

Oracle® Life Sciences Clinical One Platform

Depot User Guide



Release 24.1

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

ORACLE®

Oracle Life Sciences Clinical One Platform Depot User Guide, Release 24.1

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Preface

This preface contains the following sections:

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

Documentation accessibility

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Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

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

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

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

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1

Manage expiration dates

- [Access the Study Inventory tab](#)
As a depot user, you may have to perform kit reconciliation tasks or manage expiration dates. If these tasks are part of your responsibilities, see how to easily access the Study Inventory tab.
- [About manufacturing and blinded lots](#)
In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.
- [Manage expiration dates with lots](#)
You must create at least one manufacturing lot in each required study mode (Testing, Training, or Production) or you won't be able to dispense kits in those required study modes. You use lots to specify the expiration date for kits. Blinded lots are optional and allow you to combine one or more manufacturing lots.
- [Filter on the Study Inventory tab](#)
Inventory filters are located at the top of the page. You can use filters individually or they can be combined.
- [Assign kits to a manufacturing lot](#)
You must add every kit, including investigational product kits and device kit types, to a manufacturing lot in each required study mode (Testing, Training, or Production) so that you can specify their expiration dates. Kits that aren't added to lots can't be dispensed because they don't have expiration dates.
- [Combine manufacturing lots into a blinded lot](#)
Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot either to monitor batches of kits while protecting the study blind or to organize kits in multiple groupings.

Access the Study Inventory tab

As a depot user, you may have to perform kit reconciliation tasks or manage expiration dates. If these tasks are part of your responsibilities, see how to easily access the Study Inventory tab.

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 Testing mode, click the Testing Mode button () on the study.
 - To work with mock data in Training mode, click the Training Mode button () on the study.
2. Along the top of the page, click **Supplies**.
3. Below the study name, click the **Study Inventory** tab.

Related Topics

- [Manage expiration dates with lots](#)
You must create at least one manufacturing lot in each required study mode (Testing, Training, or Production) or you won't be able to dispense kits in those required study modes. You use lots to specify the expiration date for kits. Blinded lots are optional and allow you to combine one or more manufacturing lots.
- [Assign kits to a manufacturing lot](#)
You must add every kit, including investigational product kits and device kit types, to a manufacturing lot in each required study mode (Testing, Training, or Production) so that you can specify their expiration dates. Kits that aren't added to lots can't be dispensed because they don't have expiration dates.
- [Combine manufacturing lots into a blinded lot](#)
Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot either to monitor batches of kits while protecting the study blind or to organize kits in multiple groupings.
- [Mark a kit as missing or damaged](#)
When a kit is missing or it is damaged at a site, you must update its status in the study's inventory. This is part of a study's kit reconciliation process.
- [Mark kits that had a temperature excursion](#)
During the course of a study, you may have to mark kits that had a temperature excursion either at the depot or at a site that you support.
- [Mark a kit for destruction](#)
If another depot must destroy kits in a study, as part of the kit reconciliation process, you must update a kit's status to **Pending Destruction** so the kit can be placed in a depot shipment for destruction.

About manufacturing and blinded lots

In a study, you may have to create both manufacturing and blinded lots. Before creating your lots, you should understand the difference between these two lot types.

Manufacturing lots

You must use this type of lot in every dispensing study. Kits in a manufacturing lot share an expiration date, and you must create at least one manufacturing lot in each required study mode (Testing, Training, or Production) so that you can assign an expiration date to kits in Oracle Clinical One Platform.

You typically create a manufacturing lot before a study goes live and as needed during the study conduct period, such as when a new batch of product is released.

Blinded lots

Creating blinded lots is optional. You may choose to combine one or more manufacturing lots into a blinded lot for the following reasons:

- To monitor batches of kits while protecting the study blind.
- To organize kits in multiple groupings.

Create a blinded lot in Production mode if the study or organization requires blinded lot numbers. You can also create a blinded lot in Training mode if you want users to be able to practice the end-to-end business process.

Related Topics

- [Manage expiration dates with lots](#)
You must create at least one manufacturing lot in each required study mode (Testing, Training, or Production) or you won't be able to dispense kits in those required study modes. You use lots to specify the expiration date for kits. Blinded lots are optional and allow you to combine one or more manufacturing lots.

Manage expiration dates with lots

You must create at least one manufacturing lot in each required study mode (Testing, Training, or Production) or you won't be able to dispense kits in those required study modes. You use lots to specify the expiration date for kits. Blinded lots are optional and allow you to combine one or more manufacturing lots.

Before you perform this task, consider the following notes:

- Create one manufacturing lot for each batch of kits. Grouping kits by batch helps you monitor and search for kits to ensure quality. If multiple batches have the same expiration date, name the lots appropriately so you can identify them.
- You can update the expiration date for a manufacturing lot or a blinded lot at any time. The blinded lot must always use the earliest expiration date of all its manufacturing lots.
- After a lot expires, its kits are no longer distributed to sites or dispensed to subjects.

For more information, see [About manufacturing and blinded lots](#).

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



Create a manufacturing lot



Note:

Follow the steps below to create a manufacturing lot in all of the required study modes: Testing, Training, or Production. To return to the Home page, in the upper right, click **Home**.

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Expand the **Lots** side panel to the right of the page.
3. From the **Create Lot** drop-down, select **Manufacturing Lot**.
4. Fill in the fields and click **Create**. To view tips for completing a field, click into the field.

Field	Description
Manufacturing Lot Title	Enter a unique name for the manufacturing lot.

Field	Description
Short Name	Enter an alternative manufacturing lot label. For example, you might enter a short name if your organization's labeling conventions differ from the lot name supplied by the depot.
Expiration	Choose the expiration date for the kits in the manufacturing lot. If you're creating a manufacturing lot for devices that don't expire, you can choose a date that is very far in the future.
Do Not Ship (DNS) Days	Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site.
Do Not Count (DNC) Days	Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory.

Create a blinded lot



Note:

Follow the steps below to create a manufacturing lot in all of the required study modes: Testing, Training, or Production. To return to the Home page, in the upper right, click **Home**.

1. On the Lots side panel, from the **Create Lot** drop-down, select **Blinded Lot**.
2. Fill in the fields and click **Create**.

Field	Description
Blinded Lot Title	Enter a unique name for the blinded lot.
Short Name	Enter a short name for the blinded lot. This field is useful when multiple depots use the same lot and have different naming conventions. One depot can use the title, and another can use the short name.
Expiration	Choose the expiration date for the blinded lot. The date must be on or before the earliest expiration date of the manufacturing lots in the blinded lot.
Do Not Ship (DNS) Days	Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site.

Field	Description
Do Not Count (DNC) Days	Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory.

Related Topics

- [Assign kits to a manufacturing lot](#)
You must add every kit, including investigational product kits and device kit types, to a manufacturing lot in each required study mode (Testing, Training, or Production) so that you can specify their expiration dates. Kits that aren't added to lots can't be dispensed because they don't have expiration dates.
- [Combine manufacturing lots into a blinded lot](#)
Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot either to monitor batches of kits while protecting the study blind or to organize kits in multiple groupings.

Filter on the Study Inventory tab

Inventory filters are located at the top of the page. You can use filters individually or they can be combined.



1. Access the Study Inventory tab.
2. Determine how you want to search for kits:
 - Select **Kit** and then type the **Kit number** in the **Search Bar**, and press **Enter**.
 - Select **Sequence number** and then type the **Sequence number** in the **Search Bar**, and press **Enter**.

3. Determine which filters you want to use to view your study supply:

Option	Description
Status	Select one kit status to view kits with that specific status from the drop-down. Or select All to view all kits in the inventory no matter their status.
Lot	Filter by the Blinded Lot or select Unassigned .
Kit number	Enter a number in the fields From and To to narrow the search range.
Sequence number	Enter a number in the fields From and To to narrow the search range.

4. Click **Clear Filters** to return to the initial view.

Assign kits to a manufacturing lot

You must add every kit, including investigational product kits and device kit types, to a manufacturing lot in each required study mode (Testing, Training, or Production) so that you

can specify their expiration dates. Kits that aren't added to lots can't be dispensed because they don't have expiration dates.

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



 **Note:**

Follow the steps below to create a manufacturing lot in all of the required study modes: Testing, Training, or Production. To return to the Home page, in the upper right, click **Home**.

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Click a kit type.
3. Above the kit list, from the **Lots** drop-down, click **Unassigned** so you see only kits that aren't assigned to any lots.

 **Tip:**

You can narrow your view further using the filters above the kit list.

4. In the list, select the kits to include in the manufacturing lot.
5. From the **Add to Lot** drop-down, located to the right of the filters, select the manufacturing lot.
6. In the confirmation dialog, select a reason for the change, and click **Yes**.
7. Above the kit list, use the filters to check your work:
 - a. In the upper right corner of the page, click **Clear Filters**.
 - b. Above the kit list, from the **Lots** drop-down, select the manufacturing lot that you assigned the kits to.

Combine manufacturing lots into a blinded lot

Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded lot either to monitor batches of kits while protecting the study blind or to organize kits in multiple groupings.

For more information on blinded lots, see [About manufacturing and blinded lots](#).

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





Note:

Follow the steps below to create a manufacturing lot in all of the required study modes: Testing, Training, or Production. To return to the Home page, in the upper right, click **Home**.

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Expand the **Lots** side panel on the right of the page.
3. Drag one or more manufacturing lots to the blinded lot that you want to combine them in.



2

Manage shipments

- [Access the Shipments tab](#)
As a depot user, you must manage all of a study's shipments on the Shipments tab.
- [Create a manual shipment](#)
You might need to create a manual shipment if a shipment was damaged at the depot before it was shipped or if another depot requires more supplies sent to their facility.
- [Create a shipment for destruction](#)
You must create a shipment for destruction when there are kits pending destruction in the study inventory and another depot is supposed to receive and destroy those kits.
- [Specify a ship date and tracking number for a shipment](#)
Perform these steps only if the study doesn't use an integration with Almac, Fisher Clinical Services or Catalent Clinical Supply Services for shipments.
- [Fulfill a shipment](#)
You receive a notification when you need to fulfill a shipment. The notification contains the Shipment ID.
- [Cancel a shipment](#)
In any study, you can cancel a manual or automatically-generated shipment as long as its status is **Pending**, **Invalid**, **Confirmed**, **In Transit**, or **Pending Destruction**. You typically cancel a shipment to control costs and avoid the waste of the investigational product.
- [Check for an invalid shipment](#)
You must perform this task if your study uses an integration with Almac or Catalent Clinical Supply Services.
- [Update the contents of a shipment](#)
Update the contents of a shipment when the kits in the box don't match the contents in Oracle Clinical One Platform.
- [Mark a shipment as lost](#)
During the course of a study, you may have to mark a shipment as lost in the application.

Access the Shipments tab

As a depot user, you must manage all of a study's shipments on the Shipments tab.

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 Testing mode, click the Testing Mode button () on the study.
 - To work with mock data in Training mode, click the Training Mode button () on the study.
2. Along the top of the page, click **Supplies**.

- Below the study name, click the **Shipments** tab.

Related Topics

- [Manage shipments](#)
- [Receive and destroy kits](#)

If depot kit reconciliation is required in your study and the depot you're assigned to is drug destruction capable, then you might receive shipments containing kits that need to be destroyed.

Create a manual shipment

You might need to create a manual shipment if a shipment was damaged at the depot before it was shipped or if another depot requires more supplies sent to their facility.

Tip:

If the study doesn't allow single-kit ordering and you create a shipment with only one kit, Oracle Clinical One Platform adds an additional kit to the shipment. The sponsor specifies whether single-kit ordering is allowed in a study.

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




- Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#).
- Click **Create Shipment** and select **Manual Shipment**.
- On the Create Shipment dialog, fill in the fields. To view tips for completing a field, click into the field or choose an option.

Note:

Depending on how kits are designed in your study, a kit type may include information about its block size. If you add a number of kits that is lower than its block size, the system adds additional kits to complete the block. For example, if you include 2 vials in a shipment, the system includes 2 additional vials to complete the block of 4 units.

Field	Description
Destination	<p>Select whether the destination of this shipment is a site or a depot.</p> <ul style="list-style-type: none"> If you select Site, then you must select the destination site from the second drop-down. If you select Depot, then you must specify the destination depot (in the Destination field) and the source depot (in the Ship From field), too.

Field	Description
Kit Type and Description	For a specific kit type, turn on the toggle () to specify that the shipment must include that kit type.
Quantity	Enter the number of kits of this type to include in the shipment.
Lot	From the Select Lot drop-down, select the lot that you want to associate with the pooled kit.

 **Note:**

Specifying a lot is only available for pooled kits that are included in a shipment sent out to sites. You cannot include pooled kits in a depot-to-depot shipment.

4. Click **Create Shipment**.
5. Click **Close**.

Next, you must fulfill the shipment and then specify a ship date for the shipment after it leaves the depot. For step-by-step instructions, see:

- [Fulfill a shipment](#)
- [Specify a ship date and tracking number for a shipment](#)


Create a shipment for destruction

You must create a shipment for destruction when there are kits pending destruction in the study inventory and another depot is supposed to receive and destroy those kits.

For a depot facility to create a shipment for destruction and ship it to another depot facility, you or the clinical supply manager must update the status of the required kits to **Pending Destruction**. For more information, see [Mark a kit for destruction](#).

1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. Click **Create Shipment** and select **Shipment for Destruction**.
3. On the Create Shipment dialog, fill in the fields. To view tips for completing a field, click into the field or choose an option.

Field	Description
Destination Depot	Select the depot where the shipment needs to arrive for destruction.
Ship From	Select the depot from where the shipment for destruction is coming.

Field	Description
Kit Type and Description	For a specific kit type, turn on the toggle () to specify that the shipment must include that kit type.
Quantity	You cannot specify the quantity yourself. The quantity of kits to be destroyed is determined by the system based on how many kits were previously updated with a status of Pending Destruction .

4. Click **Create**.
5. Click **Close**.

Next, another depot user must receive and destroy those kits at the destination depot. For step-by-step instructions, see [Receive and destroy kits](#).

Specify a ship date and tracking number for a shipment

Perform these steps only if the study doesn't use an integration with Almac, Fisher Clinical Services or Catalent Clinical Supply Services for shipments.



Note:

A pooled shipment's ship date can only be updated through an integration. As a clinical supply manager or depot user, you can still manually specify a tracking number for a pooled shipment or cancel it.

- If the study uses an integration with Almac, Fisher Clinical Services or Catalent Clinical Supply Services, the integration automatically adds a ship date and tracking number and changes the status of the shipment.
- If the study doesn't use an integration, someone from either the sponsor or depot must specify a ship date so that the status of a shipment changes from **Pending** to **In Transit** and so that the site can mark the shipment as received. Site users can't see pending shipments, but they can see in-transit shipments.

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



1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. From the **Filter by Status** drop-down, select **Pending** or **Confirmed**.



Tip:

If a shipment has a status of In Transit in Oracle Clinical One Platform but hasn't shipped yet, you can remove the Ship Date, and the status changes back to **Pending**.

3. Add a ship date:

- a. Under the **Ship Date** column for the pending shipment, click **Click to Add**.
- b. Select the correct date from the calendar drop-down.

The status of the shipment changes from **Pending** to **In Transit**.

4. Specify tracking information:
 - a. If you just added a ship date to the shipment, above the table and to the right, select **In Transit** from the status drop-down.
 - b. In the Tracking Number column, click **Click to add** for 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.

5. Fill in the fields and click **Save**.

Fulfill a shipment

You receive a notification when you need to fulfill a shipment. The notification contains the Shipment ID.

Before fulfilling a shipment, you must determine its contents. To determine the contents of a shipment, do one of the following:

- Review the email message that is sent with the contents of the shipment. This option doesn't require you to sign in to Oracle Clinical One Platform.
 - Sign in to Oracle Clinical One Platform to see the contents.
1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
 2. On the Shipments tab, find the shipment using the filters, which are above the table of shipments and to the right.
 - If you copied the shipment ID from the notification, paste it into the **Search by Shipment ID** field, and press **Enter**.
 - If you don't have the shipment ID or want to see all shipments that need to be fulfilled, select **Pending** from the **Filter by Status** drop-down.
 3. In the table, select the shipment.
 4. On the right, view the contents of the shipment.

 **Tip:**

You can also [add and remove kits in the shipment](#).

5. Fulfill the shipment outside Oracle Clinical One Platform.
6. After the shipment leaves the depot, you must specify a ship date for it. For step-by-step instructions, see [Specify a ship date and tracking number for a shipment](#).

Cancel a shipment

In any study, you can cancel a manual or automatically-generated shipment as long as its status is **Pending**, **Invalid**, **Confirmed**, **In Transit**, or **Pending Destruction**. You typically cancel a shipment to control costs and avoid the waste of the investigational product.

If the study uses an integration with Almac or Catalent Clinical Supply Services for shipments, you must cancel any shipment with a status of **Invalid**. If you don't cancel an invalid shipment, a new shipment won't be created the next time inventory runs.

Tip:

You can cancel multiple shipments if they have the same status and if you select the same new status for all the kits.

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



1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. Select a shipment with a status of **Pending**, **Invalid**, **Confirmed**, **In Transit**, or **Pending Destruction**.
3. From the **Edit Shipment** drop-down, select **Cancel Shipment**.
4. Select the new status of the kits in the shipment and click **Confirm**.

Note:

For example, if you canceled your shipment because it had a temperature excursion, you should choose **Pre-quarantined**. However, if you canceled the shipment because the site did not need the inventory, you should choose **Available**.

Check for an invalid shipment

You must perform this task if your study uses an integration with Almac or Catalent Clinical Supply Services.

- **For Almac Global Depot Network:** The status of a shipment changes to **Invalid** when an issue occurs with the shipment request. You must cancel an invalid shipment so that a new shipment can be created the next time inventory runs.
 - **For Catalent Clinical Supply Services:** The status of a shipment changes to **Invalid** when Catalent Clinical Supply Services cancels the shipment request. You must cancel an invalid shipment so that a new shipment can be created the next time inventory runs.
1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)

2. Locate the shipment in the table.
 - If you know the shipment ID, enter it in the **Search by Shipment ID** field, above the table and to the right, and press **Enter**.
 - If you don't know the shipment ID, find the shipment using the Site and Created Date columns.
3. Check the status of the shipment in the Status column:
 - If the status is **Confirmed**, your depot received the shipment request successfully, and you can fulfill the shipment.
 - If the status is **Invalid**, an issue occurred, such as a system outage, and the depot was unable to process the shipment request. Either you or someone from the sponsor should cancel the shipment and allow the resupply process to create a new shipment.

Related Topics

- [Fulfill a shipment](#)
You receive a notification when you need to fulfill a shipment. The notification contains the Shipment ID.
- [Cancel a shipment](#)
In any study, you can cancel a manual or automatically-generated shipment as long as its status is **Pending**, **Invalid**, **Confirmed**, **In Transit**, or **Pending Destruction**. You typically cancel a shipment to control costs and avoid the waste of the investigational product.

Update the contents of a shipment

Update the contents of a shipment when the kits in the box don't match the contents in Oracle Clinical One Platform.



Note:

You cannot add or remove kits from a shipment containing pooled kits (also known as a pooled shipment).

Before you perform this task, consider the following:

- The kits Oracle Clinical One Platform selects for a shipment meet the following requirements (all defined on the Supplies Settings page by a clinical supply manager):
 - Have the lowest sequence number.
 - Have the earliest expiration date.
 - Meet the Do Not Ship (DNS) Days requirement. The DNS value is the number of days before the expiration date when a kit can no longer be shipped from a depot to a site.
- If your study uses an integration with Almac, Fisher Clinical Services, or Catalent Clinical Supply Services, do not perform these steps. If you need to adjust the shipment, cancel the shipment, and either allow the resupply process to create a new shipment the next time inventory runs or create a manual shipment.

1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. Select a shipment with a status of **Pending**.

 **Tip:**

If a shipment has a status of **In Transit** but hasn't shipped yet, you can remove the shipping date, and the status changes back to **Pending**.

3. To add kits:
 - a. On the right, below Shipment Details, click **Add Kits**.
 - b. Under Available Kits, select the kits you want to add to the shipment.
 - c. Use the arrow icon to move the selected kits to **Add to the Shipment** section, and click **Add**.
4. To remove kits:
 - a. On the right, below Shipment Details, select the kits you want to remove from the shipment, and click **Remove Kits**.
 - b. Select **Yes** to confirm the kits you want to remove from the shipment.

 **Tip:**

If the study doesn't allow shipments with a single kit and you need to remove all but one kit, add replacement kits first, and then remove the other kits. Oracle Clinical One Platform prevents you from removing kits and leaving only a single kit.

5. Upon adding or removing kits from a shipment, a Confirmation dialog appears asking you if you choose to update the form or not.
 - If you do not wish to update the form, click **Don't Update Form**.
 - If you want to update the form, click **Update Form**.

Related Topics

- [Cancel a shipment](#)
In any study, you can cancel a manual or automatically-generated shipment as long as its status is **Pending**, **Invalid**, **Confirmed**, **In Transit**, or **Pending Destruction**. You typically cancel a shipment to control costs and avoid the waste of the investigational product.
- [Create a manual shipment](#)
You might need to create a manual shipment if a shipment was damaged at the depot before it was shipped or if another depot requires more supplies sent to their facility.

Mark a shipment as lost

During the course of a study, you may have to mark a shipment as lost in the application.

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

 Video

1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. Select one or more shipments with statuses of **In Transit** or **Confirmed**.
3. From the **Edit Shipment** drop-down, select **Mark Shipment Lost**, and click **Confirm**.
All kits in the shipment are marked as **Missing**.

3

Manage kits

- [Mark a kit for destruction](#)
If another depot must destroy kits in a study, as part of the kit reconciliation process, you must update a kit's status to **Pending Destruction** so the kit can be placed in a depot shipment for destruction.
- [Receive and destroy kits](#)
If depot kit reconciliation is required in your study and the depot you're assigned to is drug destruction capable, then you might receive shipments containing kits that need to be destroyed.
- [Mark a kit as missing or damaged](#)
When a kit is missing or it is damaged at a site, you must update its status in the study's inventory. This is part of a study's kit reconciliation process.
- [Mark kits that had a temperature excursion](#)
During the course of a study, you may have to mark kits that had a temperature excursion either at the depot or at a site that you support.

Mark a kit for destruction

If another depot must destroy kits in a study, as part of the kit reconciliation process, you must update a kit's status to **Pending Destruction** so the kit can be placed in a depot shipment for destruction.

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Click a kit type.
3. Above the kit list, use the filter to find the kits to update:
 - a. If you work at multiple depots, below Location, click **Depots**, and select your current location from the **All Depots** drop-down.
 - b. Above the kit list, from the **Status** drop-down, select the status the kit had before it went missing or was damaged.
 - c. To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.
 - d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
4. In the list, select the kits to update.
5. On the right, make sure **Kit Settings** is expanded.
6. Below Kit Settings, from the **Status** drop-down, select **Pending Destruction**.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.
9. Above the kit list, use the filters to check your work:

- a. In the upper right, click **Clear Filters**.
- b. If you work at multiple depots, below Location, click **Depots**, and select your current location from the **All Depots** drop-down.
- c. Above the kit list, from the **Status** drop-down, select **Pending Destruction**.
- d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Next, you must add the kits that are pending destruction in a shipment for destruction. For step-by-step instructions, see [Create a shipment for destruction](#).

Receive and destroy kits

If depot kit reconciliation is required in your study and the depot you're assigned to is drug destruction capable, then you might receive shipments containing kits that need to be destroyed.

You may receive kits for destruction if a site user or Clinical Research Associate (CRA) ships kits to your drug destruction depot or if a depot user sent a shipment for destruction to your facility. In both situations, you must confirm that you've received those kits for destruction and destroy the shipment at your depot.

1. Navigate to the Shipments tab. For step-by-step instructions, see [Access the Shipments tab](#)
2. Use the filters above the table of shipments to find the shipment you want to work with:
 - If you copied the shipment ID from the notification, paste it into the **Search by Shipment ID** field, and press **Enter**.
 - If you don't have the shipment ID or want to see all shipments that need to be destroyed, select **Pending Destruction** from the **Filter by Status** drop-down.
3. In the table, select the shipment.
4. On the right, click **Confirm Receipt Per Kit**.

Note:

If depot kit reconciliation isn't required in your study, you'll only see the **Mark Shipment as Received** button to confirm you've received an entire shipment.

5. On the Confirm Receipt Per Kit dialog, either scan or manually enter a kit number or barcode for a kit that you found in the shipment and can be marked as **Received**.
6. Click **Confirm**.

Tip:

You can also click the gray checkbox () for every kit displayed in the **Not Received** column to confirm you received it.

7. On the right, select a number for the returned units that need to be destroyed.
8. After you mark all kits as received, click **Finish**.
9. On the right, click **Mark Shipment as Destroyed**.
The shipment's status is updated to **Destroyed**.

Figure 3-1 How depot users see the new Confirm Receipt Per Kit pop-up

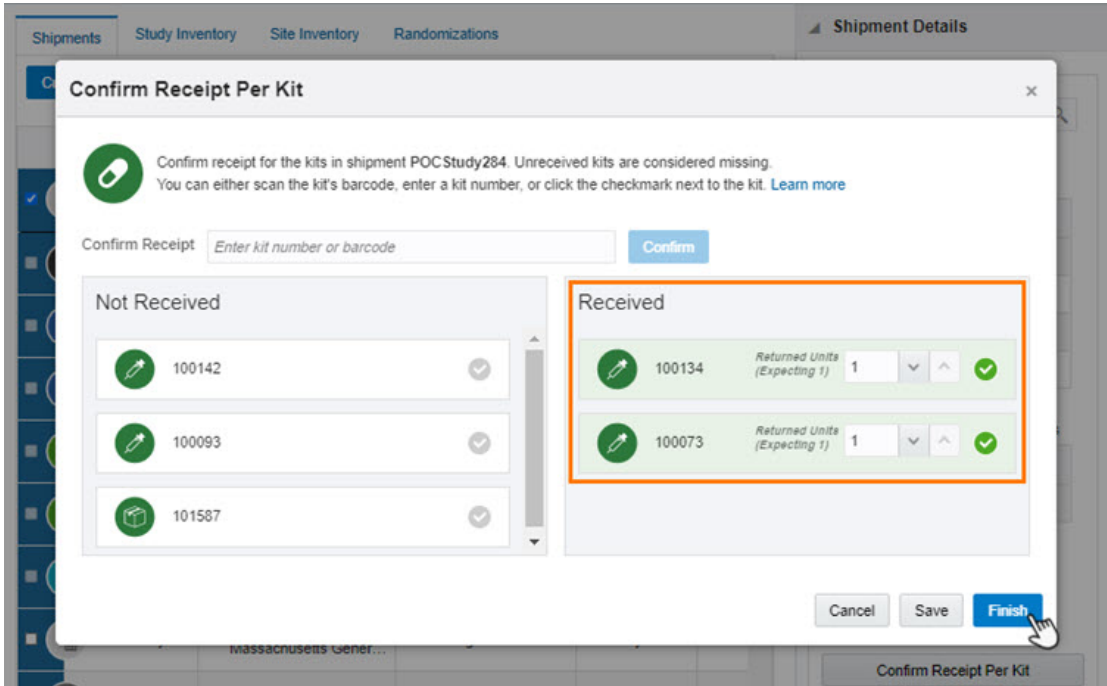
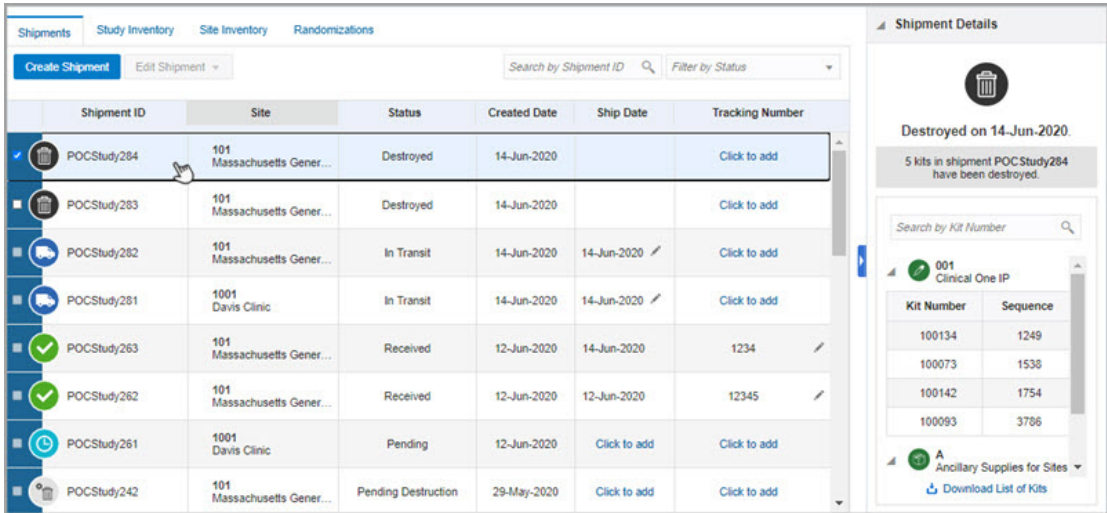


Figure 3-2 How depot users see a destroyed shipment



Related Topics

- About depot-to-depot shipments
- What is the workflow for destroying shipments at a depot facility?
- Kit status and icon meanings
- [Create a shipment for destruction](#)
You must create a shipment for destruction when there are kits pending destruction in the study inventory and another depot is supposed to receive and destroy those kits.
- [Mark a kit for destruction](#)
If another depot must destroy kits in a study, as part of the kit reconciliation process, you must update a kit's status to **Pending Destruction** so the kit can be placed in a depot shipment for destruction.

Mark a kit as missing or damaged

When a kit is missing or it is damaged at a site, you must update its status in the study's inventory. This is part of a study's kit reconciliation process.



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.

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



1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Click a kit type.
3. Above the kit list, use the filter to find the kits to update:
 - a. If you work at multiple depots, below Location, click **Depots**, and select your current location from the **All Depots** drop-down.
 - b. Above the kit list, from the **Status** drop-down, select the status the kit had before it went missing or was damaged.
 - c. To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.
 - d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.
4. In the list, select the kits to update.
5. On the right, make sure **Kit Settings** is expanded.
6. Below Kit Settings, from the **Status** drop-down, select **Missing** or **Damaged**.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.

9. Above the kit list, use the filters to check your work:
 - a. In the upper right, click **Clear Filters**.
 - b. If you work at multiple depots, below Location, click **Depots**, and select your current location from the **All Depots** drop-down.
 - c. Above the kit list, from the **Status** drop-down, select **Missing** or **Damaged**.
 - d. If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Mark kits that had a temperature excursion

During the course of a study, you may have to mark kits that had a temperature excursion either at the depot or at a site that you support.

Note:

If you are not responsible for testing kits after a temperature excursion, you don't have to perform this task. Instead, contact the clinical supply manager about testing kits that had a temperature excursion.

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



Identify kits that had a temperature excursion

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Click the type of kit that experienced a temperature excursion.
3. Above the kit list, use the filters to return only the kits you want to mark for testing:
 - a. If you work at multiple depots, below Location, click **Depots**, and select your current location from the **All Depots** drop-down.
 - b. Above the kit list, from the **Status** drop-down, select **Available**.
 - c. To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.
 - d. Above the kit list, select **Sequence** and narrow the range to the correct sequence numbers.
4. In the list, select the kits you want to mark for testing.
5. On the right, make sure **Kit Settings** is expanded.
6. Under Kit Settings, from the **Status** drop-down, select **Pre-quarantined**.
7. Click **Update Kits**.
8. In the confirmation window, select a reason for change and click **Yes**.

 **Tip:**

Pre-quarantined kits can't be included in shipments. Only available kits whose expiration dates meet the shipping requirements can be included.

9. Repeat these steps for each kit type with a kit that had a temperature excursion.

Task 2. Update the status of kits after testing them

1. Navigate to the Study Inventory tab. For step-by-step instructions, see [Access the Study Inventory tab](#).
2. Click the kit type of the kit that had a temperature excursion.
3. Above the kit list, use the filters to return only the kits you want to update:
 - a. From the **Status** drop-down at the top of the page, select **Pre-quarantined**.
 - b. If necessary, narrow the kits further by selecting **Sites** or **Depots**, under Location, and selecting the location of the kits from the **All Sites** or **All Depots** drop-down.
4. Update the kits that failed testing or were damaged in the process:
 - a. Select the kits that failed testing or were damaged in the process.
 - b. On the right, make sure **Kit Settings** is expanded.
 - c. From the **Status** drop-down, select **Quarantined**.

 **Tip:**

Quarantined is the end of life for a kit. Quarantined kits are not counted in a site's inventory.

- d. Click **Update Kits**.
 - e. In the confirmation window, select a reason for change and click **Yes**.
5. Update the kits that passed testing and can be dispensed:
 - a. Make sure that your filters are still set to only show kits with a status of **Pre-quarantined**.
 - b. In the list, select the kits that passed testing.
 - c. On the right, make sure **Kit Settings** is expanded.
 - d. Below Kit Settings, from the **Status** drop-down, select **Available**.
 - e. Click **Update Kits**.
 - f. In the confirmation window, select a reason for change and click **Yes**.

4



Manage a blinded depot's inventory

- [Access the Depot Inventory tab](#)
As a blinded depot user or a clinical supply manager, you may have to fulfill some inventory tasks while protecting the study blind. If managing blinded kits at assigned depots is part of your responsibility, then you may need to work on the Depot Inventory tab:
- [Search and filter kits on the depot inventory tab](#)
Inventory filters are located at the top of the page. You can use filters individually or they can be combined.
- [Update the status of a kit for a blinded depot user](#)
If you are a blinded depot user or clinical supply manager, now you can update the status of a kit in the Depot Inventory tab at an assigned location.

Access the Depot Inventory tab

As a blinded depot user or a clinical supply manager, you may have to fulfill some inventory tasks while protecting the study blind. If managing blinded kits at assigned depots is part of your responsibility, then you may need to work on the Depot Inventory tab:

To view or manage kits sent to and from a specific depot in the Depot Inventory tab, you must be assigned either the *Blinded Depot User* permission or the **Blinded Depot User** study role.

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 Testing mode, click the **Testing Mode** button () on the study.
 - To work with mock data in Training mode, click the **Training Mode** button () on the study.
2. Along the top of the page, click **Supplies**.
3. Below the study name, click the **Depot Inventory** tab.

The tab displays the following columns:

Option	Description
Field	Description
Kit Number	This column indicates a unique number assigned to the individual kits (serialized kit distribution).
Sequence Number	This column indicates the exact sequence number of each kit.
Block Number	This column indicates the exact block number to which a kit belongs.

Option

Kit Description

Description

This column indicates a kit type's description as entered in the system by a study designer.

 **Note:**

Blinded Depot Users will see this field as **Blinded** to protect the study.

Status

This column indicates the states of the kit during the reconciliation process went through as selected by the user:

- *Available*
- *Damaged*
- *Damaged by Subject*
- *Destroyed*
- *Dispensed*
- *Expired*
- *In Transit*
- *Lost by the Subject*
- *Misallocated*
- *Missing*
- *New*
- *Not Dispensed to Subject*
- *Not in Use*
- *Pending Destruction*
- *Pre-Quarantined*
- *Quarantined*
- *Received for Destruction*
- *Returned to Site*
- *Temporary Unavailable*

For the full description of all statuses a kit undergoes, see Kit status descriptions.

Expiration Date

This column indicates the UTC time and date when the kits in the manufacturing lot expire.

Units per Kit

This column indicates the number of individual consumable units in a kit such as pill count or mg.

Related Topics

- Filter and search the depot inventory tab
- Update the status of a kit for a blinded depot user
- Kit status descriptions
- Manage kits

Search and filter kits on the depot inventory tab

Inventory filters are located at the top of the page. You can use filters individually or they can be combined.

To view or manage kits sent to and from a specific depot in the Depot Inventory tab, you must be assigned either the *Blinded Depot User* permission or the **Blinded Depot User** study role.



1. Access the Depot Inventory tab
2. In the upper-right corner of the page, select the depot from the **Depot** drop-down.
3. Determine how you want to search for kits:
 - Select **Kit** and then type the kit number in the **Search Bar**, and press **Enter**.
 - Select **Sequence number** and then type the **Sequence number** in the **Search Bar**, and press **Enter**.
4. Determine which filters you want to use to view your depot's supply:

Option	Description
Status	Select one kit status to view kits with that specific status from the drop-down. Or select All to view all kits in the inventory no matter their status.
Lot	Filter by the Blinded Lot or select Unassigned .
Shipment ID	Enter a specific ID to narrow the list of sequence numbers that you want to view. Or click All to view all shipped kits in the inventory
Quarantine ID	Enter a specific ID to narrow the list of quarantine numbers that you want to view. Or click All to view all quarantined kits in the inventory
Kit number	Enter a number in the fields From and To to narrow the search range.
Sequence number	Enter a number in the fields From and To to narrow the search range.

5. Click **Clear Filters** to clear all of your filters.

Related Topics

- Update the status of a kit for a blinded depot user

Update the status of a kit for a blinded depot user

If you are a blinded depot user or clinical supply manager, now you can update the status of a kit in the Depot Inventory tab at an assigned location.

To view or manage kits sent to and from a specific depot in the Depot Inventory tab, you must be assigned either the *Blinded Depot User* permission or the **Blinded Depot User** study role.



Tip:

To view other details of the kit, such as the history of a kit's status or the barcode select the kit on the Depot Inventory tab and expand **Kit History** or the **Barcode** drop-down, on the right ribbon.

1. Access the Depot Inventory tab.
2. In the upper-right corner of the page, select the depot from the **Depot** drop-down.
3. Filter the Depot Inventory tab.
4. Select the kit from the list.
5. On the **Kit Settings** side panel, select the appropriate status, and click **Update Kits**. See Kit status descriptions.
 - If a kit is ready to be dispensed to subjects at a site, or ready to be shipped from a depot, mark it as **Available**.
 - If a kit went missing or was physically deteriorated at a site or depot, mark it the kit as **Missing** or **Damaged**.
 - If a kit was uploaded in error or you want to prevent a kit from being dispensed or shipped, mark it as **Not in Use**. You can also use this status for when a kit needs to be moved from one depot to another.
 - If a kit is ready to be destroyed, mark it as **Pending Destruction**. Typically, the Clinical Research Associate (CRA) verifies the kit and then marks as such. Contact your CRA for verification purposes.
 - If a kit experienced a temperature excursion and needs to be tested first, mark it as **Pre-quarantined**. If a kit experiences a temperature excursion outside of the shipment receipt process, mark it as **Quarantined**.

Note:

Pre-quarantined kits are counted in a depot's inventory, but quarantined kits aren't.

- If a kit is temporarily on hold and can't be dispensed or shipped, mark it as **Temporary Unavailable**.
6. In the Confirmation dialog, select a reason for this change from the drop-down, and click **Yes**.

- **Data entry error**
- **Expiration Update**
- **Release New Kits into Production**
- **Other** and write a custom reason in the text box.

7. Click **Yes**.

A **Kit Updated** confirmation message appears under the **Status** drop-down.

5

Run reports and view notifications

- [Run and download a report](#)
As a depot user, you typically run reports that offer you information on the supply chain or the study's inventory.
- [Receive notifications](#)
Depot users can receive a variety of notifications with the correctly assigned permissions.

Run and download a report

As a depot user, you typically run reports that offer you information on the supply chain or the study's inventory.

For step-by-step instructions on how to run and download a report, see the Reporting Guide.

Receive notifications

Depot 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.

6

What if...

- [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.
- [What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?](#)
Follow these steps to render multi-byte characters, including Chinese characters, in Microsoft Excel.

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.

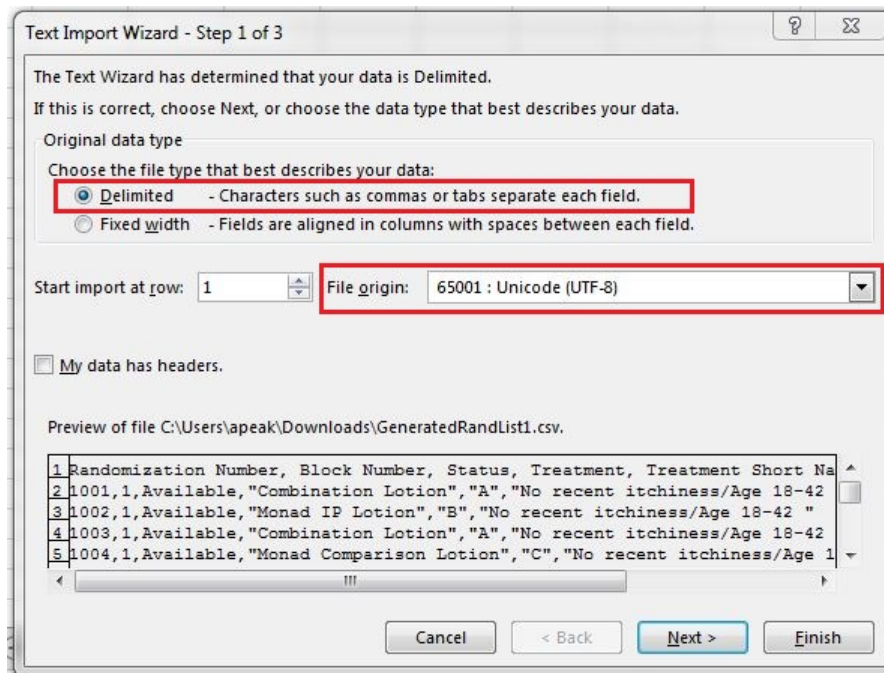
Your session will time out after 20 minutes of inactivity. However, an overall active session lasts 3 hours before it times out anyway. If this happens, close your browser, and sign in again.

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.

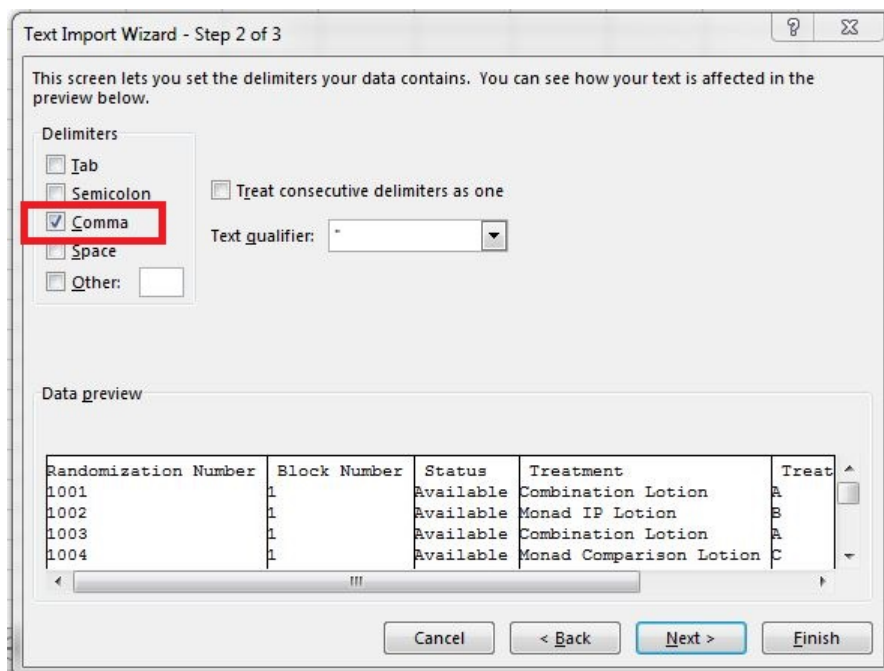
What if Chinese characters don't display correctly when I open a CSV report in Microsoft Excel?

Follow these steps to render multi-byte characters, including Chinese characters, in Microsoft Excel.

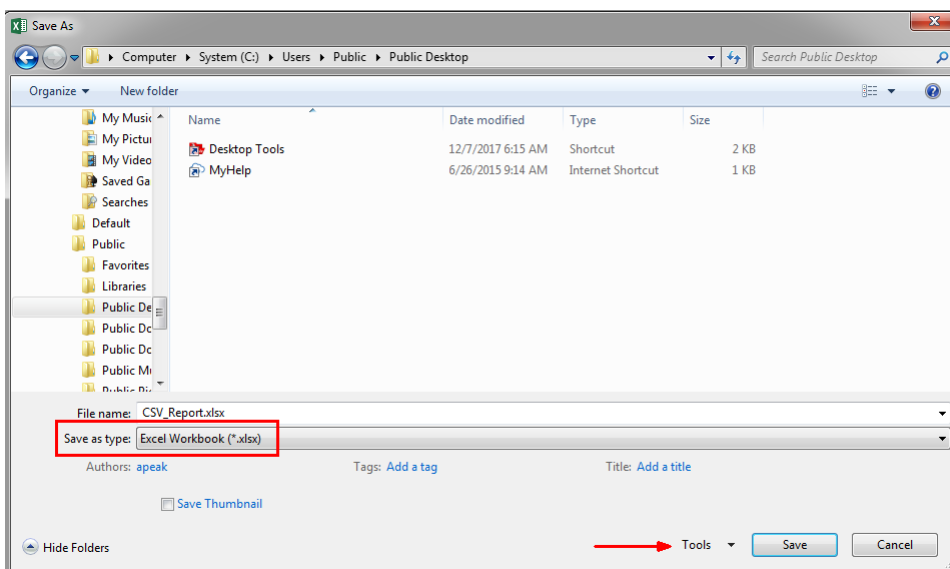
1. Open Microsoft Excel.
2. On the **Data** tab, in the Get External Data section on the left, click **From Text**.
3. Navigate to the saved report file, select it, and click **Import**.
4. In the Text Import Wizard dialog box, select the **Delimited** file type, and then from the **File origin** drop-down, select **65001: Unicode (UTF-8)**.



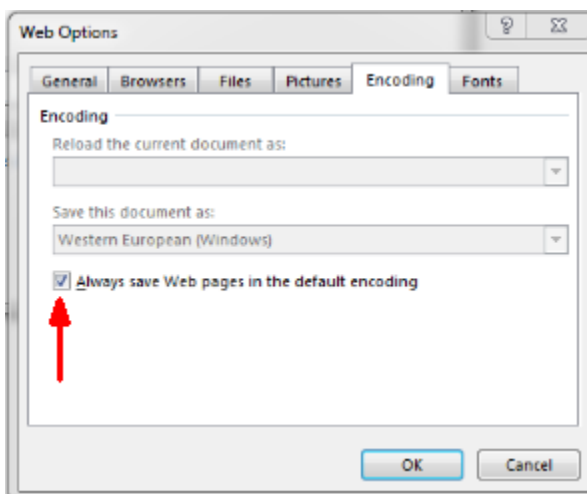
5. Click **Next**.
6. In the Delimiters section, select **Comma**.



7. Click **Finish**.
The Import Data dialog box appears.
8. Click **New Worksheet**, and then click **OK**.
9. On the **File** tab, click **Save As**, and select a location for your file.
10. Enter a name for the report in **File name**, and from the **Save as type** drop-down, choose **Excel Workbook (*.xlsx)**.



11. From the **Tools** drop-down, select **Web Options**.
12. Along the top, select the **Encoding** tab, and from the **Save this document as** drop-down, select **Unicode (UTF-8)**.
13. Select **Always save Web pages in the default encoding** button, and then click **OK** and then **Save**.



7

Frequently asked questions (FAQs)

- [How do I get training in Oracle Clinical One Platform?](#)
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 find out when a shipment is needed?](#)
Each time a shipment is requested, you receive a specific notification (both in the application and over email).
- [What keyboard shortcuts can I use?](#)
Oracle Clinical One Platform supports the following keyboard shortcuts provided by Oracle JET.
- [What should I do if a kit is missing from a shipment that needs to be destroyed?](#)
If a kit is missing and you can't receive it for destruction, the system will automatically mark it as **Missing**.

How do I get training in Oracle Clinical One Platform?

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.

How do I find out when a shipment is needed?

Each time a shipment is requested, you receive a specific notification (both in the application and over email).

- **New Shipment Request notification**

This notification is sent over email and also appears when you click Notifications on the Home page.

The notification includes the site but not the contents of the shipment.

- **Contents of New Shipment email**
This email message is sent to the email address specified for the depot and includes the contents of the shipment.

What keyboard shortcuts can I use?

Oracle Clinical One Platform supports the following keyboard shortcuts provided by Oracle JET.

Table 7-1 Keyboard shortcuts

Action	Key
Move focus from outside a table to the first column header, or from the first column header to the next focusable element outside a table.	Tab
Move focus from an actionable row in a table to the next focusable element within the row, or from the last focusable element within a row to the first focusable element in the row.	Tab
Move focus from the first row in a table to the first column header, or from a row in a table to the previous focusable element outside of the table.	Shift + Tab
Move focus from an actionable row in a table to the previous focusable element within the row, or from the first focusable element in a row to the last focusable element in the row.	Shift + Tab
Move focus to the next row in a table.	Down Arrow
Select the row and move focus to the next row in a table.	Shift + Down Arrow
Move focus from a row to the previous row in a table, or from the first row to the column header.	Up Arrow
Select the row and move focus to the previous row in a table.	Shift + Up Arrow
Move focus to the first row in a table.	Home
Move focus to the last row in a table.	End
Select a row in a table.	Space

What should I do if a kit is missing from a shipment that needs to be destroyed?

If a kit is missing and you can't receive it for destruction, the system will automatically mark it as **Missing**.

The site user typically receives a notification letting them know that one or several kits are missing from a shipment that needs to be destroyed at a depot facility. Their next

step is to work with a site user to find those kits, update their status accordingly in the study's inventory, and a site user or Clinical Research Associate (CRA) will ship those kits to you again, so you can destroy them.

For more details on how to mark a kit as received and destroy a shipment, see [Receive and destroy kits](#).

8

Revision history

Date	Part number	Description
May 2024	F91492-01	Original version of the document.