Oracle® Life Sciences Clinical One Platform

Study Designer User Guide

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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.

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.

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.

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

2

Study design prerequisites

Before you begin designing your study, a study creator (who is a global user) must create the study where you can work in. After you are added as a study designer in the study, you can open the study and begin your work.

For more information on how to create and open a study, see the links below.

- Open a study's design
  You can open a study's design either to edit it or to view its details.
- Considerations when copying a study
  Copying a study saves you time and maximizes your reuse. However, there are certain considerations you should be aware of before using this feature.
- Copy a study's design
  You can create a new study by copying a study's latest approved and active design. This feature helps you create your new study more efficiently by reusing existing content.

Open a study's design

You can open a study's design either to edit it or to view its details.

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

Video

1. To access the draft version of a study and begin your study design tasks:
   a. On the Home page, select the **Edit Study** icon  on the study you want to edit.
   b. Below Draft, click the study version.

   > **Tip:**
   >
   > After you move a study version out of Draft on the Home page, you can generate and upload randomization and kit lists, but you can't make any other changes to the study design. You can edit study settings at any time.

2. To view the design of a study:
   a. On the Home page, select the **Edit Study** icon () on a study.
   b. Select the **Menu** icon () on the study version you want to view, and select **View Study Design**.

   The study design opens.

3. To rename a study, select the **Study Settings** icon (), and select **Open Settings**. On the General tab, in the **Study Title** field, type a new study title.

4. To rename a study version, select the **Edit Study** icon on the study (). Select the **Menu** icon () on the study version, and select **Rename**. You can change the name of the study version, but not the version number.

Related Topics

- Verify a study

Considerations when copying a study

Copying a study saves you time and maximizes your reuse. However, there are certain considerations you should be aware of before using this feature.

You can only create a new study by copying the latest *approved* version of an existing study. The study must also be active (that is, not in the archived state). You can copy the same study multiple times to create new studies or you can propagate a previously copied study. This gives you the flexibility to either retain a study's original design as a template and use it for multiple new studies in the future or to duplicate your newly copied (and possibly modified) study to create yet another new study (as long as the study you are copying from has been approved).

Forms (including validation rules and programmed rules), kits, and randomization are all copied when copying a study design.

> **Note:**
>
> Visits that were inserted to the original study version become standard scheduled visits in any copied study.

For step-by-step instructions on how to copy a study's design, see Copy a study's design.

Restrictions when copying a study's design

When copying a study, keep the following restrictions in mind:

- If an approved version of the study does not exist in the application, you cannot copy that study's design. You cannot copy an archived study.
- Study roles, Sites/users, and Data Classification are not copied to the study design.
- From one study to another, you can only copy custom rules that are in the **Published** status.

Details for rule designers

All custom rules with a status of **Published** are copied when you select **Copy Study**, but they are not validated until the copied study design version is moved to Testing mode. Rules designers can still enter the rule editor while rules are in the process of saving and validating. However, we recommend you wait until the automated validation is complete. When the validation is complete, you will receive a notification with the status of the copied rules.

For more information, see Create and manage custom rules and the Rules Validation Complete notification.

Copy a study's design

You can create a new study by copying a study's latest approved and active design. This feature helps you create your new study more efficiently by reusing existing content.

Before you begin, there are some caveats and limitations related to copying a study that you should be aware of. For more information, see Considerations when copying a study.

> **Note:**
>
> Copying a study only creates that new study. The copied study must be provisioned before it can be moved to Testing or before certain updates can be made.

To copy a study's design:

1. On the Home page, select **Settings** ( ) and then select **Copy Study**.
2. In the Copy {StudyID} Study dialog, enter the details for the following fields:

   > **Note:**
   >
   > You must enter the **Study Title** and **StudyID** each time you perform this task. All other fields (**Study Phase**, **Therapeutic Area**, and **Open Label / Blinded**) contain default values from the existing study, but can be modified.

Field	Description
Study Title	The title of the study.
Study ID	A study ID as specified by the study manager when the study is created(for example, a protocol acronym and protocol number).
Study Phase	A study's phase as indicated by the study manager when the study is created.
Therapeutic Area	Indicates the therapeutic area as specified by the study manager when the study is created.
Open Label / Blinded	Indicates whether the study is an open-label or a blinded study, as specified by the study manager when the study is created.

3. Select **Copy Study**.

   A new study tile appears with a progress indicator and message that indicates that the study is being copied.
4. If the study fails to copy, a system message is displayed. You can either click **Cancel** to stop the copying process and remove the newly copied study tile from the Home page or click **Try Again** to attempt to copy the study again.

After the copying process is complete, a new study tile is added to the Home page with the copied study's attributes.

3
Visits and schedules

You can create scheduled visits, unscheduled visits, events, as well as set up dynamic visits and insert a new visit in the schedule of a live study version.

- Create a visit or event
  Create one visit for each subject visit or event that occurs in the study. Since you have to create visits before you can design the visit schedule or configure any as dynamic, create the visits in the order that they will follow in the schedule.
- Define the visit schedule
  When you define the visit schedule, you specify the amount of time that must occur between a visit and the previous visit.

Create a visit or event

Create one visit for each subject visit or event that occurs in the study. Since you have to create visits before you can design the visit schedule or configure any as dynamic, create the visits in the order that they will follow in the schedule.

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

Video

There are two different types of visits that you can create in a study: scheduled visits and unscheduled visits. These distinct types of visits appear on two different sidebars and some of them have their own particular options.

For a scheduled visit, you have to specify its schedule in your study, whether it is a screening visir or any other scheduled visit, such as a dispensation or baseline visit. An unscheduled visit doesn't require you to specify a scheduled for it. This visit can be included in a study so a site user can start an unscheduled visit whenever they might need to perform data collection or dispensation outside of the normal schedule. Withdrawal, screen failure, and study completion visits are also unscheduled.

Caution:

The completion of a hidden, required question is taken into account to determine a visit's status, but it won't be taken into account to determine a form's status. For example, if a hidden, required question isn't answered, the associated visit's status is considered **Incomplete**, while the form's status is displayed as **Complete**. If all hidden, required questions are answered, the visit is considered complete and so is the form.

While a visit's status will match between Oracle Clinical One Platform and Oracle Clinical One Analytics, a form's status is displayed as **Incomplete** in specific data sets, when the form contains a hidden and required question that's unanswered. For more information, see the following topics in the *Analytics User Guide*:

- Subject dataset
- Subject Form Items dataset
- Subject Forms dataset

Note:

Consider the following before creating a visit or an event in your study:

- If subjects will be added in the study after being screened outside Oracle Clinical One Platform, you don't need to create a Screening visit. This will allow site users to automatically enroll subjects from another system.
- You may have multiple unscheduled visits in a study, but you can only have one Adverse Event and one form assigned to an Adverse Event.
- If you want to create a visit that must be dynamically scheduled, make sure you review all details and restrictions listed in Set up a dynamic visit.
- If you want to insert a visit into the schedule of a study during study conduct period, see Set up an inserted visit into the schedule of a live study version.

1. Access the Draft version of a study as described in Open a study's design.
2. To create a scheduled visit, follow these steps:
   a. Do one of the following:
      - If you haven't created any scheduled visits, on the **Scheduled Visits** sidebar, select **Create Visit**.
      - If you already created one or more visits, on the **Scheduled Visits** sidebar, select the **+** icon to add more.
   b. Fill in the fields and select **Save** or **Save & Add Another**. To view tips for completing a field, click into the field or choose an option.

Field	Description
Title	Enter the name of the visit, such as Screening for a scheduled visit.

Field	Description
ID	Enter a short label for the visit, such as SCR for a screening visit. If your study's activities include running the Subject Data for CTMS report, make sure visit IDs are written using numbers and letters only.
Type	***Note**: If you make a screening visit optional, a subject's status may advance differently than expected. This can occur if a user completes an optional screening visit after completing future visits. The recommended practice is to notify the study users when the screening visit is optional to avoid confusion.* Select one of the following: • **Screening Visit**: choose this option if the visit is for screening. Typically, you should have one Screening visit in a study. A rollover or integrated study does not require a screening visit. • **Scheduled Visit**: choose this option to include a scheduled visit that can be used for regular data collection, randomization or dispensation purposes, or as an optional visit.
Required	This field appears only when you select **Scheduled Visit** for the **Type** field. • Select **Yes** if all subjects must complete the visit. • Select **No** to make the visit optional. An optional visit appears for site users on the **Next Visits** column next to the subject's next required visit.

3. To create an unscheduled visit or an event, follow these steps:
   a. On the **Unscheduled Visit or Event** sidebar, select the **+** icon.

      You will notice an Adverse Event is included by default.

   b. Fill in the fields and select **Save** or **Save & Add Another**:

> **Note:**
>
> You can only create a Study Completion visit once you have two required visits in your study. Make sure that these required visits are not included in a visit branch.

Field	Description
Title	Enter the name of the visit, such as Follow Up for an unscheduled event.
ID	Enter a short label for the visit, such as SCR for a screening visit. If your study's activities include running the Subject Data for CTMS report, make sure visit IDs are written using numbers and letters only.

Field	Description
Type	Select one of the following: • **Study Completion Visit**: Select to create the visit that appears when a site user completes a study for a subject. • **Screen Failure Visit**: Select to create the visit that can be used when a site user deems a subject as having failed screening. • **Unscheduled Visit**: Select to allow data collection, kit dispensation, or dose changes during an unscheduled visit. You can create multiple unscheduled visits in a study. • **Withdrawal Visit**: Select to create the visit that appears after a subject is withdrawn. Only one visit can be the withdrawal visit, and it can't be the first visit. • **Adverse Event**: Select to create an event only for collecting multiple instances of data on adverse events, concomitant medications, concomitant procedures, hospitalizations, adverse events of significant interest, or serious adverse events outside of the visit schedule. By default, every study contains an Adverse Event. You can assign any type of form to an Adverse Event to collect multiple instances of data from the same subject, when needed. You can only have one Adverse Event in a study and you can edit or delete that event. However, you can't assign kits, devices, or randomizations to the adverse event. For site users, the adverse event appears on the first column right after the Subject ID.
Earliest Visit to Complete Study	This field appears only when you select **Study Completion Visit** for the **Type** field. Select the visit that subjects must finish to complete the study. If randomization occurs in the study, the study completion event must occur after the randomization visit. A Study Completion icon () appears on the visit you select. Only required visits that take place after the randomization (or baseline) visit can be selected as the earliest visit to complete a study. Optional and dynamic visits cannot be selected.

The newly created scheduled visits appear on the **Scheduled Visits** sidebar. The newly created unscheduled visit or events appear on the **Unscheduled Visit or Event** sidebar.

Related Topics

- Set up a dynamic visit
  Use dynamic visits when you want a visit to be displayed only when relevant to the subject, whether it's for data collection or dispensation purposes.
- Visit FAQs
- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

Define the visit schedule

When you define the visit schedule, you specify the amount of time that must occur between a visit and the previous visit.

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

Video

Before you begin scheduling the visits in your study, you must add scheduled visits to your study. See Create a visit or event.

As you schedule visits, the visits are reordered in the Scheduled Visits pane, so that they appear in the planned order. Unscheduled visits are always last and in a separate pane.

> **Note:**
>
> You cannot schedule withdrawal, completion or screen failure visits.

To schedule a visit:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** screen and on the **Forms** tab.
3. In the right-side pane, under Scheduled Visits, select **Add Schedule** above the visit you want to schedule.
   - If a schedule has been added to the visit, the **Add Schedule** label above the visit is replaced with the number of days defined for the schedule. You can click on this label to edit the visit schedule for that visit.
4. Fill in the fields in the top section.

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

Field	Description
Scheduled From	Select a visit to schedule time from (anchor visit). Click the drop-down arrow to the right of the visit name to select a different visit, if needed. Dynamic visits are not available for selection. ***Note**: If the anchor visit is skipped during the study conduct period, the ideal scheduled visit date is considered to calculate the visit window for the current visit.*
Days	Specify the number of days between the visits.

5. For the **Alert if Outside the visit window** setting, select one of the following:

Option	Description
Off	Does not display any kind of alert for visits happening outside of visit window.
Warning	Displays an inline warning when entered visit date is out of window. This warning is visible only to the user entering the visit date while on the visit page at the time of data collection. Once a user specifies a date within the visit's window, the warning message disappears. This warning can be useful to catch data entry errors, such as typing an incorrect year or entering data for an incorrect subject or visit.
Query	Raises a query every time a visit date is entered and is out of the allowed visit window as per design.

6. In the Visit Window section, fill-in the following fields, and click **Save**.

Field	Description
Before Days	Specify how many days before the scheduled date the visit can occur.
After Days	Specify how many days after the scheduled date the visit can occur.

The **Add Schedule** label in Scheduled Visits pane is replaced with the number of days between the visits. Hover over this label to see the details.

7. To remove the scheduling for a visit, click the scheduling information leading to the visit, and select **Clear Schedule**.

Related Topics

- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

4

Visit branches

You can create visit branches to set up parallel visit schedules for subjects in your study.

- Understand how visit branches work
  Adding visit branches gives you better control over your subject visit schedule and allows you to customize schedules for a specific cohort or multiple treatment arms. Before designing with branches, you should understand how they work.
- Edit or manage a visit branch
  You can edit branch details only before a study version is approved. You can also delete a branch or add more branches to the study's schedule.
- Add a scheduled visit to a branch
  You can add scheduled visits to a branch as defined in your study protocol.
- Create a visit branch
  Use a visit branch to create multiple visit schedules to fit your study protocol. You can schedule visits as needed in each branch.
- Define the visit schedule for a branch
  When you define the visit schedule for a branch, you specify the amount of time that must occur between the visits included in a branch. You should be aware of how the time between visits is calculated.

Understand how visit branches work

Adding visit branches gives you better control over your subject visit schedule and allows you to customize schedules for a specific cohort or multiple treatment arms. Before designing with branches, you should understand how they work.

Think of a visit branch as a grouping of visits within the visit schedule. A branch can also be cycled. That is, all visits in that branch can be repeated for *n* number of cycles, depending on your study design.

Branches can be customized to fit the needs of your study. For example, you can create different visit schedules when dispensation and visits vary based on the treatment arm that the subject is assigned to. You can collect additional data during specific visits for only a subset of subjects. You can also include additional visits both before and after the branch completes.

While assigning subjects to a visit branch based on treatment arms may be a more common scenario, you can also assign subjects to a visit branch based on their answer to a certain question.

If you choose to assign subjects to a visit branch based on form data, remember that when the initial visit schedule includes intermediary visits between the visit in which the form is answered and the branch, a site user must skip these intermediary visits prior to moving the subject onto the visit branch. For instance, if a visit schedule includes Screening visit, Week 1 visit, Week 2 visit and two new branches (Branch 1 and Branch 2) and the form question that launches Branch 1 is in Week 1, when a subject gives the expected answer to this question, a site user must skip the Week 2 visit, so the subject can begin their visits in Branch 1.

To help understand the workflow for creating branches, let's take a simple example. In this example, you have already created two scheduled visits that apply to all subjects, a screening

visit followed by a randomization visit, for an oncology study. After the randomization visit, you want subjects to be scheduled using branches based on the treatment arm to which they are assigned. For simplicity, we'll call these Treatment Arm A and Treatment Arm B. The branch visits will cycle every 28 days for 24 cycles (over a period of two years). Once the treatment completes, you want all subjects to be scheduled for a series of follow up visits. The study ends with a study completion visit for all subjects.

The branch details are summarized as follows:

Branch	Assign Subjects Using	Cycles	Count of Cycles
Branch A	Treatment Arm A	Yes	24
Branch B	Treatment Arm B	Yes	24
Follow Up	• Treatment Arm A • Treatment Arm B	Yes	Unlimited

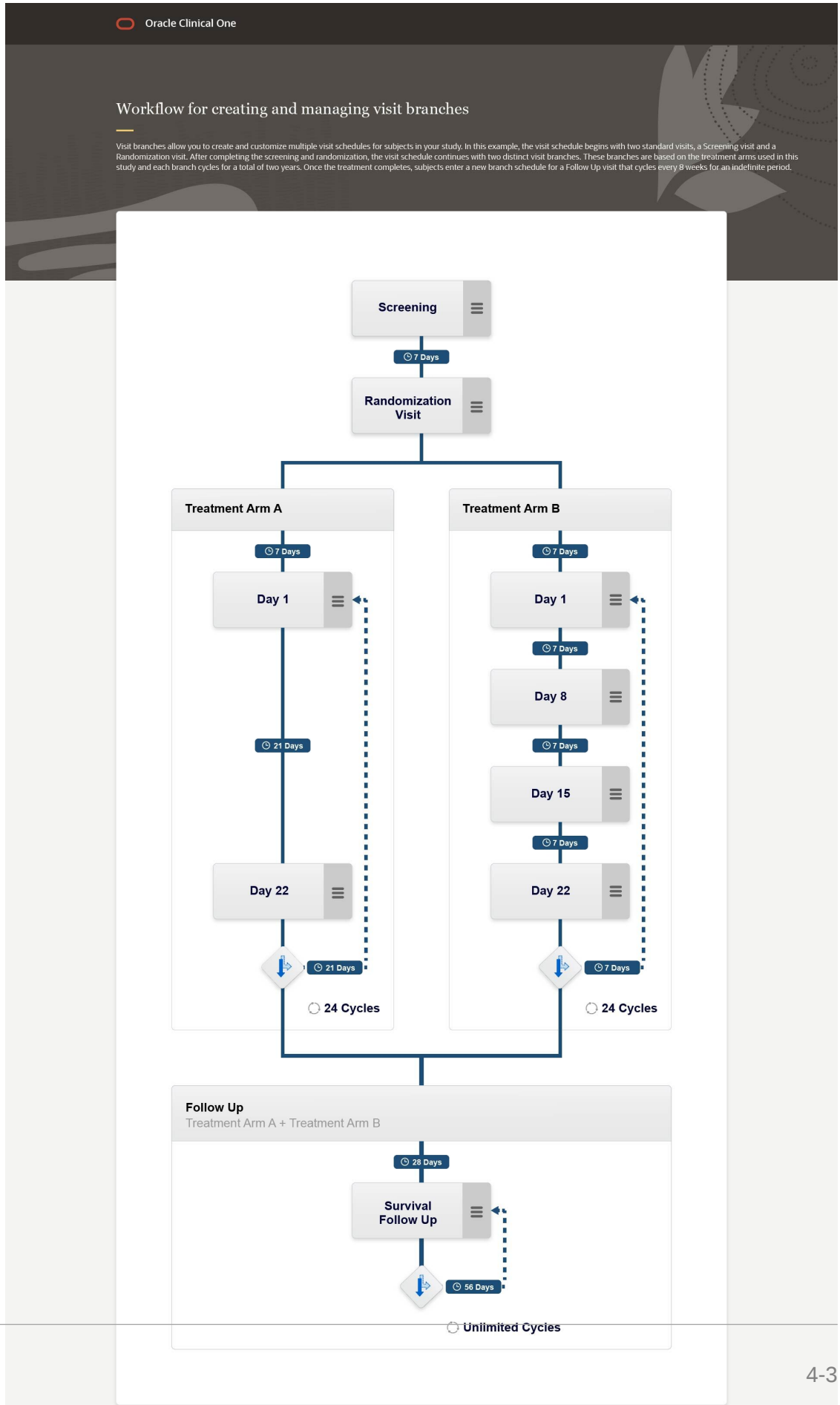
To create these branches as described, your overall workflow would look similar to the following:

1. Create your screening and randomization visits. See Create a visit or event.
2. Create Branch A. See Create a visit branch.
3. Add your scheduled visits to Branch A. See Add a scheduled visit to a branch.
4. Set the visit schedule and add cycling information for Branch A. See Define the visit schedule for a branch.
5. Create Branch B. See Create a visit branch.
6. Add your scheduled visits to Branch B. See Add a scheduled visit to a branch.
7. Set the visit schedule and add cycling information for Branch B. See Define the visit schedule for a branch.
8. Add the Follow Up branch to Branch A. This is done by adding a branch to the bottom of Branch A.
9. Add the Follow Up branch to Branch B. This is done by adding a branch to the bottom of Branch B. Note that while this branch is the same as the one added to Branch A, it must be added separately to the bottom of each branch.
10. Create a Study Completion Visit. See Create a visit or event.

Want to learn how to define visit branches for an oncology study? See your very own Tutorial for Creating and Managing Visit Branches in an Oncology Study.

More details on how visit branches might be organized in an oncology study can be seen in the image below:

Figure 4-1 A visual representation of visit branches defined for an oncology study



Edit or manage a visit branch

You can edit branch details only before a study version is approved. You can also delete a branch or add more branches to the study's schedule.

You must first create a visit branch to add visits to it. For step-by-step instructions, see Create a visit branch.

After making your changes in Draft mode, you must test your new study version in Testing mode before making it live.

To edit or manage a visit branch:

1. Access the Draft version of a study as described in Open a study's design.
2. Next to a branch's title, select the **Menu** icon () and select one of the following options, depending on what action you want to take:

Options	Description
Add Scheduled Visit	Include a Day 1 or Week 1 visit, such as a screening.
Add Branch to Tier	Include another parallel branch in your study design.
Add Branch to Bottom	Include another branch after the existing branch in your study.
Duplicate	Copy this branch.
Edit	Edit the details for this branch, such as title, ID, cycles, or other settings.
Delete	Remove this branch from your study design.

Related Topics

- Understand how visit branches work
  Adding visit branches gives you better control over your subject visit schedule and allows you to customize schedules for a specific cohort or multiple treatment arms. Before designing with branches, you should understand how they work.
- Add a scheduled visit to a branch
  You can add scheduled visits to a branch as defined in your study protocol.
- Define the visit schedule for a branch
  When you define the visit schedule for a branch, you specify the amount of time that must occur between the visits included in a branch. You should be aware of how the time between visits is calculated.
- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

Add a scheduled visit to a branch

You can add scheduled visits to a branch as defined in your study protocol.

You must first create at least one scheduled visit and a visit branch to add visits to it. For step-by-step instructions, see Create a visit or event and Create a visit branch.

To add a scheduled vist to a branch:

1. Access the Draft version of a study as described in Open a study's design.
2. On the right side panel, in the **Scheduled Visits** section, select the branch to which you want to add a scheduled visit.

> **Note:**
>
> If there are multiple branches in the carousel, use the right and left arrows next to each branch name to navigate to the branch you want.

3. Next to the branch's title, select the **Menu** icon ( ) and select **Add Scheduled Visit**.
4. Fill in the fields and select **Save** or **Save & Add Another** if you want to add another scheduled visit.

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

Field or setting	Description
Title	Enter the name of the visit. You can use duplicate visit names.
ID	Enter a short label for the visit, such as DAY15. The Visit ID must be unique. If your study's activities include running the Subject Data for CTMS report, make sure visit IDs are written using numbers and letters only.
Required	(Appears only when Scheduled Visit is selected for Type.) Click **Yes** if all subjects must complete the visit. Click **No** to make the visit optional.

5. Repeat steps 4, 5, and 6 to add as many visits as you need.

To learn more about your next task, see Define the visit schedule for a branch.

Related Topics

- Understand how visit branches work
  Adding visit branches gives you better control over your subject visit schedule and allows you to customize schedules for a specific cohort or multiple treatment arms. Before designing with branches, you should understand how they work.
- Edit or manage a visit branch
  You can edit branch details only before a study version is approved. You can also delete a branch or add more branches to the study's schedule.
- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

Create a visit branch

Use a visit branch to create multiple visit schedules to fit your study protocol. You can schedule visits as needed in each branch.

To learn more about visit branches, see Understand how visit branches work.

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

Video

If you choose to assign subjects based on form questions, here is a list of things you must first do:

- You can only use a question with checkboxes or radio buttons, as well as a drop-down question, in the process of assigning subjects to a branch. Make sure you create the appropriate question and, if needed, define a Select Exactly validation rule for that question.
- You should not include a question with multiple options for an answer in a repeating form, to use it in the process of assigning subjects to a branch.

To create a visit branch:

1. Access the Draft version of a study as described in Open a study's design.
2. On the right side panel, in the **Scheduled Visits** section, select **+**, and select **Add Branch to Bottom**.
3. In the Create Branch dialog, fill in the fields as needed, and click **Save & Add Another** to save and add another visit branch or **Save** to create the current branch:

Table 4-1 Fields and settings in the Create Branch dialog

Field or setting	Description
Title	Enter a title for the branch.
ID	Enter a short ID for the visit branch you're about to create. Branch IDs should follow the terminology standards used in data extracts.
Cycle the Branch	Select **Yes** if you want to repeat the visits in this branch or **No** if you don't want subjects to repeat the visits in this branch.
Restart Cycle Numbering	Select **Yes** if you want the cycling of visits to restart in the study once a subject reaches the final visit cycle, in a previous cycling branch. For example, if you selected a count of 5 cycles, once a subject reaches cycle 5 of the visits, the cycling is restarted, then the subject enters the first cycling branch. Select **No** if you don't want the cycling of visits to be restarted once a subject enters the new cycling branch. This setting is displayed only when you create a second or later branch.
Starting Cycle Number	Enter a number to be assigned to the first cycle in a series of cycling visits. For example, enter 1 if you want site users to know that the cycle of visits begins at cycle 1. By default, this field is set to 2.

Table 4-1 (Cont.) Fields and settings in the Create Branch dialog

Field or setting	Description
Count of Cycles	Enter the number of times the visits in this branch should be repeated. If you plan on having an unlimited number of cycles in your branch, leave the **Unlimited** default selection as it is.
Assign Subjects Using	Select **Treatment Arm** if you want subjects to be assigned to a visit branch based on the treatment arm to which they are assigned. Select **Form Item** if you want subjects to be assigned to a visit branch based on their answer to a specific question. If you choose to assign subjects to a visit branch based on treatment arms, know that you can view the treatment arm details by hovering over the treatment arm icon of the branch.
Treatment Arm Settings	If you previously selected **Treatment Arm**, you must select one or more treatment arms to consider when assigning a subject to a visit branch.
Form Item Settings	If you previously selected **Form Item**, you must further define the following fields to assign a subject to a visit branch: • Form • Question • Answer • Visit

The newly created visit branch appears on the right-side of the browser page, under Visits & Events.
To learn more about your next task, see Add a scheduled visit to a branch.

Related Topics

- Edit or manage a visit branch
  You can edit branch details only before a study version is approved. You can also delete a branch or add more branches to the study's schedule.
- Define the visit schedule for a branch
  When you define the visit schedule for a branch, you specify the amount of time that must occur between the visits included in a branch. You should be aware of how the time between visits is calculated.
- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

Define the visit schedule for a branch

When you define the visit schedule for a branch, you specify the amount of time that must occur between the visits included in a branch. You should be aware of how the time between visits is calculated.

The first visit in a branch is scheduled based on the previously scheduled visit in the non-branched visit schedule or the final scheduled visit in the previous branch tier. For example, visit A in Branch 1 can be scheduled 15 days after the Baseline visit in the non-branched

schedule. Or the Day 1 visit in Branch 3 can be scheduled 7 days after the final scheduled visit in Branch 2.

Before you begin, you must create a visit branch with scheduled visits included in it. For step-by-step instructions, see Create a visit branch and Add a scheduled visit to a branch.

Also, you cannnot schedule the first visit in a branch if no visits have been scheduled prior to the branch. This means you must have an initial (non-branched) visit schedule or another branch prior to the branch you want to schedule. If the **Add Schedule** button is not enabled, check that a scheduled visit has been added above the branch.

To define the visit schedule for a branch:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** screen and on the **Forms** tab.
3. On the right side panel,under **Scheduled Visits**, select the branch for which you want to define the visit schedule.

   If there are multiple branches in the carousel, use the right and left arrows next to each branch name to navigate to the branch you want.
4. In the branch, select **Add Schedule** above the visit you want to schedule.
   - If a schedule has been added to the visit, the **Add Schedule** label above the visit is replaced with the number of days defined for the schedule. You can click on this label to edit the visit schedule for that visit.
5. In the Schedule Visit dialog, fill-in the fields in the **Time Between Visits** section:

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

Field	Description
Scheduled From	By default, this field displays the previous visit that was scheduled either in the branch or in the section above the branch where your visit is located. Click the drop-down arrow to the right of the visit name to select a different visit, if needed. If the visit is part of a cycle, you can only select a previous visit in the cycle. The system defaults to the first visit within the cycle.
Days	Specify the number of days between the visits.

6. For the **Alert if Outside the visit window** setting, select one of the following:

Option	Description
Off	Does not display any kind of alert for visits happening outside of visit window.
Warning	Displays an inline warning when entered visit date is out of window. This warning is visible only to the user entering the visit date while on the visit page at the time of data collection. Once a user specifies a date within the visit's window, the warning message disappears. This warning can be useful to catch data entry errors, such as typing an incorrect year or entering data for an incorrect subject or visit.
Query	Raises a query every time a visit date is entered and is out of the allowed visit window as per design.

7. Fill in the fields in the **Visit Window** section:

Field	Description
Before Days	Specify how many days before the scheduled date the visit can occur.
After Days	Specify how many days after the scheduled date the visit can occur.

   In the branch, the **Add Schedule** button is replaced with the number of days between the visits. Hover over the text using your cursor to view visit window details.

8. Select **Save**.

9. If you want your visit branch to be cyclic, you need to schedule the restart of that cycle. Under the last visit in the branch, select **Add** and follow steps 4, 5, and 6 to complete the fields in the Schedule Visit dialog.

10. You can skip branches when scheduling visits, but only if they are located in different tiers.

    For instance, if you want to skip Branch 4 and schedule visits in Branch 5 starting with the last visit in Branch 3 you need to:

    a. Select the right arrow next to the branch you want to skip until the **Skip** button appears.

    b. Go to the branch for which you want to define the visit schedule and schedule the visits following steps 4, 5, 6, and 7.

Related Topics

- Understand how visit branches work
  Adding visit branches gives you better control over your subject visit schedule and allows you to customize schedules for a specific cohort or multiple treatment arms. Before designing with branches, you should understand how they work.
- Edit or manage a visit branch
  You can edit branch details only before a study version is approved. You can also delete a branch or add more branches to the study's schedule.
- Can multiple study designers edit a study at the same time?
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

5
Forms

You can create various types of forms for your study: forms with one section, forms with two sections, repeating or tabular forms, and lab forms.

> **Note:**
>
> Creating forms with more than two hundred (200) questions can result in issues with Oracle Clinical One Analytics datasets and downstream applications, like the Data Management Workbench (DMW).

- Create a form with one section
  Forms hold all the questions you must ask subjects during a study. Standard forms should include questions that verify whether subjects meet eligibility criteria, such as whether a subject has signed an informed consent document or whether the subject is eligible for being enrolled in a rollover study.
- Create a form with two sections
  Forms with two sections must contain one or more questions and a table with repeating questions that are relevant and required for a subject.
- Create lab forms
  Lab forms hold all the questions and items that allow site users to properly collect local lab results and compare the collected data against lab normals to ensure that the correct normal range is associated with lab data.
- Create a repeating form
  Create a repeating form when you want to allow site users to collect multiple instances of the same data.
- About Drug Reconciliation forms
  You use a Drug Reconciliation form to collect data related to kits in order to help site or sponsor users keep track of kits that have been sent for destruction.
- Create a Drug Reconciliation form
  Drug Reconciliation forms collect data related to kits to help site or sponsor and CRO users keep track of kits that have been sent for destruction.
- Preview a form
  Check for inconsistencies and improve the data collection process by previewing a form and sharing it with other team members (for additional review) before using it in a Production study.
- Add a form to a visit
- Import a form
  Import a form form another Production study, or library study and use it in your study design.
- Duplicate a form
  You can copy a form within the same study to create a duplicate of that form. If you need to create similar forms, you can duplicate a form multiple times, and then editing these forms instead of creating new forms from scratch.

- Leave and manage comments
  You can leave comments in Study Design (Draft) mode and Testing mode, as well as in any library study.

Create a form with one section

Forms hold all the questions you must ask subjects during a study. Standard forms should include questions that verify whether subjects meet eligibility criteria, such as whether a subject has signed an informed consent document or whether the subject is eligible for being enrolled in a rollover study.

Depending on the types of data that you want to collect, you can create questions that are used to collect relevant and valuable data for subjects. You can also create questions that help site users collect data that enhances the dispensation and randomization process. For example, you can create a question to collect a value that determines the stratum groups subjects are randomized to. Or you can create a question that collects the required value to calculate a subject's dose of the investigational product.

You'll create the calculated doses when you create kit types.

You'll create the stratum groups when you create a randomization design.

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

Video

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

To create a form with one section:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** tab.
3. Select **Create Form** and select **1 Section** from the drop-down.
4. In the **Name of the Form** field, enter a title for your form.
5. On the right, expand the Details pane and make sure the following settings and fields are configured as expected:

Field or setting	Description
Reference code	Make sure the form has a reference code. A reference code is a one-word abbreviation for the form.

Field or setting	Description
Repeating Form toggle ( )	The Repeating Form toggle (is turned off, by default. Turn the toggle on to make this one-section form a repeating form.

> **Tip:**
>
> As you create a form, consider documenting the test cases for its questions.

6. Create questions for the data that you need to collect. For more information on the available types of questions, see Question types and settings.
7. Select **Save** or **Save & Close**.

Related Topics

- Import a form
  Import a form form another Production study, or library study and use it in your study design.
- Question types and settings
  You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.
- Update a form during the study conduct period
  Updates to forms appear for all subjects, including on pages where data was already collected. This procedure also applies to rollover studies.
- Add a new form to a live study version
  You can add new forms to visits in a live study and readily implement changes into multiple study versions.

Create a form with two sections

Forms with two sections must contain one or more questions and a table with repeating questions that are relevant and required for a subject.

Before you begin creating a form with two sections, you must know the following:

- In the **Questions Before the Table** section of the form, you can include any type of question, except for Label items. This option does not appear on the user interface, in the drop-down with available types of questions.
- In the **Questions in the Table** section of the form, you can include any type of question, except for question groups. This option does not appear on the user interface, in the drop-down with available types of questions.

To create a form with two sections:

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** tab.
3. Select **Create Form** and then select **2 Sections** from the drop-down.
4. In the **Name of the Form** field, enter a title for your form.
5. On the right, expand the Details pane and make sure the following settings and fields are configured as expected:

Field or setting	Description
Reference code	Make sure the form has a reference code. A reference code is a one-word abbreviation for the form.
Repeating Form toggle ( )	The Repeating Form toggle ( ) is turned on, by default and inactive.
Allow Additional Rows toggle ( )	The Allow Additional Rows toggle ( ) is turned on, by default. To turn this toggle off, you must first include a Label item in the **Questions in the Table** section.

> **Tip:**
>
> As you create a form, consider documenting the test cases for its questions.

6. Select **Add Question** and, depending on what sections of the form you want to update, follow either one of these steps:

> **Note:**
>
> The first question in each section is present by default, so we recommend you use those placeholders first. It is required that at least one question exists in both sections.

- **Add questions in the Questions Before the Table section**: hover over **Questions Before the Table** and choose the types of leading questions you must include in this form section.

- **Add questions in the Questions in the Table section**: hover over **Questions in the Table** and choose the types of questions you must include in the second section of the form.

7. Repeat either one of these steps for each question you want to include in every section of the form.
8. To include a read-only or hidden question that could determine the display of a dynamic visit, you must make sure that the read-only field will be automatically completed either through an integration or a custom rule. Work with your study team to properly set up these types of questions.
9. Select **Save** or **Save & Close**.

Related Topics

- Import a form
  Import a form form another Production study, or library study and use it in your study design.
- Question types and settings
  You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.
- Update a form during the study conduct period
- Add a new form to a live study version

Create lab forms

Lab forms hold all the questions and items that allow site users to properly collect local lab results and compare the collected data against lab normals to ensure that the correct normal range is associated with lab data.

Before you begin, make sure you read all about subject tags and code lists. For more details, see Guidelines for subject tags and code lists in lab forms.

Watch a video on how to create a lab form!

- Tag questions on date of birth, gender, and race
- Create the lab form
  The advantage of using a lab form is that most questions (Sample Collection Date, Fasting, Lab Units, Lab Results, Normal Text Result, Low Range, and High Range) in the form are predefined and already tagged appropriately.
- Define the questions in a lab form
- What should I do if my study cannot collect data on a subject's race?
  If you can't collect any data on a subject's race, you can design your study in a way that allows you to continue collecting lab data successfully without having to collect a subject's race.

Related Topics

- Define lab normals

Tag questions on date of birth, gender, and race

When it comes to subject tags, you can only have one question tagged with the Date of Birth, Gender, and Race tags in a study.

For questions on gender and race, make sure you use a code list and that the code list is tagged with the same subject tag as the question.

Before you begin, make sure you do the following:

- Read all about subject tags and code lists. For more details, see Guidelines for subject tags and code lists in lab forms.
- If your study cannot collect data on a subject's race, you may have to implement a specific workaround. For step-by-step instructions, see What should I do if my study cannot collect data on a subject's race?.
- Create a one-section form that contains questions on a subject's date of birth, gender, and race. For step-by-step instructions, see:
  - Create a form with one section
  - Create a date/time question
  - Create a question with checkboxes or radio buttons
  - Create a drop-down question

To tag questions, follow these steps:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** tab.
3. On the Forms tab, select the form that contains your demographic questions.
4. Select **Manage Forms** and select **Edit**.
5. On the right, expand the Advanced side panel and make sure the following questions are tagged as follows:
   - A question inquiring a subject's date of birth must be tagged with the **Date of Birth** subject tag.
   - A question on gender must be tagged with the **Gender** subject tag.
   - A question on race must be tagged with the **Race** subject tag.

After you're done tagging these required questions, your next step is to create a lab form. See Create the lab form. Tagging questions with the appropriate subject tags isn't a prerequisite to creating a lab form but it would be helpful for you to tag questions early on in the lab form creation process to ensure that they're properly configured before you start testing your study or going live with your study.

Related Topics

- Predefined rules
  You can configure different types of rules in form design. Dynamic rules allow you to dynamically display a question, a form, a form section, or a visit only when relevant for a subject. Validation rules allow you to set specific criteria to be met for a given question. Additionally, you can set rules to send notifications.
- Update a form during the study conduct period
- Add a new form to a live study version
- What is the workflow for creating and managing local labs?
- What is the difference between a normal text result and ranges?
  When creating a lab form, you need to remember that the items you include in the form will be used to define lab normals for a local lab. For each lab test, you can either use a normal text result or low and high range values to define lab normals.

- Create a code list
  Code lists allow study designers to easily add standard answer options to a drop-down, checkbox, or radio button type question.

Create the lab form

The advantage of using a lab form is that most questions (Sample Collection Date, Fasting, Lab Units, Lab Results, Normal Text Result, Low Range, and High Range) in the form are predefined and already tagged appropriately.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

> **Caution:**
>
> To avoid any issues with how questions are displayed in a lab form, don't trigger the display of a lab form using a Show Question rule included in the Questions Before the Table (flat) section. You can still trigger dynamic questions within the Questions in the Table section (repeating) section of the lab form or trigger the Questions in the Table (repeating) section dynamically using a Show Section rule configured with a question in the Questions Before the Table (flat) section.

> **Tip:**
>
> Did you know you can make the Questions in the Table section dynamic? Use the Show Section predefined rule to make that section dynamic based on specific answers to specific questions. For step-by-step instructions, see Define a Show Section rule.

Before you begin, make sure you do the following:

- Read all about subject tags and code lists. For more details, see Guidelines for subject tags and code lists in lab forms.
- Tag questions on date of birth, gender, and race.

To configure a lab form's details, follow these steps:

1. On the Forms tab, select **Create Form**.
2. From the drop-down, select **Lab Form**.
3. In the **Name of the Form** field, enter a title for your form.
4. On the right, expand the Details pane and make sure the following settings and fields are configured as expected:

Field or setting	Description
Reference code	Make sure the form has a reference code. A reference code is a one-word abbreviation for the form.
Repeating Form toggle ( )	The Repeating Form toggle ( ) is turned on, by default and inactive.
Allow Additional Rows toggle ( )	In a lab form, the Allow Additional Rows toggle ( ) is turned off by default. Turn this toggle on to let a site user add new rows to a lab form. If a site user is allowed to add new rows to a lab form, they can't include or define lab normal ranges for those newly added rows.
Allow for Multiple Instances toggle ( )	The Allow for Multiple Instances toggle ( ) is turned off by default. Turn this toggle on to let a site user create multiple instances of this lab form within a visit.

After you're done creating the lab form and configuring its details, you can begin assigning the code list values for the Lab Test question and verifying the other questions, such as Lab Unit, Low Range, High Range, and Normal Text Result. See Define the questions in a lab form.

Related Topics

- Predefined rules
  You can configure different types of rules in form design. Dynamic rules allow you to dynamically display a question, a form, a form section, or a visit only when relevant for a subject. Validation rules allow you to set specific criteria to be met for a given question. Additionally, you can set rules to send notifications.
- Update a form during the study conduct period
- Add a new form to a live study version
- What is the workflow for creating and managing local labs?
- What is the difference between a normal text result and ranges?
  When creating a lab form, you need to remember that the items you include in the form will be used to define lab normals for a local lab. For each lab test, you can either use a normal text result or low and high range values to define lab normals.

Define the questions in a lab form

Most questions in a lab form are already predefined. For example, the Low Range, High Range, and Normal Text Result questions are read-only and their code list values are associated with a study's local lab, as well.

You do not have to configure any code list values in a lab form for those items.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

> **Caution:**
>
> To avoid any issues with how questions are displayed in a lab form, don't trigger the display of a lab form using a Show Question rule included in the Questions Before the Table (flat) section. You can still trigger dynamic questions within the Questions in the Table section (repeating) section of the lab form or trigger the Questions in the Table (repeating) section dynamically using a Show Section rule configured with a question in the Questions Before the Table (flat) section.

Before you begin, make sure you do the following:

- Check that your study is using the appropriate code lists. For more details, see Create a code list.
- Read all about subject tags and code lists. For more details, see Guidelines for subject tags and code lists in lab forms.
- Tag questions on date of birth, gender, and race.
- Create the lab form.

To define questions in a lab form, follow these steps:

1. In the **Questions Before the Table** section do one of the following:

   By default, the Sample Collection Date and Fasting questions are set as required. The Sample Collection Date question also has the **Allow Future Date** toggle turned on.

   - If you're creating a brand new lab form, determine whether you want to hide the Sample Collection Date and Fasting questions and make them optional.
   - If you're editing an existing lab form, these introductory questions might be hidden. To include them in the lab form for your live study, turn off the Hidden toggle () for both questions and make sure you apply this change for your live study. See Create a new Draft version of a study to update the Approved version.

     > **Note:**
     >
     > If you choose to hide the Sample Collection Date question, the system uses the visit date instead to calculate a subject's age, as well as to compare the date to the effective date for the integration of lab normals.

- If you want to add new questions to the section, select **Add**, hover over **Questions Before the Table**, and select the question type that you want to include.

2. In the **Questions in the Table** section, configure or verify the following questions:

Question or item	Action
Lab Test	By default, the Lab Test question is included as a Label (Repeating table only) item. a. Next to the Lab Test question, select **Code List**. b. On the Code List dialog, select the **Lab Test** code list from the list. c. Select **Use Selected List**. **Caution:** The **Lab Test** tag in a question form should be visible to all users. Turning on the **Hidden** toggle will prevent the expected form function.
Lab Result	By default, this question is configured as a required text type of question. If required, select the question and configure any additional details on the side panels.
Lab Unit	By default, this question is configured as a read-only text question. A site user doesn't have to answer this item. The Lab Unit item only displays the appropriate lab normal values configured for the selected lab form and displays those values in the lab form as read-only.
Low Range	By default, this question is configured as a read-only text question. A site user doesn't have to answer this item. The Low Range item only displays the appropriate lab normal values configured for the selected lab form and displays those values in the lab form as read-only.
High Range	By default, this question is configured as a read-only text question. A site user doesn't have to answer this item. The High Range item only displays the appropriate lab normal values configured for the selected lab form and displays those values in the lab form as read-only.
Normal Text Result	By default, this question is configured as a read-only text question. A site user doesn't have to answer this item. The Normal Text Restul item only displays the appropriate lab normal values configured for the selected lab form and displays those values in the lab form as read-only.

3. Select **Save** or **Save & Close**.

Your lab form is now complete.

Related Topics

- Predefined rules
  You can configure different types of rules in form design. Dynamic rules allow you to dynamically display a question, a form, a form section, or a visit only when relevant for a subject. Validation rules allow you to set specific criteria to be met for a given question. Additionally, you can set rules to send notifications.
- Update a form during the study conduct period
- Add a new form to a live study version
- What is the workflow for creating and managing local labs?
- What is the difference between a normal text result and ranges?
  When creating a lab form, you need to remember that the items you include in the form will be used to define lab normals for a local lab. For each lab test, you can either use a normal text result or low and high range values to define lab normals.

What should I do if my study cannot collect data on a subject's race?

If you can't collect any data on a subject's race, you can design your study in a way that allows you to continue collecting lab data successfully without having to collect a subject's race.

Several types of users should work together to ensure that a site user can successfully collect lab data.

Study designers

> **Note:**
>
> If you plan to apply this change to a live study version, make sure you select the appropriate live study version from the **Apply Changes to Study Version** drop-down for the question on a subject's race. For step-by-step instructions, see Update a form during the study conduct period.

In your study's design, follow the steps below:

1. In the form that you use to collect a subject's demographic data, create a question with radio buttons.
   a. Name the question "Race".
   b. Mark the question as **Hidden** and **Read-Only**.
   c. From the **Data Classification** drop-down, select the appropriate label to use for classifying the data collected for this question.

   For step-by-step instructions, see the following:

   - Create a question with checkboxes or radio buttons
   - Define data classifications for a hidden question
2. Next to the question, select **Code List** and add a new custom code list that contains only one value that is according to your protocol (for example, "No Race"). Make sure that you

specify the appropriate label and code for that value, and that you tag the Race Lab Normals tag for this newly created code list.
For step-by-step instructions, see Create a code list.

Rule designers, testers, and publishers

> **Note:**
>
> When you design the calculation rule, make sure you include JavaScript logic that clears the selection for the Race field when the Gender field is cleared.

In a study's Testing mode, create a calculation rule that allows the Race field in a form to be automatically populated when the Gender field is filled in.

For step-by-step instructions, see the following topics in the *Rules Developer Guide*:

- Create a rule for a calculated value
- Prepare your rule for testing and approval
- Publish a single rule

Data managers and site users

Whether you're a data manager or a site user working with lab normals, you might have to go into your study's settings, on the **Sites & Labs** tab. From there, go to the appropriate lab and update its lab normal value for the **Race** column to **All**.

For step-by-step instructions, see Define lab normals in the *Sponsor and CRO User Guide* (as a data manager) or Define lab normals in the *Site User Guide* (as a site user).

Related Topics

- Tag questions on date of birth, gender, and race
- Create the lab form
  The advantage of using a lab form is that most questions (Sample Collection Date, Fasting, Lab Units, Lab Results, Normal Text Result, Low Range, and High Range) in the form are predefined and already tagged appropriately.
- Define the questions in a lab form

Create a repeating form

Create a repeating form when you want to allow site users to collect multiple instances of the same data.

For example, if a subject went through multiple surgeries, a site user can add new instances of a Surgeries form to collect data for each surgery. Or if a subject experienced multiple adverse events, you can create an Adverse Events form and mark it as repeating so that the site user can re-use it for each event experienced by the subject.

If you're collecting data where multiple values are related, create separate questions for each value. For example, to collect data about blood pressure, create two number questions, one for systolic blood pressure and the other for diastolic blood pressure.

You can also include a coding question in a repeating form.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

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

Video

Make sure you first create a form. For step-by-step instructions, see Create a form with one section or Create a form with two sections.

To create a repeating form:

1. Access the Draft version of a study as described in Open a study's design.
2. On the Forms tab, locate the form you want to edit or create a new one.
3. On the right, expand the Details side panel and turn on the **Repeating Form** toggle ( ) to make the form repeating.
4. By default, the **Allow Additional Rows** toggle ( ) is turned on. If you include a Label item in the repeating form and you want to prevent a site user from adding additional rows to the repeating form, turn off the toggle.
5. Select **Save** or **Save & Close**.

Related Topics

- Import a form
  Import a form form another Production study, or library study and use it in your study design.
- Question types and settings
  You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.
- Update a form during the study conduct period
- Add a new form to a live study version

About Drug Reconciliation forms

You use a Drug Reconciliation form to collect data related to kits in order to help site or sponsor users keep track of kits that have been sent for destruction.

A single drug reconciliation form design can be created per study. To design drug reconciliation forms, the following permissions are required:

- *Design Supplies and Dispensation*
- *Design Clinical Supplies Forms*

By default, the drug reconciliation form consists of a three-section template, which can be customized to fit the requirements of your study. The following sections are included in a form:

- A flat section, containing fields related to general study information.
- A repeating section, the fields of which will be populated with the information of the kits being reconciled.
- A flat section, containing information related to the target depot or the user who has requested the form.

> **Note:**
>
> The fields of a drug reconciliation form can only be moved within the same section, not between sections.

Drug reconciliation forms support the new Existing Data field. The existing data field self-populates based on existing study data, in order to reduce the number of fields sponsor and CRO users need to complete when performing drug reconciliation using drug reconciliation forms.

A single drug reconciliation form design can be created per study. As you design your drug reconciliation form, you can configure the following existing data fields:

Table 5-1 Existing data field types available for the first section

Field name	Notes
Instructional text	Included in the template drug reconciliation form. Can also be added to the third section of the drug reconciliation form. For more information, see Add instructional text to a form.
Protocol	Included in the template drug reconciliation form.
Site ID	Included in the template drug reconciliation form. Can also be added in the repeating section.
Site Name	Included in the template drug reconciliation form. Can also be added in the repeating section.
Investigator Name	Included in the template drug reconciliation form. Reflects the first and last name of the site investigator.
Study Name	Not included in the template drug reconciliation form.
Study ID	Not included in the template drug reconciliation form.
Study Mode	Not included in the template drug reconciliation form.
Depot Name	Not included in the template drug reconciliation form.
Depot ID	Not included in the template drug reconciliation form.
Depot Address	Not included in the template drug reconciliation form.

Table 5-1 (Cont.) Existing data field types available for the first section

Field name	Notes
Main Primary Address	Not included in the template drug reconciliation form. Can also be added in the repeating section.

Table 5-2 Existing data fields available for the second section

Field name	Notes
Kit Number	Included in the template drug reconciliation form.
Blinded Lot	Included in the template drug reconciliation form.
Packaging Type	Included in the template drug reconciliation form. Can be bottle, inhaler etc., as input by the study designers when defining the kit type during study design.
Number of Units in Kit	Included in the template drug reconciliation form.
Text Field for CRA Comments	Included in the template drug reconciliation form. This field is only accessible during design.
Kit Description	Not included in the template drug reconciliation form.
Blinded Lot Expiration Date	Not included in the template drug reconciliation form.
Manufacturing Lot Expiration Date	Not included in the template drug reconciliation form.
Manufacturing Lot	N/A
Missing Units	Not included in the template drug reconciliation form.
Storage Temperature	Not included in the template drug reconciliation form.
Status	Refers to the status of the current kit. Not included in the template drug reconciliation form.
Subject ID	Not included in the template drug reconciliation form.
Screening Number	Not included in the template drug reconciliation form.
Randomization ID	Refers to the initial randomization ID. Not included in the template drug reconciliation form.
Randomization Date	Returns the randomization date added by site users. Not included in the template drug reconciliation form.
Returned Units	Not included in the template drug reconciliation form.

Table 5-2 (Cont.) Existing data fields available for the second section

Field name	Notes
Visit Name	For cycle or unscheduled visits, the visit instance will be added to the end of the contents of this field. Not included in the template drug reconciliation form.
Visit Date	Date entered by users at the time of visit. Not included in the template drug reconciliation form.

> **Note:**
>
> Users will not be able to add additional rows, this section will display the kits that are selected.

Table 5-3 Existing data fields available for the third section

Field name	Notes
Target Depot ID	Included in the template drug reconciliation form.
Target Depot Name	Included in the template drug reconciliation form.
Form Generated By	Included in the template drug reconciliation form.
For Generated Date	Included in the template drug reconciliation form.

Other fields which can be added to drug reconciliation forms

In addition to existing data fields, the following can also be added to a drug reconciliation form design:

Table 5-4 Other fields

Field name	Notes
Signature	This field is designed to accommodate a wet signature, after the form has been generated and filled in by a sponsor and CRO user.
Signature Date	Entered manually.

Printing drug reconciliation forms

Due to the limitations of the PDF format, you can only print a maximum of 9 columns from the repeating section. Although you can create as many columns as necessary, each column will wrap when the form is saved as a PDF file.

Advanced study versioning (ASV)

To add a drug reconciliation form, you must update and go through the entire study versioning process, since ASV is not supported. To apply your changes, update your form in a Draft study version, assign the new study version to the impacted sites in the appropriate modes, and then move your study version to Approved.

> **Note:**
>
> Existing drug order forms which have been used for drug reconciliation are not affected should a study designer create a drug reconciliation form.

Create a Drug Reconciliation form

Drug Reconciliation forms collect data related to kits to help site or sponsor and CRO users keep track of kits that have been sent for destruction.

> **Note:**
>
> There can only be a single Drug Reconciliation form design per study.

Drug reconciliation forms are the only ones to support the Existing Data field, which automatically populates based on existing study data.

For more details about the structure, impacts on study design, and the fields available in drug reconciliation forms, see About Drug Reconciliation forms.

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** tab.
3. Select **Create Form** and then select **Drug Reconciliation** from the drop-down.

   Drug Reconciliation forms start with a three-section template, which can be customized to fit the requirements of your study. By default, these are:

   a. A flat section, containing fields related to the general characteristics of the study, such as **Site ID** or **Investigator name**. This section also contains at least one instructional text field, which provides guidance to site users whenever they perform drug reconciliation.

   b. A self-populating repeating section, the fields of which will be populated with the information associated with the kits being reconciled.

   c. Another flat section, containing information related to the target depot or the user who has requested the form.
4. On the right, expand the Details side-panel and add a reference code for the form.
5. Depending on the requirements of your study, you can use the default set of questions the drug reconciliation form comes with. Alternatively, on the bottom left, select **Add** and, depending on the nature of the question you'd like to add, select one of the following from the drop-down:

   - **Add questions in the Questions Before the Table section**: hover over **Questions Before the Table** and choose the types of leading questions you must include in this form section.
   - **Add questions in the Question in the Table section**: hover over **Questions in the Table** and choose the types of questions you must include in the second section of the form.
   - **Add questions in the Questions After the Table section**: hover over **Questions After the Table** and choose the types of questions you must include in the third section of the form.

Repeat this step for each question you want to include in every section of the form. For information on the different question types you can add, see Question types and settings.

6. Select **Save** or **Save & Close**.

Related Topics

- Who is responsible for each step in the kit reconciliation process?

Preview a form

Check for inconsistencies and improve the data collection process by previewing a form and sharing it with other team members (for additional review) before using it in a Production study.

You can preview a form in a draft, testing, approved, or achived study. When you preview a form, you can enter data for review purposes only, and that data isn't saved in the application. Previewing a form can help you test the following use cases:

- Dynamic sections and questions
- Range checks, such as years in a date of birth
- Data entry in a table

While previewing a form, you can invite other team members to participate in the preview process. Those invited receive an email containing a link to the form preview in the Oracle Clinical One Platform. The email link is active until the study version is moved to a new state. For example, if the form preview was sent from a study in Draft, the link is active until the study version is moved to Testing.

Users must have at least one of the following permissions and be a part of the same study as you, to preview a form and invite others to participate in the preview process:

> **Note:**
>
> Contact your study manager or user administrator to check your permissions if you can't access a form preview.

- *Design Forms*
- *Design Randomization*
- *Design SDV Properties on Forms*
- *Design Supplies and Dispensation*
- *Design Visits and Events*
- *Move a Study Design to Testing or Production*
- *Run the Study Design Report*
- *Run the Study Rules Report*
- *Upload and Generate Inventory Lists*
- *Upload and Generate Randomization Lists*
- *View Study Design* (this permission is required to use the link provided in the email invite.)

To preview a form, print the form preview, or invite others to participate in the preview process:

1. Select the **Edit Study** icon  on the study, then locate and double-click the study version that you want to access (whether it's in Draft, Testing, Approved, or Archived).

   The Data Collection page opens.

2. On the Forms tab, do one of the following to access a form:
   - Single-click a form, then select **Edit** from the **Manage Forms** drop-down.
   - Double-click a form.
   - Select **Create Form** to create a new form.

3. Select **Preview** in the top-right corner of the form.

   The form preview opens in a new window. Close this window after your review is complete.

> **Note:**
>
> You can only preview a form after you've saved your updates. If you attempt to preview a form without saving, you are be prompted with a Confirmation dialog. Select **Save & Preview** to continue.

4. Select **Print** if you would like to print the form preview.

> **Tip:**
>
> To get a better layout on your print PDF copy, select **Tabloid** paper size and **Landscape** orientation.

5. Select **Share** to share the preview form link with other users.

   The Share Form dialog window opens.

6. Select the email addresses of the users that you want to share the link with, then select **Send Invite**.

   The **Email Address** list only includes email addresses of users who are part of the same study and are assigned the appropriate permissions to preview a form.

Add a form to a visit

You can add forms to visits in any order, but you'll save some time if you add forms in the order they should appear to site users.

To check the work you did on a visit, reorder forms in a visit, or add more forms to a visit, click the visit in Visits & Events.

> **Note:**
>
> The cycles that you select for your visit assignment (upon selecting **Select Cycles**) do no overwrite the cycle that you specify as your starting cycle. If you do not want to have a form included in the first cycle of a selected visit, then you must make sure you always update the **Starting Cycle** field, even if you are only using the **Select Cycles** feature to select the required cycles. If you do not do this, the first cycle automatically includes the form.

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

Video

Every visit must have at least one form, including unscheduled visits, so make sure you create visits first. For step-by-step instructions, see Create a visit or event.

To add a form to a visit:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** page.
3. Next, you can do one of the following:
   - Drag a form to the visit you want to add it to and drop it on to the visit.
   - Open the visit and select **+**. Then select the forms that you want to assign to the visit.
   - Select a form, select **Manage Forms**, and then select **Visit Assignment**.
4. On the Add Form to Visit or Event dialog, depending what you want to do, follow either one of these steps, and then select **Save**.

Options	Steps
Add a form to a scheduled visit	In the Visit column, select the checkbox next to each scheduled visit.
Add a form to an event	In the Visit column, select the checkbox next to each event.
Add a form to a specific visit cycle	a. In the Visit column, select the corresponding visit branch. b. Select **Select Cycles**. c. On the Select Cycles dialog, select the cycles that you want the form to be associated with. d. Depending on what cycles you want the form to be on, you must specify values in the following columns: • **Starting Cycle**: Enter a number that indicates the starting cycle that the form is associated with. The starting cycle represents the first cycle where the form is displayed for a site user. • **Repeat Every (Cycle)**: Enter a number to indicate the frequency for displaying the associated form. For example, enter 3 to indicate that the associated form must be displayed once every three cycles in the study. • **Ending Cycle**: Enter a number to indicate the last visit cycle during which the form must be displayed. For example, enter 20 if that is the last cycle a form should be associated with.

The **Form** icon () on a visit lists the number of forms in the visit.

Import a form

Import a form form another Production study, or library study and use it in your study design.

> **Note:**
>
> While multiple study designers cannot edit the same form, you can still import the latest saved version of a form that is edited by another study designer. For more information, see Can multiple study designers edit a study at the same time?.

Forms you import include hints, validation rules, code lists, SAS properties, dynamic rules, and all published custom JavaScript rules associated with that form. If the forms, questions, or visits referenced by the rule variables do not exist in the study the rule is imported to, the rule becomes invalid. A warning message informs you about the reason why the copied rule is invalid. You can modify and re-publish a copied custom rule following the usual worflow for publishing a rule. For step-by-step instructions, see Modify and re-publish a published rule.

You can also copy forms from within the same study. See Duplicate a form.

1. Access the Draft version of a study as explained in Open a study's design.
2. Make sure you are on the **Data Collection** page.
3. Select the **All Forms** tab.
4. Below **Import forms from**, choose one of the following, and filter your view to find the form you want to import:
   - **Production study**: you can filter by either selecting a study or a therapeutic area from the respective drop-downs, or type in the search box to search for a specific form.
     To enable the drop-down to filter by therapeutic area, you need to choose **All Studies** from the Studies drop-down.
   - **Library study**: click **Filter** and choose a value from the Study Name or Tags drop-downs.
     You can only import library objects that have a status of **Published**.
5. Select one or multiple form from the filter results.

   > **Tip:**
   >
   > - You can hover over a form to see the Reference Code and the Study ID in which the form was created.
   > - To import multiple forms at the same time, press the CTRL key on your keyboard, and select each form that you want to import.

6. Select **Add Form to Current Study**.

After the form is successfully imported and copied to your study, you can see it on the **Forms** tab and manage it as follows:

- You can hover over the icon to see the last time the form was edited.
- If the name of the form already exists in your study, an incremental counter (_1, _2, etc.) is added to the name of the imported form.

- A form imported from another Production study appears on the **Forms** tab with a Copied Form icon () in the upper right of the form.
- A form imported from a library study appears on the **Forms** tab with a Library Form icon () in the upper right of the form.
- After you edit the imported form, the Copied and Edited icon () appears in the upper right of the form.

Duplicate a form

You can copy a form within the same study to create a duplicate of that form. If you need to create similar forms, you can duplicate a form multiple times, and then editing these forms instead of creating new forms from scratch.

While multiple study designers cannot edit the same form, you can still copy the latest saved version of a form that is edited by another study designer. For more information, see Can multiple study designers edit a study at the same time?.

You can import forms from other studies in Production or library studies. See Import a form.

Forms you duplicate include hints, validation rules, code lists, SAS properties, and dynamic rules.

> **Note:**
>
> Custom JavaScript rules associated with a form are not copied when a form is duplicated within the same study.

1. Access the Draft version of a study as explained in Open a study's design.
2. Make sure you are on the **Data Collection** page.
3. On the **Forms** tab, select the form you want to duplicate.
4. From the **Manage Forms** drop-down, select **Duplicate**.

> **Note:**
>
> You can only duplicate one form at a time.

After the form is successfully copied, you can see it on the **Forms** tab and manage it however you need. As the name of the form already exists in your study, an incremental counter (_1, _2, etc.) is added to the name of the imported form.

Leave and manage comments

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

Whenever you tag somebody in a comment, a thread is created for the conversation you and other users might initiate through comments. The user you tag in a comment receives an email

notification indicating the study name, the form's reference code or the question's reference code (depending on where you left the comment), as well as the contents of that comment.

> **Tip:**
>
> To tag somebody in a comment, you can type the asperand or at symbol (@) in the text field. A list with all of the registered user names appears, and you can select the user you want to tag in the comment.

> **Note:**
>
> Consider the following notes:
>
> - In Draft mode, for you to add or reply to a comment, you must first save the form.
> - Once you delete the form or question that had associated comments, those comments are removed from the system, as well.

1. Choose where to work, whether it's in Draft mode or in Testing mode.

   For more information, see Open a study's design or Access your study in any mode.
2. Navigate to the form where you want to leave a comment, view, or reply to existing comments.
3. All comments are managed on the Comment sidebar. Depending on what your next step is, do one of the following:

Option	Steps to take
Add a comment for a specific question in a form	a. Depending on where you want to work, do one of the following: • **In Draft mode**: in a form, select the **Comments** icon ( ) next to a question that you want to comment on. • **In Testing mode**: Open a visit, select the **Menu** icon ( ) for a form or a question, and select **Add Comment**. b. On the Comments sidebar, select **Add Comment**. c. In the newly displayed field, type your comment, and select **Comment**.
Add a comment for the overall form	a. Click anywhere outside of the question to select the form. b. In the Comments sidebar, select **Add Comment**. c. In the newly displayed field, type your comment, and select **Comment**.

Option	Steps to take
Edit a comment	a. In the Comments sidebar, search for the comment that you want to edit. b. Click the **Menu** icon ( ), and select **Edit**. c. In the newly displayed field, type your edits to the comment. d. Select **Save** or **Cancel**.
Resolve a comment thread	a. In the Comments sidebar, search for the thread that you want to resolve. b. Select the **Resolve** icon ( ). The Resolve icon ( ) is highlighted in green, which indicates that the comment thread is resolved.
Delete a comment or a thread	a. In the Comments sidebar, search for the comment or the thread that you want to delete. b. Select the **Menu** icon ( ) and select **Delete**. c. On the newly displayed dialog, select **Delete** or **Cancel**.
Search or sort comments	a. In the Comment sidebar, type a keyword from a comment that you're looking for in the search bar, and hit **Enter** on your keyboard. b. Click the **Sort icon** ( ), and select either one of these options from the drop-down: • Sort by date • Sort by unread • Sort by form order • Only Designer comments • Only Testing comments (for Testing mode) • Show resolved comments

Option	Steps to take
Manage a comment thread	**a.** In the Comment sidebar, search for the thread that you want to manage. **b.** Click the **Menu icon** (⋯). **c.** Select **Mark as read**, so that the thread no longer appears highlighted as unread in the sidebar. **d.** Select **Copy link** to share the link with another study team member. The link is copied to your clipboard and you can paste it anywhere. The user who gets the link can only access the comment thread once they log into the system and if they have the appropriate access to the study. **e.** Click **Delete thread** to remove the entire comment thread.

6
Predefined rules

You can configure different types of rules in form design. Dynamic rules allow you to dynamically display a question, a form, a form section, or a visit only when relevant for a subject. Validation rules allow you to set specific criteria to be met for a given question. Additionally, you can set rules to send notifications.

- Access the Rules section
  You create and manage predefined rules on the Rules sidepanel or section in a form. In that section, you can configure validation rules or action rules, such as dynamic questions for forms.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.
- Define a validation rule for text questions
  For text questions, the only available validation rule restricts the field to alphabetic characters.
- Define a validation rule for Date/Time questions
  Date/Time questions offer multiple validation rules to restrict site users to only enter specific dates and times.
- Define a validation rule for number and age questions
  Number questions offer multiple validation rules to restrict site users to only enter specific numeric characters.
- Define a validation rule for multi-choice questions
  For drop-down questions or questions with checkboxes, you can specify the number of options that users must select, or require users to choose a given option.
- Define a validation rule for questions with radio buttons
  A question with radio buttons requires only one option as an answer. By adding a validation rule, you can require site users to choose a specific option.
- Set up a dynamic question in a form
  Use a dynamic question to show it in a form only when relevant for the subject.
- Set up a dynamic section in a form
  Configure dynamic sections to dynamically display repeating tables in two-section forms.
- Set up a dynamic form
  Dynamically displaying forms across visits in a study allows you to only display forms when it is relevant for a subject. However, you should understand the scope of dynamic forms before implementing them in your study design.
- Set up a dynamic visit
  Use dynamic visits when you want a visit to be displayed only when relevant to the subject, whether it's for data collection or dispensation purposes.
- Set up form associations
  Create form associations using a **Link & Show Form** rule to connect related data that is collected in these forms.

- Set up a question to lock automatically
  Lock questions using an **Auto-lock** rule to prevent site users from editing subject data during the study conduct period, after a specific subject event.
- Define a Send Notification rule
  You can create a rule that sends email notifications on data entries and response changes. Additionally, you can set follow-up email notifications on data changes to be sent following an initial notification. You can use this feature to notify designated team members based on specific criteria.

Access the Rules section

You create and manage predefined rules on the Rules sidepanel or section in a form. In that section, you can configure validation rules or action rules, such as dynamic questions for forms.

To access the Rules section you need to select a question in an existing form. The following steps describe the procedure whether you are working in existing forms or creating them as you go.

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** page.
3. Select the **Forms** tab.
4. Depending on what your next step is, you can do one of the following:
   - Select **Add Form** to create a new form from scratch.
   - Select an existing form and then select **Edit** to work in an existing form.
5. Select an existing question to edit or select **Add Question** to define a new question.

   See Question types and settings.
6. On the right side, locate and expand the **Rules** sidepanel.

Types of validation rules

Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Validation rules are useful when you want to block site users from entering unaccepted values to answer certain questions. Depending on the type of question you are working with, different options for a validation rule are available.

If applicable, you can define more than one validation rule for a question, but only for question types that have more than one validation rule options: Date/Time, Date of birth, number, age, drop-down, and checkbox questions. To do this you must select a logical operator:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

These operators cannot be combined if more than two validation rules are configured. For example, if you have three validation rules on a question, you can select **AND** for every rule instance or **OR** for every rule instance, but you cannot select **AND** followed by **OR**.

Question type	Validation rules	Use cases
Text question	• *Doesn't contain*	• Number of allowed characters (up to 4,000). • Type of allowed values (either alphanumeric or text only).
Date/Time questions	• *After* • *On or After* • *Before* • *On or Before* • *On* • *Not On* • *Not Between* • *Range*	• Format for collecting date and time. • Allowed date range.
Number and Age questions	• *Greater Than* • *Greater Than or Equal To* • *Less Than* • *Less Than or Equal To* • *Is* • *Not Equal To* • *Not Between* • *Range*	**Age questions** • Acceptable range of numbers for age. • Allowed date range for date of birth. **Number questions** • Number of values allowed after the decimal point. • Unit of measurement. • Acceptable range of numbers.
Drop-down questions and questions with checkboxes	• *Select at Least* • *Select at Most* • *Select Exactly* • *Answer Must Be*	• Number of options to select in a drop-down list. • Answer that users must select to continue with the visit.
Questions with radio buttons	• *Answer Must Be*	• Answer that users must select for screening requirements. • Answer that users must select for entering a rollover study.

For further details about how to set validation rules for a specific question type, browse the sections below:

Related Topics

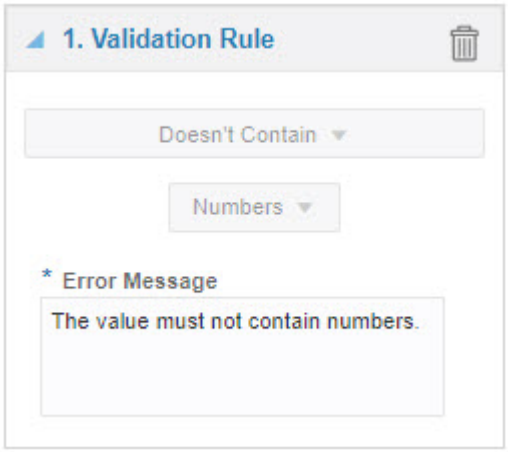
- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.

Define a validation rule for text questions

For text questions, the only available validation rule restricts the field to alphabetic characters.

1. Go to the Rules sidepanel as described in Access the Rules section.
2. On the Rules sidepanel, select **Add Rule** and then select **Doesn't Contain**

A Validation Rule dialog appears.



3. In the **Error Message** field, enter an error message that should appear for site users when the answer is invalid.

   The error message appears for site users when the answer is missing or invalid.

Related Topics

- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Define a validation rule for Date/Time questions

Date/Time questions offer multiple validation rules to restrict site users to only enter specific dates and times.

The answer to an age-related question can be a number (when you're asking a subject to specify their exact age) or a date (when you're asking a subject to specify their date of bith). To set a validation rule related to the age value, see Define a validation rule for number and age questions.

You can define more than one validation rule for a number or age question, if applicable. For age questions you can combine Age validation rules with Date validation rules.

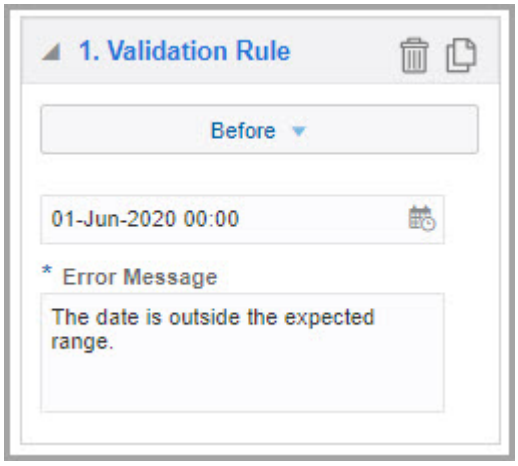
Repeat the steps to add new rules as required and, once you have added the new rules, select a logical operator from the drop-down between rules:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

1. Go to the Rules sidepanel as described in Access the Rules section.
2. On the Rules sidepanel, select **Add Rule**
3. From the drop-down, select **Date of Birth**, and choose one of the following validation rules:

Validation rule type	Description
After	A site user must enter a date that comes after the specified date.
On or After	A site user must enter either the exact same date or one that comes after the specified date.
Before	A site user must enter a date that comes before the specified date.
On or Before	A site user must enter either the exact same date or one that comes before the specified date.
On	A site user must enter the exact same date as the one specified.
Not On	A site user must not enter the exact same date as the one specified.
Not Between	A site user must enter a number that is not between the specified range of values.
Range	A site user must enter a number that is between the specified range of values.

A Validation Rule dialog appears.



4. Enter values according to the type of validation rule:

Option	Description
For rules of the following type: • **After** • **On or After** • **Before** • **On or Before** • **On** • **Not On**	Set a comparison date.
For rules of the following type: • **Not Between** • **Range**	Set lower and higher date range limits.

5. In the **Error Message** field, enter an error message that should appear for site users when the answer is invalid.

Related Topics

- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Define a validation rule for number and age questions

Number questions offer multiple validation rules to restrict site users to only enter specific numeric characters.

The answer to an age-related question can be a number (when you're asking a subject to specify their exact age) or a date (when you're asking a subject to specify their date of bith). To set a validation rule related to the age value, see Define a validation rule for number and age questions.

You can define more than one validation rule for a number or age question, if applicable. For age questions you can combine Age validation rules with Date validation rules.

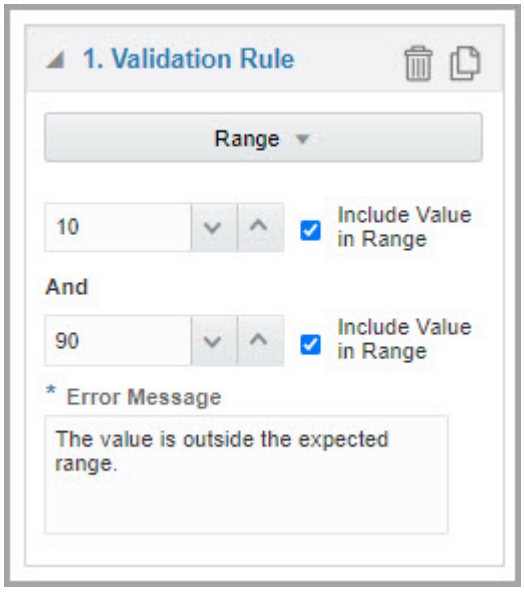
Repeat the steps to add new rules as required and, once you have added the new rules, select a logical operator from the drop-down between rules:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

1. Go to the Rules sidepanel as described in Access the Rules section.
2. On the Rules sidepanel, select **Add Rule**.
3. From the drop-down, select **Age**, and choose one of the following validation rules:

Validation rule type	Description
Greater Than	A site user must enter a number that is greater than the specified value.
Greater Than or Equal To	A site user must enter a number that is greater than or equal to the specified value.
Less Than	A site user must enter a number that is less than the specified value.
Less Than or Equal To	A site user must enter a number that is less than or equal to the specified value.
Is	A site user must enter a number that is exactly the specified value.
Not Equal To	A site user must enter a number that is not equal to the specified value.
Not Between	A site user must enter a number that is not between the specified range of values.
Range	A site user must enter a number that is between the specified range of values.

A Validation Rule dialog appears.



4. Enter values according to the type of validation rule:

Option	Description
For rules of the following type: • **Greater Than** • **Greater Than or Equal To** • **Less Than** • **Less Than or Equal To** • **Is** • **Not Equal To**	Set a comparison value.
For rules of the following type: • **Not Between** • **Range**	Set lower and higher range limits. If required, select **Include Value in Range** to specify that the limits should be included in the comparison range.

5. In the **Error Message** field, enter an error message that should appear for site users when the answer is invalid.

Related Topics

- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Define a validation rule for multi-choice questions

For drop-down questions or questions with checkboxes, you can specify the number of options that users must select, or require users to choose a given option.

For example, the **Select Exactly** validation rule is configured for questions that must be used in defining a minimization design or enrollment limit.

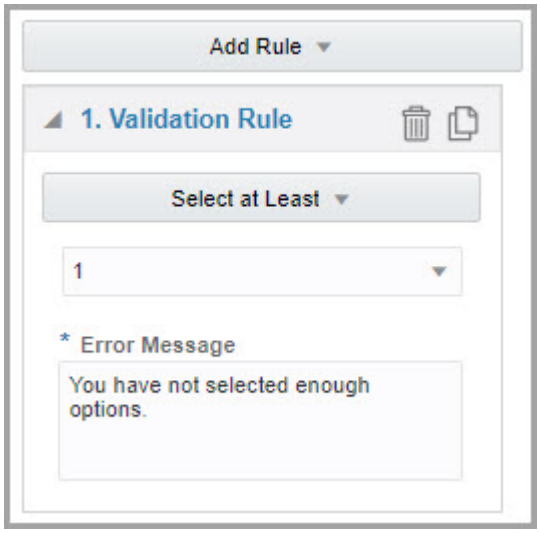
If needed, you can define more than one validation rule for a drop-down question or a question with checkboxes. Repeat the steps to add new rules as required and, once you have added the new rules, select a logical operator from the drop-down between rules:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

1. Go to the Rules sidepanel as described in Access the Rules section.
2. Select **Add Rule** and then select one of the following validation rules:

Validation rule type	Description
Select at Least	A site user must select at least the configured number of answer options.
Select at Most	A site user must select a maximum of answer options.
Select Exactly	A site user must select exactly the configured number of answer options.
Answer Must Be	A site user must select exactly the configured answer options.

A Validation Rule dialog appears.



3. To continue configuring the validation rule, choose the answer options that a user must select:

Option	Description
For rules of the following type: • **Select at Least** • **Select at Most** • **Select Exactly**	Set a number to define the amount of options allowed to be selected by the site user.
For rules of the following type: • **Answer Must Be**	Set the exact **Required Answer** to be selected by the site user.

4. In the **Error Message** field, enter an error message that should appear for site users when the answer is invalid.

Related Topics

- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

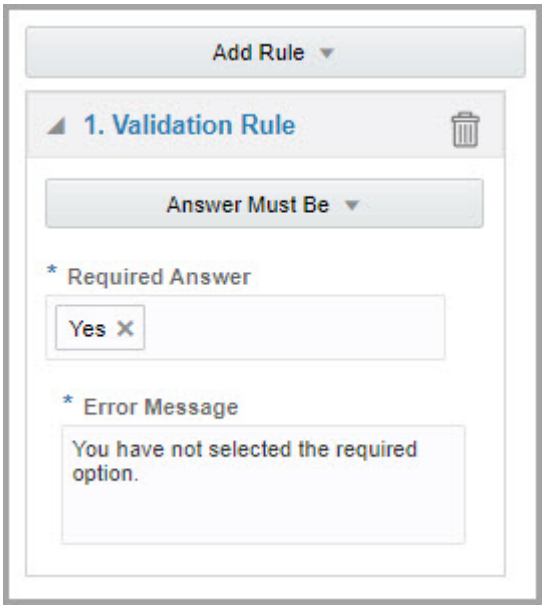
Define a validation rule for questions with radio buttons

A question with radio buttons requires only one option as an answer. By adding a validation rule, you can require site users to choose a specific option.

Validation rules for questions with checkboxes and be useful to set specific screening requirements or for transferring subjects to a rollover study.

1. Go to the Rules sidepanel as described in Access the Rules section.
2. Select **Add Rule** and then select **Answer Must Be**.

   A Validation Rule dialog appears.



3. In the **Required Answer** field, select the exact answer that a site user must select.
4. In the **Error Message** field, enter an error message that should appear for site users when the answer is invalid.

Related Topics

- Form and validation rule FAQs
- How strict should my validation rules be?
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.

- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Set up a dynamic question in a form

Use a dynamic question to show it in a form only when relevant for the subject.

Dynamic questions are displayed only when a specific answer is given to another question on a form. For instance, a question assessing the childbearing potential of a subject appears only if a site user previously selected **Female** as an answer to a drop-down question on gender. If a site user selects **Male**, the pregnancy question doesn't appear. This can save site users time from having to enter additional data that is not applicable to subjects. While you may define multiple questions that can determine the display of a dynamic question, we recommend you only use one question to dynamically display another question.

Consider the following notes:

- When an existing static question, form, or visit that includes data, is changed to a dynamic type, and the determining question is set to be hidden, the new dynamic question will be hidden. If the determining question is updated to the criteria to show the dynamic question, that question appears and the original data is still there.
- When using a **drop-down** question, if a site user selects multiple values - including one that should trigger a dynamic question - that dynamic question will **not** be displayed. To ensure proper behavior, it is recommended to apply an **Exactly 1 validation rule** to drop-down questions. In contrast, checkbox questions support multiple selections, and if any of the selected values match the dynamic trigger, the associated question is displayed as expected.
  For example, if a site user selects only **D** as an answer to Question 1 (a drop-down question), Question 2 (a dynamic question) appears. But if the site user selects A, B, and D as an answer to Question 1, the dynamic question doesn't appear.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

- Define a Show Question rule
  Create a dynamic question when you want to show it in a form only when relevant for the subject.

Define a Show Question rule

Create a dynamic question when you want to show it in a form only when relevant for the subject.

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

Video

> **Caution:**
>
> Before configuring a Show Question rule, consider the following:
>
> - For question groups, you can only select the entire question group as dynamic, which makes all of its contained questions dynamic. Questions in a question group cannot be individually set up as dynamic.
> - To avoid any issues with how questions are displayed in a lab form, don't trigger the display of a lab form using a Show Question rule included in the Questions Before the Table (flat) section. You can still trigger dynamic questions within the Questions in the Table section (repeating) section of the lab form.

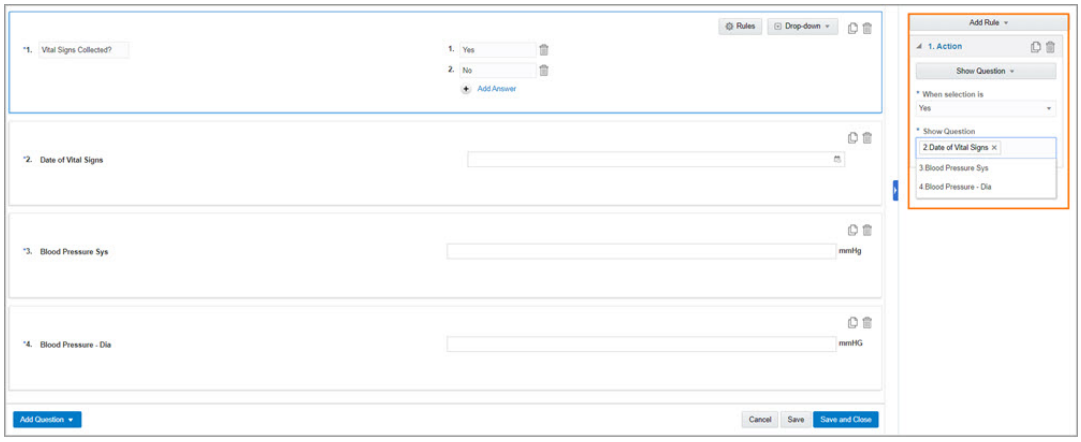
> **Note:**
>
> Depending on the data you want to collect you can create any type of question and turn it into a dynamic question. For more information on how to set up details and advanced configurations of your question, see Question types and settings.

You must create at least two questions for the form that includes the dynamic question. Otherwise, you won't be able to properly configure a **Show Question** rule. The **Show Question** drop-down shows all the questions in the form. You can add one or more questions to the **Show Question** field.

1. Access the Draft version of a study as described in Open a study's design.
2. On the **Forms** tab, do one of the following:
   - Create a new form.
   - Locate the form that you want to edit with the dynamic question and double-click it to edit.
3. Select **Add Question** and select a type for the question that should be dynamic.
4. Select or create the question that enables the dynamic question, and select the **Rules** button above the answer field.

   The determining question must be of the following type: drop-down, checkboxes, or radio buttons.
5. On the right side, select **Add Rule**.
6. From the drop-down, select **Show Question**, and fill-in the following fields:
   - **When selection is**: From the drop-down, select the answer that determines the display of a dynamic question.
     This drop-down is populated with the options you created for the question that triggers the dynamic question. If no options are entered for the question, the drop-down is empty.
   - **Show Question**: From the drop-down, select the dynamic question you want to show.

Figure 6-1 How to add a dynamic question to a form



7. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

Related Topics

- Form and validation rule FAQs
- Types of validation rules
  Create a validation rule for any type of question in a form when you want to verify that answers to a specific question meet the study requirements.

Set up a dynamic section in a form

Configure dynamic sections to dynamically display repeating tables in two-section forms.

If you use a drop-down question and the user selects more than one option for an answer, even if one of those options should determine the display of a repeating table, the table is not displayed. It is recommended to include an Exactly 1 validation rule. If checkbox questions are used and one of the selections made is the trigger for the repeating section, the repeating section is shown as expected.

While the system allows you to define multiple questions to determine the display of a section, we recommend that you use only one question to dynamically display a form section.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

- Define a Show Section rule
  Defining a Show Section rule lets you to dynamically display repeating tables in two-section forms.

Define a Show Section rule

Defining a Show Section rule lets you to dynamically display repeating tables in two-section forms.

Before you can define a **Show Section** rule, you must do the following:

- Create a two-section form. For more information, see Create a form with two sections.
- Include a drop-down question or question with checkboxes,or radio buttons as the triggering question for the dynamic section. For more information, see Create a drop-down question or Create a question with checkboxes or radio buttons.

To define a Show Section rule:

1. Access the Draft version of a study as described in Open a study's design.
2. On the **Forms** tab, do one of the following:
   - Create a form with two sections.
   - Locate the two-section form that must contain the **Show Section** rule and double-click it to edit.
3. On the two-section form, select or add a new multiple-choice question in **Questions Before the Table** section, and select **Rules** above the question.
4. On the Rules sidepanel, select **Add Rule**.
5. From the drop-down, select **Show Section** and fill-in the following fields:
   - **When Selection Is**: Select the answer that displays the repeating table section.
   - **Show Section**: By default, this field is defaulted to only show the **Question in the Table** section.
6. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

Related Topics

- Dynamically display a table in a two-section form

Set up a dynamic form

Dynamically displaying forms across visits in a study allows you to only display forms when it is relevant for a subject. However, you should understand the scope of dynamic forms before implementing them in your study design.

A dynamic form is one that appears only when a site user offers a specific answer to a question that has a Show Form rule applied to it. For example, a form contains the question "Has the subject had any surgeries in the past?". This question has a Show Form rule applied to it, so when a site user answers the question with Yes, the dynamic Surgery form appears. If a site user answers the question with No, the dynamic Surgery form doesn't appear.

To create a dynamic form, you must first create two forms. The first form (that cannot be repeating, a two-section form, or a tabular form) contains the determining question (with a Show Form rule applied to it). The second form is included in the Show Form rule and is displayed only when a specific answer is given to the determining question. For step-by-step instructions, see Create a form with one section or Create a form with two sections.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. For example, you can edit a form, while at the same time another study designer creates a new form. However, you are not allowed to work on the same form at the same time. If you try to open a form that another study designer is working on, the system displays a message informing you that another user is editing the form at that moment and you can only view the form. For more information, see Can multiple study designers edit a study at the same time?.

When it comes to a new study, your workflow is straightforward. You must create the forms (both the parent form and the dynamic form) and make sure they are assigned to the appropriate visits. Before you begin your work, here are some points to consider:

- If the determining question is assigned to a regular visit and the dynamic form is assigned to a cycle visit, the determining question applies to all cycles in the study, by default. A study designer can specify individual cycle numbers where the dynamic form must be displayed.
- If you opt for a drop-down question as the determining question of a Show Form dynamic rule, you must know that the question may not behave as expected. Specifically, after a site user selects multiple answer options for a drop-down question, the dynamic form is not displayed. This issue is not occuring when you apply a Show Form dynamic rule to a question with checkboxes.

  For more information, see issue **33282026** in the Known Issues List on My Oracle Support (MOS).
- When you configure a Show Form rule associated with an Adverse Event, remember that the form containing the determining question cannot be a repeating form (whether it is a tabular form with labels or a two-section form). Moreover, you must make sure that both the question containing the dynamic rule and the dynamic form are associated with an Adverse Event and not another type of visit or event.

Here is a list of all of the tasks that you must perform:

1. Create a visit.
2. Create forms.
3. Define a Show Form rule
4. Add a form to a visit.

- About adding dynamic forms in live studies
  Dynamically displaying forms across visits in a study allows you to only display forms when it is relevant for a subject. However, you must pay special attention when you need to make an update during the study conduct period.
- Define a Show Form rule
  You define a Show Form rule to dynamically display a form only if a certain condition is met once clinical data is entered for a subject.

About adding dynamic forms in live studies

Dynamically displaying forms across visits in a study allows you to only display forms when it is relevant for a subject. However, you must pay special attention when you need to make an update during the study conduct period.

When it comes to configuring a dynamic form for a live study, things are a bit complex. Before we dive into the list of tasks that you need to perform, you must consider the following use cases:

- When you need to apply an update for the determining question of a dynamic form to a live study version, you need to mark at least one question in the dynamic form as an update that is being applied to the same study version, as well.
- When the determining question of a dynamic form is updated during the study conduct period, you must apply that change to the appropriate live study version, if desired. That way, the update is reflected in the current study version.
- If the determining question is assigned to a regular visit and the dynamic form is assigned to a cycle visit, the determining question applies to all cycles in the study. The study designer can specify the cycle numbers where the dynamic form must be displayed.

  When configuring a Show Form dynamic rule, and you choose the **Current & Future Visits/ Events** option, the determining question's display can be limited by the presence of the same determining question in a later visit cycle. For example, the question "Does the subject need weekly hematology labs?" is added to the Week 2 visit. A site user answers "Yes" to this question. Because this question is set up as the determining question for the Hematology form at every visit - and the **Current & Future Visits/ Events** option is selected - if a site user answers the question with No at Week 8, the Hematology form's display is limited. With a positive answer during the Week 2 visit and a negative answer during the Week 8 visit, a site user will only see the Hematology form at weeks 2 to 7, but they will not see the Hematology form from Week 8 on.
- If a static form is made dynamic or a new determining question for a dynamic form is added through advanced study versioning, one of the following things may happen:
  - After you update the determining question of a dynamic form, if the already given answer to this question matches the new criteria in the Show Form rule, the dynamic form remains visible to a site user.
  - After you update the determining question of a dynamic form, if the already given answer to this question no longer matches the new criteria in the Show Form rule, the dynamic form is hidden in the system. If the dynamic form was already completed, the data that a site user collected is not cleared, it is only hidden.

- After you update the determining question of a dynamic form and the dynamic form becomes hidden, if a site user answers the newly updated question appropriately, the dynamic form is displayed again and it includes the data that was previously collected.
- Data collected in dynamic forms, whether hidden or not, is displayed in the appropriate reports in the application.

> **Note:**
>
> When an existing static question, form, or visit that includes data, is changed to a dynamic type, and the determining question is set to hide, the new dynamic item will be hidden. If the determining question is updated to the criteria to show the dynamic item, that item appears and the original data is still there.

Here is a list of all of the possible tasks that you must perform:

1. If you wish to update the determining question of a dynamic form, see Update a form during the study conduct period.
2. If you wish to include a brand new form in the study (whether as a parent form or to dynamically display it), see Add a new form to a live study version.
3. Define a Show Form rule
4. Add a form to a visit.

Define a Show Form rule

You define a Show Form rule to dynamically display a form only if a certain condition is met once clinical data is entered for a subject.

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

Video

Before you can define a **Show Form** rule, you must do the following:

- Create the form that contains the determining (or triggering question). This form cannot be a repeating form, two-section form, or a tabular form. In this form, you configure the **Show Form** rule. For more information, see Create a form with one section.
- Create the second form. This form is referenced by the **Show Form** rule and is only displayed when a specific answer is given to the determining question. For more information see,

To define a Show Form rule:

1. Access the Draft version of a study as described in Open a study's design.
2. On the **Forms** tab, open the form that contains the determining multiple-choice question.
3. Select the question and then select **Rules** above the answer field.
4. On the Rules sidebar, select **Add Rule**.
5. From the drop-down, select **Show Form** and fill-in the following fields:

> **Tip:**
>
> You can have more than one instance of the same parent form (and so the determining question) assigned to different visits to let you control specific instances of the dynamic form. Make sure the dynamic form is associated with the visits where you want to dynamically display it. Otherwise, the dynamic form won't appear for site users when the required criteria is met.

- **When selection is**: Select the answer that displays the dynamic form.
  In the user interface (UI), you only see answers that you created for that question. If the question doesn't contain any answer options, the drop-down is empty.
- **Show Form**: Select the dynamic form that will be displayed when a site user answers this question using the selected answer.
  In the UI, you see all the forms in the study. You can add one or more forms to the **Show Form** field.
- **Show Form on**: Select where you want the dynamic form to display.
  - Choose **Current Visit/ Event Only** if the form that you want to dynamically display should only be associated with the current visit. For this, make sure both forms (the parent and the dynamic form) are added to the same visit, otherwise the dynamic form won't appear for site users at all. See Add a form to a visit.
  - Choose **Current & Future Visits/ Events** if the form that you want to dynamically display should be associated with both the current visit and future visits or events in the study. This depends on which visits the form has been added to: either the current visit only, any future visits or events, or both.

6. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

Related Topics

- Import a form
  Import a form form another Production study, or library study and use it in your study design.
- Question types and settings
  You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.
- Update a form during the study conduct period
- Add a new form to a live study version

Set up a dynamic visit

Use dynamic visits when you want a visit to be displayed only when relevant to the subject, whether it's for data collection or dispensation purposes.

A dynamic visit is displayed in a subject's schedule after the site user answers the leading question with the specific answer configured in a **Show Visit** rule.

As a study designer, you must know that there are specific types of visits that can be dynamically scheduled, as well as other types of visits or events that can never be dynamically scheduled. Visits that **cannot** be dynamically scheduled include:

> **Note:**
>
> To dynamically schedule the first and last visit in a branch or cycle branch, you can copy the branch that must contain that dynamic visit, and add that visit either at the beginning or at the end of the branch.

- Screening visits
- Randomization visits
- The first visit in a schedule
- The first visit in a branch
- The first and last visit of a cycle branch
- Anchor visits
- The earliest visit to complete a study
- A withdrawal or completion event
- Adverse events

You can add a dynamic visit into the visit schedule of a live study version, too. For step-by-step instructions, see Add a dynamic visit in the schedule of a live study.

Visit type	Can be dynamically scheduled	Notes
Dispensation visit	Yes	A site user can dispense the investigational product to a subject during a dynamically-scheduled visit.
Non-dispensation visit	Yes	A site user can collect any types of data during a non-dispensation visit that is dynamically scheduled.
Unscheduled visit	Yes	You can configure an unscheduled visit to be dynamically-displayed. An unscheduled visit is different from an unplanned event (where dispensation cannot occur) such as a screening visit, a screening failure, withdrawal, completion, or an adverse event.

Visit type	Can be dynamically scheduled	Notes
An inserted visit into the schedule	Yes	None.
Any scheduled visit	Yes	None.
A required visit	Yes	None.
Optional visit	Yes	None.
Last visit in a branch	Yes	None.

Workflow for setting up a dynamic visit

Task	Notes
Create a visit or event that must be dynamically schedules.	Only certain types of visits can be dynamically scheduled. Make sure you review the information above.
Define a Show Visit rule.	To dynamically schedule a visit, you must create a question that has a Show Visit rule applied to it.
Define the visit schedule.	If you want to schedule a dynamic visit in a branch, see Define the visit schedule for a branch.

- Define a Show Visit rule
  To dynamically schedule a visit, you must create a question that determines the display of a dynamic visit based on the given answer to this question.

Define a Show Visit rule

To dynamically schedule a visit, you must create a question that determines the display of a dynamic visit based on the given answer to this question.

Before you can define a **Show Visit** rule, you must do the following:

- Create the visit to dynamically display. For more information, see Create a visit or event.
- Create a drop-down question or question with checkboxes or radio buttons as the triggering question for the **Show Visit** rule. This question must have a **Select Exactly** or **Answer Must Be** validation rule defined for it. For more information on how to create this specific type of question, see Create a drop-down question or Create a question with checkboxes or radio buttons. For more information on how to configure a validation rule, see Define a validation rule for multi-choice questions or Define a validation rule for questions with radio buttons.

> **Note:**
>
> Make sure that the form containing the question with the **Show Visit** rule configuration is included in an earlier visit in the schedule than the one to dynamically display.

To define a Show Visit rule:

1. Access the Draft version of a study as described in Open a study's design.
2. On the **Forms** tab, determine whether you're working on a new or existing form:

- Click **Create Form** to create a new form from scratch.
- Select an existing form and double click it to edit.

3. Select an existing question or create a new one as the triggering question. The question must be of the **Radio buttons**, **Drop-down**, or **Checkboxes** type.
4. Select **Rules** above the answer field of the triggering question.
5. On the Rules sidebar, select **Add Rule**.
6. From the drop-down, select **Show Visit** and fill-in the following fields:
   - **When selection is**: Select the answer that displays the dynamic visit.
   - **Show Visit**: Select one or multiple visits that will be displayed when a site user answers this question using the selected answer.
     On the User Interface (UI), you only see visits that can be dynamically scheduled.
7. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

Set up form associations

Create form associations using a **Link & Show Form** rule to connect related data that is collected in these forms.

> **Note:**
>
> Multiple study designers can create or update different forms at the same time. However, as long as another study designer is editing other areas of a study (such as randomizations, visits, or kits), you cannot create or manage links between forms. For more information, see Can multiple study designers edit a study at the same time?.

You can add multiple **Link & Show Form** rules to the same question in the form, as well as to various questions. and you can link more than one form using the same determining question. You cannot create associations between lab forms and repeating forms that contain label items. You can, however, create associations with two-section forms.

Types of form associations

You can create different types of form associations. The form that contains the determining question of the Link & Show Form rule is the **source form**. The form that is associated with the source form is the **target form**.

When you create an association between any type of source form and a two-section form, site users can choose to link to the entire instance of a two-section form or they can link to one or more rows in the repeating section (Questions in the Table) of a two-section form.

Source form	Target form
One-section form (flat) ***Warning**: When you use a one-section form as the source form in an association, the links created between a one-section form and other types of forms will not work properly.*	• Two-section form • Simple repeating form • One-section form (flat)
Two-section form	• Two-section form • Simple repeating form • One-section form (flat)
Simple repeating form	• Two-section form • Simple repeating form • One-section form (flat)

- Define a Link & Show Form rule
  When you associate forms in a study you allow site users to link related data that was collected in these forms.

Define a Link & Show Form rule

When you associate forms in a study you allow site users to link related data that was collected in these forms.

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

Video

Before you can create associations between forms you must first create a form and add questions to the forms. For step-by-step instructions, see Forms.

> **Note:**
>
> Link & Show Form rules are only available for a question with radio buttons. For more information, see Create a question with checkboxes or radio buttons.

1. Access the Draft version of a study as described in Open a study's design.
2. On the **Forms** tab, open the form that must contain the question that links the forms.
3. Select the existing **Radio Buttons** question that will link the forms or create a new one.
4. Select **Rules** above the answer field.
5. On the Rules sidebar, select **Add Rule**
6. From the drop-down, select **Link & Show Form** and fill-in the following fields:
   - **When selection is**: Select the triggering answer that displays the target form. The target form is the form that you want to link with the form that you are editing.
     This drop-down is populated with the options you created for the determining question. If no answer options were added or a code list has not been selected for the question, the drop-down is empty.
   - **Link & Show Form**: Select the target form you want to link to and display.
     This drop-down list shows all of the forms in the study, including two-section forms. You can add one or more forms to the **Link & Show Form** field.

7. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

Set up a question to lock automatically

Lock questions using an **Auto-lock** rule to prevent site users from editing subject data during the study conduct period, after a specific subject event.

> **Note:**
>
> As a sponsor user, know that the level of detail in a protocol addressing question reviews can vary, and each team should define its own criteria.

To create an auto-lock rule, you must create a form first and include at least one question in the form. The form must be assigned to the appropriate visits. For step-by-step instructions, see the Forms and Question types and settings chapters.

For step-by-step instructions on how to create an auto-lock rule, see Define an Auto-lock rule.

You can configure the **Auto-lock** rule to trigger at a specific time during the study conduct period based on the following subject events:

- **Subject is screened**: a question is automatically locked after a subject is screened.
- **Subject is randomized**: a question is automatically locked after a subject is randomized. This includes randomization and re-randomization events.
- **Subject is dispensed the kit**: a question is automatically locked only on the visit where the kit is dispensed, the current visit.
- **Visit is complete**: a question is automatically locked on the current visit when it is completed.

The **Auto-lock** triggers and locks a specific question only after a site user completes the conditioned action. For example, if you set up Question A to lock automatically when a subject receives their kit, the question will only be locked on the visit where the kit dispensation occurs, and not on any other visit.

If you configure multiple auto-lock rules for the same question, the question only becomes locked after the site user completes the first condition of a rule. For example, you configure two auto-lock rules for Question B, one is triggered after a subject is screened and the second one is triggered after a subject completes a visit. If a subject is screened first, Question B becomes locked from that moment on.

If the auto-lock of a question fails, users with the appropriate permissions receive the Auto-lock failure notification after five unsuccessful attempts of locking a question.

Impact on data collection and visits

- You can apply the auto-lock rule to most question types (text, number, age, and multiple-choice questions), as well as questions that are required, optional, and hidden in a form.
- If a subject is successfully screened, then screen failed, and screened a second time (by undoing the screen fail), no additional lock actions are applied.
- A question marked for automated locking during a randomization or screening visit gets locked if it's associated with a current or previous visit from when the subject is successfully screened or randomized. However, a question won't get locked if it appears in a visit that occurs after a subject's randomization or screening.
- When triggered, the auto-lock rule will lock a question whether it's answered, empty, read-only, or data-flagged. The exception will be in repeating and two-section forms, where the lock will not apply for not started or data entered after the lock triggering event.
- Questions do not lock if the option **Visit Completion** is selected as a trigger for not started repeating forms.
- In a visit, if a repeating or two section forms is in an **Not Started** status or if data is entered after the lock triggering event occurs, the lock will not apply.
- If a site user skips a visit that would trigger an auto-lock rule, a question with the auto-lock rule applied remains unlocked. If a site user later unskips the visit and answers questions after the locking condition was fulfilled, the question remains unlocked.

Impact on custom JavaScript rules

- A custom rule for an automated query doesn't trigger the auto-lock rule if it targets only one question. If you need to apply an auto-lock rule to an automated query's target field, choose a second target question when you expect the rule to generate a query.
- You can change the validation rule after the event happens, which does not impact its state.
- You cannot apply an auto-lock rule for instructional text items and label questions.
- If an auto-lock rule is triggered for a question included in a visit that is not started, the data still gets locked.
- For repeating forms, the lock applies to all instances of the questions.
- Dynamically displayed (child) questions, questions on dynamic forms, or dynamic visits will be locked after the site users enter a specific answer configured to that question containing a **Show Question** rule for the triggering visit to be considered complete. If the questions display subsequently, they will not be retroactively locked, and a sponsor user must be closed manually.

Impact on study version updates

- If the event has already occurred for the subject, Advance Study Version changes have no impact on auto-lock rules. If the event has not yet occurred, then the lock will happen upon event completion.
- If a site's associated study version is changed after a visit with an auto-lock rule was already started, the question with the auto-lock rule applied to it won't get locked anymore, even if the started visit exists in the newer study version, and even if the condition of the rule was fulfilled.

- Define an Auto-lock rule
  An **Auto-lock** rule can restrict site users from editing subject data during the study conduct period and after a specified event.

Define an Auto-lock rule

An **Auto-lock** rule can restrict site users from editing subject data during the study conduct period and after a specified event.

To add an **Auto-lock** rule to a question in a form's design, you must be assigned the *Design Forms* permission.
Before you can define a **Auto-lock** rule, you must do the following:

- Ensure that you're assigned with the *Design Forms* permission.
- Create a form and include at least one question it that form. For more information, see Forms.

1. Access the **Draft** version of a study as described in Open a study's design.
2. On the **Forms** tab, locate the form that you wan to add the auto-lock rule to, and double-click it.
3. Select **Rules** above the answer field of the triggering question.
4. On the Rules sidebar, select **Add Rule**.
5. From the drop-down, select **Status Rule (Auto-lock)**.
6. From the **When** drop-down, select the condition that should be met for the auto-lock rule to trigger:
   - **Subject Screened**
   - **Subject Randomized**
   - **Subject Dispensed**
   - **Visit Completion**
7. To save the form, in the lower right of the form, select **Save**.

> **Tip:**
>
> If the **Save** button is read-only, make sure there are no blank questions on the form.

The rule is saved and you can test it in Preview mode.

If a site user wants to change data that's automatically locked, they will receive an informational message about the data being locked. If the **Auto-lock** rule is triggered and attempts to lock the data for five times unsuccessfully, all users with the appropriate permissions and access to the site will receive the Auto-lock failure notification .

To add, delete or update an auto-lock rule as part of a study version change, see Update a form during the study conduct period.

Define a Send Notification rule

You can create a rule that sends email notifications on data entries and response changes. Additionally, you can set follow-up email notifications on data changes to be sent following an

initial notification. You can use this feature to notify designated team members based on specific criteria.

These settings are added to form questions in Study Design mode as predefined rules. Rule designers can also create custom rules to send email notifications in Testing mode. To learn more, see Create a rule to send an e-mail notification.

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

Video

Send Notification rules can only be set for a choice type of question, such as a dropdown question, a question with radio buttons, or checkboxes. Also, when you set study roles as recepients, you can only use custom study roles to send a notification to. Oracle template study roles cannot be selected.

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the Data Collection page.
3. Navigate to the **Forms** tab.
4. Open a form:
   - **To work in an existing form**: select a form and from the **Manage Form** dropdown, click **Edit**.
   - **To work in a new form**: Create a form with one section.
5. Select the choice type of question that should contain a rule.
6. On the right, expand the **Rules** side panel and, from the **Add Rule** drop-down, select **Send Notification**.
7. Configure the scenario to generate the notification:
   - **To notify when a specific answer is entered**: choose When Selection **Is**, then select the answer option from the dropdown.
   - **To set further follow-up notifications on data changes**: activate the option **Notify when response changes to the selected questions**, then select the questions to be monitored.

     > **Note:**
     >
     > This option is only available once you have set notifications when an answer **Is** a specific option. Follow-up notification emails are not available if you set the initial email for **Changes**.

   - **To notify only when response changes**: select When Selection **Changes**.
8. Click **Specify recipients and messages**.
9. When the Specify recipients and messages dialog appears, in the Recipients section, select the user roles to be notified or enter the recipient email addresses and distribution lists (separated with a semicolon) in the respective fields.
10. On the right section of the dialog window, within the **Message** tab, enter the **Subject Line** and **Body Message** for the email notification.

> **Note:**
>
> If you have set follow-up notifications on data changes, an additional tab displays on this section. Navigate to the **Message for Response Changes** tab to configure the follow-up notification message settings as you did for the initial message.

11. Click **Add**.

Every time the defined criteria is met, the specified recipients will be notified. The email notification will always include details regarding the:

- Study
- Site
- Subject
- Visit
- Form
- Question

To make your rules and updates effective, the draft version must be made available in the desired mode. For more information, see:

- Make a study version available in Testing mode
- Make a study version available (for Production and Training mode)

7

Code lists

You can create a code list that is available for all studies in your organization. Add that code list to a multiple-choice question to ensure you use the right answer options in a form.

- Create a code list
  Code lists allow study designers to easily add standard answer options to a drop-down, checkbox, or radio button type question.
- Add a code list to a question
  Add a code list to a drop-down, checkbox, or radio button type question to automatically populate the answer options with a predefined data set.

Create a code list

Code lists allow study designers to easily add standard answer options to a drop-down, checkbox, or radio button type question.

Code lists are sets of predefined data that also include standard codes for data analysis. To adhere to SDTM terminology sets and follow the industry's standards, code lists must contain proper codes. In turn, this allows data managers and statisticians to more easily analyze extracted data. For more information on data extracts, see the Subject Data Extract.

> **Note:**
>
> Custom code lists that you create on the **Code List** tab (in a study's settings) are displayed in the Code List dialog when you choose to apply a code list to a question. For more information, see Create a custom code list.

To create a code list:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the **Data Collection** page.
3. On the **Forms** tab, open or create the form that you want to add a code list to.
4. In your form, do one of the following:
   - Select the drop-down question or the question with checkboxes or radio buttons, and above the answer field, select **Code List**.
   - Add a new question with multiple answer options and, above the answer field, select **Code List**.

   The Code List dialog opens.
5. Do one of the following:
   - If you want to create a new custom code list, select **Add Code list**.
   - If you want to edit an existing custom code list, select it from the list, and select the **Edit** icon ( ).

6. Fill-in all of the required fields of the code list. For more details, see Create a custom code list
7. Select either **Close** or **Use Selected List** to add the code list to the question.

Related Topics

- About your code list library
- Manage a code list for all or one study

Add a code list to a question

Add a code list to a drop-down, checkbox, or radio button type question to automatically populate the answer options with a predefined data set.

Consider the following:

- Any changes you make to a code list after you added it to a question have no impact on the original code list applied to the question. This is because the applied code list is directly associated to the question and stored with the question. If you make a change to a code list that was already applied to a question in a form, you need to re-add the code list to that question in order to see its changes reflected in the form.
  This workaround may not be possible after the study version containing the question with the updated code list is moved to Approved.
- When you re-add a code list to a question, any validation rules associated with the updated question are reset and you have to configure them again.
- Make sure you have already created a code list. For step-by-step instructions, see Create a code list

> **Note:**
>
> Custom code lists that you create on the Code List tab (in a study's settings) are displayed in the Code List dialog box when you choose to apply a code list to a question. For more information, see Create a custom code list.

.

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the Data Collection tab.
3. In your form, select the drop-down, checkbox, or radio button type question.
4. In the upper-right corner of the selected question, select **Code List**.

   The **Code List** dialog box opens.
5. On the left pane, select the code list you want to add.

> **Note:**
>
> Custom code lists prefixed with EHR, for example, EHR-Birth Sex, are typically used in studies configured to allow site users to import a subject's Electronic Health Record (EHR) data. You can also apply these code lists to questions not mapped for EHR data import. For more information, see About Electronic Health Record (EHR) code lists.

6. In the lower right, select **Use Selected List**.

- About Electronic Health Record (EHR) code lists
  Designers can take advantage of pre-seeded EHR custom code lists when designing a study that permits site users to import a subject's EHR data.

Related Topics

- About your code list library
- Manage a code list for all or one study

About Electronic Health Record (EHR) code lists

Designers can take advantage of pre-seeded EHR custom code lists when designing a study that permits site users to import a subject's EHR data.

For more information, see Enable Electronic Health Record (EHR) data import.

Study designers use these code lists to define the options for form questions that are mapped for EHR data import. For example, if you create a question to capture sex and map it to the EHR item Birth Sex, a dialog window opens informing you to use the EHR-Birth Sex code list. This ensures that the EHR system options and the options on the form match, resulting in a successful data import.

> **Note:**
>
> These code lists can also be used with questions that are not mapped for EHR data import.

EHR code lists are associated with specific EHR data dictionary mapping items. The mapping items and their associated code lists are maintained in an Oracle-managed data dictionary.

As a part of each Oracle Clinical One Platform release, Oracle adopts the latest version of the dictionary, which includes updates to existing code lists and the addition of new lists. The dictionary and code lists are backward compatible, meaning existing data items are not removed or changed; only new items are adopted.

The following EHR code lists are available:

- EHR-Birth Sex
- EHR-Race
- EHR-Ethnicity
- EHR-Lab Test
- EHR-Body Height Units
- EHR-Body Weight Units

- EHR-Body Mass Index Units
- EHR-Body Surface Area Units
- EHR-Body Temperature Noninvasive Units
- EHR-Head Circumference Units
- EHR-Diastolic Blood Pressure Units
- EHR-Systolic Blood Pressure Units
- EHR-Heart Rate Noninvasive Units
- EHR-Oxygen Saturation Units
- EHR-Respiratory Rate Units

EHR code lists, like other custom code lists, are only available in English. You can perform the following actions against them.

- Hide options in an EHR code list.
  If you hide a code list option that you expect the import to select, the import does not populate the question. If necessary, unhide the code list option, then import the data.
- Download and copy an EHR code list.
- Add options to an EHR code list.
  Options added to the code list in Oracle Clinical One Platform are not eligible for data import unless the same option is added to the EHR system code list.
- Update the **Order**, **Label**, and **Code**, but not the **Value** of an EHR code list option.
- **Limitations**:
  - Do not copy EHR code lists; doing so can create issues with EHR mappings during an Oracle Clinical One Platform upgrade.

For more information about managing code lists, see Manage a code list for all or one study.

8

Question types and settings

You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.

- Add instructional text to a form
  When creating a new form, you can add read-only text to the form to provide users with additional information or instructions on how to complete it.
- Create questions for medical coding
  Create a question to capture a verbatim term, the Route of Administration, and Indication (the context items) and the coding target fields.
- Create a date/time question
  Create a date/time question when a subject's answer to a question includes times or date values, or both.
- Create a drop-down question
  Create a drop-down question when site users must select an answer from a drop-down.
- Create a label (repeating table only)
  Label items allow you to add predefined read-only values to a repeating form and better control the data that is collected. Label items are read-only and can't be edited by the site user.
- Create a number question
  Create a number question when a subject's answer to a question includes numbers only.
- Create a question group
  Create a question group when you need to collect data that is related and you want to display it on the same line.
- Create a question with checkboxes or radio buttons
  Create a question with checkboxes, if you want site users to select multiple options for an answer. Or create a question with radio buttons, if you want site users to choose one single option as an answer out of other options.
- Create a read-only item
  Create a read-only item for values that site users can see but not edit.
- Create a rollover question
  Create a rollover question when site users must select an answer from a drop-down and enroll subjects in a rollover study. A rollover type of question is typically included in a study completion form in the original study.
- Create a text question
  Create a text question when a subject's answer to a question includes letters only or letters and numbers.
- Create an age question
  Create an age question to insert a Date of Birth question and a read-only calculated age field.
- Configure source data verification settings for a question
  If your study requires a targeted Source Data Verification (SDV) strategy, you must work with your study manager to configure these two settings for certain or all questions in the study.

- Define data classifications for a hidden question
  You define data classifications for a question when you want to create exceptions on hidden questions based on the study roles assigned by a user administrator.
- Create text for a question's hint
  You can create question hint text to provide site users with guidelines for data entry. Question Hint text is displayed for site users on the right sidebar when entering data in a form.
- About mapping questions for Electronic Health Record (EHR) data import
  If your study is enabled for EHR data import, you can map form questions to EHR elements in an Oracle-managed data dictionary and use pre-seeded EHR code lists to ensure successful data import and minimize data cleaning.

Add instructional text to a form

When creating a new form, you can add read-only text to the form to provide users with additional information or instructions on how to complete it.

Before adding instructional text to a form, it's important to know the following:

- Instructional text *cannot* be used in question groups, repeating forms, or repeating tables, including lab forms.

> **Note:**
>
> Instructional text can only be added to the top section of a two-section form.

- Validation and predefined rules cannot be defined for instructional text.
- The added text can be formatted for further clarity if desired. External links and email addresses can also be included.
- You can modify or delete the text once your study version is approved.

1. Create a one-section or two-section form.
2. In the lower-left corner, select **Add**.
3. Depending on the type of form that you're working in, do one of the following:
   - If you are working in a one-section form, select **Instructional Text**. The instructional text item is included at the bottom of the form
   - If you are working in a **two-section** form, select **Questions Before the Table**, then select **Instructional Text**.
4. Enter the instructional or informational text you'd like to provide the user responsible for completing the form, and format it for further clarification if needed.

Create questions for medical coding

Create a question to capture a verbatim term, the Route of Administration, and Indication (the context items) and the coding target fields.

Understand the data flow between Oracle Clinical One Platform and Oracle Central Coding

Having a basic understanding of the data flow between an Oracle Clinical One Platform study and the Oracle Central Coding system is useful when designing the forms and fields that interact with the coding system.

> **Note:**
>
> Forms used for medical coding purposes, such as Adverse Events, Concomitant Medications, and Medical History, can be either a simple repeating form or a two-section form. For more information, see Create a repeating form and Create a form with two sections.

Based on a schedule defined in Oracle Central Coding, the system pulls verbatim terms and associated context item values from Oracle Clinical One Platform study forms.

Oracle Central Coding uses details defined during the study design and the Oracle Central Coding configuration to attempt to autocode each term. Users of Oracle Central Coding manually code terms that the system does not autocode.

A second schedule, also defined in Oracle Central Coding, returns dictionary data for coded verbatim terms to the coding targets on the form.

If a user changes the verbatim term or context values for a coded verbatim term, the coding targets are cleared by Oracle Clinical One Platform rules. Oracle Central Coding then pulls back the verbatim and its context values for recoding.

For more information about Oracle Central Coding, see the User Guide.

- Create a coding question to capture a verbatim term
  Create a coding question to capture verbatim terms, such as a medication (Ibuprofen), adverse event (headache), or a medical procedure (Appendectomy).
- Create the coding context items
  Create the context items: **Route of Administration** to capture how a medication was given, for example, orally or intravenously, and **Indication** to capture why the medication was given, for example, headache.
- Create the coding target fields
  Create the necessary coding target fields to store the details extracted from an Oracle Central Coding dictionary. For example, System Organ Class Term and Code for a MedDRA dictionary, and Trade Name Term and Code for a WHO DD dictionary.

Create a coding question to capture a verbatim term

Create a coding question to capture verbatim terms, such as a medication (Ibuprofen), adverse event (headache), or a medical procedure (Appendectomy).

1. Open the form, click **Add**, and select the **Text** option.

2. Enter the question's title.
3. On the **Details** side panel, set the **Character Limit** to 200 and define other settings for the question.
4. Expand the **Advanced** side panel, click **Add Property**, and select **Coding Question**.
   a. Select the appropriate **Dictionary**.
   b. Select **Verbatim Term** from **Coding Item Type**.
   c. Select the appropriate **Tag for Central Coding**.

   These tags can be used in the assignment rule configuration in Oracle Central Coding to separate verbatim terms into specific groupings.

Table 8-1 Tag for Central Coding details

Tag	Typically used to tag the verbatim term
AE	On the Adverse Event form.
DISEASE	On the Medical History or Medical Procedures form.
NT-DISEASE	On the Non-Target Disease form.
MEDPROD	On the Concomitant Medications form.
LABDATA	You can use this tag as necessary to further distinguish between verbatim term groups.

5. Click **Save**.

Create the coding context items

Create the context items: **Route of Administration** to capture how a medication was given, for example, orally or intravenously, and **Indication** to capture why the medication was given, for example, headache.

1. Open the form, click **Add**, select the **Text** option, and enter **Route of Administration** or **Indication** for the question title.

> **Tip:**
>
> For Route of Administration, requiring all users to select from a common list ensures the highest autocoding percentage in Oracle Central Coding. For optimal results, use a custom code list with a single-select drop-down question. For more information, see Create a custom code list and Create a drop-down question.

If you include *Other* as an option in your code list that allows users to enter text, you need to:

- Create a dynamic text question that appears when *Other* is selected. For more information, see Set up a dynamic question in a form and Define a Show Question rule.
- Create a read-only text question, for example, Mapped Route.
  After the study version is moved to the Test container, you need to add a calculation rule to map the value selected from the drop-down or the text value entered when *Other* is chosen to the read-only question. For more information, see Central coding mapping rule.

2. On the Details side panel, set the **Character Limit** to 200 (for a text context item) and define other settings for the question.
3. Expand the **Advanced** side panel, click **Add Property**, and select **Coding Question**.

   The **Dictionary** and **Tag for Central Coding** settings are populated with the values defined for the verbatim term; do not change these.
4. Select **Route of Administration** or **Indication** from the **Coding Item Type** dropdown.

> **Note:**
>
> If you're using a single-select question with a custom code list, do not map the single-select question to Route of Administration; instead, map the read-only text question to Route of Administration.

5. (For a single-select dropdown question only) Expand the **Rules** side panel and click **Add Rule**, then choose **Select Exactly**, restricting a user's ability to select only one option from the list.
6. Click **Save,** then click **Add** to create additional context item fields.

Create the coding target fields

Create the necessary coding target fields to store the details extracted from an Oracle Central Coding dictionary. For example, System Organ Class Term and Code for a MedDRA dictionary, and Trade Name Term and Code for a WHO DD dictionary.

> **Note:**
>
> **Advanced Study Versioning (ASV)** does not support the addition of new coding target fields for existing subjects.
> You can certainly add new coding targets using ASV and it would result in the new fields displaying on the forms for all existing and new subjects in Oracle Clinical One Platform. However, for existing subjects for which the given visit was initiated (before the new coding targets were added), the new fields for coded verbatim terms are not populated in Oracle Central Coding.
>
> This is because the code map, comprised of the mappings between form questions and the applicable dictionary level, is established and locked for a subject when the visit is initiated. For more information, see About Advanced Study Versioning (ASV)

1. Open the form, click **Add**, and select the **Text** option.
2. Enter the question title, for example, System Organ Class Code.
3. On the Details side panel.
   - Disable the **Required** toggle. Coding targets should not be required.
   - Enable the **Hidden** toggle and use data classification to define who can view the data. For more information, see Define data classifications for a hidden question.
   - Enable the **Read Only** toggle so users can not edit the data.

> **Note:**
>
> Coding targets should never be editable. Study design and Oracle Central Coding configuration determine the data that populates these fields.

- Set the **Character Limit** to 2000.

4. Expand the **Advanced** side panel, click **Add Property**, and select **Coding Question**.

   The **Dictionary** and **Tag for Central Coding** settings are populated with the values defined for the verbatim term; do not change these.

5. Select the matching value under **Coding Item Type**.
6. Click **Save**, then **Add** to create additional coding targets.

Create a date/time question

Create a date/time question when a subject's answer to a question includes times or date values, or both.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

To create a date/time question:

1. On the form, click **Add Question**, and select **Date/Time**.

   > **Tip:**
   >
   > If you need to change the question type, select an option from the drop-down on the question.

2. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.

3. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.

4. If screening, randomization, and dispensation can't happen until a site user enters a valid answer for the question, or if the question is required to be completed for all subjects, make sure the **Required** toggle ( ) is turned on.
5. If you want to allow for a future date to be entered, turn on the **Allow Future Date** toggle ( ).

> **Note:**
>
> This setting it set to **On** by default.
> Entering a future date when this setting is configured to **Off** results in a validation error.
>
> This control is not available for time-only questions.

6. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

7. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
8. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
9. Select the **Type** of date/time data you want to collect:
   - **Date & Time**: Collect the complete date and time.
   - **Date Only**: Collect date components only.
   - **Time Only**: Collect time components only.
10. Select the **Format** for the Type selected.
11. To collect partial dates and/or times, enable **Partial Date Allowed**. For example, you can collect just Hours and Minutes when a **Time Only** type is selected, or just Year, Month, Day, Hours when the **Date & Time** type is selected.
12. Expand the **Advanced** sidebar and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
13. To enter a validation rule, see Types of validation rules.
14. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a drop-down question

Create a drop-down question when site users must select an answer from a drop-down.

For drop-down questions, site users can select one or more answers. This type of question is typically used when there are more than 5 answer options for a question, to save space on the form layout.

To use this question in a stratum group, demography cohort group, or calculated dose, you must create a **Select Exactly** validation rule that allows only **1** selection. You determine the questions that are used in stratum groups when you create a randomization design.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

If you plan on using code lists to define the answer options for this question, you must also create a code list. For step-by-step instructions, see Create a code list.

To create a drop-down question:

1. On the form, click **Add Question**, and select **Drop-down**.

   > **Tip:**
   >
   > If you need to change the question type, select an option from the drop-down on the question.

2. Depending on how you want to define your answer types, you have multiple options:
   - To add a code list with answer options using the SDTM terminology, click **Code list**. For step-by-step instructions, see Add a code list to a question.
   - To manually add answer options, click **Add Answer** for each answer option.
   - To have a question with one answer option, click the delete icon ( ) next to each answer option to remove them, whether they are manually defined or part of a code list.
3. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.
4. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.
5. If the question is required to complete the form or if it's used to create a stratum group, make sure the **Required** toggle ( ) is turned on.
6. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

7. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
8. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
9. Expand the **Advanced** sidebar and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
10. To create a validation rule, see Types of validation rules.
11. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a label (repeating table only)

Label items allow you to add predefined read-only values to a repeating form and better control the data that is collected. Label items are read-only and can't be edited by the site user.

You cannot configure any kind of rule (validation, dynamic, or custom JavaScript) for a label item, nor can you add any advanced properties to it, such as coding or rollover properties.

You must first create a repeating form. For step-by-step instructions, see Create a repeating form.

To create a label item:

1. Make sure the **Repeating Form** toggle ( )is turned on.
2. For the first question created by default, above the answer field, click the question drop-down, and select **Label (Repeating table only)**.
3. To let site users add more rows to the repeating form, turn on the **Allow Additional Rows** toggle ( ).

   By default, the toggle is turned off. You can only turn this toggle on and off if a label item is added to a repeating form.
4. Enter the label for the label item.

In a repeating form, this is the column header.

5. Depending on how you want to define your label types, you have multiple options:
   - To add a code list with labels, click **Code list**. For step-by-step instructions, see Add a code list to a question.
   - To manually add labels, click **Add Label** for each label type.
   - To have one single label, click the delete icon () next to each label type to remove them, whether they are manually defined or part of a code list.

   In a repeating form, label types are the read-only rows that a site user cannot edit, but that they can use to understand how to fill-in the rest of the repeating form fields.
6. To add another label, click **Add Question**, and select **Label (Repeating table only)**.
7. On the right, expand the **Details** pane and enter a reference code for the form.

   A reference code is a one-word abbreviation for the form.
8. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.
9. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ().

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

10. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
11. Expand the **Advanced** pane and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
12. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a number question

Create a number question when a subject's answer to a question includes numbers only.

To use this question in a stratum group, demography cohort group, or calculated dose, you must create a **Range** validation rule for which **Include Value in Range** is selected. You determine the questions that are used in stratum groups when you create a randomization design.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

To create a number question:

1. On the form, click **Add Question**, and select **Number**.

   > **Tip:**
   >
   > If you need to change the question type, select an option from the drop-down on the question.

2. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.

3. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.

4. If the question is required to complete the form or if it's used to create a stratum group, make sure the **Required** toggle ( ) is turned on.

5. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

   > **Note:**
   >
   > A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

6. To configure data classifications for a hidden question, see Define data classifications for a hidden question.

7. To configure source data verification settings at a question level, see Configure source data verification settings for a question.

8. If applicable, turn on the **Include Unit of Measure** toggle ().
9. In the field below, enter the label that appears next to the answer field, such as **in** or **cm**, for site users.
10. From the **Format** drop-down, select the number of decimal places to record.

> **Tip:**
>
> Selecting '1' records the value to the nearest whole number.

11. Expand the **Advanced** sidebar and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
12. To add a validation rule, see Types of validation rules.
13. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a question group

Create a question group when you need to collect data that is related and you want to display it on the same line.

> **Note:**
>
> You can only dynamically display individual questions in a question group. For more information, see Define a Show Question rule.

For instance, you can create two questions for systolic and diastolic blood pressure and group them so they are displayed next to each other.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

To create a question group:

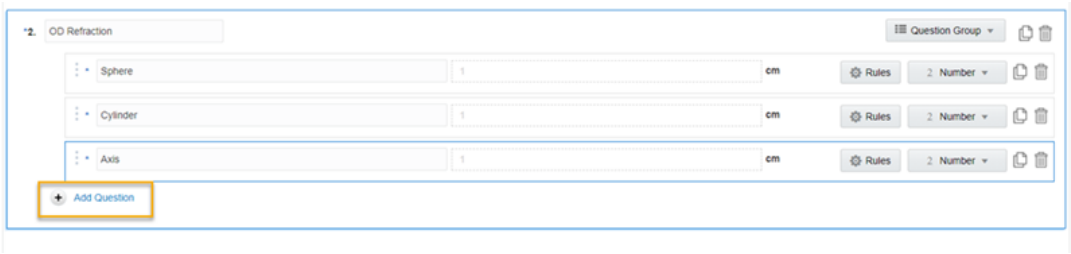
1. On the form, click **Add Question** and select **Question Group**.
2. Enter a name for the question group.

   For example, type *Blood pressure* if you want to collect parameters for blood pressure.

3. To add a new question to the group, in the lower left corner of the question group section, click **Add Question**.

   All questions included in a question group are **Required** by default.

Figure 8-1 How to add a new question in a Question Group



4. Specify the details for each question within a question group:

   a. Choose the type of question according to the data you need to capture. You can include any type of question in a question group. For more details, see Question types and settings.

   b. Expand the **Details** pane and enter a reference code and a question hint.

      For more information, see Create Question Hint text.

   c. If screening, randomization, and dispensation can't happen until a site user enters a valid answer for the question, or if the question is required to be completed for all subjects, make sure the **Required** toggle ( ) is turned on.

   d. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

      > **Note:**
      >
      > A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

   e. To configure data classifications for a hidden question, see Define data classifications for a hidden question.

   f. To configure source data verification settings at a question level, see Configure source data verification settings for a question.

   g. Expand the **Advanced** pane and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.

   h. To create a validation rule, see Types of validation rules.

5. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Create a question with checkboxes or radio buttons

Create a question with checkboxes, if you want site users to select multiple options for an answer. Or create a question with radio buttons, if you want site users to choose one single option as an answer out of other options.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

If you plan on using code lists to define the answer options for this question, you must also create a code list. For step-by-step instructions, see Create a code list.

To create a question with checkboxed or radio buttons:

1. On the form, click **Add Question** and select either:
   - **Checkboxes**, if you want site users to select multiple options for an answer.
   - **Radio Buttons**, if you want site users to choose one option for an answer.
2. Depending on how you want to define your answer types, you have multiple options:
   - To add a code list with answer options using the SDTM terminology, click **Code list**. For step-by-step instructions, see Add a code list to a question.
   - To manually add answer options, click **Add Answer** for each answer option.
   - To have a question with one answer option, click the delete icon ( ) next to each answer option to remove them, whether they are manually defined or part of a code list.
3. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.
4. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.
5. If the question is required to complete the form or if it's used to create a stratum group, make sure the **Required** toggle ( ) is turned on.
6. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

7. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
8. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
9. Expand the **Advanced** sidebar and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
10. To create a validation rule, see Types of validation rules.
11. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a read-only item

Create a read-only item for values that site users can see but not edit.

Typically, in a form you first create questions with an editable answer and then include a read only item. Site users first answer these questions, and their answers are then used to generate a value and populate the read only field with data. For example, you can create a read only item for the Body Mass Index (BMI) and automatically calculate its value. First, you need to create two editable items for Height and Weight, and then add the BMI as a read only item. You then set up a rule to calculate the BMI using the values entered by the site user for Height and Weight, and populate the read only field with the result.

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

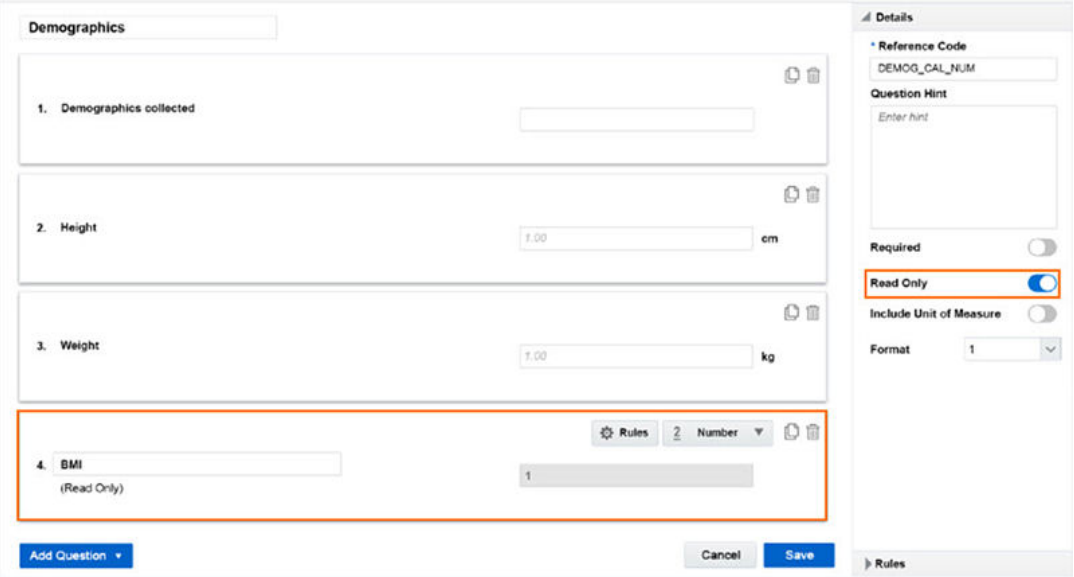
To create a read-only item:

1. On the form, click **Add Question**, and select a type of question.
2. On the right, expand the **Details** pane and enter a reference code for the form.

   A reference code is a one-word abbreviation for the form.
3. Make sure the following toggles () are turned on, according to your needs. toggle () is turned on.

- **Required**: To make the item required for the screening, randomization, or dispensation of kits to a subject.
- **Read Only**: To make the item read-only.

Figure 8-2 Figure 2-4 How to mark an item as read only



4. If you want to hide the item, so site users no longer see it, turn on the **Hidden** toggle ( ).

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

5. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
6. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
7. Expand the **Advanced** pane and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
8. To create a validation rule, see Types of validation rules.
9. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

10. Create a rule for a calculated value to automatically generate the value for the read-only field.

Related Topics

- Form and validation rule FAQs

Create a rollover question

Create a rollover question when site users must select an answer from a drop-down and enroll subjects in a rollover study. A rollover type of question is typically included in a study completion form in the original study.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

If you plan on using code lists to define the answer options for this question, you must also create a code list. For step-by-step instructions, see Create a code list.

For a rollover question, you must also create a validation rule of either Select Exactly or Answer Must Be.

To create a rollover question:

1. On the form, click **Add Question**, and select either **Drop-down** or **Checkboxes**.

   > **Tip:**
   >
   > If you need to change the question type, select an option from the drop-down on the question.

2. Depending on how you want to define your answer options:
   - To add a code list with answer options using the SDTM terminology, click **Code list**. For step-by-step instructions, see Add a code list to a question.
   - To manually add answer options, click **Add Answer** for each answer option.
   - To have a question with one answer option, click the delete icon ( ) next to each answer option to remove them, whether they are manually defined or part of a code list.
3. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.
4. In the **Question Hint** field, provide site users with guidelines that reflect the validation rule for the question.

   For more information, see Create Question Hint text.
5. If the question is required to complete the form or if it's used to create a stratum group, make sure the **Required** toggle ( ) is turned on.

6. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ().

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

7. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
8. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
9. Expand the **Advanced** pane and click **Add Property**.
10. Select **Rollover Question** and fill-in the two fields:
    - **Study Name**: From the drop-down, select the name of the rollover study where you want subjects to be enrolled in by a site user.
    - **Answer for Rollover**: From the drop-down, select the mandatory answer for enrollment in a rollover study.
      For example, if Yes is the mandatory answer for enrollment, when a site user selects that option, the subject is automatically enrolled in the rollover study.
11. Make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
12. To create a validation rule, see Types of validation rules.
13. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create a text question

Create a text question when a subject's answer to a question includes letters only or letters and numbers.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

To create a text question:

1. On the form, click **Add Question**, and select **Text**.

> **Tip:**
>
> If you need to change the question type, select an option from the drop-down on the question.

2. On the right, expand the **Details** pane and enter a reference code for the form.

   A reference code is a one-word abbreviation for the form.

3. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.

4. If screening, randomization, and dispensation can't happen until a site user enters a valid answer for the question, or if the question is required to be completed for all subjects, make sure the **Required** toggle () is turned on.

5. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ().

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

6. To configure data classifications for a hidden question, see Define data classifications for a hidden question.

7. To configure source data verification settings at a question level, see Configure source data verification settings for a question.

8. If you expect site users to provide a long answer, turn on **Multiple Line Answer** toggle ().

9. In the **Character Limit** field, enter up to the default limit of 4,000 characters.

10. Expand the **Advanced** pane and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.

11. To create a validation rule, see Types of validation rules.

12. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Create an age question

Create an age question to insert a Date of Birth question and a read-only calculated age field.

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

Video

You must first create a form. For step-by-step instructions on how to create various types of forms, see Forms.

To use this question in a stratum group, demography cohort group, or calculated dose, you must create a **Range** validation rule for which **Include Value in Range** is selected. You determine the questions that are used in stratum groups when you create a randomization design.

> **Note:**
>
> Although the **Allow a Future Date** toggle is hidden for age questions, the setting is set to **Off** by default. You can enter and save a future date of birth, however, the system prompts you with a validation error message.

To create an age question:

1. On the form, click **Add Question**, and select **Age**.

   > **Tip:**
   >
   > If you need to change the question type, select an option from the drop-down on the question.

2. On the right, expand the **Details** pane and enter a reference code for the question.

   A reference code is a one-word abbreviation for the question.

3. In the **Question Hint** field, provide site users with guidelines for data entry, if necessary.

   For more information, see Create Question Hint text.

4. If screening, randomization, and dispensation can't happen until a site user enters a valid answer for the question, or if the question is required to be completed for all subjects, make sure the **Required** toggle ( ) is turned on.

5. If you want to hide a question, so site users no longer see it, turn on the **Hidden** toggle ( ).

> **Note:**
>
> A hidden question or item can also be required in a form, so the **Required** toggle remains switched on. However, we recommend you switch off the **Required** toggle when hiding a question from a site user, so the visit status is not dependent on the completion of the question. For example, a coding question that can be populated by a coding application, if hidden, is not populated until the coding scheduled job is run.

6. To configure data classifications for a hidden question, see Define data classifications for a hidden question.
7. To configure source data verification settings at a question level, see Configure source data verification settings for a question.
8. On the **Unit** drop-down, select a type of unit for the age, typically **Years**.
9. Expand the **Advanced** sidebar and make sure the SAS properties are correctly defined for both the **SAS Variable** and **SAS Label** fields.
10. To create a validation rule, see Types of validation rules.
11. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

- Form and validation rule FAQs

Configure source data verification settings for a question

If your study requires a targeted Source Data Verification (SDV) strategy, you must work with your study manager to configure these two settings for certain or all questions in the study.

To learn more about source data verification, see Understand source data verification.

> **Note:**
>
> In order for these question-level SDV settings to be applied, your study must be configured to have targeted SDV, create an SDV strategy and assign it to sites. Work with your study manager and refer to Specify settings for source data verification and Create a source data verification strategy and assign it to a site.

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

To configure source data verification settings at a question level:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the Data Collection tab.
3. On your form, select a question.
4. On the right, expand the **Details** pane.
5. Turn on one or both of the following toggles ( ):
   - **SDV for All Subjects**: To require CRAs to verify this question for all subjects in a study, regardless of the SDV settings and whether the subject is part of the targeted SDV subject pool or not. This also applies to screen failed subjects, even if they are excluded from SDV.
   - **Critical Variables (Targeted SDV)**: To mark the questions that CRAs are required to verify for studies with Targeted SDV when the SDV strategy is set as **SDV for all subjects and critical variables**. These questions only need to be verified for subjects in the targeted SDV subject pool, determined according to the SDV strategy, see How are subjects randomly selected for targeted source data verification?.

Figure 8-3 Source data verification (SDV) toggles

Related Topics

- Question types and settings
  You can create a multitude of question types in your forms, specify settings according to the question type, and classify hidden questions in a form.
- Understanding Source Data Verification
- Create a source data verification strategy and assign it to a site

Define data classifications for a hidden question

You define data classifications for a question when you want to create exceptions on hidden questions based on the study roles assigned by a user administrator.

Access to view or edit different data classifications are defined in the context of study roles and allow you to control access for certain users to a specific hidden question. For each data classification in your form, there should be one or more study roles that are defined with the privileges to view or edit that type of data. Work with your study user administrator and refer to Specify data classifications for a study role.

How do data classifications work? For instance, you can add and hide a question for a subject's Social Security Number in a form and then classify the data as Personal Identifiable Information (PII) data. The user administrator on their side assigns to the *site user* and *unblinded data manager* study roles with the privileges to view or edit PII Data. As a reult, that field gets hidden to all users except for site users and unblinded data managers.

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

Video

Before you can define data classifications for a hidden question, you must first add a form and include at least one question in the form.

To classify a hidden queion:

1. On the form, select the question you want to hide.
2. On the right, expand the **Details** pane and make sure the **Hidden** toggle () is turned on.
3. Under **Data Classification**, click the field, and select one or more of the following data classifications:

> **Note:**
>
> If the question is part of a Show Question rule, make sure that you hide and define the same data classifications for both the leading and the dynamic questions.

Data classification	Description
Sponsor Data	Data accessible to a sponsor user
PII Data	Personal Identifiable Information Data
Public Data	Data accessible to sites or other users
Blinded Data	Data that can reveal information bias in a study
Adjudication Data	Data findings collected by an adjudicator from adjudication events or safety and efficacy clinical endpoints

4. To view which study roles have the permissions to view or edit the data classifications that you selected, click **Study Role**.
5. Depending on the data you want to collect, continue your usual process of defining the details and properties for your question. For more information, see Question types and settings.
6. To save the form, in the lower right of the form, click **Save**.

> **Tip:**
>
> If the **Save** button is disabled, make sure there are no blank questions on the form.

Related Topics

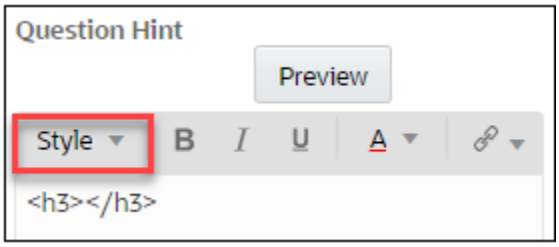
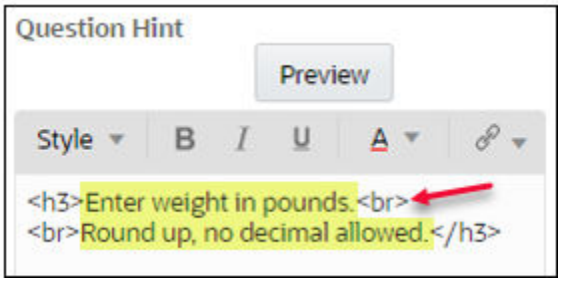
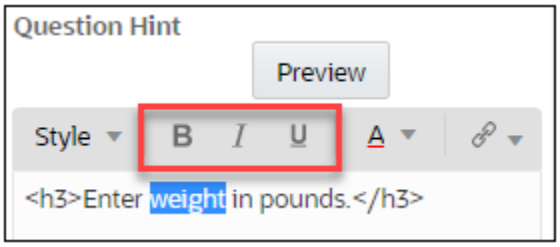
- Form and validation rule FAQs
- Specify data classifications for a study role

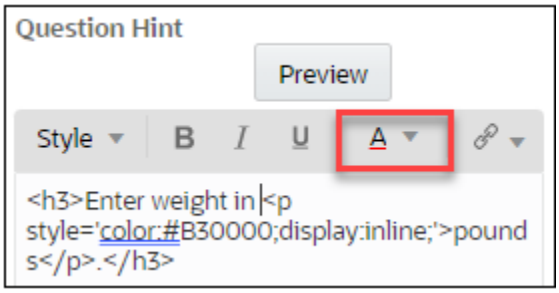
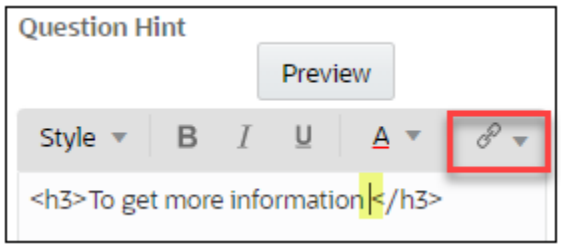
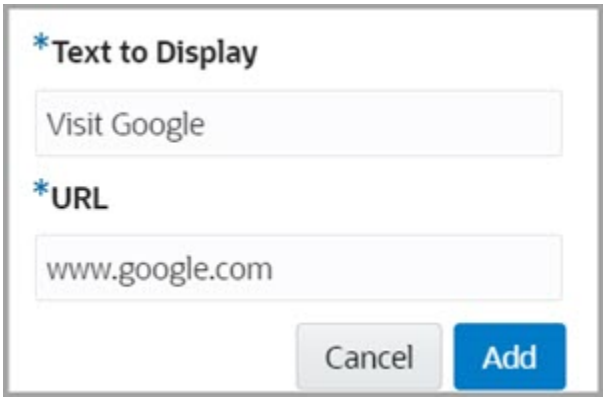
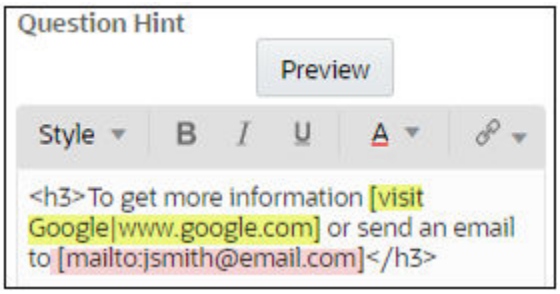
Create text for a question's hint

You can create question hint text to provide site users with guidelines for data entry. Question Hint text is displayed for site users on the right sidebar when entering data in a form.

To create a hint for a question, follow these steps:

1. Access the Draft version of a study as described in Open a study's design.
2. Access a form and select a question that you want to create hint text for.
3. Expand the **Details** sidebar and work with any of the following options:

Step	Details
Select **Style** and choose a specific style for your text: • **Heading** displays the largest font. • **Paragraph** displays the font in a regular size. • **Footer** displays the text in the smallest size. ***Note**: To undo a style, highlight the text then click the same style option again.*	
Insert the hint text between the tags and use tags to add line breaks, where applicable.	
Add emphasis to the text by selecting any of the following options: • **B** for bold text • *I* for italicized text • U for underlined text ***Note**: To undo formatting, highlight the text then click the formatting option again.*	

Step	Details
Change the default color: **a.** Highlight the text whose color you want to change. **b.** From the **Color text** drop-down, select a color. **c.** If you want to use a custom Hex code that isn't available on the Color text drop-down, highlight the Hex code in the text, and replace it with another code. ***Note**: To undo a color, highlight the text you entered (not the HTML code that specifies the color), and select the same color option from the Color text drop-down. If you inserted a custom HEX code, you will need to delete the text and start over.*	
Insert an external link or email link: **a.** Place your cursor where you want to insert the link. **b.** From the **Insert hyperlink or email** drop-down, select **External link** or **Email link**. **c.** In the newly displayed dialog, enter the required details, and click **Add**. **d.** Confirm the details. **Note:** You can do inline editing at this time or you can delete the link and insert a new one.	  

4. Select **Preview** anytime you make a change to the text to view how it'll look like.

Run the **Study Design** report and the **Annotated Case Report Forms** report to view more details about the question hints you create. The HTML versions of both reports show the formatted question hint text, while the PDF versions show the unformatted question hint text. Both output versions don't display the rich text HTML tags.

About mapping questions for Electronic Health Record (EHR) data import

If your study is enabled for EHR data import, you can map form questions to EHR elements in an Oracle-managed data dictionary and use pre-seeded EHR code lists to ensure successful data import and minimize data cleaning.

A few extra steps in the design phase can result in more efficiently designed studies with downstream benefits for site users and subjects.

For more information about importing Electronic Health Record (EHR) data and pre-seeded code lists, see Enable Electronic Health Record (EHR) data import and About Electronic Health Record (EHR) code lists.

Prerequisites

Before you can map form questions, the sponsor user must enable the study for EHR data import. For more information, see Enable Electronic Health Record (EHR) data import.

Once enabled, the **EHR Mapping** setting is available under the Advanced side panel in design mode. No additional permissions are required to use this feature.

Mapping details for study designers

After a study version is moved from the draft container, adding new ERH mappings, updating existing mappings, or removing mappings is only permitted as part of a study version change. Advanced Study Versioning (ASV) is not supported.

> **Note:**
>
> Removing a mapping does not remove the question, the associated code list, or previously imported data.

- You can map questions on flat and repeating forms.
- You cannot map questions in the following form types:
  - Two-section forms
  - Drug reconciliation forms
  - Lab Forms.

> **Note:**
>
> For lab forms, study designers are required to create a 1-section repeating form and map those questions to the items in the EHR data dictionary. Lab normals do not populate these forms; instead, you must incorporate the EHR lab normal ranges and units into the form's design.

- You can have EHR-mapped and non-EHR-mapped questions on the same form.
- You can map text, number, date time, drop-down, checkbox, radio button, and age questions, as well as labels (for a repeating table only).
  Refer to the Data dictionary question type mapping reference guide for recommended question types and a complete list of available EHR mapping elements.
- You can map question groups, except when used on a repeating form.
- You can map read-only questions, but you should not use these as calculation rule targets.
- You can map dynamic parent and child questions. For more information about dynamic questions and forms, see Define a Show Question rule and Define a Show Form rule.

> **Note:**
>
> Keep in mind, data does not import into a not-yet-triggered child question.

- After mapping has taken place, changing a question type removes the existing mapping.
- You can map the coding questions, which include the Verbatim term, Route of Administration, and Indication, but you cannot map coding targets—form items populated by an Oracle Central Coding dictionary—for data import. For more information, see Create the coding target fields.

Limitations

Certain EHR data elements, listed below, appear in the user interface (UI), on the **Advanced** side panel, under the **EHR Mapping** dropdown but should not be mapped to form questions. These are not active and are only present in the UI to support future enhancements to the EHR mapping feature.

> **Note:**
>
> For a full list of EHR data elements, see the Data dictionary question type mapping reference guide.

Table 8-2 EHR data elements do not map list

Category	EHR mapping value
Labs	Performing Lab
Medical History	Medical History End Date
Medications	Dose Original Form
Procedures	Procedure Status
Procedures	Procedure End Date
Vitals	Respiratory Rate

Table 8-2 (Cont.) EHR data elements do not map list

Category	EHR mapping value
Vitals	Heart Rate Noninvasive

For additional information on mapping form questions, refer to the following section.

- Map form questions for EHR data import

Map form questions for EHR data import

Follow the steps below to map a question to an EHR data item.

The Oracle Clinical One Platform question type being mapped determines the EHR mapping options presented to you under the **EHR Mapping** dropdown on the **Advanced** side panel. For example, only EHR radio button mapping options are available to you when mapping a radio button question. For more information, see the Data dictionary question type mapping reference guide.

- **Required code lists**: Some EHR mapping options include required code lists. For example, when mapping Birth Sex you are required to use the EHR-Birth Sex code list. This ensures the options in the source EHR system match the ones on the form. For more information, see About Electronic Health Record (EHR) code lists.
- **Pre-mapped questions**: Some EHR mapping options include pre-mapped questions that you can add to a form during the mapping process. For example, when mapping labs, you have the option to add such questions as Lab Result and Lab Result Units.

> **Note:**
>
> There are instances when the dialog window opens and includes both a required code list and pre-mapped questions. You determine if you want to add just the code list and the full or partial list of questions.

- **Limitations**: Certain EHR data elements, listed below, appear in the user interface (UI), on the **Advanced** side panel, under the **EHR Mapping** dropdown but should not be mapped to form questions. These are not active and are only present in the UI to support future enhancements to the EHR mapping feature.

Table 8-3 EHR data elements do not map list

Category	EHR mapping value
Labs	Performing Lab
Medical History	Medical History End Date
Medications	Dose Original Form
Procedures	Procedure Status
Procedures	Procedure End Date
Vitals	Respiratory Rate
Vitals	Heart Rate Noninvasive

Follow these steps to begin the mapping process.

1. Open the draft version of your study. For more information, see Open a study's design.
2. In the **Forms** tab, create a new form or open an existing one.
3. Select **Add** to add a new question or select an existing one.
4. Expand the **Advanced** side panel.
5. From the **EHR Mapping** drop-down select the appropriate category, such as Labs or Medical History or a specific value, for example, Birth Sex or Ethnicity.

   If a question requires additional mappings, the system provides additional drop-downs.
6. A dialog window opens if you select an EHR mapping option that includes a required code list and/or pre-mapped questions. Choose to add just the code list and all or some of the pre-mapped questions.

For additional information on mapping form questions, refer to the following sections:

- Map a question with units inline or separately
- Map a question group
- Map lab form questions
- Data dictionary question type mapping reference guide

Map a question with units inline or separately

Some EHR mapping items include a list of associated units. For example, the EHR mapping option *Body Temperature Noninvasive* includes the units Celsius and Fahrenheit and *Body Weight* includes lb and kg.

1. Select the appropriate option under the **EHR Mapping** drop-down.

   If you selected an EHR mapping that includes a list of associated options, the **Choose Option** drop-down is made available.
2. To add an inline unit, select one of the options available under the **Choose Option** drop-down.

   The unit selected from the list is displayed to the right of the question.

   > **Note:**
   >
   > Some EHR mappings like *Oxygen Saturation* only have one unit, which is automatically added to the right of the question.
3. To let the user select the appropriate unit, select **Value Only**.

   The applicable unit question is added to the form and displays all available options.

Map a question group

The details below describe one use case. Depending on the question group you create and the EHR mappings you select, you may encounter minor variations.

1. Open the draft version of your study. For more information, see Open a study's design.
2. In the **Forms** tab, create a new form or open an existing one.
3. Select **Add** to add a new question group or select an existing one.
4. Enter the question title, for example, *Body Temperature*.

5. Enter the question title for the first question in the group, for example, *Body Temperature Noninvasive*.

   This is the question you map for EHR data import.

6. Expand the **Advanced** side panel.
7. From the **EHR Mapping** drop-down, select the appropriate EHR category or item, for example, *Body Temperature Noninvasive*.
8. In the **Choose Option** drop-down.
   - Select **Celsius** or **Fahrenheit** to display the unit of measurement inline.
     You are presented with the option to add the pre-mapped question, *Body Temperature Noninvasive Date of Collection*.
   - Select **Value Only** to display both options. This allows the user to select the unit of measurement.
     You have the option to add the pre-mapped questions, *Body Temperature Noninvasive Units* and *Body Temperature Noninvasive Date of Collection*.

Map lab form questions

Lab forms cannot be used, a 1-section repeating form needs to be created.

1. Open the draft version of your study. For more information, see Open a study's design.
2. In the **Forms** tab, create a 1-section repeating form or open an existing one. For more information, see Create a form with one section.
3. Select **Add** to add a new question or select an existing one.

> **Note:**
>
> It is recommended to use the Label question type for a repeating form.

4. Expand the **Advanced** side panel.
5. From the **EHR Mapping** drop-down, select Labs then Lab Test Name.

> **Note:**
>
> Do not map form questions to the **Performing Lab** option. This is not an active option and is only present in the user interface to support future enhancements to the EHR mapping feature.

   The Add Questions dialog window opens providing a list of additional (pre-mapped) questions that can be added automatically. The list includes, Lab Result, Lab Units, Low Range, High Range, Collection Date, and Performing Lab.

6. Select the relevant questions, then select **Add** or select **Not Now** if you plan to add these questions manually at a later time.

   If **Add** was selected, the questions are added to the form and are marked EHR Mapped.

Data dictionary question type mapping reference guide

This table serves as a guide, listing the categories, values, and types of questions supported by Oracle Clinical One Platform for EHR question mapping.

EHR question field mappings and supported question types

- The **EHR mapping value** column provides a list of EHR elements available for mapping. The Advanced tab displays these under the **EHR Mapping** setting.
- The **Recommended question type** column lists the ideal Oracle Clinical One Platform question type that you should use when creating each question.
- Refer to the **Supported question types** column for a list of alternative question types, that if used, still result in a successful data import.

Table 8-4 EHR question mapping options

Category	EHR mapping value	Recommended question type	Supported question types
Demographics	Birth Date	Datetime	• Datetime • Age
Demographics	Birth Sex	RadioButton	• RadioButton • Dropdown
Demographics	Ethnicity	RadioButton	• RadioButton • Dropdown • Checkbox
Demographics	Race	Checkbox	• RadioButton • Dropdown • Checkbox
Labs	Lab Test Name	Label	• Label • RadioButton • Dropdown • Checkbox
Labs	Lab Result	Text	Text
Labs	Lab Result Units	Text	Text
Labs	Lab Date of Collection	Datetime	Datetime
Labs	Lab Normal Low Range	Text	Text
Labs	Lab Normal High Range	Text	Text
Labs	Performing Lab ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under* About mapping questions for Electronic Health Record (EHR) data import*.*	Text	Text
Vitals	Body Height	Number	Number
Vitals	Body Height Units	RadioButton	• RadioButton • Dropdown

Table 8-4 (Cont.) EHR question mapping options

Category	EHR mapping value	Recommended question type	Supported question types
Vitals	Body Height Date of Collection	Datetime	Datetime
Vitals	Body Weight	Number	Number
Vitals	Body Weight Units	RadioButton	• RadioButton • Dropdown
Vitals	Body Weight Date of Collection	Datetime	Datetime
Vitals	Body Mass Index (BMI)	Number	Number
Vitals	Body Mass Index Units	RadioButton	• RadioButton • Dropdown
Vitals	Body Mass Index Date of Collection	Datetime	Datetime
Vitals	Body Surface Area	Number	Number
Vitals	Body Surface Area Units	RadioButton	• RadioButton • DropDown
Vitals	Body Surface Area Date of Collection	Datetime	Datetime
Vitals	Body Temperature Noninvasive	Number	Number
Vitals	Body Temperature Noninvasive Units	RadioButton	• RadioButton • Dropdown
Vitals	Body Temperature Noninvasive Date of Collection	Datetime	Datetime
Vitals	Blood Pressure Diastolic	Number	Number
Vitals	Blood Pressure Diastolic Units	*This is not an EHR mapping item. This is an attribute of Blood Pressure Diastolic and the unit (mmHg) is added inline automatically when mapped.*	Not applicable
Vitals	Blood Pressure Diastolic Date of Collection	Datetime	Datetime
Vitals	Blood Pressure Systolic	Number	Number
Vitals	Blood Pressure Systolic Units	*This is not an EHR mapping item. This is an attribute of Blood Pressure Systolic and the unit (mmHg) is added inline automatically when mapped..*	Not applicable
Vitals	Blood Pressure Systolic Date of Collection	Datetime	Datetime
Vitals	Head Circumference	Number	Number

Table 8-4 (Cont.) EHR question mapping options

Category	EHR mapping value	Recommended question type	Supported question types
Vitals	Head Circumference Units	RadioButton	• RadioButton • Dropdown
Vitals	Head Circumference Date of Collection	Datetime	Datetime
Vitals	Heart Rate Noninvasive ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under About mapping questions for Electronic Health Record (EHR) data import.*	Number	Number
Vitals	Heart Rate Noninvasive Units	*This is not an EHR mapping item. This is an attribute of Heart Rate Noninvasive and the unit (/min) is added inline automatically when mapped..*	Not applicable
Vitals	Heart Rate Noninvasive Date of Collection	Datetime	Datetime
Vitals	Oxygen Saturation	Number	Number
Vitals	Oxygen Saturation Units	*This is not an EHR mapping item. This is an attribute of Oxygen Saturation and the unit (%) is added inline automatically when mapped.*	Not applicable
Vitals	Oxygen Saturation Date of Collection	Datetime	Datetime
Vitals	Respiratory Rate ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under About mapping questions for Electronic Health Record (EHR) data import.*	Number	Number
Vitals	Respiratory Rate Units	*This is not an EHR mapping item. This is an attribute of Respiratory Rate and the unit (/min) is added inline automatically when mapped.*	Not applicable
Vitals	Respiratory Rate Date of Collection	Datetime	Datetime

Table 8-4 (Cont.) EHR question mapping options

Category	EHR mapping value	Recommended question type	Supported question types
Medications	Medication Name	Text	Text
Medications	Medication Dose	Text	Text
Medications	Medication Dose Units	Text	Text
Medications	Dose Original Form ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under* About mapping questions for Electronic Health Record (EHR) data import.	Text	Text
Medications	Medication Frequency	Text	Text
Medications	Medication Route of Administration	Text	Text
Medications	Medication Start Date	Datetime	Datetime
Medications	Medication End Date	Datetime	Datetime
Medications	Medication Status	Text	Text
Medical History	Medical History Diagnosis	Text	Text
Medical History	Medical History Start Date	Datetime	Datetime
Medical History	Medical History End Date ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under* About mapping questions for Electronic Health Record (EHR) data import.	Datetime	Datetime
Medical History	Medical History Status	Text	Text
Medical History	Medical History Confirmation Status	Text	Text
Procedures	Procedure Name	Text	Text
Procedures	Procedure Start Date	Datetime	Datetime
Procedures	Procedure End Date ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under* About mapping questions for Electronic Health Record (EHR) data import.	Datetime	Datetime

Table 8-4 (Cont.) EHR question mapping options

Category	EHR mapping value	Recommended question type	Supported question types
Procedures	Procedure Status ***Note**: You should not map this option, as it is not active. For more details, review the limitations section under* About mapping questions for Electronic Health Record (EHR) data import.	Text	Text

9

Randomization and treatment arms

To put together a proper randomization design, you must first create treatment arms and then define the details of the appropriate randomization design for your study.

- Define a treatment arm
  If a treatment arm is used in both a blinded and open-label period, create just one treatment arm for both study periods. The unblinding setting on the randomization design determines whether the treatment arm title is visible to blinded users.
- Define the randomization
  Create a randomization design either to specify randomization details or to start an open-label period, even if the open-label period doesn't have a randomization event.
- Define the minimization
  Create a minimization design to balance the number and characteristics of subjects across treatment arms.
- Add randomization to a visit
  To associate a randomization or minimization design with a visit, just drag the design to the visit.

Define a treatment arm

If a treatment arm is used in both a blinded and open-label period, create just one treatment arm for both study periods. The unblinding setting on the randomization design determines whether the treatment arm title is visible to blinded users.

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

Video

If you're randomizing two or more times and you add a treatment arm to the first randomization design after assigning both randomization designs to visits, a red circle with a number on it appears on the Map Treatment Arms button to the right of the visit with the second randomization design in Visits & Events. Click the button to update the treatment ratio.

To create a treatment arm:

1. Access the Draft version of a study as described in Open a study's design.
2. Along the top, click **Study Supplies**.
3. Below the study name, make sure the **Randomizations** tab is selected.
4. Do one of the following:
   - If you have no treatment arms, click **Create Treatment Arms**
   - If you have one or more treatment arms, click **Edit Treatment Arms** in the upper left.
5. Fill in the fields, and click **Save**. To view tips for completing a field, click into the field.

> **Note:**
>
> Make sure you've defined treatment arms for each cohort group before you define randomization. If cohort groups don't have at least one treatment arm defined for each cohort group, you won't be able to assign demographic cohort randomization to visits.

Field	Description
Treatment Arm Title	Enter the title of the treatment arm from the protocol. If the treatment arm will be used in an open-label period or study, make sure the title is appropriate for blinded users.
Treatment Arm ID	Enter a short name that helps you identify a treatment arm, such as A or Active1.
Description	Provide additional details about the treatment arm.

6. Enter the details for the next treatment arm.
7. After you finish, click **Done**.

Next up, you should define your type of randomization design. For step-by-step instructions, see Define the minimization or Define the randomization.

Related Topics

- Drop a treatment arm, add cohorts, or update randomization during the study conduct period
- Extend the treatment period for subjects during the study conduct period

Define the randomization

Create a randomization design either to specify randomization details or to start an open-label period, even if the open-label period doesn't have a randomization event.

Before you begin, consider the following:

- You must first define treatment arms. For step-by-step instructions, see Define treatment arms.
- If you need to edit a read-only field after assigning a randomization design to a visit, remove the randomization design from the visit. You can edit the description and the settings on the last page at any time.

> **Note:**
>
> The page where you specify a treatment ratio (named either Treatment Arms or Cohorts & Treatment Arms, depending on whether the study has cohorts) doesn't appear if you selected Yes for Re-Randomization on the first page. Instead of mapping subject to treatment arms here, you'll map subjects from their current treatment arms to their new treatment arms when you drag this randomization design to a visit.

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

Video

Task 1 Specify how you will randomize subjects

1. Access the Draft version of a study as described in Open a study's design.
2. Along the top, click **Study Supplies**.
3. Make sure the **Randomizations** tab is selected.
4. Click **Create Randomization**.
5. Fill in the rest of the fields on the page and click **Next**.

> **Note:**
>
> Make sure you've defined treatment arms for each cohort group before you define randomization. If cohort groups don't have at least one treatment arm defined for each cohort group, you won't be able to assign demographic cohort randomization to visits.

Field	Description
Title	Enter the name of the randomization design, such as Simple randomization design 1:1.
Description	Provide additional information that doesn't fit in the title.
Type	If blinded users should never see any of the titles of the treatment arms used in the randomization design, choose **Blinded**. If blinded users should always see all titles of the treatment arms used in the randomization design, choose **Unblinded**.

Field	Description
Cohort	Choose one of the following: • **None** to create a study without cohorts. • **Adaptive** to create cohorts that allow you to open treatment arms in a gradual manner so that you can better measure safety and efficacy as the study progresses. • **Demography** to create population groups according to demographic criteria, such as age. You can set limits on each group and can open and close demography cohorts based on the results obtained during the study conduct period. You can also increase and decrease the number of subjects in each population group as needed.
Randomization	Specify how subjects are randomized: • Use dynamic randomization (recommended) to use the numbers in the list more efficiently. This can help reduce having large sections of unassigned numbers. • To use stratified randomization (not available for cohort studies), select a randomization type with Stratification in its name. If you want to stratify subjects by demographic criteria and want to place limits on each population group or have the ability to stop and start enrollment with just a few clicks, you should choose **Demography** from the **Cohort** drop-down.
Re-Randomization	***Note**: Appears only when you create a second or later randomization design and you select a randomization algorithm.* Select **Yes** if you'll use the randomization design for the second or later randomization event in the study.

Field	Description
Treatment Arms	***Note**: Appears when you select* **Yes** *for Re-Randomization and when you select a non-stratified randomization algorithm.* • Select **Randomized** if all subjects are randomized into new treatment arms according to a treatment ratio that you specify in the randomization design. • Select **Mapped** to map subjects to new treatment arms (or to specify that they should stay in their current treatment arms). ***Note**: If subjects in one treatment arm are mapped to multiple arms, randomization determines the subjects' new treatment arms.*

Task 2 Create stratum groups (For any stratified randomization with None selected for Cohorts)

1. On the Stratum page, from the **Select a Form** drop-down on the left, select a form that contains a question that you are using to stratify subjects.

   The questions that can be used to stratify subjects appear. Only the following questions can be used to stratify subjects:

   - A required Number or Age question with a **Range** validation rule for which **Include Value in Range** is selected.
   - A required Drop-down question with a **Select Exactly** validation rule that allows **1** selection.
   - A required question with radio buttons.

2. Drag a question to **Stratum Group 1**, on the right.
3. Finish configuring the stratum group, either by dragging questions from the selected form, or by selecting a different form from the drop-down and dragging questions.
4. Define the details of the stratum group:
   - For number questions, specify the range for subjects in each group.
   - For drop-down questions or questions with radio buttons, select one or more options for each stratum group.
5. In the upper-right, click **the plus sign**, and define as many stratum groups as you need. When defining the details of the group, make sure that:
   - All values in the range of number and age questions are captured in the stratum groups.
   - Number ranges don't overlap.
   - All options on a drop-down question or a question with radio buttons are captured in the stratum groups.
6. Click **Next**.

Task 3 Create cohort groups (for Demography selected for Cohorts)

1. On the Cohorts page, from the **Select a Form** drop-down on the left, select a form that contains a question that you are using to create population groups.

   The questions that can be used to create population groups appear. Only the following questions can be used to create population groups:

   - A required Number or Age question with a **Range** validation rule for which **Include Value in Range** is selected.
   - A required Drop-down question with a **Select Exactly** validation rule that allows **1** selection.
   - A required question with radio buttons.

2. Drag a question to the area below **Enter Cohort Name**, on the right.
3. Finish choosing questions for the stratum group, either by dragging more questions from the selected form, or by selecting a different form from the drop-down and dragging questions.
4. Define the details of the cohort group:
   - For number questions, specify the range for subjects in each group.
   - For drop-down questions or questions with radio buttons, select one or more options for each cohort group.
5. In the upper-right, click **the plus sign**, and define as many cohort groups as you need. When defining the details of the group, make sure that:
   - All values in the range of number and age questions are captured in the cohort groups.
   - Number ranges don't overlap.
   - All options on a drop-down question or a question with radio buttons are captured in the cohort groups.
6. Click **Next**.

Task 4 Specify the treatment ratio for treatment arms, stratum groups, or cohorts

1. (Only for a study with adaptive cohorts) On the Cohorts & Treatment Arms page, click the plus sign in the upper-right corner () to create all the cohorts in the study.

   Tip: The number on the Cohorts column indicates the number of cohorts you create.
2. Enter a whole number (from 0 to 99) for each stratum group, treatment arm, or cohort in the study.

   The numbers determine the treatment ratio, such as 2:2:1:1, for each treatment arm, stratum group, or cohort. If you don't enter a number, subjects aren't randomized into the treatment arm, stratum group, or cohort.
3. Click either **Finish** (for a study with cohorts) or **Next** (for a study without cohorts).

Task 5 Specify additional randomization details

> **Note:**
>
> This page doesn't appear if you're randomizing into cohorts.

1. On the Settings page, fill in the fields and click **Finish**.
   To view a tip for completing the field, choose an option.

Setting	Description
Assign New Randomization Numbers to All Subjects	***Note**: This setting appears when you select* **Yes** *for Re-Randomization on the first page).* • Select **Yes** if subjects should receive new randomization numbers after they are randomized as part of this randomization design. • Select **No** if subjects should not receive new randomization numbers after they are randomized. ***Note**: For both selections, you are required to upload a randomization list that is associated with this re-randomization design. Even though you decide that subjects should not receive new randomization numbers, a randomization list is still required to preserve the blind in a blinded re-randomization.*
Restrict Randomization to Available Kit Types	• Select **Yes** if you want randomization to skip the randomization number for an out-of-stock kit and assign the randomization number for the next available kit. • If you select **No**, a randomization failure occurs, though the site user can try to randomize the subject later.
Assign Skipped Randomization Numbers	• Select **Yes** if, when a randomization number is skipped because its kit is not in stock, the skipped randomization number is assigned to a subject who enrolls after the out-of-stock kit is available again. The analysis of randomization is sometimes easier with this option. • Select **No** if skipped randomization numbers are never assigned.

Setting	Description
Allow Randomization to Occur Outside Visit Window	• Select **Yes** if you want to let a site user start and complete a randomization visit (without dispensation) outside of the specified visit window for that randomization visit. • Select **No** if you want to restrict a site user to only randomize a subject if they start the randomization visit (without dispensation) during the specified visit window.

2. If you created a region-blocked randomization design, don't forget to Add a region.

Next up, you must add your randomization design to a visit. For step-by-step instructions, see Add randomization to a visit.

Related Topics

- Update a randomization list that ran out of numbers during the study conduct period
  You can upload or generate a new randomization list in an approved version of a study without creating a new version of a study. Consider assigning the new list to the study version before the current list runs out of numbers to avoid randomization errors at sites. This procedure also applies to rollover studies.
- When I create a randomization design, what fields should I choose?
  The fields you choose depend on whether the study is open-label, blinded, or both open-label and blinded.
- What randomization algorithms are available?
  You can use simple or stratified randomization. You can create blocks in the list and assign them either dynamically or statically to sites, countries, or regions.
- Randomization FAQs (for study designers)

Define the minimization

Create a minimization design to balance the number and characteristics of subjects across treatment arms.

You can create a minimization design if the study's aim is to create better-balanced treatment groups. Minimization can be used in conjunction with restricted randomization. In case not all kit types are available during the study, the balance is calculated based on the remaining treatment arms during the study conduct period.

To maximize the potential of allocation methods specific to minimization, you can include a site, country, or region one at a time, as a location for the stratification factors. Additionally, you may also create custom groups within a stratum factor that is based on multiple-choice questions, if you want to balance out the options in fewer groups than the existing options.

Lastly, multiple minimization stratum factors can have the same weight.

Before you begin, make sure the following prerequisites are already set up in your study design:

- Treatment arms.
  For step-by-step instructions, see Define treatment arms.

- Appropriate questions in your forms, such as questions on age, race and ethnicity, or gender.
  For step-by-step instructions, see Question types and settings.
- Validation rules.
  For step-by-step instructions, see Types of validation rules.

To create a minimization design:

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Make sure the **Randomizations** tab is selected.
4. Click **Create Randomization**.
5. Fill in the rest of the fields on the page, and click **Next**.

Field	Description
Title	Enter the name of the minimization design, such as Minimization design 1:1.
Description	Provide additional information that doesn't fit in the title.
Type	If blinded users should never see any of the titles of the treatment arms used in the randomization design, choose **Blinded**. If blinded users should always see all titles of the treatment arms used in the randomization design, choose **Unblinded**.
Randomization	Select minimization to make sure subjects are evenly placed among treatment arms based on minimization stratum factors
Re-Randomization	Planned for a future release.

6. On the Stratum page, on the right, click **Select a Form** and select a form.
7. Begin dragging and dropping the parameters to the Minimization Stratum Factors section.
8. For each stratum factor, in the **Weight** field, enter a number to define the weight (so the proportion) of each factor.
   - If you want to use the default groups for balancing subjects, you have to enter a whole number (from 0 to 99) in the **Weight** field for each stratum factor.
   - If you want to create custom groups for the stratum factors based on multiple-choice types of questions or range groups for age, click **Create Custom Group** and specify the details of the custom group. Then, define the **Weight** of each stratum factor.
9. Click **Next**.
10. On the Treatment Arms display, enter the ratio (a whole number, from 0 to 99) for assigning subjects to each treatment arm in the study.
11. On the Settings page, for the **Restrict Randomization to Available Kit Types** setting
    - Select **Yes** if you want randomization to skip the randomization number for an out-of-stock kit and assign the randomization number for the next available kit.
    - Select **No** to enable a randomization failure to occur, though the site user can try to randomize the subject later.
12. Click **Finish**.

Next up, you must add your minimization design to a visit. For step-by-step instructions, see Add randomization to a visit.

Related Topics

- Understanding minimization
- Randomization FAQs (for study designers)
- Randomization FAQs
- Randomization lists and kit lists FAQs
- Update a randomization list that ran out of numbers during the study conduct period
  You can upload or generate a new randomization list in an approved version of a study without creating a new version of a study. Consider assigning the new list to the study version before the current list runs out of numbers to avoid randomization errors at sites. This procedure also applies to rollover studies.

Add randomization to a visit

To associate a randomization or minimization design with a visit, just drag the design to the visit.

You can map subjects from one treatment arm to the same treatment arm, a different treatment arm, or multiple treatment arms. If you map all subjects in one treatment arm to a single other treatment arm, either the same or different, those subjects aren't randomized again.

In the following example, subjects in the 10 mg dose and 5 mg dose arms remain in their treatment arms and aren't randomized again. Subjects in the Placebo arm are randomized to determine whether they move to the 5 mg dose or 10 mg dose arms.

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

Video

You must create a randomization or minimization design first.

For step-by-step instructions, see Define the randomization or Define the minimization.

> **Note:**
>
> The visit that is assigned a randomization design must be required and scheduled, and it cannot be the study completion, withdrawal, an unscheduled visit, or event.

To add randomization or minimization design to a visit:

1. Access the Draft version of a study as described in Open a study's design.
2. Along the top, click **Study Supplies**.
3. Make sure the **Randomizations** tab is selected.
4. On the Visits & Events pane, locate the scheduled visit the study protocol defines as the randomization event.

> **Tip:**
>
> A scheduled visit has a blue clock leading into it; a visit that has not been scheduled yet has a gray clock.

5. On the left, identify the randomization design to assign to a visit:
   - If you're assigning the first randomization event in the study, make sure the randomization design doesn't say Re-Randomization on it.
   - If you're assigning the second or later randomization event in the study, make sure the randomization design is for re-randomization.
   - For any randomization event, make sure the randomization design is appropriately blinded or unblinded.
6. Drag the randomization design to the visit.

   > **Tip:**
   >
   > An error occurs if you try to add a randomization design before another randomization design, so you must drag the randomization designs to the visit schedule in chronological order. Drag the first randomization design, then the second randomization design, and so on.

   A blue line appears between the randomization event and the next scheduled visit, and the randomization design displays the visit you assigned it to.
7. Depending on what your previous step was, you have two options:
   - **If you just dragged the first randomization design in the study to a visit**: You have finished assigning the randomization design to the visit. Blue background shading appears behind visits that are prior to randomization and behind unscheduled visits, and orange appears behind the first randomization visit and subsequent visits.

     Additionally, an eye icon (

) appears on the visit if the randomization design is unblinded.
   - **If you dragged the second or later randomization design in the study to a visit**: If the randomization design requires that subjects be mapped to new treatment arms, the Map Treatment Arms dialog appears so you can choose the treatment arms that subjects should move to.
8. If you used a second or later randomization design to a visit, you must follow these steps next:
   a. On the right, check whether all treatment arms that you'll use after this randomization event are present.

      > **Note:**
      >
      > Any new treatment arms that are in the second but not the first randomization design don't appear. To add a treatment arm, click the plus sign in the upper-right corner, and select the treatment arm(s) to include.

b. On the left, locate the treatment arm that subjects are currently in and then choose the subjects' new treatment arm by dragging the treatment arm to the appropriate treatment arm on the right.

c. In the Ratio fields for each treatment arm, enter whole numbers for the new treatment ratio.

d. Click **Map Treatment Arms**.

   Green background shading appears for the second randomization visit and subsequent visits, and yellow appears for the third randomization visit.

9. To remove a randomization design you assigned to the wrong visit, click the visit in Visits & Events, and click the trash can ( ) on the randomization design.

   If you remove a randomization design from a visit, any subsequent randomization designs are also removed.

   If you change the visit when randomization occurs, if necessary. For step-by-step instructions, see Define the dispensation schedule.

10. To edit the way that subjects are mapped to new treatment arms after the second or later randomization event, click **Map Treatment Arms** ( ) to the right of the visit.

Related Topics

- Randomization FAQs (for study designers)
- What are the rules for randomization designs?
  You can create blinded studies with or without open-label extensions. You can also create open-label studies, as long as randomization occurs when the open-label period starts. A study can have one or more randomization events.

10

Kit types and dispensation schedules

You can define various types of kits, from kits containing the investigational product, kit type titrations, to devices and kits that only an unblinded pharmacist can dispense.

- Define the kits for investigational products
  When you create kit types, you specify details about the kits, including storage details and whether doses are calculated based on subjects' answers questions. This procedure applies for defining kit types in a rollover study, as well.
- Define kits with calculated doses
  When you create kit types for the investigational product, you can choose whether calculated doses should be included or not, along with other storage details.
- Define the kits for devices
  Create one kit type for each type of device that is dispensed. Devices might include scales or blood pressure monitors, for example. If the study doesn't dispense devices, you can skip this step.
- Define kits for titrations
  When subjects can titrate, you must define the titration rule by creating titrations. Create one titration for each treatment arm. Every kit type in the titration must contain the same product and should have the same distribution status (either blinded or unblinded). This procedure can also apply to rollover studies.
- Import a pooled kit type
  After you or another library user create the pooled kit type, approve it in a library study, and then publish it, you can import that kit type into a Production study.
- Specify when subjects can titrate
  Perform this task only if the protocol allows subjects to titrate based on input from a clinician at the site. This procedure also applies to rollover studies.
- Define the dispensation schedule
  When you define the dispensation schedule, you choose the visits in which kits are dispensed, the quantity to dispense, and other details. Kits can contain either investigational products or devices. This procedure also applies to rollover studies.

Define the kits for investigational products

When you create kit types, you specify details about the kits, including storage details and whether doses are calculated based on subjects' answers questions. This procedure applies for defining kit types in a rollover study, as well.

If your **study has both a blinded and open-label period**, you must create separate kit types for the blinded and open-label periods, so the kit type descriptions must be visible to blinded users during the open-label period. If the kit type descriptions don't need to be visible, you can use blinded kit types during the open-label period and need to create only blinded kit types.

If titration is part of your protocol, you might need to create more kit types than you expect.

Here's the rule: you can combine kit types for an up titration or down titration, but only if they're different kit types. In other words, you can't dispense two or more kits of the same type when subjects titrate up or down. Let's say a subject starts at 5 mg and can titrate up to 10 mg. You

can create two kit types, 5 mg and 10 mg, and dispense each kit for the appropriate dose. You cannot, however, dispense two 5 mg for the 10 mg dose.

For more information on kit types and their restrictions, see Serialized and non-serialized inventory.

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

Video

To create kits for the investigational product:

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. Click **Create Kit Type** and then click **Investigational Product**.
5. Fill in the following fields:

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

Field	Description
Item Type	Choose one of the following: • **Serialized**: If the kit should be individually tracked. **Item Type** *is set to* **Serialized** *by default.* • **Non-Serialized**: If the kit should be grouped and not tracked. ***Note**: Because non-serialized kits are not distributed individually or assigned a kit number to be tracked, all non-serialized inventory displays as lot numbers.*
Calculating Doses	Choose **Yes** if you need to define calculations for this kit type based on subjects' answers to one or more questions. Choose **No** if calculations aren't required for dispensation.
Distribution Settings	***Note**: When you select **Serialized**, the **Distribution Settings** field is automatically set to Blinded. When you select **Non-Serialized**, the **Distribution Settings** field is automatically switched to Unblinded. Moreover, as a study designer, you only have the option of choosing between Unblinded and Unblinded Pharmacist for a non-serialized kit.* • If blinded users should never see the kit type description, choose **Blinded**. • If blinded users should always see the kit type description, choose **Unblinded**. • If blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types, choose **Unblinded Pharmacist**. You typically choose this option for kit types that contain an investigational product that should be prepared by a pharmacist or an unblinded site user.
Kit Type ID	Enter an identifier for the kit, such as A.

Field	Description
Description	Enter the name of the product. 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.
Minimum Units to Ship	Enter the minimum number of kits to include in each shipment to meet packaging requirements. For example, for a box of 6 individually labeled vials, the value is 6.
Single Unit Dose	Specify how one unit in the kit is measured, both its value (such as 10) and its measurement (such as mg). The Single Unit Dose value should correspond to the minimum dose of the product. ***Note**: When you multiply the Single Unit Dose value by the Units Per Kit value (described below), **the answer must match the total value of the kit**. For instance, if a kit contains 50 mg of a product and has 10 pills, the Single Unit Dose is 5 mg (50 mg / 10).*
Units Per Kit	Enter the number of units in the kit, such as the number of pills in a bottle.
Hazardous Materials	Specify whether or not the kit contains hazardous materials or materials that may pose any potential risks.
Controlled Substance	Specify whether or not the kit contains any controlled or regulated substances.

6. Click **Add**.

Adding kits to your study is a multi-step process. After defining the kit types, you must:

- Define the dispensation schedule.
- Upload or generate a kit list in Testing mode or Production or Training mode. See Generate or upload a kit list .
  A kit list assigns unique numbers to every kit that will be dispensed. After you create a kit list, sponsor and depot users can start managing kits individually.

Related Topics

- Kit and dispensation FAQs (for study designers)
- Update a kit type during the study conduct period
- Import a pooled kit type
  After you or another library user create the pooled kit type, approve it in a library study, and then publish it, you can import that kit type into a Production study.

Define kits with calculated doses

When you create kit types for the investigational product, you can choose whether calculated doses should be included or not, along with other storage details.

If your **study has both a blinded and open-label period**, you must create separate kit types for the blinded and open-label periods, so the kit type descriptions must be visible to blinded users during the open-label period. If the kit type descriptions don't need to be visible, you can use blinded kit types during the open-label period and need to create only blinded kit types.

For more information on kit types and their restrictions, see Serialized and non-serialized inventory.

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

Video

If you don't want to create a kit with calculated doses, follow the simplified procedure. For step-by-step instructions, see Define the kits for investigational products.

To create kits with calculated doses:

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. Click **Create Kit Type** and then click **Investigational Product**.
5. For **Calculating Doses**, choose **Yes** to define calculations for this kit type based on subjects' answers to one or more questions.
6. Fill in the remaining fields and click **Next**.

Field	Description
Distribution Settings	*When you select* **Serialized***, the* **Distribution Settings** *field is automatically set to Blinded. When you select* **Non-Serialized***, the* **Distribution Settings** *field is automatically switched to Unblinded. Moreover, as a study designer, you only have the option of choosing between Unblinded and Unblinded Pharmacist for a non-serialized kit.* • If blinded users should never see the kit type description, choose **Blinded**. • If blinded users should always see the kit type description, choose **Unblinded**. • If blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types, choose **Unblinded Pharmacist**. You typically choose this option for kit types that contain an investigational product that should be prepared by a pharmacist or an unblinded site user.

Field	Description
Item Type	Choose one of the following: • **Serialized**: If the kit should be individually tracked. **Item Type** *is set to* **Serialized** *by default.* • **Non-Serialized**: If the kit should be grouped and not tracked. *Because non-serialized kits are not distributed individually or assigned a kit number to be tracked, all non-serialized inventory displays as lot numbers.*
Kit Type ID	Enter an identifier for the kit, such as A.
Description	Enter the name of the product. 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.
Minimum Units to Ship	Enter the minimum number of kits to include in each shipment to meet packaging requirements. For example, for a box of 6 individually labeled vials, the value is 6.
Single Unit Dose	Specify how one unit in the kit is measured, both its value (such as 10) and its measurement (such as mg). The Single Unit Dose value should correspond to the minimum dose of the product. *When you multiply the Single Unit Dose value by the Units Per Kit value (described below),* ***the answer must match the total value of the kit****. For instance, if a kit contains 50 mg of a product and has 10 pills, the Single Unit Dose is 5 mg (50 mg / 10).*
Units Per Kit	Enter the number of units in the kit, such as the number of pills in a bottle.
Hazardous Materials	Specify whether or not the kit contains hazardous materials or materials that may pose any potential risks.
Controlled Substance	Specify whether or not the kit contains any controlled or regulated substances.

7. Click the edit icon ( ) to the right of Calculated Dose 1, and specify a name for the calculated dose.

   If you create multiple calculated doses for a kit type, make sure you use names that help you distinguish them.

8. Fill in the fields and click **Finish**.

Field	Description
Form Question for Calculated Doses	• From the drop-down on the left, select the form containing the question that is used to calculate the appropriate dose for each subject. • From the drop-down on the right, select a question. The answer to the question is used to calculate the appropriate dose. Only required Number questions are listed.
Visit Where Form is Collected	• From the drop-down on the left, select the type of visit that contains the question for the dosing calculation. If the question is asked in multiple visits and you want the calculation to use the subject's answer from the visit that they're currently in, choose **Current Visit**. • From the drop-down on the right, select the visit in which the question that is used to calculate the appropriate dose is asked.
Precision for Each Dose	Choose the number of places after the decimal point that each dose should be calculated in. For example, choose **1** if the calculation should round each dose to the nearest whole number Choose **1.0** to round each dose to one number after the decimal and so on.
Round Up For	Determine how rounding is performed to reach the dose precision that you specified. For example, if the precision is 1, and the dose calculation is 2.483, should that number be rounded up to 3 or down to 2? Choose **.4** if all numbers above .4 round up to the nearest whole number.
Dosing Frequency	Determine how many doses the subject must consume: • **Once**: 1 dose per visit. • **QD**: 1 dose per day. • **BID**: 2 doses per day. • **TID**: 3 doses per day. • **QID**: 4 doses per day. • **Q3**: 8 doses per day consumed at 3-hour intervals. • **Q4**: 6 doses per day consumed at 4-hour intervals. • **Q8**: 3 doses per day consumed at 8-hour intervals. • **Q12**: 2 doses per day consumed at 12-hour intervals. • **Q24**: 1 dose per day consumed at the same time every day. • **Bedtime**: 1 dose per day consumed just before bed. • **With meals**: 3 doses per day consumed at mealtime. • **With meals and at bedtime**: 4 doses per day consumed at mealtime and just before bed.

Field	Description
Use Leftover Units in Next Dose	Select **Yes** if any units remaining after a dosing round will be consumed during the next dosing round. This option minimizes waste; for example, if a subject consumes only half the pills in a bottle during one dosing round, the calculations assume that the subject will consume the remaining pills in the next dosing round. Select **No** if you want the calculation to provide a new kit to each subject in every dosing round.
Kit Measurement	Enter the total numeric value for the product in the kit. For example, if a bottle contains 750 mg of pills, enter **750**. The Measurement unit that you specified on the previous page of the wizard, such as mg, is a read-only value below the entry field.
Subject Measurement	Enter the value that, along with the answer for the subject and the value of a single unit, determines the dose. For instance, if a unit is 10 mg and a subject weighs 150 lb, and you enter 50 lb, the dosing calculation divides the subject answer by the value you enter here and then multiplies that value by the measurement of a single kit (that is, 150 lb divided by 50 lb is 3, and 3 times 10 mg is 30 mg, so the subject's dose is 30 mg). The unit from the kit type appears as a read-only value below the entry field.

9. To create another calculated dose on the kit type, click **the plus sign** in the upper right.

If you make a change that breaks the calculated dose (for instance, if you delete a question that is used in a calculated dose), the icon for the calculated dose on the kit type turns red (). If the study hasn't been approved yet, open the kit type and locate the field outlined in red, and then make the appropriate update. For details about what to do if the study has already entered the study conduct period, see Update a form during the study conduct period. Adding kits to your study is a multi-step process. After defining the kit types, you must:

- Define the dispensation schedule.
- Upload or generate a kit list in Testing mode or Production or Training mode. See Generate or upload a kit list.
  A kit list assigns unique numbers to every kit that will be dispensed. After you create a kit list, sponsor and depot users can start managing kits individually.

Related Topics

- Kit and dispensation FAQs (for study designers)
- Update a kit type during the study conduct period
- Import a pooled kit type
  After you or another library user create the pooled kit type, approve it in a library study, and then publish it, you can import that kit type into a Production study.

Define the kits for devices

Create one kit type for each type of device that is dispensed. Devices might include scales or blood pressure monitors, for example. If the study doesn't dispense devices, you can skip this step.

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

Video

If investigational and other drug products are dispensed during the study, create kit types for each drug product.

To create a kit type device:

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. Click **Create Kit Type** and click **Device**.
5. Fill in the remaining fields and click **Add**.

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

Field	Description
Device Type	Choose the type of device from the drop-down. This value is visible to blinded users.
Device Connection	Choose the type of IoT (Internet of Things) connection option for the device. If you're not sure what to select, contact the vendor of the device. • **Cloud to Cloud**: For a device that connects to the Oracle mHealth Connector Cloud Service via the device vendor's cloud service. When a site user dispenses a device with a Cloud to Cloud (C2C) connection, the site user must enter Vendor Code to register and activate the device. • **Device to Cloud**: For a device that connects directly to the Oracle mHealth Connector Cloud Service. When a site user dispenses a device with a Device to Cloud (D2C) connection, an access code and password from Oracle mHealth Connector are displayed to the site user. The site user must enter these values into the device for the device so they can register and activate it. ***Note**: You can dispense only one Device to Cloud device to each subject in a study.* • **No Connection**: For a device that doesn't connect to the Oracle mHealth Connector Cloud Service.

Field	Description
Distribution Settings	***Note**: This field has unblinding consequences. Make sure you set it correctly.* • If blinded users should never see the kit type description, choose **Blinded**. • If blinded users should always see the kit type description, choose **Unblinded**.
Kit Type ID	Enter an identifier for the device, such as A.
Description	Enter the name of the device. If the kit type is unblinded, make sure the description is appropriate for blinded users.
Storage Temperature	Choose the storage temperature requirements for the devices (ambient, refrigerated, or frozen). If you're not sure, work with the clinical supply manager.
Minimum Units to Ship	Enter the minimum number of devices to include in each shipment to meet packaging requirements. For example, for a box of 6 individually labeled scales, the value is 6.

Adding kits to your study is a multi-step process. After defining the kit types, you must:

- Define the dispensation schedule.
- Upload or generate a kit list in Testing mode or Production or Training mode. See Generate or upload a kit list.
  A kit list assigns unique numbers to every kit that will be dispensed. After you create a kit list, sponsor and depot users can start managing kits individually.

Related Topics

- Kit and dispensation FAQs (for study designers)
- Update a kit type during the study conduct period

Define kits for titrations

When subjects can titrate, you must define the titration rule by creating titrations. Create one titration for each treatment arm. Every kit type in the titration must contain the same product and should have the same distribution status (either blinded or unblinded). This procedure can also apply to rollover studies.

You must first create all required kit types for a study. For step-by-step instructions, see Define the kits for the investigational product.

If subjects titrate based on a predefined schedule, don't perform these steps. Instead, you can choose the appropriate kits when you define the dispensation schedule by choosing the appropriate kits for each visit. For step-by-step instructions, see Define the dispensation schedule.

To define how subjects titrate:

Task 1 Start creating the kit type titration

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.

3. Click the **Kits** tab.
4. Click **Create Titration**.

> **Tip:**
>
> If the button is grayed out, that means that you haven't created any kit types that can be titrated.

Task 2 Complete fields in the Titrations section

1. On the Create Titration dialog, on the Titration page, enter a title for your titration.

> **Tip:**
>
> If applicable, consider including the treatment arm and dose levelto ensure that you associate the titration with the correct treatment arm later.

2. Complete the table with all of the required fields:

> **Caution:**
>
> For each possible start dose, you must have a titration definition included on a separate row. If you don't define at least one row for each kit type or dose that subjects can titrate, site users won't be able to dispense these kits.
>
> Also, you must specify a value for every cell in every row of the table, even when a lower or higher dose isn't available. This means that you must have a row for each kit type (or dose when using calculated doses), and its respective up, down and maintain titration kits defined.

Field	Description
Title of Dose Level	Type a name that corresponds with a kit type titration's concentration. This label is optional but might be useful for blinded kits used in kit type titrations, so site users know if subjects are on a low, medium or high dose of the investigational product without unblinding the study.
Start	Click **+ Add Kit Type** for each kit that you want to include in a titration. If the kit type has calculated doses, then the system displays a right arrow so you can select a calculated dose.

Field	Description
Down	Click **+ Add Kit Type**, and choose the kit type that subjects should receive when they want to titrate down. If the kit type has calculated doses, then the system displays a right arrow so you can select a calculated dose. ***Tip***: • *If there isn't a lower dose that subjects can move to, just select the same kit type that appears in the Start column to the left.* • *You can combine kit types for a down titration, but only if they're different kit types. In other words, you can't dispense two or more kits of the same type when subjects titrate.*
Maintain	Click **+Add Kit Type**, and choose the kit type that subjects should receive when they want to maintain their dose. If the kit type has calculated doses, then the system displays a right arrow so you can select a calculated dose.
Up	Click **+ Add Kit Type** and choose the kit type that subjects should receive when they want to titrate up. If the kit type has calculated doses, then the system displays a right arrow so you can select a calculated dose. ***Tip***: • *If there isn't a higher dose that subjects can move to, just select the same kit type that appears in the Start column to the left.* • *You can combine kit types for an up titration, but only if they're different kit types. In other words, you can't dispense two or more kits of the same type when subjects titrate.*

3. To reorder the rows in the table, such as to better show the progression through the study, click the three vertical dots on the left of a row, and drag the row up or down.
4. To add additional rows to the table (for instance, if you added a kit type after you created the kit type titration), click the plus sign **(+)** in the upper right, and specify values for each cell.
5. When you complete titration definitions for every kit type or dose that subjects can titrate, click **Next**.

Task 3 Complete fields in the Settings section

1. On the Create Titration dialog, on the Settings page, complete all of the required fields:

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

a. On the Maximum Dose Changes section, choose how you want to define restrictions:
   - Choose **Total** to restrict the total number titrations.
   - Choose **Up and Down** to restrict up titrations and down titrations separately.

b. Complete the table under Maximum Dose Changes section:

> **Tip:**
>
> You can leave any of these fields empty if you don't want to limit dose changes in any particular way.

Field	Description
Maximum Dose Changes	This column displays either 1 or 2 fields, depending on how you chose to define restrictions in previous step. • If you chose to restrict the **Total** number of titrations: – **Total:** enter a number to limit maximum dose changes. • If you chose to restrict **Up and Down** titrations separetely: – **Up Titration Limit:** enter a number to limit maximum dose changes to a higher dose. – **Down Titration Limit:** enter a number to limit maximum dose changes to a lower dose.

Field	Description
Unscheduled Dose Changes	This column displays either 1 or 2 fields, depending on how you chose to define restrictions in previous step. • If you chose to restrict the **Total** number of titrations: – **Total:** enter a number to limit the total number of times a subject can titrate during unscheduled visits throughout a study. • If you chose to restrict **Up and Down** titrations separetely: – **Up Titration Limit:** enter a number to limit the total number of times a subject can titrate up during unscheduled visits throughout a study. – **Down Titration Limit:** enter a number to limit the total number of times a subject can titrate down during unscheduled visits throughout a study.

Field	Description
Minimum Time Between Dose Changes	For the **Up Titration** and **Down Titration** fields, enter a number in the box for the minimum time that must pass between up or down titrations respectively. Then select a unit of time: • **Days** • **Hours** ***Tip**: The Days measurement is based on calendar days, not 24-hour increments. If your protocol has strict requirements on the time that must pass between titrations, consider choosing Hours instead. For instance, you can specify 48 hours if 2 whole days must pass between titrations.* If you enter a value in any of the fields in this column, a check box to **Set Exception** appears. Select the check box to enter an extended time limit between changes from a specific starting dose to a specific ending dose. For instance, you can configure this setting when you want to allow a shorter time between titration of smaller doses, for example 5 to 10 mg, but enter an extended wait between titration to the highest dose, 10 to 15 mg. In this scenario, the minimum time between titration of the smaller doses, 5 to 10 mg, is configured as described in this table, and the extended wait will be defined as an exception having the highest dose of 15 mg as Ending Dose Level. This would prevent the subject from going too quickly to the highest dose. Exceptions are configured as part of Task 4, Set exceptions to the titration restrictions.

c. On the Highest Dose section, specify wether to **Dispense When on Highest Dose and Site Wants Higher Dose** or not:

   - Choose **Yes** to keep a subject on their current dose level when the subject is already on the highest dose and the site asks to titrate up.
   - Choose **No** to prevent dispensation when the subject is already on the highest dose and the site asks to titrate up. The subject remains in the study, and if subject decides to maintain their current dose, dispensation can still occur.

d. Enter a **Message for Site Users** to display at dispensation when an up titration request occurs and the subject is already on the highest dose.

> **Note:**
>
> This field is required only when you set **Dispense When on Highest Dose and Site Wants Higher Dose** to **No** because dispensation isn't allowed. You can use this to inform site users of the possible next steps, but consider the blinding status of the kit type titration when determining the message to show.

e. On the Lowest Dose section, specify wether to **Dispense When on Lowest Dose and Site Wants Lower Dose** or not:

- Choose **Yes** to keep a subject on their current dose level when the subject is already on the lowest dose and the site asks to titrate down.
- Choose **No** to prevent dispensation when the subject is already on the lowest dose and the site asks to titrate down. The subject remains in the study, and if subject decides to maintain their current dose, dispensation can still occur.

f. Enter a **Message for Site Users** to display at dispensation when a down titration request occurs and the subject is already on the lowest dose.

> **Note:**
>
> This field is required only when you set **Dispense When on Lowest Dose and Site Wants Lower Dose** to **No** because dispensation isn't allowed. You can use this to inform site users of the possible next steps, but consider the blinding status of the kit type titration when determining the message to show.

2. Depending on how you configured these settings:
   - Click **Finish** to save your titration definition.
   - If you activated the checbox to **Set Exception** in the Minimum Time Between Dose Changes, click **Next** to continue.

Task 4 Set exceptions to the titration restrictions

> **Note:**
>
> This step is only required if, in a previous step, within Minimum Time Between Dose Changes, you chose to set exceptions to the standard time for either up titration, down titration or both.

1. **If you chose to set up titration exceptions:** On the Create Titration dialog, complete the table in the Up Titration Exceptions page:

   a. In the Starting Dose Level column, click **+ Add Dose Level** and choose a kit type representing the starting dose for this titration.

   b. In the Ending Dose Level column, click **+ Add Dose Level** and choose a kit type representing the ending dose for this titration.

c. In the Minimum Time Between Dose Change column, enter a number in the box for the minimum time that must pass before the subject can titrate from the selected starting dose to the selected ending dose. Then select a unit of time:

- **Days**
- **Hours**

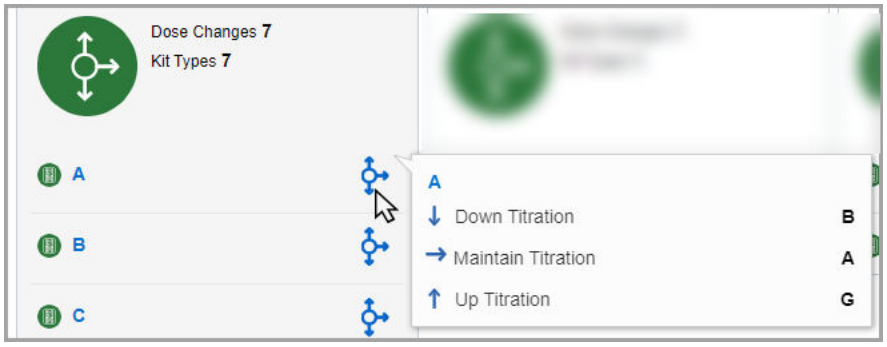
> **Note:**
>
> In the up-right corner of the screen, you can see the default minimum time between dose chaanges as previously configured in the Settings page.

d. To add another exception, click the plus sign **(+)** next to the Default Minimum label and repeat the previous steps.

2. Depending on the Titration settings:
   - Click **Finish** to save your titration definition and exceptions.
   - Click **Next** to continue with Down Titration Exceptions.
3. **If you chose to set down titration exceptions:** On the Create Titration dialog, complete the table in the Down Titration Exceptions page as described in step 1.
4. Click **Finish** to save your titration definition and exceptions.

Your titration then appears among your kits in the **Kits** tab within **Study Supplies**. To view details about the allowed titrations for a kit type, hover over the titration icon to the right of the given kit type in the titration block as in the image below.

Figure 10-1 Doses in a kit type titration



Next up, you must add the titration to the visit schedule and decide when subjects can titrate. For step-by-step instructions, see Specify when subjects can titrate.

Related Topics

- Kit and dispensation FAQs (for study designers)
- Update a kit type during the study conduct period
- Can I include Unblinded Pharmacist kits in a kit type titration?
  Yes, you can. However, you need to be very careful. Combining regular kit types with kits that can only be dispensed by a pharmacist or unblinded site user, in a kit type titration may, result in the potential unblinding of kits to blinded site users.

- What if subjects can titrate some kits and not titrate others?
  It's not a problem at all. The workflow is exactly what you expect.
- Import a pooled kit type
  After you or another library user create the pooled kit type, approve it in a library study, and then publish it, you can import that kit type into a Production study.

Import a pooled kit type

After you or another library user create the pooled kit type, approve it in a library study, and then publish it, you can import that kit type into a Production study.

Before you begin, consider the following:

- Learn more about the specifics and limitations 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.

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. Click **Import Kit Type**.
5. On the Import Kit Type from Library section, locate the kit type that you want to import.
6. For the kit object that you want to import, click **Import**.
7. On the Import Kit Type dialog, fill-in the following fields:

Field or setting	Description
Kit ID	Enter an identifier for the kit, such as A.
Description	This field displays the description that was included when the pooked kit object was created in the library study. You can choose to modify the text in this field.
Distribution Settings	***Note**: This field has unblinding consequences. Make sure you set it correctly.* • If blinded users should never see the kit type description, choose **Blinded**. • If blinded users should always see the kit type description, choose **Unblinded**. • If blinded users should never see these kits at all and only pharmacists or unblinded site users can dispense these kit types, choose **Unblinded Pharmacist**. You typically choose this option for kit types that contain an investigational product that should be prepared by a pharmacist or an unblinded site user.
Type	This field displays the packaging that was specified for the pooled kit object when it was created in a library study You can choose a different option.

Field or setting	Description
Storage Temperature	This field displays the storage temperature requirement specified when the pooled kit object was created in the library study. You can choose to modify the storage temperature requirements. If you're not sure, work with the clinical supply manager.
Calculating Dose	Turn this toggle () on if you want the pooled kit to include calculated doses.
Single Unit Dose	Specify how one unit in the kit is measured, both its value (such as 10) and its measurement (such as mg). The Single Unit Dose value should correspond to the minimum dose of the product. ***Note**: When you multiply the Single Unit Dose value by the Units Per Kit value (described below), **the answer must match the total value of the kit**. For instance, if a kit contains 50 mg of a product and has 10 pills, the Single Unit Dose is 5 mg (50 mg / 10).*
Measurement	Specify the unit for a single fose. For example, enter ml if a single dose is 10 ml.
Unit Per Kit	This field displays the unit per kit specified when the pooled kit object was created in the library study. You can choose to enter a different value.
Minimum Kits to Ship	Enter the minimum number of kits to include in each shipment to meet packaging requirements. For example, for a box of 6 individually labeled vials, the value is 6.

8. Depending on whether you chose to include calculated doses or not, do one of the following:

   - If you didn't turn the Calculated Dose toggle () on, click **Import**.
   - If you turned the Calculated Dose toggle () on, click **Next**.

9. If you decided to include calculated doses, fill-in the fields, and click **Import**.

   For more information on how to fill-in the fields, see Define kits with calculated doses.

Specify when subjects can titrate

Perform this task only if the protocol allows subjects to titrate based on input from a clinician at the site. This procedure also applies to rollover studies.

You can assign a kit type titration to an unscheduled visit the same way that you would do it for a regular kit.

You can't drag a kit type titration to the first dispensation visit. You must dispense without titration for the first dispensation visit, and then you can allow titration starting at the second or later dispensation visit. Additionally, you can't drag the kit type titration to the randomization visit, the study completion visit, the withdrawal visit, or a scheduled visit that hasn't been scheduled yet.

To perform this task, you must first create kit type titrations that determine how subjects can change dose levels and define the dispensation schedule. For step-by-step instructions, see Define how subjects titrate and Define the dispensation schedule.

To specify when subjects can titrate:

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. On the Visits & Events pane, locate the second dispensation visit.
5. Drag a kit type titration to the second dispensation visit (even if subjects aren't allowed to titrate during that visit).
6. Complete the fields on the Add Titration to Visit Schedule dialog and click **Next**.

Field	Description
Select Treatment Arm	In the field in the upper right, choose the treatment arm(s) that the dose titration applies to. ***Note**: Choosing the **All Subjects** option for an unscheduled visit won't allow site users to dispense kit type titrations to subjects who aren't randomized.*
Dispense column	Specify when subjects are allowed to titrate. Only visits in which subjects are allowed to titrate appear in the list. • To allow subjects to titrate in a visit, select both the **Dispense** checkbox to the left of the visit and the **Allow Titration** checkbox at the end of the row. • To prevent subjects from titrating in a visit, select the **Dispense** checkbox to the left of the visit and leave **Allow Titration** deselected. If titration is allowed in the future as a result of a protocol amendment, this workflow will make your future changes easier.
DND (Days) column	Enter the minimum number of days before the kit's expiration date that the kit cannot be dispensed to a subject. For example, if the kit has enough product for 30 days, and the patient can come in up to 7 days after the scheduled visit, the DND must be at least 37. Want more help with this field?
Dispense Outside Window column	**Check** this column if kits can be dispensed outside the visit window. Site users are notified that a visit is out of window but can still dispense the kits. Leave **Unchecked** to prevent site users from dispensing to subjects who come in outside the visit window. For an unscheduled visit, you don't see this column.
Allow Titration column	Instructions on how to complete cells in the column can be found on the Dispense column row, in this table.

7. Complete the remaining pages in the wizard and click **Next**. One page appears for each kit type that is dispensed in the kit type titration.
    - In the **Quantity** field, enter the number of rounds of treatment to dispense in the visit. When determining this value, consider the amount of time that will pass before the next dispensation visit and the amount of time that each dispensation visit supplies for. For instance, consider a treatment arm that dispenses 1 bottle of Kit A and 1 bottle of Kit B, and each bottle lasts 1 week. Subjects come in for dispensation visits during Week 1, Week 2, and Week 4. For Week 1, you need to supply the subject with 2 bottles, but the 2 bottles constitute 1 round of treatment, so you should enter 1. For week 2, you need to supply the subject with 4 bottles, which are 2 rounds of treatment, so you should enter 2.
8. Click **Finish**.

    An icon appears on every visit in which subjects can titrate up or down.

Tips:

- To check or change the work you did on a visit, click the visit in Visits & Events.
- To see details about dose changes, point to the kit type titration that's in the box for a treatment arm.
- To edit the dispensation schedule for individual kit types, click the **plus sign (+)** for the treatment arm.
- To edit the dispensation schedule for kit type titrations, click the edit icon on the treatment arm.
  After a kit type titration has been added to a visit, you can edit only the name and settings for a kit type titration, and you can't delete the kit type titration. The same rules apply after a study has been approved.
- If a study has been approved, you can update the name and settings for a kit type titration
- To remove a kit type titration from a treatment arm, click the trash can for the kit type titration.

Related Topics

- Kit and dispensation FAQs (for study designers)
- Update a kit type during the study conduct period
- Can I include Unblinded Pharmacist kits in a kit type titration?
  Yes, you can. However, you need to be very careful. Combining regular kit types with kits that can only be dispensed by a pharmacist or unblinded site user, in a kit type titration may, result in the potential unblinding of kits to blinded site users.
- What if subjects can titrate some kits and not titrate others?
  It's not a problem at all. The workflow is exactly what you expect.

Define the dispensation schedule

When you define the dispensation schedule, you choose the visits in which kits are dispensed, the quantity to dispense, and other details. Kits can contain either investigational products or devices. This procedure also applies to rollover studies.

Learn more about kits and dispensation in the FAQs.

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

Video

Only visits that occur during or after randomization will be available if you associated the kit type with one or more treatment arms.

1. Access the Draft version of a study as described in Open a study's design.
2. Click **Study Supplies**.
3. Click the **Kits** tab.
4. On the Visits & Events pane, locate the first dispensation event defined in the study protocol.
5. Drag the kit type to the visit. If the study allows titration, you should drag the kit type that subjects start on for a given treatment arm.
6. Click in the **Select Treatment Arm** field, and select an option from the drop-down:
   - For visits occuring before randomization, select **All Subjects**.
   - For visits occuring during or after randomization, select one or more treatment arms to associate the kit type with, or select **All Treatment Arms**.
   - For unscheduled visits, select any applicable option.
7. Select the appropriate visits:
   - If the study doesn't allow titration, select all other visits in which the kit must be dispensed. You can use the column-level checkbox to select all visits.
   - If the study allows titration, select no other visits. You'll associate the appropriate kit types with future dispensation visits when you Define kits for titrations.
8. Fill in the fields, and click **Add**.

   To view tips for completing a field, click into the field.

Field	Description
Quantity	Enter the number of kits to dispense in the visit.
DND (Days)	Enter the minimum number of days before the kit's expiration date that the kit cannot be dispensed to a subject. For example, if the kit has enough product for 30 days, and the patient can come in up to 7 days after the scheduled visit, the DND must be at least 37.
Dispense Outside Window	Choose Yes if kits can be dispensed outside the visit window. Choose No to prevent site users from dispensing to subjects who come in outside the visit window.
Calculated Dose	(Appears only for investigational product kit types): If the study determines doses based calculations, select the calculated dose that determines the dispensation requirements for the visit. You can select a different calculated dose for each visit. The question that is used to calculate the dose must be asked during or before the visit. For example, if Dosing Calculation 1 is based on weight, and you collect weight in Week 2, you can't select Dosing Calculation 1 for Week 1. If the study doesn't use calculated doses, leave the field blank.

An icon appears on the visit, indicating that dispensation occurs during the visit. A pill icon appears for an investigational product kit type, and a device icon appears for a device kit type.

Tips:

- To check the work you did on a visit, add and reorder more forms in a visit, or edit a visit ID or type, click the visit in Visits & Events.
  - To see dispensation details, click the pencil button on a treatment arm, and select a kit type from the drop-down that appears.
  - To remove the association between a kit type and visit, click the trash can for the kit type.
  - To change the visit type or ID, click the pencil for the corresponding fields in the upper-left corner of the visit flyout.
- You can't dispense kits in a withdrawal or completion visit.

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Updates during the study conduct period

After you finish designing the study, you must make a study version available in Testing mode. If you plan on making any updates to the Testing version, you must create a new Draft version of the study.

Additionally, you can perform other study design updates during the study conduct period.

> **Note:**
>
> Are you a study manager who must make a study live or verify a study in Testing mode? Tasks presented in this chapter will be helpful, but you can also see more in the *Sponsor and CRO User Guide*. Check the following sub-chapters:
>
> - Make a study live
> - Verify a study in Testing mode

About Advanced Study Versioning (ASV)

You can update a form retrospectively in a live study with Advanced Study Versioning (ASV), without going through the entire versioning process. However, there are some form updates that are not allowed after the study is approved.

To update a form using ASV, as you edit a question in a form in Draft mode, you must select a study version to apply your changes to that specific study version. Locate the **Apply Changes to Study Version** field in the Details section on the sidebar, and select a study version from the drop-down.

By selecting an older version, your changes will apply to that selected version and the subsequent ones. However, for your changes to become effective on the applicable study versions, the new study version (in which you made the changes) must follow the normal versioning process. This means that, as soon as the new study version reaches the Testing container, changes will go live in Testing mode for all applicable study versions and apply to all testing sites to which those study versions are assigned. Similarly, as the new study version reaches the Approved container, changes will go live in Production mode for the applicable study versions and apply to all sites assigned with the given study versions.

Updating a form through ASV means changes apply to all subjects, including past visits in which site users have already started or completed the given form. This means, in case of a new or modified question, the form becomes incomplete and the question will be unanswered.

> **Tip:**
>
> To make sure all missing data gets collected, we recommend that you create a rule that opens a query when incomplete data is detected in a form. For step-by-step instructions, see Create a rule for an automated query. You may also refer to Item completion check for rule examples with this purpose.

Changes you can apply to a live study with ASV

Refer to Update forms and visit schedule during the study conduct period for step-by step instructions on the different changes you can make using ASV.

All the changes allowed with ASV can also be applied through the usual study versioning process. However, using ASV can reduce time an efforts to apply them. Here are some cases when you can apply ASV changes, without having to change the study version for every site that is impacted by the change:

Change	Additional information
Add a new question to a form.	See Update a form during the study conduct period. For more information on the different questions you can create, see Question types and settings.
Reorder questions in a form.	See Update a form during the study conduct period. To reorder questions in a form, open the form to edit it, and drag and drop each question to its new position.
Modify non-label questions in a tabular form (repeating form, lab form, two-section form).	See Update a form during the study conduct period. For more information about label questions, see Create a label (repeating table only). For more information about tabular forms, see Create a form with two sections, Create lab forms, or Create a repeating form.
Change a question's label to correct spelling errors.	See Update a form during the study conduct period. When updating a form, select a question to update its label.
Add a new code list value or answer option for a choice-type question (Not applicable for Label items).	The new values are added at the bottom of the code list. For more information, see Manage a code list for all or one study.
Change the number format for a question.	For more information, see Create a number question.
Modify or add a unit of measure to a question.	This only applies to number and age questions. See Create a number question or Create an age question.
Update the character limit for an item.	This only applies to text questions. See Create a text question.
Update a Date/Time question to allow partial dates or update the minimum answer to remove required components.	For more information, see Create a date/time question.
Change the Advanced Properties for a question.	For more information on the different questiontypes and details about their advanced properties, see Question types and settings.

Change	Additional information
Add a dynamic visit in the schedule of a live study by creating a **Show Visit** rule.	See Add a dynamic visit in the schedule of a live study. For more information about dynamic visits, see Set up a dynamic visit.
Change **Show Question** or **Show Form** rules.	For more information about the **Show Question** rule, see Set up a dynamic question in a form. For more information about the **Show Form** rule, see Set up a dynamic form.
Add a new form to a visit.	The **Apply Change to Version** setting works at the question level. For this reason, to add a new form in a live study version with ASV, you need to select that live study version for all questions in the new form. See Add a new form to a live study version.
Update a question to indicate whether it should be hidden or not and to specify or remove any data classifications.	For more information on how to perform this task, see Define data classifications for a hidden question. Also, consider the following use cases: • If a locked form or question group is completely hidden using ASV (all questions are locked and then hidden), with or without data classification applied, the form will show as the last form in the visit. • If a question in a repeating form or a two-section form is locked, while other questions are not, and then is hidden using ASV, the question will be hidden in the table view but will be visible if the repeating form or when the repeating section row is opened in a new dialog.

Changes you can apply to a live study, but not possible with ASV

You can make any of these changes in your study's design, but even if you select them for ASV, they won't be applied. Instead, you should go through the usual process for updating a study design change where you create a new study version and take it through Testing and Approved.

If you need to apply these changes, the updated Draft study version must be approved and assigned to the impacted sites in the appropriate modes.

The following changes can be made, but won't be applied to a live study version even if the question is selected for ASV:

Change	Additional information
Add or change **Link & Show Form** rules.	For more information, see Set up form associations.
Update Source Data Verification settings for a question.	For more information on how to perform this task, see Configure source data verification settings for a question.
Update **Alert if Outside the Visit Window** configuration in the visit schedule.	For more information, see Define the visit schedule

Change	Additional information
Add new Oracle Central Coding target questions.	You can add new coding target questions using ASV and it would result in the new fields appearing on the forms for all existing and new subjects in Oracle Clinical One Platform. However, for existing subjects for which the given visit was initiated (before the new coding targets were added), the new fields for coded verbatim terms are not populated in Oracle Central Coding. This is because the code map, comprised of the mappings between form questions and the applicable dictionary level, is established and locked for a subject when the visit is initiated. For more information, see Create the coding target fields.

Changes you cannot perform in a live study

Some study design updates may impact your data's accuracy and integrity, so they are not allowed in the application's User Interface (UI). The following study design changes aren't allowed in your study's design:

Change	Additional information
Remove a question or a form that is used in an Approved version of the study.	Deleting a question or form that is used in an Approved version of a study could disrupt your data collection processes or cause errors in your study's design.
Change a question's type.	For example, modify a Text question to turn it into a Date/Time question.
Some changes to date/time questions: • Change the date format. • Change the type (*Date & Time*, *Date only*, or *Time only*). • Update a date/time question that allows partial dates to **not** allow partial dates. • Update the minimum answer to include components that were previously allowed to be unknown.	These types of changes might cause some previously entered dates to become incomplete or invalid. If you try to update a date/time question that is already used in an Approved version of the study, you would see most of these settings are read-only and cannot be changed. You do have the option to change the minimum answer, but you only see options that include all or some of the elements that are already part of the minimum answer currently selected.
Remove or make changes to label items in a repeating form.	This would affect any tabular forms included in your study, as well as lab forms.
Change choice-type questions (drop-down, checkboxes, or radio buttons): • Change a choice-type question's label. • Remove a code list or select a new one for a choice-type question. • Remove or re-order answer options or code list values for choice-type questions.	A code list may be modified from the **Code List** tab at a study level or on the Global Settings page, at a global level. However, these changes won't impact a question currently using that code list and the question answer options will remain unchanged in study design. This is because the applied code list is directly associated to the question and stored with the question. If you make a change to a code list that was already applied to a question in a form, you need to re-add the code list to that question in order to see its changes reflected in the form. However, this workaround is not possible if the question is used in an Approved version of the study.

Manage study versions during the study conduct period

- Create a new Draft study version
  Create a new Draft study version anytime you need to update your study's design.

- Create a new Draft version of a study to update the Testing version
  Create a new Draft version of a study when you need to update a study version that you've already moved to Testing on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.
- Make a study version available in Testing mode
  Make a study version available in Testing mode after you finish configuring the study. After the study version is available in Testing mode, you can create sites and depots, specify subject and supply settings, and create a randomization list and kit list. This procedure also applies to rollover studies.
- Create a new Draft version of a study to update the Approved version
  Create a new Draft version of a study when you need to update a study version that has already been moved to Approved on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.
- Make a study version available in Production and Training modes
  Move a study version to Approved after the study design is finished and configuration is verified to be compliant with the study protocol. Some study design activities aren't allowed after you move a study version to Approved, even if you create a new Draft version of the study.
- Update the study version that is assigned to a site
  Before updating the study version that is assigned to a site, make sure the site has signed off on the new study version, if this process is required, and make sure that regional regulatory requirements are in place. This procedure also applies to rollover studies.
- Archive an Approved version of a study
  Before archiving an Approved version of a study, make sure all sites have been assigned to a new version of the study. This procedure can also apply to rollover studies.

Create a new Draft study version

Create a new Draft study version anytime you need to update your study's design.

> **Note:**
>
> To move a study version from Draft to Testing, Training, or Production, you must be assigned the following study roles and permissions:
>
> - The *Study Designer* study template role (or a custom study design study role) assigned in Study Design mode;
> - The *Study Manager* study template role (or a custom study management study role) that must have the *Move a Study Design to Testing or Production* permission included in the study role. This study role must be assigned in the mode where you want to move the new study version: Testing, Training, or Production.

1. On the Home page, click the Edit icon ( ) on the study you want to edit.
2. In Draft, click **Create Study Version**.

If you already have a Draft version of the study, **Create Study Version** doesn't appear 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.

Related Topics

- Create a new Draft version of a study to update the Testing version
  Create a new Draft version of a study when you need to update a study version that you've already moved to Testing on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.
- Create a new Draft version of a study to update the Approved version
  Create a new Draft version of a study when you need to update a study version that has already been moved to Approved on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.
- Make a study version available in Production and Training modes
  Move a study version to Approved after the study design is finished and configuration is verified to be compliant with the study protocol. Some study design activities aren't allowed after you move a study version to Approved, even if you create a new Draft version of the study.
- Make a study version available in Testing mode
  Make a study version available in Testing mode after you finish configuring the study. After the study version is available in Testing mode, you can create sites and depots, specify subject and supply settings, and create a randomization list and kit list. This procedure also applies to rollover studies.
- Archive an Approved version of a study
  Before archiving an Approved version of a study, make sure all sites have been assigned to a new version of the study. This procedure can also apply to rollover studies.

Create a new Draft version of a study to update the Testing version

Create a new Draft version of a study when you need to update a study version that you've already moved to Testing on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.

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

Video

> **Note:**
>
> To move a study version from Draft to Testing, you must be assigned the following study roles and permissions:
>
> - The *Study Designer* study template role (or a custom study design study role) assigned in Study Design mode;
> - The *Study Manager* study template role (or a custom study management study role) that must have the *Move a Study Design to Testing or Production* permission included in the study role. This study role must be assigned in Testing mode.

To create a new Draft version of a study:

1. On the Home page, click the pencil button () on a study.
2. In Draft, if you don't already have a study version, click **Create Study Version**.

   > **Tip:**
   >
   > 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.

3. Edit the new study version and make your required updates.
4. On the Home page, click **Study Settings** () on the study you want to edit, and select **Open Settings**.
5. On the left, select **Testing Sites** and remove the study version association with all sites in Testing.
6. On the Home page, drag the old study version from Testing to Archived.

   Because you must make changes to the new Draft version, you no longer need the old Testing version.
7. Then drag the new study version from Draft to Testing.
8. Click **Study Settings** () again and select **Open Settings**.
9. On the left, select **Testing Sites** and add the new study version for all sites in Testing
10. 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.

Make a study version available in Testing mode

Make a study version available in Testing mode after you finish configuring the study. After the study version is available in Testing mode, you can create sites and depots, specify subject

and supply settings, and create a randomization list and kit list. This procedure also applies to rollover studies.

Do you need to perform this task for a production or training study? See Make a study version available in Production mode.

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

Video

> **Caution:**
>
> We recommend you don't update a study's ID after you move the study version to the Testing container. Updating the ID might interfere with other features within the application.

> **Note:**
>
> To move a study version from Draft to Testing, you must be assigned the following study roles and permissions:
>
> - The *Study Designer* study template role (or a custom study design study role) assigned in Study Design mode;
> - The *Study Manager* study template role (or a custom study management study role) that must have the *Move a Study Design to Testing or Production* permission included in the study role. This study role must be assigned in Testing mode.

Before you make a study version available in Testing mode, consider the following:

- To make sure you designed the study as you expected, run and review the Study Design report. See the Study Design report.
- You can't move a Testing version of a study back to Draft. If you need to make changes, Create a new Draft version of a study to update the Testing version.
- You can have only one study version in Testing at a time. To move another Draft version of a study to Testing, first move the current Testing version to Approved or Archives. See Make a study available in Production mode or Archive a study version.

To make a study version available in Testing mode:

1. On the Home page, click the Edit icon ( ) on the study you want to edit.
2. Drag the Draft version of the study to Testing.

Create a new Draft version of a study to update the Approved version

Create a new Draft version of a study when you need to update a study version that has already been moved to Approved on the Home page. You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study. This procedure also applies to rollover studies.

Before you create a new draft study version to move to Approved, consider the following:

- You can change the name of the study version, but not the version number.
- Oracle Clinical One Platform allows you to make changes only when they won't create issues for data that might have been collected.
- Consider the implications for subjects who are already in the study before changing visits, particularly if the edits change the visit schedule. For example, don't delete the Screenig visit because all future visits are scheduled from it or use caution when changing the visit window because you could affect the ability of active subjects to get a dispensation.
- If you need to change a visit, we recommend editing an existing visit rather than adding a new one.

> **Note:**
>
> To move a study version from Draft to Approved, you must be assigned the following study roles and permissions:
>
> - The *Study Designer* study template role (or a custom study design study role) assigned in Study Design mode;
> - The *Study Manager* study template role (or a custom study management study role) that must have the *Move a Study Design to Testing or Production* permission included in the study role. This study role must be assigned in Production mode.

Need to perform this task for a study you need to verify? See Create a new Draft version of a study to update the Testing version.

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

Video

1. On the Home page, click the Edit icon ( ) on the study you want to edit.
2. In Draft, click **Create Study Version**.

> **Tip:**
>
> If you already have a Draft version of the study, **Create Study Version** doesn't appear 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.

3. To rename a study version, click the Edit icon on the study ( ). Click the Menu icon ( ) on the study version and select **Rename**.

> **Note:**
>
> For custom JavaScript rules, you must know that only rules in the Approved state will be published once you update a study's version. These rules will run on all subject data, including existing and new data.

Make a study version available in Production and Training modes

Move a study version to Approved after the study design is finished and configuration is verified to be compliant with the study protocol. Some study design activities aren't allowed after you move a study version to Approved, even if you create a new Draft version of the study.

These steps are for Production and Training mode. For step-by-step instructions on how to perform this same task for a study that requires your verification, see Make a study live.

> **WARNING:**
>
> To avoid an interruption in the synchronization of data between Oracle Clinical One Platform and Oracle DMW, each time a new study version is moved to the Approved container, the Oracle DMW metadata must be refreshed before any further changes are made to the study design in Oracle Clinical One Platform. If you perform additional changes to your study before the metadata update is complete in Oracle DMW, then the synchronization of production data could be interrupted.

To move a study version from Draft to Approved or Training, you must be assigned the following study roles and permissions:

- The *Study Designer* study template role (or a custom study design study role) assigned in Study Design mode;
- The *Study Manager* study template role (or a custom study management study role) that must have the *Move a Study Design to Testing or Production* permission included in the study role. This study role must be assigned in both Production and Training mode.

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

Video

1. On the Home page, click the Edit icon ( ) on the study you want make available in Production and Training modes.
2. Drag the Testing version of the study to Approved.
3. Fill in the following fields:

Field	Description
For the first study version that you approve in the study	Enter a title for the study version, and click **Approve**. The study version moves, and its version number does not change.

Field	Description
For the second or higher study version that you approve in the study	Specify the reason for approving a new study version, enter a title for the study version, and click **Approve**. • For a protocol amendment, the first number increases by 1, and the second number resets to 0. For example, 1.2.0.6 changes to 2.0.0.6. • For a revision, such as when you corrected a typo or added a value to a drop-down, the second number increases by 1. For example, 1.2.0.6 changes to 1.3.0.6.

Handling multiple study version updates?

- The study won't be live until you assign a study version to a site and activate each site.
- You can have multiple study versions in Approved.
- You can't move an Approved version of a study back to Testing or Draft. If you need to make changes, see Create a new Draft version of a study to update the Approved version.
- When the study version is no longer in use, you can archive a study version.

Update the study version that is assigned to a site

Before updating the study version that is assigned to a site, make sure the site has signed off on the new study version, if this process is required, and make sure that regional regulatory requirements are in place. 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 **Sites** tab.
3. Update the study version that is assigned to a site for production:
   a. On the left, make sure **Production Sites** is selected.
   b. From the **Study Version** drop-down, select the new study version for the site.

      > **Note:**
      >
      > If a site uses predictive resupply, shipments are created for the site only when a study version is assigned to the site.

   c. In the upper-right corner, click **Apply Settings**.
4. To make the new study version available in Training mode, update the study version that is assigned to a site for training:
   - Select **Training Sites**, and use the previous steps to update the study version that is assigned to a site in the Training mode.

Archive an Approved version of a study

Before archiving an Approved version of a study, make sure all sites have been assigned to a new version of the study. This procedure can also apply 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. Drag the Approved version of the study that is no longer in use to Archived.

Tips:

- We recommend archiving a study version that is no longer in use so that it doesn't get assigned in error to a site.

Update forms and visit schedule during the study conduct period

- Add a new form to a live study version
  You can add new forms to visits in a live study and readily implement changes into multiple study versions.
- Update a form during the study conduct period
  Updates to forms appear for all subjects, including on pages where data was already collected. This procedure also applies to rollover studies.
- Set up a visit that must be inserted into the schedule of a live study version
  To insert a visit into the live study version of a schedule, you must first create that visit and define its specific display details. Afterwards, you must make sure the study version is properly updated to make this visit available to subjects.
- Add a dynamic visit in the schedule of a live study
  You can include a dynamic visit in a live study version.
- Extend the treatment period for subjects during the study conduct period
  To extend the treatment period for subjects, you must insert new visits (and forms, if required) to the study. These procedures also apply to rollover studies.
- I need to correct a multiple choice question in a live form

Add a new form to a live study version

You can add new forms to visits in a live study and readily implement changes into multiple study versions.

> **Note:**
>
> - You can add a new form to a visit that has already been completed by subjects. In order to complete the new form, the site user must return to the visit and fill in the newly added form. To notify the site user about the new form, we recommend that you create a rule that triggers a query when incomplete data is detected in a form. For step-by-step instructions, see Create a rule for an automated query.
> - When adding a form to a visit that's already started for a subject, keep in mind that you won't be able to include a label question, including lab forms, since they can't be advanced study versioned. Also, be careful when applying an Advanced Study Version (ASV) to a form containing label questions - make sure you only apply it to a version where the form first appeared, as applying it to a prior version won't work as expected.

Task 1 Create a new Draft version of a study

1. On the Home page, select the **Edit Study** icon () on the study you want to edit.
2. In Draft, select **Create Study Version**.

> **Tip:**
>
> If you already have a Draft version of the study, **Create Study Version** doesn't appear 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.

Task 2 Create a new form in the Draft version of the study and add it to a visit

1. Create the type of form that is required. For step-by-step instructions, see Forms.
2. For each question in the form, on the right, from the **Apply Changes to Version** drop-down, select the study version to which you want to add the new form.

   The update is applied to the study version you selected and to all study versions that were subsequently created.

> **Tip:**
>
> The **Apply Change to Version** setting works at the question level. For this reason, to add a new form in a live study version with ASV, you need to select that live study version for all questions in the new form.

3. After you add all questions in a form and apply them to the corresponding study version, select **Save**.
4. Add a form to a visit.

Forms appear in order within the subject visit list only when a subject does not have any started visits. If any visits were started or completed in a previous study version before the new forms were created, the forms appear out of order.

Task 3 Make the new study version live

1. Make a study version available in Testing mode.
2. If you added the new form to a visit for which data has already been collected, Create a rule for an automated query that detects missing data and triggers a query for the site user. By creating the rule you ensure the site user returns to the completed visit to fill in the new form. For the custom JavaScript expression to detect missing data in a form see Create a rule for a calculated value.

> **Note:**
>
> Only a user with the Rule designer study role can create a rule.

3. Verify a study.
4. Make a study version available in Production and Training modes. Once the new version is moved to the Approved container, the form updates also become available in the study version you selected from the **Apply Changes to Version** drop-down and to all sites to which that study version is assigned.

Update a form during the study conduct period

Updates to forms appear for all subjects, including on pages where data was already collected. This procedure also applies to rollover studies.

> **Note:**
>
> - Not all form changes may apply to Advance Study Versioning (ASV). To see what types of changes are allowed or not in a live study version, refer to About Advanced Study Versioning (ASV).
> - When you apply ASV to a question on a repeating form with a label question or a two-section form (including lab forms) with a label question, keep in mind that the ASV flag will be applied to all non-label questions on the form. This change is displayed in the the Study Design report and the Annotated Case Forms report, as well.
> - If you want to remove the ASV flag from a specific non-label question, you should remove it from all non-label questions from that form before saving the form.

Task 1 Create a new Draft version of a study
Create a new study version in Draft so you can edit your study's design. For step-by-step instructions, see Create a new Draft study version.

Task 2 Update the Draft version of the study

1. Update the form.
2. To apply the update to an existing live study version, on the right, from the **Apply Change to Version** drop-down select the study version to which you want to apply the changes. The update will apply to the study version you selected and to all study versions that were subsequently created.
3. If you removed a question that was used in one or more calculated doses, impacted kit types need to be redefined. You can't update a kit type after a study version has been approved, so you have to:
   a. Define kits with calculated doses.
   b. Update the dispensation schedule so that the appropriate treatment arm uses the new kit type and calculated dose(s).

Task 3 Make the new study version live
Tasks include:

1. Make a study version available in Testing mode.
2. Verify the study.
3. Make a study version available in Production and Training modes. Once the new version is moved to the Approved container, the form updates also become available in the study version you selected from the **Apply Change to Version** drop-down and to all sites to which that study version is assigned.

> **Note:**
>
> If the form you updated was already completed by any of the subjects during the study, the site users must return to that form and answer the questions that you added or modified.
> Also note that when an existing static question, form, or visit that includes data, is changed to a dynamic type, and the determining question is set to be hidden, the new dynamic item will be hidden. If the determining question is updated to the criteria to show the dynamic item, that item appears and the original data is still there.

Related Topics

- I need to correct a multiple choice question in a live form

Set up a visit that must be inserted into the schedule of a live study version

To insert a visit into the live study version of a schedule, you must first create that visit and define its specific display details. Afterwards, you must make sure the study version is properly updated to make this visit available to subjects.

- About inserting a visit
  At any point in time during the study conduct period you can insert a new visit into the schedule.
- Insert a visit
  You have two new options to choose from when modifying the visit schedule during the study conduct period.

About inserting a visit

At any point in time during the study conduct period you can insert a new visit into the schedule.

The option you choose in the **Shown in Timeline** field within the Create Visit dialog determines how visits appear in the study. For more information, see Insert a visit.

Types of visits you can insert into the schedule of a live study version

You cannot insert an adverse event into a live study version. The following table lists which types of visits can be inserted into existing study versions:

Visit Type	Notes
Dispensation	You can assign kit types to an inserted visit.
Non-dispensation	You can insert a visit without any kit types into the schedule of a study version.

Visit Type	Notes
Dynamic visit	On the Create Visit dialog, the **Shown in Timeline** field is displayed after a study version is approved.
Scheduled visit	On the Create Visit, the **Shown in Timeline** field is shown after a study version is approved.
Optional	On the Create Visit, the **Shown in Timeline** field is shown after a a study version is approved.
Last visit of branch	On the Create Visit, the **Shown in Timeline** field is shown after a a study version is approved.
Last visit of cycle branch	On the Create Visit, the **Shown in Timeline** field is shown after a a study version is approved.

Guidelines for assigning kits and randomization to an inserted visit

If you ever need to assign kit types to a visit inserted in the schedule with a past date, here are some notes that you need to consider:

- If a re-randomization has occurred, subjects are assigned kits based on the current treatment arm.
- Be aware that if kit type titrations are part of the study, the dispensation of kits may generate errors in the application.

Insert a visit

You have two new options to choose from when modifying the visit schedule during the study conduct period.

To create a new visit in the schedule during the study conduct period:

1. Access the Draft version of a study as described in Open a study's design.
2. Navigate to the Data Collection page and select the Forms tab.
3. In the visits panel, click **+** and select **Add Visit**.
4. Complete the following fields:

Field	Description
Title	The title of the visit.
ID	The identification code for the visit.
Type	The type of visit that is being scheduled.
Required	Whether or not the visit is required.
Shown in Timeline	How the visit will appear in the study. **Future Only - All Scheduled Visit Types** shows the visit only for subjects who did not progress past this date in the schedule. If this visit is part of a cycle then the visit is added only to future cycles. **Future & Past - All Scheduled Visit Types** shows the visit for all existing subjects in the study, including subjects who have progress past this date in the schedule. If this visit is part of a cycle then the visit is added to all cycles in the study.

5. Click **Save & Add Another** or **Save**.

After creating the visit, you must schedule it and update the study version. For step-by-step instructions, see Extend the treatment period for subjects during the study conduct period.

Related Topics

- About inserting a visit
  At any point in time during the study conduct period you can insert a new visit into the schedule.
- Insert a visit into the visit schedule of a live study
  You have two new options to choose from when modifying the visit schedule during the study conduct period.
- Can multiple study designers edit a study at the same time?

Add a dynamic visit in the schedule of a live study

You can include a dynamic visit in a live study version.

Dynamic visits and their questions can be included in a live study version, too. The steps presented in this task take into account the fact that you choose to either create a new form or edit an existing form to include a question that determines the display of dynamic visit.

Before you create the question that determines the display of a dynamic visit, you must first create and insert in the schedule the visit to dynamically display. For step-by-step instructions, see Insert a visit.

The question used in a Show Visit rule must either be a question with radio buttons or a multiple-choice type of question, but with a Select Exactly or Answer Must Be validation rule defined for it.

To create a dynamically scheduled visit for a live study version:

1. Access the Draft version of a study as described in Open a study's design.
2. Make sure you are on the Data Collection page.
3. Click the Forms tab.
4. Depending on what your next step is, you can:
   - Click **Add Form** to create a new form from scratch.
   - Select an existing form and click **Edit** to work in an existing form.
5. You can then either:
   - Click **Add Question** to create new questions to include in your form.
   - Select an existing question to edit it, if you are working in an existing form.
6. Expand the Details pane and make sure the question has a corresponding reference code and a question hint, if needed.
7. On the Details pane, make sure any other properties are defined for the selected question.
   - To hide a question, you can click the **Hidden** toggle.
   - To make a question read-only, you can click the **Read Only** toggle.

> **Note:**
>
> To include a read-only or hidden question that could determine the display of a dynamic visit, you must make sure that the read-only field will be automatically completed either through integration or a custom rule. Work with your study team to properly set up these types of questions.

8. From the **Apply Change to Study Version** drop-down, select the study version to which you want to apply this either new or updated question.
9. Expand the Rules pane and click **Add Rule**.
10. From the drop-down, select **Show Visit** and fill-in the two fields:
    - **When Selection is**: Select the answer that triggers the display of the dynamic visit.
    - **Show Visit**: Select one or multiple visits that will be displayed when a site user answers this question using the selected answer.
      On the user interface, you only see visits that can be dynamically scheduled.
11. Click **Save** or **Save and Close**.

Next up, you must move the study version you just made this change on into Testing, and then Production. For step-by-step instructions, see Extend the treatment period for subjects during the study conduct period.

Extend the treatment period for subjects during the study conduct period

To extend the treatment period for subjects, you must insert new visits (and forms, if required) to the study. These procedures also apply to rollover studies.

> **Caution:**
>
> Consider the following recommendations when modifying the visit schedule of a live study:
>
> - Do not re-order visits in a schedule that is already running in a live study version. This will not only affect the schedule of your study, but may also interfere with site users' data collection tasks.
> - Do not delete a visit from the schedule of a live study version and then re-create it with the same visit title. Even though the newly created visit has the same title as the one that you deleted, visits will have different system IDs associated with them. This might affect custom JavaScript rules and data collection.

Task 1 Create a new Draft version of a study
Create a new study version in Draft so you can edit your study's design. For step-by-step instructions, see Create a new Draft study version.

Task 2 Update the Draft version of the study

1. Create the visit that you want to include in the new Draft version of the study. For step-by-step instructions, see Visits and schedules.

2. Next up, add forms and schedule the visits. If you plan on assigning kits, you must also define dispensation. For step by step instructions, see the following:
   - Add a form to a visit
   - Define the visit schedule
   - Define the dispensation schedule
3. Make a study version available in Testing mode.
4. If you plan on assigning kits, you must check whether the kit list has enough kit numbers to continue dispensing. If not, generate a kit list or upload a kit list with additional numbers for Testing mode.
   - If you uploaded the original kit list, you must upload a new kit list. Make sure the kit numbers and sequence numbers don't overlap with the original list.
   - If you generated the kit list, you must generate a new kit list. Make sure the kit numbers and sequence numbers don't overlap with the original list.

Task 3 Make the new study version live
Perform the following tasks in the order below:

1. Verify the study.
2. Approve the study version. For more information, see Make a study version available in Production and Training modes.
3. If needed, upload or generate new kit lists for Production and Training modes.
4. Assign the randomization list to the appropriate study version in Production and Training modes. For more information, see Assign a randomization list to a randomization design and study version.
5. Update sites so that they are assigned to the new study version.

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.

Update randomization and kit types definitions during study conduct period

- Drop a treatment arm, add cohorts, or update randomization during the study conduct period
  You can drop a treatment arm, add cohorts, and update randomization during the study conduct period. These procedures also apply to rollover studies.
- Update a kit type during the study conduct period
  Some fields for a kit type are editable, even during the study conduct period. If you need to update a read-only field, you must create a new kit type and use it to replace the kit type with the inaccurate field. These procedures also apply to rollover studies.

- Update the way that subjects titrate during the study conduct period
  Depending on the changes you need to make, you might be able to update the existing kit type titration, or you might need to create a new kit type titration and use it to replace the current kit type titration. These procedures also apply to rollover studies.
- Update a randomization list that ran out of numbers during the study conduct period
  You can upload or generate a new randomization list in an approved version of a study without creating a new version of a study. Consider assigning the new list to the study version before the current list runs out of numbers to avoid randomization errors at sites. This procedure also applies to rollover studies.
- Update a kit list that ran out of numbers during the study conduct period
  You can upload or generate a new kit list in an Approved version of a study. You do not need to create a new version of a study to perform this task. This procedure also applies to rollover studies.

Drop a treatment arm, add cohorts, or update randomization during the study conduct period

You can drop a treatment arm, add cohorts, and update randomization during the study conduct period. These procedures also apply to rollover studies.

Before making any changes to your randomization design during the study conduct period, consider the following:

- For treatment arms, you can change their names, as well as the treatment ratios for existing cohorts. For treatment arm ratios, you can change them only to 0 or leave them blank.
- For randomization with cohorts, you can add cohorts and specify their treatment ratios.
- For randomization without cohorts, you can update the randomization settings on the last page of the wizard for creating a randomization design. (These settings aren't applicable to randomization with cohorts.). For more information, see Define the randomization.

Task 1 Create a new Draft version of a study
Create a new study version in Draft so you can edit your study's design. For step-by-step instructions, see Create a new Draft study version.

Task 2 Update the Draft version of the study

> **Note:**
>
> You can't change the type of randomization or edit the treatment arm ratios, so you can't drop a treatment arm.

If you must change the type of randomization or edit the treatment arm ratios, follow the steps below:

1. Create a new randomization design.
   If you need to drop a treatment arm, **leave its value for the treatment ratio blank in the wizard**. If you enter 0, you won't be able to save your changes.

2. Add randomization to a visit.

   You don't need to remove the previously assigned randomization design from the visit before you assign the new design.

3. Make a study version available in Testing mode.
4. Generate a randomization list or upload a randomization list.

   Make sure of the following:

   - The numbers in the new list don't overlap with the numbers in the existing list.
   - The list doesn't reference the dropped treatment arm.

5. Determine whether you need to generate a kit list or upload a kit list for Testing mode. Typically, unless you are running out of kit numbers, you don't need to create a new list. If you do create a new list, make sure it doesn't reference the dropped treatment arm.
6. Make all kits from the dropped treatment arm unavailable for distribution. For more information, see Reserve kits for a quality check.

Task 3 Make the new study version live
Perform the following tasks in the order below:

1. Verify the study.
2. Approve the study version. For more information, see Make a study version available in Production and Training modes.
3. If needed, upload or generate new kit lists and randomization lists for Production and Training modes.
4. Assign the randomization list to the appropriate study version in Production and Training modes. For more information, see Assign a randomization list to a randomization design and study version.
5. Update sites so that they are assigned to the new study version.
6. After sites are no longer using the previous study version, archive the study version.

Update a kit type during the study conduct period

Some fields for a kit type are editable, even during the study conduct period. If you need to update a read-only field, you must create a new kit type and use it to replace the kit type with the inaccurate field. These procedures also apply to rollover studies.

Task 1 Create a new Draft version of a study
Create a new study version in Draft so you can edit your study's design. For step-by-step instructions, see Create a new Draft study version.

Task 2 Update the Draft version of the study

1. Update the kit type.

> **Note:**
>
> Most fields are read-only. For instance, for investigational product kit types, you can't change the type, such as switching from a bottle to a blister pack, or the ID of the kit type. If you need to change a read-only field, create a new kit type.

For titration studies: You will get notified if you edit a kit type that is used in a titration. Review the given titration and make sure your updates don't affect the titration definition, otherwise make the necessary changes. See Update the way that subjects titrate during the study conduct period.

Task 3 Make the new study version live
Tasks include:

1. Make a study version available in Testing mode.
2. Verify the study.
3. Approve the study version. For more information, see Make a study version available in Production and Training modes.
4. Generate a randomization list or upload a randomization list and generate a kit list or upload a kit list for Production and Training modes.
5. Assign the randomization list to the appropriate study version in Production and Training modes. For more information, see Assign a randomization list to a randomization design and study version.
6. Update sites so that they are assigned to the new study version.
7. After sites are no longer using the previous study version, archive the study version.

Update the way that subjects titrate during the study conduct period

Depending on the changes you need to make, you might be able to update the existing kit type titration, or you might need to create a new kit type titration and use it to replace the current kit type titration. These procedures also apply to rollover studies.

Task 1 Create a new Draft version of a study
Create a new study version in Draft so you can edit your study's design. For step-by-step instructions, see Create a new Draft study version.

Task 2 Update the Draft version of the study

1. Determine the scope of your changes:
   - You can update the name and settings for a kit type titration at any time.
   - To add or remove kits, you must create a new kit type titration.
   - To update the visits in which subjects can titrate, you might not need to create a new kit type titration; it depends on how you set up the study:
     - When you dragged the kit type titration to a visit and filled in the fields in the Add Titration to Visit Schedule pop-up, if you selected **Dispense** for the visit and left **Allow Titration** deselected, all you have to do is select **Allow Titration** and then make the new study version live.
     - If you didn't select **Dispense** for the visit, you'll have to create a new kit type titration.
2. If you created a new kit type titration, remove the existing kit type titration from all visits, and associate the new kit type titration with all appropriate visits.

Task 3 Make the new study version live
Tasks include:

1. Make a study live

2. Verify the study
3. Approve the study version. For more information, see Make a study version available in Production and Training modes.
4. Assign the randomization list to the appropriate study version in Production and Training modes. For more information, see Assign a randomization list to a randomization design and study version.
5. Update sites so that they are assigned to the new study version
6. After sites are no longer using the previous study version, archive the study version.

Update a randomization list that ran out of numbers during the study conduct period

You can upload or generate a new randomization list in an approved version of a study without creating a new version of a study. Consider assigning the new list to the study version before the current list runs out of numbers to avoid randomization errors at sites. This procedure also applies to rollover studies.

1. Generate a randomization list or upload a randomization list.

> **Note:**
>
> Make sure the randomization numbers and block numbers do not overlap with the previous list.

   - If you uploaded the original randomization list, you must upload a new randomization list.
   - If you generated the randomization list, you must generate a new randomization list.
2. Assign a randomization list to a randomization design and study version.

   Only one randomization list can be associated with a study version at a time.

   If you create the list in the study version that goes live, you can skip this step.

Update a kit list that ran out of numbers during the study conduct period

You can upload or generate a new kit list in an Approved version of a study. You do not need to create a new version of a study to perform this task. This procedure also applies to rollover studies.

- If you uploaded the original kit list, you must upload a new kit list. Make sure the kit numbers and sequence numbers don't overlap with the original list.
- If you generated the kit list, you must generate a new kit list. Make sure the kit numbers and sequence numbers don't overlap with the original list.

12

Run and download a report

As a study designer, you typically run reports that offer you information on a study's design.

For step-by-step instructions on how to run and download a report, see the Reporting Guide.

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Frequently Asked Questions (FAQs)

Learn more about details, tips, or tricks of each feature you must work with, as a study designer.

Form and validation rule FAQs

- **Can multiple study designers edit a study at the same time?**
  Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.
- **Can I re-use a form's reference code?**
  We recommend you do not re-use a form's reference code.
- **What if I include a standalone coding question in a form?**
  You can include a coding question in any form, but if you don't include read-only items in the same form, having a single coding question won't be effective.
- **Can I use a form in more than one visit?**
  Yes.
- **Do I need to design the layout of a form?**
  No. Oracle Clinical One Platform creates the layout for each form based upon the questions and the answer formats that you specify.
- **Guidelines for subject tags and code lists in lab forms**
  If you ever find yourself stuck with defining subject tags or code lists for your lab forms, these additional guidelines might help you troubleshoot or work around some of the issues you may encounter.
- **How many coding questions can I include in a form?**
  Typically, you include only one coding question mapped as a verbatim term, indication, or route of administration in a form.
- **How strict should my validation rules be?**
  When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.
- **I am using a full data collection system for my study. Which forms should I create in Oracle Clinical One Platform, and which forms should I create in my data capture system?**
  In this scenario, we recommend creating only the forms required to perform randomization and trial supply management in Oracle Clinical One Platform.

- Should I add validation rules as I create a form or save them for later?
  You might find it more efficient to create validation rules as you create a form; however, you can create all forms and then return to them to add validation rules.
- Understand the options for creating a coding question and coding targets
  Learn more about the options available in the system to define a coding question and its coding targets.
- What answer formats can I use for questions on forms?
  Text, numeric, date/time, and drop-down (for which site users can select multiple answers from drop-down lists).
- What information should I include in the error message for a validation rule?
  Say what the validation rule is for and what the site user should do. For example: **Date of informed consent must be on or after the production date for the study. Please confirm the date.**
- When can I mark a form item as read-only?
  You can mark a form item as read-only whenever you want to display a value that is automatically generated by the system. By default, when you create a read-only item you don't allow manual data entry for that item.
- When should I tag a question as required?
  Only when the question is necessary for screening, randomization, or dispensation. For instance, questions that determine whether a subject meets inclusion criteria are typically required. Choose required questions carefully so that you don't inadvertently prevent screening, randomization, and dispensation from occurring.
- Why do I have to define SAS properties?
  SAS variables and labels are displayed in data extracts and play an important role in data analysis. By adding SAS properties to questions in a form, study designers ensure data is easy to review in the SAS v8 format.
- What is the difference between a normal text result and ranges?
  When creating a lab form, you need to remember that the items you include in the form will be used to define lab normals for a local lab. For each lab test, you can either use a normal text result or low and high range values to define lab normals.

Can multiple study designers edit a study at the same time?

Multiple study designers can edit different forms at the same time, in Draft mode. However, there are several restrictions and locks that are placed upon areas of a study's design when multiple study designers access it.

> **Note:**
>
> If you know that another study designer is planning to work on the study as you, at the same time, we recommend you refresh your browser's page frequently. If another study designer is already working in a study, an appropriate information message is displayed on screen.

Two study designers attempt to edit the same form at the same time

Two or multiple study designers cannot edit the same form at the same time. The first study designer who opens a form automatically places a lock on that form. When another study designer attempts to open that form, an information message is displayed that lets the other

study designer know the form is currently being edited by another user. The second study designers also sees a lock icon displayed on the form that they are trying to edit.

Multiple study designers attempt to edit forms and a treatment arm at the same time

Multiple study designers can edit different forms at the same time, all the while another study designer is editing the details of a treatment arm. In this case, the automatic lock is only placed on other areas of a study's design, but not on the Forms tab.

Multiple study designers attempt to edit the study schedule and a randomization's design

If the first study designer begins editing the study's schedule, an automatic lock is placed on the whole study design (except for the Forms tab). This lock does not allow other study designers to edit any other areas of the study design, such as: visits, kits, randomization, treatment arms, or assigning forms to visits. When another study designer attempts to access another area of the study's design (such as the Randomizations tab), an information message is displayed that lets the other study designer know the study is currently locked and edited by another user.

A study designer is editing a form and another study designer attempts to copy that form

If a form is locked by another study designer, another study designer cannot duplicate that form.

Can I re-use a form's reference code?

We recommend you do not re-use a form's reference code.

You cannot use identical reference codes for any type of form in the application. Even if you delete a form from your study, and then attempt to re-use the former reference code, you cannot do that.

Re-using a form's reference code will result in data errors for your reports and extracts that are generated in Testing mode, in particular.

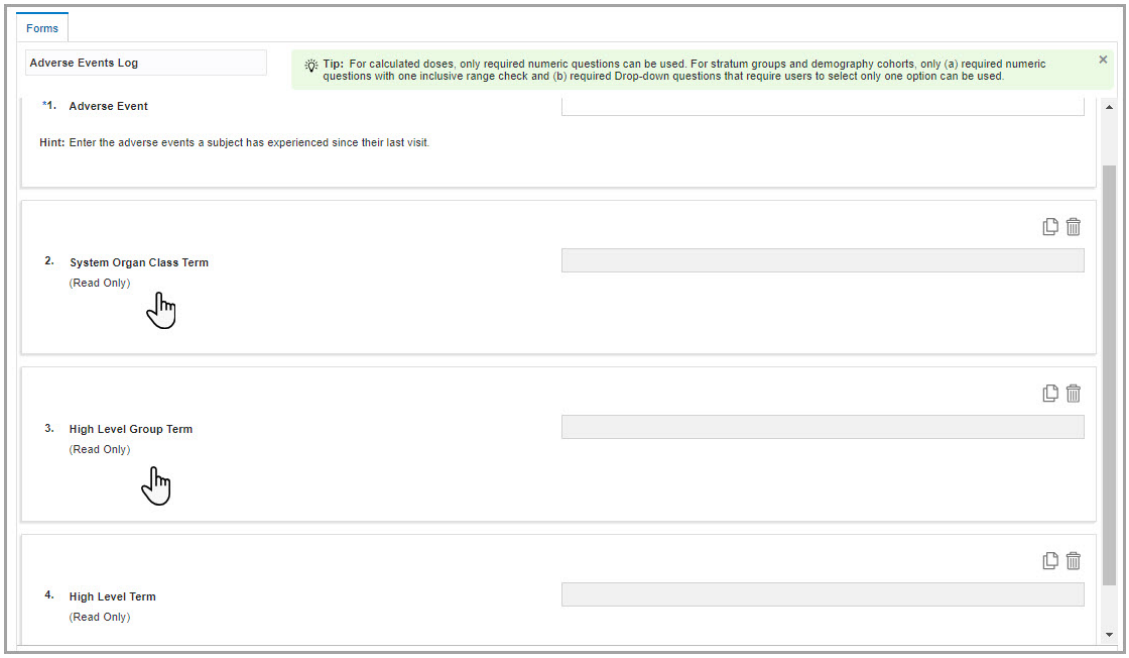
What if I include a standalone coding question in a form?

You can include a coding question in any form, but if you don't include read-only items in the same form, having a single coding question won't be effective.

Here's why: a coding question's answer should be translated into various other terms, based on the dictionary that you're using: WHODrug or MedDRA. Without a read-only item in place that indicates how you want the term to be coded, data for coding questions won't be properly mapped in your study.

For example, you should create an adverse events repeating form that contains a coding question for a verbatim term. You map it to the MedDRA dictionary, and then create various read-only items to translate the verbatim terms using high level dictionary term paths. And remember: the question for a Verbatim Term, Indication, or Route of Administration should always be required in a form, whereas the read-only items should be left as regular questions.

Figure 13-1 A repeating form for adverse events containing coding questions



Can I use a form in more than one visit?

Yes.

Do I need to design the layout of a form?

No. Oracle Clinical One Platform creates the layout for each form based upon the questions and the answer formats that you specify.

Guidelines for subject tags and code lists in lab forms

If you ever find yourself stuck with defining subject tags or code lists for your lab forms, these additional guidelines might help you troubleshoot or work around some of the issues you may encounter.

All of the required questions in a lab form are already predefined in the system, therefore all you have to do is either add items or questions that you think are required in a lab form and edit lab tests, so site users can know which lab tests they're collecting data for. Moreover, lab tests and lab results are already tagged with the appropriate lab normals tag, so you don't have to do that. If you need to create multiple lab forms, we recommend you create new code lists for the items requiring code lists, and tag those code lists appropriately.

The guidelines listed below are organized by type of element, including subject tags and predefined code lists for forms.

How dates work when it comes to lab normal values

In the absence of a sample collection date, the visit date is also used to trigger the effective date of a lab normal value or range, as well as calculate the age of a subject against the date of birth.

Code lists

When it comes to code lists, you can create multiple code lists with the same tag, whether it's Gender, Race, Lab Tests, or Lab Units, as long as those code lists don't contain duplicate values or codes. You can also modify the pre-existing code lists as you see fit for your lab form and lab normal values.

Consider the following notes, as well:

- 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.
- Any changes you make to a code list after you added it to a question have no impact on the original code list applied to the question. This is because the applied code list is directly associated to the question and stored with the question. For more information about a potential workaround, see About Advanced Study Versioning (ASV).
- For the Fasting question, if there is only one code list defined for Fasting and tagged as such, the system automatically uses the values in those code list to integrate the appropriate lab normal values. If there are multiple code lists created and tagged for Fasting, the system does not select one code list by default and a study designer must select the appropriate code list for the Fasting question in the respective lab form.

Subject tags

When it comes to subject tags, you must know that in order to effectively collect lab data using a lab form, you must have three types of questions defined and tagged in your study: a question on a subject's date of birth, a question on gender, and a question on race.

> **Note:**
>
> You should define questions on race and gender as questions with radio buttons. We typically recommend you include these questions on a Screening form, but it's ultimately up to you where you choose to include these questions.

Subject tag	Description
Race subject tag	The predefined Race code list is already tagged appropriately with the Race tag. You can always modify the code list values. For more details, see Tag questions on date of birth, gender, and race. As for lab normal ranges, a site user or data manager can only select a single option when defining the lab normal values and ranges for lab tests.
The Gender subject tag	The predefined Gender code list is already tagged appropriately with the Gender tag. You can always modify the code list values or create a new one as long as you tag it appropriately. For more details, see Tag questions on date of birth, gender, and race. As for lab normal ranges, a site user or data manager should select a single option when defining the lab normal values and ranges for lab tests.

Subject tag	Description
The Date of Birth subject tag	First off, you must have a date/time question appropriately tagged with the Date of Birth subject tag in order for the system to calculate a subject's age. The date/time question may also allow partial dates to collect a subject's age. If your study uses partial dates to collect a subject's date of birth, a subject's age is then calculated by comparing the collected date of birth against the Visit Date or the Sample Collection Date.
Sample Collection Date	The question can be defined to include a time element, as well as partial dates with a minimum accepted date format. This question allows a site user to enter the collection date of a lab test and the system to properly calculate a subject's current age, as well as choose the normal range with the correct effective date. **Note:** Keep the **Collection** field visible and required. Avoid turning the question toggle on for the **Hidden** or 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.

Subject tag	Description
Fasting	This question uses the Fasting code list, tagged appropriately. You can edit that code list as you see fit for your study design. This question allows a site user to collect data on a subject's fasting status and must have a single answer.

> **Note:**
>
> Keep the **Fasting** field visible and required. Avoid turning the question toggle on for the **Hidden** or 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.

How many coding questions can I include in a form?

Typically, you include only one coding question mapped as a verbatim term, indication, or route of administration in a form.

However, you can include multiple verbatim terms in a form, as long as they're not mapped to the same dictionary.

How strict should my validation rules be?

When planning your validation rules, consider how strictly you will interpret the study guidelines, and create a validation rule only if you will never accept data outside a certain range.

For example, consider an enrollment criterion for age: Subjects must be at least 18 years old. With a strict validation rule for age, a prospective subject who is 17 years old at the screening visit fails screening, even if the subject will be 18 years old by the time of the first visit. This strict validation rule would prevent a site user from enrolling a subject who nearly meets the enrollment criteria, though a site user could rescreen a subject who later becomes eligible.

I am using a full data collection system for my study. Which forms should I create in Oracle Clinical One Platform, and which forms should I create in my data capture system?

In this scenario, we recommend creating only the forms required to perform randomization and trial supply management in Oracle Clinical One Platform.

Should I add validation rules as I create a form or save them for later?

You might find it more efficient to create validation rules as you create a form; however, you can create all forms and then return to them to add validation rules.

Understand the options for creating a coding question and coding targets

Learn more about the options available in the system to define a coding question and its coding targets.

Below are listed the available options that you can select in the User Interface (UI) for each field required to configure a coding question: Dictionary, Coding Item Type, and Tag for Central Coding.

> **Caution:**
>
> While the documentation for coding questions is regularly updated, make sure you check the user interface first to see the exact list of options available for selection. If you notice a discrepancy in the documentation, let us know at **clinical_one_doc_feedback_us_grp@oracle.com**!

Dictionary

From this drop-down, you select the dictionary that is used by Oracle Central Coding to search for the term that you want to convert.

Dictionary	Description
MedDRA	Medical Dictionary for Regulatory Activities (MedDRA) is the dictionary used for adverse events and medical history of subjects.
WHODrug	World Health Organization Drug Dictionary is the dictionary used for concomitant medications that subject take during a study.
WHO DD B2	The WHO-DD B2 is another version of the WHO Drug Dictionary (WHO-DD).
WHO DD B3	The WHO-DD B3 is another version of the WHO-DD dictionary.
WHO DD C	The WHO-DD C is yet another specific format within the WHO Drug Dictionary system.
WHO DD C3	The WHO-DD C3 is a variation of the WHO-DD C dictionary type.
MedDRAJ	The MedDRAJ refers to the Japanese version of the MedDRA dictionary.
JDrug	JDrug is a Japanese drug dictionary mainly used in the Japanese pharmaceutical industry and regulatory environment.

Coding Item Type

The Coding Item Type identifies a question for coding mapping. The options you see in this drop-down depend on the selection you make for the Dictionary field above.

Associated dictionary	Corresponding coding item types
MedDRA	• Verbatim Term • System Organ Class Term • High Level Group Term • High Level Term • Preferred Term • Low Level Term • System Organ Class Code • High Level Group Code • High Level Term Code • Preferred Term Code • Low Level Term Code • International Agreement Order • Dictionary Name • Coder Name • Approver Name
WHO DD B2	• Verbatim Term • Indication • Route of Administration • ATC1 Term • ATC2 Term • ATC3 Term • ATC4 Term • ATC1 Code • ATC2 Code • ATC3 Code • ATC4 Code • Preferred Name Term • Trade Name Term • Preferred Name Code • Trade Name Code • Ingredients • Base Substance Code • Base Substance Name • Dictionary Name • Coder Name • Approver Name
WHO DD B3	The same options displayed for WHO DD B2 are displayed for the WHO DD B3 dictionary version, as well.

Associated dictionary	Corresponding coding item types
WHO DD C	The same options displayed for WHO DD B2 and WHO DD B3 are diplayed for the WHO DD C dictionary version, as well. Additionally, the following options are displayed: • Name Specifier • Country of Sale • MA Holder Country • Company • Company Country • ICH Med Prod ID • Sequence Number 3 • Sequence Number 4 • MA Number • MA Date • MA Withdrawal Date • Product Type • Product Group • Pharmaceutical Product
WHO DD C3	The same options displayed for WHO DD C are diplayed for the WHO DD C3 dictionary version, as well.
MedDRAJ	The same options displayed for MedDRA are diplayed for the MedDRAJ dictionary version, as well.

Associated dictionary	Corresponding coding item types
JDrug	• Verbatim Term • Indication • Route of Administration • TC1 Term • TC1 Code • TC1 (Kana) • TC2 Term • TC2 Code • TC2 (Kana) • TC3 Term • TC3 Code • TC3 (Kana) • TC4 Term • TC4 Code • TC4 (Kana) • Generic Name Term • Generic Name Code • Generic Name (Kana) • Generic Synonym Flag • Generic Use Class 1 • Generic Use Class 2 • Generic Common Name • Generic Common Name (Kana) • Generic Dosage Forms • Generic Drug Class 1 • Trade Name Term • Trade Name Code • Trade Name (Kana) • Trade Synonym Flag • Trade Use Class 1 • Trade Use Class 2 • Trade Common Name • Trade Common Name (Kana) • Trade Dosage Forms • Trade Drug Class 1 • Manufacturer Code • Manufacturer Abbreviation • Case Name Term • Case Name Code • Case Name (Kana) • Case Type • Dictionary Name • Coder Name • Approver Name

Tag for Central Coding

From this drop-down, you select a tag that categorizes your data in Oracle Central Coding.

Tag for Central Coding	Description
AE	Identifies the verbatim term as an adverse event.

Tag for Central Coding	Description
DISEASE	Identifies the verbatim term as medical history.??
NT-DISEASE	??
MEDPROD	Identifies the verbatim term as concomitant medication. ??
LABDATA	Identifies the verbatim term as lab data.

Related Topics

- What if I include a standalone coding question in a form?
  You can include a coding question in any form, but if you don't include read-only items in the same form, having a single coding question won't be effective.
- How many coding questions can I include in a form?
  Typically, you include only one coding question mapped as a verbatim term, indication, or route of administration in a form.

What answer formats can I use for questions on forms?

Text, numeric, date/time, and drop-down (for which site users can select multiple answers from drop-down lists).

What information should I include in the error message for a validation rule?

Say what the validation rule is for and what the site user should do. For example: **Date of informed consent must be on or after the production date for the study. Please confirm the date.**

When can I mark a form item as read-only?

You can mark a form item as read-only whenever you want to display a value that is automatically generated by the system. By default, when you create a read-only item you don't allow manual data entry for that item.

What are the most common use cases for creating a read-only item?

- **Calculated values:** Mark an item as read-only when you want to display a value that is automatically calculated by the system. For instance, the Body Mass Index (BMI) can be calculated automatically based on a subject's height and weight. Also, the Age can be calculated based on the date of birth entered by the site user.
- **Lab data:** Mark an item as read-only when you want to display lab data that is automatically extracted from the system. For instance, blood test results can be automatically populated in a form. If you use a third-party system to collect and store lab data, you can still send the data to Oracle Clinical One Platform and populate read-only fields by using REST APIs.
- **Coding items coming from drug/medical dictionaries:** Mark an item as read-only when the value is received from a Coding application. Coding questions allow you to collect and map different types of data such as adverse events or concomitant medications, according to the terminology listed in dictionaries in Oracle Central Coding. For example, you can create an editable item for the symptoms subjects experience while taking a specific medication and read-only items for the terms returned from the Coding application. If a site user lists "splitting headache" as a subject's symptom after consuming Ibuprofen, the

coding feature will translate the symptom as "severe headache" and populate the read-only field with the coded medical term.

When should I tag a question as required?

Only when the question is necessary for screening, randomization, or dispensation. For instance, questions that determine whether a subject meets inclusion criteria are typically required. Choose required questions carefully so that you don't inadvertently prevent screening, randomization, and dispensation from occurring.

Why do I have to define SAS properties?

SAS variables and labels are displayed in data extracts and play an important role in data analysis. By adding SAS properties to questions in a form, study designers ensure data is easy to review in the SAS v8 format.

Under the **Advanced** sidebar define the SAS properties:

- **SAS Variable**: Usually completed by default with the question's Reference Code. You can modify it, as long as you make sure the variable is unique in the form and it doesn't exceed 32 characters as indicated by the SAS v8 format.
- **SAS Label**: Usually completed by default with the question's label. You can modify it, as long as you make sure the variable is unique in the form and it doesn't exceed 256 characters as indicated by the SAS v8 format.

We recommend you define SAS properties in your study, to make sure that data is properly reflected in the enhanced data extracts.

What is the difference between a normal text result and ranges?

When creating a lab form, you need to remember that the items you include in the form will be used to define lab normals for a local lab. For each lab test, you can either use a normal text result or low and high range values to define lab normals.

Some lab tests answer straightforward questions, such as a pregnancy test or an infection test that can have a **Positive** or **Negative** result. Another example for a text result might be **Inconclusive**. This usually means the lab doesn't have a clear answer based on the sample provided for the test.

Reference ranges, on the other hand, don't offer straightforward answers. But they can offer valuable information for a multitude of lab tests. Think about a creatinine test or a test measuring your cholesterol levels. The number that results after your blood samples are analyzed isn't relevant unless you compare it to a reference range or value. For example, a creatinine test may be defined with a low range value of 0.84 mg/dl and a high range value of 1.21 mg/dl.

When you define your lab normals, make sure you choose the right lab normal value for each test: whether it's a normal text result or a set of low and high range values.

Kit and dispensation FAQs (for study designers)

- Can I create kit type titrations for blinded studies with open-label periods?
  Yes, you can. Create separate kit types for the blinded and open-label periods if the kit type description must be visible to blinded Oracle Clinical One Platform users during the open-label period.

- Can I dispense the same kit types in more than one treatment arm?
  Yes. You can dispense a kit type in one or more treatment arms, or you can dispense a kit type to all subjects without associating it with a treatment arm.
- Can I include Unblinded Pharmacist kits in a kit type titration?
  Yes, you can. However, you need to be very careful. Combining regular kit types with kits that can only be dispensed by a pharmacist or unblinded site user, in a kit type titration may, result in the potential unblinding of kits to blinded site users.
- If a study has multiple periods, how many kit types should I create?
  When a study has both an open-label and blinded period, your process for creating kit types depends on whether kit type descriptions should be visible to blinded users.
- How many treatment arms should I create when the same treatment arm is part of both blinded and open-label periods?
  Create only one treatment arm. The unblinding setting on the randomization design determines whether the treatment arm title is visible to blinded users.
- I'm not using Oracle Clinical One Platform for dispensation and supply management. Do I have to create kit types?
  No.
- How do I define the requirements for the investigational product?
  Create kit types to define the requirements, such as storage temperature, type of drug and calculated doses. You create one kit type for each category of kit that will be dispensed.
- Can dispensation occur outside the visit window?
  Yes. When you create the dispensation schedule, you specify whether a kit can be dispensed out of window for each visit or if site users can dispense kits to subjects during an unscheduled visit.
- Can dispensation occur outside a randomization visit?
  Yes. You can dispense when you randomize, and before and after you randomize.
- Can an open-label product be dispensed to all subjects?
  Yes. When you create the dispensation schedule, associate the kit type either with all subjects (if the visit occurs before randomization) or with all treatment arms (if the visit occurs after randomization), and select the visits with dispensation events.
- Can I create an open-label study or an open-label period?
  Yes. You can create open-label periods, including open-label extensions, and an entirely open-label study.
- What do I need to do to use calculated doses?
  You create a study as you normally do, but you need to make sure to set up forms, visits, kit types, and the dispensation schedule in a specific way.
- Can more than one kit type be dispensed in a treatment arm?
  Yes.
- What is my workflow if subjects need to titrate?
  Your workflow depends on whether you titrate according to a predefined schedule, or you let subjects change doses based on input from a clinician at the site.
- What happens when subjects aren't allowed to titrate?
  Your next steps depend on the reason the subject wasn't allowed to titrate.
- What if subjects can titrate some kits and not titrate others?
  It's not a problem at all. The workflow is exactly what you expect.
- Can I include multiple products in the same kit type titration?
  We recommend you include only one product in a kit type titration. A kit type titration can include multiple dose levels (for example, 5 mg and 10 mg kit types), typically for the same

compound. You can assign only one kit type titration to a treatment arm, so subjects can titrate only one compound for each treatment arm.

- Can a site user change doses after re-randomization occurs?
  Yes. Site users can dispense kits during titration visits after a subject is re-randomized to either the same treatment arm or a different treatment arm after the titration period.
- Can a site user change doses prior to randomization during the study?
  Yes, they can. There is no study design rule that doesn't allow site users to dispense kits to subjects during titration visits, before randomization happens.
- What is my workflow for creating device kit types managed with Oracle mHealth Connector?
  Your workflow for creating device kit types managed with Oracle mHealth Connector so that the study can dispense devices is similar to your workflow for creating kit types for dispensing drug kits, with one important addition: you must configure the connection to Oracle mHealth Connector when the study dispenses devices.

Can I create kit type titrations for blinded studies with open-label periods?

Yes, you can. Create separate kit types for the blinded and open-label periods if the kit type description must be visible to blinded Oracle Clinical One Platform users during the open-label period.

If the kit type descriptions don't need to be visible, you can use blinded kit types during the open-label period and need to create only blinded kit types.

Don't forget to define any kit that was part of the previous kit type titration when you create the transition kits for subjects to move to the open-label period.

Can I dispense the same kit types in more than one treatment arm?

Yes. You can dispense a kit type in one or more treatment arms, or you can dispense a kit type to all subjects without associating it with a treatment arm.

Can I include Unblinded Pharmacist kits in a kit type titration?

Yes, you can. However, you need to be very careful. Combining regular kit types with kits that can only be dispensed by a pharmacist or unblinded site user, in a kit type titration may, result in the potential unblinding of kits to blinded site users.

When using Unblinded Pharmacist kits in a kit type titration, make sure you also create a treatment arm that contains Unblinded Pharmacist kits with a placebo compound. The Unblinded Pharmacist kits should be defined on both treatment arms of the titration.

If any Unblinded Pharmacist kits are combined with regular kit types in a kit type titration, when performing dose changes, blinded site users will be instructed to contact their unblinded pharmacists for every treatment arm.

If a study has multiple periods, how many kit types should I create?

When a study has both an open-label and blinded period, your process for creating kit types depends on whether kit type descriptions should be visible to blinded users.

- If the kit type description must be visible to blinded Oracle Clinical One Platform users during the open-label period, you have to create 2 kit types for each kit:

  - Create a blinded kit type, which must be dispensed during the blinded period. The kit type description won't be visible to blinded users during this period.
  - Create an unblinded kit type, which must be dispensed during the open-label period. The kit type description will be visible to blinded users during this period.
- If it's okay for the kit type description to never be visible to blinded users, you can create only blinded kit types and dispense them in both the blinded and unblinded periods.

How many treatment arms should I create when the same treatment arm is part of both blinded and open-label periods?

Create only one treatment arm. The unblinding setting on the randomization design determines whether the treatment arm title is visible to blinded users.

I'm not using Oracle Clinical One Platform for dispensation and supply management. Do I have to create kit types?

No.

How do I define the requirements for the investigational product?

Create kit types to define the requirements, such as storage temperature, type of drug and calculated doses. You create one kit type for each category of kit that will be dispensed.

For details, see Define the kits.

Can dispensation occur outside the visit window?

Yes. When you create the dispensation schedule, you specify whether a kit can be dispensed out of window for each visit or if site users can dispense kits to subjects during an unscheduled visit.

If you don't allow dispensation outside the visit window and a subject comes in past the visit window for a dispensation event, a dispensation error occurs, and site users won't be able to dispense for the visit.

Can dispensation occur outside a randomization visit?

Yes. You can dispense when you randomize, and before and after you randomize.

For example, before subjects are randomized, you can dispense during a run-in visit, also known as a wash-out visit, or you can dispense an open-label product weekly to all subjects in all treatment arms.

Can an open-label product be dispensed to all subjects?

Yes. When you create the dispensation schedule, associate the kit type either with all subjects (if the visit occurs before randomization) or with all treatment arms (if the visit occurs after randomization), and select the visits with dispensation events.

Can I create an open-label study or an open-label period?

Yes. You can create open-label periods, including open-label extensions, and an entirely open-label study.

What do I need to do to use calculated doses?

You create a study as you normally do, but you need to make sure to set up forms, visits, kit types, and the dispensation schedule in a specific way.

1. When you design forms, make sure that the question(s) you will use to calculate doses are required numeric questions, such as a Number or Age question.
2. Add required forms to each visit. The required forms depend on the how you will set up your calculated dose. For example, consider a scenario where the calculated dose is based on a subject's weight:
   - If you collect a weight value in every dispensation visit, and you want the calculation to use a subject's answer in the current visit, every dispensation visit must have a form with the weight question.
   - On the other hand, if you collect a weight value only during the randomization visit, and you want the calculation to use the same weight value throughout the study, the form with the weight question has to be only in the randomization visit.

   > **Tip:**
   >
   > If you don't add forms to visits as required for the calculated doses, Oracle Clinical One Platform will prompt you about adding the forms when you define the dispensation schedule.

3. While creating kit types, select **Yes** for the **Calculating Doses** field, and then define one or more dosing calculations for each kit type.
4. While defining the dispensation schedule, choose a calculated dose for each visit that requires it.
   If the calculated dose you choose requires forms to be added to the visit, Oracle Clinical One Platform will add the forms for you after confirming that it's okay.

Can more than one kit type be dispensed in a treatment arm?

Yes.

What is my workflow if subjects need to titrate?

Your workflow depends on whether you titrate according to a predefined schedule, or you let subjects change doses based on input from a clinician at the site.

- If subjects must titrate according to a predefined schedule, you just assign the appropriate kit type to each visit when defining the dispensation schedule.
- If subjects have the option of changing doses based on the input from a clinician at the site, you must define kit type titrations. Use the following workflow when defining the kits in the study:
  1. Define all the kit types.

Sometimes subjects can titrate the investigational product but don't titrate another kit type, such as a box of syringes or a rescue inhaler. Create kit types for all the products, including those that can be titrated and those that can't be titrated.

2. Define the kit type titrations.
   If you're dispensing a kit separately, such as the syringes or rescue inhaler, don't include it in the kit type titration.
3. Define the dispensation schedule.
4. Associate kit type titrations with the appropriate visits.

What happens when subjects aren't allowed to titrate?

Your next steps depend on the reason the subject wasn't allowed to titrate.

The subject is already on the highest dose or lowest dose

If the subject wants to titrate but is already on the highest dose, then site users can either maintain the same dose, go lower (or higher), or take any other appropriate action according to what the sponsor user or CRO has decided. For example, for subjects who have reached their dosing limit, site users may receive a message from the sponsor advising them to withdraw the subject from the study.

If site users want to learn more about their study settings, they should contact their CRA.

Not enough time has passed since the subject last titrated

Site users shouldn't be able to change doses if not enough time has passed after the last time a subject titrated. Instead, they go straight through to the Dispense Kits pop-up and see a message letting them know that not enough time has passed since the last titration.

If they think they should be able to titrate, but can't, they should contact their CRA to learn more about the study's settings.

To learn more about how to specify when subjects should titrate, see Specify when subjects can titrate

The subject has already reached their maximum number of titrations in a study

If this happens, site users shouldn't see the options for changing doses. Instead, they go straight through to the Dispense kits pop-up and see a message letting them know that they can't change the subject's dose anymore, because they've already changed doses the maximum number of allowed times in the study.

To learn more about how to design a study that allows subjects to titrate, see Define kits for titrations

Titration is not made available for a study

This means that the protocol for the study you are working in doesn't allow titration. In that case, you shouldn't define how subjects titrate, because site users can't change doses for subjects.

What if subjects can titrate some kits and not titrate others?

It's not a problem at all. The workflow is exactly what you expect.

1. Define all the kits as you do normally, including:

- The kits that subjects need to titrate, such as the investigational product.
- The kits that subjects don't need to titrate, such as a box of syringes or a rescue inhaler.

2. Define the kit type titrations.
   When you create the kit type titrations, make sure you include only one kit type, the one that you're titrating. Don't include the kit types that you're dispensing separately.
3. Define the dispensation schedule by associating every kit type with the appropriate visits.
4. Associate the kit type titrations with the appropriate visits.

Can I include multiple products in the same kit type titration?

We recommend you include only one product in a kit type titration. A kit type titration can include multiple dose levels (for example, 5 mg and 10 mg kit types), typically for the same compound. You can assign only one kit type titration to a treatment arm, so subjects can titrate only one compound for each treatment arm.

Can a site user change doses after re-randomization occurs?

Yes. Site users can dispense kits during titration visits after a subject is re-randomized to either the same treatment arm or a different treatment arm after the titration period.

Can a site user change doses prior to randomization during the study?

Yes, they can. There is no study design rule that doesn't allow site users to dispense kits to subjects during titration visits, before randomization happens.

What is my workflow for creating device kit types managed with Oracle mHealth Connector?

Your workflow for creating device kit types managed with Oracle mHealth Connector so that the study can dispense devices is similar to your workflow for creating kit types for dispensing drug kits, with one important addition: you must configure the connection to Oracle mHealth Connector when the study dispenses devices.

1. Make sure the Study Name field in Oracle mHealth Connector is identical to the Study ID field (on the General tab in Study Settings) in Oracle Clinical One Platform. If these fields aren't identical, data from the devices won't appear as expected in the appropriate application.
2. Study Name in Oracle mHealth Connector must match the Oracle Clinical One Platform Study ID.
3. Configure the connection to Oracle mHealth Connector:
   a. Obtain the following information from Oracle:
      - Production, Training, and Testing URLs for Oracle mHealth Connector.
      - User name and password for an Oracle mHealth Connector user. 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 IAMS to obtain the user name and password.

b. Using the URLs and account information you obtained from Oracle, configure the connection to Oracle mHealth Connector so you can dispense devices.

4. Design the study as usual, including performing the following steps required for devices:
   a. Define the kits for devices.
   b. Define the dispensation schedule.
5. Specify settings for Testing mode as usual, including performing the following steps required for devices:
   a. Associate each device kit type with the depot(s) that ship the devices.
   b. Include device kit types in resupply strategies.
   c. Generate or upload a kit list.
   d. Create at least one manufacturing lot for the devices for Testing mode so you can specify their expiration dates, and combine the manufacturing lots into blinded lots if required.
   e. If you're using blinded groups for devices, create a blinded group of kits for devices for Testing mode.
6. Specify settings for Production mode as usual, including performing the following steps required for devices:
   a. Create a predictive resupply strategy [Testing].
   b. Generate or upload kit lists for Production and Training modes.
   c. Create at least one manufacturing lot for the devices for Production and Training modes so you can specify their expiration dates, and combine the manufacturing lots into blinded lots if required.
   d. If you're using blinded groups for devices, create blinded groups of kits for devices for Production and Training modes.
7. Throughout the study, perform kit reconciliation for returned devices, if required.

Randomization FAQs (for study designers)

- What randomization algorithms are available?
  You can use simple or stratified randomization. You can create blocks in the list and assign them either dynamically or statically to sites, countries, or regions.
- What are the rules for randomization designs?
  You can create blinded studies with or without open-label extensions. You can also create open-label studies, as long as randomization occurs when the open-label period starts. A study can have one or more randomization events.
- When I create a randomization design, what fields should I choose?
  The fields you choose depend on whether the study is open-label, blinded, or both open-label and blinded.
- 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 randomization algorithms are available?

You can use simple or stratified randomization. You can create blocks in the list and assign them either dynamically or statically to sites, countries, or regions.

For stratified randomization, subjects are grouped during the randomization event to maintain a balance of treatment arms. For both simple and stratified randomization, you can create blocks in the list and assign them to sites, countries, or regions.

> **Tip:**
>
> You have two options for grouping subjects: Either choose a stratified randomization design and then create stratum groups, or use demography cohorts. Demography cohorts offer more flexibility for controlling your enrollment because they let you set limits on population groups and stop and start enrollment for a group with just a few clicks.

How the sequence number is used with an existing randomization

If you use this option, you must already have a randomization algorithm in place. The sequence number acts as additional layer of shuffle to the existing randomization list. For example, if the randomization algorithm assigns numbers in a list, such as 1001, 1042, 1203, the sequence number option will reorganize this list into a less predictable format, such as 4, 50, 993. This is achieved by sorting the original list based on the lowest sequence number assigned to each item.

The sequence number is compatible with any randomization type, except for minimization.

If you leave the sequence number field blank, Oracle Clinical One Platform will default to the original randomization order, and no additional shuffling will occur.

The sequence number option is useful when a study is being run for a very small set of subjects, as it adds an additional layer of blindness by making the randomization numbers being less predictable.

You choose from the following algorithms for randomizing subjects.

Type of randomization algorithm	When a subject is randomized	How blocks of randomization numbers are assigned	When a block is exhausted by a stratum group at the country	Additional details
Central randomization	Oracle Clinical One Platform selects the next treatment arm in a central randomization list.	Not applicable.	Not applicable.	Not applicable.
Central Stratified randomization	Not applicable.	Not applicable.	Oracle Clinical One Platform selects the next treatment arm in a central randomization list based on strata.	This type of randomization is useful when you want to balance treatment arms within stratum groups.
Country Blocked Dynamic randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the site's country.	Oracle Clinical One Platform dynamically allocates blocks of randomization numbers to countries.	The next available block is allocated to the country.	This type of randomization helps you balance treatment arms within a country while minimizing gaps between blocks.

Type of randomization algorithm	When a subject is randomized	How blocks of randomization numbers are assigned	When a block is exhausted by a stratum group at the country	Additional details
Country Blocked Dynamic Stratified randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the country based on strata.	Oracle Clinical One Platform dynamically allocates blocks of randomization numbers to stratum groups at each country.	The next available block is allocated to the stratum group at the country.	This type of randomization is useful when you want to balance treatment arms within the stratum groups in each country.
Country Blocked Fixed Stratified randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the country based on strata.	You assign blocks to each country when you create the randomization list.	Oracle Clinical One Platform selects the next treatment arm in the next block that is allocated to the site's country. If all blocks allocated to a country are exhausted, a randomization failure occurs.	This type of randomization is useful when you want to balance treatment arms within a country. You must pre-allocate blocks of randomization numbers to countries when you create the randomization list, and if all blocks are exhausted, a randomization failure occurs. Additionally, gaps between blocks can occur when sites don't use randomization numbers as expected.

Type of randomization algorithm	When a subject is randomized	How blocks of randomization numbers are assigned	When a block is exhausted by a stratum group at the country	Additional details
Country Blocked Fixed randomization	Oracle Clinical One Platform selects the next treatment arm from a block assigned to the site's country.	You assign blocks to each country when you create the randomization list.	Oracle Clinical One Platform selects the next treatment arm in the next block that is allocated to the site's country. If all blocks allocated to a country are exhausted, a randomization failure occurs.	This type of randomization helps you balance treatment arms within a country. You must pre-allocate blocks of randomization numbers to countries when you create the randomization list, and if all blocks are exhausted, a randomization failure occurs. Additionally, gaps between blocks can occur when sites don't use randomization numbers as expected.
Minimization	Oracle Clinical One Platform selects a treatment arm using equal randomization.	Blocks are not assigned in the randomization list.	This type of randomization helps you balance subjects with different stratum factors and can be particularly useful within smaller cohorts.	Minimization is deterministic which means that some blinded users are at risk of predicting which minimization stratum group a subject is enrolled in. Additionally, it is a type of randomization that is not often used due to its complexity.
Site Blocked Dynamic randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the site.	Oracle Clinical One Platform dynamically allocates blocks of randomization numbers to sites.	The next available block is allocated to the site.	This type of randomization helps you balance treatment arms within a site while minimizing gaps between blocks.
Site Blocked Dynamic Stratified randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the site.	Oracle Clinical One Platformdynamically allocates blocks of randomization numbers to stratum groups at each site.	The next available block is allocated to the stratum group at the site.	This type of randomization is useful when you want to balance treatment arms within the stratum groups in each site.

Type of randomization algorithm	When a subject is randomized	How blocks of randomization numbers are assigned	When a block is exhausted by a stratum group at the country	Additional details
Site Blocked Fixed randomization	Oracle Clinical One Platform selects the next treatment arm from a block assigned to the site.	You assign blocks to each site when you create the randomization list.	Oracle Clinical One Platform selects the next treatment arm in the next block that is allocated to the site. If all blocks allocated to a site are exhausted, a randomization failure occurs.	This type of randomization helps you balance treatment arms within a site. You must pre-allocate blocks of randomization numbers to sites when you create the randomization list, and if all blocks are exhausted, a randomization failure occurs. Additionally, gaps between blocks can occur when sites don't use randomization numbers as expected.
Region Blocked Dynamic randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the site's region.	Oracle Clinical One Platform dynamically allocates blocks of randomization numbers to regions.	The next available block is allocated to the region.	This type of randomization helps you balance treatment arms within a region while minimizing gaps between blocks.
Region Blocked Fixed randomization	Oracle Clinical One Platform selects the next treatment arm from a block assigned to the site's region.	You assign blocks to each region when you create the randomization list.	Oracle Clinical One Platform selects the next treatment arm in the next block that is allocated to the site's region. If all blocks allocated to a region are exhausted, a randomization failure occurs.	This type of randomization helps you balance treatment arms within a region. You must pre-allocate blocks of randomization numbers to regions when you create the randomization list, and if all blocks are exhausted, a randomization failure occurs. Additionally, gaps between blocks can occur when regions don't use randomization numbers as expected.

Type of randomization algorithm	When a subject is randomized	How blocks of randomization numbers are assigned	When a block is exhausted by a stratum group at the country	Additional details
Region Blocked Dynamic Stratified randomization	Oracle Clinical One Platform selects the next treatment arm from the block assigned to the region.	Oracle Clinical One Platform dynamically allocates blocks of randomization numbers to stratum groups at each region.	The next available block is allocated to the stratum group at the region.	This type of randomization is useful when you want to balance treatment arms within the stratum groups in each region.

What are the rules for randomization designs?

You can create blinded studies with or without open-label extensions. You can also create open-label studies, as long as randomization occurs when the open-label period starts. A study can have one or more randomization events.

Rules for randomization designs

- You must drag randomization designs to visits in order (drag the first randomization design first, the second randomization design second, and so on).
- The first randomization design must randomize subjects (that is, you cannot start with an open-label period that doesn't involve randomization).
- The first randomization design in a study must have **No** selected for the **Re-Randomization** field.
- Only one randomization design in the study can randomize into cohorts.
- If a randomization design randomizes subjects into cohorts, it must be the first randomization design in the study.
- The second and later randomization designs must have **Yes** selected for the **Re-Randomization** field.
- If you are stratifying subjects:
  - You can use only one stratified randomization design in a study.
  - A stratified randomization design can be used only as the first randomization design.
- A randomization design must be assigned to a required and scheduled visit.
- A randomization design can't be assigned to the study completion or withdrawal visits.

Options for a second randomization event

If you randomize a second time, you have the following options for the second randomization event:

- Randomize all subjects again.
- Map subjects to new treatment arms, with or without randomization.
  For example, consider a study with 3 treatment arms: 5 mg, 10 mg, and placebo. Subjects in the 5 mg and 10 mg arms remain in their treatment arms throughout the study, and subjects in the placebo arm are randomized to determine whether they move into either the 5 mg or 10 mg arms.

More variations are possible. For instance, the study can add or drop treatment arms, and subjects can be mapped or randomized into a new treatment arm.

> **Tip:**
>
> If you're doing a crossover study where all subjects swap treatment arms without being randomized, you don't need to create a second randomization design. Instead, you can simply update the dispensation schedule so that subjects receive the appropriate treatment for each visit.

When I create a randomization design, what fields should I choose?

The fields you choose depend on whether the study is open-label, blinded, or both open-label and blinded.

First (or only) period of the study is open-label

Subjects must be randomized when the study starts with an open-label period.

- Type: Choose **Unblinded**.
- Randomization: Choose any algorithm. Do not choose **None - Open Label**; a study that starts with an open-label period must randomize subjects.
- Re-Randomization: Choose **No**.

First (or only) period of the study is blinded

With this randomization design, subjects are randomized, and the study remains blinded.

- Type: Choose **Blinded**.
- Randomization: Choose any algorithm.
  If you choose a stratified option: In your second randomization design, you must choose **Randomized**. You won't be able to assign a randomization design to a visit if you choose **Mapped**.
- Re-Randomization: Choose **No**.

Second or later period of the study (if required) is an open-label extension

What do you want to happen when you start the open-label extension?

- Keep all subjects on their current treatment arms while revealing the treatment description:
  - Type: Choose **Unblinded**.
  - Randomization: Choose **Open Label - None**.
  - Re-Randomization: Choose **Yes**.
- Move subjects to new treatment arms, or keep subjects in their treatment arms (or do a combination of the two options). When subjects in 1 treatment arm are moved to multiple treatment arms, randomization determines their new treatment arms:
  - Type: Choose **Unblinded**.
  - Randomization: Choose an algorithm without "stratified" in its name for subjects who will be randomized. You can't map subjects to treatment arms if you choose a stratified algorithm.
  - Re-Randomization: Choose **Yes**.

- Treatment Arms: Choose **Mapped**.

> **Tip:**
>
> You'll specify how subjects change treatment arms when you assign the randomization design to a visit.

Second or later period of the study (if required) is blinded

Do I need to create a second randomization design? Only if you need to start a blinded period with randomization.

What do you want to happen when the blinded period begins?

- Randomize all subjects (either again or for the first time):
  - Type: Choose **Blinded**.
  - Randomization: Choose any algorithm.
  - Re-Randomization: Choose **Yes**.
  - Treatment Arms: (Appears only if you choose a non-stratified algorithm; for stratified algorithms, the only option is to randomize all subjects again) Choose **Randomized**.
- Move subjects to new treatment arms, or keep subjects in their treatment arms (or do a combination of the two options). When subjects in 1 treatment arm are moved to multiple treatment arms, randomization determines their new treatment arms.
  - Type: Choose **Blinded**.
  - Randomization: Choose a non-stratified algorithm for randomizing the subjects who will be randomized. You can't map subjects to treatment arms if you choose a stratified algorithm.
  - Re-Randomization: Choose **Yes**.
  - Treatment Arms: Choose **Mapped**.

> **Tip:**
>
> You'll specify how subjects change treatment arms when you assign the randomization design to a visit.

Small study with smaller cohorts

Subjects must be randomized in a balanced manner across stratum groups.

- Type: Choose **Unblinded** or **Blinded**, based on your study period.
- Randomization: Choose **Minimization**.

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.

Study version and rollover study FAQs (for study designers)

- 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.
- 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 designing a rollover study?
Your workflow for designing a rollover study is almost the same as the one for designing any other study in Oracle Clinical One Platform, with one important mention: a rollover study shouldn't contain a screening visit. Subjects enrolled in a rollover study are already screened in the original study, so you can't screen them again in the rollover study.

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 designing a rollover study?

Your workflow for designing a rollover study is almost the same as the one for designing any other study in Oracle Clinical One Platform, with one important mention: a rollover study shouldn't contain a screening visit. Subjects enrolled in a rollover study are already screened in the original study, so you can't screen them again in the rollover study.

1. Work with your user administrator to make sure you're added as a study designer in the rollover study that you need to design and where subjects need to be enrolled by site users.
2. In the original study, make sure you add a rollover type of question in the study completion form. The rollover type of question shows up for site users as a drop-down question with typically 2 or 3 options for the answer. If a site user selects Yes as an answer for the rollover question in a form, the subject is automatically enrolled in the rollover study that you defined for that rollover type of question.

   > **Note:**
   >
   > It is the original study that must contain the rollover type of question, not the rollover study. The rollover type of question allows site users to enroll subjects from the original study to a rollover study.

3. Open a study's design.
4. Create visits or events in the rollover study. For more information, see Visits and schedules and Visit branches. Remember that a rollover study shouldn't contain a screening visit.
5. Define the visit schedule
6. Create forms. For more information, see Forms.
7. Add questions in each form. For more information on how to create questions, see Question types and settings.
8. Then add your forms to visits. For more information, see Add a form to a visit.
9. Define the treatment arms and randomization.
10. Add the randomization to the visits.

11. Define the kit types.
12. Define the dispensation schedule.
13. When you're ready to test the rollover study's design, make a study version available in Testing mode.. Also, remember that you can always create a new Draft version of the study to update it in Testing mode.
14. If needed, work with your study manager to test, verify, and make the rollover study live in Testing and Production mode. For more information, see What is my workflow for setting up a rollover study?.
15. You can always make any necessary changes during the study conduct period, as well. For more information, see Updates during the study conduct period

Use our Quick Start for Study Designers to have a checklist at handy for designing your rollover study.

Visit FAQs

- What order should I create visits in?
  You can create visits in any order. However, you might find that creating visits in the order in which they occur helps you find visits more easily when you're designing the visit schedule.
- Can I schedule a visit backwards from another visit, such as with a Screening visit (Day -30 to -1) and a Baseline visit (Day 0)?
  No, you can schedule visits only going forward, but you can set up this visit schedule a different way.
- Can I specify what happens when a subject comes in outside the visit window or misses the visit window?
  A visit without dispensation can always occur outside the visit window. A dispensation visit can occur out of window only if, on the Study Settings tab, you indicate that the kit can be dispensed out of window.
- What are the requirements for a screening visit?
  There are no specific study requirements for a screening visit, but it is recommended to include one. Not every study contains a screening visit. For example, there are rollover studies, enrollment (or registration) studies where subjects are screened in an external system and do not require you to create a screening visit in the system. However, by not including a screening visit, a subject's status may not be able to progress within the study as expected if they are not screened accordingly.
- When should I mark a visit as required?
  When every subject in the study is required to complete it.
- Do I have to schedule all visits from the same visit?
  No. You can schedule each visit from any visit that occurs before it. For instance, you can schedule all visits from Screening, or you can schedule Week 1 from Screening, Week 2 from Week 1, and so on.
- How is the visit schedule affected when a visit is skipped?
  The visit window is affected only when one or more visits are scheduled from the visit that is skipped. When another visit is scheduled from the skipped visit, Oracle Clinical One Platform uses the expected visit date to calculate the schedule for subsequent visits.
- What time zone are visit windows calculated in?
  In the time zone of the site, if the time zone is specified. If the time zone isn't specified, they're calculated in the UTC (Coordinated Universal Time) time zone, which corresponds to the Greenwich Mean Time zone.

What order should I create visits in?

You can create visits in any order. However, you might find that creating visits in the order in which they occur helps you find visits more easily when you're designing the visit schedule.

Can I schedule a visit backwards from another visit, such as with a Screening visit (Day -30 to -1) and a Baseline visit (Day 0)?

No, you can schedule visits only going forward, but you can set up this visit schedule a different way.

Here's what to do: Schedule the Baseline visit based on the Screening visit. Baseline occurs 30 days after Screening, with the following visit window:

- For the Before visit window, one of the following:
  - If you want to allow Baseline to occur on the same day as Screening, 30 days before.
  - If a day must occur between Baseline and Screening, 29 days before.
- For the After visit window, 0 days

You schedule all other visits that are relative to Day 0 from Baseline.

Can I specify what happens when a subject comes in outside the visit window or misses the visit window?

A visit without dispensation can always occur outside the visit window. A dispensation visit can occur out of window only if, on the Study Settings tab, you indicate that the kit can be dispensed out of window.

You choose whether to allow dispensation outside the visit window when you define the dispensation schedule. If you do not allow site users to dispense kits outside of window for the visit, a site user cannot complete the visit for a subject who comes in past the window.

What are the requirements for a screening visit?

There are no specific study requirements for a screening visit, but it is recommended to include one. Not every study contains a screening visit. For example, there are rollover studies, enrollment (or registration) studies where subjects are screened in an external system and do not require you to create a screening visit in the system. However, by not including a screening visit, a subject's status may not be able to progress within the study as expected if they are not screened accordingly.

When should I mark a visit as required?

When every subject in the study is required to complete it.

Do I have to schedule all visits from the same visit?

No. You can schedule each visit from any visit that occurs before it. For instance, you can schedule all visits from Screening, or you can schedule Week 1 from Screening, Week 2 from Week 1, and so on.

Out-of-window calculations are done based on the visit you select, so selecting the right visit while scheduling visits is important.

How is the visit schedule affected when a visit is skipped?

The visit window is affected only when one or more visits are scheduled from the visit that is skipped. When another visit is scheduled from the skipped visit, Oracle Clinical One Platform uses the expected visit date to calculate the schedule for subsequent visits.

For example, consider the following visit schedule:

- Visit 1 occurs on January 1
- Visit 2 is scheduled for 7 days after Visit 1
- Visit 3 is scheduled for 7 days after Visit 2

Visit 2 should occur 7 days after Visit 1, on January 8. If you skip Visit 2, Oracle Clinical One Platform sets the visit date as January 8. The expected visit date of Visit 3 is then January 15.

If a site user skips a visit, completes the next visit, and then starts the skipped visit...

The Visit Start Date for the skipped visit must meet both of the following requirements:

- The date must meet the visit schedule requirements based on the original schedule of the visit.
- The date must be earlier than the date of the next completed visit.

What time zone are visit windows calculated in?

In the time zone of the site, if the time zone is specified. If the time zone isn't specified, they're calculated in the UTC (Coordinated Universal Time) time zone, which corresponds to the Greenwich Mean Time zone.

14
Revision history

Table 14-1 Revision history

Date	Part Number	Description
09-April-2025	G18146-08	Included more precise information about how to set up a dynamic question. See Set up a dynamic question in a form.
18-March-2025	G18146-07	Made the following updates: • Included more accurate information for creating scheduled and unscheduled visits. See Create a visit or event. • Revised and update details to define visit and branch schedules. See Define the visit schedule and Define the visit schedule for a branch.
18-March-2025	G18146-06	Made the following updates: • Updated the following topics: – Add a code list to a question • Included the following new topics: – About Electronic Health Record (EHR) code lists – About mapping questions for Electronic Health Record (EHR) data import – Map form questions for EHR data import – Map a question with units inline or separately – Map a question group – Map lab form questions – Data dictionary question type mapping reference guide
25-February-2025	G18146-05	We updated the content for the auto-lock rule conditions to ensure accuracy. For more information, see the Set up a question to lock automatically.

Table 14-1 (Cont.) Revision history

Date	Part Number	Description
21-February-2025	G18146-04	The guide now includes a comment about the impact on downstream systems like DMW when forms contain more than 200 questions. For more information, see the Forms section.
06-February-2025	G18146-03	We updated the content related to the algorithms for randomizing subjects. For more information, see What randomization algorithms are available?.
31-January-2025	G18146-02	We updated the content for creating questions for Oracle Central Coding to ensure accuracy. For more information, see Create questions for medical coding. Details about coding targets and Advanced Study Versioning (ASV) were added to About Advanced Study Versioning (ASV) under *Changes you can apply to a live study, but not possible with ASV*.
17-January-2025	G18146-01	Original version of the document.