

# Oracle® Life Sciences Clinical One Platform

## Site User Guide



Release 25.1.1

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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

ORACLE®

Oracle Life Sciences Clinical One Platform Site User Guide, Release 25.1.1

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# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

## Documentation accessibility

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## Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

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- 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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# 1

## Before you sign in


- [Access study modes and pages](#)  
As a site user, you can perform different types of tasks in specific study modes. Knowing in which study mode you should operate can represent a learning curve for you, so let's learn more about the various study modes and how to access them.
- [Filter subjects in a study](#)  
Subject filters are located at the top of the subjects table. You can use these filters individually or in a combined way.

## Access study modes and pages

As a site user, you can perform different types of tasks in specific study modes. Knowing in which study mode you should operate can represent a learning curve for you, so let's learn more about the various study modes and how to access them.

### A study's settings


 **Note:**

On the Home page, click the study settings (  ) for the study you want to edit. Select **Open Settings**.

As a site user, you rarely have to access a study's settings. In a study's settings, sponsor users typically configure all settings and details of a study. However, if you are a site user who has the permission to create and manage local labs in a study, you may need to access the Sites & Labs tab to handle associations between local labs and your site.

### Training mode

 **Note:**

To work with mock data in Training mode, click the Training Mode button (  ) on the study.

While your study is in Training mode, you can practice data entry as the study contains the same forms, visits, and other elements as in Production mode. You may opt to first work in Training mode before you begin your actual work in the live study (in Production mode).

## Production mode

### Note:

To work with real data in Production mode, click the title of the study.

Production mode is your go-to place to handle all site-related activities. You access the study in this mode most frequently as this is where you need to handle all of your work from collecting data to dispensing kits, and running reports. Data entered in Training mode isn't available in Production mode, just as data entered in Production mode isn't available in Training mode.

## The Subjects page

When you access a study in Production mode, you land directly onto the Subjects page. On the Subjects page, you can perform all tasks related to subject management. You can add, screen, randomize, or withdraw a subject. You can view a subject's visit schedule, view their answer history, their associated queries, and you can access any visits to collect data.

## The Supplies page


On the Supplies page, you typically have access to the Site Inventory and Shipments page. By default, you land on the Shipments page. In here, you manage all shipments that must be requested or received at your site, as well as ship kits to a drug destruction depot. On the Site Inventory page, you can perform all tasks related to kit reconciliation.

# Filter subjects in a study

Subject filters are located at the top of the subjects table. You can use these filters individually or in a combined way.

### Note:

Depending on your study role and site assignments, only certain countries and sites are available when filtering through subjects. For more information, see Best practices for study role assignment.

1. On the Home page, determine where to work:
  - To work with real data in Production mode, click the title of the study.
  - To work with mock data in Training mode, click the Training Mode button (  ) on the study.  
The study in Training mode is typically identical to the study in Production mode, but Training mode is just for practicing. Data entered in Training mode isn't available in Production mode, just as data entered in Production mode isn't available in Training mode.
2. Along the top, click **Subjects**.
3. Determine which filters you want to use and select an option for each filter.

 **Note:**

For the Countries and Sites filter, if you only have access to one site in the study, that single site is selected by default for your filter and the Sites filter is inactive. Moreover, the Countries filter is not displayed at all.

Filter	Description
<b>Countries</b>	Select one country that you want to view subjects for. This filter includes the countries that you have access to. By default, the filter is set to <b>All countries</b> .
<b>Sites</b>	Select one site that you want to view subjects for. This filter includes the sites that you have access to. By default, this filter is set to <b>All sites</b> . If you only have access to one site in the study or the country that you previously selected (for the Countries filter) only has one associated site organization, that site is automatically selected for this filter. The Sites filter is inactive (you cannot change its selection).
<b>Subjects</b>	Select one or multiple subject statuses if you want to view subjects in a specific state. This filter includes all of the statuses a subject can have. By default, this filter is set to <b>All subjects</b> .
<b>Review status</b>	Select one review status to view subjects whose visits are in a specific state. This filter includes all of the review-related statuses that a visit can have. By default, this filter is set to <b>All reviews</b> .
<b>Search for Subject</b>	Manually type the name of the subject you are looking for. As you type, the list of subjects will automatically narrow down. <b>Note:</b> If you separate your search terms using spaces, the filter will treat them as distinct, which may broaden the scope of your results. For example, typing <i>CLIN-0004</i> will only display results containing this exact search query. However, typing <i>CLIN</i> and <i>0004</i> separately will display all the results containing at least one of these keywords, thus providing a much broader set of results.

4. Browse the list of displayed subjects.
5. To remove the filters, click **Clear Filters**.

The filters you select are preserved until you sign out of the application, but they are not preserved if you switch to another study.

#### Related Topics

- Signing, verifying, and freezing icons and their meanings
- Visit statuses and their icons

# 2

## Manage subjects

- [Add and screen a subject](#)  
Ready to screen a new subject? Here's where you start. Remember that this procedure doesn't apply to rollover studies. Subjects enrolled in a rollover study have already been screened in the original study, and don't need to be screened again in the rollover study.
- [Dispense kits after a titration error](#)  
Maybe you tried to change the dose for one of the subjects in your study but it seemed like titration wasn't available. This could have happened because not enough time had passed after the last titration. If you don't know the minimum time between titrations, contact your Clinical Research Associate (CRA) or medical monitor. After enough time has passed, you can follow these steps to dispense kits.
- [Enroll a subject in a rollover study](#)  
Enroll a subject in a rollover study by answering the rollover question, typically included in the Study Completion Form in the original study. After enrolling a subject, they're marked as **Enrolled** in the rollover study, while also keeping their original subject number. In the rollover study, you can dispense kits, devices or perform dose changes for subjects.
- [Mark a subject as complete](#)  
Mark a subject as complete after the subject has concluded all visits, all data has been entered for the subject, or has been screen failed.
- [Undo or edit a subject's completion of a study](#)  
If you marked a subject as Complete in error or an additional visit was included in the study's schedule, you can undo the action. Additionally, you can also edit a subject's study completion date.
- [Mark a visit that a subject misses as skipped](#)  
Depending on how a study is set up, you might be able to skip a visit that a subject misses. You can always skip an optional visit.
- [Randomize a subject after Oracle Clinical One Platform didn't allow you to randomize](#)  
You might need to randomize a subject again if you weren't able to randomize during the original visit, such as if your site was out of stock for the required kit.
- [Cancel a subject](#)  
Have you added a subject in error and would like to cancel it? You can cancel a subject as long as no data has been entered for it.
- [Re-sign a subject's data](#)  
If a site user updates the answer to a question for a subject who is already signed, that subject becomes unsigned. To make sure the updated data is accurate, you need to re-sign a subject's data.
- [Screen fail a subject](#)  
If a subject has already been screened but is actually ineligible for the study, or becomes ineligible for the study prior to randomization, you can manually mark the subject as screen failed.
- [Undo or edit a subject's screen failure](#)  
If you screen failed a subject error, you can undo this action. You can also edit a subject's date of when their screen failure occurred, and their reason for screen failure.

- [Start a dynamic visit for a subject](#)  
If available in your study, by giving a certain answer to a question in a form, you may determine the display of a dynamic visit for a subject.
- [Sign at the form level](#)  
If your study requires you to sign data for forms then you must perform this task to ensure that the data is accurate.
- [Sign at the subject level](#)  
If your study requires you to sign data for subjects then you must perform this task to ensure that the data is accurate.
- [Sign at the visit level](#)  
If your study requires you to sign data for visits then you must perform this task to ensure that the data is accurate.
- [Unblind a subject's treatment arm \(code break\)](#)  
You unblind a subject's treatment arm by performing a code break. Depending on the study protocol, Oracle Clinical One Platform might automatically withdraw the subject, and you might be required to complete a Withdrawal visit. Whether a subject is withdrawn is a study-specific setting. If you're not sure whether a subject will be withdrawn, contact your clinical research associate.
- [Update a subject number](#)  
If you ever need to update a subject number, you can do so during the study conduct period.
- [Withdraw a subject](#)  
You can withdraw a subject at any time if the subject is no longer available or eligible to continue in the study, including if they failed screening. The same applies to subjects in a rollover study.
- [Undo or edit a subject's withdrawal](#)  
If you withdrew a subject in error, you can undo the action. However, if the subject was automatically withdrawn due to a code break, you can't undo the withdrawal.
- [What states can a subject have?](#)  
Depending on the protocol, site users can update a subject's state through multiple actions for a number of times during the study. But have you ever wondered what each state really means for the way you manage subjects' data at a site?
- [After undoing the event I cannot complete or withdraw a subject](#)  
After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.
- [Link subjects for Electronic Health Record \(EHR\) data import](#)  
With just a few clicks, you can link a subject to their Medical Record Number (MRN) in preparation to import their EHR data, removing the need for redundant data entry.

## Add and screen a subject

Ready to screen a new subject? Here's where you start. Remember that this procedure doesn't apply to rollover studies. Subjects enrolled in a rollover study have already been screened in the original study, and don't need to be screened again in the rollover study.

You must answer all required questions to be able to screen a subject. If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria. If the question is marked as required, you can't screen the subject until it is answered.

- The completion of hidden questions is taken into account to determine a visit's status. If hidden questions aren't answered, the visit is considered **Incomplete**. If all hidden questions are answered, the visit is considered **Complete**.
- When the visit contains a two-section form, if you completed all of the required questions in the first section of the form and there are no table rows added to the second section of the form, then the two-section form is considered complete. Conversely, if there are any incomplete rows in the table section of the form, then the two-section form is considered incomplete.

 **Note:**

You must add all subjects directly into Oracle Clinical One Platform, not from an external system. Subjects that are added after being screened and randomized outside Oracle Clinical One Platform are automatically enrolled in the study and you don't need to screen them again. However, if the study design includes a screening visit you might need to screen the subject. A subject that is added from another system receives a status of **Enrolled**.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
4. Click **Add Subject**.
5. If entering subject numbers is allowed at your site, in the **Add Subjects** dialog, enter the subject number, and click **Add Subject**.
6. If the form contains an editable **Visit Start Date** question, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form. The current day is always the latest date that you can select.
7. Answer the questions on each form.

 **Tip:**

For questions with a drop-down or checkboxes, you might be able to select more than one option, depending on the study protocol. On the right, below Question Hint, check if there are any instructions about the number of answers you are allowed to select.

8. Click **Save**, and then **Screen**, or click **Save & Close** to save your changes and screen later.
9. Note the Subject Number in the confirmation window.
10. Click **Return to All Subjects** to return to the list of subjects at the site or click **Cancel** to remain in the visit.

### Related Topics

- [Cancel a subject](#)  
Have you added a subject in error and would like to cancel it? You can cancel a subject as long as no data has been entered for it.

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Dispense kits after a titration error

Maybe you tried to change the dose for one of the subjects in your study but it seemed like titration wasn't available. This could have happened because not enough time had passed after the last titration. If you don't know the minimum time between titrations, contact your Clinical Research Associate (CRA) or medical monitor. After enough time has passed, you can follow these steps to dispense kits.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject for whom you want to try dispensing again. The subject must have a status of **Screened**.
5. Select the checkbox to the left of the subject.
6. Above the table of subjects, from the Manage Subjects drop-down, select **Dispense**.
7. If you're able to see the dosing options in the Dispense kits dialog, make the right choice for your subject.
8. Select the checkbox.
9. Click **Next**.
  - If the subject can indeed titrate, if you may get a message from a Sponsor. Read it carefully, and click **Next**.
  - If not enough time has passed since the subject last titrated, you will go straight through the Dispense Kits pop-up for like any other dispensation visit. Contact your CRA to know more about time limits for titration.
  - If the subject has already reached their highest or lowest dose, read the sponsor message carefully, and click **OK**. If you want to reconsider your dosing option, click **Back**.
10. In the confirmation window, click **Return to Subjects** to return to the list of subjects at the site, or click **Close** to remain in the visit.


## Enroll a subject in a rollover study

Enroll a subject in a rollover study by answering the rollover question, typically included in the Study Completion Form in the original study. After enrolling a subject, they're marked as **Enrolled** in the rollover study, while also keeping their original subject number. In the rollover study, you can dispense kits, devices or perform dose changes for subjects.

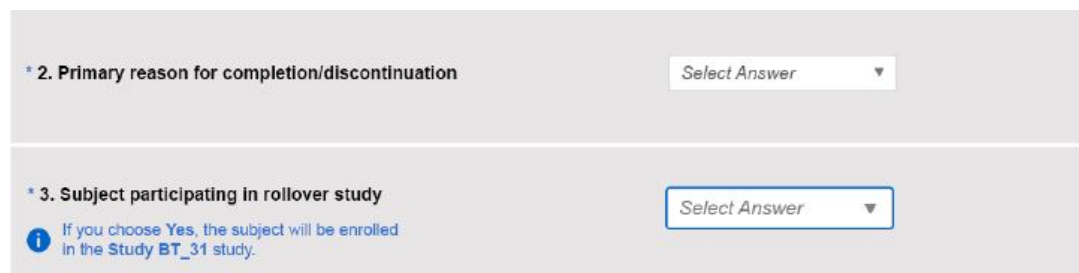
Before you enroll a subject in a rollover study, consider the following:

- You must have access to the original study, as well as the target study (where the subject is rolled over). The same applies to sites.




- The site's ID must match between the original study (where the subject was initially enrolled) and the rollover study.
  - Make sure that the target study (where the subject is rolled over) does not have another subject with the same subject number as the newly enrolled subject.
1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
  2. Along the top, make sure **Subjects** is selected.
  3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
  4. In the table, locate the subject you want to mark as complete. The subject must have a green avatar with a checkbox in the upper-right corner , indicating that they completed the minimum required visits in the study.
  5. Select the checkbox to the left of the subject.
  6. Above the table of subjects, from the Manage Subjects drop-down, select **Complete or Withdraw**.
  7. Click **Complete Study**.
  8. Confirm that you want to proceed, and click **Complete Study**.
  9. If the study completion form also contains a rollover question, select an answer from the drop-down next to it. Selecting **Yes** automatically enrolls the subject in a rollover study.

**Figure 2-1 Answer a rollover question to enroll a subject in a rollover study**



\* 2. Primary reason for completion/discontinuation

\* 3. Subject participating in rollover study

 If you choose Yes, the subject will be enrolled in the Study BT\_31 study.

10. Click **Complete Study**.

### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Mark a subject as complete

Mark a subject as complete after the subject has concluded all visits, all data has been entered for the subject, or has been screen failed.

Until a subject's visits are complete, you can only withdraw a subject from the study. A subject's progress through a study can be considered complete in the following instances:

- They completed all of the required visits in a study.

- They completed all visits until the earliest visit to complete, as specified by a study designer.

After a subject is marked as complete, you can't save any visits that weren't started, or take any other action on a subject, such as screening, randomizing, withdrawing, dispensing, or skipping a visit. You can still save or modify their associated forms.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on your desired criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to mark as complete. For a subject to be eligible

for completing a study, they should be displayed as **Active**



. This specific icon indicates that a subject is active in the study and that they've also completed the minimum required visits in the study. They are eligible to complete the study.

5. Select the checkbox to the left of the subject.
6. From the **Manage Subjects** drop-down, select **Complete**.
7. On the Complete Subject dialog, verify or update the date specified in the **Date of Completion** field.
8. Select the required checkbox to confirm that you want to complete the study for this subject.
9. Select **Complete Subject**.

If the study contains a Study Completion Visit, the visit is opened. The Study Completion Visit is also displayed on the **Next Visits** column.

10. If needed in your study, complete the forms for the subject's Study Completion Visit, and select **Save** or **Save & Close**.

A subject that completed all the visits in their study is displayed on the Subjects page as *Complete*



### Related Topics

- [Undo or edit a subject's completion of a study](#)  
If you marked a subject as Complete in error or an additional visit was included in the study's schedule, you can undo the action. Additionally, you can also edit a subject's study completion date.
- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

- [After undoing the event I cannot complete or withdraw a subject](#)  
After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.

## Undo or edit a subject's completion of a study

If you marked a subject as Complete in error or an additional visit was included in the study's schedule, you can undo the action. Additionally, you can also edit a subject's study completion date.

If your study includes a Study Completion Visit with associated forms that you already completed, when you undo a subject's completion, the associated Study Completion Visit remains visible until you clear the data associated with that visit. A subject's Study Completion Visit is displayed on the **Previous Visits** column.

To hide the visit you must clear all of its data and close all of its associated queries. You should ensure that [you clear the following data](#) points (and not delete the data manually):

- All data, including hidden data
- All queries, including manual, automated, or candidate queries. If you need help closing a query, reach out to your Clinical Research Associate (CRA).
- All data flags. Remember to clear data flags, not remove them manually by selecting the X icon next to the data flag.

Additionally, consider the following notes:

### Note:

- You cannot undo a subject's completion if the Study Completion Visit contains any frozen or locked data. When you attempt to undo a Study Completion Visit that contains frozen or locked data, an error message is displayed advising you to contact your Clinical Research Associate (CRA) to work with them for unlocking or unfreezing the data. Moreover, you don't see the option to undo a subject's event if their status is *Locked* overall.
- When a subject isn't in the appropriate state, don't try to enter extra data into the Withdrawal, Completion, or Screen Failure visit, as that data might not be saved.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on your desired criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose completion you want to undo or edit.

A completed subject appears with a **Complete** icon ().

5. If you want to undo a subject's completion of a study, do the following:
  - a. From the **Manage Subjects** drop-down, select **Undo Complete Study**.

- b. On the Undo Completion dialog, do the following, from the **Reason for Change** drop-down, select a reason for undoing the subject's completion of the study.
  - c. Select the checkbox informing you of the subject's status change and the visibility of the visit until its data is cleared.
  - d. Select **Undo Complete Study**.
  - e. If applicable, determine whether you want to clear data for a subject's Study Completion Visit.
6. If you want to edit a subject's completion details, do the following:
    - a. From the **Manage Subjects** drop-down, select **Edit Completion**.
    - b. On the Edit Completion dialog, if required, update the **Date of Completion**.
    - c. From the **Reason for change** drop-down, select a reason for the edits you want to make.
    - d. Select **Save**.

Anytime you edit a subject's study completion details, if included in the study, the Study Completion visit opens up again. You can choose to edit and save any data in the visit, or close the visit.

After you undo a subject's study completion, their state changes from *Complete* to the state the subject had before being completed, such as *Active*.

#### Related Topics

- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?
- [After undoing the event I cannot complete or withdraw a subject](#)  
After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.

## Mark a visit that a subject misses as skipped

Depending on how a study is set up, you might be able to skip a visit that a subject misses. You can always skip an optional visit.

Before you mark a visit that a subject missed, consider the following:

- You cannot skip any visits for which data has been entered, a screening visit or a required visit that occurs before the screening visit, a randomization visit, and a visit that start an open-label period.
  - If you skipped a visit in error and need to enter data for the visit, click the visit in the table of subjects and confirm that you want to start it.
  - A skipped visit cannot be populated by a Data Intake integration. If applicable, undo the skipped visit then request the vendor place the file back on sFTP for re-import.
1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
  2. Along the top, make sure **Subjects** is selected.

3. Filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject.
5. Click the visit in the **Next Visits** column.
6. At the top of the page, from the Manage Subject drop-down, select **Skip this Visit**.
7. Enter a reason for skipping the visit and click **Skip Visit**.

The visit turns purple in the table of subjects and has an X above the visit name.

#### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Randomize a subject after Oracle Clinical One Platform didn't allow you to randomize

You might need to randomize a subject again if you weren't able to randomize during the original visit, such as if your site was out of stock for the required kit.

#### Note:

Remember that you can dispense kits with a **Misallocated** status to subject who haven't been randomized yet, and are not in an **Active** state. This is especially useful if your sponsor organization uses a different system to dispense kits to subjects, but also uses Oracle Clinical One Platform to randomize subjects.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to randomize.
5. Select the checkbox to the left of the subject.
6. Above the table of subjects, from the Manage Subjects drop-down, select **Randomize**.
7. Confirm or update the values on the forms for the randomization event.
8. Click **Save** and then **Randomize** at the bottom of the form.
9. In the confirmation window, click **Return to Subjects** to return to the list of subjects at the site or click **Cancel** to remain in the visit.

#### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Cancel a subject

Have you added a subject in error and would like to cancel it? You can cancel a subject as long as no data has been entered for it.

Only subjects which have had no data added for them can be canceled. Actions which add data for subjects include:

- Locking a subject.
- Freezing a subject's data.
- Verifying a subject's data at a visit and question level.
- Signing at the subject level.
- Transferring a subject.
- Clearing or deleting data for a subject.
- Updating a subject's number.
- Adding a visit date.

### **WARNING:**

If as part of your study's design, the first visit date has been entered and saved, resulting in the Visit Date field getting automatically filled-in, this prevents the cancellation of your subject.

Once a subject has been canceled, it will no longer appear on the subjects list page and its subject number can be reused..

1. On the Home page, determine where to work and access your study.

For more information, see [Access study modes and pages](#)

2. Along the top, make sure **Subjects** is selected.

3. Filter your view based on country and sites.

For more information, see [Filter subjects in a study](#).

4. Select the subject added in error.

If you have just added the subject and are viewing the visit screen, click **Return to All Subjects**, then select it from the subjects list.

5. Click **Manage Subjects**.

6. Select **Undo Add Subject**.

7. In the pop-up window, confirm your action by clicking **Continue**.

Note the subject is no longer visible within the list.

### Related Topics

- [Add and screen a subject](#)

Ready to screen a new subject? Here's where you start. Remember that this procedure doesn't apply to rollover studies. Subjects enrolled in a rollover study have already been screened in the original study, and don't need to be screened again in the rollover study.

- [Forms FAQs](#)

- [Subjects and visits FAQs](#)

## Re-sign a subject's data

If a site user updates the answer to a question for a subject who is already signed, that subject becomes unsigned. To make sure the updated data is accurate, you need to re-sign a subject's data.

Before you re-sign a subject's data, consider the following:

- You need the appropriate permission to sign a subject's data.
- If a site user removes a completed and signed repeating form instance, the visits and subjects associated with that repeating form become unsigned and you must re-sign the subject's data again.

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




1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. From the **View** drop-down, select **Ready to Sign** to filter your search for subjects who need to be re-signed.

Subjects that are ready to sign are subjects whose visits are completed.




### Tip:

You can use the **View** drop-down to filter displayed in a visit to identify forms and questions that have to be re-signed.

4. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
5. In the table, locate a subject who has the unsigned icon next to it  and select the checkbox to the left of the subject.
6. Along the top, click **Manage Subjects**.
7. From the drop-down, select **Sign**.
8. On the Sign Data dialog, enter the user name and password that you use to sign in Oracle Clinical One Platform.
9. Click **Sign**.



Once you re-sign data for a subject, all visits are marked with the signed icon . The same icon appears next to the subject and on every form and question within a form.

### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Screen fail a subject

If a subject has already been screened but is actually ineligible for the study, or becomes ineligible for the study prior to randomization, you can manually mark the subject as screen failed.

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



1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on the required criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to screen fail.

 **Tip:**

If the subject has been randomized with a status of **Active**, you can't screen fail the subject, but you can withdraw the subject. See [Withdraw a subject](#). Subjects who can be screen failed typically have a status of *New*, *Enrolled*, or *Screened*.

5. Select the checkbox to the left of the subject.
6. From the **Manage Subjects** drop-down, select **Screen Fail**.
7. On the Screen Fail dialog, from the **Reason for Screen Fail** drop-down, select a reason for manually screen failing this subject.
8. Verify or update the date specified in the **Date of Screen Fail** field.
9. Select the required checkbox to confirm that you want to screen fail this subject.
10. Select **Screen Fail**.

If the study contains a Screen Failure visit, the visit is opened. The Screen Failure Visit is also displayed on the **Next Visits** column.

A subject who is screen failed appears with a **Screen Failed** icon on the Subjects page



### Related Topics

- [Undo or edit a subject's screen failure](#)  
If you screen failed a subject error, you can undo this action. You can also edit a subject's date of when their screen failure occurred, and their reason for screen failure.
- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?



- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Undo or edit a subject's screen failure

If you screen failed a subject error, you can undo this action. You can also edit a subject's date of when their screen failure occurred, and their reason for screen failure.

If your study includes a Screen Failure Visit with associated forms that you already completed, when you undo a subject's screen failure, the associated Screen Failure Visit remains visible until you clear the data associated with that visit. A subject's Screen Failure Visit is displayed on the **Previous Visits** column.

To hide the visit you must clear all of its data and close all of its associated queries. You should ensure that [you clear the following data](#) points (and not delete the data manually):

- All data, including hidden data
- All queries, including manual, automated, or candidate queries. If you need help closing a query, reach out to your Clinical Research Associate (CRA).
- All data flags. Remember to clear data flags, not remove them manually by selecting the X icon next to the data flag.

Consider the following notes:

### Note:

- When a subject isn't in the appropriate state, don't try to enter extra data into the Withdrawal, Completion, or Screen Fail visit, as that data might not be saved.
- If you select **Edit Screen Fail** for a subject who's been automatically screen failed, the reason for this change displayed on the Edit Screen Fail dialog is locked in and you cannot update it.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on your desired criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose screen failure you want to undo or edit.
5. Select the checkbox to the left of the subject.



A screen failed subject appears with a **Screen Failed** icon (  ).

6. If you want to undo a subject's screen failure, follow these steps:
  - a. From the **Manage Subjects** drop-down, select **Undo Screen Fail**.
  - b. On the Undo Screen Fail dialog, do the following, from the **Reason for Change** drop-down, select a reason for undoing the subject's screen failure.
  - c. Select the checkbox informing you of the subject's status change and the visibility of the visit until its data is cleared.

- d. Select **Undo Screen Fail**.
  - e. If applicable, determine whether you want to clear data for a subject's Screen Failure Visit.
7. If you want to edit a subject's screen failure details, follow these steps:
- a. From the **Manage Subjects** drop-down, select **Edit Screen Fail**.
  - b. On the Edit Screen Fail dialog, from the **Reason for Screen Fail** drop-down, select a different reason for screen failing the subject, if needed.

 **Note:**

If the subject is automatically screen failed, you cannot modify this field.

- c. If required, update the **Date of Screen Fail**.
- d. From the **Reason for change** drop-down, select a reason for the edits you want to make.

Anytime you edit a subject's screen failure details, if included in the study, the Screen Failure visit opens up again. You can choose to edit and save any data in the visit, or close the visit.

After you undo a subject's screen failure, their state changes from *Screen Failed* to the state the subject had before being screen failed, such as *New*, or *Screened*.

#### Related Topics

- [A subject failed screening, and I need to rescreen the subject](#)  
You might need to rescreen a subject if you made a mistake while completing the screening visit, if the subject's eligibility has changed, or if you manually screen failed a subject in error.
- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?

## Start a dynamic visit for a subject

If available in your study, by giving a certain answer to a question in a form, you may determine the display of a dynamic visit for a subject.

A dynamic visit only appears in a subject's schedule if it is relevant or needed in the process of data collection or dispensation of the investigational product. When a dynamic visit appears in a subject's schedule, you can also skip that visit, as long as data has not been entered for it. For more information, see [Mark a visit that a subject misses as skipped](#).

You must know that, depending on when a dynamic visit is scheduled, the visit card may or may not appear in the Next Visits column, on the Subjects page. For example, on 28-May-2021 you answer a question related to a female subject's childbearing potential. The answer to that question determines the display of a dynamically scheduled visit with some associated relevant forms. However, that visit is scheduled for a visit window between 15-June-2021 and 20-June-2021. If there are any other visits that must happen before the dynamically scheduled one, then that dynamic visit does not appear right away on the Next Visits column. However, the visit is now part of the subject's schedule and will become visible on the Subjects page once you get closer to its visit window.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Complete data in the forms associated with that visit..
5. Once a dynamic visit becomes active in a subject's schedule, depending on when its visit window is scheduled, a visit card may or may not appear on the Next Visits column, on both the Subjects page and on the visit page.
6. If you have a dynamic visit that you don't think is correct for the subject:
  - Review the response provided for the question that displayed the dynamic visit and confirm it is correct.
  - If the answer is incorrect, update that answer, providing an appropriate reason for change.

The dynamic visit is no longer included in a subject's visit schedule.

#### Related Topics

- [Enter data and dispense kits](#)
- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Sign at the form level

If your study requires you to sign data for forms then you must perform this task to ensure that the data is accurate.

Before signing off at the form level:

- Be sure that you have the appropriate permissions. For more information, see Descriptions of permissions in Clinical One.
- If changes are made to signed data, the data becomes unsigned and requires re-signing.
- Be aware that it may take up to 60 minutes for signature request details to become available once form data has been entered.

To sign one or multiple forms:

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. From the **View** drop-down, select **Ready to Sign** to filter your search for subjects with forms that need to be signed.
4. If you're assigned to more than one site, filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
5. In the list, locate a subject, and select the checkbox to the left of the subject.
6. In the Signature Request side panel, select **Sign** for one or multiple forms that require your signature.

The system opens the Visit window.

7. In the Signature Request side panel, click **Select** for one or more forms that require your signature.
8. Select one of the following:
  - Click **Sign**
  - Click **Sign & Close**.
9. Perform one of the following:
  - If you're signing one form, or multiple forms with an identical affidavit, read the affidavit in the Sign dialog.
  - If you're signing multiple forms with unique affidavits, read the affidavit for each form in the **Affidavits List** in the Sign Data dialog.
10. Acknowledge the affidavit by entering your **Username** and **Password**, then click **Sign**.

### Related Topics

- [Sign at the visit level](#)  
If your study requires you to sign data for visits then you must perform this task to ensure that the data is accurate.
- [Sign at the subject level](#)  
If your study requires you to sign data for subjects then you must perform this task to ensure that the data is accurate.
- [Re-sign a subject's data](#)  
If a site user updates the answer to a question for a subject who is already signed, that subject becomes unsigned. To make sure the updated data is accurate, you need to re-sign a subject's data.

## Sign at the subject level

If your study requires you to sign data for subjects then you must perform this task to ensure that the data is accurate.

Before you sign a subject's data, consider the following:

- If you're a principal investigator who needs to review the accuracy of data, then you should perform this task. Contact your sponsor for more details on this task in your workflow.
- You need the appropriate permission to sign a subject's data.
- Visits that have been started but not completed can be signed.
- You need to authenticate using your credentials every time you sign a subject's data.
- Be aware that it may take up to 60 minutes for signature request details to become available once subject data has been entered.

### Tip:

On the Subjects List page, you can use the **View** drop-down to filter to identify subjects and visits that require signing.

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




1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. From the **View** drop-down, select **Ready to Sign** to filter your search for subjects who need to be signed.
4. If you're assigned to more than one site, filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
5. In the list, locate a subject, and select the checkbox to the left of the subject.
6. Perform one of the following:
  - Along the top, click **Manage Subjects**, then from the drop-down, select **Sign**.

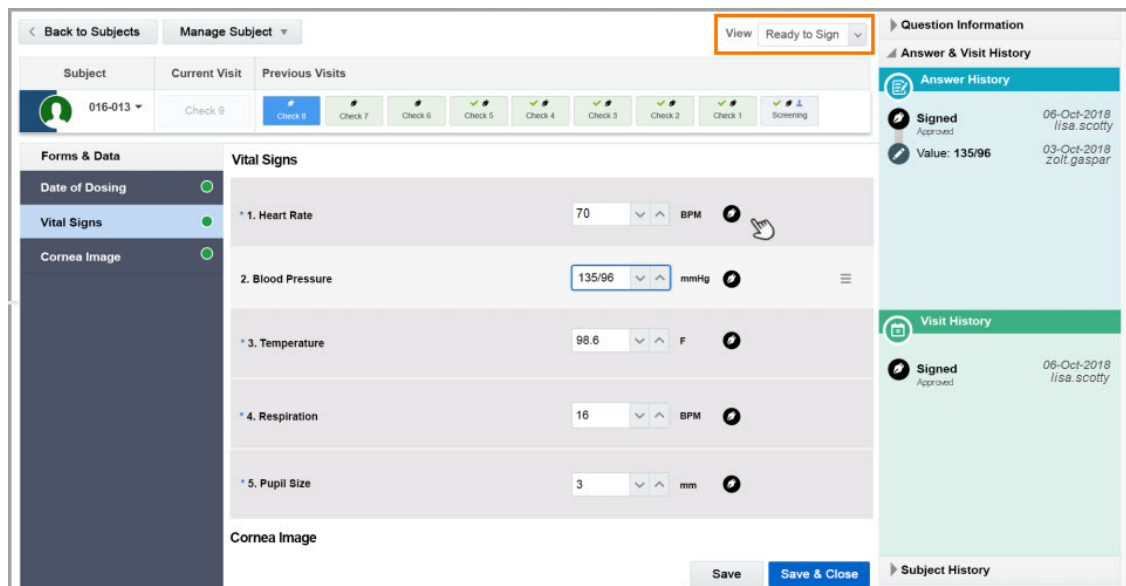
 **Note:**

The **Last Signed Date** that appears next to the **Sign** option indicates the last time the subject's casebook was signed.

- In the Signature Request side panel, select **Sign**.
7. In the **Sign** dialog, enter your user name and password that you use to sign in Oracle Clinical One Platform.
  8. Click **Sign**.

Once you sign data for a subject, all visits are marked as signed with the signed icon . The same icon appears next to the subject and on every form and question within a form. Additionally, you can view the **Signed - Approved** update on the Answer History sidebar.

**Figure 2-2 How a lead site user sees a signed visit**



### Related Topics

- [Sign at the form level](#)  
If your study requires you to sign data for forms then you must perform this task to ensure that the data is accurate.
- [Sign at the visit level](#)  
If your study requires you to sign data for visits then you must perform this task to ensure that the data is accurate.
- [Re-sign a subject's data](#)  
If a site user updates the answer to a question for a subject who is already signed, that subject becomes unsigned. To make sure the updated data is accurate, you need to re-sign a subject's data.
- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Sign at the visit level

If your study requires you to sign data for visits then you must perform this task to ensure that the data is accurate.

Before signing off at the visit level:

- Be sure that you have the appropriate permissions. For more information, see [Descriptions of permissions in Clinical One](#).
- If changes are made to signed data, the data becomes unsigned and requires re-signing.
- Be aware that it may take up to 60 minutes for signature request details to become available once visit data for a subject has been entered.

To sign off on a visit:

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. From the **View** drop-down, select **Ready to Sign** to filter your search for subjects with forms that need to be signed.
4. If you're assigned to more than one site, filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
5. In the list, locate a subject, and select the checkbox to the left of the subject.
6. In the Signature Request side panel, select **Sign** for the visit that requires your signature. The system opens the Visit window.
7. In the Signature Request side panel, click **Select** for the visit that requires your signature.
8. Perform one of the following:
  - Click **Sign** to sign for the selected visit and sign another.
  - Click **Sign & Close**.
9. In the Sign Data dialog, read the affidavit.
10. Acknowledge the affidavit by entering your **Username** and **Password**, then click **Sign**.

### Related Topics

- [Sign at the form level](#)  
If your study requires you to sign data for forms then you must perform this task to ensure that the data is accurate.
- [Sign at the subject level](#)  
If your study requires you to sign data for subjects then you must perform this task to ensure that the data is accurate.
- [Re-sign a subject's data](#)  
If a site user updates the answer to a question for a subject who is already signed, that subject becomes unsigned. To make sure the updated data is accurate, you need to re-sign a subject's data.

## Unblind a subject's treatment arm (code break)

You unblind a subject's treatment arm by performing a code break. Depending on the study protocol, Oracle Clinical One Platform might automatically withdraw the subject, and you might be required to complete a Withdrawal visit. Whether a subject is withdrawn is a study-specific setting. If you're not sure whether a subject will be withdrawn, contact your clinical research associate.



### Note:

After you unblind a subject's treatment arm, you can perform the code break as many times as necessary to retrieve the unblinding results again.

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



1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to unblind.
5. Select the checkbox to the left of the subject.
6. Above the table of subjects, from the Manage Subjects drop-down, select **Code Break**.
7. Click **Continue**.
8. Confirm the subject number and study name and select the checkbox to confirm the code break.
9. Indicate whether an adverse event occurred and click **Unblind**.
10. Review the unblinding results for the subject, and click one of the following options:
  - If the study has a withdrawal visit, click **Start Withdrawal Visit**. You can complete the visit now or later. The subject's status changes to **Withdrawn** even if you don't complete the visit.
  - If the study doesn't have a withdrawal visit, click **Done**. The subject's status changes to **Withdrawn**.

### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Update a subject number

If you ever need to update a subject number, you can do so during the study conduct period.

Before you perform this task, consider the following:

- When a subject number is updated, that subject is temporarily locked in the system and you cannot perform any other updates related to it. After the update is complete, you can manage your subject as required.
- If you attempt to update multiple subject numbers at the same time, and some of the new numbers do not adhere to the subject number format required by the system, none of the subject numbers are updated and you will receive the appropriate validation messages. To ensure that you successfully update multiple subject numbers at once, you must check that the updated subject number is according to the format requirements.


1. On the homepage, determine where to work. For more information, see [Access study modes and pages](#).
2. On the Subjects page, select a subject.
3. Click **Manage Subjects** and select **Update Subject Number(s)**.


The Update Subject Numbers dialog appears.

4. Depending on whether you want to update one or multiple subject numbers, do one of the following:

#### Note:

You cannot change the subject number to one that already exists. Also, if you need to swap two subject numbers, they need to be updated at the same time.

Option	Steps
To update a single subject number	In the <b>Update To</b> column, enter the new subject number.
To update multiple subject numbers	<ol style="list-style-type: none"> <li>a. Click <b>Add</b> .</li> <li>b. For the new row, in the <b>Selected Subject</b> column, select another subject number to update.</li> <li>c. In the <b>Update To</b> column, enter the new subject number.</li> </ol> <p>Repeat these steps for every subject number that you want to add and update.</p>

5. On the Update Subject Number(s) dialog, if you want to remove a subject number that you added for an update, click **Delete**  next to the corresponding row.
6. In the **Reason for Change** text box, enter a reason for your change.



The text you enter here must not exceed 255 characters.

7. Click **Update**.

A dialog appears indicating that the update of the subject numbers is complete. Click **OK**.

Based on your permissions, you may receive an email notification for each subject for whom the subject number was updated.

To view the history of subject number updates for a subject, select the subject, and expand the **Subject History** side panel. A **Subject Number Changed** update is displayed in the subject's history.

#### Related Topics

- Workflow for updating a subject's number during the study conduct period
- Subject Events Report

## Withdraw a subject

You can withdraw a subject at any time if the subject is no longer available or eligible to continue in the study, including if they failed screening. The same applies to subjects in a rollover study.

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



1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on the required criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to withdraw.

#### Note:

Except for subjects whose status is *Complete*, subjects in any other state are eligible for withdrawal.

5. Select the checkbox to the left of the subject.
6. From the **Manage Subjects** drop-down, select **Withdraw**.
7. On the Withdraw Subject, from the **Reason for Withdrawal** drop-down, select a reason for withdrawing the subject from this study.
8. Verify or update the date specified in the **Date of Withdrawal** field.
9. Select the required checkbox that confirms you want to withdraw the subject.
10. Select **Withdraw Subject**.

If the study contains a Withdrawal visit, the visit is opened. The Withdrawal Visit is also displayed on the **Next Visits** column.
11. If needed in your study, complete the forms for the subject's Withdrawal Visit, and select **Save** or **Save & Close**.



A withdrawn subject appears with the **Withdrawn** icon (  ).

### Related Topics

- [Undo or edit a subject's withdrawal](#)  
If you withdrew a subject in error, you can undo the action. However, if the subject was automatically withdrawn due to a code break, you can't undo the withdrawal.
- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?
- [After undoing the event I cannot complete or withdraw a subject](#)  
After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.
- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Undo or edit a subject's withdrawal

If you withdrew a subject in error, you can undo the action. However, if the subject was automatically withdrawn due to a code break, you can't undo the withdrawal.

If your study includes a Withdrawal Visit with associated forms that you already completed, when you undo a subject's withdrawal from a study, the associated Withdrawal Visit remains visible until you clear the data associated with that visit. A subject's Withdrawal Visit is displayed on the **Previous Visits** column.

If your study includes a Study Completion Visit with associated forms that you already completed, when you undo a subject's completion, the associated Study Completion Visit remains visible until you clear the data associated with that visit. A subject's Study Completion Visit is displayed on the **Previous Visits** column.

To hide the visit you must clear all of its data and close all of its associated queries. You should ensure that [you clear the following data](#) points (and not delete the data manually):

- All data, including hidden data
- All queries, including manual, automated, or candidate queries. If you need help closing a query, reach out to your Clinical Research Associate (CRA).
- All data flags. Remember to clear data flags, not remove them manually by selecting the X icon next to the data flag.


Additionally, consider the following notes:

 **Note:**

- You cannot undo a subject's withdrawal if the associated Withdrawal visit contains any frozen or locked data. When you attempt to undo a Withdrawal visit that contains frozen or locked data, an error message is displayed advising you to contact your Clinical Research Associate (CRA) to work with them for unlocking or unfreezing the data. Moreover, you don't see the option to undo a subject's even if their status is *Locked* overall.
- When a subject isn't in the appropriate state, don't try to enter extra data into the Withdrawal, Study Completion, or Screen Fail visit, as that data might not be saved.
- If a subject is withdrawn due to a code break, you cannot undo the withdrawal event or edit any details of the event, such as the reason for withdrawal or the withdrawal date. The withdrawal date associated with a code break is displayed on the Subject History bar, in the Subject Events report, and the Subject dataset.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on the required criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose withdrawal you want to undo or edit.
5. Select the checkbox to the left of the subject.



A withdrawn subject appears with a **Withdrawn** icon (  ).

6. If you want to undo a subject's withdrawal, do the following:
  - a. From the **Manage Subjects** drop-down, select **Undo Withdrawal**.
  - b. On the Undo Withdrawal dialog, from the **Reason for Change** drop-down, select a reason for undoing the subject's withdrawal from the study.
  - c. Select the checkbox informing you of the subject's status change and the visibility of the visit until its data is cleared.
  - d. Select **Undo Withdrawal**.
  - e. If applicable, determine whether you want to clear data for a subject's Withdrawal Visit.
7. If you want to edit a subject's withdrawal details, do the following:
  - a. From the **Manage Subject** drop-down, select **Edit Withdrawal**.
  - b. On the Edit Withdrawal dialog, from the **Reason for Withdrawal** drop-down, select a different reason for withdrawing the subject from the study, if needed.
  - c. If required, update the **Date of Withdrawal**.
  - d. From the **Reason for Change** drop-down, select a reason for the edits you want to make.
  - e. Select **Save**.

Anytime you edit a subject's withdrawal details, if included in the study, the Withdrawal visit opens up again. You can choose to edit and save any data in the visit, or close the visit.

After you undo a subject's withdrawal, their state changes from *Withdrawn* to the state the subject had before being withdrawn, such as *New*, *Enrolled*, or *Active*.

### Related Topics

- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?
- [After undoing the event I cannot complete or withdraw a subject](#)  
After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.

## What states can a subject have?

Depending on the protocol, site users can update a subject's state through multiple actions for a number of times during the study. But have you ever wondered what each state really means for the way you manage subjects' data at a site?

What is a state and what does it say about a subject? A state is an indicator that gives you a general view of where the subject is in the study. Have they just been added? Are they in the "waiting room", ready to effectively enter the study? Are they active participants in the study? Have they left the study? These are just some of the questions a subject's state can answer.

### Note:

A subject's state appears under a subject's ID, in the Subjects table. Information about subject states can also be found in the Subject Events report.

### New

**What it means:** The subject has just been added to a study, but they weren't screened or randomized yet.

**How a subject reaches this state:** A site user adds a subject to a study but doesn't screen them yet.

### Screened

**What it means:** The subject successfully completed the Screening visit and is ready to be randomized.

**How a subject reaches this state:** A site user successfully screens a subject during the Screening visit, without any errors appearing on any forms.

### Active

**What it means:** The subject is an active participant in the study and data is collected on them.

**How a subject reaches this state:** A site user successfully randomized a subject during the Randomization visit, without any data collection or dispensation errors.

## Screen failed

**What it means:** The subject doesn't meet the screening criteria and can't participate in the study.

**How a subject reaches this state:** A site user either:

- Tried screening the subject but forms for the Screening visit contained errors.
- Manually screen failed the subject. For example, a site user can manually screen fail a subject after they find out data from their screening form isn't correct.



### Note:

In the case that a study does not have a randomization visit, users can manually mark a subject as screen failed before the next visit.

## Enrolled

There are different scenarios for how a subject reaches an **Enrolled** state:

**What it means:**

- The subject is an active participant in a rollover study.
- The subject was added in the study after being screened outside Oracle Clinical One Platform.
- The subject was screened in a study without a randomization (or baseline) visit.

**How a subject reaches this state:**

- The subject answered 'Yes' to the rollover type question that typically appears in the study completion form and was automatically enrolled from a baseline study to a rollover study.
- The site user clicked **Add subject** on the **Subjects** tab and the subject was automatically enrolled in the study after being screened in a different system.

## Withdrawn

**What it means:** The subject is no longer available or eligible to continue participating in the study.

**How a subject reaches this state:** Typically, a site user manually withdrew the subject because they were no longer eligible or became unavailable to participate in the study. Additionally, a subject's state permanently changes to Withdrawn when a site user performs a code break on the subject, unblinding their results.

## Complete

**What it means:** A subject has completed all visits, and all data has been entered for the subject.

**How a subject reaches this state:** A site user marked the subject as Complete after they completed all of their visits in a study. Once a subject's state changes to Complete a site user can no longer save forms that weren't started, screen, randomize, withdraw or dispense kits to a subject.

## After undoing the event I cannot complete or withdraw a subject

After undoing a subject's withdrawal or study completion, their associated visits remain in the schedule until you clear their data. To withdraw or complete the subject again, saving and closing these visits won't update their status.

For example, if you need to undo a subject's study completion, the process requires additional steps to ensure their status updates correctly. Suppose you originally completed Subject 001-100 by filling in their study completion details and collecting data for their Study Completion visit. Later, you undo their completion, but the data for the Study Completion visit remains visible in the user interface.

After managing or reviewing other visits' data, you determine that Subject 001-100 are eligible for study completion again. You open the Study Completion visit, review or modify existing data, and select **Save & Close**, expecting the subject's status to update to **Complete**. However, this action alone does not complete the subject. Instead, you must select Subject 001-100, choose **Complete Subject** from the Manage Subjects drop-down, and go through the subject completion workflow again.

You should follow the same steps when you want to withdraw a subject again.

## Link subjects for Electronic Health Record (EHR) data import

With just a few clicks, you can link a subject to their Medical Record Number (MRN) in preparation to import their EHR data, removing the need for redundant data entry.

### Prerequisites

Before you can link a subject, the sponsor must complete the following tasks:

- Enable the study for EHR data import. For more information, see [Enable Electronic Health Record \(EHR\) data import](#).
- Map the site to the EHR connector. For more information, see [Manage your EHR site connections](#). As a result, **Link EHR Patient** and **Remove EHR Link** are available under **Manage Subjects** on the Subjects page.

### Required permissions

To link subjects to their MRN, you must be assigned a study role that includes the *Link and Unlink Subject with EHR Patient* permission.

### Link and unlink a subject, and address a subject that is incorrectly linked.

Follow these steps to link a new or existing subject to their MRN, unlink a subject, or address an incorrectly linked subject.



#### Note:

You are required to provide the subject's MRN during the linking process.

1. **Link a new subject**
  - a. Start on the **Subjects** page.
  - b. Select **Add Subject**.

The Add Subject dialog window opens.

- c. If you are associated with more than one site, make the appropriate selection from the **Site** dropdown.
- d. If you want to link the subject, enter the subject's Medical Record Number (MRN), then select **Next**. If you do not want to link them, select **Add Subject**.

For linked subjects, the full name, date of birth, gender, city, and state are displayed.

- e. Select **Add Subject**.

The Subject History side panel displays *Linked to EHR* along with the associated date and time.

You can import EHR data once you've linked your subject. For more information, see [Import Electronic Health Record \(EHR\) data](#).

## 2. Link an existing subject

- a. Start on the **Subjects** page.
- b. Select the checkbox to the left of the subject you want to link.
- c. From the **Manage Subjects** dropdown, select **Link EHR Patient**.

The Link EHR Patient dialog window opens.

- d. Enter the subject's MRN and select **Next**.

The full name, date of birth, gender, city, and state of the linked subject are displayed.

- e. Select **Link**.

The Subject History Side Panel displays *Linked to EHR* along with the associated date and time.

You can import EHR data once you've linked your subject. For more information, see [Import Electronic Health Record \(EHR\) data](#).

## 3. Unlink a subject

Previously imported EHR data remains in the study if you unlink a subject. If necessary, you can clear or delete it. You can also modify imported data, as long as you are assigned to a study role that includes the *Manually Update EHR Imported Data* permission.

- a. Start on the **Subjects** page.
- b. Select the checkbox to the left of the subject you want to unlink.
- c. From the **Manage Subjects** dropdown, select **Remove EHR Link**.

The Unlink EHR Patient dialog window opens, asking that you confirm the action.

- d. Select **Confirm**.

The Subject History Side Panel displays *Unlinked from EHR* along with the associated date and time.

## 4. Address an incorrectly linked subject

- a. Follow the steps above to unlink the subject.
- b. Did you import any EHR data when the subject's link was incorrect? If so, you can manually clear it.
- c. If applicable, follow the steps above to link a new or existing subject.

Review the following section to learn how events affect a linked subject.

- [How do subject events affect a linked subject?](#)  
Learn how Oracle Clinical One Platform subject events like screen fail, subject transfer, and subject lock impact a subject linked for EHR data import.

## How do subject events affect a linked subject?

Learn how Oracle Clinical One Platform subject events like screen fail, subject transfer, and subject lock impact a subject linked for EHR data import.

**Table 2-1 Subject event impact on EHR linked subjects**

Subject event	Impact to the EHR link
Undo add subject	The link is removed and the subject must be re-linked if they are added again.
Screen fail	The link remains active, allowing you to import EHR data for a screen failed subject.
Subject withdrawal	The link remains active, allowing you to import EHR data for a withdrawn subject.
Subject transfer	<p>A dialog window opens and informs you that this action also removes the EHR patient link.</p> <p><b>Note:</b> <i>The Subject History side panel records this action, along with the corresponding date and time.</i></p> <p>If necessary, the subject can be manually relinked. For more information, see <a href="#">Link subjects for Electronic Health Record (EHR) data import</a>.</p>
Subject rollover	<p>The link remains active in the current study if a linked subject enrolls in a rollover study.</p> <p>If you need to import additional EHR data for the rollover study, you must manually relink the subject. For more information, see <a href="#">Link subjects for Electronic Health Record (EHR) data import</a>.</p>
Subject lock	The system prohibits you from linking or unlinking a locked subject.



# 3

## Enter data and dispense kits

- [About clearing or removing data](#)  
Clearing saved data in a form differs from simply removing data from a field. There are differences in behavior and audit tracking, as well as noticeable differences in specific cases.
- [About the Query List](#)  
The Query List allows you to view and work on all of the queries at your site. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and answer your queries, all in one place.
- [About updates to a dynamic question](#)  
When you update or clear the answer of a determining (parent) question or a dynamically-displayed (child) question, you must keep in mind the specifics of this update according to each use case.
- [Answer a query](#)  
You can answer a sponsor's queries at any time.
- [Apply a data flag to a question](#)  
Mark questions in a form as **Not Applicable**, **Unknown** or **Not Done** if you don't have an answer for these questions.
- [Clear a visit date](#)  
Clear a subject's visit date in order to skip the visit, hide a branch, or hide a dynamic visit added in error.
- [Clear form data](#)  
Clear the data collected in a form in order to remove it.
- [Complete a randomization or dispensation visit](#)  
During a site visit, you collect data as required using the forms associated with the visit. You may also randomize a subject or dispense a kit as part of the visit. To randomize or dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.
- [Complete a dispensation visit with dose changes](#)  
You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Complete an unscheduled dispensation visit](#)  
During an unscheduled visit, you can dispense kits containing an investigational product, Unblinded Pharmacist kits, devices, perform dose changes or converse and confirm the dispensation of kits, but you can't randomize subjects. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.
- [Enter data for an adverse event](#)  
To continuously collect a subject's data on adverse events, and possibly concomitant medication, hospitalizations, and many more, then depending on how your study has been designed you can access and complete the forms within the Adverse Events visit, at any time during the course of the study.

- [Enter data in a form with two sections](#)  
The first part in a two section form represent the flat part of the form, which creates the overall form instance, and contains the leading questions. The second part contains the repeating table where multiple rows of data can be added as it relates to the applicable form instance.
- [Enter data in a repeating form](#)  
Repeating forms allow you to collect multiple instances of the same type of data.
- [Link forms](#)  
You link forms in order to connect related data within your study. If form associations are designed in your study, you can link data from one or more forms (repeating, two-section or one-section forms) to the source form (repeating or two-section). And keep in mind that only data that has been previously entered appears in the launched form.
- [Update a value on a completed form](#)  
Go back and update a question on a form, such as when you discover a data-entry error. This procedure also applies to rollover studies.
- [Update the answer to a dynamic question](#)  
You can update the answer to a determining question (parent question) and automatically clear or hide the answers to its dynamically-displayed questions (children questions), too.
- [Work in the Query List](#)  
The tasks you can fulfill in the Query List focus on working with the details of a query, as well as their source form questions.
- [View dispensed kit numbers and dosing instructions](#)  
You can always get a reminder if you've forgotten the kit numbers or need to review the dosing instructions one more time. This procedure also applies to rollover studies.
- [Import Electronic Health Record \(EHR\) data](#)  
Learn how to import EHR data for a linked subject. This includes demographics, medical history, medications, labs, vitals, and procedures.

## About clearing or removing data

Clearing saved data in a form differs from simply removing data from a field. There are differences in behavior and audit tracking, as well as noticeable differences in specific cases.

When you clear a question, it becomes unanswered, with no data associated to it. This can be compared to a reset and is a change that occurs in the backend. When a question's answer is removed by using the **Delete** or **Backspace** keys, this can be compared to replacing the answer with an empty string or value. In this case, there is data associated to the question, just that the data is an empty answer.

### Required permissions

To clear or remove data, as well as visit dates, you should be assigned with the following permissions:

- The *Edit Form Data for Subjects* permission lets you clear or remove form data.
- The *Edit Visit Dates* permission lets you clear visit dates.

 **Note:**

You can only edit or clear visit dates when this action is specifically allowed in your study. Study managers determine which visits site users can edit the visit date for, even after a form has been saved, through the **Site Edits Visit Date** setting.

**Impact on forms and visits**

Whether you are clearing or removing data, your form is always impacted in the following ways:

- When you clear or remove a required question, a form's status is set to **Incomplete**. However, when you clear or remove an optional question, a form's status is not impacted.
- When you update a question that has an open manual query raised against it (either by updating, removing or clearing data), the query's status is updated to **Answered**. In the case of an automated query, it always depends on the rule logic.
- When a question used in a rule's logic is updated (cleared, removed, or replaced with a new value), the system processes the change causing the impacted rules to re-run. The end result depends on how the rule is configured.

 **Tip:**

You can view the resulting actions in the Answer & Visit History sidebar, each stated as the result of rule execution.

**Differences between clearing and removing data**

You may get different results depending on if you clear or remove a question's answer. The following table lists the impacts and breaks down the various differences between data clear and data removal:

Case	Clear data	Remove data
<b>Reason for change</b>	<ul style="list-style-type: none"> <li>• When you clear a question, a reason for this change is required.</li> <li>• When you attempt to answer a cleared question, a reason for this change is not required.</li> </ul>	<ul style="list-style-type: none"> <li>• When you remove a question's answer, a reason for change is required to either save the empty answer or a new value.</li> <li>• When you attempt to answer an empty question which was previously removed, you must provide a reason for this change as well.</li> </ul>
<b>Answer &amp; Visit History sidebar</b>	<ul style="list-style-type: none"> <li>• When you clear a question's answer, this action is listed as <b>Cleared</b> in that question's answer history. The reason for this change and other audit details are included.</li> </ul> <p><i><b>Note:</b> All actions performed on a question are listed on the Answer &amp; Visit History sidebar. Even if you clear a question's data, the whole answer history is retained .</i></p>	<ul style="list-style-type: none"> <li>• When you remove a question's answer, this action is listed as <b>Value:&lt;Answer Removed&gt;</b> in that question's answer history. The reason for this change and other audit details are included.</li> </ul>

Case	Clear data	Remove data
<b>Unsaved form questions</b>	<ul style="list-style-type: none"> <li>You cannot clear unsaved form data. The <b>Clear</b> option is not available.</li> </ul>	<ul style="list-style-type: none"> <li>You can remove form data even if you haven't save it yet.</li> </ul>
<b>Verified or signed questions</b>	<ul style="list-style-type: none"> <li>The question becomes unverified or unsigned, respectively.</li> <li>The Unsigned and Unverified icons aren't displayed next to a question whose data was cleared. On the Answer &amp; Visit History sidebar, you can view a record of the data clearing action, as well as records of the unsigned and unverified actions performed. These records are attributed to the system as a consequence of data being cleared. Other previous actions, such as data entry, signing, verifying, locking or unlocking, are also displayed on the Answer &amp; Visit History sidebar.</li> </ul>	<ul style="list-style-type: none"> <li>The question becomes unverified or unsigned, respectively.</li> <li>The Unsigned and Unverified icons remain displayed for a given question, as well as their details on the Answer &amp; Visit History sidebar.</li> </ul>
<b>Unlocked questions</b>	<ul style="list-style-type: none"> <li>You can clear an unlocked question and this reverts the status of the question to that of a new question.</li> <li>The Unlocked icon isn't displayed next to a cleared question. On the Answer &amp; Visit History sidebar, you can view a record of the data clearing action, as well as records of previous actions, such as data entry, signing, verifying, locking or unlocking data.</li> </ul>	<ul style="list-style-type: none"> <li>You can remove data from an unlocked question.</li> <li>The Unlocked icon remains displayed for a given question, as well as its details on the Answer &amp; Visit History sidebar.</li> </ul>
<b>Unfrozen questions</b>	<ul style="list-style-type: none"> <li>You cannot clear unfrozen form data. The <b>Clear</b> option is not available.</li> </ul>	<ul style="list-style-type: none"> <li>You can always remove data from an unfrozen question.</li> <li>After data removal, the question automatically freezes and details display on the Answer &amp; Visit History sidebar.</li> </ul>
<b>Visit dates</b>	<ul style="list-style-type: none"> <li>When you clear a complete visit's date, that visit's status is updated to Incomplete. However, when you clear an incomplete visit's date, its status remains unchanged.</li> <li>Clearing a visit date does not affect the signed or verified state of a visit.</li> <li>You cannot clear a visit date if all questions in the visit are frozen.</li> </ul>	<ul style="list-style-type: none"> <li>You cannot remove a visit's date.</li> </ul>

Case	Clear data	Remove data
<b>Date/Time questions or visit dates used for calculations</b>	<ul style="list-style-type: none"> <li>When you clear a visit date that is used to determine lab normal ranges in lab forms, the system's date at the time of the update is used instead to populate the calculated values.</li> <li>When you clear a date that is used for calculations (like a subject's age or any custom calculation), the calculation fails and the calculated value is not populated, hence the question remains incomplete.</li> </ul>	<ul style="list-style-type: none"> <li>You cannot remove a visit date's data.</li> <li>For removed Date/Time questions used in calculations, the impacted calculation fails and the calculated value is not populated, hence the question remains incomplete.</li> </ul>
<b>Clear option availability</b>	<ul style="list-style-type: none"> <li>Once you clear a question, the <b>Clear</b> option is no longer displayed as you no longer have any data to clear.</li> </ul>	<ul style="list-style-type: none"> <li>Even if you remove data from a question and leave it blank (by using the <b>Delete</b> key or the <b>Reset</b> option for radio buttons questions), the <b>Clear</b> option is still available.</li> </ul>

### Related Topics

- Clear a visit date
- Clear form data
- How does clearing data impact my study?

## About the Query List

The Query List allows you to view and work on all of the queries at your site. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and answer your queries, all in one place.

### Required permissions

The Query List requires the same set of permissions associated with viewing and working with queries. For more information, see Descriptions of permissions in Clinical One.

### Actions available on the Query List page

The availability of the functionalities of the Query List depends on your permissions. See the table below for a full list of the available features.

**Table 3-1 Query List features overview**

Feature	Description
Show all queries	All of the queries you have permission to view are listed in the Query List. These queries are also grouped according to their status. For more information on the ways you can group your queries, see Filter the Query List.
Filter queries	You can apply one or more filters to the list of queries you have permission to see. You can also sort them based on age. For more information on how to perform this task, see Filter the Query List.

**Table 3-1 (Cont.) Query List features overview**

Feature	Description
View query details	In a separate page, brings together all of the details of a query, including its history in detail. For more information on how to perform this task, see Explore a query's details and history.
View in form, update value	You can quickly access a question for which a query has been submitted, in order to update its answer. Depending on your permissions, in the page dedicate to a query's details, you can select <b>Update Data</b> or <b>View in Form</b> . For more information on how to perform this task, see Explore a query's details and history.

### Views, columns and filters of the Query List

For more information on performing this task, see Filter the Query List.

In order to interact with queries more efficiently, you can switch between views of your queries in the Query List based on the actions you need to perform for them. Accordingly, the following views are available:

- **To Do:** brings together all of the queries you have not yet answered or closed.
- **Unresolved Queries:** brings together all of the queries you have permission to view and that do not have a status of *Closed*. This includes queries that are pending the action of other users, for which you only have viewing permissions.
- **Closed:** includes all of the queries with at status of *Closed* you have permission to see.

#### **Caution:**

Switching between views will reset any filters you have applied to your list of queries.

You can also use the **Search by Query Details** field to quickly narrow down your list of queries. This field searches your queries' text for the keywords you input.

#### **Note:**

Be aware that if you include "\_" or "%" characters when searching query records, the system will show all records that contain the key words also included, as opposed to the specific string of text. For example, if you search "Site\_Query\_", the system returns all queries containing "Site" and "Query".

We recommend using this field for all of your searches, instead of the **Search for Query** field, found in the queries sidebar, on a subject's page.

The Query List displays all of the queries you have permission to view. To help you find the queries you are looking for, the following columns are available:

**Table 3-2 Query List columns**

Column	Description
<b>Subject</b>	Indicates the subject number your query is associated with.
<b>Query</b>	Shows the query message.
<b>Visit</b>	Indicates the visit for which the query has been raised.
<b>Created By</b>	Indicates the author of the query. For queries that have been automatically opened by the system, the creator is indicated as Auto Calculation. This column is only available in the <b>Unresolved Queries</b> and <b>Closed</b> views.
<b>Age</b>	Indicates the age of the query, from when it was opened to the current date. Can be used to sort the list of queries in an ascending or descending order.
<b>Closed On</b>	Indicates the date when a query was closed. Only available in the <b>Closed</b> view.
<b>Status</b>	The current status of the query. For a detailed description of each status, see Understand query statuses.

The table below describes the filters available in the Query List, as well as the behavior of each filter in the context of each view.



**Note:**

Your filters panel may change in accordance with your view of the Query List and your permissions.

**Table 3-3 Descriptions of filters in the Query List**

Filter	Description	In the To Do view	In the Unresolved view	In the Closed view
<b>Type</b>	Allows you to select your query type, based on its author or source.	Choose one of the following options: <ul style="list-style-type: none"> <li>• <b>Auto</b></li> <li>• <b>Manual</b></li> </ul>	Choose one of the following options: <ul style="list-style-type: none"> <li>• <b>Auto</b></li> <li>• <b>Manual</b></li> </ul>	Choose one of the following options: <ul style="list-style-type: none"> <li>• <b>Auto</b></li> <li>• <b>Manual</b></li> </ul>
<b>Status</b>	Filter your list of queries based on one or several statuses.	Choose one or several of the following options: <ul style="list-style-type: none"> <li>• <b>All</b></li> <li>• <b>Candidate</b></li> <li>• <b>Answered</b></li> <li>• <b>Opened</b></li> </ul>	Choose one or several of the following options: <ul style="list-style-type: none"> <li>• <b>All</b></li> <li>• <b>Candidate</b></li> <li>• <b>Answered</b></li> <li>• <b>Opened</b></li> </ul>	Choose one or several of the following options: <ul style="list-style-type: none"> <li>• <b>All</b></li> <li>• <b>Closed</b></li> <li>• <b>Deleted</b></li> </ul>
<b>Age</b>	Filter your list of queries based on the age of your queries.	Choose one of the following options: <ul style="list-style-type: none"> <li>• <b>&lt;7 Days</b></li> <li>• <b>&lt;14 Days</b></li> <li>• <b>&lt;30 Days</b></li> <li>• <b>30+ Days</b></li> </ul>	Choose one of the following options: <ul style="list-style-type: none"> <li>• <b>&lt;7 Days</b></li> <li>• <b>&lt;14 Days</b></li> <li>• <b>&lt;30 Days</b></li> <li>• <b>30+ Days</b></li> </ul>	Filter not available in this view.

Table 3-3 (Cont.) Descriptions of filters in the Query List

Filter	Description	In the To Do view	In the Unresolved view	In the Closed view
<b>Last Updated Date</b>	Filter your list of queries based on a single date when they were last updated.	Select a date in the calendar field. You can also type a date in the DD- MMM-YYYY format.	Select a date in the calendar field. You can also type a date in the DD- MMM-YYYY format.	Filter not available in this view.
<b>Closed On Date</b>	Filter your list of queries based on the date they were closed.	Filter not available in this view.	Filter not available in this view.	Select a date in the calendar field. You can also type a date in the DD- MMM-YYYY format.
<b>Subject</b>	Filter your list of queries based on a subject number, at a particular site.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Select the site, then choose from a list of subjects, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.
<b>Form Name</b>	Filter your list of queries based on a form name.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of forms, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.
<b>Creator</b>	Filter your list of queries based on the names of their creators or their roles.	Select between <b>Name</b> or <b>Role</b> , then select the form name. You can also begin typing and the list will narrow down as you type.	Select between <b>Name</b> or <b>Role</b> , then select the form name. You can also begin typing and the list will narrow down as you type.	Select between <b>Name</b> or <b>Role</b> , then select the form name. You can also begin typing and the list will narrow down as you type.
<b>Assigned User Role</b>	Filter your list of queries based on the role of the assigned user. Only available for assigned queries.	Choose from a list of roles, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Choose from a list of roles, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.	Filter not available in this view.
<b>Closed By User</b>	Filter your list of queries based on the user who has closed the query.	Filter not available in this view.	Filter not available in this view.	Choose from a list of users, which is populated based on the queries in your list. You can also begin typing and the list will narrow down as you type.



### Related Topics

- Understand query statuses
- Access the Query List
- Filter the Query List
- Explore a query's details and history
- [Work in the Query List](#)  
The tasks you can fulfill in the Query List focus on working with the details of a query, as well as their source form questions.
- Descriptions of permissions in Clinical One

## About updates to a dynamic question

When you update or clear the answer of a determining (parent) question or a dynamically-displayed (child) question, you must keep in mind the specifics of this update according to each use case.

### Note:

Dynamically-displayed questions that are frozen, locked, read-only, hidden, assigned a data classification that you don't have permission to see, or associated with future visits cannot be automatically cleared. You must manually clear the data of those impacted questions first.

Anytime you update or clear the answer of a determining (parent) question, you get an Information dialog detailing what's going to happen next. The information on that dialog may vary depending on what types of questions, forms or visits your action is impacting, whether they're frozen, locked, associated with other visits, and so on.

### Update the determining question of multiple dynamic questions

- When you want to update or clear the answer of a determining question, after you perform this action, an Information dialog appears indicating the dynamic questions, forms, or other dynamic elements that you are about to automatically clear as part of this process. On that dialog, you have the option to update the questions or cancel the action.
- When you want to update or clear the answer of a determining question, and the dynamic elements associated with it are either locked, frozen, read-only, hidden, or associated with forms in future visits, the Information dialog will indicate that you need to manually update or clear the dynamic (children) questions before you can update the determining (parent) question. If the fields that are locked, frozen, read-only or hidden contain no data, then you don't have to manually update those fields.
- If there are multiple layers of dynamically-displayed questions (for example, a child question can act as the determining parent question for other dynamic questions), then you must manually clear any "grandchildren" questions. For example, if you attempt to clear the answer for parent question A, the system could clear the answer to child question B. But if child question B has other dynamic questions determined by its answer (questions C and D), then you must first clear the answers for the grandchildren questions (questions C and D). When you attempt to update or clear parent question A, the dialog only displays the child questions that are directly impacted by the given parent question.

- If there is an open manual query raised against a dynamic question that is about to be hidden, the manual query is automatically closed with a reason of 'Dynamic has been untriggered' specified in the system.
- If there is an automated query raised against the dynamic question that is about to be hidden, the hiding of that rule target field (whether it is a dynamic question, a question on a dynamic form or a question in a dynamic section) automatically closes the query with the reason 'Dynamic has been triggered' specified in the system.

### Update the determining question of multiple forms or visits

Anytime you want to update or clear the determining (parent) question of multiple dynamic forms or visits, the Information dialog indicates which forms or visits will be cleared of their data in the process.

Consider the following notes, as well:

- By default, a dynamically-displayed repeating form, a two-section form, a repeating section, or a lab form is completely cleared and hidden from the visit.
- For a dynamically-displayed visit, if the **Visit Date** field is the only completed field in the visit, after updating its determining question, the **Visit Date** field is cleared, and the dynamic visit is hidden from a subject's schedule. If the visit had other fields completed, you won't be able to clear or update the determining question until you manually clear all of the other fields.

### Clear a dynamically-displayed question

When you want to clear the answer for a dynamically-displayed (child) question, you must indicate a reason for this change in the **Reason for Change** field for that question. When you submit that reason for change and the update becomes effective, you can view the question's update in the Answer & Visit History side panel. Every automatically-cleared dynamic question is displayed as **Clearing - Dynamic hidden** in the User Interface (UI). This new status is displayed again at a later time since it is not possible to see the Answer and Visit History data for a question that you cannot view.

If you skip a dynamic visit for a subject, you can hide the visit by changing the answer to the determining question to a value that doesn't display the dynamic question, without un-skipping the visit first.

### Other use cases for clearing dynamic elements

- While the system is clearing that question's answer, you can continue working on other questions in the form, but you won't be able to modify the questions that are being currently cleared.
- If a dynamic question is **locked**, then a sponsor user must first unlock it before you can clear its answer.
- If a dynamic question is **frozen** or **unanswered** (without a data flag) the question is simply hidden without a reason for change being required.
- If a dynamic question is unanswered but it contains a data flag, you must first remove its data flag before you can clear it. The question is displayed in the Information dialog.
- If a dynamic question is signed or verified, it becomes unsigned or unverified after you clear or update the question. It remains unsigned or unverified even when its determining question is updated or cleared, and the questions become hidden.
- If the age question is dynamically displayed and you attempt to clear or update its parent question, the system only automatically clears the Date of Birth field. This re-runs the

calculation of the rule and clears the Age field, as well. The Information dialog only references the Date of Birth question as being automatically cleared.

- If the value of a dynamic parent question is updated before any data in the dynamic child question is saved, the answer provided for the dynamic child question is not saved, and the question is hidden. In this case, the dynamic child questions are not displayed in the Information dialog.
- When you automatically clear dynamic child questions that are linked to other forms, your username appears in the Answer & Visit History side panel as the user who unlinked those forms. The unlinking action is attributed to you clearing the dynamic parent question.

## Answer a query

You can answer a sponsor's queries at any time.

### Note:

For more efficient query management, we recommend using the Query List instead. For more information, see [About the Query List](#).

Before you answer a query, consider the following:

- To view the history of queries on a question, select the question as to perform any action, and expand **Answer & Visit History** on the right. Recent activity appears first.
- To see all queries, return to the Subjects page, and expand **Queries** on the right. You can also scroll through forms within a visit to identify queries. Questions that contain open or answered queries will be highlighted in red.
- There is a length limit of 2048 characters for a query's text. However, if the query is longer than 1068 characters it will display partially and you will need to use the sidebar to view the full text.


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



### Note:

If you cannot see the Queries sidebar, that means that you might not have the right roles assigned to yourself. Contact your Clinical Research Associate (CRA) for help.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
4. View queries through the Queries sidebar:

You can get an overview of queries on the Subjects page or on a visit's containing the query that you need to answer. Look for visits that are displayed in red and marked with a question mark (  ) and click that visit to open it.


- a. On the right side pane, expand **Queries**.

If you expand the Queries sidebar while on the Subjects page, with a site filter applied, all queries for all subjects are displayed. To view queries related to a single subject, select that subject.

 **Tip:**

You can type in to search for a query or filter them by status.

- b. Click on a query to expand its details.

5. Review the text provided by the sponsor, then click the menu icon (  ) and select one of the following options:

 **Note:**

If a question with an open or answered query becomes unavailable through the user interface, you cannot locate or manage that query directly in the form. Use the **Answer** option to manage it directly from the Queries sidebar instead.

- **View:** This option takes you directly to the question in the form containing the query. From this point on, you can take action as described in the next step to either answer the query or update the field.
  - **Answer:** This option lets you answer the query. A Comment to Answer Query dialog is displayed. Enter a comment and click **Answer Query**.
6. If you choose to locate the query in the form or access the query directly within the visit, review the comment provided by the sponsor and take appropriate action:
    - To correct an issue, click **Update value**, then enter a new value, select a Reason for Change, and click **Submit**.
    - To keep the value as-is and provide additional information, click **Answer**, add a comment, and click **Submit**.

The status of the query changes to Answered.

### Related Topics

- [About the Query List](#)  
The Query List allows you to view and work on all of the queries at your site. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and answer your queries, all in one place.

## Apply a data flag to a question

Mark questions in a form as **Not Applicable**, **Unknown** or **Not Done** if you don't have an answer for these questions.

Data flags can't be added to required questions in a screening, randomization or dispensation visit. Instead, you can use data flags for every type of question, including question groups, as well as in repeating forms.

### Tip:

You cannot complete the intended action if you add a data flag to a required question. Only after the visit action took place, you can add a data flag to an item (required or not).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject, and click the visit in the Next Visits column.
5. If you don't know the answer to a question on the form, hover over that question.
6. Click the menu icon to the right of the question, and from the drop-down select either one of these data flags:
  - **Mark Not Done:** Use this flag if the answer to a question can't be provided at the moment. For example, a subject can't be weighed during a visit, so a required question about their weight can be marked as Not Done to proceed with form completion.
  - **Mark Not Applicable:** Use this flag if the answer to a question isn't applicable at the moment. For example, a subject doesn't need its heart rate measured during this visit, so the answer to a BPM question isn't applicable during this visit.
  - **Mark Unknown:** Use this flag if the answer to a question is unknown at the moment. For example, a subject doesn't know their blood type and there's no way to determine that on the spot.

### Note:

If you want to update a data flag, you also need to mention a reason for the update, in the **Reason for Change** text field.

7. Click **Submit**.

Despite not being answered, a question marked with a data flag can be left unanswered in the system. This allows you to complete the form and the visit.

## Clear a visit date

Clear a subject's visit date in order to skip the visit, hide a branch, or hide a dynamic visit added in error.

Before you work with this feature, consider the following:

- Make sure you have the *Edit Subject Data* permission to clear the visit date.
- If you cannot clear a visit's date, this means that your study is not configured to allow a site user to edit a visit's date. For more information, reach out to your Clinical Research Associate (CRA).

To clear a visit date:

1. On the Home page, determine where to work. For step-by-step guidelines, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate the visit which you would like to remove the visit date for.
5. Locate the **Visit Date** question and select the menu icon (☰) to the right of the field.

### Note:

If all questions in your form are frozen, you will not be able to clear the Visit Date. At least one question other than the Visit Date needs to be unfrozen if you would like to clear the Visit Date. This is also applicable for locked questions. For more information, see [Freeze and unfreeze data and Lock a form or visit](#).

6. Select **Clear**.
7. From the **Reason for Change** drop-down, select the applicable reason for change, then click **Submit**.
8. Click **Save & Close**.


### Related Topics

- [Clear form data](#)  
Clear the data collected in a form in order to remove it.
- [About clearing or removing data](#)  
Clearing saved data in a form differs from simply removing data from a field. There are differences in behavior and audit tracking, as well as noticeable differences in specific cases.
- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Clear form data

Clear the data collected in a form in order to remove it.

Before you work with this feature, consider the following:

- Make sure you have the *Edit Form Data for Subjects* permission to clear the visit date.
  - If the question you want to clear impacts other dynamically-displayed questions, you will be asked to clear the data of those impacted questions first without having to manually remove those questions' answers.
1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
  2. Along the top, make sure **Subjects** is selected.
  3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
  4. Locate the subject and click the visit whose questions you want to clear.
  5. Locate the question that you want to clear and select the menu icon () to the right of the field.

### Tip:

Although you cannot clear the data of frozen questions, you can still remove the data by selecting the question and using the **Delete** or **Backspace** keys on your computer's keyboard.

6. Select **Clear**. This option clears the answer saved to the question and reverts the question's status to that of a newly introduced question that's never been answered before, in the context of that form.

### Note:

For a question with radio buttons, a **Reset** option is also available. This option removes the radio button selection and keeps the question in the form. To understand the difference see [About clearing or removing data](#).

7. From the **Reason for Change** drop-down, select the applicable reason for change, then click **Submit**.
8. Click **Save & Close**.

### Related Topics

- [Clear a visit date](#)  
Clear a subject's visit date in order to skip the visit, hide a branch, or hide a dynamic visit added in error.
- [About clearing or removing data](#)  
Clearing saved data in a form differs from simply removing data from a field. There are differences in behavior and audit tracking, as well as noticeable differences in specific cases.
- [Forms FAQs](#)

- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Complete a randomization or dispensation visit

During a site visit, you collect data as required using the forms associated with the visit. You may also randomize a subject or dispense a kit as part of the visit. To randomize or dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.

You must complete all required fields to be able to dispense or randomize. This procedure applies to rollover studies, as well.

### Note:

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria.

- If the question is marked as required, you can't randomize or dispense until it is answered.
- If the question isn't marked as required, you can randomize or dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

### WARNING:

If your study is set to randomize upon kits availability you may get an error if the required kits are not available at the site. Make sure all your shipments are marked as received and kits are added to inventory with a status of Available, then try to randomize the subject again. See [Randomize a subject after Oracle Clinical One Platform didn't allow you to randomize](#).

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

### Video

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate a subject on subjects list, and click the visit in the Next Visits column.  
Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.
5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.



 **Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Answer questions on each form.
7. Click **Save** and complete the visit:
  - If the visit doesn't include randomization or dispensation, clicking **Save** marks the visit as complete.
  - If you want to save your changes and randomize or dispense later, click **Save & Close**.
8. Next, do one of the following:
  - For a randomization visit, click **Randomize**.
  - For a dispensation visit, click **Dispense**.

 **Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available and the visit will remain in incomplete status.

- If your study allows to dispense re-usable kits, see [Conserve and re-dispense kits](#)
  - If the subject is allowed to titrate, see [Complete a dispensation visit with dose changes](#).
  - If your study requires to confirm dispensation, see [Confirm dispensation of kits](#).
  - If there are not enough kits available at a site to dispense and partial dispensation is allowed, see [Perform a partial dispensation](#).
9. In the Dispense Kits dialog, verify the subject number.
  10. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.
  11. Click **Return to All Subjects** to return to the list of subjects at the site or click **Cancel** to remain in the visit.

In the subjects page you can see the visit for the subject:

- When the visit contains a two-section form, if you completed all of the required questions in the first section of the form and there are no table rows added to the section section of the form, then the two-section form is considered complete. If you completed all of the required questions in the first section of the form, but there are any incomplete rows in the table section of the form, then the two-section form is considered incomplete.
- 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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#)

## Related Topics

- [Complete a dispensation visit with dose changes](#)  
You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Confirm dispensation of kits](#)  
If confirmation of dispensed kits is enabled in your study, then this task can be part of your workflow. You can confirm dispensation of any type of kit: kits for investigational products, kits used to change doses for a subject, reusable kits or devices.
- [Conserve and re-dispense kits](#)  
Before conserving and re-dispensing kits, you need to determine whether the subject has any reusable kits. You can conserve and re-dispense these reusable kits during unscheduled visits, as well.
- [Perform a partial dispensation](#)  
Perform a partial dispensation to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when a visit requires to dispense multiple kits of the same type and you have at least two kits available of each kit type that must be dispensed.
- [Pause dispensation by placing a dose hold](#)  
As a blinded site user or a pharmacist, you have the option of pausing dispensation during a scheduled or unscheduled dispensation visit to ensure a subject's safety.
- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

# Complete a dispensation visit with dose changes

You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.



### Note:

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria.

- If the question is marked as required, you can't dispense until it is answered.
- If the question isn't marked as required, you can dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).

4. Locate a subject on subjects list, and click the visit in the **Next Visits** column.  
Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.
5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.



**Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Answer questions on each form.
7. Click **Save**, and then **Dispense**.



**Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available and the visit will remain in incomplete status.

Option	Steps
If the subject is allowed to titrate	<p>You can change the subject's dose, so you must select an option:</p> <ol style="list-style-type: none"> <li>a. In the Dispense Kits wizard, review the details and options that you have for dose changes: In a blinded study, the subject's number appears; in an unblinded study, the kits that the subject received last also appear.</li> <li>b. Select one of the following: <ul style="list-style-type: none"> <li>• To keep a subject on their current dose, choose <b>Maintain Dose</b>.</li> <li>• To titrate down, choose <b>Decrease Dose</b>.</li> <li>• To titrate up, choose <b>Increase Dose</b>.</li> </ul> </li> <li>c. Review the message and select the checkbox.</li> <li>d. Click <b>Next</b>.</li> </ol> <p><i><b>Note:</b> If either the <b>Decrease Dose</b> or <b>Increase Dose</b> options are grayed out, that type of titration isn't allowed right now. The subject might have reached the limit for the maximum number of allowed dosing changes or not enough time has passed since the subject's last titration. To learn more about visit and dispensation settings, contact your Clinical Research Associate (CRA).</i></p>
If the subject isn't allowed to titrate	<p>You can't change the subject's dose, so a message from the sponsor or CRO appears:</p> <ol style="list-style-type: none"> <li>a. Review the message, and click <b>OK</b>.</li> <li>b. In the Dispense kits wizard, do the following: <ul style="list-style-type: none"> <li>• Check the kit details and click <b>Next</b>.</li> <li>• To go back and choose a different option for titration, click <b>Back</b>.</li> </ul> </li> </ol>

8. In the Dispense Kits wizard, verify the subject number.  
If there are not enough kits available at a site to dispense, [Perform a partial dispensation](#).

 **Tip:**

After a partial dispensation, you can do an unscheduled titration to decrease the dose so that the subject doesn't need to come back to receive more kits.

9. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.
10. Click **Return to All Subjects** to return to the list of subjects at the site, or click **Cancel** to continue operating the visit.

In the subjects page you can see the visit for the subject:

- When the visit contains a two-section form, if you completed all of the required questions in the first section of the form and there are no table rows added to the section section of the form, then the two-section form is considered complete. If you completed all of the required questions in the first section of the form, but there are any incomplete rows in the table section of the form, then the two-section form is considered incomplete.
- 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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#)

**Related Topics**

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Complete an unscheduled dispensation visit

During an unscheduled visit, you can dispense kits containing an investigational product, Unblinded Pharmacist kits, devices, perform dose changes or converse and confirm the dispensation of kits, but you can't randomize subjects. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.

 **Note:**

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria.

- If the question is marked as required, you can't dispense until it is answered.
- If the question isn't marked as required, you can dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

To view dosing instructions, run the Kit Dispensation report. For more information, see Kit Dispensation report.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).

2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate a subject on the subjects list and select the checkbox to the left of it.  
Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.
5. From the **Manage Subjects** drop-down, select **Unscheduled Visit**, and then choose the unscheduled visit you want to start.
6. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.

 **Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

7. Answer questions on each form.
8. Click **Save**, and then **Dispense**.

The button you click to submit the form depends on the type of event associated with the visit.

 **Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available.

- If you do not have to dispense any kits during this unscheduled visit, clicking **Save** marks the visit as complete.
  - If you only have to dispense kits with an investigational product, see [Complete a randomization or dispensation visit](#).
  - If the subject is allowed to titrate, see [Complete a dispensation visit with dose changes](#).
  - If one or more devices must be dispensed to the subject, see [Enter data and complete a dispensation visit for devices](#).
  - If there are not enough kits available at a site to dispense, [Perform a partial dispensation](#).
9. Verify the subject number in the confirmation window.
  10. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.
  11. Click **Return to All Subjects** to return to the list of subjects at the site or click **Cancel** to remain in the visit.

In the subjects page you can see the visit for the subject:

- When the visit contains a two-section form, if you completed all of the required questions in the first section of the form and there are no table rows added to the section section of the form, then the two-section form is considered complete. If you completed all of the required

questions in the first section of the form, but there are any incomplete rows in the table section of the form, then the two-section form is considered incomplete.

- 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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#).

### Related Topics

- [Complete a dispensation visit with dose changes](#)  
You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Confirm dispensation of kits](#)  
If confirmation of dispensed kits is enabled in your study, then this task can be part of your workflow. You can confirm dispensation of any type of kit: kits for investigational products, kits used to change doses for a subject, reusable kits or devices.
- [Conserve and re-dispense kits](#)  
Before conserving and re-dispensing kits, you need to determine whether the subject has any reusable kits. You can conserve and re-dispense these reusable kits during unscheduled visits, as well.
- [Perform a partial dispensation](#)  
Perform a partial dispensation to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when a visit requires to dispense multiple kits of the same type and you have at least two kits available of each kit type that must be dispensed.
- [Pause dispensation by placing a dose hold](#)  
As a blinded site user or a pharmacist, you have the option of pausing dispensation during a scheduled or unscheduled dispensation visit to ensure a subject's safety.
- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Enter data for an adverse event

To continuously collect a subject's data on adverse events, and possibly concomitant medication, hospitalizations, and many more, then depending on how your study has been designed you can access and complete the forms within the Adverse Events visit, at any time during the course of the study.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

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



Video


 **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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#)

 **Note:**

Consider the following:




- If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria. If the question is marked as required, you can't randomize or dispense until it is answered. If the question isn't marked as required, you can randomize or dispense without answering.
- If the form you want to delete contains an open query, you must close the query.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. In the table, locate the subject, and click the first column, right after the Subject ID.  
This column is created specifically for collecting data on adverse events, concomitant medications, hospitalizations, and many more. Typically, this column might be called "Adverse Event" or "ConMed".
4. Enter data in a form:
  - If you are entering data in a regular form, follow the usual steps for completing a form.
  - If you are entering the first instance of data in the repeating form, click any cell in the first row to enter data directly into the table.
  - If you already entered data in the repeating form and want to add a new instance, in the upper-left corner of the form section, click the **Add** button and then click each cell in the row to add data.
5. To edit or modify data in a repeating form, click the table cell that you want to edit.
6. To delete data in a repeating form, click the Delete icon () on the left of the table row.
7. Once you added data in the repeating form, in the lower right of the form click **Save** or **Save & Close**.

 **Tip:**

You can also save the repeating form by clicking outside the table.

Depending on a form's status, you may see one of the following status icons on the **Forms** sidebar:

- When complete, a form displays a **Complete** icon .
- When a required question is not answered, a form displays an **Incomplete** icon .
- When a required question contains a validation error, a form displays a **Validation error** icon .

Want to learn more about the possible statuses of a form? See Form status icon descriptions in the *Icon Reference* guide.

#### Related Topics

- [Forms FAQs](#)
- [Subjects and visits FAQs](#)

## Enter data in a form with two sections

The first part in a two section form represent the flat part of the form, which creates the overall form instance, and contains the leading questions. The second part contains the repeating table where multiple rows of data can be added as it relates to the applicable form instance.

#### **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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#)

Depending on your protocol, you can create as many form instances of the two-section form you need.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Enter data in the form with multiple sections:
  - a. Answer the introductory questions first.
  - b. Complete the fields in the table below the introductory questions.
4. To add a new instance of the form (including its introductory questions) click **Add**




in the form.

5. To add a new row in the repeating form table (located in the second section of the form)

click the **Add a record icon**  to the left of the table.






6. To delete an instance of a form with multiple sections, click the Delete icon  to the left of the form title.

On the **Forms** sidebar, you can view a cumulative status of all two-section form instances and navigate to a specific form instances, if needed.

**Figure 3-1** How you may see the Forms sidebar



Depending on a form's status, you may see one of the following status icons on the **Forms** sidebar:

- When complete, a form displays a **Complete** icon .
- When a required question is not answered, a form displays an **Incomplete** icon .
- When a required question contains a validation error, a form displays a **Validation error** icon .

Want to learn more about the possible statuses of a form? See Form status icon descriptions in the *Icon Reference* guide.

#### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)

- [Subjects and visits FAQs](#)

## Enter data in a repeating form

Repeating forms allow you to collect multiple instances of the same type of data.

### **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. To learn more about how a visit's status and a form's status is recorded, see [How does a hidden and required question impact a form and visit's status?](#).

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



For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Depending on what type of visit you need to start, choose the steps you should follow:
  - If you need to start a scheduled visit, in the table, locate the subject, and click the visit in the **Next Visits** column.
  - If you need to start an unscheduled visit, in the table, locate the subject, and from the **Manage Subjects** drop-down select **Unscheduled Visit**, and choose the right unscheduled visit.

Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.


5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.

### **Tip:**


To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Enter data in a form:
  - If you are entering the first instance of data in the repeating form: click any cell in the first row to enter data directly into the table.

- If you already entered data in the repeating form and want to add a new instance: click

**Add**  in the form and then click each cell in the row to add data.


7. To edit or modify data in a repeating form, click the table cell that you want to edit.

8. To delete data in a repeating form, click the Delete icon  on the left of the table row.

 **Note:**

If the form you want to delete contains an open query, you must first close the query.

 **Tip:**




When clearing all the data in a row, the Delete icon  disappears, as there is no more data to remove. If you want to delete the row, consider keeping the question and not clearing the data.

9. Once you added data in the repeating form, do one of the following:
  - Click **Save** and then **Screen, Randomize, or Dispense**.
  - Click **Save & Close** to save your changes and randomize or dispense later

 **Tip:**

You can also save the repeating form by clicking outside the table.

On the **Forms** sidebar, you can see a cumulative status of all repeating form instances. Depending on a form's status, you may see one of the following status icons on the **Forms** sidebar:

- When complete, a form displays a **Complete** icon .
- When a required question is not answered, a form displays an **Incomplete** icon .
- When a required question contains a validation error, a form displays a **Validation error** icon .

Want to learn more about the possible statuses of a form? See Form status icon descriptions in the *Icon Reference* guide.

**Related Topics**

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Link forms

You link forms in order to connect related data within your study. If form associations are designed in your study, you can link data from one or more forms (repeating, two-section or one-section forms) to the source form (repeating or two-section). And keep in mind that only data that has been previously entered appears in the launched form.

Depending on the type of form that you want to link, you have several options:

- To link a **two-section form** you must choose the correct visit or event from the **Visit/ Event** drop-down and the form instance from the **Form Instance** drop-down you want to link. Then you can choose to either link both the flat and repeating sections of a two-section form with the **Link all form data** toggle. You may also choose to link just a particular row in the repeating section.
- To link a **repeating form** you must choose the correct visit or event from the **Visit/ Event** drop-down and then select the rows you want to link to your source form.
- To link a **one-section (flat) form** you must turn on the **Link all form data**.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

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



Video

### Note:

To change the answer that links two forms, first you must unlink any linked forms. Before you change the answer to this question you must first answer or update any relevant queries, as well as remove the links to the related forms.

**To link forms, follow these steps:**

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Select a visit and start completing the two-section form that you want to link. For step-by-step instructions, see [Enter data in a form with two sections](#).
4. Navigate to the form that you want to link.
5. Upon answering the question that determines the forms that can be linked to form, the Associated Forms section is displayed.
6. In the Associated Forms section, depending on the form that you want to link to, you have multiple options:

 **Tip:**

If you get the message that there is no data to display, you can finish your form entry, click **Save**, and add data in the form you want to associate. Once that data exists, you may go back to the parent form and make the appropriate links.

Option	Steps
To link a two-section form	<p>You can link specific rows in the repeating section only or you can turn on the <b>Link form data</b> toggle to link the flat section of a two-section form along with all rows in the repeating section.</p> <ol style="list-style-type: none"> <li data-bbox="943 621 1464 678">a. From the <b>Select a Form</b> drop-down, select the two-section form that you want to link.</li> <li data-bbox="943 695 1464 772">b. From the <b>Visit/ Event</b> drop-down, select the visit, cycle, or event that is associated with that two-section form.</li> <li data-bbox="943 789 1464 867">c. From the <b>Form Instance</b> drop-down, select the specific form instance of the two section form that you want to link.</li> </ol>
To link a simple repeating form	<ol style="list-style-type: none"> <li data-bbox="943 919 1464 997">a. From the <b>Select a Form</b> drop-down, select the simple repeating form that you want to link.</li> <li data-bbox="943 1014 1464 1092">b. From the <b>Visit/ Event</b> drop-down, select the visit, cycle, or event that is associated with that repeating form.</li> <li data-bbox="943 1108 1464 1186">c. To link specific rows, select the checkbox next to a row in the repeating form table.</li> </ol>
To link a one-section (flat) form	<ol style="list-style-type: none"> <li data-bbox="943 1213 1464 1291">a. From the <b>Select a Form</b> drop-down, select the one-section (flat) form that you want to link.</li> <li data-bbox="943 1308 1464 1386">b. From the <b>Visit/ Event</b> drop-down, select the visit, cycle, or event that is associated with that one-section form.</li> <li data-bbox="943 1402 1464 1497">c. Turn the <b>Link all form data</b> toggle on. This is the only available option to link a one-section (flat) form.</li> </ol>
When there is no data in the form that you want to link to	<p>The Associated Forms section displayed the following message: "No data to display". This means that you have to first complete the form that you're attempting to link.</p>
<ol style="list-style-type: none"> <li data-bbox="354 1665 1464 1696">7. To hide forms from your view, click <b>Hide Forms</b>.</li> <li data-bbox="354 1707 1464 1738">8. Click <b>Save</b>.</li> <li data-bbox="354 1749 1464 1845">9. When you change the link details for a form, a Confirmation dialog is displayed. From the <b>Reason for Change</b> drop-down select a reason for the change, and click <b>Change Form Links</b>.</li> </ol>	

### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Update a value on a completed form

Go back and update a question on a form, such as when you discover a data-entry error. This procedure also applies to rollover studies.

### Note:

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria. If the question is marked as required, you can't randomize or dispense until it is answered. If the question isn't marked as required, you can randomize or dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).


1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. On the Next Visits column, click the visit you want to update.
5. In the form, click the field the field that you want to update and make the required changes.
6. Enter a reason for the change and click **Submit**.



For example, if you are rescreening a subject who has become eligible for the study since their initial screening visit, indicate that you are updating the value to rescreen the subject at a later date.

7. Click **Save** at the bottom of the form to keep the form open, or click **Save & Close** to save your changes and return to the Subjects table.
8. If you need to rescreen the subject because of the incorrect value, click **Screen** at the bottom of the form.
9. In all other visits, click **Dispense**.

If you already dispensed a kit to the subject and are updating a value that doesn't affect dispensation, you don't need to click Dispense again unless you want to see which kit the subject received.

Depending on a form's status, you may see one of the following status icons on the **Forms** sidebar:

- When complete, a form displays a **Complete** icon .

- When a required question is not answered, a form displays an **Incomplete** icon .
- When a required question contains a validation error, a form displays a **Validation error** icon .

Want to learn more about the possible statuses of a form? See Form status icon descriptions in the *Icon Reference* guide.

#### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Update the answer to a dynamic question

You can update the answer to a determining question (parent question) and automatically clear or hide the answers to its dynamically-displayed questions (children questions), too.

#### Note:

- You can only automatically clear dynamically-displayed questions, forms, and form associations that are included in the same visit as the parent question.
- Dynamically-displayed questions that are frozen, locked, read-only, hidden, associated with forms in other visits, or with future visits cannot be automatically cleared. You must manually clear the data of those impacted questions first. We recommend you remove the data from dynamically-displayed questions (using the **Delete** or **Backspace** keys), instead of clearing their data.
- Dynamically-displayed questions that are hidden will not be displayed on the Information dialog guiding you on your next steps for clearing or updating dynamic questions.
- If a dynamically-displayed question is associated with a future visit in the study, and that question has been verified, locked, or signed, and it contains a data flag, you must first clear data flag before updating the determining (parent) question.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate the subject and click the visit whose dynamic questions you want to clear.
5. Locate the question that you want to clear or update and select the menu icon (



) to the right of the field.

6. Select either one of the following options:
  - For a question with radio buttons, select **Reset**.  
This option removes the radio button selection and keeps the question in the form.
  - For any other question type, select **Clear**.  
This option removes the answer to the question and reverts the question's status to that of a newly introduced question that's never been answered before, in the context of that form.

An Information dialog appears. On the dialog, you are informed that changing the answer to this question will hide any dynamically-displayed questions or forms, and also clear data from their answer fields.

7. On the dialog, select the checkbox for **I confirm that updating the value will clear all data of the question or forms above**.

 **Note:**

Questions that are locked, frozen, read-only, hidden, associated with forms in other visits, or with future visits cannot be automatically cleared. In those cases, the dialog displays a warning that indicates that answers for these types of questions must be manually cleared before updating the determining (parent) question.

8. Click **Update**.

After you performed this action, here's what the outcome might be depending on what you decided to clear or update:

- If you cleared the determining question of multiple dynamically-displayed questions in the same visit, those questions will be cleared and hidden from the form.
- If you cleared the determining question of multiple dynamically-displayed forms in the same visit, those forms will be cleared and hidden from the visit. If the dynamically-displayed forms were repeating or two-section forms, all data in all instances of those forms was cleared and then hidden.
- If you cleared the determining question of a dynamically-displayed visit, and the only completed field of that visit was its **Visit Date** field, the visit is hidden and the **Visit Date** field is automatically cleared. If the visit had other fields completed, you won't be able to clear or update the determining question until you manually clear all of the other fields.

## Work in the Query List

The tasks you can fulfill in the Query List focus on working with the details of a query, as well as their source form questions.

The actions you can perform in the Query List depend on your permissions. For more information, see [Descriptions of permissions in Clinical One](#).

1. Access the Query List in the study mode you need to work in. For step-by-step instructions, see [Access the Query List](#).
2. Filter your query list as needed. For more information on how to perform this task, see [Filter the Query List](#).
3. Select the **View** button on the right of the row of your query.



4. Depending on the state of the query, you may have to perform one or several of the following:
  - a. In the History panel on the right, type in the **Answer** field, then select either **Answer** or **Cancel**.
  - b. In the panel below the query title, select **Update Value** for any data that requires an update.

You will be taken to the form item the query was submitted for.

5. Once you have finished viewing the form, you can select **Return to Query Details** or navigate elsewhere.

#### Related Topics

- [About the Query List](#)

The Query List allows you to view and work on all of the queries at your site. Obtain an overview of the queries you have permissions to view, apply filters to your list of queries, and answer your queries, all in one place.

## View dispensed kit numbers and dosing instructions

You can always get a reminder if you've forgotten the kit numbers or need to review the dosing instructions one more time. This procedure also applies to rollover studies.

To view dosing instructions, run the Kit Dispensation report. For more information, see Kit Dispensation report.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Select the checkbox to the left of the subject.
5. On the right, below **Subject History**, view the Dispensation History.

#### Related Topics

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Import Electronic Health Record (EHR) data

Learn how to import EHR data for a linked subject. This includes demographics, medical history, medications, labs, vitals, and procedures.

#### Prerequisites

Before you can import data, the following tasks must be completed:

1. The sponsor enabled the study for EHR data import. For more information, see [Enable Electronic Health Record \(EHR\) data import](#).
2. The study designer mapped form questions to EHR data elements. For more information, see [Map form questions for EHR data import](#)

3. The sponsor mapped the site to its EHR connector. For more information, see [Manage your EHR site connections](#).
4. The site user linked the subject to their Medical Record Number (MRN). For more information, see [Link subjects for Electronic Health Record \(EHR\) data import](#).

### Required permissions

Users assigned to a study role that includes the *Edit Form Data for Subjects* permission can import EHR data. If a user needs to edit EHR data after import, the study role needs to include the *Manually Update EHR Imported Data* permission.

### Things to know about importing data

- Imported data undergoes the same validation as manually entered data, ensuring data integrity.
- The data classification rules, defined in Oracle Clinical One Platform, determine the EHR data presented to the user.
  - If a user cannot see a hidden question in the study, the associated EHR data is not presented to them and is not available for import.
  - If the user has the required data classification permissions to view/edit the hidden question, then they can import the EHR data.
- Data import is not available for a locked or frozen subject, visit, form, row, or question.
- You can import EHR data to read-only questions.
- EHR values intended to trigger dynamically hidden questions or forms are available for import.

 **Note:**

Importing data for a child question is not possible if the value for a parent question hides it.

- If an EHR value does not match the study design, for example, an option defined in a code list, the data is not imported.

### Import EHR data

Follow these steps to import a subject's EHR data into Oracle Clinical One Platform forms.

1. From the **Subjects** page, select the visit for the subject which you wish to import data for.
2. Select **Import EHR Data**.

The EHR data for the first mapped data set in the visit is displayed.

- The first column displays the questions that were mapped for import during the study design.
- If data was previously entered or imported on a form, the **Current Value** column is displayed, reflecting the data currently stored on the form.
- The subsequent rows display EHR data that is available for import.
- Sometimes a form contains multiple pages of data. If this is the case, it is represented in the upper right, for example, 1-3 of 27, which indicates that results 1 through 3 of the 27 total are currently displayed. Use the left and right arrows to toggle through each page of results.

3. Adjust the view is necessary
  - If you do not initially see the data you are looking for, adjust the date range using the calendar toggles.
  - Select **Newest First** or **Oldest First** to determine the data presentation order.
4. Select the checkbox to the left of a date to import all data, or select the checkbox to the left of each data point to import specific values. You can select data across dates by selecting the checkbox to the left of each item under different columns.

Some data is grouped by observation, which is presented based on the date collected. You can check the box to the left of the date to import all observations (and the associated data) in a column or you can select individual observations.

5. Select **Next** to progress to the next data set.

*No Available EHR Data, Please try a different date range* is displayed if there is no data available for import. Review the following table to see how the default dates are determined when the data is initially displayed.

**Table 3-4 Default date details**

Data category	Default date range
Demographics	Demographic data is displayed without a date.
Vitals and Labs	The default date range displayed is calculated using the visit date +/- the visit window. If a visit window is not available, the date defaults to the visit date.
Medications, Medical History, and Procedures	The system looks back sixty (60) days from the screening date to determine what to present. If a screening date is not available, the current date is used.

6. Continue to select **Next** to progress through each data set in the visit.
7. Once you've made all of your selections, select **Submit**.
  - The screen shows that the import was successful, and the Answer & Visit History side panel logs each item's import using the *Imported from EHR* tag.
  - Successful data import triggers any associated rules and other activities related to data submission.
  - Data flags are not supported. For instance, if a question's EHR item is null, the system imports no data and sets no data flags.

For further details about importing EHR data, browse the sections below:

- [Details about lab data, repeating form data, and data validation](#)  
Learn how EHR data import works when importing lab results and repeating form data, and how precision is handled.
- [Details about reimporting data](#)  
Learn how reimporting data affects the data in your study.

## Details about lab data, repeating form data, and data validation

Learn how EHR data import works when importing lab results and repeating form data, and how precision is handled.

### Details for importing lab data

You have two options when importing lab results:

- You can select one or more records, for example, White Blood Cell Count and Sodium, which results in the importation of all associated data points, like collection date, result, and units.
- You can choose to import all records in a column by selecting the checkbox to the left of the date at the top of a column.

The data import compares the EHR value, for example, White Blood Cell Count, to the list on the form to determine which row the data is imported to.

Data import is unsuccessful if the EHR lab test name does not correspond to one of the lab test names on the form.



#### Note:

If the form-level setting **Add Additional Rows** is enabled, EHR lab tests that don't match one of the values on the form are imported at the end of the lab form.

### Details for importing repeating form data

Similar to lab forms, when you import data for a repeating form, you select a record to import and not specific data points.

- Importing the same record after clearing or updating a data point only imports the cleared or updated data. The Answer & Visit History side panel accurately reflects this.
- After import, deleting an entire row removes both the data and the row from the study. Then, if you import the same record:
  - The deleted row data is no longer present under the Current Value column when the EHR data is presented to you.
  - The import is inserted as a new row on the form, which is standard functionality. The row has a fresh audit entry in the Answer & Visit History side panel and has no association with the deleted row.

### Data validation and conversion details

Review the following details to better understand when and why data is converted and how to identify this in the Answer & Visit side panel.

- **Handling units**

To maintain the Oracle Clinical One Platform study design, we convert some EHR units to match the study's defined units. This includes length units (for height and head circumference), body weight units, and body temperature units.

  - For example, if the study design only allows temperatures to be entered in degrees Celsius, an EHR value collected in degrees Fahrenheit is converted on import.

- The Answer & Visit History side panel captures the action and includes the date and time, as well as the source and converted units.
- **Handling precision**  
 For numbers, the import maintains the precision as defined in the EHR system.
  - If the precision defined in the study is less than the EHR value presented—for example, if the EHR value is 96.574 but the question precision is 0.00—the data is imported, and a red box appears around the question, which indicates that a validation error is present.

 **Note:**

Users assigned to a study role that includes the *Manually Update EHR Imported Data* permission can update the data if needed.

- If the precision defined in the study is greater than the EHR value, the system adds trailing zeros to maintain the study's design. For instance, if the study design precision is 0.000 and the EHR value is 6.54, the system converts the value to 6.540.
- The Answer & Visit History side panel captures these actions and includes the date and time, along with the source and converted values.
- **Handling code lists**
  - If the EHR value does not match one of the options in the EHR code list, data is not imported for that question, and nothing is tracked in the Answer & Visit side panel.
- **Handling date time**
  - EHR date time values are converted to match the format defined for the question in the study, for example, DD-MON-YYYY.
  - Partial dates are allowed when the question setting **Partial Date Allowed** is enabled. If the EHR date time value is a partial value and the setting is not enabled, the partial value is not displayed for import selection.

## Details about reimporting data

Learn how reimporting data affects the data in your study.

### What should you know about reimporting data?

- A **Current Value** column, when viewing EHR data, indicates a previous import of the data and reflects the current data in the study.
- You can import EHR data as often as needed to ensure you have the latest data for your subjects. When you do this, Oracle Clinical One Platform overwrites the previously imported data. The Answer & Visit History side panel tracks these actions.
- If a previously imported record or value matches the current record or value selected for reimport, no update is applied upon import, and nothing is added to the Answer & Visit History side panel.
- When you manually delete a previously imported value or row before re-importing data, the study views the subsequent import as new data.

### What should you know about reimporting data in a repeating table?

- If you manually clear or update all previously imported items in a row, it no longer qualifies as an EHR import. Reimporting the same data results in a new row.

- If you partially manually clear or update previously imported items in a row, it still counts as an EHR import. It is considered an update if you subsequently reimport the same data.

# 4

## Manage and dispense devices

- [Activate or deactivate a device](#)  
You can activate a device that was already dispensed to a subject, as well as deactivate it if the subject is no longer using it or something happened with it.
- [Enter data and complete a dispensation visit for devices](#)  
You must complete all required fields to be able to dispense devices to a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Replace a device](#)  
If something happened to a device that was already dispensed to a subject, you can always replace it. Both devices with a cloud-to-cloud and device-to-cloud connection can be replaced.
- [Refresh a device's access code and password](#)  
Devices with a device-to-cloud connection come with an initial access code and password that may not work or expire at some point. If that happens, you can always refresh them and activate your device.
- [See a dispensed device in your inventory](#)  
If you want to see more details about a device that you dispensed to a subject, you can always go straight to the inventory to read more about the particular device.

### Activate or deactivate a device

You can activate a device that was already dispensed to a subject, as well as deactivate it if the subject is no longer using it or something happened with it.

For example, if the status of an IoT-enabled device configured through Oracle mHealth Connector is set to Returned to Site, Pending Destruction, Misallocated, Lost, or Damaged, you can deactivate that device.

#### Note:

Activation and deactivation of a device can only be done by a site user and doesn't affect the kit reconciliation process. Changing the status of a kit containing an IoT-enabled device configured through Oracle mHealth Connector can only be done by a clinical supply manager.

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

#### Video

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).

4. In the table, locate the subject whose dispensed device kit types you want to update.
5. Select the checkbox to the left of the subject.
6. On the right, below Subject History, click the menu button (☰) for the device that you want to manage.
7. From the drop-down menu, select one of the following options:
  - If you want to deactivate an active device, click **Deactivate**. A pop-up message appears asking if you want to deactivate the device. Click **Deactivate Device** to proceed or **Cancel** to go back.
  - If you want to activate a deactivated or inactive device, click **Activate**. A pop-up message appears asking if you want to activate the device. Click **Activate Device** to proceed or **Cancel** to go back. In the next Refresh Device Codes pop-up, click **Refresh**.

#### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Enter data and complete a dispensation visit for devices

You must complete all required fields to be able to dispense devices to a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.



#### Note:

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria.

- If the question is marked as required, you can't dispense until it is answered.
- If the question isn't marked as required, you can dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

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



1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate a subject on subjects list, and click the visit in the **Next Visits** column.

Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.



5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.

 **Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Answer questions on each form.
7. Click **Save** and then **Dispense**.

 **Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available and the visit will remain in incomplete status.

8. In the Dispense Kits wizard, review details of the kits and click **Next**.
9. Locate the devices to configure for the subject:
  - For a device with a cloud-to-cloud connection, enter the unique vendor code that comes with the device.
  - For a device with a device-to-cloud connection, make sure they're using the right access code and password. If they don't work, click **Refresh Codes**.

 **Note:**

Remember that you can only activate one device with a device-to-cloud connection for a subject in a study.

- If you need to dispense devices that aren't created through Oracle mHealth Connector, just follow your regular workflow for dispensing devices.
10. Click **Finish** to dispense the kits to the subject. Just as it happens with investigational product kits, you don't see kit descriptions for devices that are blinded. Instead, you only see the kit type.
  11. In the Dispense Kits wizard, verify the subject number.
  12. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.
  13. Click **Return to All Subjects** to return to the list of subjects at the site, or click **Cancel** to remain in the visit.

**Related Topics**


- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)
- [Manage and dispense devices](#)

## Replace a device

If something happened to a device that was already dispensed to a subject, you can always replace it. Both devices with a cloud-to-cloud and device-to-cloud connection can be replaced.

If you need to dispense the same device to another subject in the study, work with your clinical supply manager. For the exact workflow, see [How do I dispense the same device to another subject?](#)

**Want to see how to perform this task? Watch the video below.**  [Video](#)

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose dispensed device kit types you want to update.
5. Select the checkbox to the left of the subject.
6. On the right, below Subject History, click the menu button () for the device that you want to manage.
7. From the drop-down menu, select **Replace**.
8. In the Replace Kits pop-up, the device that you want to replace is already selected. Select a **Reason for Replacement**, and click **Finish**.
9. In the Replace Device pop-up, click **Finish**.

 **Note:**

You can only replace one device at a time.

### Related Topics


- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Refresh a device's access code and password

Devices with a device-to-cloud connection come with an initial access code and password that may not work or expire at some point. If that happens, you can always refresh them and activate your device.

Want to see how to perform this task? Watch the video below.  [Video](#)

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose dispensed device kit types you want to update.


5. Select the checkbox to the left of the subject.
6. On the right, below Subject History, click the menu button () for the device that you want to manage.
7. From the drop-down menu, select **Refresh Access Code**.
8. In the Refresh Device Code pop-up, click **Refresh**.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## See a dispensed device in your inventory

If you want to see more details about a device that you dispensed to a subject, you can always go straight to the inventory to read more about the particular device.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject whose dispensed device kit types you want to update.
5. Select the checkbox to the left of the subject.
6. On the right, below Subject History, click the menu button () for the device that you want to manage.
7. From the drop-down menu, select **Go to Inventory**.

The Site Inventory page opens.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

# 5

## Manage labs and lab forms

- [Add a lab to a study](#)  
You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- [Assign a lab to a site at the study level](#)  
To ensure that a site user can successfully collect lab data, a lab must be assigned to a site.
- [Complete a lab form](#)  
You collect a subject's lab test results using lab forms. To collect lab test results you need to select the appropriate lab and have it associated with the form.
- [Define lab normals](#)  
Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.

### Add a lab to a study

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

As a site user, if adding labs to your study is part of you responsibilities, see [Add a lab to a study](#) in the *Sponsor and CRO User Guide* for step-by-step guidelines.

### Assign a lab to a site at the study level

To ensure that a site user can successfully collect lab data, a lab must be assigned to a site.

As a site user, if assigning labs to sites in a study is part of you responsibilities, see [Assign a lab to a site](#) in the *Sponsor and CRO User Guide* for step-by-step guidelines.

### Complete a lab form

You collect a subject's lab test results using lab forms. To collect lab test results you need to select the appropriate lab and have it associated with the form.

#### **Note:**

We recommend that you do not pre-fill information in forms. Instead, start data entry for a form when a visit occurs. If you start a visit for a subject and then your site starts using a new study version, the started visit is unchanged for the subject, even if the new study version includes changes for the visit.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate a subject on subjects list, and click the visit in the **Next Visits** column.
5. Navigate to the lab form that you want to complete.
6. If included, answer the introductory questions displayed at the top of the lab form.
7. If displayed, click the **Select Lab** drop-down and do one of the following:
  - If your site is already associated with a lab, select an existing lab from the **Select Lab** drop-down.
  - If there are no labs created in your study or the lab you must select isn't on the list, click **Go to Sites & Labs** to create labs and define their lab normals.

 **Note:**

You must be assigned the following permissions to create a lab and define lab normals: *Add and Update Lab Normal Ranges* and *Create and Add Labs to a Site*.


8. On the **Result** column, enter the lab result for each test.  
If you want to edit a value, click the number hyperlink.
9. To add a new instance of the lab form (including its introductory questions), click **Add**



next to the form's title.

 **Note:**

For each new lab form instance that you add, you must answer the Sample Collection Date and Fasting questions, as well as select the appropriate lab from the **Select Lab** drop-down.

10. To add a new row in the table (located in the second section of the lab form), click the **Add a record icon**  to the left of the table.

11. Click **Save**.

When complete, the form displays a **Complete** icon  on the **Forms** sidebar.

Want to learn more about the possible statuses of a form? See Form status icon descriptions in the *Icon Reference* guide.

### Related Topics

- [Assign a lab to a site at the study level](#)  
To ensure that a site user can successfully collect lab data, a lab must be assigned to a site.

- [Add a lab to a study](#)  
You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- [Define lab normals](#)  
Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- How are lab normal updates reflected in completed lab forms?

## Define lab normals

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

As a site user, if defining lab normal values is part of your responsibilities, see *Define lab normals* in the *Sponsor and CRO User Guide* for step-by-step guidelines.

# 6

## Receive and manage an investigational product

- [Confirm dispensation of kits](#)  
If confirmation of dispensed kits is enabled in your study, then this task can be part of your workflow. You can confirm dispensation of any type of kit: kits for investigational products, kits used to change doses for a subject, reusable kits or devices.
- [Conserve and re-dispense kits](#)  
Before conserving and re-dispensing kits, you need to determine whether the subject has any reusable kits. You can conserve and re-dispense these reusable kits during unscheduled visits, as well.
- [Conserve and re-dispense kits during a titration visit](#)  
You can also conserve and re-dispense reusable kits for a visit when you have to perform dose changes for subjects.
- [Perform a partial dispensation](#)  
Perform a partial dispensation to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when a visit requires to dispense multiple kits of the same type and you have at least two kits available of each kit type that must be dispensed.
- [Pause dispensation by placing a dose hold](#)  
As a blinded site user or a pharmacist, you have the option of pausing dispensation during a scheduled or unscheduled dispensation visit to ensure a subject's safety.
- [Register a shipment](#)  
You must register every shipment you receive or Oracle Clinical One Platform won't be able to dispense the kits in the shipment. If you don't register the first shipment you receive, you won't be able to dispense kits to any subjects.
- [Replace a subject's lost or damaged kit](#)  
You replace a kit only if a subject needs a replacement kit for a lost or damaged kit.
- [Mark a kit as missing or damaged at your site](#)  
Mark a kit as missing or damaged only when it hasn't been dispensed yet and has gone missing or got damaged at your site.
- [Mark a kit that you didn't dispense to a subject](#)  
Whenever a kit that was dispensed by Oracle Clinical One Platform never makes it to any subject's hands, you should update your inventory to indicate that the kit was never distributed.
- [Mark a kit that was dispensed in error](#)  
If a kit was dispensed in error at your site, contact your CRA for assistance, and work together to correct the issue.
- [Request extra supply for a clinic day](#)  
You should request a manual shipment only if you're having a clinic day and anticipate a surge of new subjects who will need the product dispensed on or soon after the clinic day. Otherwise, shipments are created as needed according to your site's planned or actual enrollment. If you are concerned that your site doesn't have adequate supply to meet day-to-day needs, talk to your CRA.

- [Check on a late shipment](#)  
If a shipment is late, you can check its ship date to see when it left the depot.

## Confirm dispensation of kits


If confirmation of dispensed kits is enabled in your study, then this task can be part of your workflow. You can confirm dispensation of any type of kit: kits for investigational products, kits used to change doses for a subject, reusable kits or devices.



### Note:

If you plan on confirming the dispensation of kits using barcodes, then they must be included in the kit list.  
A barcode can be the same number as the kit ID.

**Do I have to do this for any other visit besides dispensation visits?** No. This task is only available for visits when you dispense kits to subjects.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate the subject and click the visit in the **Next Visits** column.
5. Answer the questions on each form. Required questions have a blue asterisk to the left of the question number.
6. Click **Save**, and then **Dispense**.
7. Next, depending on how you want to confirm the dispensation of kits, you can do one of the following:
  - On the **Dispense Kits** dialog, above the table, type a kit's barcode or scan it.
  - If you want to confirm the dispensation of an individual kit, on the Subject History pane, click the menu icon (  ) next to each kit, and select **Confirm Dispensation**.
  - If you want to confirm the dispensation of multiple kits, on the Subject History pane, click **Confirm Dispensation** above the kit list.
  - If a subject is not candidate to be dispensed a kit, use a value of 0 for the undesired kits to continue with the dispensation.
8. Click **Confirm**.

Repeat step 6 for every kit in the table until all kits are marked confirmed in the Confirmed Dispensation column.



Figure 6-1 How to confirm dispensation of kits, as a site user

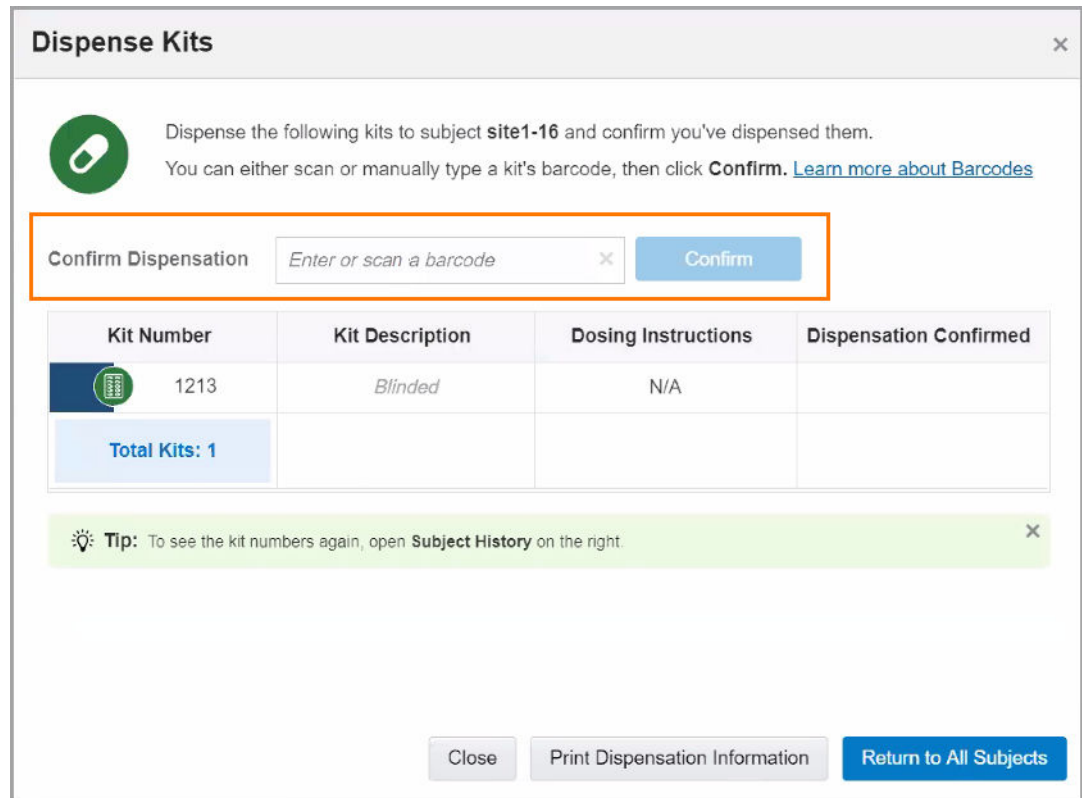
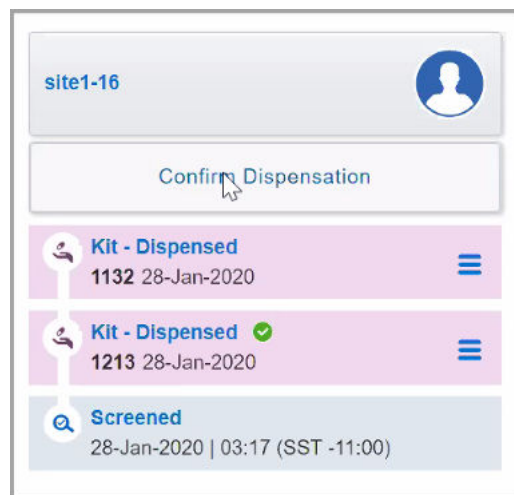


Figure 6-2 How to confirm dispensation of all kits after a visit



**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Conserve and re-dispense kits

Before conserving and re-dispensing kits, you need to determine whether the subject has any reusable kits. You can conserve and re-dispense these reusable kits during unscheduled visits, as well.

 **Note:**

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria.

- If the question is marked as required, you can't dispense until it is answered.
- If the question isn't marked as required, you can dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).

4. Locate a subject on the subjects list and click the visit in the Next Visits column.

Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.

5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.

 **Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Answer questions on each form.
7. Click **Save** and then **Dispense**.

 **Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available and the visit will remain in incomplete status.

8. Determine whether the subject has any reusable kits.
9. In the Kits from Previous Visits dialog click one of the following, as applicable:
  - **The Subject Doesn't Have Any Reusable Kits**

- **The Subject Has Some Reusable Kits.** If you choose this option, in the Reusable Kits dialog, click **Yes** on the **Reusable Kit?** column for each kit that you want to conserve and re-dispense. The system verifies whether the kits can be conserved or not.
10. Click **Continue to Dispensation.**
  11. Review the tables in the Dispense Kits wizard.
    - The first table contains a list of reusable kits that can be conserved and re-dispensed to the same subject.
    - The second one contains a list of all the new kits that can be dispensed.
    - If any of the new kits that you are about to dispense are devices, click **Next** to activate them.
  12. Verify the subject number in the confirmation window.
  13. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.



**Tip:**

The dosing instructions are in the Kit Dispensation report. [This report can be run](#) from the Reports page at any time.

14. Click **Return to All Subjects** to return to the list of subjects at the site or click **Cancel** to remain in the visit.

**Related Topics**

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Conserve and re-dispense kits during a titration visit

You can also conserve and re-dispense reusable kits for a visit when you have to perform dose changes for subjects.



**Note:**

If you enter data that doesn't meet the requirements specified by the sponsor in the form fields, a message explains why the answer does not meet the required criteria. If the question is marked as required, you can't randomize or dispense until it is answered. If the question isn't marked as required, you can randomize or dispense without answering.

For more information on how to handle reference information during the process of collecting data, as well as tips and tricks on how to answer certain question types, see [Best practices for collecting data](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.

3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate a subject on subjects list, and click the visit in the Next Visits column.  
Upon selecting a subject, you can view whether certain visits in a subject's schedule are part of a branch or what cycle they are on.
5. For the **Visit Start Date** field, select today or an earlier date. Depending on how the study is set up, you might be allowed to edit the date after saving the form.

 **Tip:**

To complete exact times, in the Date & Time wizard, first select **Now**, and then start filling in the fields with the appropriate time.

6. Click **Save** and then **Dispense**.
7. In the Dispense Kits wizard, choose whether to maintain, decrease, or increase a subject's dose.
8. Select the **I understand that the titration can't be changed after dispensation occurs** checkbox.
9. Click **Next**.
10. Determine whether the subject has any reusable kits.
11. In the Kits from Previous Visits dialog, click either **The Subject Has Some Reusable Kits** or **The Subject Doesn't Have Any Reusable Kits**.
12. If you chose **The Subject Has Some Reusable Kits**, click **Yes** from the **Reusable Kit?** column for each kit that you want to conserve and re-dispense.  
The system verifies whether the kits can be conserved or not.
13. Click **Continue to Dispensation**.
14. Review the tables in the Dispense Kits wizard.
  - The first table contains a list of reusable kits that can be conserved and re-dispensed to the same subject.
  - The second one contains a list of all the new kits that can be dispensed.
  - If any of the new kits that you are about to dispense are devices, click **Next** to activate them.
15. Verify the subject number in the confirmation window.
16. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.

 **Tip:**

The dosing instructions are in the Kit Dispensation report. [This report can be run](#) from the Reports page at any time.

17. Click **Return to All Subjects** to return to the list of subjects at the site, or click **Cancel** to remain in the visit.

**Related Topics**

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Perform a partial dispensation

Perform a partial dispensation to complete a visit when there are not enough kits available at the site to dispense. Partial dispensation is only available when a visit requires to dispense multiple kits of the same type and you have at least two kits available of each kit type that must be dispensed.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate the subject and click the visit in the **Next Visits** column.
5. Fill-in the forms and click **Dispense**.

 **Note:**

You cannot dispense to a withdrawn subject. If the subject is in withdrawn state, the dispense button is not available and the visit will remain in incomplete status.

- If your study allows reusable kits dispensation, see [Conserve and re-dispense kits](#).
- If the subject is allowed to titrate, see [Complete a dispensation visit with dose changes](#).

 **Tip:**

You can perform an unscheduled titration to decrease the dose after a partial dispensation, so that the subject doesn't need to come back to receive more kits.

6. On the Dispense Kits dialog, note any dispensation instructions and notices about partial dispensation.

On the same dialog, you will see a message confirming the partial dispensation and specifying the amount of kits pending to dispense.


7. Verify the subject number in the confirmation window, and review the kit numbers to dispense and their descriptions.

If your study requires to confirm dispensation, see [Confirm dispensation of kits](#).

8. Depending on what your next step is, do one of the following things:
  - Click **Close**.
  - Click **Print Dispensation Information** to view and print dosing instructions.

- Click **Return to All Subjects** to go back to the Subjects page.

On the Subject History pane, a partial dispensation for a subject is displayed in blue with the partial dispensation icon.

9. To complete a partial dispensation:
  - a. Locate and select the subject in the Subjects page.
  - b. Look for the partial dispensation occurrence on the Subjects History pane.
  - c. click the menu icon ().
  - d. Click **Dispense**.

 **Tip:**

If the site still doesn't have enough kits upon a subject's return, you will be able to perform another partial dispensation until the amount of pending kits is available and dispensation is complete.

 **Caution:**

Make sure you complete partial dispensations before moving forward with the visit schedule. If you dispense kits for a subject in a subsequent visit, scheduled or unscheduled, you cannot go back to that visit and complete the partial dispensation.

**Related Topics**

- [Complete a dispensation visit with dose changes](#)  
You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Confirm dispensation of kits](#)  
If confirmation of dispensed kits is enabled in your study, then this task can be part of your workflow. You can confirm dispensation of any type of kit: kits for investigational products, kits used to change doses for a subject, reusable kits or devices.
- [Conserve and re-dispense kits](#)  
Before conserving and re-dispensing kits, you need to determine whether the subject has any reusable kits. You can conserve and re-dispense these reusable kits during unscheduled visits, as well.
- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)

## Pause dispensation by placing a dose hold

As a blinded site user or a pharmacist, you have the option of pausing dispensation during a scheduled or unscheduled dispensation visit to ensure a subject's safety.

You can perform a dose hold on multiple types of kits that appear available for this task. Any other kits can then be dispensed to a subject as usual.

To learn more about the particularities of your workflow, see [Learn the details of performing a dose hold](#).

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. Locate the subject and click the visit in the **Next Visits** column.
5. Fill-in the forms. For step-by-step instructions, see [Enter data and dispense kits](#).
6. Click **Dose Hold**.
7. On the Dose Hold dialog, select any of the available types of kits that you must put a dose hold on.

 **Note:**

If a dose hold must be placed on an Unblinded Pharmacist type of a kit, you see a notice to contact your unblinded site user or pharmacist, so they can perform this task.

8. Click **Next**.  
If there are any other kits to dispense, the Dispense Kits dialog appears.
9. On the Dispense Kits dialog, review the kit numbers and descriptions.
10. Verify the subject number in the confirmation window, and note the kit numbers to dispense, any dispensation instructions, and notices about dose holds.
11. Depending on what is your next step, do one of the following things:
  - Click **Close**.
  - Click **Print Dispensation Information** to view and print dosing instructions.
  - Click **Return to All Subjects** to go back to the Subjects page.

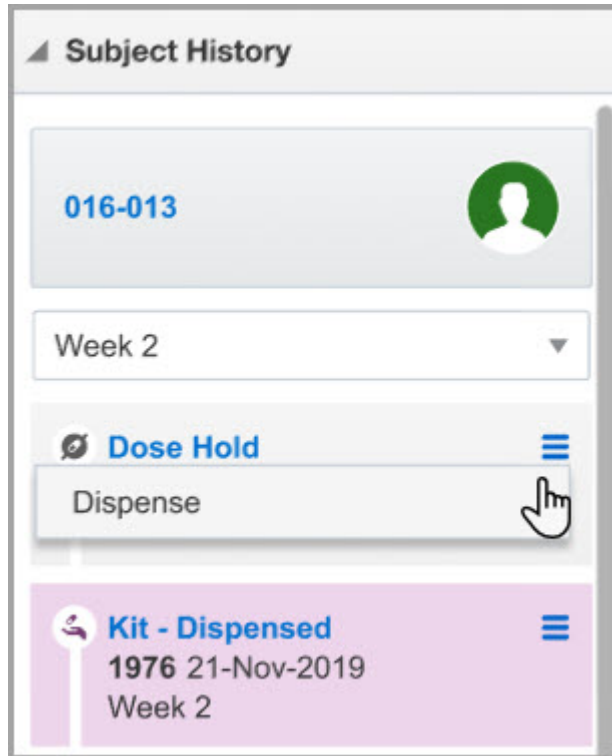
On the Subject History pane, a kit that was put on hold is displayed as a dose hold.

12. To dispense a kit that was previously put on hold, look for the kit on the Subjects History

pane, click the menu icon () and then click **Dispense**.

On the Subject History pane, a kit that was put on hold is displayed as a dose hold. When multiple types of kits are put on hold, the Subject History pane only displays one dose hold for each type of kit. Upon clicking **Dispense**, all kit types previously put on hold are displayed. You must select the kit types that you want to no longer hold and plan on dispensing.

Figure 6-3 How a site user sees a kit put on hold in the Subject History pane



#### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Register a shipment

You must register every shipment you receive or Oracle Clinical One Platform won't be able to dispense the kits in the shipment. If you don't register the first shipment you receive, you won't be able to dispense kits to any subjects.

#### Before you work with this feature

Before registering a shipment, be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.

#### Note:

Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

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





1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, make sure the **Shipments** tab is selected.
3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
4. From the **Filter by Status** drop-down on the right, select **In Transit**.
5. If more than one In Transit shipment appears, enter the **Shipment ID** in the **Search by Shipment ID** field, and press Enter.
6. Select the checkbox next to the shipment.
7. On the right, review the list of kits that are supposed to be in the shipment, and compare this list to the kits you received.
8. Click **Add Shipment to Inventory**.
9. Follow the steps prompted in the Add Shipment to Inventory dialog:

 **Note:**

Depending on the temperature monitor configurations in your study's supply settings, some of these steps might not be available to you.

Option	Steps
Temperature Monitor	<p>If your study allows for temperature excursions, you will be requested to mark any irregularity of temperature monitors in the shipment. Choose the appropriate option:</p> <ul style="list-style-type: none"> <li>• <b>No, a temperature monitor inside of the shipment did not go off.</b></li> <li>• <b>Yes, a temperature monitor inside of the shipment went off.</b></li> <li>• <b>I didn't find any temperature monitors in the shipment.</b></li> </ul> <p><i><b>Note:</b> Depending on your study settings, the system may skip forward to the Review dialog. In this case, continue to the final step. Otherwise, go to the next step.</i></p>
Quarantined kits	<p>If the shipment has experienced a temperature excursion, perform one of the following:</p> <ul style="list-style-type: none"> <li>• If your study allows for single kit quarantine, select the kits needed to be quarantined, then click <b>Next</b>.</li> <li>• Select the lot that needs to be quarantined. In the <b>How many?</b> field, enter the amount of individual kits you'd like to quarantine, click <b>Save</b>, then click <b>Next</b>.</li> </ul>
Damaged Kits	<p>If any kits/lot(s) are damaged, select the affected kits/lot(s) and click <b>Next</b>.</p>
Missing Kits	<p>If any kits/lot(s) are missing, select the affected kits/lot(s) and click <b>Next</b>.</p>
Review	<p>Review the information in the Add Shipment to Inventory dialog and click <b>Finish</b>.</p>

Kits are added to inventory and the status of the selected kits are updated accordingly to Quarantined, Damaged, Missing or Available.

#### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Replace a subject's lost or damaged kit

You replace a kit only if a subject needs a replacement kit for a lost or damaged kit.


#### Note:

The steps for replacing a dispensed device managed through Oracle mHealth Connector are different. If you want to replace a device that was already dispensed to a subject, see how to [replace a device](#).

Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.

#### Note:

Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
3. In the table, locate the subject with a lost or damaged kit. To filter your view of subjects, enter some or part of the subject number in the **Search** field in the upper right above the table of subjects, and press **Enter**.
4. Select the checkbox to the left of the subject.
5. On the right in Subject History, click the Menu icon (  ) next to the kit that a subject returned.
6. From the drop-down, select **Replace**.
7. On the **Replace Kits** dialog, choose one of the following:
  - **Kits**: Select the kit you would like to replace.
  - **Lots**: Select a lot, and enter the quantity of non-serialized kits you would like to replace.
8. Select a reason for the replacement, and click **Replace Kits**.

 **Note:**

If the kit or lot you want to replace isn't lost or damaged, but it simply wasn't dispensed to the subject, select **Not Dispensed to Subject** as the reason for replacement.

When you choose to mark a kit as Damaged or Lost, you can see both the original kit and the replaced kit associated to the subject at the visit where the dispensation initially occurred. When you choose to mark a kit as Not Dispensed, you can see that the original kit is no longer associated with the subject.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Mark a kit as missing or damaged at your site

Mark a kit as missing or damaged only when it hasn't been dispensed yet and has gone missing or got damaged at your site.

 **Note:**

Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see [Allowed updates for inventory status](#).

Be aware that all non-serialized inventory is grouped. Instead of individual kit numbers, non-serialized kits display in the user interface (UI) as lot numbers followed by the quantity.

 **Note:**

Because non-serialized kits can arrive at different date and times, the **Date Received** column on the Site Inventory page does not include any data and appears blank for all non-serialized inventory.

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



1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, click the **Site Inventory** tab.
3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
4. Above the kit list, use the filter to return only the kits you want to mark as missing or damaged:
  - a. To view the kits dispensed to a subject, select the subject from the **Subject Number** drop-down.

- b. To find all kits with one or more statuses, use the **Status** drop-down.
- c. To narrow the list of kit numbers, use the **Number Range**.
- d. To search for a specific kit, use the **Search by Kit Number** field.
5. Select the kit that is missing or damaged.
6. On the right, below Inventory Management, click **Update Kit**.
7. From the Kit Status drop-down, select the kit's new status, either **Missing** or **Damaged**.

 **Tip:**

If a kit experiences a temperature excursion while at your site, select **Pre-Quarantined** from the **Kit Status** drop-down.

8. Enter a reason for the change, and click **Update Kit**.

 **Note:**

If you marked a kit in error as Missing or Damaged, you can set the kit back to Available by following the previous steps.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Mark a kit that you didn't dispense to a subject

Whenever a kit that was dispensed by Oracle Clinical One Platform never makes it to any subject's hands, you should update your inventory to indicate that the kit was never distributed.

A subject might not have received a kit for a few reasons. For example, they accidentally left the kit at the site after their visit, or you intentionally chose not to distribute the kit to them.

 **Note:**

Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see [Allowed updates for inventory status](#).

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

 **Video**

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, click the **Site Inventory** tab.
3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.

4. In the **Search by Kit Number** field, enter the number of the kit that Oracle Clinical One Platform dispensed to the subject but that the subject didn't receive.
5. Select the kit.
6. On the right in Inventory Management, click **Update Kit**.
7. From the Kit Status drop-down, select **Not Dispensed to Subject**.
8. In the **Reason for Change** field, indicate that the kit was not dispensed to the subject, and click **Update Kit**.

#### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Mark a kit that was dispensed in error

If a kit was dispensed in error at your site, contact your CRA for assistance, and work together to correct the issue.

A kit might have been dispensed in error for several reasons. For example, when you enter data for the wrong subject or visit. Or when a kit is dispensed to the subject that is different from the kit that Oracle Clinical One Platform said to dispense.

If the error occurred because someone at your site entered data for the wrong subject, enter data for the correct subject. For example, if subject 001-002's data was entered in 001-001's visit, enter the data for subject 001-002 in the visit for subject 001-002. Oracle Clinical One Platform dispenses a kit; it's up to your CRA to determine whether to exchange the kit that's in the subject's hands for the new kit that Oracle Clinical One Platform dispensed. If your CRA determines that the subject should not receive this kit, [indicate that the kit wasn't dispensed to the subject](#).

#### Note:

Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see [Allowed updates for inventory status](#).

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



#### Note:

On the Home page, determine where to work. For more information, see [Access study modes and pages](#).

1. [Dispense a replacement kit to the subject](#) whose kit was dispensed in error. For example, if subject 001-001's kit was given to subject 001-002 by mistake, dispense a replacement kit to subject 001-001.

 **Caution:**

You must dispense a replacement kit before marking the kit as Misallocated. If you mark a kit as Misallocated before dispensing a replacement kit, you won't be able to dispense a replacement kit.

2. Along the top, click **Supplies**.
3. Below the study name, click the **Site Inventory** tab.
4. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
5. In the **Search by Kit Number** field, enter the number of the kit that was dispensed in error, and press **Enter**.
6. Select the kit.
7. On the right, below Inventory Management, click **Update Kit**.
8. From the **Kit Status** drop-down on the right, select **Misallocated**.
9. From the **Subject Number** drop-down, select the subject that received the kit.  
For example, if Oracle Clinical One Platform dispensed the kit to subject 001-001, but the kit was actually handed to subject 001-002, select 001-002.
10. Enter a reason for correction and click **Update Kit**.

The kit is added to the dispensation history for the subject you selected.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Request extra supply for a clinic day

You should request a manual shipment only if you're having a clinic day and anticipate a surge of new subjects who will need the product dispensed on or soon after the clinic day. Otherwise, shipments are created as needed according to your site's planned or actual enrollment. If you are concerned that your site doesn't have adequate supply to meet day-to-day needs, talk to your CRA.

 **Note:**

You receive a notification for each shipment you request. [Check your notifications](#) to verify your requests.

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

 **Video**

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, make sure the **Shipments** tab is selected.

3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
4. Click **Request Shipment**.



**Tip:**

If the button doesn't appear, the study doesn't allow you to request shipments. Contact your clinical research associate for assistance.

5. Enter the **Reason for Change**, and click **Request**.  
A confirmation of your request appears.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Check on a late shipment

If a shipment is late, you can check its ship date to see when it left the depot.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, make sure the **Shipments** tab is selected.
3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
4. From the **Filter by Status** drop-down, select **In Transit**.
5. Locate the missing shipment and check the **Ship Date** to see when it left the depot.  
If there are no In Transit shipments, that means the shipment has not left the depot yet.
6. If the shipment is missing or late, contact your CRA.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

# 7

## Perform kit reconciliation

- [Update a kit returned by a subject to reconcile kits](#)  
You can reconcile kits with the following statuses: Damaged by Subject, Dispensed, Misallocated, or Lost by Subject. Ask subjects to bring any unused investigational product to their next dispensation visit and update accordingly. We recommend reconciling kits as the study progresses.
- [Destroy kits \(for sites that are drug destruction capable\)](#)  
If your site is drug destruction capable, kit destruction occurs onsite. Otherwise, destruction occurs at a depot that is a drug destruction facility.
- [Ship kits to a drug destruction depot](#)  
If your site isn't drug destruction capable, kit destruction occurs at a depot that is a drug destruction facility. Either you or your CRA is responsible for sending kits to the drug destruction facility.

### Update a kit returned by a subject to reconcile kits

You can reconcile kits with the following statuses: Damaged by Subject, Dispensed, Misallocated, or Lost by Subject. Ask subjects to bring any unused investigational product to their next dispensation visit and update accordingly. We recommend reconciling kits as the study progresses.




#### Note:

Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see [Allowed updates for inventory status](#).

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



Video

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Along the top, make sure **Subjects** is selected.
3. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject who returned a kit.
5. Select the checkbox to the left of the subject.
6. On the right in Subject History, click the menu icon (  ) next to the kit that is missing or damaged at your site.
7. From the drop-down, select **Reconcile**.
8. On the **Inventory Management** pop-up, from the Kit Status drop-down, select **Returned to Site**.



- Specify the number of returned and missing units and an optional reason. You can specify a whole number or decimal value for the returned and missing units.

 **Note:**

If you cannot see these fields, reach out to your clinical supply manager and make sure Kit Reconciliation is set as required in the study's supply settings. Refer to What if a site user can't see the Returned Units and Missing Units fields?

- Click **Update Kit**.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Destroy kits (for sites that are drug destruction capable)

If your site is drug destruction capable, kit destruction occurs onsite. Otherwise, destruction occurs at a depot that is a drug destruction facility.

If your site doesn't handle drug destruction, you have to [ship kits to the drug destruction facility](#).

 **Note:**

- Kits in certain statuses can not be directly updated to the statuses described in this task. For more information see [Allowed updates for inventory status](#).
- If the study allows titration, don't mark the last kits that were dispensed as destroyed until a subject receives their next kits.

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



**What has to happen first?** The CRA must mark all kits that are ready for destruction as Pending Destruction.

- On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
- Below the study name, click the **Site Inventory** tab.
- If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
- From the Filter by Status drop-down above the table, select **Pending Destruction**.

 **Tip:**

Only Pending Destruction kits can be marked as Destroyed. If you want the table to also list the kits that you mark as destroyed, select the Destroyed status, too.

5. Destroy the kits according to the protocol and any relevant SOPs, and mark the kits as Destroyed, if required:
  - a. Select a kit.
  - b. On the right, below Inventory Management, click **Update Kit**.
  - c. From the Kit Status drop-down, select **Destroyed**.
  - d. Enter a reason for the change, and click **Update Kit**.

#### Related Topics

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

## Ship kits to a drug destruction depot

If your site isn't drug destruction capable, kit destruction occurs at a depot that is a drug destruction facility. Either you or your CRA is responsible for sending kits to the drug destruction facility.

If your site handles drug destruction, you can [destroy kits onsite](#).

#### Note:

If the study allows titration, don't ship the last kits that were dispensed as destroyed until a subject receives their next kits.

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



The Clinical Research Associate (CRA) must mark all kits that are ready for destruction as **Pending Destruction**.

1. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
2. Below the study name, make sure the **Shipments** tab is selected.
3. If you have access to multiple sites for the study, select a site from the **Site** drop-down in the upper-right.
4. From the **Filter by Status** drop-down, select **Pending Destruction**.
5. Select a shipment.
6. On the right, below Shipment Details, click **Download List of Kits**.

#### Tip:

Consider printing the report so you know the receiving depot and so you can include the report as a packing list.

7. Fulfill the shipment outside Oracle Clinical One Platform.
8. To add a ship date and tracking number after the shipment departs the site:

- a. Under the **Ship Date** column, click the **Click to Add** link, and select the correct date from the calendar drop-down.
- b. In the Tracking Number column, click the **Click to add** link of the shipment you added a ship date to.

 **Tip:**

You can add tracking information to any shipment at any time. Adding this information is optional.

- c. Fill in the fields, and click **Save**.

The depot can destroy the kits according to applicable requirements.

**Related Topics**

- [Troubleshoot](#)
- [Frequently Asked Questions \(FAQs\)](#)

# 8

## Run reports, generate archives, and view notifications

- [Run and download a report or an archive](#)  
As a site user, you typically run a variety of reports in the application, from standard reports to Oracle CRF Submit archives.
- [Receive notifications](#)  
Site users can receive a variety of notifications with the correctly assigned permissions.

### Run and download a report or an archive

As a site user, you typically run a variety of reports in the application, from standard reports to Oracle CRF Submit archives.

Whether you need to run and download a report, add customized fields to a report, schedule a report, or generate an Oracle CRF Submit archive, see the Reporting Guide.

### Receive notifications

Site users can receive a variety of notifications with the correctly assigned permissions.

For descriptions of the different notifications and their required permissions, along with instructions on how to view notifications, see the Notifications and Permissions Guide.

# 9

## Perform end-of-study activities

- [Run reports at the end of a study](#)  
Principal investigators are responsible for a number of tasks at the end of a study, including identifying all the users who had access to the study data and obtaining a copy of all forms completed at the site.

### Run reports at the end of a study

Principal investigators are responsible for a number of tasks at the end of a study, including identifying all the users who had access to the study data and obtaining a copy of all forms completed at the site.

Getting this information from Oracle Clinical One Platform is easy. All you have to do is run and then save a few reports.

1. Run a report.
2. Download a report.

The following reports are especially useful at the end of a study:

- Kit Dispensation report
- Subject Data report
- Subject Events report
- User Assignment and User Assignment by Site report

#### **Related Topics**

- Standard reports
- Data extracts
- Oracle CRF Submit archives and reports

# 10

## Troubleshoot

- [Kits and dispensation](#)
- [Navigation](#)
- [Subjects and visits](#)

### Kits and dispensation

- [A shipment contains extra kits](#)  
If you receive a shipment that contains extra kits that are not listed in Oracle Clinical One Platform, contact your CRA with the kits' information. The CRA can add the kits to your inventory.
- [I can't conserve a subject's reusable kits](#)  
If you can't conserve and re-dispense reusable kits, there are two options.
- [I can't dispense devices](#)  
If you can't dispense devices there are several ways to troubleshoot the issue, according to the type of device that you're trying to dispense.
- [I can't find the kit Oracle Clinical One Platform dispensed to a subject](#)  
First, you must dispense a replacement kit. Next, work with your CRA to figure out your next steps.
- [I dispensed a device in error](#)  
If you dispensed a device in error at a site, contact your clinical research associate for assistance, and work together to correct the issue.
- [I titrated up or down in error](#)  
If you titrated up or down in error, there are ways to fix the error from within Oracle Clinical One Platform. Your next steps depend on the blinding status of the kits that were dispensed.
- [Oracle Clinical One Platform doesn't let the subject titrate](#)  
There are multiple situations when a subject might not be allowed to titrate. Depending on the situation, the subject might be able to remain on their current treatment arm, or you might need to reach out to your CRA to learn about other options.

### A shipment contains extra kits

If you receive a shipment that contains extra kits that are not listed in Oracle Clinical One Platform, contact your CRA with the kits' information. The CRA can add the kits to your inventory.

### I can't conserve a subject's reusable kits

If you can't conserve and re-dispense reusable kits, there are two options.

1. Your study might not allow the conservation and re-dispensation of a subject's kit. If you think your workflow should include kit conservation, reach out to your clinical research associate (CRA).

2. A subject's reusable kit might be expired or damaged. For example, if a kit is expired or suffered a temperature excursion, the system doesn't conserve it, because it isn't safe to be re-dispensed to the subject. If none of a subject's reusable kits can be conserved, just dispense new kits to them.  
If you think some of the reusable kits that can't be conserved aren't damaged at all or shouldn't expire, work with your clinical research associate (CRA) to make sure those kits are correctly marked in the inventory.

## I can't dispense devices

If you can't dispense devices there are several ways to troubleshoot the issue, according to the type of device that you're trying to dispense.

### **For devices with device-to-cloud connections: When I enter the access code, a message says that the code expired**

If you want to dispense devices to subjects, but you aren't able to do so, maybe the initial access code and password for those devices expired. If that's the case, follow these steps to see if you can troubleshoot the issue:

1. Along the top, make sure **Subjects** is selected.
2. If you have access to multiple sites for the study, select a site from the Site drop-down in the upper-right.
3. In the table, locate the subject that you want to dispense devices to. To filter your view of subjects, enter some or part of the subject number in the Search field in the upper right above the table of subjects, and press **Enter**.
4. Click the visit during which you want the dispensation to take place.
5. Enter the data for that visit, and click **Save**.
6. Click **Dispense**.
7. In the Dispense Kits wizard, review the devices that you're about to dispense. Click **Next**.
8. Click **Refresh Codes** for the device that you're about to dispense.
9. If you want to dispense multiple devices that may have expired initial access codes, click **Next**, and repeat this step for every device.

### **For devices with a cloud-to-cloud connection: Vendor code doesn't work**

If your study is using a cloud-to-cloud connection with Oracle mHealth Connector and you aren't able to activate your devices using the vendor code, contact your CRA.

### **I can't dispense an IoT-enabled device configured through Oracle mHealth Connector**

If your study allows dispensing IoT-enabled devices configured through Oracle mHealth Connector but this option doesn't appear as you expect, contact your CRA.

## I can't find the kit Oracle Clinical One Platform dispensed to a subject

First, you must dispense a replacement kit. Next, work with your CRA to figure out your next steps.

1. [Dispense a replacement kit](#) to the subject who needs the kit right now.
2. Contact your CRA to determine if the kit was dispensed in error and, if so, which subject received it. Your CRA will walk you through your next steps, which might include

dispensing a replacement kit, re-entering subject data, and updating the status of kits that were dispensed in error or never dispensed to a subject.

3. If the kit was not dispensed to any other subjects in the study, mark the kit as Missing.

## I dispensed a device in error

If you dispensed a device in error at a site, contact your clinical research associate for assistance, and work together to correct the issue.

For more details, see how to [Mark a kit that was dispensed in error](#).

## I titrated up or down in error

If you titrated up or down in error, there are ways to fix the error from within Oracle Clinical One Platform. Your next steps depend on the blinding status of the kits that were dispensed.

### Unblinded kits

You should work with the Clinical Research Associate (CRA) and other members of the study team as needed to determine whether they can fix the error by not dispensing one or more kits.

For example, consider a subject who is currently consuming 5 mg of an investigational product and wants to stay on the dose. If you titrated up in error, the subject might switch to a 7.5 mg dose, consisting of a 5 mg kit and a 2.5 mg kit. Here's what should happen in this situation:

1. You work with the study team to determine whether removing one of the kits from the dispensation will solve the error. In this case, removing the 2.5 mg kit does solve the problem.  
**What if the error can't be solved by removing a kit?** The error can't be solved from within Oracle Clinical One Platform. The study team must determine the next steps for the subject.
2. Along with the study team, identify the kit number of the kit to remove.
3. You then mark the kit as Not Dispensed to Subject. When a kit is marked as Not Dispensed to Subject, the kit is no longer considered part of the subject's current dose. So when the subject has their next dispensation visit and they choose to maintain their current dose, they'll stay on the 5 mg dose.

### Blinded kits

For unblinded kits, you should reach out to your Clinical Research Associate (CRA), who should contact the clinical supply manager. The clinical supply manager should look at the kits that were dispensed to see whether they can fix the error by not dispensing one or more kits.

For example, consider a subject who is currently consuming 5 mg of an investigational product and wants to stay on the dose. If you titrated up in error, the subject might switch to a 7.5 mg dose, consisting of a 5 mg kit and a 2.5 mg kit. Here's what should happen in this situation:

1. The clinical supply manager determines whether removing one of the kits from the dispensation will solve the error. In this case, removing the 2.5 mg kit does solve the problem.  
**What if the error can't be solved by removing a kit?** The error can't be solved from within Oracle Clinical One Platform. The study team must determine the next steps for the subject.
2. The clinical supply manager identifies the kit number of the kit to remove and shares the kit number with the Clinical Research Associate (CRA), who then tells you.



3. You then mark the kit as Not Dispensed to Subject. When a kit is marked as Not Dispensed to Subject, the kit is no longer considered part of the subject's current dose. So when the subject has their next dispensation visit and they choose to maintain their current dose, they'll stay on the 5 mg dose.

## Oracle Clinical One Platform doesn't let the subject titrate

There are multiple situations when a subject might not be allowed to titrate. Depending on the situation, the subject might be able to remain on their current treatment arm, or you might need to reach out to your CRA to learn about other options.

### **The subject is already on the highest dose or lowest dose**

If the subject wants to titrate down but is already on the lowest dose, your options might include maintaining the dose and titrating up, or taking another action specified by the sponsor. Similar rules apply when the subject is already on the highest dose and wants to titrate up. For example, for subjects who have reached their dosing limit, you may receive a message from the sponsor advising you to withdraw the subject from the study.

To learn more about your study settings and what is or isn't allowed, contact your CRA.

### **Not enough time has passed since the subject last titrated**

If not enough time has passed before titration is allowed again, you won't see the options for changing doses. Instead, you go straight through to the Dispense Kits pop-up and see a message letting you know that there's a time limit between titrations. In the meantime, contact your CRA to know more details about the time limit between subject titrations.

### **The subject has already reached their maximum number of titrations in a study**

If this happens, you won't see the options for changing doses. Instead, you go straight through to the Dispense kits pop-up and see a message letting you know that you can't change the subject's dose anymore because they've already changed doses the maximum number of allowed times in the study.

### **Titration is not available for your study**

This means that the study that you're working in doesn't allow titration. In that case, you don't have the ability to change doses for subjects. Instead, you go straight through to the Dispense Kits pop-up like for any other dispensation visit.

If your study allows titration but the titration options don't appear as you expect, contact your CRA.

## Navigation

- [I can't see a study on the Home page](#)  
If you are signed in to Oracle Clinical One Platform and you do not see a study on the Home page or you are not able to open a study, you might not have been added to the study, or your user name might not have been associated with the appropriate roles within Oracle Clinical One Platform. Contact your CRA for help.
- [I step away and then can't work in Oracle Clinical One Platform anymore](#)  
Your session might have timed out. Close your browser, and sign in again.

## I can't see a study on the Home page

If you are signed in to Oracle Clinical One Platform and you do not see a study on the Home page or you are not able to open a study, you might not have been added to the study, or your user name might not have been associated with the appropriate roles within Oracle Clinical One Platform. Contact your CRA for help.

## I step away and then can't work in Oracle Clinical One Platform anymore

Your session might have timed out. Close your browser, and sign in again.

Your session will time out after 20 minutes of inactivity. However, an overall active session lasts 3 hours before it times out anyway. If this happens, close your browser, and sign in again.

If you are working in Oracle Clinical One Analytics, make sure you keep your session active in Oracle Clinical One Platform.



### Tip:

Save your work regularly to avoid any loss of data in case of session time out.

Be careful when entering your password. Five consecutive failed login attempts will lock your account. You will be forced to reset your password on the next successful attempt.

## Subjects and visits

- [An error occurs when I try to randomize a subject](#)  
If an error occurs when you try to randomize, the subject might have arrived outside the visit window, or the site might have insufficient stock to dispense kits.
- [A query is added on a form after I sign data](#)  
As long as the assigned query has an **Open** status, that form will remain signed. As soon as you or another user updates the value of the question, to close or update a query, data will have to be re-signed.
- [A subject failed screening, and I need to rescreen the subject](#)  
You might need to rescreen a subject if you made a mistake while completing the screening visit, if the subject's eligibility has changed, or if you manually screen failed a subject in error.
- [A submitted visit remains in the Next Visit column](#)  
Sometimes a completed visit remains in the Next Visit column, when it should move to the Previous Visits column. This issue can occur when a network interruption occurs after you complete a form but before you click a button to submit it.
- [I can't click Randomize or Dispense during a visit](#)  
If the Randomize or Dispense button is grayed out, an answer might be missing or invalid for a required question.
- [I can't edit a value in a form](#)  
If the answer field is grayed and you can't edit the value it means the item is read-only.
- [I can't enroll a subject in a rollover study](#)
- [I can't sign a subject's data](#)  
If you can't sign a subject's data, you have two options for solving the issue.

- [I flagged a question in error](#)  
If you flagged a question in error or simply added the wrong data flag, don't worry. You can always go back and change or remove the flag altogether.
- [I need to transfer a subject](#)  
If you need to transfer a subject, contact your CRA for further instructions.
- [I randomized a subject in error](#)  
If you randomized a subject in error, inform your CRA of the error and ask what to do next.
- [I started a randomization or dispensation visit before the visit date](#)  
If you started a randomization or dispensation visit before the start date, you might be able to update the visit start date field so that the visit start date is correct. Some studies allow you to update this field on or after the date when the subject comes in.

## An error occurs when I try to randomize a subject

If an error occurs when you try to randomize, the subject might have arrived outside the visit window, or the site might have insufficient stock to dispense kits.

If you are able to click **Randomize**, and Oracle Clinical One Platform says you can't randomize the subject, check that the subject arrived within the visit window. If the visit also includes dispensation, and the study protocol doesn't allow dispensation outside the visit window, the subject can't be randomized.

If the subject arrived within the visit window, or the study protocol allows dispensation outside the visit window, check your stock against the shipments listed in Oracle Clinical One Platform.

- If you have a shipment waiting to be marked as received, [register the shipment](#), and then [randomize the subject](#) again.
- If there are no shipments waiting to be marked as received in Oracle Clinical One Platform, and the study doesn't allow randomization when a required kit type is unavailable, contact your CRA for further instruction. You will have to [randomize the subject](#) again at a later time.

## A query is added on a form after I sign data

As long as the assigned query has an **Open** status, that form will remain signed. As soon as you or another user updates the value of the question, to close or update a query, data will have to be re-signed.

## A subject failed screening, and I need to rescreen the subject

You might need to rescreen a subject if you made a mistake while completing the screening visit, if the subject's eligibility has changed, or if you manually screen failed a subject in error.

### **I made a mistake while completing the screening visit**

[Update the value on that form](#), and then rescreen the subject by clicking **Screen** at the bottom of the form to submit the correct value.

### **The subject wasn't eligible before but is now**

If a subject didn't meet the requirements of the study protocol during the screening visit but is eligible now, you can [update the subject's information in the screening visit](#).

### I manually screen failed a subject in error

You can undo a subject's screen failure. For step-by-step instructions, see [Undo or edit a subject's screen failure](#).

## A submitted visit remains in the Next Visit column

Sometimes a completed visit remains in the Next Visit column, when it should move to the Previous Visits column. This issue can occur when a network interruption occurs after you complete a form but before you click a button to submit it.

**What you should do:** Open the visit that you submitted, and click **Return to All Subjects** in the upper-left. The table updates so that the next visit is available.

## I can't click Randomize or Dispense during a visit

If the Randomize or Dispense button is grayed out, an answer might be missing or invalid for a required question.

If you finish filling out all the forms in a visit, and the **Randomize** or **Dispense** button is disabled, review all questions.

- If at least one field contains a blank or invalid value. Enter or [update the invalid values](#), then you can click **Randomize** or **Dispense**.
- If one or more required values are invalid because the subject is no longer eligible for randomization or dispensation, leave the values as they are, click **Save** at the bottom of the form, and then click **Return to All Subjects**.
  - Randomization visits remain in the Next Visits column.
  - Dispensation visits are marked as incomplete and move to the Previous Visits column. Incomplete visits display in yellow with a warning icon.

If the **Dispense** button is disabled and there are no invalid values, it might be due to the subject's state.

- To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.
- Check the randomization visit. If a required field for randomization was updated with an invalid value after the subject was randomized, the **Dispense** button is disabled in all following dispensation visits.
  - If the invalid values in the randomization visit are incorrect, [update the invalid values](#), click **Randomize**, and return to the current dispensation visit.
  - If the subject is no longer eligible to continue the study, click **Save** in the dispensation visit, and then click **Return to All Subjects**.

## I can't edit a value in a form

If the answer field is grayed and you can't edit the value it means the item is read-only.

Although a read-only item can't be manually edited, the value it contains can be updated. Values in read-only fields are populated based on other information you add to the form. So all you have to do to update the value in a read-only field is to edit the answers that generated the read-only value.

For instance, the Body Mass Index (BMI) is automatically calculated based on a subject's height and weight. If you want to edit the BMI value (because you noticed an error) you need to

update one or both of the values you entered for Height and Weight. The read-only value will automatically get updated.

 **Note:**

If a read-only value in a form is calculated based on data entered during a previous visit, you need to go back to that visit and edit the answers accordingly to update the read-only field.

## I can't enroll a subject in a rollover study

If you can't enroll a subject in a rollover study, work with your clinical research associate to make sure both studies are designed and set up correctly: the original study and the rollover study.

## I can't sign a subject's data

If you can't sign a subject's data, you have two options for solving the issue.


Remember that you can only sign data at a subject level. To make sure you sign a subject's data completely, all visits of that subject must be completed. With that in mind:

1. If you tried to sign a subject's data, but there are still visits that are not signed, make sure those visits are complete. Certain visits might be incomplete, so when you sign a subject's data, those visits won't be marked as signed in the user interface.
2. If you signed a subject's data, but no visits were signed, either none of their visits are complete or there might be something wrong with your Oracle Life Sciences IAMS electronic signature. Try signing a subject's data again. If it still doesn't work, contact Life Sciences Support.


## I flagged a question in error

If you flagged a question in error or simply added the wrong data flag, don't worry. You can always go back and change or remove the flag altogether.

**If you need to remove a data flag, you need to answer the question. Here's how to do it:**

1. On the Home page, determine where to work:
  - To work with real data in Production mode, click the title of the study.
  - To work with mock data in Training mode, click the Training Mode button (  ) on the study.
2. Along the top of your page, select the **Subjects** tab.
3. If you have access to multiple sites for the study, select a site from the Site drop-down in the upper-right.
4. In the table, locate the subject, and click the visit in the Next Visits column.
5. Look for the flagged question on the form. Type an answer to that question.
6. In the **Reason for Change** field, type a reason for making this change.
7. Click **Submit**.

**And here's what you need to do if you want to update a data flag:**

1. On the Home page, determine where to work:
  - To work with real data in Production mode, click the title of the study.
  - To work with mock data in Training mode, click the Training Mode button (  ) on the study.
2. Along the top of your page, select the **Subjects** tab.
3. If you have access to multiple sites for the study, select a site from the Site drop-down in the upper-right.
4. In the table, locate the subject, and click the visit in the Next Visits column.
5. Look for the flagged question on the form. Hover over it, and click the menu icon to the right of the question.
6. From the drop-down, select the right option for the question:
  - **Mark Not Done:** Use this flag if the answer to a question can't be provided at the moment. For example, a subject can't be weighed during a visit, so a required question about their weight can be marked as Not Done to proceed with form completion.
  - **Mark Not Applicable:** Use this flag if the answer to a question isn't applicable at the moment. For example, a subject doesn't need its heart rate measured during this visit, so the answer to a BPM question isn't applicable during this visit.
  - **Mark Unknown:** Use this flag if the answer to a question is unknown at the moment. For example, a subject doesn't know their blood type and there's no way to determine that on the spot.
7. In the **Reason for Change** field, type a reason for making this change.
8. Click **Submit**.

## I need to transfer a subject

If you need to transfer a subject, contact your CRA for further instructions.

**Note:**

A subject's incomplete visits aren't transferred from one site to another, so remember to always complete a subject's visits at a site before transferring them.

## I randomized a subject in error

If you randomized a subject in error, inform your CRA of the error and ask what to do next.

You might have randomized a subject in error if you performed any of the following tasks:

- Randomized a subject and there is no intention to treat the subject.
- Randomized the wrong subject.
- Accidentally randomized a subject before you were ready to randomize.

## I started a randomization or dispensation visit before the visit date

If you started a randomization or dispensation visit before the start date, you might be able to update the visit start date field so that the visit start date is correct. Some studies allow you to update this field on or after the date when the subject comes in.

The visit schedule is calculated based on the visit start date, so if other visits are scheduled from the visit and you don't update the visit start date, the visit schedule might not be calculated as you expect.

# 11

## Frequently Asked Questions (FAQs)

- [Forms FAQs](#)
- [Kits and dispensation FAQs](#)
- [Subjects and visits FAQs](#)
- [How do I get training in Oracle Clinical One Platform?](#)  
You can take and retake training from within the product, and you can practice working in Training mode.
- [What keyboard shortcuts can I use?](#)  
Oracle Clinical One Platform supports the following keyboard shortcuts provided by Oracle JET.

### Forms FAQs

- [Best practices for collecting data](#)  
You must pay attention to certain details during your process of filling out forms in the application.
- [Can I enter a partial date on a form?](#)  
If partial dates are allowed on a date/time type of question during the design of your study, then you can use a partial date when answering that question.
- [How can I update an auto-locked question?](#)
- [How do I know if a repeating form is complete?](#)  
Every repeating form displayed in a table view has a status icon beside it.
- [How does a hidden and required question impact a form and visit's status?](#)  
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.
- [I cannot enter data or save the data I entered in a form](#)  
If you can't enter data in a form, save data in a form, or the form becomes completely unresponsive, there might be something wrong with your browser.
- [What can I do when subject data is locked?](#)  
If a subject's data is locked or unlocked at the question, form, or visit level, site users will be able to view the status of the items they have permissions to see.
- [Which types of questions can I flag?](#)  
Almost every type of question can be flagged during a study.

### Best practices for collecting data

You must pay attention to certain details during your process of filling out forms in the application.

#### **Pre-filling information in forms**

We recommend that you do not pre-fill information in forms. Instead, start data entry for a form when a visit occurs. If you start a visit for a subject and then your site starts using a new study



version, the started visit may be unchanged for the subject, even if the new study version has changes to the visit.

### Note any additional information when you dispense kits

After you dispense kits to a subject, you must verify the subject number. Additionally, there is more information that you should note:

- The kit number to dispense.
- Any dispensation instructions. If the study calculates a subject's dose based on a subject's answer to a question, such as weight, the Dispensation Instructions column includes the subject's dose and the frequency of the dose. If you see Blinded, someone else at your site, such as a pharmacist, must dispense the dose to the subject. The user who can view the Dispensation Instructions receives a notification with the instructions whenever a dispensation visit occurs. The dosing instructions are in the Kit Dispensation report.

### How to answer certain question types

For drop-down questions and questions with checkboxes, you might be able to select more than one option, depending on the study protocol. On the right, below Question Hint, check if there are any instructions about the number of answers you are allowed to select. For a question with radio buttons, you can clear the option that you previously selected.

### Move subjects between visit branches

If a subject needs to return to a previous branch, we recommend you clear all data from the subject's current branch before you move the subject to the previous branch. For example, if you determine that a subject should continue visits at Branch A after starting visits at Branch B, first clear all collected data from Branch B's visit forms. Only then move the subject back to Branch A's scheduled visits.

### Related Topics

- Kit Dispensation report

## Can I enter a partial date on a form?

If partial dates are allowed on a date/time type of question during the design of your study, then you can use a partial date when answering that question.

Partial dates may be allowed on certain date/time type of questions in the study. For example, the start date of a concomitant medication may not be known, so it can be designed with a partial date. In this case, you would only need to complete the month and year of the concomitant medication start date and may select UNK for the day that's part of the date, if that is unknown.

Depending on what the minimum allowed format is, you can enter:

- The month and year
- The year

If you don't know the day or the month in a date, from the drop-down for each element, select **UNK**. UNK stands for Unknown.

## How can I update an auto-locked question?

### Workflow to update an auto-locked question

 **Note:**

In a protocol, know that the level of detail in addressing question reviews can vary, and each team should define its own criteria.

In a live study, when a question's answer field gets automatically locked, data related to that question becomes read-only for you.

To edit an automatically locked question's values in a form, you must contact the designated sponsor representative to notify them and give a reason for the change. After documenting the decision, the sponsor user reviews your request against study guidelines or protocol for change, and determines if they unlock the data for you to edit it.





Based on the established protocol, the sponsor user notifies you about the next steps. If approved, the question will be unlocked so that you can update it.

## How do I know if a repeating form is complete?

Every repeating form displayed in a table view has a status icon beside it.

Here's what each icon means:

**Table 11-1 Repeating form status icons**

Status icon	Status icon description
	Data in the repeating form is complete.
	Data entered in the repeating form is outside the expected range.
	Data in the repeating form is incomplete.
	The repeating form contains a query.

## How does a hidden and required question impact a form and visit's status?

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. If you work with Oracle Clinical One Analytics, see the following topics in the *Analytics User Guide*:

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

### Related Topics

- [Complete a randomization or dispensation visit](#)  
During a site visit, you collect data as required using the forms associated with the visit. You may also randomize a subject or dispense a kit as part of the visit. To randomize or dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.
- [Complete a dispensation visit with dose changes](#)  
You must complete all required fields to be able to perform dose changes for a subject during a dispensation visit. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject. This procedure applies to rollover studies, as well.
- [Complete an unscheduled dispensation visit](#)  
During an unscheduled visit, you can dispense kits containing an investigational product, Unblinded Pharmacist kits, devices, perform dose changes or converse and confirm the dispensation of kits, but you can't randomize subjects. To dispense, the subject must be screened and active. You cannot dispense to a withdrawn subject.
- [Enter data for an adverse event](#)  
To continuously collect a subject's data on adverse events, and possibly concomitant medication, hospitalizations, and many more, then depending on how your study has been designed you can access and complete the forms within the Adverse Events visit, at any time during the course of the study.
- [Enter data in a form with two sections](#)  
The first part in a two section form represent the flat part of the form, which creates the overall form instance, and contains the leading questions. The second part contains the repeating table where multiple rows of data can be added as it relates to the applicable form instance.
- [Enter data in a repeating form](#)  
Repeating forms allow you to collect multiple instances of the same type of data.

## I cannot enter data or save the data I entered in a form

If you can't enter data in a form, save data in a form, or the form becomes completely unresponsive, there might be something wrong with your browser.

If any of these issues are occurring, try the following troubleshooting options.

### Clear your browser's cache

1. First, sign out of the application.
2. Go to your browser's settings and clear the cache.  
Make sure you clear the browsing history, cookies and other site data, as well as cached images and files.
3. Close your browser and then open it up again.
4. Sign into the application and verify if it's working properly.

### Make sure your browser is up-to-date

Make sure your browser's version is updated to the most current one. For more information on browser requirements, see [Browser requirements](#).



### Restart your device

Whether you choose to clear your cache or update your browser, we recommend you also restart your system. Sometimes, an unresponsive website may be caused by the device's performance.

## What can I do when subject data is locked?

If a subject's data is locked or unlocked at the question, form, or visit level, site users will be able to view the status of the items they have permissions to see.

The following icons for locked and unlocked data are visible to site users, so long as they have permissions to view the corresponding items:

- A Locked icon (  ) is visible next to a locked question for a subject with open queries.
- An Unlocked icon (  ) appears next to an unlocked question, indicating that the question has been unlocked by a sponsor user.

For more information on locked and unlocked data icons, see [Signing, verifying, and freezing icon descriptions](#).

## Which types of questions can I flag?

Almost every type of question can be flagged during a study.

You can add data flags to all types of questions: text, number, age, date/time, and drop-down questions, coding questions, and rollover questions. You can also add data flags to questions in a question group. The only questions that cannot be flagged are required questions used in a screening, randomization or dispensation visit.

## Kits and dispensation FAQs

- [Can I conserve a kit and re-dispense it during any of the next visits?](#)  
Studies that allow kit conservation have two options, conserving kits from either the most recent dispensation visit or from any previous dispensation visit. Your CRA or study

materials can help you figure out whether the study allows kit conservation, and if so, which option is allowed.

- [Can I dispense a subject's conserved kits to another subject?](#)  
No. The system doesn't let you dispense a subject's conserved kits to other subjects in the study.
- [Can I dispense misallocated kits again?](#)  
You can also dispense kits with a Misallocated status to subject who haven't been randomized yet, and are not in an Active state.
- [Can I still dispense kits if titration isn't allowed?](#)  
You can still dispense kits if titration isn't allowed. The subject just maintains the dose they received in the last dispensation visit.
- [How do I dispense the same device to another subject?](#)  
If you want to dispense a device that was already dispensed to another subject, you need to work with the clinical supply manager on your team to make sure the kit is correctly updated in the site's inventory.
- [Learn the details of performing a dose hold](#)  
Whether you're a site user or an investigator, dose holds give you the ability to pause dispensation of the investigational product within the boundaries that are defined in your study.
- [What do I do with kits that can't be conserved?](#)  
If a reusable kit can't be conserved by the system, you need to perform kit reconciliation.
- [What is the workflow for dispensing Unblinded Pharmacist kits?](#)  
Unblinded Pharmacist kits can only be dispensed by a pharmacist or an unblinded site user in the study. Blinded site users are never allowed to dispense these kits, but receive a notice to see their pharmacist instead.
- [Available inventory statuses for kits](#)  
Kit statuses allow you to manage shipments and inventory in your study. Here's a list of every status a kit might have in Oracle Clinical One Platform and their descriptions.
- [Where can I view unblinding details during an open-label period?](#)  
You can view subjects' current treatment arms and kit details during an open-label period.
- [Why are barcodes useful in a study?](#)  
Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.

## Can I conserve a kit and re-dispense it during any of the next visits?

Studies that allow kit conservation have two options, conserving kits from either the most recent dispensation visit or from any previous dispensation visit. Your CRA or study materials can help you figure out whether the study allows kit conservation, and if so, which option is allowed.

For example:

- **If you can conserve kits from all previous dispensation visits:** In the Reusable Kits pop-up, after you've determined that the subject has reusable kits, you'll see all kits from all previous dispensation visits.
- **If you can only conserve kits from a subject's latest dispensation visit:** In the Reusable Kits pop-up, after you've determined that the subject has reusable kits, you'll only see kits from a subject's latest dispensation visit.

If you think you should be able to conserve kits from all previous dispensation visits, but the kits don't appear in the list for reusable kits, reach out to your clinical research associate (CRA) to see how the study that you're working in is set up.

## Can I dispense a subject's conserved kits to another subject?

No. The system doesn't let you dispense a subject's conserved kits to other subjects in the study.

A reusable kit is a kit that belongs to a specific subject and that can be safely re-dispensed to them because it is still sufficient to meet their needs and those of the study. If a subject has some unexpired medication left from a previous dispensation that can be used in place of dispensing a new kit, you can't conserve that unexpired medication and dispense it to another subject.

## Can I dispense misallocated kits again?

You can also dispense kits with a Misallocated status to subject who haven't been randomized yet, and are not in an Active state.

This is especially useful if your sponsor organization uses a different system to dispense kits to subjects, but also uses Oracle Clinical One Platform to randomize subjects.

## Can I still dispense kits if titration isn't allowed?

You can still dispense kits if titration isn't allowed. The subject just maintains the dose they received in the last dispensation visit.

## How do I dispense the same device to another subject?

If you want to dispense a device that was already dispensed to another subject, you need to work with the clinical supply manager on your team to make sure the kit is correctly updated in the site's inventory.

### **Note:**

This procedure also applies to IoT-enabled devices managed through Oracle Health Sciences mHealth Connector Cloud Service.

### **Site user: Locate and replace the device that you want to dispense to another subject**

1. Locate the device that you want to dispense to another subject, replace it, and select **Not Dispensed to Subject** as the reason for replacement.  
For step-by-step instructions on how to replace a device, see [Replace a device](#).
2. After getting the device back from the subject, let your clinical supply manager know that the device is now part of the site's inventory again.

### **Clinical supply manager: Mark the device as Available in the inventory**

1. On the Site Inventory tab, search for the device with a status of **Not Dispensed to Subject**, and update its status to **Available**.  
For step-by-step instructions on how to update a kit's status, see [Update the status of a kit for a site user](#).

**Note:**

Keep in mind that this device might be unblinded in the study when you update its status to **Available**.

**Site user: Dispense the device to another subject**

Once the device is made available in the site inventory, you can dispense it again to another subject in the study. Details about the updates appear in the kit's history.

## Learn the details of performing a dose hold

Whether you're a site user or an investigator, dose holds give you the ability to pause dispensation of the investigational product within the boundaries that are defined in your study.

Before you begin performing any dose holds in a study, here are some considerations that you should take into account to make sure you have the best user experience while working with this feature.

Consideration	Notes
Unblinding kits	Dose holds can be performed for both blinded and unblinded kits.  If a dose hold is required for an Unblinded Pharmacist type of kit, you must contact your pharmacist or unblinded site user at the site to pause the dispensation for that kit. The user interface also gives you a notice about this.
Limits on dose holds	If you reach the maximum number of dose holds for a certain type of kit, then that kit type is no longer displayed on the Dose Hold dialog for you to pause dispensation on. If you reach the maximum number of dose holds for every type of kit available in a study, then the <b>Dose Hold</b> button is no longer displayed in a visit.

## What do I do with kits that can't be conserved?

If a reusable kit can't be conserved by the system, you need to perform kit reconciliation.

For example, if a reusable kit is nearing its expiration date, the system may not be able to conserve it. If some of the kits that you mark as reusable in the user interface can't be conserved, write their numbers down. After you finish the dispensation visits for your subjects, go to your kit inventory, look for those reusable kits, and perform kit reconciliation.

And as a general practice, remember to always reconcile kits that can't be conserved, whether you use Oracle Clinical One Platform or any other system to perform this task.

## What is the workflow for dispensing Unblinded Pharmacist kits?

Unblinded Pharmacist kits can only be dispensed by a pharmacist or an unblinded site user in the study. Blinded site users are never allowed to dispense these kits, but receive a notice to see their pharmacist instead.

### For blinded site users

Whether you need to perform dose changes, conserve kits, dispense devices, or confirm the dispensation of blinded kits, you can follow your regular workflow for these types of kits. For more details, see [Enter data and dispense kits](#).

If during the same visit certain kits can only be dispensed by a pharmacist or unblinded site user, you will be instructed to see your pharmacist or unblinded site user, so they can dispense these kits.

If during a dispensation visit, only kits that can be dispensed by a pharmacist or unblinded site user are required, there's nothing left for you to do but contact the pharmacist or unblinded site user at your site.

After you dispense the blinded kits to subjects, you'll receive a successful dispensation notification that also contains a notice to see your pharmacist or unblinded site user for dispensing the Unblinded Pharmacist kits. Additionally, the notification contains a list of all blinded kits you just dispensed. For more details on the notification, see [Subject dispensation notification \(with failures\)](#).

### For pharmacists or unblinded site users

After you receive the Unblinded Pharmacist dispensation notification that contains the list of kits that you need to prepare and dispense, you can give those kits to subjects that arrive at a site you're assigned to.

To dispense these kits, simply follow your regular workflow in the system. For more details, see [Enter data and dispense kits](#).



#### Note:

You can run the Subject Dispensation report to see the Unblinded Pharmacist kits that you just dispensed during a visit.

## Available inventory statuses for kits

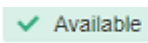
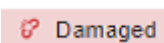
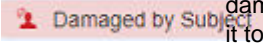
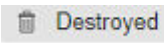
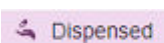
Kit statuses allow you to manage shipments and inventory in your study. Here's a list of every status a kit might have in Oracle Clinical One Platform and their descriptions.
















#### Tip:

Depending on your role and the permissions assigned to it, you can see a kit's changed status at either a site or depot, on the Study Inventory, Site Inventory, or Kit Reconciliation tabs, or in Subject History. Information about all kit statuses in your inventory can also be found in the Kit Inventory (Blinded) and Kit Inventory (Unblinded) reports in Oracle Clinical One Platform.




Kit status	Description	How a kit reaches this status
<p> Available</p>	<p>A kit is ready to be dispensed to subjects at a site, or ready to be shipped from a depot.</p>	<p>A kit's status is updated to Available as follows:</p> <ul style="list-style-type: none"> <li>Automatically: when kits are released to a depot for Testing mode, and when a site user marks a shipment as received.</li> <li>Manually: when a sponsor user releases kits to a depot for Production or Training mode.</li> </ul>
<p> Damaged</p>	<p>A kit was physically deteriorated at a site or depot. For example, a kit might have been damaged as a result of being dropped.</p>	<p>A site user or sponsor user marks the kit as Damaged.</p>
<p> Damaged by Subject</p>	<p>A kit was physically deteriorated after it was dispensed to the subject. In this case, the subject needs to return it to the site to be destroyed. Usually, if the kit is damaged by the subject, after returning it to the site, a new one is dispensed.</p>	<p>A site user marks the kit as Damaged by Subject.</p>
<p> Destroyed</p>	<p>A kit was destroyed during the kit reconciliation process. Most kits are destroyed after the subjects return them to site. Additionally, a kit is destroyed if it was damaged, it expired, or wasn't dispensed to a subject at all.</p>	<p>Only Pending Destruction kits can be marked as Destroyed.</p> <p>Typically, before destruction, a Clinical Research Associate (CRA) verifies the kit and marks it as being ready for destruction. The next step depends on the location of the drug destruction facility:</p> <ul style="list-style-type: none"> <li>If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to Destroyed.</li> <li>If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility. After the kit is destroyed, its status is updated to Destroyed.</li> </ul>
<p> Dispensed</p>	<p>A kit was dispensed to a subject during a dispensation visit.</p>	<p>A kit's status automatically changes to Dispensed after a site user dispenses it to a subject.</p>

Kit status	Description	How a kit reaches this status
 Expired	The investigational product exceeded its expiration date.	A site or sponsor user marks a kit as Expired.
 In Transit	A kit is being shipped from a depot to a site.	A shipment request was made by a site or sponsor user for that kit, and the ship date has been provided.
 Lost by Subject	A kit went missing after being dispensed to a subject. Usually, if the kit is lost by a subject, a new one is dispensed to them.	A site user marks the kit as Lost by Subject.
 Misallocated	A kit was dispensed in error. There are several reasons why a kit can be dispensed in error. For example, someone at the site might have given a subject a kit that was different from the kit that Oracle Clinical One Platform said to dispense, and the subject left the site with it; or someone at the site might have entered data in the wrong subject's visit and dispensed a kit.	A site user must dispense a replacement kit before marking the kit as Misallocated. If a site user marks a kit as Misallocated before dispensing a replacement kit, the site user won't be able to dispense a replacement kit. A site user manually updates a kit's status to Misallocated.
 Missing	A kit hasn't been dispensed yet and has gone missing from the site or depot.	A site user or sponsor user manually updates a kit's status to Missing.
 New	The kit has just been uploaded in Production mode, and it's going to be manufactured and made ready for use.	The kit was created in Production mode.
 Not Dispensed to Subject	A dispensed kit was never distributed. A subject might not receive a kit for various reasons. For example, they accidentally left the kit at the site after their visit, or the site user intentionally chose not to distribute the kit to them.	A site user marks the kit as Not Dispensed to Subject. A site user must dispense a replacement kit before marking the kit as Not Dispensed to Subject. If a site user marks a kit as Not Dispensed to Subject before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

Kit status	Description	How a kit reaches this status
 Not in Use	<p>A kit can't be dispensed or shipped. Think of this status as an "emergency brake". Whenever users want to prevent a kit from being dispensed or shipped they mark it as Not in Use. For example, they would use this status if a kit needs to be moved from one depot to another.</p>	<ul style="list-style-type: none"> <li>A site user or sponsor user marked a kit as Not in Use.</li> <li>Kits included in a generated kit list in Production mode first appear in a study's inventory with a status of Not in Use.</li> </ul>
 Pending Destruction	<p>A kit is ready to be destroyed.</p>	<p>Typically, the Clinical Research Associate (CRA) verifies the kit and then marks it as Pending Destruction. The user must provide a reason for the status update.</p>
 Pre-quarantined	<p>A kit failed to comply with the shipment or storage requirements. For instance, it could have suffered a temperature or humidity excursion. After the kit is pre-quarantined, a clinical supply manager determines whether the kit can still be dispensed or not. If it can be dispensed, the kit changes its status to Available. If the kit can't be dispensed, the kit's status is updated to Quarantined so that it isn't considered part of the site's inventory anymore.</p>	<p>The sponsor user marks the kits as Pre-quarantined.</p> <p>A pre-quarantined kit is counted in a site's inventory.</p>
 Quarantined	<p>A kit failed to comply with the shipment or storage requirements, and it was damaged as a result. A Quarantined status marks the end of life for a kit. Quarantined kits can no longer be dispensed to subjects, and aren't counted in a site's inventory. Multiple quarantined kits from the same depot might be a sign of issues with a shipping procedure.</p>	<p>A clinical supply manager marks the kit as <b>Quarantined</b>.</p>
 Received for Destruction	<p>The site user or Clinical Research Associate (CRA) has shipped the kit to a drug destruction depot and a depot user confirmed they received the kit for destruction at their facility. For instance, if a kit suffered some sort of irreversible damage, the site user might send it back to the depot facility to destroy it.</p>	<p>A depot user confirms a receipt per kit that they have received it at the depot.</p>
 Returned to Site	<p>The subject returned the kit to the site. Subjects are required to bring any used and unused investigational products to their next dispensation visit. For instance, if the subject received three blisters of pills, and at his next dispensation visit they're left with three pills, they're required to return both the empty blisters and remaining pills to the site.</p>	<p>A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.</p>

Kit status	Description	How a kit reaches this status
<b>Temporarily Unavailable</b>	A kit is temporarily on hold and can't be dispensed or shipped.	A site or sponsor user marks the kit as Temporarily Unavailable.

 Temporarily Unavailable

### Related Topics

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## Where can I view unblinding details during an open-label period?

You can view subjects' current treatment arms and kit details during an open-label period.

### Where to view subjects' current treatment arms

When a study has an open-label period, subjects' treatment arms are always visible, and you can view them in the following places on the Subjects page:

- **Dispense Kits pop-up:** When Oracle Clinical One Platform tells you the kits to dispense to a subject, the title of the treatment arm appears in the popup.
- **Randomize Subject pop-up:** After a successful randomization, the title of the treatment arm appears in the popup that contains the subject's randomization number.
- **Subject History:** Select a subject, and view treatment arm details at the top of Subject History, which is on the right.

### Where to view kit details

If the study is set up so that kits have unblinded distribution during the open-label period, you can view kit details in the following locations:

- **Subject History:** Select a subject, and then in Subject History on the right, point to a dispensation event. The kit description appears in a tooltip.
- **Dispense Kits pop-up:** When Oracle Clinical One Platform tells you the kit to dispense, the kit description appears in the popup.
- **Inventory tab:** View the description in the Kit Description column. If the text is truncated, point to a cell to view the full description.
- **Shipments page:** Select a shipment, and then in Shipment Details on the right, you can see the kit description.

## Why are barcodes useful in a study?

Whether you're a clinical supply manager or a site user, here's why barcodes are useful for you.

### For clinical supply managers

Including barcodes in your kit list lets you assign a barcode to every kit that needs to be dispensed to subjects during the study. After you do that, you can also enable site users to use these barcodes for confirming dispensation of the kits dispensed to subjects during visits.

Overall, barcodes allow you and the site team to have better control over the kits that are dispensed during visits without running the risk of unblinding a study.

When uploading a kit list, you can map barcodes in the system to make sure they're correctly assigned to each kit in the study.

When generating a kit list, you can either use kit numbers to generate those barcodes or ask the system to generate new numbers for barcodes.

For more details on how to include barcodes in your kit lists, see [Generate a kit list](#).

For more details on how to enable site users to confirm kit dispensation, see [Specify supply settings \[Testing mode\]](#).

### For site users

Using barcodes to confirm kit dispensation allows you to have better control over what kits you dispense to subjects during dispensation visits. You can either type a kit's barcode in the user interface (if, for example, a kit's barcode is the same as a kit's number) or you can scan a kit's barcode to confirm its dispensation. You can only confirm the dispensation of kits using barcodes if this feature is enabled in your study by a clinical supply manager.

For details on how a site user can confirm dispensation of kits, see [Confirm dispensation of kits](#).

## Subjects and visits FAQs

- [How is the visit schedule affected when I skip a visit or update a visit start date?](#)  
The visit schedule is sometimes affected when you skip a visit or update a visit start date.
- [How do visits display in subject listings view, when integrations populate a future visit?](#)  
When data is populated in a visit by an integration, specifically Data Intake integrations, visits in the subject listings view display differently compared to standard data entry. This occurs, if the Data Intake integration populates data, in an order other than what is defined in the visit schedule.
- [What actions impact subjects?](#)  
Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?
- [What does each icon mean for signing, verifying, or freezing data?](#)  
Each sign, verify, or freezing action has an impact on the study data. Learn more about what each icon means.
- [What do I do when a subject has reached their dosing limit?](#)  
When trying to dispense to a subject who has reached either one of their dosing limits, you will receive a message from the sponsor advising you what to do about a subject who has reached their dosing limit and can no longer titrate.
- [What statuses can a visit have?](#)  
A visit can have various statuses depending on the state of the collected data how its type.
- [What time zone is subject data in?](#)  
If the time zone is specified for your site, all values on the Subjects page are in the site's local time zone with the following exception: Date and time values in Answer & Visit History, which is on the right when you open a visit, are in the Coordinated Universal Time (UTC) zone.

- **When is a visit considered complete?**  
You complete a scheduled or unscheduled visit when you answer all of its required questions.

## How is the visit schedule affected when I skip a visit or update a visit start date?

The visit schedule is sometimes affected when you skip a visit or update a visit start date.

### How is the visit schedule affected when I skip a visit?

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.



#### Note:

You must always specify a date for the Start Visit Date field.

### How is the visit schedule affected when I update a visit start date?

Visit schedules are calculated based on the Start Visit Date for a visit. If you edit a visit date, the dates for any visits that are scheduled from that visit are updated.

### What if I skip a visit, complete the next visit, and then start 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.

## How do visits display in subject listings view, when integrations populate a future visit?

When data is populated in a visit by an integration, specifically Data Intake integrations, visits in the subject listings view display differently compared to standard data entry. This occurs, if the Data Intake integration populates data, in an order other than what is defined in the visit schedule.

For more information on visit status icons, see Visit statuses and icons

### How are visits displayed after a Data Intake integration loads data into Oracle Clinical One Platform?

- If data is populated in a future visit by an integration, specifically a Data Intake integration, prior to preceding visits being started manually, the user interface displays any preceding, not-yet-started visits defined by the visit schedule, making them available for data entry. The Data Intake visit will appear in the Next Visit column.

 **Note:**

If all preceding visits were started prior to a Data Intake integration loading data, the Data Intake visit also displays in the Next Visit column.

- The preceding visits, displayed on the subject listing and visit details pages are identified by a dotted border, and the label, (Not Started).

### How are the Next and Previous Visit columns affected by a Data Intake integration?

- If the visit populated by a Data Intake integration is in progress the visit appears in the **Next Visit** column.
- If the visit populated by a Data Intake integration is complete the visit appears in the **Previous Visits** column.
- Screening, pre-screening, and any first visits defined in the visit schedule display in the previous visit column with all other (Not Started) visits in the order defined by the visit schedule. If the Screening visit is incomplete it will be moved to the Previous Visit column should a Data Intake integration populate a future visit.
- In the event of sequential Data Intake integrations, the last integrated data intake visit appears in the Next Visit column if the visit is in progress, and if complete it appears under Previous Visits.

### What happens if a visit is added to the schedule with a site study version change?

- If the sponsor chose to apply new visits as future and past during design, the new visits display for all subjects in the correct location in the visit train, even if a subject has already passed the visit in their visit schedule. This is true, even if the visit is added between not started visits.
- If the sponsor chose to apply new visits as future only during design, the new visits display only for those subjects who have not yet progressed past that point in the visit schedule.

### Are subjects in different status affected differently?

- Subjects with a **Screen Fail** or **Withdrawn** status:
  - Data can be entered for existing Not Started visits through the user interface or a Data Intake integration after a subject status changes to Screen Fail or Withdrawn, however, future visits cannot be added.
- Subjects with a **Complete** Status:
  - If an earliest visit completion requirement was defined for a study, the visits up to the completion visit need to be completed before the subject can be marked complete. This includes any (Not Started) visits.

- If an earliest visit completion requirement was not defined for a study, the subject can be marked complete even when (Not Started) visits are present. Data entry is allowed for Not Started visits even after the subject is marked complete.

#### How does this impact subjects at a retired site?

- Users are prevented from clicking into (Not Started) visits for any subject at a retired site, but a Data Intake integration can still populate data for a subject at a retired site.

#### Is there an impact to reporting?

Yes, to the Subject Visits report (both blinded and unblinded).

- Report output displays what is visible in the user interface.
- Not Started visits appear at the end of the report with **visitdate** and **projectedvisitdate** showing as N/A.
- If data is integrated after the screening visit, or the first visit in the visit schedule, where no data has been entered, including visit date, the screening visit does not include a date value for **visitdate** and **projectedvisitdate**

## What actions impact subjects?

Depending on the protocol, site users can perform multiple actions that have an impact on a subject's state. Most of these updates appear in each subject's history, but do you know what each update means and what's the impact for every subject and the overall user interface?

An action is a task that site users usually perform for subjects in order to collect and manage their data at a site during the study. From dispensing the right kits to a subject during a randomization visit to transferring or reinstating them, here are some of the actions that impact a subject's state.



#### Note:

For each action there's a corresponding update in Subject History that shows the date, time, and other specific details such as randomization numbers or site names.

Subject status	What it means	How this action impacts a subject's state	Other changes
Randomized	A subject has successfully completed a Randomization visit.	When a site user randomizes a subject, their state changes to Active.	When a subject is randomized, this update shows up on the <b>Subject History</b> sidebar, along with the randomization number, date, and time of the randomization visit.





Subject status	What it means	How this action impacts a subject's state	Other changes
Transferred	A subject was transferred from one site to another.	When a site user transfers a subject from site A to site B, the subject maintains whatever state they were in at site A. For example, a subject will keep their Active state after being transferred from one site to another.	When a subject is transferred, this update shows up in Subject History, along with the site that the subject came from, and the date and time of the transfer.
Enrolled	A site user enrolled a subject in a rollover study.	After a site user screens a subject in a study that doesn't contain a randomization (or baseline) visit. After a site user enrolls a subject in a rollover study, the subject remains in a state of Enrolled. In a rollover study, an enrolled subject is also active, so site users can start dispensing kits to them at any time.	None.
Withdrawn	The subject is no longer available or eligible to continue participating in the study, so a site user withdrew them from the study.	When a site user withdraws a subject from the study, their state changes to Withdrawn. <b>Note:</b> <i>If a site user performs a code break on a subject, and chooses to withdraw that subject after unblinding their details, that subject's withdrawal can no longer be undone.</i>	When a subject is withdrawn from a study, this update shows up in Subject History, along with the date of the withdrawal, whether specified by default or subsequently edited by a site user.
Screen failed	The subject doesn't meet the screening criteria so either they can't complete their screening visit or a site user manually screen fails them.	When a site user screen fails a subject, their state changes to Screen Failed. <b>Note:</b> <i>A subject who is marked as Active can no longer be automatically screen failed or manually screen failed by a site user.</i>	When a subject fails screening, this update shows up in Subject History, along with the date of the screen failure, whether specified by default or subsequently edited by a site user.
Reinstated (Undo Withdrawal)	A site user withdraw a subject in the study, but then brought them back into the study by undoing their withdrawal.	When a site user undoes the withdrawal of a subject in the study, they go back to the state that they had before being withdrawn.	When a subject's withdrawal is undone, this update shows up in Subject History, along with the date and time of the action.

Subject status	What it means	How this action impacts a subject's state	Other changes
Reinstated (Undo Screen Failure)	A subject was automatically or manually screen failed by a site user, and now they're brought back into the study by being re-screened or by undoing their screen failure.	When a site user undoes the screen failure of a subject in the study, they go back to the state that they had before failing the screening: <ul style="list-style-type: none"> <li>If they automatically failed screening due to errors in a form, they go back into a Screened state.</li> <li>If they were previously manually screen failed by a site user, they go back into a New state.</li> </ul>	When a subject's screen failure is undone, this update shows up in Subject History, along with the date and time of the action.
Reinstated (Undo Study Completion)	A site user marked a subject as Complete, but then brought them back into the study by undoing their study completion.	When a site user undoes a subject's study completion, they go back to the state that they had before being completed, such as Active. <b>Note:</b> A subject who is marked as Complete cannot be withdrawn from the study.	When a subject's completion is undone, this update shows up in Subject History, along with the date and time of the action.







## What does each icon mean for signing, verifying, or freezing data?

Each sign, verify, or freezing action has an impact on the study data. Learn more about what each icon means.


**Table 11-2 Icons for signing, verifying, and freezing a subject's data**

Icon	What it means
	This icon appears whenever a principal investigator signed a subject's data. It typically appears on a visit card, next to every question on a form, and a subject's icon.
	This icon appears whenever a site user in the study updates data on a completed form, and the subject's data becomes unsigned. It typically appears on a visit card, next to every updated question on a form, and a subject's icon.

**Table 11-2 (Cont.) Icons for signing, verifying, and freezing a subject's data**



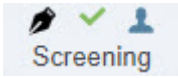
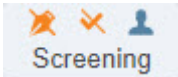
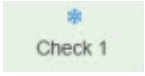
Icon	What it means
	This icon appears whenever a Clinical Research Associate verifies a question.
	This icon appears on the visit title, whenever a question requires verification.
	This icon appears whenever a site user in the study updates data on a completed form, and the subject's data becomes unverified. It typically appears on a visit card, next to every updated question and form, and a subject's icon.
	For this icon to appear, the <b>SDV Override</b> setting must be turned on. It appears next to questions that have been marked as Critical Variables, for subjects that have not been selected for the SDV pool.
	This icon appears whenever data is frozen on a completed or incomplete form, and the subject's data becomes read-only. It appears next to every question and form associated with a visit.
	This icon appears next to each question that is unfrozen by a data manager on a completed or incomplete form.

Additionally, these icons can appear together if a subject is both signed and verified, or both unsigned and unverified. This also applies to visit cards.

Icon	What it means
	Both of these icons appear next to a subject whenever their data is both signed and verified.

**Figure 11-1 Subject is signed and verified**



Icon	What it means
<p><b>Figure 11-2 Subject is unsigned and unverified</b></p> 	<p>Both of these icons appear next to a subject whenever their data is both unsigned and unverified.</p>
	<p>This icon appears next to a subject whenever all of their visits have been frozen.</p>
	<p>Both of these icons appear in a visit card, whenever data in that visit is both signed and verified.</p>
	<p>Both of these icons appear in a visit card, whenever data in that visit is both unsigned and unverified.</p>
	<p>This icon appears in a visit card, whenever all forms in that visit are frozen.</p>

## What do I do when a subject has reached their dosing limit?

When trying to dispense to a subject who has reached either one of their dosing limits, you will receive a message from the sponsor advising you what to do about a subject who has reached their dosing limit and can no longer titrate.

## What statuses can a visit have?

A visit can have various statuses depending on the state of the collected data how its type. For more information, see Visit statuses and icons.

## What time zone is subject data in?

If the time zone is specified for your site, all values on the Subjects page are in the site's local time zone with the following exception: Date and time values in Answer & Visit History, which is on the right when you open a visit, are in the Coordinated Universal Time (UTC) zone.

## When is a visit considered complete?

You complete a scheduled or unscheduled visit when you answer all of its required questions.

If you cannot answer a question during a visit, you can flag that question. For more information, see [Apply a data flag to a question](#).

Once a visit is complete, click **Return to All Subjects**. On the **Subjects** page, you see the next visit in a subject's schedule displayed on the **Next Visits** column.

### Related Topics

- [How does a hidden and required question impact a form and visit's status?](#)  
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.

## How do I get training in Oracle Clinical One Platform?

You can take and retake training from within the product, and you can practice working in Training mode.

### How do I take training?

Each time you navigate to a new page, you'll be prompted to complete the training assigned to you for that page. After you complete the training, you can start working on that page. After you complete all assigned training, you'll receive a notification with a list of all completed training.

### How do I rewatch training?

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

### Can I practice somewhere?

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

### I work in multiple studies. Do I have to take training in every study?

Your training is linked to your email address, so as long as your user account uses the same email address in every study, you'll have to take training only one time.

### Will I have to retake training after a system update?

Only if a video is changed or added.

## What keyboard shortcuts can I use?

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

**Table 11-3 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

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## Revision history

Date	Part number	Description
09-April-2025	G16748-03	Fixed some layout issues that don't impact the information presented in this user guide. For more information, see <a href="#">Mark a subject as complete</a> and <a href="#">Undo or edit a subject's completion of a study</a> .
18-March-2025	G16748-02	Made the following updates: <ul style="list-style-type: none"><li>• Updated the following topics:<ul style="list-style-type: none"><li>– <a href="#">A subject failed screening, and I need to rescreen the subject</a></li><li>– <a href="#">Mark a subject as complete</a></li><li>– <a href="#">Screen fail a subject</a></li><li>– <a href="#">Withdraw a subject</a></li><li>– <a href="#">What actions impact subjects?</a></li><li>– <a href="#">Best practices for collecting data</a></li></ul></li><li>• Included the following new topics:<ul style="list-style-type: none"><li>– <a href="#">Link subjects for Electronic Health Record (EHR) data import</a></li><li>– <a href="#">How do subject events affect a linked subject?</a></li><li>– <a href="#">Import Electronic Health Record (EHR) data</a></li><li>– <a href="#">Details about lab data, repeating form data, and data validation</a></li><li>– <a href="#">Details about reimporting data</a></li><li>– <a href="#">Undo or edit a subject's completion of a study</a></li><li>– <a href="#">Undo or edit a subject's screen failure</a></li><li>– <a href="#">Undo or edit a subject's withdrawal</a></li><li>– <a href="#">After undoing the event I cannot complete or withdraw a subject</a></li></ul></li></ul>
17-January-2025	G16748-01	Original version of this document.