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If you are a site manager that currently works in Oracle Clinical One Platform Platform, this is your go-to guide for all site-related issues.

Note: All tasks in this guide can be performed in both **Production** and **Training** modes.

Manage subjects: What do you want to do?

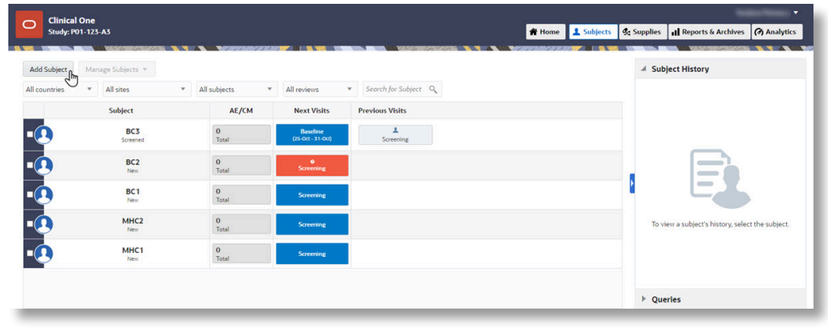
1. Add and screen a subject
2. Enter data, complete a visit, and dispense kits
3. Enter data in a repeating form
4. Mark a subject as complete
5. Withdraw or transfer a subject
6. Enroll a subject in a rollover study
7. Perform a code break
8. What if something happened?

Manage shipments and supplies: What do you want to do?

9. Receive a shipment
10. Reconcile kits
11. Destroy or ship kits to a drug destruction facility
12. What if something happens to a kit or shipment?
13. What if I need extra supply for a clinic day?

Manage subjects: What do you want to do?

1 Add and screen a subject



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

   Can't see the study on the Home page?

2. Along the top, make sure **Subjects** is selected, and click **Add Subject**.

3. Answer the questions on each form, and click **Save** and then **Screen**.

   Need to screen fail or rescreen a subject?

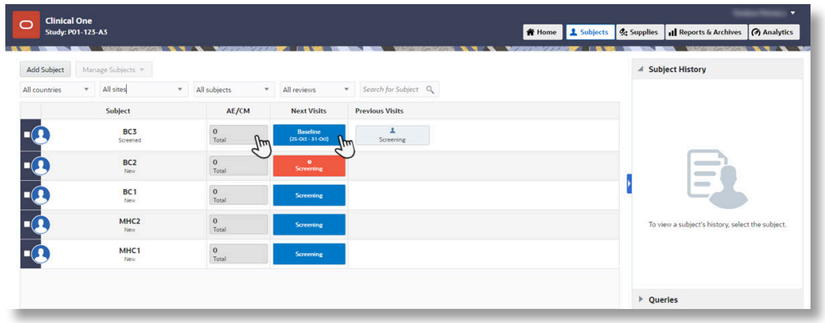
4. Take note of the subject number, and click **Return to All Subjects**.

   Note: In a rollover study, subjects are no longer screened since they've already been screened in the original study.

   Read detailed instructions or watch training!

2 Enter data, complete a visit, and dispense kits

Did you start the visit before scheduled?



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

2. Click the **Subjects** tab if it is not already selected.

3. Locate the subject to update. 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.

4. Depending on what your next step is, do one of the following:

   - To start a scheduled visit, locate it in the **Next Visits** column. Click that visit.
   - To start an Adverse Event (AE) or Concomitant Medications (CM) event, click an entry in the **AE/CM** column.
   - If you want to dispense during an unscheduled visit, locate the subject, select the checkbox next to the subject, and choose **Unscheduled visit** from the **Manage subjects** drop-down.

5. Answer the questions on each form, and click **Save** and then **Randomize** or **Dispense**.

   Note: A scheduled visit is only complete after you answer all of the required questions. If you don't have the subject's answer to one or more questions, flag the question. Read step-by-step instructions on flagging questions.

6. After you click **Dispense**, do one of the following:

   - If the subject is allowed to titrate, choose whether to maintain the current dose, titrate up, or titrate down, and click **Next**.
   - If the subject brought back any reusable kits to the site, mark the kits as reusable on the Reusable Kits pop-up, and click **Continue to Dispensation**.

- If your study features devices managed through an Oracle mHealth connection, activate each device.

7. If needed, answer queries or update your answers on certain queries.

Can't click Randomize or Dispense?

Did you run into an error?

Can't find the subject's kit?

Need to find the kit numbers to dispense?

Don't know how to answer a query?

Titrated up or down in error?

Dispensed a device in error?

Read detailed instructions or watch training!

3 Enter data in a repeating form

1. On the Home page, to enter study data, click the name of the study or click Training Mode to practice.

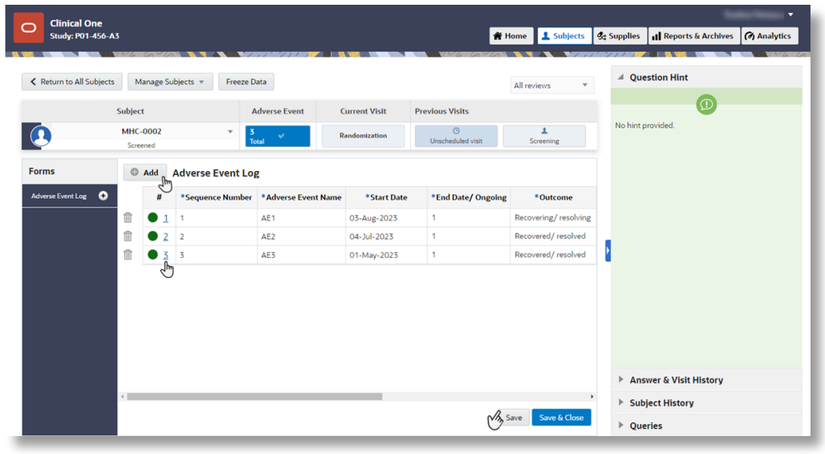
2. Click the **Subjects** tab if it is not already selected.

3. Locate the subject to update. To filter subjects, enter part of the subject number in the **Search** field on the upper right above the table.

4. Locate the scheduled visit in the **Next Visits** column.

5. Repeating forms are displayed in a table view. If this is the first time you add data in a repeating form, double-click anywhere in the first row of the table.
If you already added a repeating form and you want to add a new one click the **Add** button in the upper right corner of the form section.

6. The form appears in a new pop-up window. Answer the questions on the form and click **Save**.

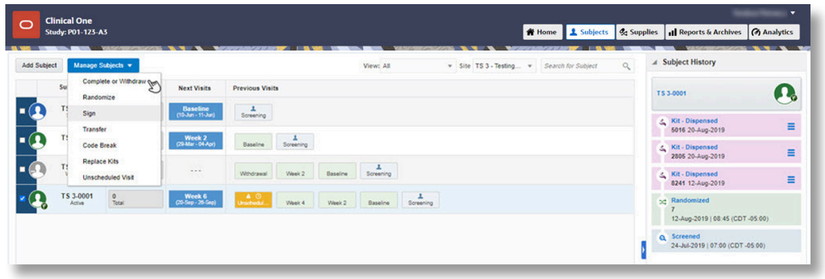


7. To edit or modify values in a repeating form, double-click the table row where the data is displayed. Edit the data and click **Save**.

8. When you have finished adding data in the repeating form, click **Save**.

   Read detailed instructions or watch training!

4 Mark a subject as complete



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

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

3. Select a subject with a checkbox in the upper-right corner of their avatar. 

4. From the **Manage Subjects** drop-down, select **Complete** or **Withdraw**.

5. Click **Complete Study**.

6. Confirm the decision, and click **Complete Study**.

7. If a study completion visit opens, complete it now or later. A subject's status is updated to **Complete** only when all of their visits in a study are completed.

   Marked a subject as complete in error?

   Read detailed instructions or watch training!

5 Withdraw or transfer a subject

Does the subject need to transfer? Contact your CRA for assistance.

To withdraw a subject:

1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

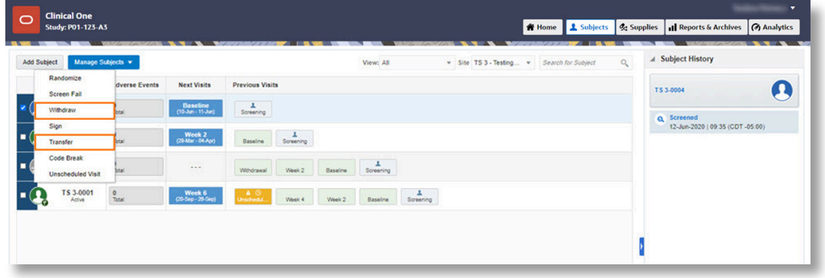
2. Along the top, make sure **Subjects** is selected.

3. Select the subject to withdraw.

4. From the **Manage Subjects** drop-down, select **Withdraw**.

5. Confirm the withdrawal, enter a reason, and click **Withdraw**.

6. If your study has a withdrawal visit, you can complete it now or later.

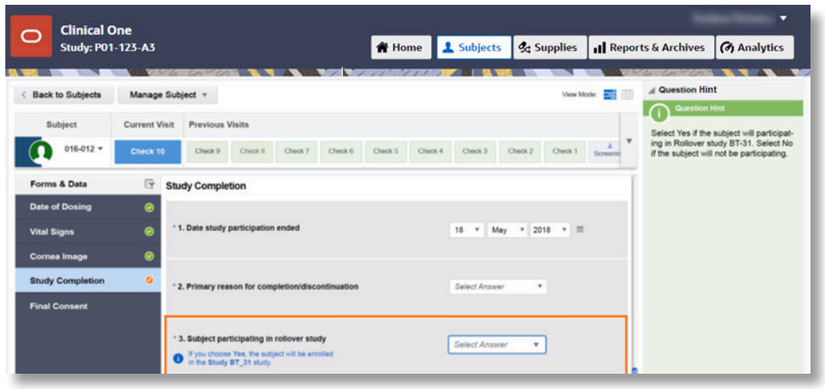


Withdrew a subject in error?

Read detailed instructions or watch training!

6 Enroll a subject in a rollover study

If your study allows you to enroll subjects in a rollover study you now see a rollover question in the study completion form.



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

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

3. Select a subject with a checkbox in the upper-right corner of their avatar. 

4. From the **Manage Subjects** drop-down, select **Complete or Withdraw**.

5. Click **Complete Study**.

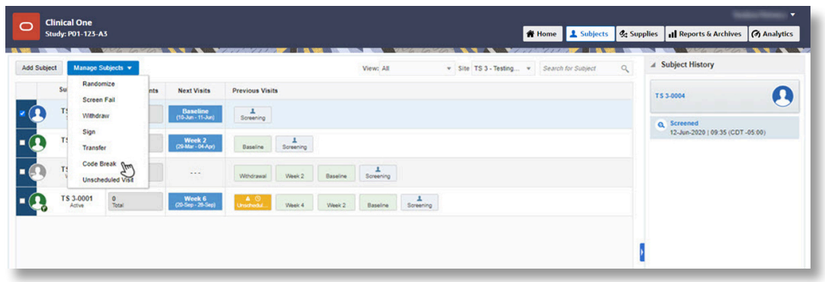
6. Fill out the study completion form attached to the visit. When you reach the rollover question, if the subject consents, select **Yes** from the **Select Answer** drop-down to enroll the subject in the rollover study.

7. Click **Complete Study**.

Read detailed instructions.

7 Perform a code break

A code break unblinds a subject's treatment arm. Depending on the study protocol, Oracle Clinical One Platform might automatically withdraw a subject that you unblind using a code break, and you might be required to complete a withdrawal visit



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
2. Along the top, make sure **Subjects** is selected.
3. In the table, select the checkbox to the left of the subject you want to unblind.
4. Above the table of subjects, from the **Manage Subjects** drop-down, select **Code Break**.
5. Click **Continue**.
6. Confirm the subject number and study name, and select the checkbox to confirm the code break.
7. Indicate if an adverse event occurred, and click **Unblind**.
8. 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**.

Read detailed instructions or watch training!

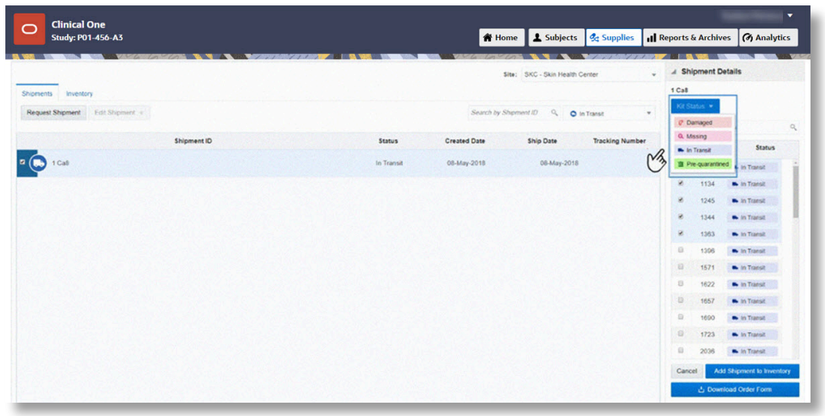
8 What if something unexpected happened with a subject?

What happened?

- I need to change an answer.
- I screen failed a subject in error.
- I randomized a subject in error.
- I need to randomize after a randomization failure.
- I need to decide what to do with a subject who cannot titrate.

Manage shipments and supplies: What do you want to do?

9 Receive a shipment



1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

   Can't see the study on the Home page?

2. Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.

3. From the **Filter by Status** drop-down, select **In Transit**.

4. Select the checkbox next to the shipment that arrived, and on the right, review the kits in the packing list against the kits in the shipment.

5. Click **Add Shipment to Inventory**.

6. 6. Follow the steps prompted as required according to the temperature excursion settings in your study:

   Note: Some steps may not be required for your study.

   a. **Temperature excursion?** Enter Temperature monitor status.

   b. **Quarantined kits?** Select the kits with **Quarantined** status.

   c. **Damaged kits?** Select them, and select the **Damaged** status.

   d. **Missing kits?** Select them, and select the **Missing** status.

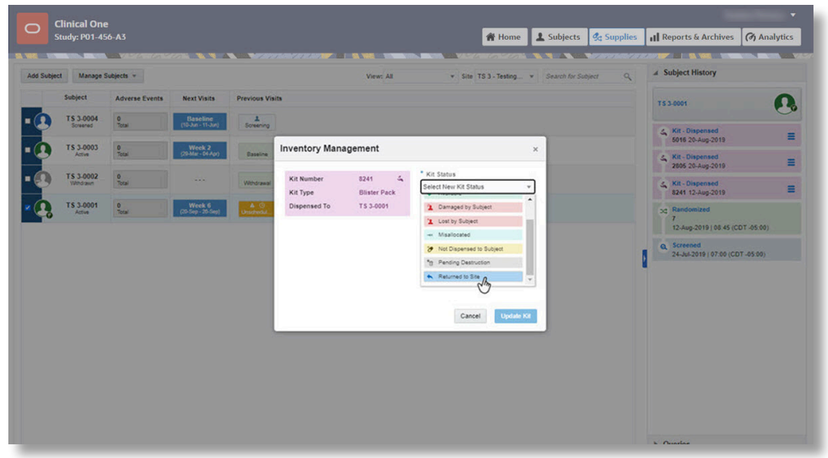
   e. **Review** the kit list and make sure every kit is tagged accordingly. Remaining kits will be added to inventory as available.

7. Click **Finish**.

Read detailed instructions or watch training!

10 Reconcile kits

Some studies require kit reconciliation. If you're not sure whether this step is required, contact your CRA.



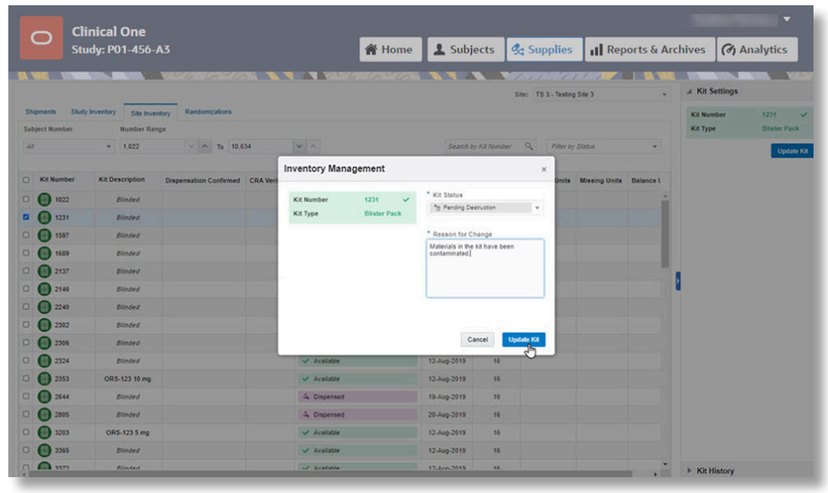
1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
2. Along the top, make sure **Subjects** is selected.
3. Select the subject who returned the kit.
4. On the right in **Subject History**, click the kit.
5. From the **Kit Status** drop-down, select **Returned to Site**.
6. Specify the returned and missing units and a reason, and click **Update Kit**.

Read detailed instructions or watch training!

11 Destroy kits, or ship kits to a drug destruction facility

Some studies require kit destruction, which can occur either at your site (if the site is drug destruction capable) or at a depot that is a drug destruction facility. If you're not sure whether this step is required, contact your CRA.

Before you can perform these steps, your CRA has to mark kits as **Pending Destruction**.



1. On the Home page, click either the name of the study (to enter study data) or the **Training Mode** button (to practice).
2. To destroy kits at your site:

   a. Destroy kits outside Oracle Clinical One Platform according to the protocol and any relevant SOPs.

   b. Along the top, click **Supplies**, and click the **Inventory** tab.

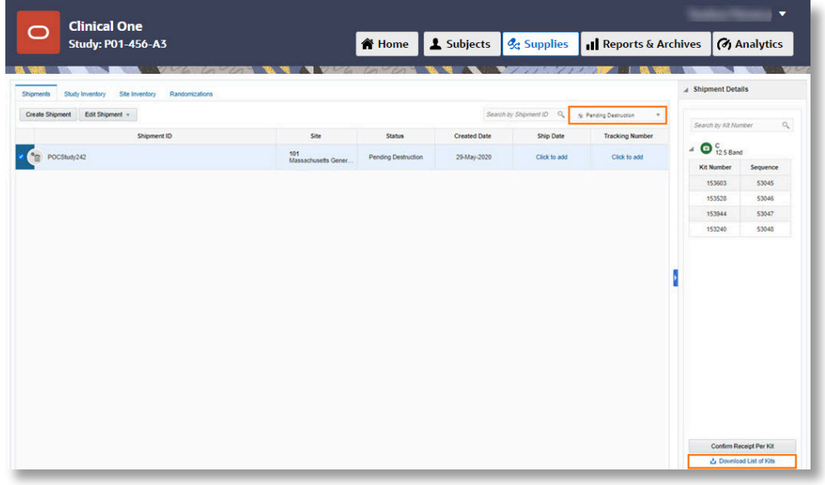
c. From the **Status** drop-down above the table, select **Pending Destruction**.

d. On the right, below **Inventory Management**, select **Update Kit**.

e. From the **Kit Status** drop-down, select **Destroyed**.

f. Enter a reason, and click **Update Kit**.

Read detailed instructions or watch training!



3. To ship kits to a drug destruction depot:

a. Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.

b. From the **Filter by Status** drop-down, select **Pending Destruction**.

c. Select a shipment, and on the right, click **Download List of Kits**. We recommend printing the report.

d. Fulfill the shipment outside Oracle Clinical One Platform.

Read detailed instructions.

12 What if something happens to a kit or shipment?

What happened?

- A subject lost or damaged a kit.
- A kit was lost or damaged at our site.
- A kit wasn't dispensed to a subject.
- A kit was dispensed in error.
- A shipment didn't arrive.
- A device can't be activated.

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13 What if we need extra supply for a clinic day?

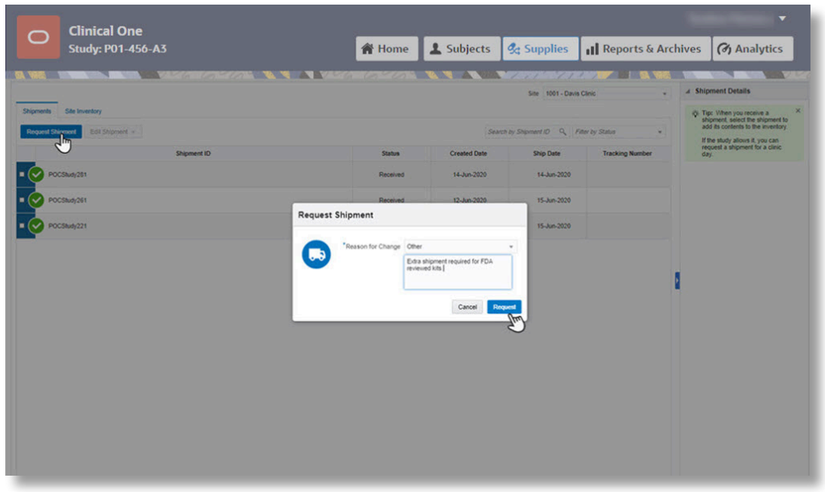
1. On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

2. Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.

3. Click **Request Shipment**.

   Don't see the button? This study doesn't allow sites to request shipments. Contact your CRA for assistance.

4. Enter a reason, and click **Request**.



Read detailed instructions or watch training!

You're done!

Find out more about **Clinical One Suite**

Get more information

See the Oracle Clinical One Platform documentation library on the Oracle Help Center.

Other resources

Watch short training videos on the Oracle Help Center for subjects and site supplies.

Contact Support

For assistance, contact Oracle Life Sciences Support.

Can't find what you need?

Write to us at clinical_one_doc_feedback_us_grp@oracle.