

[← Back to Oracle Help Center](#)

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

**Note:** All tasks in this guide can be performed in **Training Mode**.

### Manage Subjects: What do you want to do?

1. Add and screen a subject
2. Enter data, complete a visit, and dispense kits
3. Mark a subject as complete
4. Withdraw or transfer a subject
5. Perform a code break
6. What if something happened with a subject?

### Manage Shipments and supplies: What do you want to do?

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

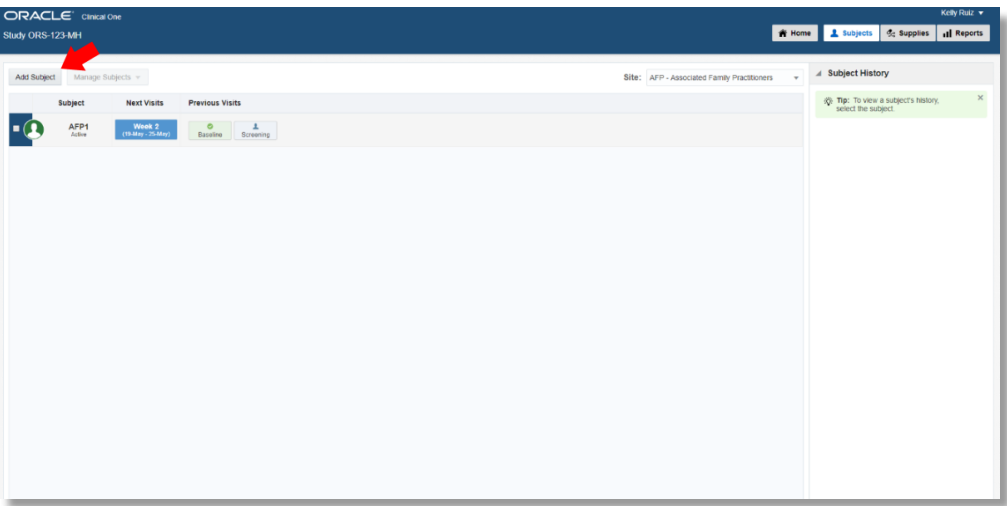
## Manage Subjects: What do you want to do?

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. Note the subject number, and click **Return to All Subjects**.

Read [detailed instructions](#) or [watch training!](#)



2

### Enter data, complete a visit, and dispense kits

Did the [subject arrive outside the visit window](#), or did you [start the visit before the subject came in](#)?

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. Locate the visit in the **Next Visits** column.
4. Answer the questions on each form, and click **Save** and then **Randomize** or **Dispense**.

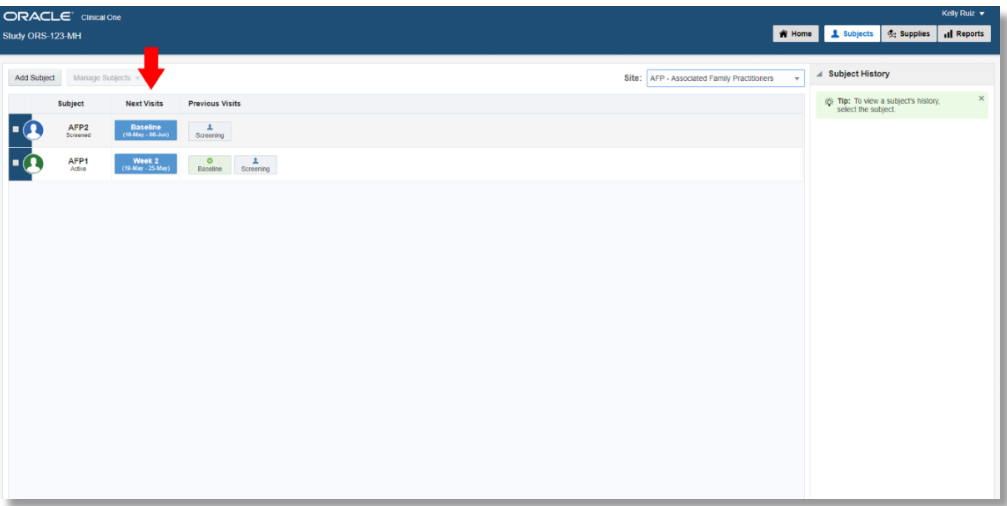
[Can't click Randomize or Dispense?](#)

[Did you run into an error?](#)

[Can't find the subject's kit?](#)

[Need to find the kit numbers to dispense?](#)

Read [detailed instructions](#) or [watch training!](#)



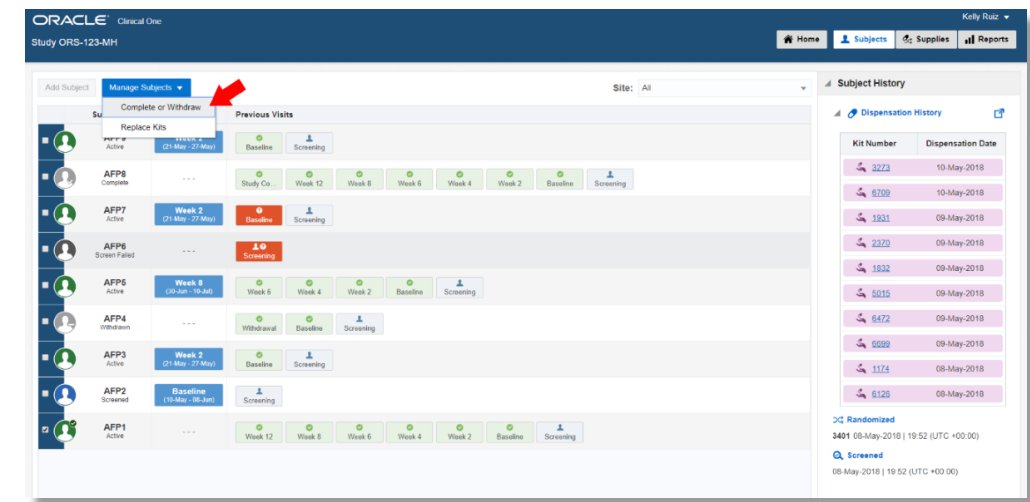
3

### Mark a subject as complete

- On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- Along the top, make sure **Subjects** is selected.
- Select a subject with a checkbox in the upper-right corner of their avatar.
- From the **Manage Subjects** drop-down, select **Complete** or **Withdraw**.
- Click **Complete Study**.
- Confirm the decision, and click **Complete Study**.
- If a study completion visit opens, complete it now or later.

Marked a subject as complete in error?

Read [detailed instructions](#) or [watch training!](#)



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### Withdraw or transfer a subject

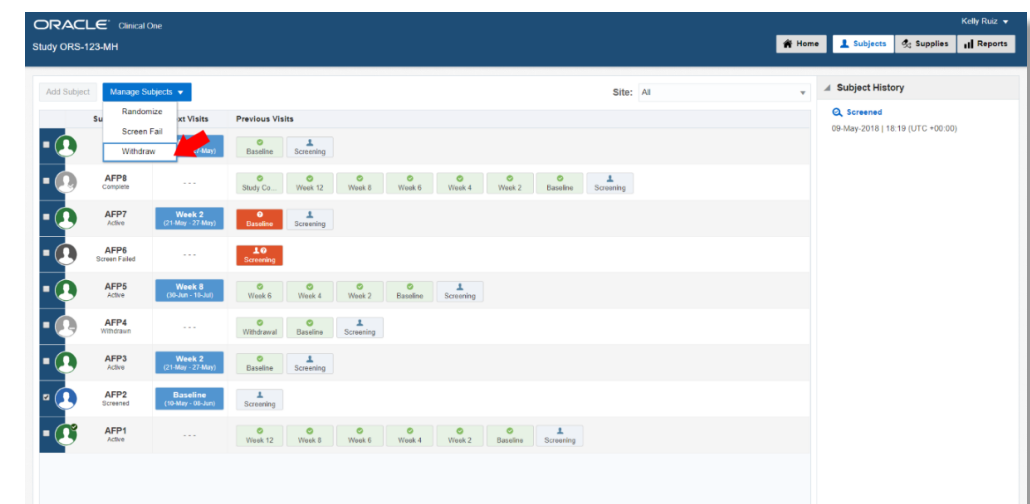
**Does the subject need to transfer?** Contact your CRA for assistance.

To withdraw a subject:

- On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- Along the top, make sure **Subjects** is selected.
- Select the subject to withdraw.
- From the **Manage Subjects** drop-down, select **Withdraw**.
- Confirm the withdrawal, enter a reason, and click **Withdraw**.
- 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!](#)



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### Perform a code break

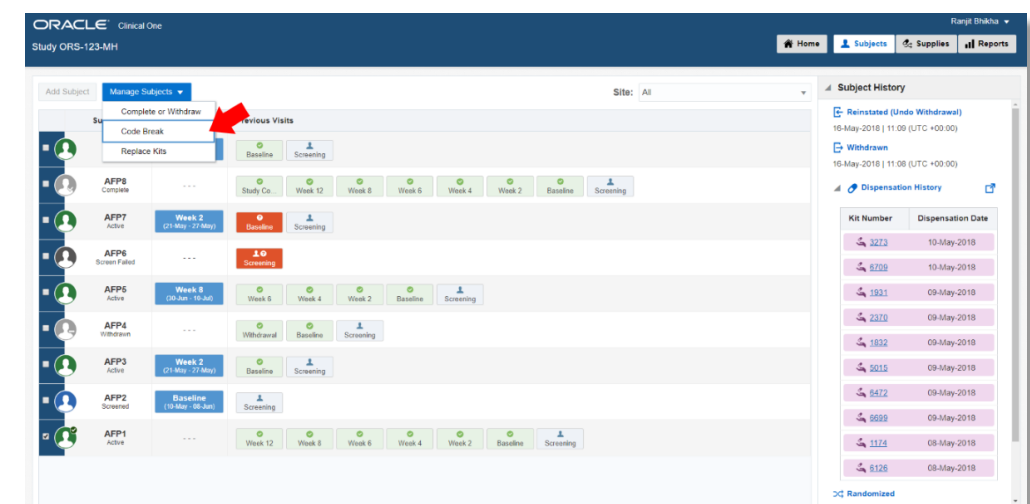
A code break unblinds a subject's treatment arm. Depending on the study protocol, Clinical One might automatically withdraw a subject that you unblind using a code break, and you might be required to complete a withdrawal visit

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



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.

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

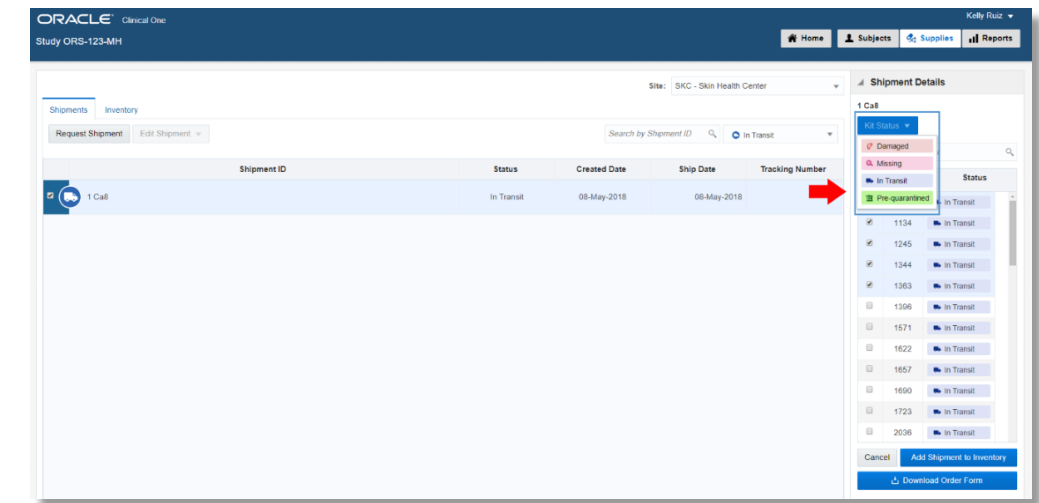
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## Receive a shipment

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. Use the Kit Status drop-down to update kits with issues:
  - a. Temperature excursion? Select all kits, and select the **Pre-Quarantined** status.
  - b. Missing kits? Select them, and select the **Missing** status.
  - c. Damaged kits? Select them, and select the **Damaged status**.
  - d. Extra kits in the shipment? Contact your CRA.

6. Add all remaining kits to inventory: Click **Add Shipment to Inventory**.

[Read detailed instructions](#) or [watch training!](#)



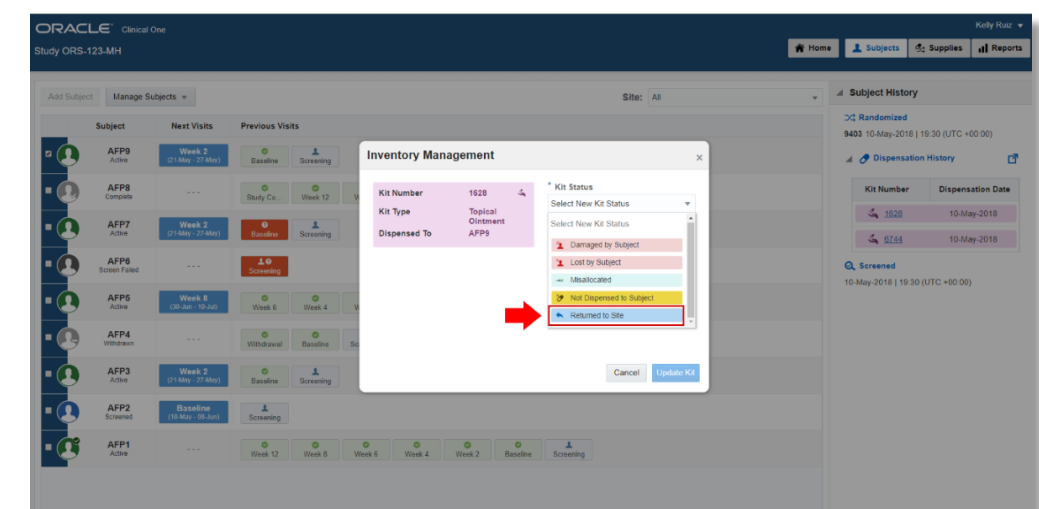
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## Reconcile kits

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!](#)



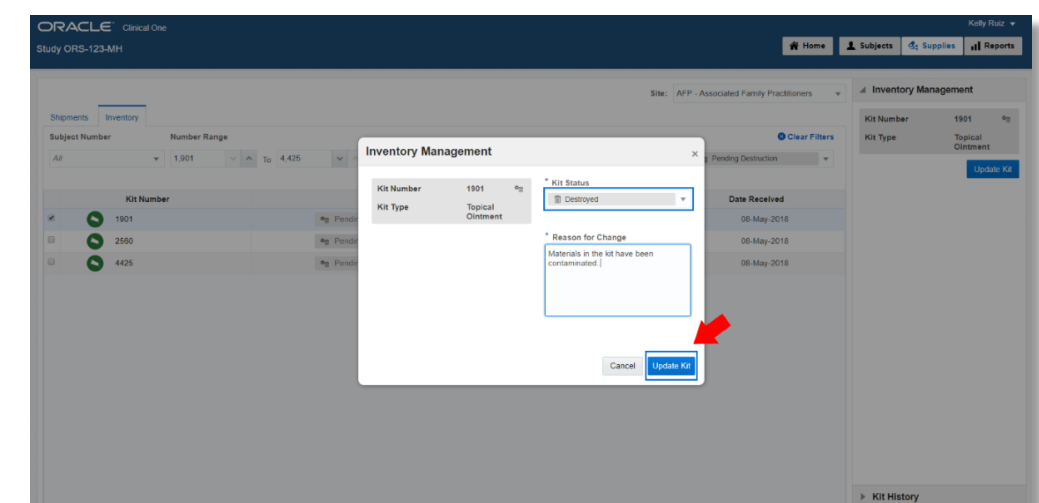
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## Destroy kits, or ship kits to a drug destruction facility

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.

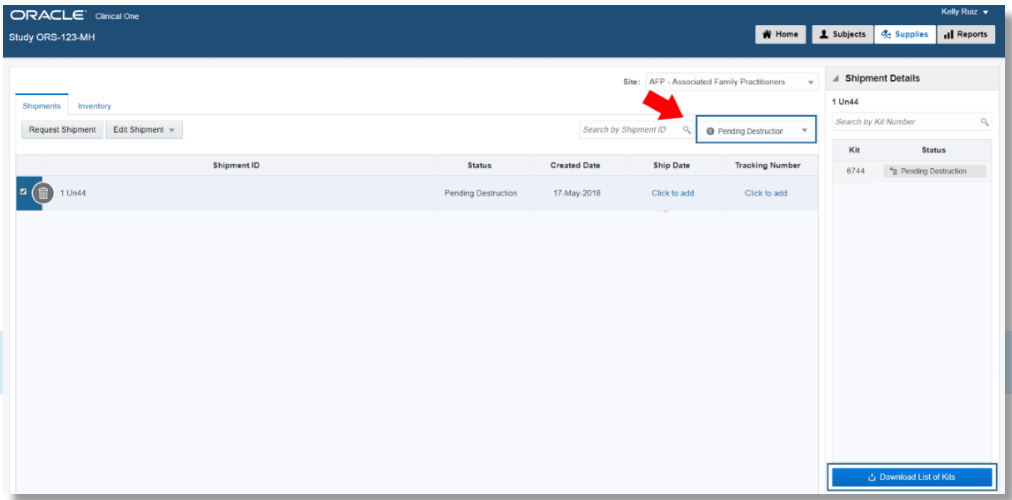
Before you can perform these steps, your CRA has to mark kits as **Pending Destruction**.

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 Clinical One 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**.
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 Clinical One.

Read [detailed instructions](#) or [watch training!](#)



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What if something happens to a kit or shipment?

What happened?

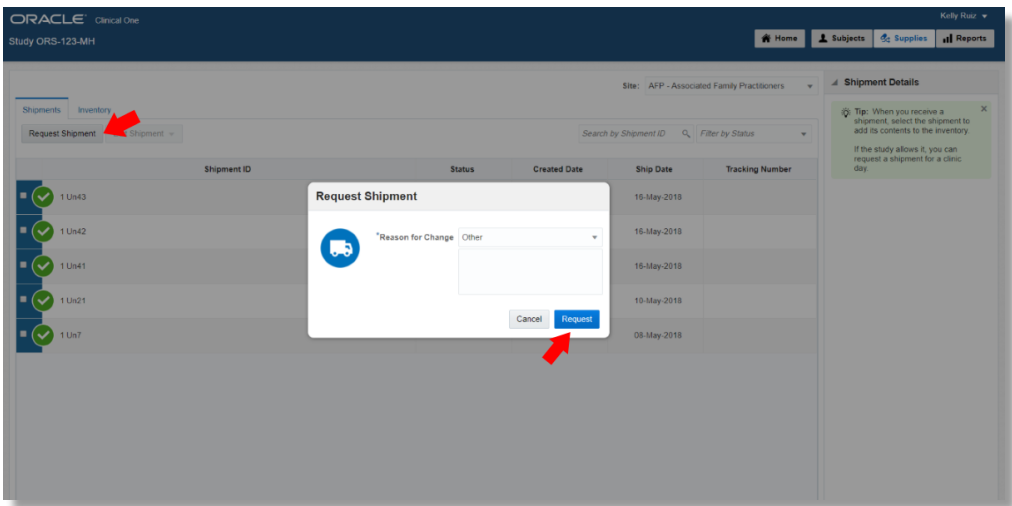
- A subject lost or damaged a kit.
- A kit was lost or damaged at our site.
- A kit wasn't dispensed to a subject.
- A kit was dispensed in error.
- A shipment didn't arrive.

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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!

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Get more information

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Other resources

Watch [short training videos](#) on the Oracle Help Center.

Contact Support

For assistance, contact [Health Sciences Cloud Support](#).

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