
  Once you have accessed the Query List, you can choose to filter the queries you have permission to view.
- Explore a query's details and history
  For an in-depth understanding of a query, you can navigate from the Query List to a page with a query's full details and history, all in one place. You can also view the question a query was submitted for, in a form.
- Work in the Query List
  The Query List allows you to manage all of the queries in a study, all in one place.
- View and monitor queries
  There are different ways to find and monitor queries. You can find queries for all subjects within a site or for a specific subject, and you can view them in the sidebar directly on the Subjects tab or within the visit containing the query. You can also view the history of a single query. This procedure also applies to rollover studies.
- Create a query
  You have three options for queries: candidate queries, which are visible only to sponsor users; assigned queries, which you can assign to specific user roles from both site and sponsor, and site queries, which are visible to and assigned only to site users. This procedure also applies to rollover studies.
- Lock a question or query
  Sponsor users can lock questions and queries to prevent users from editing subject data.

- Unlock a question or query
  Sponsor users can unlock questions and queries that have been previously locked to prevent users from modifying subject data.
- Open or delete a candidate query
  After evaluating a candidate query, you can either open the query so that it can be assigned to a site user, or you can delete the query if the query is no longer applicable. This procedure also applies to rollover studies.
- Review a query, and either close or re-open it
  After a site answers a query, you should review their answer, and then either close the query (if the answer is acceptable) or reopen the query (if the conversation with the site must continue). This procedure also applies to rollover studies.

About the Query List

The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.

Required permissions

The Query List requires the same set of permissions associated with viewing and working with queries. For more information, see Descriptions of permissions in Clinical One.

Actions available on the Query List page

What you can or cannot do on the Query List page depends on your permissions. See the table below for a full list tasks that a user can perform on the Query List page.

Table 5-1 Query List tasks overview

Feature	Description
Show all queries	All of the queries you have permission to view are listed in the Query List. These queries are also grouped according to their status. For more information on the ways you can group your queries, see Filter the Query List.
Filter queries	You can apply one or more filters to the list of queries you have permission to see. You can also sort them based on age. For more information on how to perform this task, see Filter the Query List.
View query details	In a separate page, view all of the details of a query, including its history in detail. For more information on how to perform this task, see Explore a query's history and details.
View in form	You can quickly access a question for which a query has been submitted, in order to view its answer. For more information on how to perform this task, see Explore a query's details and history.
Close and re-open a query, open a candidate query	You can close or re-open answered queries, and provide a reason for taking this action. You can also open candidate queries. For more information on how to perform this task, see Work in the Query List.

Table 5-1 (Cont.) Query List tasks overview

Feature	Description
Delete query	You can delete queries with the status of *Candidate*. For more information on how to perform this task, see Work in the Query List.

Columns included in the Query List

The Query List page displays all of the queries you have permission to view. To help you find the queries you are looking for, the following columns are available:

Table 5-2 Query List columns

Column	Description
Subject	Indicates the subject number your query is associated with.
Query	Shows the query message.
Visit	Indicates the visit for which the query has been raised. Cyclic visits indicate the visit followed by the cycle number. For example: **Week 8 Follow-Up: Group A (Cycle 3)**.
Form Name	Indicates the form to which the query was associated.
Created By	Indicates the author of the query. For queries that have been automatically opened by the system, the creator is indicated as Auto Calculation. This column is only available in the **Unresolved Queries** and **Closed** views.
Age	Indicates the age of the query, from when it was opened to the current date. Can be used to sort the list of queries in an ascending or descending order.
Status	The current status of the query. For a detailed description of each status, see Understand query statuses.

Views of the Query List

> **Caution:**
>
> Switching between views will reset any filters you have applied to your list of queries.

In order to interact with queries more efficiently, you can switch between views of your queries in the Query List based on the actions you need to perform for them. Accordingly, the following views are available:

- **To Do**: brings together all of the queries which require your action.
- **Unresolved Queries**: brings together all of the queries which you have permission to view and that do not have a status of *Closed* or *Deleted*. This view includes queries that are pending the action of other users, for which you only have viewing permission.
- **Closed**: includes all of the queries with a status of *Closed* or *Deleted* you have permission to see.

You can also use the **Search by Query Details** field to quickly narrow down your list of queries. This field searches your queries' text for the keywords you input.

> **Note:**
>
> Be aware that if you include "_" or "%" characters when searching query records, the system will show all records that contain the key words also included, as opposed to the specific string of text. For example, if you search "Site_Query_", the system returns all queries containing "Site" and "Query".
>
> We recommend using this field for all searches, instead of the **Search for Query** field, found in the queries sidebar, on a subject's page.

Filters of the Query List

> **Note:**
>
> Your filters panel may change in accordance with your view of the Query List and your permissions.

For step by step guidance on filtering the Query List, see Filter the Query List.

The table below describes the filters available in the Query List, as well as the behavior of each filter in the context of each view.

Table 5-3 Descriptions of filters in the Query List

Filter	Description	In the To Do view	In the Unresolved view	In the Closed view
Type	Allows you to select your query type, based on its author or source.	Choose one of the following options: • **Auto** • **Manual**	Choose one of the following options: • **Auto** • **Manual**	Choose one of the following options: • **Auto** • **Manual**
Status	Filter your list of queries based on one or several statuses.	Choose one or several of the following options: • **All** • **Candidate** • **Answered** • **Opened**	Choose one or several of the following options: • **All** • **Candidate** • **Answered** • **Opened**	Choose one or several of the following options: • **All** • **Closed** • **Deleted**
Age	Filter your list of queries based on the age of your queries.	Choose one of the following options: • **<7 Days** • **<14 Days** • **<30 Days** • **30+ Days**	Choose one of the following options: • **<7 Days** • **<14 Days** • **<30 Days** • **30+ Days**	Filter not available in this view.
Last Updated Date (UTC)	Filter your list of queries based on a single date when they were last updated.	Select a date in the calendar field. You can also type a date in the UTC format: DD-MMM-YYYY.	Select a date in the calendar field. You can also type a date in the UTC format: DD-MMM-YYYY.	Filter not available in this view.

Table 5-3 (Cont.) Descriptions of filters in the Query List

Filter	Description	In the To Do view	In the Unresolved view	In the Closed view
Closed On Date (UTC)	Filter your list of queries based on the date they were closed.	Filter not available in this view.	Filter not available in this view.	Select a date in the calendar field. You can also type a date in the UTC format: DD-MMM-YYYY.
Subject	Filter your list of queries based on a subject number, at a particular site.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.
Form Name	Filter your list of queries based on a form name.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.
Creator	Filter your list of queries based on the names of their creators or their roles.	Select between **Name** or **Role**, then select the form name. You can also being typing and the list will narrow down as you type.	Select between **Name** or **Role**, then select the form name. You can also being typing and the list will narrow down as you type.	Select between **Name** or **Role**, then select the form name. You can also being typing and the list will narrow down as you type.
Assigned User Role	Filter your list of queries based on the role of the assigned user. Only available for assigned queries.	Choose from a list of roles, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of roles, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Filter not available in this view.
Closed By User	Filter your list of queries based on the user who has closed the query.	Filter not available in this view.	Filter not available in this view.	Choose from a list of users, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.

Related Topics

- Understand query statuses
  The status of a query helps users identify whether they need to take action for that query.

- Access the Query List
  The Query List helps you investigate and work with all of the queries you have permission to view.
- Filter the Query List
  Once you have accessed the Query List, you can choose to filter the queries you have permission to view.
- Explore a query's details and history
  For an in-depth understanding of a query, you can navigate from the Query List to a page with a query's full details and history, all in one place. You can also view the question a query was submitted for, in a form.
- Work in the Query List
  The Query List allows you to manage all of the queries in a study, all in one place.
- Descriptions of permissions in Clinical One Platform

Understand query statuses

The status of a query helps users identify whether they need to take action for that query.

Required permissions

For more information about the permissions required to view and work with queries with particular statuses, see Descriptions of permissions in Clinical One Platform.

Query statuses explained

Table 5-4 Query statuses

Status	Description
Opened	A query that has been viewed by a user, but has not yet had any work performed on it.
Candidate	A query that is only visible to sponsor users. Used whenever a query requires internal review before assigning it to a site.
Answered	A query that has received an answer from the site it is assigned to. Sponsor users can choose to either re-open or close the query.
Closed	A query that has either been closed by a sponsor user or has been closed automatically based on subject data update.
Deleted	A candidate query that has been marked for deletion by a sponsor user.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Descriptions of permissions in Clinical One

Access the Query List

The Query List helps you investigate and work with all of the queries you have permission to view.

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. At the top of the Subjects page, select **Query List**.

> **Tip:**
>
> Whenever you are working in Production, you can select the Queries icon ( ), on the Study List page, to navigate directly to the list of queries.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.

Filter the Query List

Once you have accessed the Query List, you can choose to filter the queries you have permission to view.

Before you start working with the filters panel, you can start by checking an overview of all the ways the Query List makes it easier for you to identify and work with queries. To do so, see About the Query List.

1. Access the Query List in the study mode you need to work in. For step-by-step instructions, see Access the Query List.
2. Select the view that is most suitable for your work:
   - **To Do**
   - **Unresolved Queries**
   - **Closed**

> **Caution:**
>
> Switching between views will reset any filters you have applied to your list of queries.

3. Select the **Filter** button at the top of the list of queries.
4. Configure your filters as necessary, then select **Apply**. For a list of available filters, see Table 5-3.

> **Tip:**
>
> to reset your filters, select **Clear All**.

5. Optional: In the **To Do** and **Unresolved Queries** views, you can also sort your list based on the **Age** of your queries.

Explore a query's details and history

For an in-depth understanding of a query, you can navigate from the Query List to a page with a query's full details and history, all in one place. You can also view the question a query was submitted for, in a form.

When viewing the details of a query, you can also view its full, consolidated history in the sidebar on the right. A query's history lists all related events, with the most recent event at the top: when the query was last updated and the author of the update, the query's author and the date of its creation, their roles, as well as any information added by users.

Whenever your access a query's details page, the following sections are available:

Table 5-5 Descriptions of sections

Section	Notes
Query description	N/A
Query title	N/A
Original query text	N/A
Query status	N/A
Visit label	If applicable, this section also displays the query's cycle number.
Form label	If applicable, this section also displays the instance of the form the query is associated with.
Target question label	N/A
Assigned to roles	Only available for assigned queries.
Rule name	Only available for automatically-generated queries.

To access a query's details page, follow these steps

1. Access the Query List in the study mode you need to work in. For step-by-step instructions, see Access the Query List.
2. Filter your query list as needed. For more information on how to perform this task, see Filter the Query List.
3. Select the **Actions** button on the right of the row of your query, then select **View Query**.
4. To navigate to the query's source question, select **View In Form** above the History panel.
5. Optional: Once you have finished viewing the form, you can select **Return to Query Details** or navigate elsewhere.

> **Note:**
>
> Any filters you have applied to your list of queries will remain unchanged whenever you navigate to the Query Details page or the form associated with the query, then back to the list.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.

Work in the Query List

The Query List allows you to manage all of the queries in a study, all in one place.

The actions you can perform in the Query List depend on your permissions. For more information, see Descriptions of permissions in Clinical One.

1. Access the Query List in the study mode you need to work in. For step-by-step instructions, see Access the Query List.
2. Filter your query list as needed. For more information on how to perform this task, see Filter the Query List.
3. Locate the query you want to manage and select the **Actions** to the right of your query. Depending on the status of the query, the following options are available:

> **Note:**
>
> When working in the **Closed** view, every query displays a **View** button instead of the Actions button. Select View to go to a query's details and history. For more information, see Explore a query's details and history.

Table 5-6 Query statuses and actions

Query status	Available actions
Answered	• **View Query**: takes you to the query's details and history page. • **Re-open**: re-open the query if additional information is required. • **Close**: marks the query as **Closed**, indicating no further information is necessary.
Candidate	• **View Query**: takes you to the query's details and history page. • **Open**: marks the candidate question as having been opened, making it visible to site users. • **Delete**: deletes the candidate query.
Opened	• **View Query**: takes you to the query's details and history page. • **Close**: marks the query as **Closed**, indicating no further information is necessary.
Deleted	• **View**: takes you to the query's details and history page.

4. When you close or delete a query, or decide to open a candidate query, you are prompted to type a justification.

a. On the new dialog, enter your comment and select **Submit**.

b. You may also select **Cancel** to start again.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Understand query statuses
  The status of a query helps users identify whether they need to take action for that query.

View and monitor queries

There are different ways to find and monitor queries. You can find queries for all subjects within a site or for a specific subject, and you can view them in the sidebar directly on the Subjects tab or within the visit containing the query. You can also view the history of a single query. This procedure also applies to rollover studies.

> **Tip:**
>
> For more efficient query management, we recommend using the Query List instead. For more information, see About the Query List.

Show me how!

1. On the Home page, determine where to work. For more information, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. Access a query through the Queries sidebar:

   You can do this at this point from the Subjects screen or within a visit. Look for visits that are displayed in red and marked with an Open Queries icon (

) and click to open.

   a. On the right side pane, expand **Queries**.

      If you do this from the Subjects screen filtered by site, all queries for all site subjects will display. Select a subject to view queries related to a single subject.

      > **Tip:**
      >
      > You can type in to search for a query or filter them by status.

   b. Click on a query item to expand its details.

   c. Click the Menu icon () and from the drop-down select **View**.

   The system will take you into the form, directly to the question containig the query. Within a visit, you can also scroll through the forms, questions with Open or Answered queries will be highlighted in red.

> **Note:**
>
> There is a text length limit of 2048 characters. However, if the query message is longer than 1068 characters it will display partially and you will need to use the sidebar to view the full text.

5. To view the history of a query:
   a. Click anywhere on the item with the query as to perform any action.
   b. On the right, expand **Answer & Visit History**, and review. Recent activity appears first.
   c. Numeric ordering tags are dynamically assigned to queries and display for each query-related action in the **Answer & Visit History** sidebar.

> **Note:**
>
> The numeric ordering tags are dependent on which queries a user can view; the same query may display a different number to different users if they have different permissions.

If an item with an open or answered query becomes unavailable through the UI, either the question gets removed from design or hidden by user's action, you will not be able to **View** it or manage it directly from the form. Review queries and manage them directly from the **Queries** sidebar using the menu options as described in Open or delete a candidate query and Review a query, and either close or re-open it.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Access the Query List
  The Query List helps you investigate and work with all of the queries you have permission to view.

Create a query

You have three options for queries: candidate queries, which are visible only to sponsor users; assigned queries, which you can assign to specific user roles from both site and sponsor, and

site queries, which are visible to and assigned only to site users. This procedure also applies to rollover studies.

Tip:

- To view the history of queries on a question, select the question, and expand **Answer & Visit History** on the right.
- Numeric ordering tags are dynamically assigned to queries and display for each query-related action in the **Answer & Visit History** sidebar.

  Note:

  The numeric ordering tags are dependent on which queries a user can view; the same query may display a different number to different users if they have different permissions.

- To see all queries, return to the Subjects page, and expand **Queries** on the right.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, determine where to work. For more information, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. Locate a subject in the table, and click a visit in the Previous Visits column.
5. Review the data entered for the visit by scrolling down the forms.
6. Point to a question, and click the gray question mark ( ) that appears to the right of the answer. You can create a query for any type of question: text, number, date/time, drop-down, age, rollover, coding, and question groups.

   Note:

   You cannot raise queries against virtual (not yet started) repeating forms.

   Can't see the gray question mark?

   A red background appears behind the question, and query details appear below the question.
7. On the left, enter the query text.
8. On the right, below Type, choose the type of query to create:
   - **Site Query**: Assign the query to the site.
   - **Assigned Query**: Assign the query to a specific user role.

> **Note:**
>
> The query will be visible to all users with that given role that have the permission to view this new type of query, but only the users with the permission to answer a query will be able to also update the query.

- **Candidate Query**: Create a query that is only visible to sponsor users. Use this query when you want to review a query internally before assigning it to the site.

> **Tip:**
>
> After completing the review, you can either delete it or change the query to an open query, so that it will be assigned to the site.

9. If you chose **Assigned Query**, click the field below **Roles** and from the drop-down list select the user roles that should get notified about the query.

> **Note:**
>
> The **Roles** drop-down list contains only the study roles that have been created in the study. The template study roles are not included in the list.

10. Click **Save**.
11. In the lower-right corner of the form, click either **Save** (to keep the visit open) or **Save & Close** (to return to all subjects).

    The query is created.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.

Lock a question or query

Sponsor users can lock questions and queries to prevent users from editing subject data.

Sponsor users assigned the *Lock Subject Data Entered at a Site* permission have the ability to lock questions and queries to disallow other users from modifying that subject's data.

> **Tip:**
>
> If the item's data you would like to lock has been previously cleared, it may be necessary to refresh the page to view the **Lock** option in the menu.

Use the following procedure to lock a query:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.

2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Select a visit with open queries.
5. On the Visit screen, click the **Lock Data** drop-down and select **Lock**.
6. Choose one of the following:
   - The checkbox next to the question or form that you would like to lock.
   - The checkbox next to **Forms** in the Forms side panel to lock the entire visit.
7. In the Lock Data dialog, select **Lock** to confirm you would like to lock the question.

   A lock icon () appears next to the query.

Related Topics

- Unlock a question or query
  Sponsor users can unlock questions and queries that have been previously locked to prevent users from modifying subject data.

Unlock a question or query

Sponsor users can unlock questions and queries that have been previously locked to prevent users from modifying subject data.

Sponsor users provided with the *Lock Subject Data Entered at a Site* permission have the ability to unlock queries that were locked in order to prevent other users from updating that subject's data.

> **Tip:**
>
> If the item's data you would like to unlock has been previously cleared, it may be necessary to refresh the page to view the **Unlock** option in the menu.

Use the following steps to unlock a query:

1. Determine in which mode you need to work. For step-by-step instructions, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site. For step-by-step instructions, see Filter subjects in a study.
4. Select a visit with locked queries.
5. On the Visit screen, click the **Unlock Data** drop-down and select **Unlock**.
6. Choose one of the following:
   - The checkbox next to the question or form that you would like to unlock.
   - The checkbox next to **Forms** in the Forms side panel to unlock the entire visit.
7. In the Unlock Data dialog, choose an option from the **Reason for Change** drop-down, then select **Unlock**.

The Unlocked icon () appears next to the query.

8. Select **Save & Close**.

Open or delete a candidate query

After evaluating a candidate query, you can either open the query so that it can be assigned to a site user, or you can delete the query if the query is no longer applicable. This procedure also applies to rollover studies.

> **Tip:**
>
> For more efficient query management, we recommend using the Query List instead. For more information, see About the Query List.

1. On the Home page, determine where to work. For more information, see Access your study in a specific mode.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. On the right side pane, expand **Queries** to open the Queries sidebar.
5. From the filter at the top of the list of queries and on the right, select **Candidate**.
6. Find the query in the list, and click on it to expand its details.
7. Click the **Menu** icon () and select one of the following options:

> **Note:**
>
> If an item with an open or answered query becomes unavailable through the UI, either the question gets removed from design or hidden by user's action, you will not be able to **View** it or manage it directly from the form. Choose **Delete** from the menu options to close it directly from the sidebar instead.
> Keep in mind that, considering the same scenario, if you choose to **Open** the query it is still going to be inaccessible through the UI.

- **View**: This option will take you directly to the item in the form containing the query as described in View and monitor queries. From this point you can take action as described in the next step.
- **Open**: This option opens the query for site users.
  A Comment for Site Query dialog will open. Enter a comment and click **Open Query**.
- **Delete**: This option deletes the candidate query.
  A Comment to Delete Query dialog will open. Enter a comment and click **Delete Query**.

8. If you choose to view a query in a form, or access the query directly within the visit, click one of the following to take action:

> **Note:**
>
> If there are two or more queries on the question, click the **Actions** button, and from the drop-down choose either **Open** or **Delete**.

- **Open** to open the query for site users.
- **Delete** to delete the candidate query.

9. Then enter a comment and click **Submit**.

Deleted queries get removed from the question, but the record of each can be accessed through **Answer & Visit History** on the right side pane within the visit.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Work in the Query List
  The Query List allows you to manage all of the queries in a study, all in one place.

Review a query, and either close or re-open it

After a site answers a query, you should review their answer, and then either close the query (if the answer is acceptable) or reopen the query (if the conversation with the site must continue). This procedure also applies to rollover studies.

> **Tip:**
>
> For more efficient query management, we recommend using the Query List instead. For more information, see About the Query List.

Show me how!

1. On the Home page, determine where to work. For more information, see About the Query List.
2. Along the top, make sure **Subjects** is selected.
3. From the **Site** drop-down, select a site.
4. In the lower right, expand **Queries**.
5. From the status filter at the top of the list of queries and on the right, select **Answered**.
6. Find the query in the list, and click on it to expand its details.
7. Click on the menu icon ( ) and select one of the following options:

> **Note:**
>
> If an item with an open or answered query becomes unavailable through the User Interface (UI), either the question gets removed from design or hidden by user's action, you will not be able to **View** it or manage it directly from the form. Choose **Close** from the menu options to close it directly from the sidebar instead. Keep in mind that, considering the same scenario, if you choose to **Re-Open** the query it is still going to be inaccessible through the UI.

- **View**: This option will take you directly to the item in the form containing the query as described in View and monitor queries. From this point you can take action as described in the next step.
- **Re-Open**: This option re-opens the query for site users to continue the conversation. A Comment to Re-Open Query dialog will open. Enter a comment and click **Re-open Query**.
- **Close**: This option closes the query.
  A Comment to Close Query dialog will open. Enter a comment and click **Close Query**.

8. If you choose to **View** the query in the form, or access the query directly within the visit, review the answer provided by the site and take appropriate action:
   - If the issue identified in the query is resolved, click **Close Query** , add a comment and **Submit**.
     The status of the query changes to Closed. Closed queries appear in the Queries section with a green check mark.
   - If the issue identified in the query is not resolved, click **Re-Open**, add a comment and **Submit**.
     The status of the query changes back to Open.

Related Topics

- About the Query List
  The Query List allows you to view and work on all of the queries in your study. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and depending on the statuses of the queries and your permissions, perform actions on your queries, all in one place.
- Work in the Query List
  The Query List allows you to manage all of the queries in a study, all in one place.

Perform kit reconciliation

- Verify returned kits to confirm site reconciliation
  After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.
- Mark kits as ready for destruction at the site or at a depot
  If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.
- Complete a drug reconciliation form
  Complete a drug reconciliation form as part of the process to mark kits for destruction in drug-destruction facilities. Use this form to keep track of drug reconciliation as you mark your kits for destruction.

- Complete a drug reconciliation form for kits already sent for destruction
  If a site is not drug-destruction capable, a shipment to a drug-destruction facility is automatically generated when you mark kits as ready for destruction. Complete this form for those shipments and use it to keep track of drug reconciliation for kits which have already been marked for destruction.
- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.
- Mark kits as destroyed
  Mark kits as destroyed in accordance with the protocol and any applicable SOPs. This procedure also applies to rollover studies.

Verify returned kits to confirm site reconciliation

After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.

Before you can perform this task the site user must have set the kits as **Retured to site**. Refer to Update a kit that a subject returned, and reconcile kits.

> **Note:**
>
> If a site user later updates a kit that has been verified, the green verified checkbox is removed, and you must verify the kit again.

Want to see how to perform this task? Watch the video below.

Video

1. Access the Site Inventory tab
2. From the **Site** drop-down, select a site.
3. Filter kits in a site's inventory.
4. On the CRA Verified column, select a kit that has a gray checkbox ( ).
5. On the Inventory Management side panel, verify that site reconciliation is correct.
   - If site reconciliation is correct, click the gray checkbox (( ))in the CRA Verify column. The checkbox turns green ( ).
   - If site reconciliation isn't correct, on the Inventory Management side panel, click **Update Kit** and update as necessary.

Next, you can now mark kits for destruction. For more information, see Mark kits as ready for destruction at the site or at a depot.

Related Topics

- Mark kits as ready for destruction at the site or at a depot
  If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.

- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.
- Kit reconciliation FAQs

Mark kits as ready for destruction at the site or at a depot

If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.

> **Note:**
>
> Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.

Want to see how to perform this task? Watch the video below.

Video

You must verify all kits that were returned to the site. For more information, see Verify returned kits to confirm and correct site reconciliation.

1. Access the Site Inventory tab
2. From the **Site** drop-down, select a site.
3. Use the **Status** drop-down to filter the view so you see only the kits that are ready for destruction. For example, you might select all statuses except Available, Dispensed, In Transit, and Missing, though you might select Available if the site is shut down.

   For more information, see Filter kits in a site's inventory.
4. Select the kits that are ready for destruction.
5. On the **Inventory Management** side panel, click **Update Kits**.
6. From the **Kit Status** drop-down, select **Pending Destruction**.
7. Enter the number of **Total Returned Units** and **Total Missing Units** in the fields.

   > **Note:**
   >
   > If you cannot see these fields, reach out to your clinical supply manager and make sure Kit Reconciliation is set as required when you Specify supply settings.
8. Enter a **Reason For Change** in the text box.
9. Depending on your study configuration, click the available option to update
   - **Update & Open Form**: This option is available when a drug reconciliation form exists and the current site is drug-destruction capable. Clicking this updates the kits status and opens the drug reconciliation form for you to complete it. See Complete a drug reconciliation form.
     Next step for a drug-destruction facility would be to destroy kits and Mark kits as destroyed.
   - **Update & Ship Kits**: This option is available for sites that are not drug-destruction capable. Clicking this updates the kits and generates the shipment.

For the next step you are redirected to the shipments page to Complete a drug reconciliation form for kits already sent for destruction (if applicable) and Ship kits to a drug destruction depot .

If the depot that sent the kits to the site is drug destruction capable, the kits are sent back to that depot.

If the depot that sent the kits isn't drug destruction capable, the kits are sent to the depot that is marked as a drug destruction facility and that is associated with the country that the site is in.

If multiple drug-destruction depots ship kits to a site, you can choose the destination depot. From the **Send Option** drop-down, select either:

- **Send back to a supply depot**
- **Send to a destruction facility** and select the destruction facility from the drop-down.

Shipments are created based on the temperature requirements for the kits. For example, if you mark a refrigerated kit and a frozen kit as Pending Destruction, one shipment is created for the refrigerated kit, and another shipment is created for the frozen kit. If the return shipments don't have temperature requirements, consider combining multiple packing lists in one shipment.

Related Topics

- Verify returned kits to confirm site reconciliation
  After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.
- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.
- Mark kits as destroyed
  Mark kits as destroyed in accordance with the protocol and any applicable SOPs. This procedure also applies to rollover studies.
- Kit reconciliation FAQs

Complete a drug reconciliation form

Complete a drug reconciliation form as part of the process to mark kits for destruction in drug-destruction facilities. Use this form to keep track of drug reconciliation as you mark your kits for destruction.

The drug reconciliation form is considered a report in Oracle Clinical One Platform studies. Like any standard report, it is auto-purged at 120 days old. For more information, see About standard reports.

> **WARNING:**
>
> You should not **Resend** an auto-purged drug reconciliation form, as it will be resent to the depot. Applicable details for an auto-purged form are still available on the **Shipment Details** right-side panel in the user interface, even after the system deletes a form.

Complete a drug reconciliation form

1. Update the kit status to **Pending Destruction** as described in Mark kits as ready for destruction at the site or at a depot.
2. Enter a reason, then select **Update Kits & Open Form**.

> **Note:**
>
> If the destination site for the kits you are performing drug reconciliation for does not have the capability to destroy kits, you will see **Update & Ship Kits** instead. This option updates the kits and generates a shipment to a drug destruction facility. In this case, refer to Complete a drug reconciliation form for kits already sent for destruction.

3. Complete the fields of the form as necessary.
4. Click either **Save** or **Save & Close**.

Related Topics

- Mark kits as ready for destruction at the site or at a depot
  If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.
- Verify returned kits to confirm site reconciliation
  After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.
- Complete a drug reconciliation form for kits already sent for destruction
  If a site is not drug-destruction capable, a shipment to a drug-destruction facility is automatically generated when you mark kits as ready for destruction. Complete this form for those shipments and use it to keep track of drug reconciliation for kits which have already been marked for destruction.
- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.
- Mark kits as destroyed
  Mark kits as destroyed in accordance with the protocol and any applicable SOPs. This procedure also applies to rollover studies.
- Kit reconciliation FAQs
- Who is responsible for each step in the kit reconciliation process?
  The workflow is flexible so that you can opt to use the parts that are required for the protocol and any relevant SOPs. All of these steps are available in Oracle Clinical One Platform when you require kit reconciliation, but they're not required.

Complete a drug reconciliation form for kits already sent for destruction

If a site is not drug-destruction capable, a shipment to a drug-destruction facility is automatically generated when you mark kits as ready for destruction. Complete this form for

those shipments and use it to keep track of drug reconciliation for kits which have already been marked for destruction.

The drug reconciliation form is considered a report in Oracle Clinical One Platform studies. Like any standard report, it is auto-purged at 120 days old. For more information, see About standard reports.

> **WARNING:**
>
> You should not **Resend** an auto-purged drug reconciliation form, as it will be resent to the depot. Applicable details for an auto-purged form are still available on the **Shipment Details** right-side panel in the user interface, even after the system deletes a form.

Complete a drug reconciliation form

1. On the Home page, select the study you would like to work on. For more information, seeAccess your study in any mode.
2. Along the top of the page, select **Supplies**.
3. Below the study name, select the **Shipments** tab.
4. Filter your view for kits with a status of *Pending destruction.*
5. In the table, check the boxes of the kits you would like to appear on your drug reconciliation form.

> **Note:**
>
> Only users with the appropriate permission will be able to see and select unblinded pharmacist kits. For more information on permissions, see Descriptions of permissions in Clinical One.

6. Select **Order Forms**, then **Drug reconciliation form**.
7. Complete the fields of the form as necessary.
8. Click either **Save** or **Save & Close**.

Related Topics

- Mark kits as ready for destruction at the site or at a depot
  If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.
- Verify returned kits to confirm site reconciliation
  After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.
- Complete a drug reconciliation form
  Complete a drug reconciliation form as part of the process to mark kits for destruction in drug-destruction facilities. Use this form to keep track of drug reconciliation as you mark your kits for destruction.
- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.

- Mark kits as destroyed
  Mark kits as destroyed in accordance with the protocol and any applicable SOPs. This procedure also applies to rollover studies.
- Kit reconciliation FAQs
- Who is responsible for each step in the kit reconciliation process?
  The workflow is flexible so that you can opt to use the parts that are required for the protocol and any relevant SOPs. All of these steps are available in Oracle Clinical One Platform when you require kit reconciliation, but they're not required.

Ship kits to a drug destruction depot

If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

First, you must update the status of all kits that are ready for destruction. For more information, see Mark kits as ready for destruction at a site or depot.

1. Below the study name, make sure the **Shipments** tab is selected.
2. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
3. From the **Filter by Status** drop-down, select **Pending Destruction**.
4. Select a shipment.
5. On Shipment Details side panel, click **Download List of Kits**.

   > **Tip:**
   >
   > Consider printing the report so you know the receiving depot and so you can include the report as a packing list.

6. Fulfill the shipment outside Oracle Clinical One Platform.
7. To add a ship date and tracking number after the shipment departs the site:
   a. Under the **Ship Date** column, click the **Click to Add** link, and select the correct date from the calendar drop-down.
   b. In the Tracking Number column, click the **Click to add** link of the shipment you added a ship date to.

      > **Tip:**
      >
      > You can add tracking information to any shipment at any time. Adding this information is optional.

   c. Fill in the fields and click **Save**.

The depot can destroy the kits according to applicable requirements.

Related Topics

- Kit reconciliation FAQs

Mark kits as destroyed

Mark kits as destroyed in accordance with the protocol and any applicable SOPs. This procedure also applies to rollover studies.

> **Note:**
>
> - Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see Allowed updates for inventory status.
> - If the study allows titration, don't mark the last kits that were dispensed as destroyed until a subject receives their next kits.

Want to see how to perform this task? Watch the video below.

Video

1. Access the Study Inventory tab.
2. Click a kit type.
3. Above the kit list, from the Status drop-down, select **Pending Destruction**.
4. In the list, select the kits you want to mark as destroyed.
5. On the right, make sure **Kit Settings** is expanded.
6. Under Kit Settings, from the **Status** drop-down, select **Destroyed**.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change, and click **Yes**.
9. Update kits of other kit types as needed.

Related Topics

- Mark kits as ready for destruction at the site or at a depot
  If the study requires kit reconciliation and the site is drug destruction capable, you must mark the kits as ready for destruction. This procedure also applies to rollover studies.
- Verify returned kits to confirm site reconciliation
  After a subject returns a kit to a site and the site user reconciles the kit, you verify the kits. This procedure also applies to rollover studies.
- Ship kits to a drug destruction depot
  If the study requires kit reconciliation and a site isn't drug destruction capable, you must send the kits to a depot for destruction. This procedure also applies to rollover studies.
- Kit reconciliation FAQs

Run and download a report, data extract, or archive

As a sponsor user, you can typically run a multitude of standard reports and Oracle CRF Submit archives, as well as extract subject data.

With the appropriate permissions assigned to you, you can:

- Run and download standard reports, such as the Study Design report or the Minimization List report, for example.
- Schedule standard reports to run automatically.
- Add customized fields to the Subject Events report.
- Run and download the Subject Data Extract.
- Generate and download Oracle CRF Submit archives and reports.

For step-by-step instructions on how to perform all of these tasks, see the Reporting Guide.

6

Archive a study version, decommission and recommission a study

- Close enrollment for a country or study
  If you close enrollment for a country, sites in the country won't be able to add new subjects or randomize subjects who were already added. If you close enrollment for a study, no subjects can be added or randomized. This procedure also applies to rollover studies.
- Archive a study version
  Archive a study version when you no longer need the study version, such as if you found an issue during verification, or when sites are no longer using it because they have switched to a newer study version. This procedure also applies to rollover studies.
- Delete a study
  You can delete a study in the Draft or Archived build phases if no study design objects have been defined, meaning a study was created, possibly in error and no one edited the study or added any design objects, for example, forms, kits or visits.
- Revoke a user's access to the study
  If a person's role has changed, or if the person no longer needs access to the study, you can revoke the person's access to a study. This procedure also applies to rollover studies.
- Retire a depot at the study level
  You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.
- Retire a site at a study level
  Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.
- Decommission a Production study
  Review the details below to familiarize yourself with some reasons for decommissioning a study and the necessary steps.
- Decommission other studies
  Certain customer environments contain non-production studies that may require decommissioning.
- Recommission a study
  Scenarios may arise that require your organization to review or action study data in the Oracle Clinical One Platform after study decommissioning. Reach out to your Oracle point of contact for information about recommissioning a study.

Close enrollment for a country or study

If you close enrollment for a country, sites in the country won't be able to add new subjects or randomize subjects who were already added. If you close enrollment for a study, no subjects can be added or randomized. This procedure also applies to rollover studies.

1. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Study Settings** tab.
3. Along the top, select **Testing Settings**.
4. To close enrollment for the study:
   a. Below Enrollment Settings, locate the Study Total row.
   b. To the left of Study Total, click the toggle so that the color of the toggle changes from blue to gray and the circle moves from the right to the left.
5. To close enrollment for a country:
   a. Below Enrollment Settings, locate the row for the country.
   b. To the left of the country name, click the toggle so that the color of the toggle changes from blue to gray and the circle moves from the right to the left.

Archive a study version

Archive a study version when you no longer need the study version, such as if you found an issue during verification, or when sites are no longer using it because they have switched to a newer study version. This procedure also applies to rollover studies.

Show me how!

1. Make sure that there are no sites assigned to the study version:
   a. On the Home page, click **Study Settings** () on the study you want to edit, and select **Open Settings**.
   b. Below the study name, click the **Sites** tab.
   c. In the table, review the Study Version column for Production, Testing, and Training modes, and make sure that no sites are using the study version that you want to archive:
      - If the study version you are archiving is assigned to a site, and the study is ending, remove the site from the study version and then retire the site.
      - If the study version you are archiving is assigned to a site, and the sites are moving to a new study version, assign the sites to a new study version.
      - If the study version you are archiving isn't assigned to any sites, proceed to the next step.
   d. In the upper right, click **Home**.
2. On the Home page, click the **Edit icon** () on the study.
3. Locate the study version that you want to archive, and drag it to **Archived**.

Tip:

Managing multiple study versions?

- You can move an archived study version back to Approved, but only if the study version was previously approved.
- If a study version contains mistakes—for example, a typo on the name of a form—it's a good idea to archive the study version so that no sites are assigned to it accidentally.
- You might want to rename the Archived version to something like RETIRED - V1 DESIGN to make it clear that it isn't meant for use.

  To rename a study version, click the pencil button on the study (). Click the menu button () on the study version, and select **Rename**. You can change the name of the study version, but not the version number.

Delete a study

You can delete a study in the Draft or Archived build phases if no study design objects have been defined, meaning a study was created, possibly in error and no one edited the study or added any design objects, for example, forms, kits or visits.

The **Delete Study** option appears under **Study Settings** if the above criteria are met, if not the **Delete Study** option is grayed out.

To delete a study that no one has worked in:

1. On the Home page, click the study settings button () for the study you want to delete, and select **Delete Study**.
2. In the confirmation window, click **Yes**.

Revoke a user's access to the study

If a person's role has changed, or if the person no longer needs access to the study, you can revoke the person's access to a study. This procedure also applies to rollover studies.

1. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Users** tab.
3. Select the user whose access you want to revoke.
4. From the **Manage Users** drop-down, select **Edit**.
5. On the first page of the wizard, modify the user's **Effective Date Range** to the appropriate date.

   The user can no longer see the study on their Home page.
6. In the lower right, click **Next**.
7. Click **Finish**, and then click **Close**.

Retire a depot at the study level

You may retire a depot because you changed distribution vendors for the study or because the depot was activated in error and you want to prevent depot users from accessing the study. Automatic shipments are stopped after a depot is retired.

> **Tip:**
>
> Do you want to retire a depot at the global level so that it can no longer be used by any study at your organization? For step-by-step instructions, see Retire a depot at a global level.

You can switch a retired depot back to Active at any time.

1. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
2. Click the **Depots** tab.
3. Along the top of the screen, make sure **Production Depots** is selected.

   > **Tip:**
   >
   > You're not required to retire Testing or Training depots.

4. Select one or more depots.
5. From the **Manage Depots** drop-down, select **Retire**.
6. In the Confirmation window, confirm the name of the depot, select the **Retire the depot?** checkbox, and click **Yes**.

Related Topics

- Activate a depot
  You must activate a depot in Testing mode to be able to test your study. Activate depots in Production mode to begin distribution in a live study. If you activated a depot in error, or if a depot is no longer active, mark the depot as retired. You can activate a retired depot at any time. This procedure also applies to rollover studies.
- Assign a resupply strategy to a depot
  When you create a depot that can supply other depots with kits, you can specify a resupply strategy for the receiving depot so the depot always has the appropriate number of kits.
- Release kits to sites or depots
  Release kits to a depot in Testing mode so that the kits are associated with the depot and you can begin testing distribution in Testing mode. Release kits to a depot in Production mode to begin distribution and in Training mode to practice. This procedure also applies to rollover studies.
- Edit a depot at a study level
  You can modify certain details of a depot at the study level
- Delete a depot at a study level
  If necessary, a study-level depot can be deleted by a sponsor or CRO user.

- Create and manage institutions, vendors, and contacts
- Site, depot, labs, and source data verification FAQs

Retire a site at a study level

Retire a site when the site stops participating in the study, when the study ends, or when a site was activated in error. In a retired site, site users can only view data, run reports, and perform code breaks.

> **Tip:**
>
> Do you want to retire a site at the global level so that it can no longer be used by any study at your organization? For step-by-step instructions, see Retire a site at a global level.

You can switch a retired site back to Active at any time. For more information, see Verify that a site has been activated.

Work with the Principal Investigator (PI) at the site to make sure that they've downloaded all of their end-of-study reports. For more information, see Decommission a Production study.

> **Note:**
>
> If you're retiring sites because the study is ending, make sure that you repeat these steps for all sites in each mode at a study level. You won't be able to archive a study version if any sites are assigned to it.

1. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
2. Click **Sites & Labs**.
3. Along the top, select the study mode that is appropriate: **Production Sites**, **Testing Sites**, or **Training Sites**.
4. In the table, locate the site to retire and, from the **Study Version** drop-down, select **Select Study Version**.
5. Select the site you want to retire and click **Manage Sites**.
6. From the drop-down, select **Retire**.
7. In the Confirmation dialog, select **Yes, I want to retire the site**.
8. Click **Yes**.
9. In the upper right, click **Apply Changes**.

The site is no longer assigned to a study version. Removing sites from a study version as you retire them ensures that you can archive the study version when the study conduct period is over.

Decommission a Production study

Review the details below to familiarize yourself with some reasons for decommissioning a study and the necessary steps.

When should a study be decommissioned?

- During the renewal process, you determined that a study is no longer needed.
- The study conduct period ended as planned, and you no longer require access to the study or its data through the Oracle Clinical One Platform user interface.
- The study conduct period ended sooner than expected, and you no longer require access to the study or its data through the Oracle Clinical One Platform user interface.

There are three steps in the process of decommissioning a study. First, confirm you have access to generate reports and archives, generate and download them, and finally initiate the decommissioning process.

1. **Confirm you have access to generate and download reports and archives.**
   a. Log in to Oracle Clinical One Platform.
   b. Locate the study that is to be decommissioned and open a study's settings. See Open the study settings.
   c. Select the **Users** tab.
   d. On the Users tab, select your user. Select **Manage Users**, then select **Edit**.
   e. On the Edit User dialog, the Details & Roles section, confirm that you are assigned the *View Only for Unblinded Support Users* study role in Production Mode.
   f. Select **Next** and, on the Sites & Depots section, confirm that all sites and depots are assigned to you.

      > **Note:**
      >
      > If you need your assignments updated, contact your delegated administrator.

   g. If you need to decommission multiple studies, repeat this process for each study.
2. **Generate and download the final reports and archives.**

   It is the customer's obligation to retrieve all necessary study data before the end of the Services Period.

   Generate and download the necessary reports and archives before contacting Oracle to initiate decommissioning. For more information about reports and archives, see the Reporting Guide.

   > **WARNING:**
   >
   > You cannot generate reports and archives in the Oracle Clinical One Platform user interface approximately seven to ten (7 to 10) days after Oracle initiates the decommissioning process.

   a. From the Home page, open the study, then select the **Reports & Archives** page.

b. Select and generate each end-of-study report and archive you require for decommissioning a study.

   For more information, see Standard reports and Available archive types and reports in the *Reporting Guide*.

c. To include all required information in the output, select a date range comprising the study's beginning and ending dates.

d. Generate the output for each report and archive, then save the output (in a CSV and PDF format) to a secure location.

3. **Request to have a study decommissioned.** You can do either one of the following:

- Decommission a single study that is part of a **single study order**:

  a. The customer initiates the process by informing their sales contact that they are not renewing the contract or are requesting early study termination.
  Oracle requires advanced notice for studies terminated earlier than expected. Your contract includes the notification period required. The decommissioning process starts once the notification period ends.

  b. After being contacted, the sales team initiates the decommissioning process.
  When decommissioning a study, the first step is to delete all previously generated study-level standard reports from all modes. Removing this large volume of historical reporting data minimizes the possibility of issues when exporting the study.

  > **Note:**
  >
  > This step includes the Drug Order and Drug Reconciliation forms, which are considered reports in Oracle Clinical One Platform studies.

  This process does not include the following global-level reports: the Global Study Roles report, the Life Sciences Learn Training Report, the Study Roles Report by Study, and the User Assignment Across Studies report.

  c. Oracle places a copy of the study data in a pluggable database (PDB) package, consisting of one .DMP file, on the Oracle sFTP server and notifies the customer's primary study contact that the PDB package is ready for retrieval.
  The primary study contact must retrieve the package within 60 days of Oracle's initial notification. The primary contact receives reminders seven (7) days and twenty-four (24) hours before deleting the study.

  > **Note:**
  >
  > Reach out to your Oracle point of contact if you do not know the primary contact, want to change it, or need other assistance.

  d. After 60 days, Oracle deletes the study data and its components from the Oracle server. This final step completes the decommissioning process.

- Decommission a single study that is part of a **multi-study capacity order**:

Table 6-1 Study decommission - multi-study capacity order

Study type	Owner & Responsibilities
Oracle-built study	The **customer** initiates the process by informing their sales contact that they are not renewing the contract or are requesting early study termination. ***Note**: Oracle requires advanced notice for studies terminated earlier than expected. Your contract includes the notification period required. The decommissioning process starts once the notification period ends*. After being contacted, sales initiates the decommissioning process. For details about what happens after sales initiates the process, refer to steps c. and d. above in section 3. Request to have a study decommissioned.
Customer-built studies	The **customer** creates the Change Request (CR) to initiate the decommissioning process. ***Note**: For information about creating a CR, see* LSGBU Support Cloud Guide for Change Requests. If you encounter issues with the link above, log into Oracle Life Sciences Support Cloud. In the upper-left corner of the page, select the Menu icon, then select **Documents & Request Forms**. For details about what happens after creating the CR, refer to steps c. and d. above, in section **3. Request to have a study decommissioned**.

Decommission other studies

Certain customer environments contain non-production studies that may require decommissioning.

> **Note:**
>
> The following content is not relevant to studies in the Release Assessment Environment.

Consider the following before decommissioning a non-production study

- Should I generate any reports?
- Should I generate any Oracle CRF Submit extracts?

Things to be aware of before decommissioning a non-production study

- A decommissioned non-production study cannot be recommissioned.
- Unlike a production study, Oracle does not provide a pluggable database (PDB) package when they decommission a non-production study.

Decommission a non-production study

1. Log into Oracle Clinical One Digital Gateway to disable active integrations.
2. Then, log into Oracle Life Sciences Support Cloud.
3. In the upper-right corner, click **Create Request**, then select **Change Request**.
4. Click the **Decommission an application** option and complete the request using the details below:

> **WARNING:**
>
> Complete the Change Request precisely as defined below to ensure the correct study is decommissioned.

Field	Description
Summary	Decommission a non-production study
Severity	Medium
Description	Requesting the decommission of a non-production study, `<enter study names>`
Category	• Change - Cloud Environment • Application • Decommission
Customer	Customer name
Product	Clinical One
Business Service	Clinical One - customer name
Environment	Other
Implementation Window	As Soon As Possible
Action	Business Service Decommission
Impact Analysis	Leave blank
sFTP Path	Enable the setting
Date Required By	Select the ideal date for decommission

Recommission a study

Scenarios may arise that require your organization to review or action study data in the Oracle Clinical One Platform after study decommissioning. Reach out to your Oracle point of contact for information about recommissioning a study.

- A study decommissioned in an earlier version can still function when recommissioned in a newer version. However, the user interface and underlying tech stack may have evolved, so the data is not guaranteed to maintain the same layout once recommissioned. For more information about study decommissioning, see Decommission a production study
- You should follow the standard process to add users once the study is recommissioned. For more information, see Create user accounts in Oracle Clinical One Platform.
- Oracle Clinical One Digital Gateway integrations and the Oracle Central Coding integration are inactive for a recommissioned study. However, Oracle CRF Submit and Oracle Clinical One Analytics are available.

7

In-product training

- Track training and send training reminders
  You can track a user's training completion and send a reminder about training at any time.
- Turn off the training requirement for an organization
  If you turn off the training requirement for your organization, you can turn training on again at any time, and then all users will be required to complete training before they can work on each page.
- Practice data entry in Training mode
  Training mode is just for study users to practice with the real study configuration using mock data. Typically contains the same forms, visits, design and settings as Production mode. This procedure also applies to rollover studies.
- Can I watch the training videos without signing in to Oracle Clinical One Platform?
  Yes, but the training won't be tracked, and you'll be required to watch the videos again after signing in to Oracle Clinical One Platform.
- Will I have to retake training after a system update?
  Only when a new video is added.
- I work in multiple studies. Do I have to take training in every study?
  Your training is linked to your email address at the organization level, so as long as your user account uses the same email address in every study and tenant (also known as your organization's product environment), you'll have to take training only one time.

Track training and send training reminders

You can track a user's training completion and send a reminder about training at any time.

To see all completed in-product training in a study, run the Clinical One Training report.

1. On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Users** tab.

   > **Tip:**
   >
   > See a snapshot of each user's training status in the **Training** column.

3. Select a user, and make sure **User Training** is expanded to the right. This section lists all assigned training.
4. To send a reminder to the user, click **Send Training Record**, above the list of assigned training.

   The user receives an email with the subject "Training Status Reminder". The information is presented in two columns: in the Training Name column they see the name of each training video. In the Date Completed column, they see either the date when they completed a specific training video or if the video wasn't started yet.

Related Topics

- Clinical One Training report

Turn off the training requirement for an organization

If you turn off the training requirement for your organization, you can turn training on again at any time, and then all users will be required to complete training before they can work on each page.

Before starting to work in Oracle Clinical One Platform, users at your organization should take either the in-product training or another form of training that you determine. If you turn off the training requirement, users won't be able to open the in-product training videos.

> **Tip:**
>
> Training is still available on the Oracle Help Center. Navigate to the Oracle Clinical One Platform page (http://docs.oracle.com/health-sciences/clinical-one/index.html), and click **Training** on the left.

1. On the home page, in the upper right, click **Global Settings**.
2. Select the **Users** tab.
3. Above the table and to the right, click the **Product User Training** toggle.

   When disabled, the toggle turns gray.

Practice data entry in Training mode

Training mode is just for study users to practice with the real study configuration using mock data. Typically contains the same forms, visits, design and settings as Production mode. This procedure also applies to rollover studies.

Want to see how to perform this task? Watch the video below.

Video

1. On the Home page, click the pencil button ( ) on a study, and make sure a study version is in *Approved* container.
2. Click the graduation cap button ( ) on the study you want to practice in.
3. If you are associated with more than one site, from the **Site** drop-down in the upper-right corner, select a site to work in.

- For more information for sponsor users about operating a live study, see Work during the study conduct period.
- For more information for site users about entering data, see Add subjects and enter data.

Can I watch the training videos without signing in to Oracle Clinical One Platform?

Yes, but the training won't be tracked, and you'll be required to watch the videos again after signing in to Oracle Clinical One Platform.

To watch training outside Oracle Clinical One Platform:

1. Navigate to the Oracle Clinical One Platform page on the Oracle Help Center.
2. On the left, click the appropriate option under the **Videos** section.

Will I have to retake training after a system update?

Only when a new video is added.

I work in multiple studies. Do I have to take training in every study?

Your training is linked to your email address at the organization level, so as long as your user account uses the same email address in every study and tenant (also known as your organization's product environment), you'll have to take training only one time.

8

Reference information

- Receive notifications
  Sponsor users can receive a variety of notifications with the correctly assigned permissions.
- Troubleshoot
- Frequently Asked Questions (FAQs)

Receive notifications

Sponsor users can receive a variety of notifications with the correctly assigned permissions.

For descriptions of the different notifications and their required permissions, along with instructions on how to view notifications, see the Notifications and Permissions Guide.

Troubleshoot

- What if users have problems working in a live study?
  If users run into problems while working in a live study, these troubleshooting tips will help you get everyone back on track.
- A site user receives a message that a subject's age couldn't be calculated
  When a study contains an age question, and an error appears about the age not being calculated, the site user can continue attempting to enter the subject's date of birth. If the age still can't be calculated, you should contact Life Sciences Support.
- I need to correct a multiple choice question in a live form
- I step away and then can't work in Oracle Clinical One Platform anymore
  Your session might have timed out. Close your browser, and sign in again.
- More troubleshooting help
  If you run into issues while verifying a study, working in a live study, randomizing subjects, dispensing kits, reconciling kits, or running reports, these troubleshooting tasks can help.
- Error Messages in retired and re-activated vendor lab
  When you retire and then re-activate a vendor lab with previous institution information, an error message will appear **You must clear all data in the lab form before you can clear the lab selection**.

What if users have problems working in a live study?

If users run into problems while working in a live study, these troubleshooting tips will help you get everyone back on track.

Having problems trying to verify a study?

What if someone can't work in a live study?

1. Ask a user administrator to confirm the user's effective date range in the study is not in the past or future. For instructions, see Create study user accounts.
2. Contact Oracle Support.

What if someone opens a study, and it says they have no sites?

1. Verify that you created sites for Production mode.
2. Make sure the sites are all activated.
3. Contact Oracle Support.

What if shipments aren't being raised?

1. **If shipments were created in the past and aren’t being created anymore**: Make sure a study version is assigned to the site. If the site uses predictive resupply and doesn’t have a study version assigned to it, the supplies that are needed at the site can’t be predicted, so no shipments are created.
2. Make sure the study has a kit list for production mode.
3. Check the depots:
   a. Make sure a depot is assigned to send shipments to the country in which the site exists.
   b. Check that depots are activated for production mode.
   c. Check that kits are assigned to depots.
4. **If your study requires label groups**:
   a. Make sure each kit is assigned to a label group.
   b. Make sure that kits of each type allowed to be sent to sites are assigned to a label group, specially check for those sites that are missing shipments.
5. Verify the following information for the manufacturing and blinded lots, if you are using them:
   a. Make sure kits of every type are assigned to a lot.
   b. Check expiration dates of all lots to be in the future.
   c. Check expiration dates of all lots to be late enough that kits can still be dispensed in consideration of the Do Not Ship (DNS) Days value for the manufacturing lot.
6. Check the site:
   a. Verify the site has been activated.
   b. Make sure the site has a resupply strategy associated with it.
7. Check the event that triggers initial shipment defined when specifying supply settings, either site activation or the first subject who starts a specified visit, has happened.

   > **Note:**
   >
   > An initial shipment is created only after the selected event occurs.

8. Contact Oracle Support.

What if a depot can't raise shipments in a study, or a site can't request manual shipments?

1. If the site can't request a manual shipment, check whether the study allows sites to request shipments specified in supply settings.
2. Check the depots:
   a. Make sure a depot is assigned to send shipments to the country in which the site exists.
   b. Check that kits are assigned to depots.
3. Make sure that kits that are assigned to the depot are also assigned to a manufacturing lot.
4. **If your study requires label groups**:
   a. Make sure each kit is assigned to a label group.
   b. Make sure that kits of each type allowed to be sent to sites are assigned to a label group, specially check for those sites that are missing shipments.
5. Verify the following information for the manufacturing and blinded lots, if you are using them:
   a. Make sure kits of every type are assigned to a lot.
   b. Check expiration dates of all lots to be in the future.
   c. Check expiration dates of all lots to be late enough that kits can still be dispensed in consideration of the Do Not Ship (DNS) Days value for the manufacturing lot.
6. Verify in the supply settings if the study allows single kit ordering and check whether the depot has the right combination of kits. If not, make kits aavailable at the depot.
7. Contact Oracle Support.

What if a site user can't see shipments that are In Transit?

- Make sure the site user is assigned to the appropriate sites and depots.

What if a site user can't add subjects in a study?

1. If the site user has access to multiple sites, tell the user to make sure the site is selected from the **Site** drop-down, to the right of the Manage Subjects drop-down.
2. Make sure the user has a site user role for Production mode. For instructions, see Create study user accounts.
3. Check in the study, enrollment and visit settings, whether the limits for the study have been met, and make sure enrollment isn't closed.
4. Contact Oracle Support.

What if a site user can't randomize subjects or dispense kits in a study?

1. Make sure the subject came in within the visit window, if the study doesn't allow dispensation out of window.
2. Ask the site user to make sure that all required questions are answered.
3. Ask a user administrator to verify that the site user is assigned to:
   - A site user role for Production mode. For instructions on assigning roles, see Create study user accounts.

- The site that the user is trying to work with for Production mode.

4. Make sure the study has a kit list for production mode.
5. Make sure the study has a randomization list for production mode.
6. Confirm that the randomization list is mapped to the correct study version, the one you are making live.
7. Verify that kits are assigned to depots and have the status of Available.
8. Make sure the site has kits to dispense.
9. Verify the following information for the manufacturing and blinded lots, if you are using them:
    a. Make sure kits of every type are assigned to a lot.
    b. Check expiration dates of all lots to be in the future.
    c. Check expiration dates of all lots to be late enough that kits can still be dispensed in consideration of the Do Not Ship (DNS) Days value for the manufacturing lot.
10. Check in the study, enrollment and visit settings whether the screening, randomization, and cohort limits have been met. If the cohort limit has been met, make sure the next cohort is open.
11. If you are randomizing into stratum groups, make sure the stratum groups don't have overlapping number ranges.
12. Contact Oracle Support.

A site user receives a message that a subject's age couldn't be calculated

When a study contains an age question, and an error appears about the age not being calculated, the site user can continue attempting to enter the subject's date of birth. If the age still can't be calculated, you should contact Life Sciences Support.

I need to correct a multiple choice question in a live form

Multiple choice type of questions (Drop-down, Check boxes, Radio Buttons, and Labels) can not be updated or deleted after a study version is approved. The restriction applies to both typed in values and code lists. However, there is a **workaround** you can use in case you need to correct an error: You can hide the question containing the error and then create a new one with the correct code list or values.

I step away and then can't work in Oracle Clinical One Platform anymore

Your session might have timed out. Close your browser, and sign in again.

Your session will time out after 20 minutes of inactivity. However, an overall active session lasts 3 hours before it times out anyway. If this happens, close your browser, and sign in again.

If you are working in Oracle Clinical One Analytics, make sure you keep your session active in Oracle Clinical One Platform.

> **Tip:**
>
> Save your work regularly to avoid any loss of data in case of session time out.

Be careful when entering your password. Five consecutive failed login attempts will lock your account. You will be forced to reset your password on the next successful attempt.

More troubleshooting help

If you run into issues while verifying a study, working in a live study, randomizing subjects, dispensing kits, reconciling kits, or running reports, these troubleshooting tasks can help.

- I have problems trying to verify a study
- Users have problems working in a live study
- A site user randomized a subject in error
- A site user dispensed a kit in error
- A site user can't see the Returned Units and Missing Units fields
- Chinese characters don't display correctly when I open a CSV report in Microsoft Excel

Error Messages in retired and re-activated vendor lab

When you retire and then re-activate a vendor lab with previous institution information, an error message will appear **You must clear all data in the lab form before you can clear the lab selection**.

When you open a subject that must complete a form that contains lab normal ranges associated to the retired lab previously used in an active study, you should contact Life Sciences Support.

Frequently Asked Questions (FAQs)

- Integration FAQs
- Inventory management and dispensation FAQs (for clinical supply managers)
- Kit reconciliation FAQs
- Query FAQs
- Randomization FAQs
- Randomization lists and kit lists FAQs
- Site, depot, labs, and source data verification FAQs
- Study version and rollover study FAQs
- Subject and data entry FAQs

Integration FAQs

- Which products can Oracle Clinical One Platform integrate with?
  SaaS Services can help you integrate Oracle Clinical One Platform with a number of Oracle and third-party products.
- How do I set up an integration?
  Integrations are set up by SaaS Services using the Oracle Life Sciences Clinical One Digital Gateway. Reach out to your Sales contact for information and assistance in setting up an integration.

- Which data can be shared with Oracle InForm?
  All data on scheduled and unscheduled events is sent to Oracle InForm at the intervals defined in the integration schedule.
- Which data can be shared with a third-party electronic data capture system?
  All event data is sent to a third-party EDC system at the intervals defined in the integration schedule.
- What is the workflow for shipments when I use an integration?

Which products can Oracle Clinical One Platform integrate with?

SaaS Services can help you integrate Oracle Clinical One Platform with a number of Oracle and third-party products.

- **Global depot networks such as Almac, Fisher Clinical Services and Catalent Clinical Supply Services.**
  These integrations allow the shipment status in Oracle Clinical One Platform to update automatically.

  > **Tip:**
  >
  > You can find details about the workflow in What is the workflow for shipments when I use an integration?

- **Oracle Life Sciences InForm**
  Oracle InForm is a data collection and study management application. The integration sends selected study data from Oracle Clinical One Platform to Oracle InForm so that you enter data only once.
- **A third-party electronic data capture system**
  If you are not using Oracle InForm for data capture, you can create an integration with another data capture system. The integration sends selected study data from Oracle Clinical One Platform to Oracle InForm so that you enter data only once.
- **SmartSupplies PMD**
  This integration lets you automatically track the status and location of kits from your clinical inventory by sending these updates from Oracle Clinical One Platform to SmartSupplies PMD.
- **Clinical trial management systems such as Veeva Vault CTMS and Oracle Siebel Clinical Trial Management System**
  This integration lets you automatically send general subject information (to Oracle Siebel CTMS) or subject enrollment information (to Veeva Vault CTMS) from Oracle Clinical One Platform.

How do I set up an integration?

Integrations are set up by SaaS Services using the Oracle Life Sciences Clinical One Digital Gateway. Reach out to your Sales contact for information and assistance in setting up an integration.

Which data can be shared with Oracle InForm?

All data on scheduled and unscheduled events is sent to Oracle InForm at the intervals defined in the integration schedule.

All data on scheduled and unscheduled events (including unscheduled dispensation data) is sent to Oracle InForm at the intervals defined in the integration schedule. For more details on what types of data you can integrate, see below.

When integrating date fields between Oracle Clinical One Platform and Oracle InForm, make sure a date rule is created in Oracle Clinical One Platform to prevent data that is not accepted by Oracle InForm from being collected. Otherwise, the integration fails with no possible workaround. Learn how to prevent this error and make sure your integrations with Oracle InForm won't fail.

Subject event data

Type of data	Notes
Screen a subject.	You choose the data to send.
Screen fail a subject and undo screen failure	• For screen failure, the screen failure date and reason along with any other relevant information related to the screen failure event are sent to Oracle InForm. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in Oracle InForm isn't changed. • For undo screen failure, the screen failure date is updated to blank in Oracle InForm. The status for the subject in Oracle InForm isn't changed.
Randomize a subject	You choose the data to send.
Update a form for a subject.	You choose the data to send.
Complete a subject's visit.	You choose the data to send.
Transfer a subject.	You choose the data to send.
Withdraw a subject and undo withdrawal.	• For subject withdrawal, the withdrawal form in Oracle InForm is updated with the withdrawal date and reason, as well as any other relevant information. • For undo subject withdrawal, the completion date and other details that were sent are cleared out in Oracle InForm. Oracle Clinical One Platform retains the information in the withdrawal form.
Complete a study for a subject and undo study completion.	• For a study completion, the completion date and any other relevant information for a subject completion event is sent to Oracle InForm. • For undo study complete, the completion date and other details that were sent are cleared out in Oracle InForm. The information in the study completion form in Oracle Clinical One Platform remains.

Kit event data

Type of data	Notes
Replace a kit that was damaged or lost	Data about replaced kits and new kits that are dispensed is sent to Oracle InForm and included in a visit form. The new information includes dispensation date, original kit number and new kit number, amongst others.
Re-dispense a conserved kit.	The conserved kit number and any other relevant data can be sent to Oracle InForm and included in a visit form.

Form data

Type of data	Notes
Apply, update, or clear a data flag.	In Oracle InForm, data flags correspond to the Reason Incomplete options available in the user interface for incomplete form answers. In Oracle InForm the Data Entry Flag is collected in the item comment section. Clicking the Comments icon in Oracle InForm displays the Reason Incomplete options, equivalent to those in Oracle Clinical One Platform. The Reason for Change from Oracle Clinical One Platform is featured on the Comment field above the Reason Incomplete options. These are the default configurations in Oracle InForm. Make sure these settings are configured appropriately, so that data flag information can be sent from Oracle Clinical One Platform to Oracle InForm. • The Require a comment setting (when entering N/A, Unknown, or Not Done) in Oracle InForm is set to No. • The Display Comment Text Boxes setting is set to Yes.

Which data can be shared with a third-party electronic data capture system?

All event data is sent to a third-party EDC system at the intervals defined in the integration schedule.

- **Screen a subject**
  You choose the data to send.
- **Screen fail a subject, and undo screen failure**
  - For screen failure, the screen failure date and reason along with any other relevant information related to the screen failure event are sent to the third-party EDC system. You can map these fields to any form you use to collect the screen failure reason. The status for the subject in the third-party EDC system isn't changed.
  - For undo screen failure, the screen failure date is updated to blank in the third-party EDC system. The status for the subject in the third-party EDC system isn't changed.
- **Randomize a subject**
  You choose the data to send.

- **Complete a subject's visit**
  You choose the data to send.
- **Withdraw a subject, and undo withdrawal**
  - For subject withdrawal, the withdrawal form in the third-party EDC system is updated with the withdrawal date and reason, as well as any other relevant information.
  - For undo subject withdrawal, the completion date and other details that were sent are cleared out in the third-party EDC system. Oracle Clinical One Platform retains the information in the withdrawal form.
- **Code break**
  If a user performs a code break in Oracle Clinical One Platform, Oracle Clinical One Platform sends the date and time when the code break was performed to the third-party EDC system.
- **Kit replacement**
  When a kit is replaced, the dispensed kit information is updated with the replacement kit information on the specified form and item in the third-party EDC system.

What is the workflow for shipments when I use an integration?

- Workflow for an integration with Almac Global Depot Network
  This workflow applies to shipments when you use an integration with Almac Global Depot Network. It applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when a resupply runs, and a manual shipment.
- Workflow for an integration with Catalent Clinical Supply Services
  This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.
- Workflow for an integration with Fisher Clinical Services
  This workflow applies to shipments when you use an integration with Fisher Clinical Services . It applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Workflow for an integration with Almac Global Depot Network

This workflow applies to shipments when you use an integration with Almac Global Depot Network. It applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when a resupply runs, and a manual shipment.

Want details about the workflow when you don't use an integration for shipments?

> **Note:**
>
> If you need to update a shipment after the shipment request has been sent to the depot, you must contact the organization managing the depot directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depots.

Workflow for a shipment when you use an integration with Almac for shipments

1. When a new shipment is raised, the status of the shipment changes to **Pending**. This activity is automated.
2. When the shipment request is sent to the depot, the status of the shipment changes to one of the following:
   - **Confirmed**, if the depot received the request.
   - **Invalid**, if an issue occurred with the request.

   Both status changes are automated.
3. The depot adds a ship date and tracking number to the shipment, and the status of the shipment changes to **In Transit**. The setting of the ship date, tracking number, and the status change are all automated.
   For an invalid shipment, a clinical supply manager should cancel the shipment and do one of the following:
   - Allow the resupply process to create a new shipment the next time inventory runs.
   - Create a new manual shipment.
4. A site marks the shipment as received, changing its status to **Received**.

Prerequisites for sending the depot order form to Almac-managed depot facilities

To make sure depot users at an Almac-managed depot facility get this email notification in their inbox, in Oracle Clinical One Platform, on the Depots tab, check that the Almac-managed depots are correctly defined and their Depot IDs match the exact names of the depot facilities.

Workflow for an integration with Catalent Clinical Supply Services

This workflow applies to shipments when you use an integration with Catalent Clinical Supply Services for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Want details about the workflow when you don't use an integration for shipments?

Prerequisites for clinical supply managers

1. Shipment ID prefixes created in Oracle Clinical One Platform must consist only of numbers. When you set the prefix on the Supply Settings tab, in the Shipment Settings section, choose one of the following options:
   - **Use Depot ID**: If Depot IDs have been defined using numbers only
   - **Enter Prefix**: Enter a prefix and make sure the value consists only of numbers
   - **None**: If no prefix is used
2. To make sure depot users at a Catalent-managed depot facility are notified by email about an order, in Oracle Clinical One Platform, on the Depots tab, check that the email field for depots managed by Catalent Clinical Supply Services is left blank. The integration is configured to send emails to the appropriate recipients.
3. Catalent expects protocol values between 5 and 30 characters long, therefore the value for **Study Title** in Oracle Clinical One Platform must be defined accordingly.

Workflow for a shipment when you use an integration with Catalent Clinical Supply Services for shipments:

1. When a new shipment is raised, the status of the shipment changes to **Pending** in Oracle Clinical One Platform. This activity happens both manually or automatically, depending on how the resupply conditions are set in the study.
2. When the shipment request is acknowledged by the depot, the status of the shipment changes to **Confirmed** in Oracle Clinical One Platform. This activity is automated.
3. The depot adds a ship date and a tracking number to the shipment, if available. The status of the shipment changes to **In Transit** in Oracle Clinical One Platform. These updates are automated.
4. The following updates can happen both automatically or manually, depending on how the integration is configured:
   - **If the integration is configured to support this and the courier provides the information**: Catalent Clinical Supply Services receives delivery information from the courier. The integration sets the status of the shipment to **Received** in Oracle Clinical One Platform. The status of all the kits included in the shipment automatically changes to **Available**.
     Additionally, the Date Received is updated in Oracle Clinical One Platform to reflect the date the integration processed the delivery file. This date may not always match the date at which the shipment is delivered by Catalent Clinical Supply Services.
   - **If the integration isn't configured to interpret the delivery as a receipt**: A site user must manually mark the shipment as **Received** in Oracle Clinical One Platform.

> **Note:**
>
> If you need to update (add or remove kits from a shipment) or cancel a shipment after the shipment request has been sent to the depot, you must contact Catalent Clinical Supply Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depot. When the shipment is marked as **Received**, this status update applies to the entire shipment and all its kits are presumed **Available**. Therefore, all the kits in the shipment, including kits added after the original request, are updated once the shipment is received.

What if an order is sent to Catalent Clinical Supply Services in error?

If a shipment request is sent in error, the clinical supply manager must contact Catalent Clinical Supply Services and request the shipment's cancellation. Once Catalent Clinical Supply Services cancels the order in their system, the shipment status changes to **Invalid** in Oracle Clinical One Platform. To allow the resupply process to create a new shipment the next time inventory runs, the clinical supply manager must also explicitly cancel the shipment in Oracle Clinical One Platform.

> **Note:**
>
> Catalent Clinical Supply Services will only be able to cancel the order if the shipment hasn't been sent yet.

Workflow for an integration with Fisher Clinical Services

This workflow applies to shipments when you use an integration with Fisher Clinical Services . It applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

Want details about the workflow when you don't use an integration for shipments?

> **Note:**
>
> If you need to update a shipment after the shipment request has been sent to the depot, you must contact Fisher Clinical Services directly. If you make any updates to shipments from within Oracle Clinical One Platform, the changes won't be sent to the depots.

Prerequisites for clinical supply managers

For shipments sent through this integration, only IDs that contain numbers are accepted. To make sure you use the right Shipment ID Prefix, go to the Supply Settings tab. In the Shipment Settings section, either select **Use Depot ID** or **None**. If a depot ID contains leading zeros, they do not appear in the Shipment Request file as part of the Shipment ID format for Fisher Clinical Services.

Workflow for a shipment when you use an integration with Fisher Clinical Services for shipments

1. When a new shipment is raised, the status of the shipment changes to **Pending**. This activity is automated.
2. The depot adds a ship date to the shipment, and the status of the shipment changes to **In Transit**. The setting of the ship date and the status change are both automated.
3. A site receives the shipment and marks the shipment as received, changing its status to **Received**.

Inventory management and dispensation FAQs (for clinical supply managers)

- What if I have to include kits of the same type from different lots in a manual shipment?
  If you have concerns about the availability of kits to include in a manual shipment, the application is designed to include kits from all associated lots with the available quantity in an automated manner.
- What if a site anticipates an enrollment surge?
  Sites have a couple options when they are preparing for a clinic day.
- How often should I run inventory?
  You should consider a few factors when determining how often to run inventory.
- What levels of the supply chain can I manage in Oracle Clinical One Platform?
  You can manage shipments from depots to sites and manage inventory at each site.
- Which resupply strategy should I use?
  When choosing a resupply strategy for a site, consider the factors that should determine when a new shipment is created.

- Do I need to monitor product levels at sites?
  No. Oracle Clinical One Platform runs inventory to monitor product levels at sites, so as long as you created resupply strategies that meet sites' enrollment needs, you don't need to monitor product levels.
- How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?
  A few settings help you manage the expiration dates of kits.
- How do I manage temperature excursions for kits and shipments?
  When a kit or shipment has a temperature excursion, a site user changes the status of all affected kits to Pre-quarantined. Next, you determine whether the kits can still be dispensed.
- How are the required kits calculated in a predictive resupply strategy?
  When using a predictive resupply strategy, the application uses the number you specify for the strategy to calculate the number of kits that are required in a shipment.
- How do I set the expiration dates for kits?
  You set expiration dates for kits by assigning them to manufacturing lots. Manufacturing lots in Oracle Clinical One Platform typically correspond to the lots created at the factory, though they don't have to. You must create at least one manufacturing lot in each study so you can set the expiration dates for kits.
- How does Oracle Clinical One Platform determine the kits that are selected for shipment or distribution to subjects?
  The following settings are considered: sequence numbers, expiration dates, and Do Not Ship and Do Not Dispense settings.
- Are all kits at a site counted in inventory?
  Only kits with certain statuses are counted in inventory.
- What if a subject loses or damages a kit?
  A site user can replace a lost or damaged kit during any visit.
- Can I track a kit from manufacturer to depot to site to subject?
  Yes. The Kit Chain of Custody (Unblinded) report contains this information.
- Can I change the contents of an automatic shipment?
  It depends on whether Oracle Clinical One Platform uses an integration for shipments.
- Understand kit conservation
  If some of the kits returned to the site by a subject are not expired or damaged, those kits can be conserved, and re-dispensed to the same subject.
- What is the workflow for shipments?
  This workflow applies to shipments when you don't use an integration for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.
- How do depots find out when a shipment is needed?
  Depots have two ways to find out when to create new shipments.
- What can I do to prevent my shipments from revealing unblinding information to site users?
  When you specify supply settings for a study, you indicate whether a shipment can contain only one kit. If the study is blinded, you typically do not allow a shipment to contain only one kit.
- When should I send initial shipments to sites?
  You have two options: After each site is activated, and after subjects start a specific visit.
- What if a depot has insufficient stock to resupply a site?
  After running inventory, Oracle Clinical One Platform checks whether the primary depot for the site has sufficient stock to fulfill the shipment. If the depot doesn't have sufficient stock,

Oracle Clinical One Platform checks whether the secondary depot for the site has sufficient stock. If there is no secondary depot, the shipment cannot be fulfilled.

- Can depots ship different kit types?
  Yes. Just check that kit types and countries are associated appropriately in the settings for the depots.
- What if a site doesn't mark a shipment as received?
  The site might not be able to dispense. Only kits with a status of Available can be dispensed, so a site must mark shipments as received to be able to dispense the kits in the shipment.
- What do I do if a shipment is lost?
  You must mark the shipment as lost, and then check the supply settings to see when the resupply process runs next.
- What is my workflow for enabling confirmation of dispensed kits?
  To allow site users to confirm the dispensation of kits to subjects, you typically need to perform the following tasks in this order:
- Why are barcodes useful in a study?
  Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.
- Define kit dispensation logic
  Clinical supply managers choose how to define the dispensation logic in a study. Kits can be dispensed based on the lowest kit number or by the lowest sequence number.

What if I have to include kits of the same type from different lots in a manual shipment?

If you have concerns about the availability of kits to include in a manual shipment, the application is designed to include kits from all associated lots with the available quantity in an automated manner.

For example, if you need to create a manual shipment with 10 kits of the same type A, and one lot (Lot I) only has 5 available kits, the system will include the rest of the required kits from the next available lot (Lot II) that contains the selected kit type A. That way, you don't have to create two separate manual shipments to send your desired quantity of kits to the site or depot.

What if a site anticipates an enrollment surge?

Sites have a couple options when they are preparing for a clinic day.

- Requests a manual shipment, if the study allows it.
  When you set up supply settings for the study, you choose whether sites can request manual shipments, and you define the contents of the shipments in the resupply strategy that you assign to each site. You can modify the contents of any pending shipment.
- Tells their CRA that they need additional supply.
  You choose the contents when you create the manual shipment.

A manual shipment does not affect the resupply shipments that sites receive automatically, though an increase in supply at a site from a manual shipment might mean that a new resupply shipment isn't created until the supply is dispensed.

If the enrollment surge changes the number of anticipated subjects for the site, you might need to change the resupply strategy for the site so that they have sufficient supply going forward.

How often should I run inventory?

You should consider a few factors when determining how often to run inventory.

- Days that the depot ships.
  For instance, some organizations don't run inventory on Thursday, Friday, and Saturday nights because depots aren't able to send those shipments until Monday.
- The risk associated with the planned frequency.
  - If you run inventory two times per week, shipments might not contain enough kits to accommodate high enrollment activity in a short period of time.
    Additionally, a replacement shipment might be generated late. For example, if a shipment arrives at a site damaged, the site probably requires a replacement shipment immediately. However, the new shipment is created only after inventory runs again. If inventory doesn't run for a few days, the site might have inventory issues for planned visits that occur before the new shipment is delivered.

    The risk is greater when a site's entire inventory is damaged or experiences a temperature excursion.
  - If you run inventory daily, a depot might send a site many small shipments, which can be expensive and inefficient.

What levels of the supply chain can I manage in Oracle Clinical One Platform?

You can manage shipments from depots to sites and manage inventory at each site.

Which resupply strategy should I use?

When choosing a resupply strategy for a site, consider the factors that should determine when a new shipment is created.

- To resupply a site only when the site's inventory is low, use Min/Max Resupply.
  When Oracle Clinical One Platform runs inventory, shipments are created as needed to bring the inventory at sites up to the maximum number of kits you specify.
- To resupply a site based on actual enrollment and planned dispensation visits, use Predictive Resupply.
  After running inventory, Oracle Clinical One Platform creates shipments to meet each site's inventory requirements for the coming weeks. You specify the number of weeks to consider and the number of weeks to order for.

  You also set minimum and maximum levels so that sites have sufficient supply for new subjects.

Do I need to monitor product levels at sites?

No. Oracle Clinical One Platform runs inventory to monitor product levels at sites, so as long as you created resupply strategies that meet sites' enrollment needs, you don't need to monitor product levels.

Of course, you can check site and depot stock levels at any time. If you find that sites need frequent shipments, or if the shipments are taking longer than expected to arrive at sites, consider adjusting or switching their resupply strategy.

How do I manage expiration dates and replenish stock to prepare for imminent expiration dates?

A few settings help you manage the expiration dates of kits.

Setting	Description
Do Not Dispense (DND) Days	**What you specify** Number of days that a kit can be in a subject's hands before the kit expires. **When you set it** A study designer typically specifies the value for the kits in each visit while defining the dispensation schedule. **Details** When planning this setting, consider when a subject will consume the investigational product. For example: • For an injection that is administered on the day of dispensation, you could set the DND (Days) value to 0, indicating that the kit can expire that day, typically at midnight. • For a single pill that the subject takes at home the day after the visit, you could set the DND (Days) value to 1, indicating that the kit can expire tomorrow. If your organization has a standard time buffer, add the days in the buffer to the number of days the subject will consume the product from the kit. For a buffer of 60 days: • If you dispense a single pill that the subject consumes that day at the site, use 60 for the DND (Days) value. • If you dispense a blister pack containing 28 pills, and the subject consumes one pill daily starting on the dispensation day, use 88 for the DND (Days) value.
Do Not Count (DNC) Days	**What you specify** Number of days before the expiration date when the kit is no longer counted in a site's inventory. **When you set it** When you create a blinded lot and a manufacturing lot. If a manufacturing lot is part of a blinded lot, the expiration date of the blinded lot takes precedence. For a blinded lot, you can choose between setting this as the default value for all countries in your study, setting a specific default for selected countries in your study, or both. Custom values you specify for certain countries take precedence over what you specified as your default value. You can adjust this setting at any time. **Details** This setting helps you resupply a site before stock expires. This value is typically higher than the highest DND Days value.

Setting	Description
Do Not Ship (DNS) Days	**What you specify** Number of days before the expiration date when a kit can no longer be shipped from a depot to a site. **When you set it** When you create a blinded lot and a manufacturing lot. If a manufacturing lot is part of a blinded lot, the expiration date of the blinded lot takes precedence. For a blinded lot, you can choose between setting this as the default value for all countries in your study, setting a specific default for selected countries in your study, or both. Custom values you specify for certain countries take precedence over what you specified as your default value. You can adjust this setting at any time. **Details** This setting helps you meet safety standards by preventing a kit that will expire before it is consumed from being shipped to a site. This value is typically higher than the Do Not Count (DNC) value.

How do I manage temperature excursions for kits and shipments?

When a kit or shipment has a temperature excursion, a site user changes the status of all affected kits to Pre-quarantined. Next, you determine whether the kits can still be dispensed.

- Mark any kits that were destroyed during testing as Damaged.
- If the remaining kits can be dispensed, change the status of the kits to Available.
- If the remaining kits can't be dispensed, change the status of the kits to Quarantined so that they aren't considered part of the site's inventory.
  Multiple Quarantined kits from the same depot might be a signal of a problem with a shipping procedure.

  If you change the status to Quarantined, consider checking your supply settings to see when the resupply process runs next. For instance, if the resupply process won't run for another 6 days, you might need to update the settings so that the resupply process runs sooner and the site can be restocked.

How are the required kits calculated in a predictive resupply strategy?

When using a predictive resupply strategy, the application uses the number you specify for the strategy to calculate the number of kits that are required in a shipment.

The process of calculating the required kits

For each kit type, the application first looks at the specified number for the **Trigger Weeks** field to determine the number of subjects that might be coming during a specified time in the study.

Next, the application also looks at the number of kits that each randomized subject will need to have on hand at the site to cover the upcoming visits. Based on these numbers, the application adds the number specified for the **Minimum Buffer** field.

After this calculation is made, the application calculates the exact number of kits at the site and adds any kits to the site that have a status of **In Transit**. If the number that results from this calculation (also known as the number of required kits) is greater than the number of kits at a site or the number of kits that have a status of **In Transit**, then a shipment is raised.

If a site's available inventory has a quantity of kits that is equal or less than the projected need, as part of the resupply strategy, then a shipment is automatically created for the site. The quantity of that shipment will contain all of the kits that are required for resupply minus what already exists in a site's available inventory.

```
Site available inventory = < Projected need => Triggered shipment.
The number of kits in that triggered shipment = Resupply need - Site
available inventory.
```

Parameters of the calculation

> **Note:**
>
> - If a visit's projected date is 10-June-2024, and that visit's window starts 5 days before the visit's date, then a visit's date can be considered 5-June-2024.
> - You can also use the Subject Visit (Unblinded) report to view more data about your projected kits. The Subject Visit (Unblinded) report, only displays a visit's projected date, but not a visit's date with its specified visit window. For example, in the Subject Visit (Unblinded) report, you will see a visit's projected date as being 10-June-2024, not 5-June-2024.
> - If your study is set up with visits that have unlimited cycles, only one cycle is used in the calculation for a resupply or trigger week shipment.

The following parameters are used in the calculation of the required kits in a predictive resupply shipment:

Parameter	Description
Site available Inventory	The application counts all kits that have a status of **Available**, **In Transit**, and **Pre-Quarantined**.
Kits needed in trigger weeks	Based on the calculation steps described earlier, the application counts the number of kits needed for all visits during the trigger weeks for subjects that have a status of **Screened**, **Enrolled**, or **Active** at a site.
Kits needed in resupply weeks	Based on the calculation steps described earlier, the application counts the number of kits needed for all visits during the resupply weeks for subjects that have a status of **Screened**, **Enrolled**, or **Active** at a site.
Projected need	The projected need represents the number of kits that are projected to be required when a site is running low on kits. This is a number that is calculated by adding the number specified in the **Trigger Weeks** field to the number specified in the **Minimum Buffer** field. The resulting number represents the number of kits to be included in a shipment that is automatically triggered during a trigger week.

Parameter	Description
Resupply need	The resupply need represents the number of kits that are typically needed during the usual resupply weeks at a site. This is a number that is calculated by adding the number specified in the **Resupply Weeks** field to the number specified in the **Maximum Buffer** field. The resulting number represents the number of kits to be included in a shipment that is automatically triggered during a resupply week.

How do I set the expiration dates for kits?

You set expiration dates for kits by assigning them to manufacturing lots. Manufacturing lots in Oracle Clinical One Platform typically correspond to the lots created at the factory, though they don't have to. You must create at least one manufacturing lot in each study so you can set the expiration dates for kits.

You have the option of combining one or more manufacturing lots into a blinded lot. Kits in a blinded lot are labeled with the blind lot number rather than the manufacturing lot number to protect the study blind. You must set expiration dates on blinded lots. A blinded lot's expiration must be no later than the earliest expiration date for its manufacturing lots.

How does Oracle Clinical One Platform determine the kits that are selected for shipment or distribution to subjects?

The following settings are considered: sequence numbers, expiration dates, and Do Not Ship and Do Not Dispense settings.

At both depots and sites, Oracle Clinical One Platform selects kits that:

- Have the lowest sequence number.
- Have the earliest expiration date.
- Meet the requirements for one of the following settings:
  - For kits at the depot, the Do Not Ship (DNS) setting.
  - For kits at the site, the Do Not Dispense (DND) Days setting.

Are all kits at a site counted in inventory?

Only kits with certain statuses are counted in inventory.

Kit statuses that are counted in inventory numbers for sites	Kit statuses that aren't counted in inventory numbers for sites
• Available • In Transit • Pre-Quarantined • Temporarily Unavailable ***Tip**: These statuses are counted in inventory so that another resupply shipment isn't created. However, only kits with the Available status can be dispensed.*	• Damaged • Damaged by Subject • Destroyed • Dispensed • Expired • Lost by Subject • Misallocated • Missing • Not In Use • Quarantined • Processed for Destruction

What if a subject loses or damages a kit?

A site user can replace a lost or damaged kit during any visit.

Can I track a kit from manufacturer to depot to site to subject?

Yes. The Kit Chain of Custody (Unblinded) report contains this information.

Can I change the contents of an automatic shipment?

It depends on whether Oracle Clinical One Platform uses an integration for shipments.

If your study uses an integration with Almac or Fisher Clinical Services for shipments, no. You can cancel the shipment, though.

If your study doesn't use an integration for shipments, yes. You can add and remove kits and cancel the shipment.

However, if a site is enrolling more or fewer subjects than is appropriate for its resupply strategy, you should update the resupply strategy for the site rather than update individual shipments. If you anticipate an enrollment surge, such as for a clinic day, you can create a manual shipment.

Understand kit conservation

If some of the kits returned to the site by a subject are not expired or damaged, those kits can be conserved, and re-dispensed to the same subject.

Clinical supply managers can set their studies to conserve reusable kits that were brought back to the site by subjects. And site users can dispense these conserved kits to the same subjects during the next visit in the study.

A reusable kit is a kit that can be safely re-dispensed to a subject because it is still sufficient to meet the needs of the subject and the study. For example, a subject might have unexpired medication left from a previous dispensation that can be used in place of dispensing a new kit. Sometimes, that product can be conserved by the system, and you can re-dispense it to the same subject during the next visit.

Clinical supply managers workflow

In a study's setting, for every study mode, you can configure these settings to make sure the site staff can conserve and dispense reusable kits.

- **Dispense reusable kits**: Choose **Yes** if you want to let site users conserve and re-dispense a subject's reusable kits. Or choose **No** if you want to restrict site users from conserving and re-dispensing reusable kits to subjects.
- **Dispense only reusable kits from a subject's last dispensation visit**: Click the checkbox if you want to set a limit for site users to only see conserved kits from a subject's last dispensation visit. If this setting is enabled, site users only see reusable kits from a subject's latest dispensation visit as opposed to seeing reusable kits from all previous dispensation visits.

For more details, see Specify supply settings.

Site users workflow

Studies that allow kit conservation have two options, conserving kits from either the most recent dispensation visit or from any previous dispensation visit. A site user should consult CRA or study materials that can help them figure out whether the study allows kit conservation, and if so, which option is allowed in terms of kit conservation.

For example, a site user may have two options.

Option for kit conservation	Workflow in the user interface
Conserve kits from all previous dispensation visits	In the Reusable Kits dialog, after a site user determines that the subject has reusable kits, they will see all kits from all previous dispensation visits.
Only conserve kits from a subject's latest dispensation visit	In the Reusable Kits dialog, after a site user determines that the subject has reusable kits, they will only see kits from a subject's latest dispensation visit.

Lastly, if a reusable kit cannot be conserved by the system, a site user may need to perform kit reconciliation. For example, if a reusable kit is nearing its expiration date, the system may not be able to conserve it. If some of the kits that a site user marks as reusable in the user interface cannot be conserved, a site user should remember or keep the kit numbers stored somewhere. After they finish the dispensation visits for subjects, they must search for those same kit numbers in the inventory, and perform kit reconiliation.

For more details, see Conserve and re-dispense kits.

What is the workflow for shipments?

This workflow applies to shipments when you don't use an integration for shipments, and it applies to all types of shipments, including the initial shipment to a site, a resupply shipment that is generated automatically when resupply runs, and a manual shipment.

1. When a new shipment is created in Oracle Clinical One Platform, the recipient specified in the Email field for the depot receives an email with an attachment specifying the contents of the shipment and the site that requires it.
2. The designated person at the depot fulfills the shipment request and then adds a ship date to it. Adding a ship date changes the status of the shipment to Pending.

3. A site receives the shipment and marks the shipment as received, changing its status to Received.

Want details about the workflow when you use an integration with Almac or Fisher Clinical Services?

How do depots find out when a shipment is needed?

Depots have two ways to find out when to create new shipments.

- **New Shipment Request notification**
  This notification is sent over email and also appears when you click Notifications on the Home page.

  The notification includes the site but not the contents of the shipment.
- **Contents of New Shipment email**
  This email message is sent to the email address specified for the depot and includes the contents of the shipment.

What can I do to prevent my shipments from revealing unblinding information to site users?

When you specify supply settings for a study, you indicate whether a shipment can contain only one kit. If the study is blinded, you typically do not allow a shipment to contain only one kit.

If you choose supply settings that don't allow single kit ordering, or if the kits in your study use different packaging or have different storage requirements, you should create blinded groups. Blinded groups determine the kit or kits that are added to a shipment to protect the study blind.

When should I send initial shipments to sites?

You have two options: After each site is activated, and after subjects start a specific visit.

You make a choice when you specify supply settings.

- When you choose site activation, sites typically receive supply before they enroll subjects, so they don't have to turn subjects away due to lack of supply. However, if a site never enrolls a subject, supply is sent to the site unnecessarily.
- When you choose a specific visit, you send supply only to sites that enroll subjects. We recommend this option, if your study has a number of visits prior to randomization. This option doesn't work if randomization occurs on the same day as screening or soon after screening.

What if a depot has insufficient stock to resupply a site?

After running inventory, Oracle Clinical One Platform checks whether the primary depot for the site has sufficient stock to fulfill the shipment. If the depot doesn't have sufficient stock, Oracle Clinical One Platform checks whether the secondary depot for the site has sufficient stock. If there is no secondary depot, the shipment cannot be fulfilled.

Can depots ship different kit types?

Yes. Just check that kit types and countries are associated appropriately in the settings for the depots.

What if a site doesn't mark a shipment as received?

The site might not be able to dispense. Only kits with a status of Available can be dispensed, so a site must mark shipments as received to be able to dispense the kits in the shipment.

What do I do if a shipment is lost?

You must mark the shipment as lost, and then check the supply settings to see when the resupply process runs next.

- You mark the shipment as lost so that the kits in the shipment are no longer counted in inventory for the sites they were headed to, so the next time inventory runs, new shipments are created.
- When you check the supply settings to see when the resupply process runs next, consider whether the next shipment will meet the site's needs. For example, if the resupply process won't run for another 6 days, you might need to create a manual shipment or update the settings so that the resupply process runs sooner and the site can be restocked.

What is my workflow for enabling confirmation of dispensed kits?

To allow site users to confirm the dispensation of kits to subjects, you typically need to perform the following tasks in this order:

1. Map barcodes in your uploaded kit list or generate a new kit list with barcodes.
   For more details on how to perform this task, see Generate a kit list.
2. Configure the setting that allows site users to confirm the dispensation of kits.
   For more details on how to perform this task, see Specify supply settings.

Why are barcodes useful in a study?

Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.

For clinical supply managers

Including barcodes in your kit list lets you assign a barcode to every kit that needs to be dispensed to subjects during the study. After you do that, you can also enable site users to use these barcodes for confirming dispensation of the kits dispensed to subjects during visits. Overall, barcodes allow you and the site team to have better control over the kits that are dispensed during visits without running the risk of unblinding a study.

When uploading a kit list, you can map barcodes in the system to make sure they're correctly assigned to each kit in the study.

When generating a kit list, you can either use kit numbers to generate those barcodes or ask the system to generate new numbers for barcodes.

For more details on how to include barcodes in your kit lists, see Generate a kit list.

For more details on how to enable site users to confirm kit dispensation, see Specify supply settings [Testing mode].

For site users

Using barcodes to confirm kit dispensation allows you to have better control over what kits you dispense to subjects during dispensation visits. You can either type a kit's barcode in the user

interface (if, for example, a kit's barcode is the same as a kit's number) or you can scan a kit's barcode to confirm its dispensation. You can only confirm the dispensation of kits using barcodes if this feature is enabled in your study by a clinical supply manager.

For details on how a site user can confirm dispensation of kits, see Confirm dispensation of kits.

Define kit dispensation logic

Clinical supply managers choose how to define the dispensation logic in a study. Kits can be dispensed based on the lowest kit number or by the lowest sequence number.

To learn more about kit dispensation, see Specify supply settings.

Kit dispensation by lowest kit number

Dispensing kits by the lowest sequence number can potentially lead to partial unblinding in a study if multiple kits are dispensed to a subject one at a time. For example, a site user could have a new patient who gets dispensed a kit from the same resupply order as another patient on the same treatment arm. In this situation, a site user may put together what treatment arm the patients are on.

Kit dispensation by lowest sequence number

The default dispensation method is to release kits by sequence number.

Sequence numbers are an efficient way to group a random assortment of kit numbers. Sequence numbers can be helpful when a depot user is pulling the investigational product with random kit numbers at a depot, when they are creating shipments. In turn, this allows a randomization and trial supply management system (RTSM) the ability to identify which kits should be shipped based on expiry and sequence number. Sequence numbers ultimately allow more flexibility to further randomize a list in order to protect the blind based on the dispensing schedule or overall complexity of a study design. To maintain study blindness in a study, clinical supply managers can change the dispensation protocol to dispense kits by the lowest expiration date and the lowest kit number.

Kit reconciliation FAQs

- Who is responsible for each step in the kit reconciliation process?
  The workflow is flexible so that you can opt to use the parts that are required for the protocol and any relevant SOPs. All of these steps are available in Oracle Clinical One Platform when you require kit reconciliation, but they're not required.
- How do I turn on kit reconciliation?
  You must update each site, each depot, and the supply settings.
- Can I modify a Pending Destruction shipment?
  No. But a couple workarounds are available if you need to add kits and all kits are going to the same depot.
- What is the workflow for destroying shipments at a depot facility?
  If you want your study to have a depot kit reconciliation process here's what you need to know whether you're a clinical supply manager, Clinical Research Associate (CRA), site, or depot user.
- What if a site user can't see the Returned Units and Missing Units fields?
  Issue: A site user clicks the link for a dispensed kit in Subject History, selects a new kit status, and doesn't see the Returned Units and Missing Units fields in the Inventory Management pop-up.

Who is responsible for each step in the kit reconciliation process?

The workflow is flexible so that you can opt to use the parts that are required for the protocol and any relevant SOPs. All of these steps are available in Oracle Clinical One Platform when you require kit reconciliation, but they're not required.

1. Reconcile and verify kits:
   a. A subject returns a kit to the site.
   b. A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.
   c. A CRA verifies the kit.
2. Destroy kits:
   a. A CRA marks kits that are ready for destruction, including the returned kits that the CRA verified as well as damaged, expired, and undispensed kits.
   b. A CRA completes the drug reconciliation form. For more information, see Complete a drug reconciliation form.
   c. The next step depends on the location of the drug destruction facility:
      - If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to Destroyed according to the protocol and relevant SOPs.
      - If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility, where they are destroyed according to the protocol and relevant SOPs. The receiving depot can be either the depot that shipped the product to the site or a tertiary depot that provides destruction capabilities. If required, the clinical supply manager can change the status of the kits to Destroyed, or sponsors can opt to skip this final step.

How do I turn on kit reconciliation?

You must update each site, each depot, and the supply settings.

1. Specify whether each site and depot is drug destruction capable.
2. Indicate that kit reconciliation is required.

Can I modify a Pending Destruction shipment?

No. But a couple workarounds are available if you need to add kits and all kits are going to the same depot.

- Create a secondary shipment and include both packing lists in the shipment.
- Cancel a shipment and create a new shipment by marking kits as Pending Destruction again.
  Before canceling the shipment, consider noting the kits in the shipment so you can find them again easily.

Keep in mind the following rules for how shipments are created in Oracle Clinical One Platform:

- If the depot that sent the kits to the site is drug destruction capable, the kits are sent back to that depot. If multiple depots ship kits to a site, and all depots are drug destruction capable, kits are sent back to their originating depots for destruction.

If the depot that sent the kits isn't drug destruction capable, the kits are sent to the depot that is marked as a drug destruction facility and that is associated with the country that the site is in.

- Shipments are created based on the temperature requirements for the kits. For example, if you mark a refrigerated kit and a frozen kit as Pending Destruction, one shipment is created for the refrigerated kit, and another shipment is created for the frozen kit. If the return shipments don't have temperature requirements, consider combining multiple packing lists in one shipment.

What is the workflow for destroying shipments at a depot facility?

If you want your study to have a depot kit reconciliation process here's what you need to know whether you're a clinical supply manager, Clinical Research Associate (CRA), site, or depot user.

Clinical supply managers: Configure the study

First things first, you must configure the setting for required depot kit reconciliation in both Testing and Production mode. For more details, see Specify supply settings.

Clinical Research Associates (CRAs) or site users: Mark kits that are ready for destruction

Next up, you must mark all kits that are ready for destruction as **Pending Destruction** in the site inventory. For more details, see Mark kits as ready for destruction at the site or at a depot. This task can also be performed by a site user.

Clinical Research Associates (CRAs) or site users: Ship kits to a drug destruction depot

If kit destruction should occur at a depot that is a drug destruction facility, either the Clinical Research Associate (CRA) or the site user should be responsible for sending kits to the drug destruction facility.

- If you're a Clinical Research Associate (CRA), see Ship kits to a drug destruction depot
- If you're a site user, see Ship kits to a drug destruction depot

Depot users: Confirm you received the kits and destroy the shipment

If you received kits that need to be destroyed at the depot, you can either mark the entire shipment as **Received for Destruction** or confirm each kit within the shipment as received, along with their returned units.

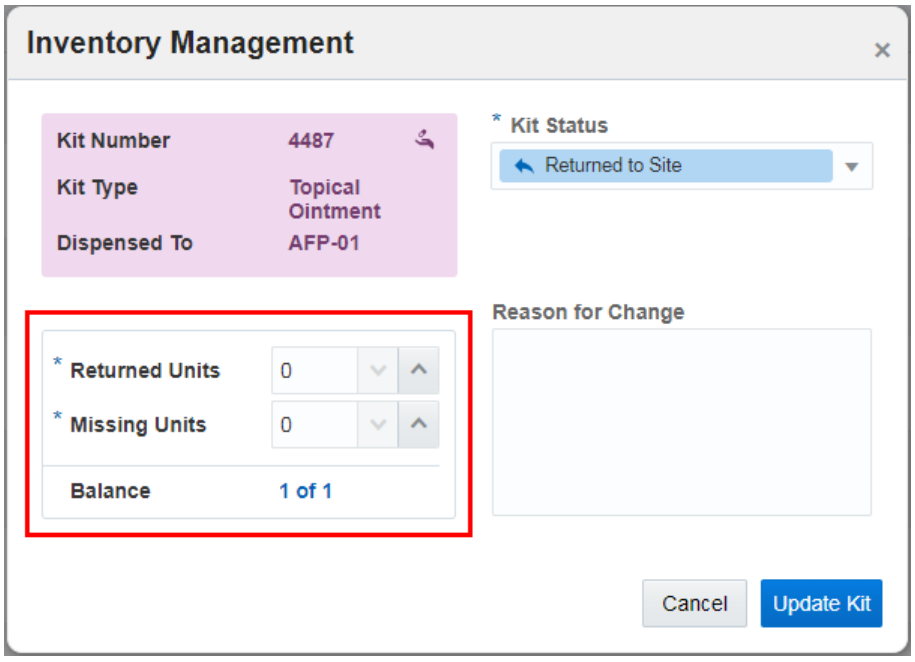
For more details on how to confirm you've received the kits and destroyed them, see Receive and destroy kits.

Site users: Check notifications

Whenever a new shipment for destruction is created, a kit is missing from a destruction shipment, or a destruction shipment wasn't received by the depot user, you'll receive a notification.

What if a site user can't see the Returned Units and Missing Units fields?

Issue: A site user clicks the link for a dispensed kit in Subject History, selects a new kit status, and doesn't see the Returned Units and Missing Units fields in the Inventory Management pop-up.



What to do: Select Yes for Kit Reconciliation Required on the Supply Settings tab for both Production and Training modes.

Query FAQs

- How can I tell when a site has responded to a query?
  The status of the query changes to Answered.
- Do I get notified when queries are created or responded to?
  No, and we suspect your inbox thanks us for that.
- How do I get information about the age of queries?
  You can see the age of all queries you have access to in the Subject Queries report.
- What do I need to do before I can start using queries?
  All the user manager needs to do is assign the appropriate roles, and then all query functionality is available.

How can I tell when a site has responded to a query?

The status of the query changes to Answered.

You can filter the list of queries, so you see only the answered queries.

Do I get notified when queries are created or responded to?

No, and we suspect your inbox thanks us for that.

But you can easily filter the list of queries so you see only the queries that the site has responded to.

How do I get information about the age of queries?

You can see the age of all queries you have access to in the Subject Queries report.

For more information, see the Subject Queries report.

What do I need to do before I can start using queries?

All the user manager needs to do is assign the appropriate roles, and then all query functionality is available.

- Assign the Sponsor Query Manager role to the appropriate sponsor users.
- Assign the Site Query User role to the appropriate site users.

Randomization FAQs

- How many times can I randomize in a study?
  It depends on whether your study uses cohorts.
- If my randomization list is blocked by site, country, or region, how are blocks assigned?
  Blocks are assigned either automatically or manually, depending on whether you use dynamic or static randomization.
- How are subjects randomized when multiple cohorts are open?
  During randomization, subjects are assigned the first available randomization number associated with an open cohort. This rule is true whether there are one, two, or more cohorts open.
- What is my workflow for setting up a study with multiple periods?
  You have to perform many of the same tasks, regardless of whether a study is blinded, open label, or both.
- What is my workflow for creating a study that uses cohorts?
- Can I randomize subjects without dispensing kits to them?
  Yes.
- Can I determine what happens when the next randomization number is associated with a code for a kit type that is not in stock at a site?
  Yes. You must determine this requirement when you create a randomization design, typically after consulting a standard operating procedure (SOP) at your organization.

How many times can I randomize in a study?

It depends on whether your study uses cohorts.

- For cohort studies, you can randomize into cohorts only one time.
- For studies without cohorts, you can randomize one or more times in a study.

When subjects are randomized a second or higher time, you can move some or all subjects into new treatment arms. And the study can change from being blinded to open label (or open label to blinded) after randomization, or you can leave it unchanged.

You can also move subjects into different treatment arms without randomizing again. If the protocol requires subjects to swap treatment arms without a second randomization event,

simply select the appropriate treatment for each week while defining the dispensation schedule.

If my randomization list is blocked by site, country, or region, how are blocks assigned?

Blocks are assigned either automatically or manually, depending on whether you use dynamic or static randomization.

- With dynamic assignment, Oracle Clinical One Platform assigns a block to a given site, country, or region during randomization.
  We recommend using dynamic assignment. This type of randomization uses the numbers in the list more efficiently and can help reduce having large sections of unassigned numbers.

  For instance, for site-blocked randomization, Oracle Clinical One Platform assigns the first block to the first site that enrolls a subject. Subsequent subjects who enroll at the site are randomized using the numbers in that block until all numbers are used. Oracle Clinical One Platform assigns another block to the site after all numbers are used and another subject enrolls.
- With static assignment, a statistician assigns blocks to sites, countries, or regions in the randomization list.
  Static assignment can sometimes lead to randomization failures that are difficult to troubleshoot.

How are subjects randomized when multiple cohorts are open?

During randomization, subjects are assigned the first available randomization number associated with an open cohort. This rule is true whether there are one, two, or more cohorts open.

What is my workflow for setting up a study with multiple periods?

You have to perform many of the same tasks, regardless of whether a study is blinded, open label, or both.

1. Create and schedule all visits, including the visit(s) in which randomization occurs.
2. Define the treatment arms.
3. Create the randomization designs in chronological order (create the first randomization design first, the second randomization design second, and so on).
   Is the study open label, or does it start with an open-label period and doesn't involve randomization? You still have to create a randomization design. The randomization design is how you indicate when the open-label period starts.
4. Add the first and then the second (if it exists) randomization design to the appropriate visits. You have to associate randomization designs with visits in chronological order.
   For the second or higher randomization event in a study, if you chose to map subjects to new treatment arms, the Map Treatment Arms pop-up appears.
5. (If the Map Treatment Arms pop-up appears) Perform the following tasks:
   a. Choose the new treatment arms for subjects:
      - If you map all subjects in a treatment arm to a single treatment arm, subjects aren't randomized.

- If you map subjects in one treatment arm to 2 different treatment arms, randomization determines their new treatment arm.

b. Specify the treatment ratio for the treatment arms.

6. Create kit types.

What is my workflow for creating a study that uses cohorts?

The following entries outline key tasks for creating a study that uses cohorts.

1. Study designers: Create a randomization design that randomizes subjects into cohorts.
2. Randomization list managers: Generate or upload a randomization list for the cohort randomization.
3. Study managers:
   a. Specify limits and notification levels for each cohort.
   b. Open and close cohorts when appropriate in the study.

Can I randomize subjects without dispensing kits to them?

Yes.

If you're not dispensing kits, you don't have to create kit types or define the dispensation schedule.

Can I determine what happens when the next randomization number is associated with a code for a kit type that is not in stock at a site?

Yes. You must determine this requirement when you create a randomization design, typically after consulting a standard operating procedure (SOP) at your organization.

If you allow sites to randomize when the required kit type is not in stock (sometimes known as forced randomization), you also must determine whether the randomization number that you skipped over is assigned to another subject.

When a site randomizes even though a required kit type is not in stock, information about the forced randomization appears in the Randomization List (Unblinded) report. The letter Y appears in the Restricted to Available Kits column.

Randomization lists and kit lists FAQs

- Guidelines for creating a kit or randomization list
  If you choose to upload a kit or randomization list into the system, there are certain guidelines related to special characters and file formatting that you should keep in mind before performing this task.
- Can I check that the randomization list or kit list generated by Oracle Clinical One Platform matches my requirements?
  Yes. On the last page of the wizard that generates a list, you can export the list to a CSV file.
- Can I test using a randomization list or kit list that Oracle Clinical One Platform generates and then upload a list from a statistician for a production study?
  Yes. You can also provide the generated lists to the statistician to simplify the process of creating the production lists.

- Can Oracle Clinical One Platform generate a kit list for my study?
  Yes. The kit list is scrambled to protect the study blind. You can also upload a kit list from a statistician.
- Can Oracle Clinical One Platform generate a randomization list for my study?
  Yes, or you can upload a randomization list from a statistician.
- How do I specify the size of the blocks in my randomization list to prevent unblinding?
  You specify a multiplier that is used to calculate the number of randomization numbers in each block in the randomization list. Oracle Clinical One Platform adds the numbers in a treatment ratio and multiplies the sum by the multiplier.
- How many randomization lists should I have for a study?
  To prevent potential unblinding, create separate lists for Testing, Production, and Training modes. If a statistician provides only the production list for a study, we recommend that you upload it for use in Production mode and generate lists for use in Testing and Training modes.

Guidelines for creating a kit or randomization list

If you choose to upload a kit or randomization list into the system, there are certain guidelines related to special characters and file formatting that you should keep in mind before performing this task.

The guidelines listed below apply to both a randomization and a kit list. While some of the information below is comprised of several tips, there are some points that simply explain any odd behavior the system may exhibit when uploading a randomization or kit list.

Special characters in lists

Here are a couple things to keep in mind before uploading a kit or randomization list.

- UTF-8 special characters such as "|", "/", "$", "&", "-" can be used in kit lists.
- Follow the standard CSV file name format. For example, use "KitList.CSV" or "Kit_List.CSV", but do not use "Kit.List.CSV".
- Commas are not permitted within randomization list fields. For example, use "PartB(400 mg) 65 more than one non-US" instead of "Part B(400 mg) 65, more than one, non-US".

Leading zeros in lists

When uploading a list, any leading zeros in your upload list are removed.

Formatting of the CSV file

When it comes to the format and structure of your lists, here are some things that you need to know before uploading a list in the system:

- First row in a CSV file must be populated with the column headers for the mapping to be done in the system. For example, if you upload a kit list where the first row is populated with your internal naming convention for the file within column A and the rest of the columns are blank, the kit list won't be mapped in the system, except for column A.
- Cells within the CSV file cannot contain any values if no column headers are populated in the file. For example, if you upload a list with four column headers, but you populated some rows in the fifth column, the system won't be able to upload your file.
- Maximum allowed number of rows in a randomization and kit list is 500.000 rows.

Difficulties during the upload process

Sometimes, after having already uploaded one or two lists, a caching issues occurs in the system. For example, if you upload a second list in the system, you might get an error message stating that your list cannot be uploaded during this time. Usually, the cause of this error lies within the saving process. The system saved data from the first upload attempt, such as the list's name, therefore it won't allow you to upload another list again, as though you're attempting to load the same list with the same name a second time.

You can work around this issue by clearing the cache in your browser.

Can I check that the randomization list or kit list generated by Oracle Clinical One Platform matches my requirements?

Yes. On the last page of the wizard that generates a list, you can export the list to a CSV file.

Can I test using a randomization list or kit list that Oracle Clinical One Platform generates and then upload a list from a statistician for a production study?

Yes. You can also provide the generated lists to the statistician to simplify the process of creating the production lists.

Can Oracle Clinical One Platform generate a kit list for my study?

Yes. The kit list is scrambled to protect the study blind. You can also upload a kit list from a statistician.

Can Oracle Clinical One Platform generate a randomization list for my study?

Yes, or you can upload a randomization list from a statistician.

When you generate a list, you can specify the size of the blocks within the list. The numbers within each block are scrambled. In a scrambled list, randomization numbers are assigned to treatment arms in a different order in each block so that people cannot predict the treatment arm that a subject is assigned to.

If you generate a randomization list for each mode of the study, the lists are scrambled differently, so that subjects are assigned to treatment arms differently in Testing than in Production.

If you selected a type of randomization with Fixed in its name, you must assign blocks of randomization numbers to each site, country, or region after either uploading or generating a list.

How do I specify the size of the blocks in my randomization list to prevent unblinding?

You specify a multiplier that is used to calculate the number of randomization numbers in each block in the randomization list. Oracle Clinical One Platform adds the numbers in a treatment ratio and multiplies the sum by the multiplier.

For example:

- For a 1:2 ratio, the sum is 3 (1 + 2 = 3).
- For a multiplier of 4, the block size is 12 (3 x 4 = 12).

We recommend that you use a multiplier of 2 or higher to prevent unblinding.

How many randomization lists should I have for a study?

To prevent potential unblinding, create separate lists for Testing, Production, and Training modes. If a statistician provides only the production list for a study, we recommend that you upload it for use in Production mode and generate lists for use in Testing and Training modes.

Site, depot, labs, and source data verification FAQs

- About depot-to-depot shipments
  Depot-to-depot shipments offer full traceability of kits used within a study, so it is important to understand a user's role in the lifecycle of a depot shipment.
- I'm ready to go live. What do I need to do with sites?
  Assign a study version to each site, and then activate the sites. After you activate a site, the site can start collecting data, so don't activate a site until you're ready for the site to go live, such as after all contracts have been signed.
- How are subjects selected for targeted source data verification?
  If your study only requires partial source data verification (SDV), then you might opt for configuring targeted SDV and create a partial SDV strategy. This configuration defines a specific number of subjects randomly selected at a site and the specific questions that a Clinical Research Associate (CRA) must verify.
- How do changes in Source Data Verification settings impact a study?
  The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.
- If a site is involved in more than one study, do I need to create multiple instances of the site?
  No. You can create a site in a study, and then you can add it to any other study without having to re-enter details about the site.
- If a depot is involved in more than one study, do I need to create multiple instances of the depot?
  Yes. You must define the depots for each study individually.
- What is the workflow for creating and managing local labs?
  The following steps outline key tasks for creating and managing local labs, whether you're a study designer, a data manager, or another user at a sponsor organization assigned with creating and managing laboratories in a study.

About depot-to-depot shipments

Depot-to-depot shipments offer full traceability of kits used within a study, so it is important to understand a user's role in the lifecycle of a depot shipment.

> **Tip:**
>
> You can create a depot-to-depot shipment to stage kits at the depot before they're released at a site. To do this, a clinical supply manager or depot user should configure a specific setting called **Release for Depot to Depot**. For more information, see Manage expiration dates with lots.

Create and activate a depot

A clinical supply manager creates both the source depot and the destination depot in the application. Once created, make sure that a resupply strategy is assigned to the source depot, and that every depot in this supply chain is activated.

For step-by-step instructions, see:

- Add a depot for a study
- Activate a depot
- Assign a resupply strategy to a depot

Create and manage a min/max resupply strategy

A clinical supply manager creates a min/max resupply strategy for the destination depot. For step-by-step instructions, see Create a min/max resupply strategy.

Create a depot-to-depot shipment

A clinical supply manager or a depot user can create a depot-to-depot shipment. For step-by-step instructions, see Create a manual shipment.

Manage kits for destruction

Besides a manual shipment, a depot user may have to create a shipment for destruction. A shipment for destruction may be required when the study is configured to accept the destruction of kits at a depot facility and a depot in your study is configured as drug destruction capable. A shipment for destruction contains all kits marked as Pending Destruction in the study inventory.

For step-by-step instructions, see

- Mark a kit for destruction
- Create a shipment for destruction
- Receive and destroy kits

Stay up-to-date with changes in the supply chain

Depending on whether you have the associated permissions or not, you may receive some or all of the notifications listed below, All these notifications contain information about the source and destination depots for depot-to-depot shipments:

- New Shipment for Destruction Created notification
- Kit Missing from Shipment for Destruction notification
- New Shipment Request notification
- Kit Missing from Shipment notification
- Shipment Failure notification
- Depot Shipment notification

For more information, see Notifications.

I'm ready to go live. What do I need to do with sites?

Assign a study version to each site, and then activate the sites. After you activate a site, the site can start collecting data, so don't activate a site until you're ready for the site to go live, such as after all contracts have been signed.

For details, see Assign a study version to a site and Activate a site.

How are subjects selected for targeted source data verification?

If your study only requires partial source data verification (SDV), then you might opt for configuring targeted SDV and create a partial SDV strategy. This configuration defines a specific number of subjects randomly selected at a site and the specific questions that a Clinical Research Associate (CRA) must verify.

To set SDV in your study as partial targetd SDV, see Specify settings for Source Data Verification.

To create an SDV strategy, see Create a source data verification strategy and assign it to a site.

When you create a strategy for targeted SDV, you have to specify the total number of initial subjects and the percentage of remaining subjects that a CRA must verify. When the SDV strategy is assigned to a site, these numbers define the criteria for the targeted SDV subject pool, which are the selected subjects that will require verification for that site.

The **Initial Subjects** are selected as they are screened or added to the site (depending on the **Include Screen Failures** setting), until the defined number is reached. From there on, subjects are randomly selected among the **Remaining Subjects** to reach the defined percentage. Any subject that has not already been selected in the SDV pool and is eligible for selection, can be included in the SDV pool, even if there is a subject already selected that was added after it in the study.

Depending on whether screen failed subjects are included or not (as per the study's general SDV settings), the initial subjects may be selected differently and the calculation for the remaining subjects may be different as well:

- When the **Include Screen Failures** setting is set to **Yes**, the SDV pool considers subjects for data verification as soon as they have been added to the site.
  Given that screen failed subjects are eligible for SDV, the total count of subjects used to calculate the percentage of remaining subjects to be selected, also considers screen failed subjects.
- When the **Include Screen Failures** setting is set to **No**, the SDV subject pool doesn't consider subjects for data verification until their status is **Enrolled** or **Randomized**. When considering the initial subjects selection, subjects are evaluated in the order that they are added to a site and a subject is not skipped for data verification unless it gets a status of **Screen Failed**, even if a subject added later is enrolled first.
  Given that screen failed subjects are not eligible for SDV, newly added subjects, screen failed subjects, and subjects whose screening is in progress are excluded from the total count of subjects, which is used to calculate the percentage of remaining subjects to be selected. These subjects can only be later included in the total count if they become eligible for SDV, and this may happen if they later get successfully screened or become completed.

> **Note:**
>
> Questions that are marked as **SDV for All Subjects** still require verification for excluded subjects.

Let's consider the following example: *A CRA must verify **3** initial subjects at a site and an additional **25%** of the remaining subjects.*

If screen failures are included:

After the first three added subjects are selected for SDV, the system continuously strives to match and maintain the percentage of subjects from the remaining subjects (excluding the first three) to be randomly selected, which is 25%. However, this calculation is always converted to the next whole number to ensure the defined percetage is reached. For instance, if there is only 1 remaining subject, the 25% percent of all remaining subjects would be 0.25, but since the system cannot select 0.25 subjects, 1 subject is selected (which is the next whole number). For this reason, the first subject added after the initial subjects subset will always be selected as part of the remaining subjects subset. When a new subject is added, if that subject causes the number of randomly selected subjects to fall below the specified 25% threshold, then the system randomly selects a subject among all eligible subjects that aren't already selected.

If screen failures are excluded:

In this scenario, the initial subjects are selected only once they are enrolled or randomized (depending on the study protocol). So the first 3 subjects that get added to a site, and are either enrolled or randomized, are selected. If there is any subject that fails screening, the next added subject is considered to take its place in the initial subject pool, if it gets sucessfully screened and either enrolled or randomized. So for instance, if subject 3 becomes screen failed, and subject 4 is successfully screened, subject 4 becomes the third and last initial subject selected for SDV. However, a subject will only get skipped from the initial subject count once it gets screen failed. So, following the same example, if subject 4 is randomized while subject 3 is not yet screen failed, the system reserves the spot for subject 3 as an initial subject in case it gets randomized. At this point, subject 4 is randomized, which makes it eligible for SDV as a remaining subject. At the time subject 3 is screen failed, the system makes a new calculation and identifies subject 4 as the 3rd initial subject (regardless if it was already selected for SDV as a remaining subject). Then, the system evaluates the percentage of remaining subjects that require SDV, making a new selection out of the eligible remaining subjects if necessary.

The calculation for the remaining subjects proceeds as explained above, but in this case it is always among the enrolled or randomized subjects added after the first 3 initial subjects selected. In this case starting from subject 5. While new and screen failed subjects are not eligible for SDV and have no effect on the total count, every time an added subject becomes enrolled or randomized, the total count of subjects increases and the remaining subjects percentage is recalculated. Again, if the increased amount of total subjects makes the selected subjects to fall below the specified 25% threshold, the system will randomly select the necessary subjects to meet the defined percentage.

Updates that may impact subject selection

During the study conduct period, you may update SDV settings and the SDV strategy assigned to a site. Some of these updates may impact SDV requirements for a question and subject, thus the subject selection for SDV may change.

- If you update the **Include Screen Failures** setting from **Yes** to **No** after adding subjects in a specific study mode (Testing or Production), any screen failed subjects previously

selected for the **Initial Subjects** or **Remaining Subjects** pools get excluded and no longer require data verification.

> **Note:**
>
> If there was any data previously verified for these subjects, that data remains verified unless it is subsequently changed. Any subsequent data changes will not impact the SDV status of the excluded subjects. For more information on changes to the SDV status, see About Source Data Verification statuses.

A new subject is to be selected only if the site's current strategy requires replacement. For example, if you had selected three initial subjects and one of them was a screen failure and gets deselected, a new subject will be selected to meet the initial subjects count. But, if you also changed the strategy to two initial subjects, no new subject would be selected since two initial subjects would remain.

- If you update the **Include Screen Failures** setting from **No** to **Yes**, no changes occur for existing screen failed subjects, although they become eligible for SDV moving forward, based on your existing SDV strategy's algorithm.
- If a screen failed subject gets withdrawn or completed, it is no longer considered as screen failed but as either withdrawn or completed. Completed subjects are eligible for selection of the SDV subject pool, but withdrawn subjects are not.

> **Note:**
>
> These scenarios are only possible if the **Screen Failed Subjects** setting in the study settings is set to **Allow Withdrawal** or **Allow Completion** respectively. See Specify study, enrollment, and visits settings.

- If you increase the number of initial subjects in the SDV strategy after remaining subjects have already been selected for the SDV pool, the system selects the immediate next subjects that were added or screened for the initial subjects pool. Then, the system makes a new calculation for the remaining subjects, and randomly selects additional subjects if the current selection drops below the specified percentage.
- If the SDV strategy changes to reduce the number of subjects requiring SDV, a subject already selected for SDV cannot be deselected. The new strategy will apply to newly entered subjects and the system will adjust to match and maintain the percentage of selected subjects as the total number of subjects increases.

For other impacts on your study when the SDV settings change, see How do changes in Source Data Verification settings impact a study?

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.

- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- Configure source data verification settings for a question

How do changes in Source Data Verification settings impact a study?

The Source Data Verification (SDV) settings can be updated at any time. This includes the study level settings to either include or exclude screen failed subjects, or to require different levels of SDV (full, targeted or none). For targeted SDV, you may also update the SDV strategy associated with a site or the SDV settings for a specific question in form design.

For more information about SDV settings and use cases see Understand source data verification.
Whenever the SDV configuration is updated, your study is impacted in different ways and you must consider the following:

- Any changes to a study's **Source Data Verification** settings are only reflected on a subject once a visit for that subject is started subsequently. For example, if new questions are made SDV required making the whole visit verification required for the subject.
- If you update the **Include Screen Failures** setting from **Yes** to **No** after adding subjects in a specific study mode (Testing or Production), any screen failed subjects previously selected for the **Initial Subjects** or **Remaining Subjects** pools will be excluded. Any data that was previously verified remains verified, but any subsequent data changes will not impact the SDV status of the subject.

  > **Note:**
  >
  > Even when screen failed subjects are excluded, questions marked as **SDV for All Subjects** remain SDV required for them.

  In the case of a previously selected screen failed subject getting excluded, a new subject is to be selected only if the site's current strategy requires replacement. For example, if you had selected three initial subjects and one of them was a screen failure and gets deselected, a new subject will be selected to meet the initial subjects count. But, if you also changed the strategy to two initial subjects, no new subject would be selected since two initial subjects would still remain.
- If you update the **Include Screen Failures** setting from **No** to **Yes**, no changes occur for existing screen failed subjects, although they will be eligible for SDV moving forward, based on your existing SDV strategy's algorithm.
- Other changes to the selection criteria for the targeted SDV subject pool, derived from changes on an SDV strategy assigned to a site, are reflected once the next subject is selected for SDV.

  - If, in the SDV strategy, you increase the number of initial subjects after remaining subjects have already been selected for the SDV pool, the system selects the immediate next subjects that were added or screened for the initial subjects pool. Then, the system makes a new calculation for the remaining subjects, and randomly selects additional subjects if the current selection drops below the specified percentage.
  - If the SDV strategy changes to reduce the number of subjects requiring SDV, a subject already selected for SDV can not be deselected. The new strategy will apply to newly entered subjects and the system will adjust to match and maintain the percentage of selected subjects as the total number of subjects increases.

  For more information, see How are subjects selected for targeted source data verification?

- Forms, visits, or subjects with a **Verified** status or that do not require SDV can change status to **Verification Required**. This may happen in the following situations:
  - Questions requiring SDV are added or updated through a change in SDV settings.
  - A parent question is updated and the new answer triggers the display of a dynamic question that is SDV required, or a dynamic form with at least one question that requires verification.
  - A subject is now selected for the targeted SDV subject pool (Targeted SDV only).
- The number of questions requiring SDV may decrease and this can change the status of a visit from **Verification Required** to **Verified**. For example, if a study manager changes the SDV settings from 100% to Targeted SDV.
- All verification records in the **Answer & Visit History** are attributed to the user who performed the verification actions. However, if the SDV requirements of a study change, the verification records associated to the change are attributed to **AutoSDV** and display the time when the SDV status was updated.

Related Topics

- Understand source data verification
  Source Data Verification (SDV) allows you to validate the accuracy of the data collected during the study. The SDV settings allow you to tailor the level of data verification required for a study and site.
- Specify settings for Source Data Verification
  Source Data Verification (SDV) settings allow you to tailor the level of data verification required for each study and site. These settings apply to all study versions and you can edit them at any time. This procedure is typically done by a study manager and also applies to rollover studies.
- Create a source data verification strategy and assign it to a site
  If your study uses targeted Source Data Verification (SDV), the SDV strategy ensures that SDV is performed for a specific number of subjects and for either all questions or only critical questions in a study. Any SDV strategy must be associated with a site to become effective.
- Verify a subject's data
  If Source Data Verification (SDV) is required in your study, then you must perform this task to make sure the data collected during a study is accurate.
- About Source Data Verification statuses
  Depending on how your study has defined your Source Data Verification (SDV) settings, you can encounter different statuses and icons in subjects' questions, forms and visits.
- Configure source data verification settings for a question

If a site is involved in more than one study, do I need to create multiple instances of the site?

No. You can create a site in a study, and then you can add it to any other study without having to re-enter details about the site.

When you add an existing site to a study, you can change details about the site for the study without affecting the site in other studies. For instance, you change the address or phone number.

Additionally, a site can have different statuses in each mode. For example, a site can be Active in Testing mode so you can verify a study and New in Production and Training modes.

If a depot is involved in more than one study, do I need to create multiple instances of the depot?

Yes. You must define the depots for each study individually.

What is the workflow for creating and managing local labs?

The following steps outline key tasks for creating and managing local labs, whether you're a study designer, a data manager, or another user at a sponsor organization assigned with creating and managing laboratories in a study.

Global users: Set up a vendor (lab) at the global level

As a global user, you need to first set up a vendor (lab) at the global level. Only after that can a data manager or another site user add that lab in their study. For step-by-step instructions, see Create a vendor (lab). For more information on how to manage institutions, vendors, and contacts, see the chapter Create and manage institutions, vendors, and contacts.

Study designers: Create a lab form and tag lab items

As a study designer, you need to perform specific tasks to make sure created labs contain the appropriate lab normals associated with them. For the exact steps of your tasks, see Create a lab form.

The above-mentioned topic describes your required tasks in the following order:

1. Make sure questions on age, gender, and race are created and included in a Demography form, as well as tagged with the appropriate subject tag.
2. Create a lab form.
3. Define lab tests, including the code list used for this item, as well as tag the code list and the lab results item.
4. Define code lists for lab units and normal text results.

Data manager: Create and manage a lab

1. Add a lab to a study.
2. Define lab normals.
3. Assign a local lab to a site.

Study version and rollover study FAQs

Can I work on and test two versions of a study at the same time?

At any given time in a study, you can design one version, and you can test one version.

I need to update my Production study because of a revision or protocol amendment. What do I do?

Create a new version of the study. The new version is identical to the latest study version.

Need step-by-step instructions? See Updates during the study conduct period in the *Study Designer User Guide*.

Can I have multiple versions of a study in production?

Yes.

How many different study versions can I have for a study?

As many as you need, though you can configure the study only in the Draft version. Additionally, you can have only one study version in Draft at a time and only one study version in Testing at a time.

How do I know which is the latest version of a study?

The latest study version has the highest number in the last position (for example, 4 in 1.0.0.4).

What is my workflow for setting up a rollover study?

Your workflow as a study team member in a rollover study is the same with your workflow in the original study.

See the workflow to Operate a clinical study in Oracle Clinical One Platform.

1. To get ready for Testing mode, you have to Set up facilities and Define settings. At a minimum, you will have to:
   a. Add and activate depots.
   b. Add sites.
   c. Add regions.
   d. Specify subject, visit, limit, and cohort settings.
   e. Specify supply settings.
   f. Create a resupply strategy and blinded groups of kits.
2. After that,Manage randomization and supplies. At a minimum, you will have to:
   a. Generate or Upload a randomization list and kit list.
   b. Manage expiration dates with lots, and assign kits to manufacturing lots.
   c. Create label groups.
3. Moving on, you can make the rollover study live in Testing mode. Make sure you:
   a. Assign a study version to a site.
   b. Select a resupply strategy for the site.
   c. Open and close a cohort.
   d. Activate the sites.
   e. Release kits to sites or depots.
4. Verify the rollover study.
5. You have to repeat some of these steps to configure your study in production mode. Only then will you be able to make the rollover study live in production mode.

Learn more about how to work during the study conduct period.

Use our Quick Start for the Study Team to have a checklist at handy for setting up your rollover study.

Update study settings during the study conduct period

You can edit all study settings at any time, but use caution when changing the subject numbering fields, particularly if subjects have already been screened. Updating these fields could result in inconsistent subject numbers. This also applies to subjects who are enrolled in a rollover study and keep their original study ID. Changing their number might result in inconsistencies when it comes to subject numbers in your rollover study.

The subject numbering fields are:

- Include Hyphen in Subject Numbers
- Leading Zeros in First Subject Number
- First Subject Number
- Subject Numbering
  - If you change to a higher value mid-study, there will be a gap in the subject numbers.
  - If you change to a lower value mid-study, you don't have to worry about duplicate subject numbers because subject numbers are never reused.

Subject and data entry FAQs

- About clearing dynamic questions
  Consider these points when it comes to clearing dynamic questions.
- Can a subject who screen failed be rescreened?
  It depends on the reason the subject failed screening.
- How does clearing data may impact my study?
  Clearing saved data on a form differs from simply deleting data in a question. Clearing data has different effects on the different study areas.
- How is data impacted when a site user undoes a subject's event?
  Whenever a site user or any other user undoes a subject's withdrawal, screen failure, or study completion, your study's data is impacted in several places.
- What is a change for encoding?
  In Oracle Clinical One Platform, *Change for encoding* represents a predefined reason included in your organization's default system code list. You can typically select this option for justifying an update to data that was already collected and saved for a subject.
- What is the difference between an XPORT and CPORT file format?
  The SAS Transport file format (XPORT) is an openly documented file specification maintained by SAS, a commercial company with a variety of software products for statistics and business analytics. The CPORT file format is not openly documented. In Oracle Clinical One Platform, SAS Transport File Formats are currently running on Version 8.
- What are my options for defining a subject's number format?
  If you allow site users to enter subject numbers, you must define the subject number format. This ensures consistency for all subject numbers assigned in a study. When defining this format, you have several options.
- What does a site user do when a subject moves?
  The study team can transfer the subject to a site that is closer to home, as long as the new site uses the same or a newer study version as the subject's original site.
- What happens if a site user enters invalid data?
  A message explains why the answer does not meet the required criteria, but if the question isn't marked as required, then screening, randomization, and dispensation can still occur.
- What happens to coded terms when the answer to a coding question is cleared or updated?
  When a site user modifies or removes a coding question's answer, coding targets are automatically cleared.
- What happens if a site user doesn't answer a required question?
  The site user can save the form, but the subject can't be screened or randomized, and kits cannot be dispensed.

- What time zone is subject data in?
  If the time zone is specified for the site, all values on the Subjects page are in the site's local time zone except the date and time values in Answer & Visit History, which is on the right when you open a visit.
- What can't be done after a subject completes a study?
  Forms that weren't started prior to study completion can't be started. Additionally, other subject actions, such as screening, randomizing, withdrawing, dispensing, and skipping a visit, can't be done.
- What states can a subject have?
  Depending on the protocol, site users can update a subject's state through multiple actions for a number of times during the study. But have you ever wondered what each state really means for the way you manage subjects' data at a site?
- What actions impact subjects?
  Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?
- What does each icon mean for signing, verifying, or freezing data?
  Each sign, verify, or freezing action has an impact on the study data. Learn more about what each icon means.
- Workflow for updating a subject number during the study conduct period

About clearing dynamic questions

Consider these points when it comes to clearing dynamic questions.

Impact on integrations

The inbound multi-IWR integration that is configured to send data for dynamically-displayed questions only (and not the determining question) requires an external request to clear the data before you can update their determining question. If you're using this integration and you configured it to send data into the system for both types of questions (determining and dynamically-displayed), then you must work with the integration manager to ensure that the external request first clears the dynamically-displayed questions, and then their determining question.

Impact on reports

When it comes to reports, consider the following:

- If a label question in a repeating form is cleared, the Answer and Visit History and the Subject Data report record an event that the labeled question's value was cleared.
- The Subject Data report includes a new value of **Cleared - Dynamic hidden** in the **Reason for Change** column for each dynamic question that is hidden. This value is included only when you select **Yes** for the **Include Cleared Data** setting.

> **Note:**
>
> Data that is cleared will not be included in the Subject Data Extract.

Related Topics

- About updates to the dynamic questions

- Update the answer to a dynamic question

Can a subject who screen failed be rescreened?

It depends on the reason the subject failed screening.

- If the subject failed screening based on an error in data entry and didn't meet the requirements on the form, a site user can edit the form, enter the reason for the change, and screen the subject.
- If a site user selected Screen Fail from the Manage Subjects drop-down, the site user can't rescreen the subject. The site user must add the subject to the study again.

How does clearing data may impact my study?

Clearing saved data on a form differs from simply deleting data in a question. Clearing data has different effects on the different study areas.

When a question is cleared it gets returned to an unanswered state, with no data associated to it. This can be compared to a reset and is a change that occurs in the backend. Conversely, when a question's answer is removed, by using the **Delete** or **Backspace** keys, it replaces the answer by an empty string or value. In turn, there is still data associated to the question, just that this data is an empty answer.

> **Note:**
>
> Even if you clear a question's data, its whole answer history is retained. All actions performed on a question are listed on the Answer & Visit History sidebar and in the audit trail.

Impact on data collection

If you are a Clinical Research Associate (CRA), a data manager, or any other sponsor user involved in maintaining data integrity, you should know how clearing form data impacts the data collection process. Understanding the impacts on data collection is important as it may affect data review and the Source Data Verification (SDV) processes.

- When you clear or remove a required question, a form's status is set to Incomplete. However, , when you clear or remove an optional question, a form's status is not impacted.
- If you update a question that has an open manual query (either by updating, removing or clearing data), the query status is updated to **Answered**. For the case of automated queries, it always depends on the rule logic, see Impact on custom rules.
- When a site user updates a question that was previously cleared, a reason for change is not provided.
- All icons next to a cleared question disappear. However, the respective actions on the question (such as unsign, unverify or unlock) are listed on the Answer & Visit History sidebar.
- When a site user clears a verified or signed question, it becomes unverified or unsigned, respectively. As mentioned, the Unsigned and Unverified icons do not display for the question, but the action is listed on the Answer & Visit History sidebar.
- When you clear a completed visit date, the visit's status is updated to Incomplete.

- When you clear a date that is used to determine lab normal ranges, the system date at the time of the update is used instead to populate the calculated values. For calculations using the visit date (like age questions), clearing the visit date results in a failed calculation and an incomplete question.

Impact on custom rules

When a question used as a rule's input is updated (cleared, removed or replaced with a new value), the system processes the change causing the impacted rule or rules to be re-run. The end result depends on the rule logic and is applicable to all types of custom rules:

> **Tip:**
>
> You can view the resulting actions in the Answer & Visit History sidebar, each stated as the result of rule execution.

- For rules that populate calculated values, if a question used as an input for the calculation is removed or cleared, the rule re-runs with an empty value as the input. This would typically result in the calculated value also getting removed or cleared (respectively). However, you should keep in mind that the output always depends on what the rule logic dictates.

  > **Note:**
  >
  > Clearing or removing a value makes it null and it is not the same as making it zero.

- If a question with an opened automated query is cleared or removed, either directly or as a result of calculation rule, the query will behave according to what the rule dictates. Typically, the automated query would get **Closed**, but this is only if the condition for the query no longer applies and as long as the rule logic doesn't dictate differently.
- For rules that raise queries or send notifications, the result of clearing the input depends on how an empty input would trigger the rule. So, only for the case of rules that raise queries or send notifications when detecting empty values, clearing a value results on a notification being sent or a query being raised against the question.

Impact on reports and data extracts

- The Subject Data Extract does not include records of forms for which all data has been removed (either deleted using the **Backspace** key, reset or cleared).
  - This also applies to when the *Not Answered* data flag populates for form items as a result of Source Data Verification (SDV), sign, freeze or lock actions.
- The Subject Data report has an option to include or exclude cleared data available in the Settings pane on the right.
- In the Subject Events Report, for the event of clearing a visit date in Oracle Clinical One Platform, a *Visit Date Cleared* value displays under the Event Type column.

Impact on integrations

If you're an integration manager working with Oracle Clinical One Digital Gateway, clearing data in a form only impacts the following integrations:

Integration with	Impacts of data clear
Oracle InForm	Upon data being cleared in Oracle Clinical One Platform, a clear data action is issued in Oracle InForm along with the specified reason for change.
Oracle Central Coding	When a site user clears a Verbatim or coding context item (Route of Administration or Indication) Oracle Central Coding operates as though a user has removed or updated the value in that field. The update is properly reflected in Oracle Central Coding and the new data that is entered for a Verbatim, Route of Administration, or Indication is coded as new data.
Any other third-party electronic data capture (EDC) system	Upon data being cleared in Oracle Clinical One Platform, a null value is sent through Oracle Clinical One Digital Gateway to the third-party system.

For more information, reach out to your Oracle point of contact.

Related Topics

- About data clear and data removal
- Clear a visit date
- Clear form data
- Subject Data Extract
- Subject Data report
- Subject Events Report

How is data impacted when a site user undoes a subject's event?

Whenever a site user or any other user undoes a subject's withdrawal, screen failure, or study completion, your study's data is impacted in several places.

If a subject's withdrawal, screen failure, or study completion is associated with a visit with data already collected, that data can be impacted, depending on its nature. For example, certain custom JavaScript rules may need to be re-run, while signed or verified data may become unsigned or unverified. See the different use cases below.

General impact on the study's data for undone events

Consider the following notes:

- Whether you're a user working on the sponsor team or you're part of the site staff, you should not attempt to enter additional data into the Screen Failure, Study Completion, or Withdrawal visit when the subject is not in the applicable state. This is because the data may not be retained in the system.
- If you select **Edit Screen Fail** for a subject who was automatically screen failed, the reason for that subject's screen failure is read-only and you cannot update it on the Edit Screen Failure dialog.
- The Undo Subject Screen Failure notification is only sent when a site user manually screen fails a subject. If you update data related to a validation that resulted in a subject being automatically screen failed, no notification is sent to you if the subject is then successfully re-screened.
- To hide an associated Screen Failure, Study Completion, or Withdrawal visit, all data should be cleared from the visit. This includes the following:

  - All data, including hidden data;
  - All queries, whether automated or manual, should be closed;
  - All data flags should be cleared, not manually removed.

Impact on custom JavaScript rules

Here's what you need to know when it comes to how custom rules behave when a subject event is undone:

- Whether it's specified or edited by a site user, or defaulted by the application, the date of a subject's withdrawal, completion, and screen failure (as well as the date of their undoing) is returned to the **Subject Object** attributes for the respective dates. The subject object used in custom rules throughout your study reflects the updated data.
- If clearing a question triggers a calculation rule to populate a target field, in a visit that is being cleared, that visit should not be hidden until the calculation is cleared by the user. In a withdrawal, completion, or screen fail visit, when a site user clears data using the **Clear** option (and not by pressing the Backspace or Delete keys) and a subject's status doesn't match the status required to trigger the visit, the following may happen:
  - For example, if a subject's status is *Completed* and a site user attempts to clear data in a withdrawal visit, any rules that make use of questions in that visit will re-run.
  - After all rules run, the visit is evaluated for any data being present. This is to ensure that no calculation rules have populated values in the visit. If no data is present in the visit but there are open or answered queries, or open candidate queries the visit isn't hidden until the queries are closed, either manually by a sponsor user or automatically. Once all queries are closed, the visit is hidden, and a site user is redirected to the **Subjects** page.
  - If a subject's status is *Withdrawn*, their screen fail visit should not be hidden if the study setting to allow withdrawal after screen fail is selected, and a subject's status of *Screen Failed* has not been undone by a site user (through undoing the screen failure or rescreening the subject).

Impact on signed, verified, frozen, locked, or queried data

Here's how signed, verified, frozen, locked, or queried data may be impacted when a subject's visit is undone:

- When a subject's Withdrawal, Screen Fail, or Study Completion event is undone, if the associated visit's data remains unverified, and is subsequently cleared, the subject's status is not marked as *Unverified*. This is due to unverified questions no longer being considered by the system. If not all data is cleared at once from a visit associated with an undone event, and the visit remains visible for sometime, any uncleared and unverified data is reflected in the subject's status.
- When a subject is locked, while multiple visits associated with undone events are displayed, these visits become locked, as well. For a site user to clear their associated data, and hide them from the **Subjects** page, subject and their visits need to be unlocked by a sponsor user. Moreover, for a subject's whose status is Locked, the option to undo that subject's events is not displayed on the Manage Subjects drop-down.
- If a subject's data is signed at the casebook level while a Withdrawal, Screen Failure, or Study Completion visit is visible, after clearing that visit's data, the visit is no longer included in the signature.
- A site user may not have the permission to close all queries raised against a visit that's associated with an undone event. To get help with closing queries, they should reach out to their Clinical Research Associate (CRA).

- Study Completion and Withdrawal visits should not be frozen until it is confirmed that the visits are required in a study. While it is possible to clear the visit's data and undo the subject's status, the visit remains visible in the User Interface (UI) due to the presence of the frozen question in the associated visit.

Impact on reports, data extracts, and archives

When a subject's visit is undone, data can be displayed differently in certain reports:

- When a Withdrawal, Screen Failure, or Study Completion visit is undone and its data is cleared, data for that visit is no longer displayed in the Subject Data Extract. Any data associated with these visits that isn't cleared by a site or sponsor user, continues to be included in the Subject Data Extract.
- The Subject Events Report, in the Visit/ Event Date column, displays the date of a subject's withdrawal, screen failure, or study completion event as entered by a site user. When a site user edits a subject's date for their withdrawal, screen failure, or study completion, the Event Type column displays this as a separate event (Completion Update, Withdrawal Update, or Screen Fail Update). The Visit/Event Date column also displays the new date for the event.

Impact on integrations

If your study has any EDC-related integrations, you can find more information in the *Digital Gateway User Guide* on how data on undone visits is sent to other applications:

- Clinical One to Oracle InForm
- Outbound subject data integration
- CTMS Subject Visit (SV)

Related Topics

- Manage subjects
- Subject notifications
- The Subject object

What is a change for encoding?

In Oracle Clinical One Platform, *Change for encoding* represents a predefined reason included in your organization's default system code list. You can typically select this option for justifying an update to data that was already collected and saved for a subject.

Changes to encoding refer to modifications in the encoding scheme of clinical data to ensure compatibility, reduce errors, and optimize data transfer or file conversions. This is particularly relevant for integrations, where data may need to be standardized across different systems or formats.

For more information on system code lists, see Browse the list of system default code lists.

What is the difference between an XPORT and CPORT file format?

The SAS Transport file format (XPORT) is an openly documented file specification maintained by SAS, a commercial company with a variety of software products for statistics and business analytics. The CPORT file format is not openly documented. In Oracle Clinical One Platform, SAS Transport File Formats are currently running on Version 8.

If you need to make a decision on what file format to choose when extracting data for regulatory submissions, learn more about the differences between the SAS Transport file

formats XPORT and CPORT. For more information, see SAS Transport File Format (XPORT) Family. Moreover, we recommend you consult the SAS Help Center.

XPORT file format	CPORT file format
• Designed primarily to support short-term transfer of data sets between statistical software systems • Not designed for long-term archiving • Consists of records 80 bytes in length • Character data is stored in ASCII, regardless of the operating system • Runs on Version 8 in Oracle Clinical One Platform • Recommended for statisticians and data managers extracting data during the study conduct period for data analysis purposes	• Designed only for transfer between statistical software systems running compatible versions of the CPORT files • Not compatible with XPORT file formats • Not openly documented, so there is very little information available about the file format • Data in this file format can be compressed and the file may be password-protected • Recommended for statisticians and data managers extracting data for regulatory submissions to the FDA or other regulatory agencies

What are my options for defining a subject's number format?

If you allow site users to enter subject numbers, you must define the subject number format. This ensures consistency for all subject numbers assigned in a study. When defining this format, you have several options.

The subject number format settings are defined using a textural description of the allowed characters in the subject number (also known as a regular expression). You can specify the characters allowed at each position of the subject number, moving from left to right. For example, you can use the expression **[0-9]** to indicate that this position allows a single digit between 0 and 9. In this way, you can specify the format for a multi-digit subject number as **[0-9] [0-9] [0-9]**, which means the subject number must be specified as a 3-digit number ranging from **000** to **999**. For example, subject numbers such as **123**, **001**, and **998** are all valid for this format.

In addition to this simple example, the subject number format also allows alphabetic characters and the dash (-) character. This allows you to create more complex subject number formats. Let's build on our previous example, **[0-9] [0-9] [0-9]**. For this example, let's assume you want to allow subject numbers that are prefixed with an alphabetic character and a dash. The alphabetic characters can be any English letter and can be either upper- or lowercase. The alphabetic character is followed by a dash (-) and then a 3-digit number. The expression for this example is **[a-z, A-Z]-[0-9][0-9][0-9]**. Subject numbers such as **A-123**, **C-459**, and **b-031** all conform to this formatting expression.

In both of our previous examples, we allowed a continuous range of numbers or letters at each position in the subject number, as well as the dash character. More complex numbering schemes are allowed. Additional options include the following:

- You can limit the available characters for any position by specifying a comma-separated list of allowed characters in place of a range. For example, the expression **[A,B,C, a,b,c]-[1,5] [0-9][0-9]** requires all numbers to begin with only the characters **A**, **B**, or **C** (in either upper- or lowercase) followed by either the number **1** or the number **5,** followed by two additional digits of **0-9**. In this case, allowed subject numbers include **A-124**, **b-599**, and **C-130** but **A-734** would not be allowed as the first numeric character following the dash must be either a **1** or a **5**.
- You can require a mandatory character by omitting the brackets in your expression (**[]**). For example, to always require the subject number to begin with **A**, you can specify something like **A[0-9][0-9]** which allows a subject number from **A00** to **A99**. Numbers such as **A13**, **A89**, and **A01** are all valid.

- Finally, you can also specify how many times a character can be repeated in a subject number. For example, to allow a subject number that contains a repeated digit, you can specify an expression such as **[0-9]{1,3}[A-Z]**. This expression allows subject numbers such as **123Z** or **12A**.

> **Note:**
>
> No matter which format you choose, the subject number will always be prefixed with the Site Number.

Recommended practices when defining the subject number format

For more information about the following study settings, see Specify study, enrollment, and visits settings

1. Set the Study Setting **Subject Numbering** to **Sequential in Study**.
2. Set the Study Setting **Leading Zeros in First Subject Number** to a minimum value of two (2).
3. Set the Study Setting **Include Hyphen Between Site and Subject Number** to **Yes**. This ensures you will avoid duplicate subject number issues like the one defined below.

Table 8-1 Recommended practice example

Without a hyphen	With a hyphen
Site name: s1 • s11 is subject 1 at site 1 • s111 is subject 11 at site 1	**Site name:** s1 • s1-1 is subject 1 at site 1 • s1-11 is subject 11 at site 1
Site name: s11 • s111 is subject 1 at site 11	**Site name:** s11 • s11-1 is subject 1 at site 11
Result: Duplicate subject numbers	**Result:** No duplicate subject numbers

Commonly Used Subject Number Formats

Numeric Digits Only:

- Subject numbers with up to 3 numeric digits: [0-9]{1,3}
- Subject numbers with up to 4 numeric digits: [0-9]{1,4}
- Subject numbers with up to 5 numeric digits: [0-9]{1,5}
- Subject numbers with up to 6 numeric digits: [0-9]{1,6}

Numeric Digits terminated by a single alphabetical character

- Subject numbers with up to 3 numeric digits followed by the letters ‘a’ through ‘z’: [0-9]{1,3}[a-z]
- Subject numbers with up to 3 numeric digits followed by the letters ‘a’ or ‘c’: [0-9]{1,3}[a,c]
- Subject numbers with up to 6 numeric digits followed by the letters ‘a’ through ‘z’: [0-9]{1,6}[a-z]
- Subject numbers with up to 6 numeric digits followed by the letters ‘a’ through ‘z’ OR ‘A’ through Z’: [0-9]{1,6}[a-z, A-Z]

Starting with an alphabetical character followed by numeric Digits

- Subject numbers with ‘a’ or ‘c’ as the first character followed by up to 3 numeric digits: [a,c][0-9]{1,3}

A dash in the middle

- Subject numbers with up to 3 numeric digits, followed by a dash ‘-‘, and finally followed by 3 numeric digits: [0-9]{1,3}-[0-9]{1,3]
- Subject numbers with up to 3 numeric digits, followed by a dash ‘-‘, followed by 3 numeric digits, finally the letter ‘a’ through ‘z’: [0-9]{1,3}-[0-9]{1,3][a-z]

What does a site user do when a subject moves?

The study team can transfer the subject to a site that is closer to home, as long as the new site uses the same or a newer study version as the subject's original site.

When someone on the study team transfers a subject, the following events occur:

- The transfer occurs immediately.
- Site users at the new site have full access to the subject's data in Oracle Clinical One Platform.
- Site users at the original site have read-only access to the data that was entered for the subject while the subject was at the original site.
- The subject number doesn't change.

What happens if a site user enters invalid data?

A message explains why the answer does not meet the required criteria, but if the question isn't marked as required, then screening, randomization, and dispensation can still occur.

When site users correct invalid data, Oracle Clinical One Platform requires them to provide a reason for changing a value.

What happens to coded terms when the answer to a coding question is cleared or updated?

When a site user modifies or removes a coding question's answer, coding targets are automatically cleared.

Coding targets are read-only fields that are populated with coded terms, either automatically or manually coded with a dictionary translation from Oracle Central Coding. If you modify a coding question's answer (a route of administration, for example), coding targets are automatically cleared on that form. After that, according to your modified term, Oracle Central Coding will pick up the new translations and coding targets will be refreshed in Oracle Clinical One Platform.

Keep in mind that once you modify a coding question's answer, coding targets will not be refreshed immediately. First, the items are cleared and after the terms are coded in Oracle Central Coding, the coding targets will be populated with the updated coded term. If you remove a coding question's answer, coding targets are automatically cleared on that form and will remain clear until you add a new answer to the coding question.

If you want to view audit trail data of coding questions and coding targets, we recommend running the Subject Data report.

What happens if a site user doesn't answer a required question?

The site user can save the form, but the subject can't be screened or randomized, and kits cannot be dispensed.

> **Note:**
>
> Screening, Randomizing, or Dispensing is still available for users when the item in the visit is invisible to them. This is also true if a different user enters incomplete data unavailable to the current user. Users are only prevented by the required items they can see and fill.

- In a screening visit, the Screen button is grayed out, so a site user can't screen the subject.
- In a randomization visit, the Randomize button is grayed out, so a site user can't randomize the subject.
- In a dispensation visit, the Dispense button is grayed out, so a site user can't dispense a kit to the subject.

What time zone is subject data in?

If the time zone is specified for the site, all values on the Subjects page are in the site's local time zone except the date and time values in Answer & Visit History, which is on the right when you open a visit.

You specify a site's time zone when you add the site.

What can't be done after a subject completes a study?

Forms that weren't started prior to study completion can't be started. Additionally, other subject actions, such as screening, randomizing, withdrawing, dispensing, and skipping a visit, can't be done.

What states can a subject have?

Depending on the protocol, site users can update a subject's state through multiple actions for a number of times during the study. But have you ever wondered what each state really means for the way you manage subjects' data at a site?

What is a state and what does it say about a subject? A state is an indicator that gives you a general view of where the subject is in the study. Have they just been added? Are they in the “waiting room”, ready to effectively enter the study? Are they active participants in the study? Have they left the study? These are just some of the questions a subject's state can answer.

> **Note:**
>
> A subject's state appears under a subject's ID, in the Subjects table. Information about subject states can also be found in the Subject Events report.

New

What it means: The subject has just been added to a study, but they weren't screened or randomized yet.

How a subject reaches this state: A site user adds a subject to a study but doesn't screen them yet.

Screened

What it means: The subject successfully completed the Screening visit and is ready to be randomized.

How a subject reaches this state: A site user successfully screens a subject during the Screening visit, without any errors appearing on any forms.

Active

What it means: The subject is an active participant in the study and data is collected on them.

How a subject reaches this state: A site user successfully randomized a subject during the Randomization visit, without any data collection or dispensation errors.

Screen failed

What it means: The subject doesn't meet the screening criteria and can't participate in the study.

How a subject reaches this state: A site user either:

- Tried screening the subject but forms for the Screening visit contained errors.
- Manually screen failed the subject. For example, a site user can manually screen fail a subject after they find out data from their screening form isn't correct.

> **Note:**
>
> In the case that a study does not have a randomization visit, users can manually mark a subject as screen failed before the next visit.

Enrolled

There are different scenarios for how a subject reaches an **Enrolled** state:

What it means:

- The subject is an active participant in a rollover study.
- The subject was added in the study after being screened outside Oracle Clinical One Platform.
- The subject was screened in a study without a randomization (or baseline) visit.

How a subject reaches this state:

- The subject answered 'Yes' to the rollover type question that typically appears in the study completion form and was automatically enrolled from a baseline study to a rollover study.
- The site user clicked **Add subject** on the **Subjects** tab and the subject was automatically enrolled in the study after being screened in a different system.

Withdrawn

What it means: The subject is no longer available or eligible to continue participating in the study.

How a subject reaches this state: Typically, a site user manually withdrew the subject because they were no longer eligible or became unavailable to participate in the study. Additionally, a subject's state permanently changes to Withdrawn when a site user performs a code break on the subject, unblinding their results.

Complete

What it means: A subject has completed all visits, and all data has been entered for the subject.

How a subject reaches this state: A site user marked the subject as Complete after they completed all of their visits in a study. Once a subject's state changes to Complete a site user can no longer save forms that weren't started, screen, randomize, withdraw or dispense kits to a subject.

What actions impact subjects?

Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?

An action is a task that site users usually perform for subjects in order to collect and manage their data at a site during the study. From dispensing the right kits to a subject during a randomization visit to transferring or reinstating them, here are some of the actions that impact a subject's state.

> **Note:**
>
> For each action there's a corresponding update in Subject History that shows the date, time, and other specific details such as randomization numbers or site names.

Subject status	What it means	How this action impacts a subject's state	Other changes
Randomized	A subject has successfully completed a Randomization visit.	When a site user randomizes a subject, their state changes to Active.	When a subject is randomized, this update shows up on the **Subject History** sidebar, along with the randomization number, date, and time of the randomization visit.

Subject status	What it means	How this action impacts a subject's state	Other changes
Transferred	A subject was transferred from one site to another.	When a site user transfers a subject from site A to site B, the subject maintains whatever state they were in at site A. For example, a subject will keep their Active state after being transferred from one site to another.	When a subject is transferred, this update shows up in Subject History, along with the site that the subject came from, and the date and time of the transfer.
Enrolled	A site user enrolled a subject in a rollover study.	After a site user screenes a subject in a study that doesn't contain a randomization (or baseline) visit. After a site user enrolls a subject in a rollover study, the subject remains in a state of Enrolled. In a rollover study, an enrolled subject is also active, so site users can start dispensing kits to them at any time.	None.
Withdrawn	The subject is no longer available or eligible to continue participating in the study, so a site user withdrew them from the study.	When a site user withdraws a subject from the study, their state changes to Withdrawn. ***Note**: f a site user performs a code break on a subject, and chooses to withdraw that subject after unblinding their details, that subject's withdrawal can no longer be undone.*	When a subject is withdrawn from a study, this update shows up in Subject History, along with the date of the withdrawal, whether specified by default or subsequently edited by a site user.
Screen failed	The subject doesn't meet the screening criteria so either they can't complete their screening visit or a site user manually screen fails them.	When a site user screen fails a subject, their state changes to Screen Failed. ***Note**: A subject who is marked as Active can no longer be automatically screen failed or manually screen failed by a site user.*	When a subject fails screening, this update shows up in Subject History, along with the date of the screen failure, whether specified by default or subsequently edited by a site user.
Reinstated (Undo Withdrawal)	A site user withdraw a subject in the study, but then brought them back into the study by undoing their withdrawal.	When a site user undoes the withdrawal of a subject in the study, they go back to the state that they had before being withdrawn.	When a subject's withdrawal is undone, this update shows up in Subject History, along with the date and time of the action.

Subject status	What it means	How this action impacts a subject's state	Other changes
Reinstated (Undo Screen Failure)	A subject was automatically or manually screen failed by a site user, and now they're brought back into the study by being re-screened or by undoing their screen failure.	When a site user undoes the screen failure of a subject in the study, they go back to the state that they had before failing the screening: • If they automatically failed screening due to errors in a form, they go back into a Screened state. • If they were previously manually screen failed by a site user, they go back into a New state.	When a subject's screen failure is undone, this update shows up in Subject History, along with the date and time of the action.
Reinstated (Undo Study Completion)	A site user marked a subject as Complete, but then brought them back into the study by undoing their study completion.	When a site user undoes a subject's study completion, they go back to the state that they had before being completed, such as Active. ***Note**: A subject who is marked as Complete cannot be withdrawn from the study.*	When a subject's completion is undone, this update shows up in Subject History, along with the date and time of the action.

What does each icon mean for signing, verifying, or freezing data?

Each sign, verify, or freezing action has an impact on the study data. Learn more about what each icon means.

Table 8-2 Icons for signing, verifying, and freezing a subject's data

Icon	What it means
	This icon appears whenever a principal investigator signed a subject's data. It typically appears on a visit card, next to every question on a form, and a subject's icon.
	This icon appears whenever a site user in the study updates data on a completed form, and the subject's data becomes unsigned. It typically appears on a visit card, next to every updated question on a form, and a subject's icon.

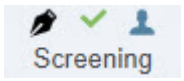
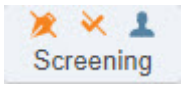
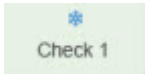
Table 8-2 (Cont.) Icons for signing, verifying, and freezing a subject's data

Icon	What it means
	This icon appears whenever a Clinical Research Associate verifies a question.
	This icon appears on the visit title, whenever a question requires verification.
	This icon appears whenever a site user in the study updates data on a completed form, and the subject's data becomes unverified. It typically appears on a visit card, next to every updated question and form, and a subject's icon.
	For this icon to appear, the **SDV Override** setting must be turned on. It appears next to questions that have been marked as Critical Variables, for subjects that have not been selected for the SDV pool.
	This icon appears whenever data is frozen on a completed or incomplete form, and the subject's data becomes read-only. It appears next to every question and form associated with a visit.
	This icon appears next to each question that is unfrozen by a data manager on a completed or incomplete form.

Additionally, these icons can appear together if a subject is both signed and verified, or both unsigned and unverified. This also applies to visit cards.

Icon	What it means
	Both of these icons appear next to a subject whenever their data is both signed and verified.

Figure 8-1 Subject is signed and verified

Icon	What it means
Figure 8-2 Subject is unsigned and unverified 	Both of these icons appear next to a subject whenever their data is both unsigned and unverified.
	This icon appears next to a subject whenever all of their visits have been frozen.
	Both of these icons appear in a visit card, whenever data in that visit is both signed and verified.
	Both of these icons appear in a visit card, whenever data in that visit is both unsigned and unverified.
	This icon appears in a visit card, whenever all forms in that visit are frozen.

Workflow for updating a subject number during the study conduct period

There might be situations when you (as a sponsor user) or your site staff are required to correct one or multiple subject numbers.
A site user is only allowed to update a subject number when assigned with the appropriate permission.

For a site user to properly update a subject number, sponsor users and site users must collaborate in an efficient manner.

How updating a subject number works

> **Note:**
>
> The subject number displayed in the audit trail is the number assigned to a subject when the update occurred in the system. While looking at a subject's audit trail, use their GUID (not their updated subject number) to ensure that all changes relate to the same subject.

Oracle Clinical One Platform automatically assigned a subject number and a site user updates subject numbers in a way that may create a gap in the subject number sequence, the application fills in that gap when the next subject is added. In other words, a skipped subject number will not be the next available subject number. Subject numbers will be assigned to subjects sequentially starting with the highest subject number.

Once a user updates a subject number, that change is reflected throughout the application: on the Subject History side panel, on the Subjects page, in any integrations, subject extracts, and reports that contain subject numbers.

Related to reports, the only exception can be found in the CRF Submit archives. For example, if a subject is transferred from site A to site B, and the subject number is updated at site B, archives generated in association with site A will include the subject number as it was at the time of the transfer, instead of displaying the updated subject number.

Workflow for updating a subject number

After a site user adds a new subject in a study or a subject number is assigned by an integrated third-party application, either the site or sponsor user may recognize that there was a data entry error for one or more subject numbers.

> **Note:**
>
> Consider the following notes before updating a subject number:
>
> - If you set any of these two settings (**Allow Site to Enter Subject Number** and **Allow Subjects to be Manually Added**) to No, after they were previously marked as Yes, this may prevent you or a site user from updating a subject number. When the abilty to add subjects and their numbers is changed from being manual to automated this interferes with the way you update subject numbers.
> - If you plan on updating the **Subject Numbering Setting** setting during the study conduct period, make sure you re-configure this setting after subject numbers are updated in the system.
> - Before the first subject is added in a study, you should carefully review the study settings impacting a site user's ability to add subjects and how they enter their subject numbers. This reduces the probability of updating a subject number after the settings are updated and the subject is already created.

Step	Description
A user administrator must grant the user the appropriate study role.	After the data entry error is recognized, you must temporarily grant a user the *Update Subject Number after Creation* permission so they can perform the update. We recommend you create a custom study role (perhaps at a study level) that contains this specific permission, as well as all other permissions that a site user may require to view and edit data in a study. To make sure both the site and sponsor users are notified of the subject number updates, assign them the *Receive the Subject Number Update Notification* permission. For step-by-step instructions, see Create a study role for one study.
A site user or sponsor user makes the appropriate subject number updates.	On the Subjects page, a user can select one or multiple subjects and correct the data entry errors that were identified. For step-by-step instructions, see Update a subject number.
A sponsor user reviews the updates	After a site user or another sponsor user completes their subject number updates, you must sign into the application and check the updated subject numbers to ensure they are correct. Upon selecting a subject, you can view the subject number update on the Subject History side panel. To get notified of a subject number update, make sure that you are assigned the *Receive the Subject Number Update Notification* notification.
A user administrator updates the site user's study role again	After a sponsor user validates the subject number updates, you can then remove a site user's custom study role and assign them with their previous site user study role. It is important to ensure that the site user no longer has the permission to update a subject number.

How a subject number update may impact integrations

The table below describes the possible use cases for how a subject number may impact your configured integrations.

> **Note:**
>
> While updating a subject number is possible when your study is integrated with other applications, we advise you to carefully consider the impact of a subject number change on any of your current integrations. Reach out to your study point of contact for additional information before changing a subject number.

Use case	Description
You are required to swap two subject numbers in Oracle Clinical One Platform and the study is integrated with Oracle InForm.	If two subject numbers need to be replaced with one another in Oracle Clinical One Platform, the setting to allow duplicate subject numbers in Oracle InForm should be set to **Yes**. If not, in Oracle Clinical One Digital Gateway the job fails and subsequent jobs are blocked until the issue is resolved in Oracle InForm. ***Note**: Work with your study point of contact to ensure Oracle InForm is configured correctly prior to swapping subject numbers in the Oracle Clinical One Platform.*
You cannot update a subject number in Oracle Clinical One Platform when your study is integrated with Veeva Vault CTMS. For more information about this integration, see Send subject enrollment information to Veeva Vault CTMSSend subject enrollment information to Veeva Vault CTMS.	If a subject number is updated in Oracle Clinical One Platform, the subject number change event is not processed for the Oracle Clinical One Platform to Veeva Vault CTMS integration. This will create subject number discrepancies between the two systems. As a best practice, we recommend you do not update a subject number for a study that is integrated with **Veeva Vault CTMS**.
You cannot update a subject number in Oracle Clinical One Platform when an inbound integration is configured. For more information about this integration, see Load lab results and other data into Oracle Clinical One Platform.Load lab results and other data into forms in Oracle Clinical One Platform	If a subject number is updated in a third-party system, the data intake integration cannot process a subject number update in Oracle Clinical One Platform. In this case, the subject number must be updated in Oracle Clinical One Platform, as well. Not doing this can result in failed data import or data being imported for the wrong subject.
You update a subject number after verbatim terms were already coded in Oracle Central Coding.	There is no impact. The Oracle Central Coding user interface, reports, and exports reflect the updated subject number.

9 Revision history

Table 9-1 Revision History

Date	Part number	Description
26-March-2025	G16746-04	Made the following updates: • All empty table cells in Test the EHR data import were populated to adhere to accessibility standards. • Corrected Status field descriptions on the following pages: Create a vendor (depot), Create a vendor (lab), Create an organization (institution), and Create a contact at your organization. • Included a new note about Visit Date fields on the following pages: Understand source data verification and Freeze and unfreeze data.

Table 9-1 (Cont.) Revision History

Date	Part number	Description
18-March-2025	G16746-03	Made the following updates: • Included the following new topics: – How is data impacted when a site user undoes a subject's event? – What if I have to include kits of the same type from different lots in a manual shipment? – Enable a study for Electronic Health Record (EHR) data import – Enable and manage your EHR site connections – Test the EHR data import – Actions that impact an EHR-connected site – EHR standard report and Oracle Clinical One Analytics details – What is a change for encoding? • Updated the following existing topics: – How do changes in Source Data Verification settings impact a study? – How are subjects selected for targeted source data verification? – About Source Data Verification statuses – Create a source data verification strategy and assign it to a site – Specify settings for Source Data Verification – Understand source data verification – Create a query – Create a manual shipment – About pooling kits in a study – What actions impact subjects? – Create a custom code list

Table 9-1 (Cont.) Revision History

Date	Part number	Description
27-February-2025	G16746-02	Made the following updates: • Included information on how to proceed when a user receives the Auto-lock failure notification. For more information, see Lock a subject at the form or visit level. • Corrected information on how lab normals are refreshed. For more information, see How are lab normal updates reflected in existing lab forms?.
17-January-2025	G16746-01	Original version of the document.