

Oracle® Health Sciences Clinical One Platform

Site User Guide



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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.

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Primary Author:

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Preface

This preface contains the following sections:

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

Documentation accessibility

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

Related resources

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

Access to Oracle Support

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

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

- English interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> 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**.

- 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 |
|----------------------|--|
| Countries | 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 All countries . |
| Sites | 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 All sites . 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). |
| Subjects | 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 All subjects . |
| Review status | 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 All reviews . |

- Browse the list of displayed subjects.
- 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

Enter data and dispense kits

- [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.
- [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. You must complete all required fields to be able to dispense or randomize. This procedure applies to rollover studies, as well.
- [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. This procedure applies to rollover studies, as well.
- [Complete an unscheduled dispensation 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 during an unscheduled visit.
- [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](#)
Forms with two sections contain two parts. The first part contains the leading questions that represent the flat part of the form and create the overall form instance. 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. You can associate two or more forms at once. And keep in mind that only data that has been previously entered appears in the launched form.
- [Update a value on a completed form](#)
Sometimes you have to 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.
- [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.

Answer a query

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

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.

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

| Option | Description |
|---------------|--|
| 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 . |

 **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.

- 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.

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.

- On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
- Along the top, make sure **Subjects** is selected.
- Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
- In the table, locate the subject, and click the visit in the Next Visits column.
- If you don't know the answer to a question on the form, hover over that question.
- 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.

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. 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.

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](#).

 **Caution:**

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.

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 **Randomize** or **Dispense**.
 - 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. In the Dispense Kits wizard, verify the subject number.
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 remain in the visit.

Related Topics

- [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. 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.

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

Video

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](#).

Caution:

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.

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**.

Option

If the subject is allowed to titrate and you can change their dose, you must select an option.

Description

- 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.
- b. To keep a subject on their current dose, choose **Maintain Dose**.
- c. To titrate down, choose **Decrease Dose**.
- d. To titrate up, choose **Increase Dose**. If either the **Decrease Dose** or **Increase Dose** 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).
- e. Review the message and select the checkbox.
- f. Click **Next**.

If the subject isn't allowed to titrate and you can't change their dose, a message from the sponsor or CRO appears.

- a. Review the message, and click **OK**.
- b. In the Dispense kits wizard, check the kit details and click **Next**. To go back and choose a different option for titration, click **Back**.

8. In the Dispense Kits wizard, verify the subject number.
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 remain in the visit.

Related Topics

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

Complete an unscheduled dispensation 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 during an unscheduled visit.

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](#).

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

Caution:

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.

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. Select the checkbox to the left of the subject.
6. From the **Manage Subjects** drop-down, select **Unscheduled Visit**, and then choose the unscheduled visit you want to start.
7. 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.

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

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

- If you do not have to dispense any kits during this unscheduled visit, clicking **Save** marks the visit 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 you one or more devices must be dispensed to the subject, see [Enter data and complete a dispensation visit for devices](#).
10. Verify the subject number in the confirmation window.
 11. If applicable, click **Print Dispensation Information** to view the dosing instructions. You can print the report after it opens.
 12. 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](#)

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.

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

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

 Video


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. 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:

| Option | Description |
|--|--|
| If you are entering data in a regular form. | Follow the usual steps. |
| 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 trashcan 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.

Related Topics


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

Enter data in a form with two sections

Forms with two sections contain two parts. The first part contains the leading questions that represent the flat part of the form and create the overall form instance. The second part contains the repeating table where multiple rows of data can be added as it relates to the applicable form instance.

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), on the Forms pane, click +.
5. To add a new row in the table (located within the second section of the original form), to the left of the table, click +.
6. To delete an instance of a form with multiple sections, click the delete icon () to the left of the form title.

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.



Note:

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

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



Video

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: In the upper-left corner of the form section, click the **Add** button 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 trashcan icon () on the left of the table row.
9. Once you added data in the repeating form, either:
 - 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.

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. You can associate two or more forms at once. And keep in mind that only data that has been previously entered appears in the launched form.

For instance, you can link the Concomitant Medications form and the Adverse Events form to showcase the different medications that are taken by subjects to treat adverse events. After you enter a medication in the Concomitant Medications form and answer "Yes" to the question assessing if the medication is related to a specific adverse event,

the Adverse Events form is displayed. You can then select from this form the adverse event for which the medication is used to treat. The question assessing if the medication is related to a specific adverse event is the connecting item that the study designer used to associate the two forms and to determine if further information is required. The audit history for linking forms will appear under **Answer History**.

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



 **Note:**

Forms are associated in study design by a certain question. This means that the new forms that you can link to your initial form are displayed only if you enter a specific answer in the form you are editing. Moreover, make sure the data with which you want to link your new form entry was previously added in the specific form. For instance, if you want to link a specific medication to an adverse event, first you have to add the adverse event in the Adverse Events form.

1. Enter data in the form.
 - If you are entering the first instance of data in the repeating form: Click the number in the first column of 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 the number in the first column of the table.

If you enter the answer that launches the forms association one or more forms are displayed in the same window.

2. To link the forms:
 - a. In the new form that appears below, click the check box in the first column to select the instance of data that is related to the data you entered in the initial form.

 **Note:**

You can select one or multiple instances of data.

- b. In the lower right, click **Save**.
3. If you don't want to link forms because the data is not related:
 - a. In the lower right, click **Save** without selecting any instance of data in the new form.
 - b. In the Confirmation message click **Continue without linking**.
4. To remove a link between forms, change the answer to the question that links the two 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.

Related Topics

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

- [Subjects and visits FAQs](#)

Update a value on a completed form

Sometimes you have to 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.

Related Topics

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

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](#)

3

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 only after the subject has completed all visits, and all data has been entered for the subject. After a subject is marked as complete, you can't save any forms that weren't started, or take any other action on a subject, such as screening, randomizing, withdrawing, dispensing, or skipping a visit.
- [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.
- [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, you can manually mark the subject as screen failed.
- [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 a subject's data](#)
If your study requires you to sign data for subjects 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.

- [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. The same applies to subjects in a rollover study.

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.

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



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**.

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.

Caution:

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.

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

- [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:


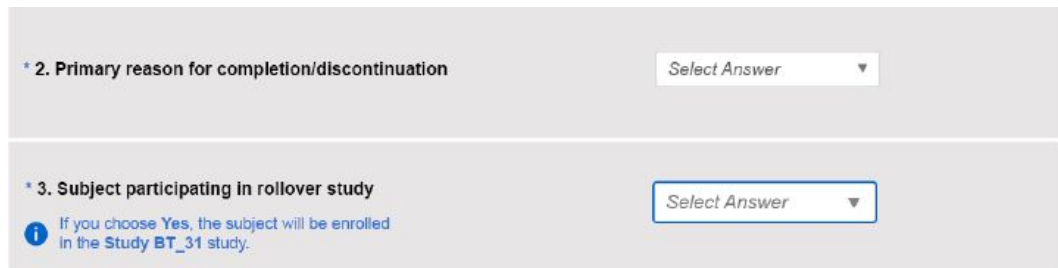
- You must have access to the original study, as well as the target study (where the subject is rolled over). The same applies to sites.
 - The site's ID must match between the original study (where the subject was initially enrolled) and the rollover study.
 - Make sure that the target study (where 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 3-1 Answer a rollover question to enroll a subject in a rollover study

* 2. Primary reason for completion/discontinuation

* 3. Subject participating in rollover study

i 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 only after the subject has completed all visits, and all data has been entered for the subject. After a subject is marked as complete, you can't save any forms that weren't started, or take any other action on a subject, such as screening, randomizing, withdrawing, dispensing, or skipping a visit.

1. Along the top, make sure **Subjects** is selected.
2. On the Home page, determine where to work. For more information, see [Access study modes and pages](#).
3. Along the top, make sure **Subjects** is selected.
4. Filter your view based on several criteria. For more information, see [Filter subjects in a study](#).
5. 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.
6. Select the checkbox to the left of the subject.
7. Above the table of subjects, from the Manage Subjects drop-down, select **Complete or Withdraw**.
8. Click **Complete Study** .
9. Confirm that you want to proceed, and click **Complete Study** .
If a study completion visit opens, complete it now or later.
10. Answer the questions on the form and click **Complete Study** .

Related Topics

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

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](#)

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.


 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. 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:**

Although you can only re-sign data at a subject level, you can still 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, you can manually mark the subject as screen failed.

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 you want to screen fail. The subject must have a status of **Screened**.

 **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.

5. Select the checkbox to the left of the subject.
6. Above the table of subjects, from the Manage Subjects drop-down, select **Screen Fail**.
7. Fill in the fields and click **Screen Fail**.

Related Topics

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

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 a subject's data

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.
- Remember that only completed visits that were attended by a subject can be signed.
- You need to authenticate using your credentials every time you sign a subject's data.

Tip:

Although signing data can only be done at a subject level, you can still use the **View** drop-down to filter displayed in a visit to identify forms and questions that aren't signed.

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. From the **View** drop-down, select **Ready to Sign** to filter your search for subjects who need to be signed.

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

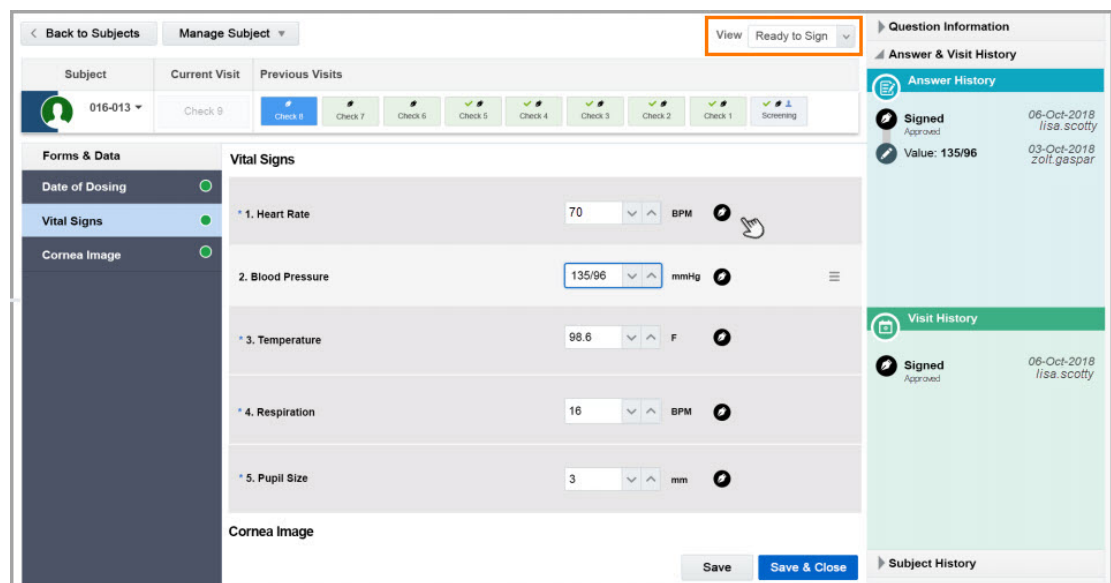
4. Filter your view based on country and sites. For more information, see [Filter subjects in a study](#).
5. In the table, locate a subject, and select the checkbox to the left of the subject.
6. Along the top, click **Manage Subjects**.

7. From the drop-down, select **Sign**.
8. On the **Sign Data** pop-up, enter your user name and password that you use to sign in Oracle Clinical One Platform.
9. 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.

Hover over the Approved text to view the Affidavit displayed on the **Sign Data** pop-up.

Figure 3-2 How a lead site user sees a signed visit



Related Topics

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

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 \(FAQs\)](#)

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. 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 several criteria. For more information, see [Filter subjects in a study](#).
4. In the table, locate the subject you want to withdraw.
5. Select the checkbox to the left of the subject.
6. Above the table of subjects, from the Manage Subjects drop-down, select **Withdraw**.

7. Select the checkbox to confirm the withdrawal.
8. Select a reason for the withdrawal, and click **Withdraw**.
If the study contains a withdrawal visit, the visit appears.
9. If the withdrawal visit appears, complete the visit now or later.

Related Topics

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

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. 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.



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. 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.

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

Video

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**.
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

- [Complete a lab form](#)
Lab test results for subjects are collected using lab forms. To collect lab test results you need to make sure the appropriate lab is associated with the form.
- [Create a local lab](#)
You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- [Define lab normals](#)
Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- [Assign a local lab to a site](#)
You create a local lab within the context of a site. Local labs that are created in the context of a site are automatically associated with that site. You can assign additional labs to the same site.

Complete a lab form

Lab test results for subjects are collected using lab forms. To collect lab test results you need to make sure the appropriate lab is 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 has changes to 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. If included, answer the two introductory questions displayed before the lab form: **Sample Collection Date** and **Fasting**.
6. On the Lab Form, you can perform either one of the following tasks, depending on how your laboratories are set up:
 - 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.
7. On the Result column, enter the lab result for each test.
If you want to edit a value, click the number hyperlink.
 8. Click **Save**.
 9. Repeat steps 7 to 9 for every lab test you need to collect data for.

Related Topics

- [Create a local lab](#)
You can associate a local laboratory with your site. This allows you to associate lab normals with commonly used laboratories and quickly select these labs when adding subject test data. You can add and edit local laboratories at any time, without creating a new version of a study.
- [Define lab normals](#)
Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- [Assign a local lab to a site](#)
You create a local lab within the context of a site. Local labs that are created in the context of a site are automatically associated with that site. You can assign additional labs to the same site.

Create a local lab

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.

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

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

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



1. From the Select Lab drop-down, click the **Go to Sites & Labs** shortcut.
2. Locate the site that you want to create a lab for.
3. In the Labs column, click **View Labs** for the site that you want to create a lab for.
4. Click **Create Lab**.
5. In the Create Lab dialog, fill in the following fields:
 - **Lab Name:** Enter a unique name for the local laboratory that you're creating
 - **Short Name or Lab ID:** Enter a short name or ID for the local laboratory. A lab ID can contain other characters such as numbers or special characters

6. Click **Save**.
7. Along the top, click the **Back to Subject's Visit** button to go back to the visit view.

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

Related Topics

- [Assign a local lab to a site](#)
You create a local lab within the context of a site. Local labs that are created in the context of a site are automatically associated with that site. You can assign additional labs to the same site.
- [Define lab normals](#)
Once you have added a laboratory to your site, you can define the standard values that lab applies to collected lab results. These values are also known as lab normals.
- [Complete a lab form](#)
Lab test results for subjects are collected using lab forms. To collect lab test results you need to make sure the appropriate lab is 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.

Lab normals are typically numeric values or predefined options that you need to set for lab units, low and high data ranges, normal text results, and so forth.

You must define lab normals for every lab test collected for a subject. For example, if you need to collect results for a creatinine test, you must define lab normal ranges, including the lab unit, low range and high range, as well as the gender, age, and effective date for that lab test.



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

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



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

| Lab Normal | Description |
|------------|---|
| Lab Unit | Select the unit of measure used for collecting and measuring data for the lab test. For example, U/L or ng/mL for a creatine kinase (CK) test |

| Lab Normal | Description |
|---|--|
| Low Range | Enter the lower limit of the reference range for the lab test. For example, 24 for a creatine kinase (CK) test |
| High Range | Enter the upper limit of the reference range for the lab test. For example, 174 for a creatine kinase (CK) test |
| Normal Text Result | Select the value that can be used as a reference for a lab test. For example, Negative for an HPV test |
| <div style="border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>For a lab test, you can either define values for the low range and high range or the normal test results. You cannot define both types of lab normals.</p> </div> | |
| Fasting | <p>Select the value that can be used (Yes, No, or All) as a reference for a subject's fasting status. By default, the All option is selected for each lab test.</p> <p>Options for the Fasting normal range can also be different (Fasting and Not Fasting, for example) depending on how they are defined in the study's design. Options Yes, No, and All are predefined in the system, but a study designer can use other options when defining the code list for the Fasting question in a lab form.</p> |
| Gender | <p>Select the gender that the laboratory normals apply to for a the lab test. For example, for a creatine kinase (CK) test you can select Male if the values for a lab unit and low range are defined according to laboratory normals typical to men. You can select All if the lab normals apply to all genders or if your study doesn't collect data on gender.</p> |
| <div style="border-left: 2px solid #0070C0; padding-left: 10px;"> <p> Note:</p> <p>A site user can only select one option for the Gender lab normal.</p> </div> | |
| Age From | Enter a number for the minimum age included in the age range for a lab test |
| Age From Units | Select the unit of measure for a subject's age |
| Age To | Enter a number for the maximum age included in the age range for a lab test |
| Age to Units | Select the unit of measure for a subject's age |

| Lab Normal | Description |
|-----------------------|---|
| Race | <p>Select the race that the laboratory normals apply to for the lab test. You can select All if the lab normals apply to all races or if your study doesn't collect data on race.</p> <p>If your study doesn't collect data on race, then lab normals can be defined to use the All option from the Race code list.</p> |
| Effective Date | <p>Enter the date from which the lab normal range became effective at the laboratory. If a second normal range with matching unit, age, gender, and race values is entered with a later effective date, those values are used for any visit date on or after the new effective date. The effective date is compared to the sample collection date or the visit date, if the sample collection date is not being used in a lab form.</p> |

 **Note:**


A site user can only select one option for the Race lab normal.

5. Click **Save**, if you want to make any other changes to the lab normals. Or click **Save & Close** to complete this task.

Assign a local lab to a site

You create a local lab within the context of a site. Local labs that are created in the context of a site are automatically associated with that site. You can assign additional labs to the same site.

Assigning a local lab to a site allows site users to indicate which local lab they are collecting lab data from.

1. On the Home page, click the study settings () for the study you want to edit. Select **Open Settings**.
2. Below the study name, click the **Sites & Labs** tab.
3. Locate the site that you want to assign the laboratory to.
4. On the Labs column, click **View Labs** next to the site.
5. Along the top of the table, click **Assign/Manage Labs**, and select **Assign**.
6. In the Assign Lab dialog, click **Labs**, and select the laboratory that you want to assign to the site.

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.
- [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. 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.
- [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, 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.
- [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

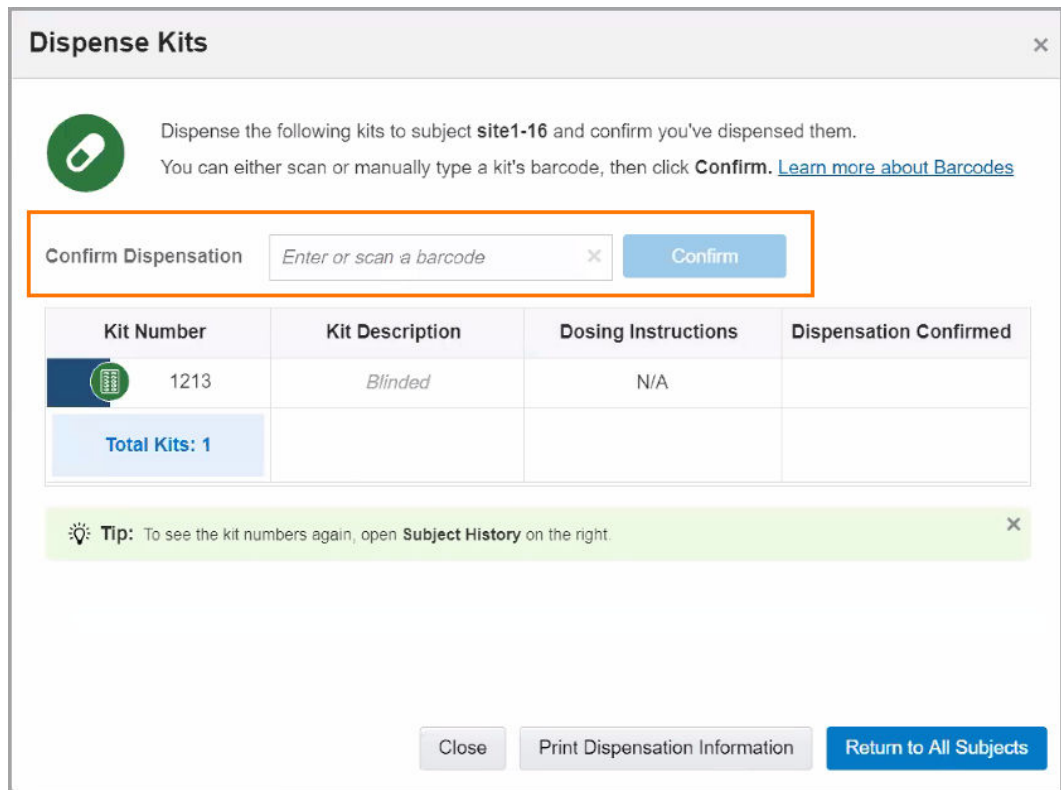
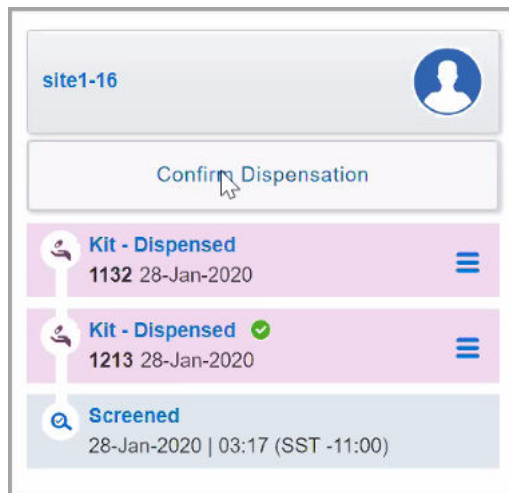


Figure 6-2 How to confirm dispensation of all kits after a visit



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 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 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**.
8. Determine whether the subject has any reusable kits.
9. In the Kits from Previous Visits dialog click either **The Subject Has Some Reusable Kits** or **The Subject Doesn't Have Any Reusable Kits**.
10. If you chose **The Subject Has Some Reusable Kits**, 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.
11. Click **Continue to Dispensation**.
12. 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.
13. Verify the subject number in the confirmation window.
 14. 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.

15. 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](#)

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:**

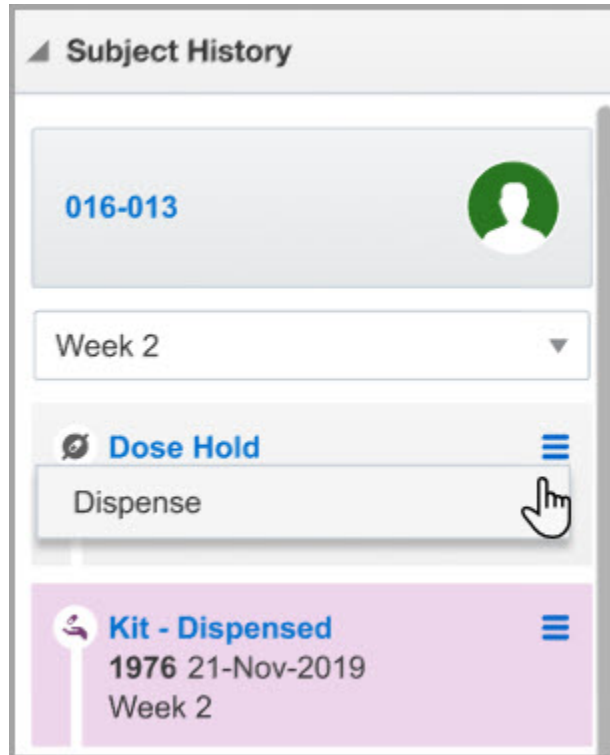
If a dose hold must be placed on an Unblinded Pharmacist type of a kit, you see a notice to contact your unblinded site user or pharmacist, so they can perform this task.

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.

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. 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**Temperature Monitor****Description**

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:

- **No, a temperature monitor inside of the shipment did not go off.**
- **Yes, a temperature monitor inside of the shipment went off.**
- **I didn't find any temperature monitors in the shipment.**

 **Note:**

Depending on your study settings, the system may skip forward to the Review dialog. In this case, continue to the final step. Otherwise, go to the next step.

Quarantined kits

If the shipment has experienced a temperature excursion and your study allows for single kit quarantine, select the kits needed to be quarantined, then click **Next**.

Damaged Kits

If any kits are damaged, select the affected kits and click **Next**.

Missing Kits

If any kits are missing, select the affected kits and click **Next**.

| Option | Description |
|---------------|--|
| Review | Review the information in the Add Shipment to Inventory dialog and click Finish . |

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.

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



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](#).

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** pop-up, select the kit you want to replace.
8. Select a reason for the replacement, and click **Replace Kits**.

Note:

If the kit 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.

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.

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.

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. 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, 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.

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](#).

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.



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 that a subject returned, and reconcile kits](#)
We recommend reconciling kits as the study progresses. For instance, ask subjects to bring any unused investigational product to their next dispensation visit. You can reconcile kits with the following statuses: (1) Damaged by Subject, (2) Dispensed, (3) Misallocated. and (4) Lost by Subject.
- [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 that a subject returned, and reconcile kits

We recommend reconciling kits as the study progresses. For instance, ask subjects to bring any unused investigational product to their next dispensation visit. You can reconcile kits with the following statuses: (1) Damaged by Subject, (2) Dispensed, (3) Misallocated. and (4) Lost by Subject.

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 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**.
9. 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.
10. 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:

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.

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. 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.

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 marked a subject as complete in error](#)
If you marked a subject as complete in error, you can undo the action.
- [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.
- [I withdrew a subject in error](#)
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.

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 the screen failure:

1. Select the subject, and from the Manage Subjects drop-down, select **Undo Screen Fail**.
2. Enter a reason, and click **Undo Screen Fail**.

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 the fields. At least one field contains a blank or invalid value. Enter or [update the invalid values](#), and 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 orange with a question mark.

If the **Dispense** button is disabled and there are no invalid values, check the randomization visit. If you or someone else updated a required field for randomization 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 Health IAMS electronic signature. Try signing a subject's data again. If it still doesn't work, contact Health 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 marked a subject as complete in error

If you marked a subject as complete in error, you can undo the action.

1. Select a subject with the status of **Complete**.
2. From the Manage Subjects drop-down above the Subjects table, select **Undo Complete Study**.

3. Specify a reason for the change, and click **Undo Complete Study**.

The subject state changes from Complete to the state the subject had before being completed, such as Active.

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.

I withdrew a subject in error

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.

1. Select a subject with a status of **Withdrawn**.
2. Above the table of subjects, from the **Manage Subjects** drop-down, select **Undo Withdrawal**.
3. Specify a reason for the change, and click **Undo Withdraw**.

The subject state changes from Withdrawn to the state the subject had before being withdrawn, such as Active.

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 do I know if a repeating form is complete?](#)
Every repeating form displayed in a table view has a status icon beside it.
- [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.

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 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. |

Table 11-1 (Cont.) Repeating form status icons

| Status icon | Status icon description |
|---|---|
|  | Data entered in the repeating form is outside the expected range. |
|  | Data in the repeating form is incomplete. |
|  | The repeating form contains a query. |

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.
- [What statuses can kits have?](#)
Have you ever wondered what each kit status really means for how you manage shipments 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 Dispersed 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 Dispersed 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 Dose Hold 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.

What statuses can kits have?

Have you ever wondered what each kit status really means for how you manage shipments 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 Inventory and 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

Available Available

What it means: The kit is ready to be dispensed to subjects at a site, or ready to be shipped from a depot.

How a kit reaches this status: A kit's status is updated to Available:

- Automatically: when kits are released to a depot for Testing mode, and when a site user marks a shipment as received
- Manually: when a sponsor user releases kits to a depot for Production or Training mode.

Damaged Damaged

What it means: A kit was physically deteriorated at a site or depot. For example, a kit might have been damaged as a result of being dropped.

How a kit reaches this status: A site user or sponsor user marks the kit as Damaged.

Damaged by Subject Damaged by Subject

What it means: 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.

How a kit reaches this status: A site user marks the kit as Damaged by Subject.

Destroyed Destroyed

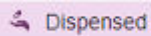
What it means: The kit was destroyed during the kit reconciliation process. Most kits are destroyed after the subjects return them to site. Additionally, a kit is destroyed if it was damaged, it expired, or wasn't dispensed to a subject at all.

How a kit reaches this status: Typically, before destruction, a Clinical Research Associate (CRA) verifies the kit and marks it as being ready for destruction. The next step depends on the location of the drug destruction facility:

- If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to Destroyed.
- If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility. After the kit is destroyed, its status is updated to Destroyed.

**Note:**

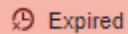
Only Pending Destruction kits can be marked as Destroyed.

Dispensed

Dispensed

What it means: The kit was dispensed to a subject during a dispensation visit.

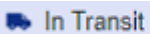
How a kit reaches this status: The kit's status automatically changes to Dispensed after a site user dispenses it to a subject.

Expired

Expired

What it means: The investigational product exceeded its expiration date.

How a kit reaches this status: A site or sponsor user marks it as Expired.

In Transit

In Transit

What it means: The kit is being shipped from a depot to a site.

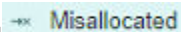
How a kit reaches this status: A shipment request was made by a site or sponsor user for that kit, and the ship date has been provided.

Lost by Subject

Lost by Subject

What it means: The 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.

How a kit reaches this status: A site user marks the kit as Lost by Subject.

Misallocated

Misallocated

What it means: 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.

How a kit reaches this status: A site user manually updates a kit's status to **Misallocated**.

 **Note:**

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.

Missing  Missing

What it means: A kit hasn't been dispensed yet and has gone missing from the site or depot.

How a kit reaches this status: A site user or sponsor user manually updates a kit's status to **Missing**.

New  New

What it means: The kit has just been uploaded in Production mode, and it's going to be manufactured and made ready for use.

How a kit reaches this status: The kit was created in Production mode.

Not Dispensed to Subject  Not Dispensed to Subject

What it means: The 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.

How a kit reaches this status: A site user marks the kit as Not Dispensed to Subject.

 **Note:**

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.

Not in Use  Not in Use

What it means: The 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.

How a kit reaches this status: The site user or sponsor user marked the kit as Not in use.

Pending Destruction  Pending Destruction

What it means: The kit is ready to be destroyed.

How a kit reaches this status: Typically, the Clinical Research Associate (CRA) verifies the kit and then marks it as Pending Destruction. The user must provide a reason for the status update.

Pre-quarantined Pre-quarantined

What it means: The 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.

How a kit reaches this status: The sponsor user marks the kits as Pre-quarantined.



Note:

A pre-quarantined kit is counted in a site's inventory.

Quarantined Quarantined

What it means: 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.

How a kit reaches this status: A clinical supply manager marks the kit as **Quarantined**.

Received for Destruction Received for Destruction

What it means: 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.

How a kit reaches this status: A depot user confirms a receipt per kit that they have received it at the depot.

Returned to Site Returned to Site

What it means: 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.

How a kit reaches this status: A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.

Temporarily unavailable Temporarily Unavailable

What it means: A kit is temporarily on hold and can't be dispensed or shipped.

How a kit reaches this status: A site or sponsor user marks the kit as Temporarily Unavailable.

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 or upload a kit list](#).

For more details on how to enable site users to confirm kit dispensation, see [Specify supply settings](#).

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 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 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.

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?

What is an action? It's a task 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.

Randomized

What it means: A subject has successfully completed a Randomization visit.

How this action impacts a subject's state: When a site user randomizes a subject, their state changes to Active.

Other changes: When a subject is randomized, this update shows up in Subject History, along with the randomization number, date, and time of the randomization visit.

Transferred

What it means: A subject was transferred from one site to another.

How this action impacts a subject's state: 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.

Other changes: 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

What it means: A site user enrolled a subject in a rollover study.

How this action impacts a subject's state: After a site user screens a subject in a study without a randomization (or baseline) visit. Also 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.

Withdrawn

What it means: The subject is no longer available or eligible to continue participating in the study, so a site user withdrew them from the study.

How this action impacts a subject's state: When a site user withdraws a subject from the study, their state changes to Withdrawn.



Note:

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.

Other changes: When a subject is withdrawn from a study, this update shows up in Subject History, along with the date and time of the withdrawal.

Screen failed

What it means: 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.

How this action impacts a subject's state: When a site user screen fails a subject, their state changes to Screen Failed.



Note:

A subject who is marked as Active can no longer be automatically screen failed or manually screen failed by a site user.

Other changes: When a subject fails screening, this update shows up in Subject History, along with the date and time of the screen failure.

Reinstated (Undo Withdrawal)

What it means: A site user withdraw a subject in the study, but then brought them back into the study by undoing their withdrawal.

How this action impacts a subject's state: 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.

 **Note:**

Only subjects in an Active or New state can be withdrawn from a study.

Other changes: When a subject's withdrawal is undone, this update shows up in Subject History, along with the date and time of the action.

Reinstated (Undo Screen Failure)

What it means: 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.

How this action impacts a subject's state: When a site user undoes the screen failure of a subject in the study, they go back to the state that they had before failing the screening.

- If they automatically failed screening due to errors in a form, they go back into a Screened state.
- If they were previously manually screen failed by a site user, they go back into a New state.

Other changes: 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)

What it means: A site user marked a subject as Complete, but then brought them back into the study by undoing their study completion.

How this action impacts a subject's state: When a site user undoes a subject's study completion, they go back to the state that they had before being completed, such as Active.

 **Note:**

A subject who is marked as Complete cannot be withdrawn from the study.

Other changes: When a subject's completion is undone, this update shows up in Subject History, along with the date and time of the action.




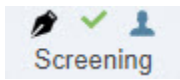
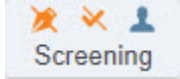

What does each icon mean for signing, verifying, or freezing data?

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. |
|  | This icon appears whenever a Clinical Research Associate verifies a question. |
|  | 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. |
|  | 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 |
|--|---|
| <p>Figure 11-1 Subject is signed and verified</p>  | <p>Both of these icons appear next to a subject whenever their data is both signed and verified.</p> |
| <p>Figure 11-2 Subject is unsigned and unverified</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 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.

Enrolled

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

What it means:

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

How a subject reaches this state:

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

Withdrawn

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

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

Complete

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

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

What 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.

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 |

Table 11-3 (Cont.) Keyboard shortcuts

| Action | Key |
|--|--------------------|
| 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 |