# Oracle® Life Sciences Clinical One Platform

**Notifications and Permissions Guide** 





Oracle Life Sciences Clinical One Platform Notifications and Permissions Guide, Release 25.1.1

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# **Preface**

This preface contains the following sections:

- Documentation accessibility
- · Diversity and Inclusion
- · Related resources
- Access to Oracle Support
- Additional copyright information

# Documentation accessibility

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.

# **Diversity and Inclusion**

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.

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

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.



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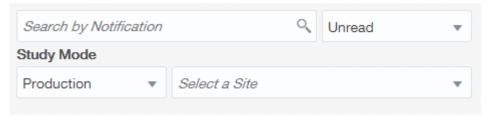
1

# View notifications

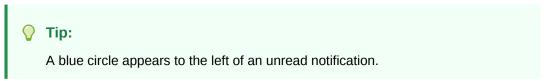
The notifications that you receive depend on your role during each mode of the study. If you're not getting the notifications that you expect, contact your system administrator. Notifications are also sent to your email.

#### Show me how!

- 1. On the Home page, click the notification button  $(\stackrel{\triangleright}{\sim})$  on a study.
- In the upper right, from the Study Mode drop-down, select the mode that you want to view notifications for.
- **3.** Filter your view as needed:
  - To view notifications about specific sites, choose a site from the Select a Site dropdown.
    - If the Select a Site drop-down is disabled, remove the search terms from the Search by Notification field.
  - To find notifications by name, enter the notification name in the Search by Notification field.
    - If the Search by Notification field is disabled, remove any filters for sites.
  - To sort notifications, select an option from the drop-down to the right of the Search by Notification field.



4. Click a notification to view its details. For descriptions of the notifications and details about who receives them, see Notifications.



# **Permissions**

- Permissions for report notifications
   View the descriptions and required permissions for report notifications.
- Permissions for rule notifications
   View the descriptions and required permissions for rule notifications.
- Permissions for subject notifications
   View the descriptions and required permissions for subject notifications.
- Permissions for supply notifications
   View the descriptions and required permissions for supply notifications.
- Permissions for user management notifications
   View the descriptions and required permissions for user upload notifications

# Permissions for report notifications

View the descriptions and required permissions for report notifications.

Notification	Permission required	Notes
Report failed to generate notification	None.	There are report specific permissions that allow you to run a given report. Any user that tries to generate a specific report can receive this notification if it fails.
Report is ready notification	None.	There are report specific permissions that allow you to run a given report. Any user that generates a specific report receives this notification when ready.
Scheduled report notifications	Schedule Reports to Run	This permission is for Sponsor users and should only be granted to one Sponsor level user.

# Permissions for rule notifications

View the descriptions and required permissions for rule notifications.

Notification	Permission required	Notes
Rule Re-run notification	Re-run Rules	This permission is for sponsor users only.
Rules Validation Complete notification	Design Custom Rules	This permission is for sponsor users only.
Rule Lock notification	Receive Rule Failure Notification for Locked Data	This permission is for sponsor users only.

# Permissions for subject notifications

View the descriptions and required permissions for subject notifications.

Notification	Permission required	Notes
Code Break notification	Receive the Code Break Notification	This permission is for both sponsor and site users.
First subject screened in study notification	Study Limits Notifications	This permission is for both sponsor and site users.
<ul> <li>First subject screened at site notification</li> </ul>		
<ul> <li>First subject randomized in study notification</li> </ul>		
First subject randomized at site notification		
Screening update notification	Receive the Subject Screening Notification	This permission is for both sponsor and site users.
Signature requests notification	Receive the Pending Signatures Notification	This permission is for both sponsor and site users.
Subject completion notification	Receive the Subject Completion Notification	This is a permission for sponsor users.
Subject undo completion notification	Receive the Subject Undo Completion Notification	This is a permission for both sponsor and site users.
Subject dispensation notification (with failures)	<ul> <li>Receive the Unblinded Dispensation Notification</li> </ul>	These permissions are for both sponsor and site users.
	Receive the Dispensation     Notification	These permissions can unblind users. Use with caution.
	<ul> <li>Receive the Dispensation with Dosing Instructions Notification</li> </ul>	
Subject Number Update notification	Receive the Subject Number Update Notification	This permission is for both sponsor and site users.
Subject randomization notification (with failures)	Receive the Randomization     Notification	These permissions are for both sponsor and site users.
	<ul> <li>Receive the Unblinded Randomization Notification</li> </ul>	These permissions can unblind users. Use with caution.
Subject rollover notification	Receive the Subject Rollover Notification	This is a permission for sponsor users.
Subject screening notification (with error)	Receive the Subject Screening Notification	This permission is for both sponsor and site users.
Subject undo screen failure notification	Receive the Subject Undo Screen Failure Notification	This is a permission for both sponsor and site users.
Subject transferred notification	Receive the Subject Transferred Notification	This permission is for both sponsor and site users.
Subject unscheduled visit notification	Receive the Unscheduled Visit Notification	This is a permission for sponsor users.
Subject visit notification (with failures)	Receive the Subject Visit Notification	This is a permission for sponsor users.
Subject withdrawal notification	Receive the Subject Visit Notification	This is a permission for sponsor users.



Notification	Permission required	Notes
Subject undo withdrawal notification	Receive the Subject Undo Withdrawal Notification	This is a permission for both sponsor and site users.
Training complete notification	None.	Any role that is assigned training will receive this notification.
Unblinded Pharmacist dispensation notification	Receive the Unblinded Pharamcist Dispensation	This permission is for both sponsor and site users.
	Notification	This permission can unblind users. Use with caution.

# Permissions for supply notifications

View the descriptions and required permissions for supply notifications.

Notification	Permission required	Notes
Depot shipment notification	Receive Notification of Depot Shipments	This permission is for both sponsor and site users.
		This permission can unblind users. Use with caution.
Low kit depot (Unblinded) notification	Receive Notification of Depot Shipments	This permission is for both sponsor and site users.
		This permission can unblind users. Use with caution.
Kit List Deactivated notification (with failures)	Upload and Generate Inventory Lists	This permission is for both sponsor and site users.
Kit missing from shipment for destruction notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
Kit status changed to "Misallocated" notification	Receive the Unblinded Kit Misallocation Notification	This permission is for both sponsor and site users.
		This permission can unblind users. Use with caution.
Kit status changed to "Not Dispensed to Subject" notification	Receive the Not Dispensed to Subject Notification	These permissions are for both sponsor and site users.
	<ul> <li>Receive the Not Dispensed to Subject (Unblinded) Notification</li> </ul>	These permissions can unblind users. Use with caution.
	Receive the Not Dispensed to Subject (Unblinded Pharmacist) Notification	
Kits Quarantined notification	Receive the Quarantined     Depot Shipment Notification	These permissions are for both sponsor and site users.
	<ul> <li>Receive the Quarantined Site Shipment Notification</li> </ul>	These permissions can unblind users. Use with caution.
Kits Released from Quarantine notification	Receive the Released from Quarantine Notification	These permissions are for both sponsor and site users.
	<ul> <li>(Depot)</li> <li>Receive the Released from Quarantine Notification (Site)</li> </ul>	These permissions can unblind users. Use with caution.
Pending shipment notification	Receive Notification of Shipments	This permission is for both sponsor and site users.



Notification	Permission required	Notes
Randomization update notification	Receive the Randomization Notification	This permission is for both sponsor and site users.
Shipment cancellation notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
Shipment failure notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
Shipment for destruction created notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
Shipment for destruction not received notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
Shipment Quarantined notification	<ul> <li>Receive the Quarantined         Depot Shipment Notification</li> <li>Receive the Quarantined         Site Shipment Notification</li> </ul>	These permissions are for both sponsor and site users.
Shipment Released from Quarantine notification	<ul> <li>Receive the Released from Quarantine Shipment Notification (Depot)</li> <li>Receive the Released from Quarantine Notification (Site)</li> </ul>	These permissions are for both sponsor and site users.
Shipment request notification	Receive Notification of Shipments	This permission is for both sponsor and site users.
State of a site has changed notification	Receive Site has been Updated Notification	This permission is for both sponsor and site users.
Study inventory notification	Receive the Quarantined Depot Shipment Notification	This permission is for both sponsor and site users.
		This permission can unblind users. Use with caution.
Unblinded dose hold performed notification	Receive the Unblinded Dose Hold Notification	sponsor and site users.
		This permission can unblind users. Use with caution.

# Permissions for user management notifications

View the descriptions and required permissions for user upload notifications

Notification	Permission required	Notes
Bulk User Upload notifications	Upload Users in Bulk	This permission is for Sponsor users in Design mode only.



# **Notifications**

- Oracle Clinical One Platform notifications
- Oracle CRF Submit notifications

# Oracle Clinical One Platform notifications

- · Institution, vendor, and contact notifications
- Report notifications
- · Rule notifications
- Subject notifications
- Supply notifications
- User management notifications

# Institution, vendor, and contact notifications

- Contact status has been updated notification
   This notification is sent whenever the status of a contact is updated at the global level.
- Organization status has been updated notification
   This notification is sent whenever the status of an organization is updated at the global level.
- Study/Site has been transferred notification
   This notification is sent whenever a site within a study has been transferred to a new contact at the global level.
- Depot has been reassigned notification
   This notification is sent whenever a depot is reassigned to a new vendor depot at the global level.

### Contact status has been updated notification

This notification is sent whenever the status of a contact is updated at the global level.

#### Permissions required to receive the notification

To receive this notification, assign the *Receive Site has been Updated notification* permission to anyone who wants to receive this notification. Users receive notifications only for the studies that they are assigned to. Both site and sponsor users can receive this notification.

#### Field descriptions

The table below describes all fields and details in the **Contact status has been updated to <Restricted / Retired / Debarred>** notification.

Field	Description
Title	The title of the notification, for example, Contact Status has been Updated to < Retired >, followed by a message to the recipient stating, "A Contact has been updated."
Name	Indicates the full name of the contact as specified by the study manager when they created the contact.
Investigator ID	Indicates the contact's associated unique identifier as specified by the study manager when they created the contact.
Main Primary Address	Indicates the contact's full primary address as specified by the study manager when they created the contact.
Phone	Indicates the contact's phone number.
Email	Indicates the contact's email address.
Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Status	Indicates the status of the contact. For descriptions of the statuses contacts can be assigned, see Update the status of a contact.
Modified By	Indicates the user's ID who updated the contact.
Modified Date	Indicates the date when the contact was updated. For example, 10-Nov-2022.

# Organization status has been updated notification

This notification is sent whenever the status of an organization is updated at the global level.

#### Permissions required to receive the notification

To receive this notification, assign the *Receive Site has been Updated notification* permission to anyone who wants to receive this notification. Users receive notifications only for the studies that they are assigned to. Both site and sponsor users can receive this notification.

#### **Field descriptions**

The table below describes all fields and details in the **Organization status has been updated** to <Restricted > notification.

Field	Description	
Title	The title of the notification, for example, Organization Status has been Updated to < Restricted >, followed by a message to the recipient stating, "An Organization has been updated."	
Туре	Indicates the type of organization. For example, Vendor Lab.	
Name	Indicates the name of the institution, lab, or depot as specified by the study manager when they created the organization.	



Field	Description
Institution ID	Indicates the unique identifier associated with the organization as specified by the study manager when they created the organization.
Parent Institution ID	Indicates the unique identifier associated with the parent organization as specified by the study manager when they created the organization.
	If there is no parent institution assigned to the organization, this field displays as <b>N/A</b> .
Main Primary Address	Indicates the full primary address associated with the organization as specified by the study manager when they created the organization.
Phone	Indicates the phone number associated with the organization.
Email	Indicates the email address associated with the organization.
Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Status	Indicates the status of the organization. For example, <i>Restricted</i> .
Modified By	Indicates the user's ID who updated the organization.
Modified Date	Indicates the date when the organization was updated. For example, 10-Nov-2022.

# Study/Site has been transferred notification

This notification is sent whenever a site within a study has been transferred to a new contact at the global level.

#### Permissions required to receive the notification

To receive these notifications, assign the *Receive Site has been Updated notification* permission to anyone who wants to receive this notification. Users receive notifications only for the studies that they are assigned to. Both site and sponsor users can receive this notification.

#### Field descriptions

The table below describes all fields and details in the **Study/Site has been Transferred to a new Contact** notification.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The Site ID.</li> <li>The title of the notification, for example, Study/ Site has been Transferred to a new Contact.</li> </ul>
Transferred from Contact	Indicates the full name of the contact the site is being transferred from.
Transferred to Contact	Indicates the full name of the contact the site is being transferred to.



Field	Description
Transferred By	Indicates the user's ID who transferred the site.
Transferred Date	Indicates the date when the site was transferred. For example, 10-Nov-2022.

### Depot has been reassigned notification

This notification is sent whenever a depot is reassigned to a new vendor depot at the global level.

#### Permissions required to receive the notification

To receive this notification, assign the *Receive Site has been Updated notification* permission to anyone who wants to receive this notification. Users receive notifications only for the studies that they are assigned to. Both site and sponsor users can receive this notification.

#### Field descriptions

The table below describes all fields and details in the **Depot has been Reassigned to a new Vendor Depot** notification.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The Depot ID.</li> </ul>
	<ul> <li>The title of the notification, for example, Depot has been Reassigned to a new Vendor Depot.</li> </ul>
Transferred from Depot	Indicates vendor depot's full name and ID the was depot transferred from.
Transferred to Depot	Indicates the vendor depot's full name and ID the depot is being transferred to.
Transferred By	Indicates the user's ID who reassigned the depot.
Transferred Date	Indicates the date when the depot was reassigned. For example, 10-Nov-2022.

# Report notifications

- Report failed to generate notification
   This notification is sent when a report doesn't generate correctly.
- Report is ready notification
   This notification is sent when a report is ready.
- Report Space Limit Exceeded notification
   This notification informs users when a generated report exceeds the storage server limit.
- Scheduled report notifications

  These notifications are sent to users whose email address is included in the report schedule configuration.



# Report failed to generate notification

This notification is sent when a report doesn't generate correctly.

#### Permissions required to receive the notification

Any role can receive this notification without assigning it a specific permission. You receive the notification if a report you tried to run didn't generate.

#### **Field descriptions**

The table below describes all fields and details in the **Report failed to generate notification**.



This notification also contains an introductory statement indicating that your report has failed to generate in the application.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A statement about the report failing to generate.</li> </ul>
File Name	Indicates the parameters chosen for the report to run.
Study Name	Indicates a study's ID, as specified by the global study creator when they created the study.
Number of Records	Indicates the number of data records in the report.
Server Run Date	Indicates the exact date and time when the report failed to generate. For example: 10-Nov-2022 08:07 AM.
Report Run ID	Indicates the GUID of the report in the application's backend system. For example:  08B6771F54DE45A0BB576E86326BE84D.

# Report is ready notification

This notification is sent when a report is ready.

#### Permissions required to receive this notification

Any role can receive this notification without assigning it a specific permission. You receive the notification after a report that you run is ready.

#### **Field descriptions**

The table below describes all fields and details in the **Report is ready notification**.





This notification also contains an introductory statement indicating that your report is now ready in the application. For example: Subject Events Report is now ready in Clinical One. You can log on to Clinical One Portal to download the report.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A statement about the report being ready. For example: Subject Events Report is ready in Clinical One.</li> </ul>
File Name	Indicates the parameters chosen for the report to run.
Site(s) selection	Indicates where the data of the report originated. If all sites of a study have been selected, "All sites" will be displayed. Otherwise, the sites will be listed, separated by commas.
	Only appears in the Subject Data Extract notification.
Study Name	Indicates a study's ID again, as specified by the global study creator when they created the study.
Number of records	Indicates the number of data records in the generated report.
Server Run Date	Indicates the exact date and time when the report was generated. For example: 10-Nov-2022 08:07 AM.
Report Run ID	Indicates the GUID of the report generation in the application's backend system. For example: 08B6771F54DE45A0BB576E86326BE84D.
File Type	Indicates the format your report has been generated in, such as CSV, CPORT, XPORT, or SAS7BDAT.
	Only appears in the Subject Data Extract notification.

# Report Space Limit Exceeded notification

This notification informs users when a generated report exceeds the storage server limit.

Each study mode is allocated 200 GB on the report storage server. When a report exceeds the limit (in a mode), the report fails, and the person generating the report receives the notification. For scheduled reports, the person who scheduled the report gets the notification.



#### Note:

The system does not notify users if one of the following tenant-level reports exceeds the limit.

- Global Study Roles Report
- Life Sciences Learn Training Report
- Study Roles Report by Study
- User Assignment Across Studies

#### Permissions required to receive this notification

Users who generate or schedule reports receive this notification. No additional permissions need to be assigned.

#### Field descriptions

The table below describes the details included in the **Report Space Limit Exceeded** notification.

Table 3-1 Notification field descriptions

Field	Description
Study Name	Indicates a study's name, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Study ID	Indicates a study's ID, as specified by the global study creator when they created the study.
Report Name	Indicates the type of report.
Settings	Contains the customer selected report settings.
Scheduled Report	Indicates if the report was scheduled or not.
Date Requested	Indicates the date when the report was run.
Requested By	Indicates the user who ran the report.

# Scheduled report notifications

These notifications are sent to users whose email address is included in the report schedule configuration.

#### Permissions required to receive these notifications

Users included in the report schedule configuration, and who have permissions for the report being scheduled can receive the following notifications:

- Scheduled Report Failure Notification
- Scheduled Report sFTP Failure Notification
- Scheduled Report sFTP Success Notification
- Report Scheduled Created Notification
- Report Scheduled Activated Notification



#### Report Scheduled Deactivated Notification

#### **Field descriptions**

The table below describes all fields and details in the **Report failed to generate notification**.



sFTP notifications include additional information on sFTP location.

This notification also contains an introductory statement indicating that your report is now ready in the application. For example: *Scheduled report has run in Clinical One and is successfully uploaded to sFTP.* 

Field	Description
Title	The title is comprised of two distinct elements:  The study's ID. For example, a study's ID can be P01-123-A3.
	<ul> <li>The report name.</li> </ul>
	<ul> <li>The title of the notification, for example, Scheduled Report sFTP Success Notification.</li> </ul>
Study Name	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Report Name	Indicates the name of the scheduled report.
Upload Date	Indicates the date the report was uploaded.

### Rule notifications

Rule Re-run notification

This notification is sent when a rule re-run is completed.

Rules Validation Complete notification

This notification is sent once the validation of custom rules is complete, after a study has been copied and moved to testing mode, and when a form has been copied.

Rule Lock notification

This notification is sent when a rule is unable to update a target due to it being locked.

Auto-lock failure notification

This notification is sent after five unsuccessful attempts to automatically lock a form question.

### Rule Re-run notification

This notification is sent when a rule re-run is completed.

#### Permissions required to receive the notification

Assign the Re-run rules permission to anyone who wants to receive this notification.



#### Field descriptions

The table below describes all fields and details in the Rule re-run notification.



This notification includes details on rules that failed during execution when applicable.

Field	Description
Title	Indicates the title of the notification, for example, Rule re-run is completed.
Jobs group ID	The internal ID name of the job created when a rule is re-run.

# Rules Validation Complete notification

This notification is sent once the validation of custom rules is complete, after a study has been copied and moved to testing mode, and when a form has been copied.

#### Permissions required to receive this notification

Anyone who is assigned the *Design Custom Rules* permission will receive a **Rules Validation Complete notification**. Rules designers will receive this notification by default when the process of validating custom rules is finished.

#### Field descriptions

The table below describes all fields and details in the Rules validation complete notification.



This notification includes a statement suggesting to run the Rules report for more information on invalid rules below the following fields.

Field	Description
Title	The title is comprised of two distinct elements:  The study's ID. For example, a study's ID can be P01-123-A3.
	<ul> <li>The title of the notification, for example, Rules Validation Complete.</li> </ul>
Total Count of Copied Rules	Indicates the total number of copied rules.
Total Validated Rules	Indicates the total number of validated rules.
Validation Error Count	Indicates the number of rules that encountered an error during validation.
Date/Time Completed	Indicates the exact date and time of copying or rule validation. For example: 10-Nov-2022 08:07 AM.



#### Rule Lock notification

This notification is sent when a rule is unable to update a target due to it being locked.

#### Permissions required to receive the notification

Sponsor users assigned the *Receive Rule Failure Notification for Locked Data* will receive this notification.

#### **Field descriptions**

The table below describes all fields and details in the **Rule lock notification**.

Field	Description
Title	The title of the notification, for example, Rule Lock Notification.
Study Name	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Subject Number	Indicates the number of the subject.
Visit Branch	Indicates the name of the visit branch.
Visit	Indicates the name of the visit.
Form	Indicates the name of the form containing the locked target.
Form Sequence Number	Indicates the form sequence number for a repeating form.
Form Section Number	Indicates the form section number for a two-section form.
Question	Indicates the title of the question.
Date & Time of Notification	Indicates the exact date and time of the notification. For example: 10-Nov-2022 08:07 AM.

#### Auto-lock failure notification

This notification is sent after five unsuccessful attempts to automatically lock a form question.

If you receive the Auto-lock failure notification, take one of the following actions based on your study's setup:

- If your study doesn't include auto-lock predefined rules, you can ignore any Auto-lock failure notifications you receive in your inbox.
- If your study includes auto-lock predefined rules, but not for the visit and event mentioned in the Auto-lock failure notification, you can ignore the notification.
- If your study includes auto-lock predefined rules for the visit and event mentioned in the notification, you need to manually lock the relevant questions. Locate the visit that is referenced in the Auto-lock failure notification, identify which questions have the auto-lock rule configured, and lock them in your study. For step-by-step guidelines on how to manually lock data, see Lock a form or visit.





#### Tip:

Having trouble finding the question to lock? Run the Study Design report and check the **Action Rules** column. Any question with an Auto-lock rule will indicate that in this column.

#### Permissions required to receive the notification

Sponsor users with the *Lock Subject Data* permissions and assigned to the impacted sites will receive this notification.

#### Field descriptions

This notification also contains an introductory statement indicating that the rule for automatic data locking, for one or more questions, triggered by a visit has failed. It also prompts the user to lock the questions manually and contact support for assistance.

Field	Description
Title	Title of the notification, for example, Auto-Lock failed.
Study Name	Study's ID again, as specified by the global study creator when they created the study.
Study Mode	Study mode associated with this notification. Displayed values can be: Production Testing Training
Site Name	Name of the site as specified by a site manager when they created the site.
Subject Number	Number of the subject.
Visits	Name of the visit where the locking was scheduled to trigger.

# Subject notifications

#### Code Break notification

This notification is sent when a subject is unblinded due to a code break. The notification does not include unblinded data.

- First subject screened in a study notification
  - This notification is sent when the first subject is screened or enrolled in the study.
- · First subject screened at a site notification
  - This notification is sent when the first subject is screened or enrolled in a site.
- First subject randomized at a site notification
  - This notification is sent when the first subject is randomized at a site.
- First subject randomized in a study notification
  - This notification is sent when the first subject is randomized in a study.
- Screening update notification
  - This notification is sent when the screening limit or a percentage of the screening limit is reached for a study, site, or country.
- Signature requests notification
  - This notification is sent when a required signature has a target date that has been reached or become overdue for a site you are assigned to.

#### Subject completion notification

This notification is sent when a subject completes a study. This happens when the site user marks the subject as Complete and can only be done once the subject has completed all minimum required visits and all data has been entered.

#### Subject dispensation notification (with failures)

This notification is sent when a dispensation event is successfully completed or when the dispensation failed at a site you're assigned to. Additionally, this notification is sent when a dispensation event with dosing instructions is successfully completed or has failed. Details about partial dispensation are included when they occur.

#### Subject randomization notification (with failures)

This notification is sent when a subject is either successfully randomized or their randomization failed at a site that you're assigned to.

#### Subject Number Update notification

This notification is sent when a site or sponsor user has successfully updated a subject number, and contains the site number, the original subject number, and the new subject number.

#### Subject rollover notification

This notification is sent when a subject is enrolled into a rollover study.

#### Subject screening notification (with error)

This notification is sent when a subject is either successfully screened or their screening failed at a site that you're assigned to.

#### Subject transferred notification

This notification is sent when a subject transfers to another site.

#### Subject undo completion notification

This notification is sent when a subject's completion of the study is undone at a site that you're assigned to.

#### Subject undo screen failure notification

This notification is only sent when you manually undone a subject's screen failure at a site that you're assigned to. If data is updated to resolve a validation that results in the automated screen failure of a subject, no notification is sent if the subject is then successfully screened.

#### Subject undo withdrawal notification

This notification is sent when a subject's withdrawal is undone at a site that you're assigned to.

#### Subject unscheduled visit notification

This notification is sent when a subject completes an unscheduled visit.

#### Subject visit notification (with failures)

This notification is sent when a subject completes a non-dispensation or optional visit at a site that you're assigned to. The notification is sent both when the subject successfully completes the visit and when one or more questions have errors.

#### Subject withdrawal notification

This notification is sent when a subject withdraws from a study.

#### Training complete notification

This notification is sent when you complete all training assigned to you.

#### Unblinded Pharmacist dispensation notification

Pharmacists or unblinded site users receive this notification when kits need to be dispensed by them to subjects during a dispensation or randomization visit.

# Code Break notification

This notification is sent when a subject is unblinded due to a code break. The notification does not include unblinded data.

#### Permissions required to receive the notification

Assign the *Receive the Code Break Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### **Field descriptions**

The table below describes all fields and details in the Code Break notification.

Field	Descriptions
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Code Break.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who was unblinded due to a code break.
Date of Transaction (UTC)	Indicates the exact date and time of the code break. For example: 10-Nov-2022 08:07 AM.
Adverse Event	Indicates whether or not the subject experienced an adverse event.
Performed By	Indicates the username of the user who reported the code break.

# First subject screened in a study notification

This notification is sent when the first subject is screened or enrolled in the study.

#### Permissions that receive the notification

To receive these notifications, assign the *Receive the Study Limits Notifications* permission to anyone who wants to receive this notification. Users receive notifications only for the study and sites that they are assigned to. Both site users and sponsors can receive this notification.



Table 3-2 Field descriptions

Field	Description
Subject line	Indicates the summary of the alert information. The subject would include a short description of the study name and the first subject screened.
Study ID	Indicates a study's ID, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification.  Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID, as specified by the global study creator when they created the site.
Subject ID	Indicates the number of the subject who just completed the scheduled visit.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 22-Jan-2023 07:09 AM.
Performed By	Indicates the user name of the user who performed the screening of the subject.

#### **Related Topics**

Specify study, visit, limit, and cohort settings

# First subject screened at a site notification

This notification is sent when the first subject is screened or enrolled in a site.

#### Permissions that receive the notification

To receive these notifications, assign the *Receive the Study Limits Notifications* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they are assigned to. Both site and sponsor users can receive this notification.

Table 3-3 Field descriptions

Field	Description
Study Name	Indicates the summary of the alert information. The subject would include a short description of the study name and the first subject screened.
Study ID	Indicates a study's ID, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID, as specified by the global study creator when they created the site.



Table 3-3 (Cont.) Field descriptions

Field	Description
Subject ID	Indicates the number of the first subject at a site who just completed the scheduled screening visit.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 22-Jan-2023 07:09 AM.
Performed By	Indicates the user name of the user who performed the screening of the subject.

# First subject randomized at a site notification

This notification is sent when the first subject is randomized at a site.

#### Permissions that receive the notification

Assign the *Receive the study limits notifications* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they are assigned to. Both site and sponsor users can receive this notification.

Only assigning the permissions to the role wouldn't suffice. Site enrollment toggle must be enabled and study managers must activate the **First subject randomized notification** checkbox for the site enrollment row in the study settings. See how to define enrollment settings in Specify study, enrollment, and visits settings.

Table 3-4 Field description

Field	Description
Study Name	Indicates the summary of the alert information. The subject would include a short description of the study name and the first subject screened.
Study ID	Indicates a study's ID, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be <b>Test</b> , <b>Active</b> , or <b>Training</b> .
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID, as specified by the global study creator when they created the site.
Subject ID	Indicates the number of the first subject at a site who just completed the scheduled randomization visit.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 22-Jan-2023 07:09 AM.
Performed By	Indicates the user name of the user who performed the screening of the subject.



### First subject randomized in a study notification

This notification is sent when the first subject is randomized in a study.

#### Permissions that receive the notification

To receive these notifications, assign the *Receive the Study Limits Notifications* permission to anyone who wants to receive this notification. Users receive notifications only for the studies that they are assigned to. Both site and sponsor users can receive this notification.

Only assigning the permissions to the role wouldn't suffice. Site enrollment toggle must be enabled and study managers must activate the **First subject randomized notification** checkbox for the study enrollment row in the study settings. See how to define enrollment settings in Specify study, enrollment, and visits settings.

Table 3-5 Field description

Field	Description
Study Name	Indicates the summary of the alert information. The subject would include a short description of the study name and the first subject screened.
Study ID	Indicates a study's ID, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be <b>Test</b> , <b>Active</b> , or <b>Training</b> .
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID, as specified by the global study creator when they created the site.
Subject ID	Indicates the number of the subject who just completed the scheduled visit.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 22-Jan-2023 07:09 AM.
Performed By	Indicates the user name of the user who performed the screening of the subject.

### Screening update notification

This notification is sent when the screening limit or a percentage of the screening limit is reached for a study, site, or country.

#### Permissions that receive the notification

Assign the *Receive the Subject Screening Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### Field descriptions

The table below describes all fields and details in the Screening update notification.



Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Screening Notification.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Subject Number	Indicates the number of the subject who just completed the visit.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who performed the screening of the subject.
GUID	Indicates the notification's GUID.

# Signature requests notification

This notification is sent when a required signature has a target date that has been reached or become overdue for a site you are assigned to.

#### Permissions required to receive the notification

Assign the *Receive the Pending Signatures Notification* permission to any roles that should receive this notification. Users receive notifications only for the sites that they're assigned to.

#### Field descriptions

The table below describes all fields and details in the **Signature requests notification**.

Field	Description
Title	The title of the notification, for example, Signature Requests, followed by a message to the recipient stating, "One or more Signature Requests are overdue."
Study Name	Indicates the study name, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.



### Subject completion notification

This notification is sent when a subject completes a study. This happens when the site user marks the subject as Complete and can only be done once the subject has completed all minimum required visits and all data has been entered.



When a site user updates a subject's date of completion, the system efficiently avoids sending duplicate notifications, ensuring users receive only the most relevant and timely updates.

#### Permissions required to receive the notification

Assign the *Receive the Subject Completion Notification* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they're assigned to.

#### Field descriptions

The table below describes all fields and details in the Subject completion notification.

Description
<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Completion Notification.</li> </ul>
Indicates a study's ID again, as specified by the global study creator when they created the study.
Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Indicates the name of the site as specified by a site manager when they created the site.
Indicates a site's ID as specified by the site manager who created the site.
Indicates the number of the subject who just completed the study.
Indicates the exact date and time of the completion. For example: 10-Nov-2022 08:07 AM.
Indicates the username of the user who updated the subject's status.

# Subject dispensation notification (with failures)

This notification is sent when a dispensation event is successfully completed or when the dispensation failed at a site you're assigned to. Additionally, this notification is sent when a dispensation event with dosing instructions is successfully completed or has failed. Details about partial dispensation are included when they occur.





If Unblinded Pharmacist kits are assigned to a visit, this notification will also contain a notice for blinded site users to contact their pharmacist or unblinded site user to dispense those Unblinded Pharmacist kits.

#### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Unblinded Dispensation Notification: Includes a kit description for each kit number and the number of dose holds.
- Receive the Dispensation Notification: Includes the kit description only if the dispensed kits are of the Blinded distribution type. If not, this information is not included in the notification. The number of dose holds and any titration details are also included in the notification. If a titration does not have a blinded title, then these details are not present in the notification.
- Receive the Dispensation with Dosing Instructions Notification: Includes the kit description and dosing instructions, along with the number of dose holds.

#### Field descriptions

The table below describes all fields and details in the **Subject dispensation notification**.



Details on treatment arms are included in successful unblinded dispensation notifications.

Information on kits is displayed in successful dispensation notifications.

Description
<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification and whether the dispensation succeeded or not. For example, Dispensation succeeded or Dispensation failed.</li> </ul>
Indicates a study's ID again, as specified by the global study creator when they created the study.
Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Indicates a site's ID as specified by the site manager who created the site.
Indicates the number of the subject who just completed the dispensation or randomization visit.



Field	Description
Treatment Arm	Indicates the corresponding treatment arm.
Visit Name	Indicates the name of a dispensation or randomization visit.
Number of Kits	Indicates the quantity and type of kits that were dispensed, along with a description. For example, if the kits are locally sourced, and the type, such as a device.
Date of Transaction (UTC)	Indicates the exact date and time of the dispensation. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the kit dispensation.

### Subject randomization notification (with failures)

This notification is sent when a subject is either successfully randomized or their randomization failed at a site that you're assigned to.

#### Permissions required to receive the notification

Assign either or both of these permissions to anyone who needs to receive this notification:

- Receive the Unblinded Randomization Notification: Includes treatment details.
- Receive the Randomization Notification: It doesn't include treatment details. However, if
  the current randomization is unblinded, users who are assigned this blinded permission will
  also receive information on treatment arms.

#### Field descriptions

The table below describes all fields and details in both the Unblinded randomization and Randomization notifications.



Treatment arm details are included only for the **Unblinded randomization notification**.

If the **Blind Randomization Number** option in your study's settings is set to **Yes**, all randomization number instances display as **Blinded** throughout the notification. For more information, see Specify study, enrollment, and visits settings.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification and whether the subject successfully randomizaed or not. For example, Randomization succeeded or Randomization failed.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.



Field	Description
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the randomization visit.
Visit Name	Indicates the name of a randomization visit.
Date of Transaction (UTC)	Indicates the exact date and time of the randomization. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the randomization.

# Subject Number Update notification

This notification is sent when a site or sponsor user has successfully updated a subject number, and contains the site number, the original subject number, and the new subject number.

#### Permissions required to receive the notification

Assign the *Receive the Subject Number Update Notification* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they're assigned to.

#### Field descriptions

The table below describes all fields and details in the **Subject number update notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Subject Number Update.</li> </ul>
Study Name	Indicates a study's ID, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Original Subject Number	Indicates the original number of the subject that was updated.
New Subject Number	Indicates the new number of the subject.
Date Performed (UTC)	Indicates the exact date and time of the subject number update. For example: 10-Nov-2022 08:07 AM.
Subject Number Changed By	Indicates the username of the user who updated the subject's number.



# Subject rollover notification

This notification is sent when a subject is enrolled into a rollover study.

#### Permissions required to receive the notification

Assign the *Receive the Subject Rollover Notification* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they're assigned to.

#### **Field descriptions**

The table below describes all fields and details in the **Subject rollover notification**.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Rollover visit (Success).</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who was enrolled in a rollover study.
Visit Name	Indicates the name of the visit the subject has just completed.
Visit Date / Time	Indicates the date and time the visit took place.
Date Performed (UTC)	Indicates the exact date and time the subject was enrolled in a rollover study. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who enrolled the subject in a rollover study.

# Subject screening notification (with error)

This notification is sent when a subject is either successfully screened or their screening failed at a site that you're assigned to.



When a site user updates a subject's date of screen fail, the system efficiently avoids sending duplicate notifications, ensuring users receive only the most relevant and timely updates.



#### Permissions required to receive the notification

Assign the *Receive the Subject Screening Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### **Field descriptions**

The table below describes all fields and details in the **Subject screening notification**.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Screening Notification or Screening Failure Notification.</li> </ul>
Study Name	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Subject Number	Indicates the number of the subject.
Date Performed (UTC)	Indicates the exact date and time of the completion of the screening visit. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who performed the screening of the subject.

# Subject transferred notification

This notification is sent when a subject transfers to another site.

#### Permissions required to receive the notification

Assign the *Receive the Subject Transferred Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### Field descriptions

The table below describes all fields and details in the Subject transferred notification.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>A subject's number. For example: MUHC22.</li> <li>The previous site name.</li> <li>The name of the site the subject was transferred to.</li> </ul>
Study Name	Indicates a study's ID again, as specified by the global study creator when they created the study



Field	Description
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Previous Site Name	Indicates the name of the previous site the subject was assigned to, as specified by a site manager when they created the site.
Previous Study Org ID	Indicates the previous study org number.
New Site Name	Indicates the name of the new site the subject was transferred to.
New Study Org ID	Indicates the new study org number.
Previous Subject Number	Indicates the subject's previous number before transferring to another site.
New Subject Number	Indicates the new ID the subject was assigned after transferring.
Date Performed (UTC)	Indicates the exact date and time of the subject transfer. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who transferred the subject.

# Subject undo completion notification

This notification is sent when a subject's completion of the study is undone at a site that you're assigned to.

#### Permissions required to receive the notification

Assign the *Receive the Subject Undo Completion Notification* permission to anyone who needs to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### **Field descriptions**

The table below describes all fields and details in the **Subject Undo Completion** notification.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Undo Completion Notification.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be:  Test Active Training
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.



Field	Description
Subject ID	Indicates the number of the subject whose completion statsus was undone.
Date Performed (UTC)	Indicates the exact date and time of undoing the subject's completion of all required visits in a study. For example: 10-Nov-2022 08:07.
Performed By	Indicates the username of the user who updated the subject's status.

### Subject undo screen failure notification

This notification is only sent when you manually undone a subject's screen failure at a site that you're assigned to. If data is updated to resolve a validation that results in the automated screen failure of a subject, no notification is sent if the subject is then successfully screened.

### Permissions required to receive the notification

Assign the *Receive the Subject Undo Screen Failure Notification* permission to anyone who needs to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Subject Undo Screen Failure** notification.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Undo Screen Failure Notification.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be:  Test Active Training	
Site Name	Indicates the name of the site as specified by a site manager when they created the site.	
Site ID	Indicates a site's ID as specified by the site manager who created the site.	
Subject ID	Indicates the number of the subject.	
Date Performed (UTC)	Indicates the exact date and time of the undoing of a subject's screen failure. For example: 10-Nov-2022 08:07.	
Performed By	Indicates the username of the user who performed the undoing of the subject's screen failure.	



### Subject undo withdrawal notification

This notification is sent when a subject's withdrawal is undone at a site that you're assigned to.

### Permissions required to receive the notification

Assign the *Receive the Subject Undo Withdrawal Notification* permission to anyone who needs to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Subject Undo Withdrawal** notification.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Undo Withdrawal Notification.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be:  Test Active Training	
Site Name	Indicates the name of the site as specified by a site manager when they created the site.	
Site ID	Indicates a site's ID as specified by the site manager who created the site.	
Subject ID	Indicates the number of the subject whose withdrawal from the study was just undone.	
Date Performed (UTC)	Indicates the exact date and time of when the subject's withdrawal from the study was undone. For example: 10-Nov-2022.	
Performed By	Indicates the username of the user who performed the undoing of a subject's withdrawal.	

### Subject unscheduled visit notification

This notification is sent when a subject completes an unscheduled visit.

#### Permissions required to receive the notification

Assign the *Receive the Unscheduled Visit Notification* permission to anyone who wants to receive this notification. Users receive notifications only for the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Subject unscheduled visit notification**.



Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification and whether the visit was successfully completed or not. For example Unscheduled Visit (Success) or Unscheduled Visit (Failure).</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the unscheduled visit.
Visit Name	Indicates an unscheduled visit's name, as specified by a study designer when they defined the study's visit schedule.
Visit Date/ Time	Indicates the unscheduled visit's exact date and time of the completion. For example: 10-Nov-2022 08:07 AM.
Date Performed (UTC)	Indicates the exact date and time of the subject completed the unscheduled visit. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who performed the unscheduled visit completion.

# Subject visit notification (with failures)

This notification is sent when a subject completes a non-dispensation or optional visit at a site that you're assigned to. The notification is sent both when the subject successfully completes the visit and when one or more questions have errors.

### Permissions required to receive the notification

Assign the *Receive the Subject Visit Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

#### **Field descriptions**

The table below describes all fields and details in the **Subject visit notification**.



Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification and whether the visit was successfully completed or not.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the visit.
Visit Name	Indicates a visit's name, as specified by a study designer when they defined the study's visit schedule.
Visit Date/ Time	Indicates the visit's exact date and time of the completion. For example: 10-Nov-2022 08:07 AM.

# Subject withdrawal notification

This notification is sent when a subject withdraws from a study.



When a site user updates a subject's date of withdrawal, the system efficiently avoids sending duplicate notifications, ensuring users receive only the most relevant and timely updates.

### Permissions required to receive the notification

Assign the *Receive the Subject Completion Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the Subject withdrawal notification.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Withdrawal Notification.</li> </ul>



Description
Indicates a study's ID again, as specified by the global study creator when they created the study.
Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Indicates the name of the site as specified by a site manager when they created the site.
Indicates the number of the subject who just withdrew from the study.
Indicates the exact date and time of the subject withdrawal. For example: 10-Nov-2022 08:07 AM.
Indicates the username of the user who performed the subject withdrawal.

### Training complete notification

This notification is sent when you complete all training assigned to you.

### Permissions required to receive the notification

Any role that is assigned training will receive this notification after they completed all training assigned to them. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Training complete notification**.

Field	Descriptions
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The title of the notification, for example, Training complete.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site as specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Date of Transaction (UTC)	Indicates the exact date and time the training was complete. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the username of the user who completed the training.

### Unblinded Pharmacist dispensation notification

Pharmacists or unblinded site users receive this notification when kits need to be dispensed by them to subjects during a dispensation or randomization visit.



Details about partial dispensation are included when they occur.

### Permissions required to receive the notification

Assign the *Receive the Unblinded Pharmacist Dispensation Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Unblinded Pharmacist dispensation notification**.



This notification also contains an introductory statement suggesting you see your pharmacist or unblinded site user, as there may be kits for this visit only the pharmacist can dispense.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification and whether the dispensation succeeded or not. For example Unblinded dispensation succeeded or Unblinded dispensation failed.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the dispensation or randomization visit.
Visit Name	Indicates the name of a dispensation or randomization visit.
Number of Kits	Indicates the total number of kits.
Kit Number / Lot Number	Indicates the number of the specific kit(s), or quantity of non-serialized kits, that have been dispensed successfully or failed to be dispensed.  For example, Lot Number: ABC345 (4).
Description	A description of the kit, for example, Matching placebo.



Field	Description
Date of Transaction (UTC)	Indicates the exact date and time of the dispensation. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the kit dispensation.

### Supply notifications

#### · Depot shipment notification

This notification is sent when a depot-to-depot shipment is generated. The notification is created for both automatic and manual shipments.

### Kit List Deactivated notification (with failures)

This notification is sent to a clinical supply manager when a kit list was successfully deactivated or the system failed to deactivate it.

### Kit missing from shipment for destruction notification

This notification is sent when a depot user marks a kit as missing from a shipment for destruction.

### Kit status changed to "Misallocated" notification

This notification is sent once a site user changes the status of a kit to Misallocated.

#### Kit status changed to "Not Dispensed to Subject" notification

This notification is sent when a site user updates the status of a kit to Not Dispensed to Subject.

#### Kits Quarantined notification

This notification is sent when individual kits have been marked as Ouarantined.

#### Low kit depot notification

This notification is sent when the depot kits run below the limit set up in depot configuration.

### Kits Released from Quarantine notification

This notification is sent when individual kits have been released from quarantine.

#### Pending shipment notification

This notification is sent when a shipment has not yet been registered at a site within the time span specified in the supply settings.

#### Randomization update notification

This notification is sent when the randomization limit is reached for a study, site, country, or cohort; or a percentage of the randomization limit is reached for a study, site, country, or cohort.

#### Replace kits notification

This notification is sent when a kit has been replaced for a subject.

#### Shipment cancellation notification

This notification is sent every time a shipment is cancelled.

### Shipment failure notification

This notification is sent when a shipment can't be created, such as because of lack of inventory.

#### Shipment for destruction created notification

This notification is sent when a new shipment for destruction is generated.

### Shipment for destruction not received notification

This notification is sent when a depot doesn't confirm that they received one or all kits in a shipment.

### Shipment Quarantined notification

This notification is sent when a shipment has been quarantined.

#### Shipment Released from Quarantine notification

This notification is sent when a shipment has been released from quarantine.

### · Shipment request notification

This notification is sent when a site requests a shipment, and when a new shipment is generated. The notification is created for both automatic and manual shipments.

### State of a site has changed notification

This notification is sent when a site changes status, such as going from New to Active.

### Study inventory notification

This notification is sent when available kits at a site or depot are marked as Quarantined.

### Unblinded dose hold performed notification

This notification is sent once a site user performs a dose hold.

# Depot shipment notification

This notification is sent when a depot-to-depot shipment is generated. The notification is created for both automatic and manual shipments.

### Permissions required to receive the notification

Assign the *Receive Notification of Depot Shipments* permission to anyone who wants to receive this notification. Users receive notifications only for the depots that they are assigned to.

#### Field descriptions

The table below describes all fields and details in the **New depot shipment notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The title of the notification, for example, New Depot Shipment .</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Destination ID	Indicates a facility's ID as specified by the user who created the facility in the study. For example:  For a site, it indicates a site's ID as specified by a site manager.
	<ul> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>



Field	Description
Destination	<ul> <li>Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates the site's title as specified by a site manager.</li> <li>For a depot, it indicates a depot's title as specified by a clinical supply manager.</li> </ul>
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Shipment ID	Indicates a shipment's ID assigned at creation.
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction
Date of Transaction (UTC)	Indicates the exact date and time of the shipment
	creation. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who created the new depot shipment.

# Kit List Deactivated notification (with failures)

This notification is sent to a clinical supply manager when a kit list was successfully deactivated or the system failed to deactivate it.

### Permissions required to receive the notification

Assign the *Upload and Generate Inventory Lists* to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the Kit List Deactivated notification.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The title of the notification, for example, Kit List Deactivated.</li> </ul>
Study Name	Indicates a study's name, as specified by the global study creator when they created the study.
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Kit List	Indicates the deactivated kit list's title, as specified by the clinical supply manager or statistician when they created the kit list.

Field	Description
Number of Kits	Indicates the number of kits specified in the deactivated kit list.
Date of Transaction (UTC)	Indicates the exact date and time of the shipment request. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who deactivated the kit list.

### Kit missing from shipment for destruction notification

This notification is sent when a depot user marks a kit as missing from a shipment for destruction.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Kit missing from shipment for destruction notification**.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The shipment ID.</li> <li>The title of the notification, for example, Kit missing from shipment for destruction.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the kit is missing. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Depot	Indicates the depot's name as specified by a clinical supply manager when they created the facility in the study.
Depot Shipping Address	Indicates the depot's shipping address as specified by the clinical supply manager when they created the facility in the study.
Shipment	Indicates a shipment's ID.
Missing Kits	Indicates the exact number of missing kits from a shipment, as well as the kit numbers that are missing from that specific shipment.
Date Shipment Received (UTC)	Indicates the exact date and time the kit was marked as missing from the shipment. For example: 10-Nov-2022 08:07 AM.



### Kit status changed to "Misallocated" notification

This notification is sent once a site user changes the status of a kit to Misallocated.

### Permissions required to receive the notification

Assign the *Receive the Unblinded Kit Misallocation Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Kit status changed to "Misallocated" notification**.



This notification also contains an introductory statement notifying the receiver that a user has changed the status of a kit to *Misallocated*.

Description
<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The kit's ID.</li> <li>The title of the notification, for example, Kit status changed to "Misallocated."</li> </ul>
Indicates a study's ID again, as specified by the global study creator when they created the study.
Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Indicates the name of the site where the kit was marked as Misallocated. The name is displayed as it was specified by a site manager when they created the site.
Indicates a site's ID as specified by the site manager who created the site.
Indicates the number of the subject who is associated with the misallocated kit.
Indicates the number of the specific kit(s), or quantity of non-serialized kits, whose statuses have been updated.
For example,Lot Number: ABC345 (4).
Indicates the exact date and time the status of the kit was updated. For example: 10-Nov-2022 08:07 AM.
Indicates the user who updated the status of the kit.



### Kit status changed to "Not Dispensed to Subject" notification

This notification is sent when a site user updates the status of a kit to Not Dispensed to Subject.



The unblinded pharmacist user will receive both Blinded and Unblinded Pharmacist kit notifications.

### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Not Dispensed to Subject (Unblinded) notification: Includes a description for
  the kit that has been updated with the status Not Dispensed to Subject and notifies the
  user that the kit has been removed from the subject's history.
- Receive the Not Dispensed to Subject notification: Notifies users that the status of a kit has been updated to Not Dispensed to Subject and that the kit has been removed from the subject's history. It includes the kit description only if the updated kit is of Blinded distribution type. If not, this information is not disclosed in the notification.
- Receive the Not Dispensed to Subject (Unblinded Pharmacist) notification: Notifies users
  that the status of a kit has been changed to Not Dispensed to Subject and that the kit has
  been removed from the subject's history. A description for the updated kit is also included.

### Field descriptions

The table below describes all fields and details in the **Kit status changed to "Not Dispensed to Subject" notification**.



This notification also contains an introductory statement notifying the receiver that a user has changed the status of a kit to *Not Dispensed to Subject*, and that the kit has been removed from the subject's history.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The kit's ID.</li> <li>The title of the notification, for example, Kit status changed to "Not Dispensed to Subject."</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.



Field	Description
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the dispensation or randomization visit.
Kit Number / Lot Number	Indicates the number of the specific kit(s), or quantity of non-serialized kits, whose statuses have been updated.
	For example,Lot Number: ABC345 (4).
Date of Transaction (UTC)	Indicates the exact date and time of the dispensation. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who updated the status of the kit.

# Kits Quarantined notification

This notification is sent when individual kits have been marked as Quarantined.

### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Quarantined Depot Shipment Notification: Includes the kit number and quantity of kits quarantined at the associated depot.
- Receive the Quarantined Site Shipment Notification: Includes the kit number and quantity of kits quarantined at the associated site.

### Field descriptions

The table below describes all fields and details in both the **Quarantined depot shipment** and **Quarantined site shipment notifications**.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The shipment ID.</li> <li>The title of the notification, for example, Shipment Quarantined.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Shipment ID	Indicates a shipment's ID assigned at creation.
Temperature Excursion ID	Indicates the tracking number associated with the kit(s) that experienced a temperature excursion and have been quarantined.



Field	Description
Kit Number / Lot Number	Indicates the number of the specific kit(s), or quantity of non-serialized kits, that have been quarantined.
	For example,Lot Number: ABC345 (4).
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Destination	Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>
Shipping Address	Indicates the address of the shipment destination.
Date of Transaction (UTC)	Indicates the exact date and time of the kit quarantine. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the kit quarantine.

# Low kit depot notification

This notification is sent when the depot kits run below the limit set up in depot configuration.

The **Low kit depot notification** alerts clinical supplies managers that the depot is running low on supplies. An alert will be sent when the resupply algorithm detects the low inventory limit set in the depot configuration is reached. Users receive it until they restock on supplies.

### Permissions that receive the notification

To receive these notifications, assign the *Receive Notification of Depot Shipments* permission to anyone who wants to receive this notification. Users receive notifications only for the depots that they are assigned to.

Table 3-6 Field descriptions

Field	Description
Subject line	Indicates the summary of the alert information.
Study Name	Indicates the name of the study for which the given depot is running low on supplies.
Study ID	Indicates a study's ID, as specified upon study creation.
Study Mode	Indicates the study mode in which the given depot is running low on supplies: <i>Production, Testing</i> or <i>Training.</i>



Table 3-6 (Cont.) Field descriptions

Field	Description
Depot ID	Indicates a short identifier for the depot.
Depot Name	Indicates the depot's descriptive name
Depot Address	Indicates the depot's address.
Kit Type ID	Indicates the unique identifier of the given kit that reached the low inventory limit.
	Line will repeat for each kit type.
Kit Type Description	Indicates the description of the given kit that reached the low inventory limit.
Current Inventory Available	Indicates the number of the kits available at the moment of the inquiry.
	In transit and Pre-Quarantined kits will count in the total Current Inventory Available as if they were in Available status.
Date Alert Raised	Indicates the exact date and time of the alert. For example: 22-Jan-2023 09:15 AM.

### Kits Released from Quarantine notification

This notification is sent when individual kits have been released from quarantine.

### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Released from Quarantine Shipment Notification (Depot): Includes the kit number and quantity of kits released from quarantine at the associated depot.
- Receive the Released from Quarantine Notification (Site): Includes the kit number and quantity of kits released from quarantine at the associated site.

### **Field descriptions**

The table below describes all fields and details in both the **Shipment released from quarantine (Depot)** and **Shipment released from quarantine (Site) notifications**.

Field	Description
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The shipment ID.</li> <li>The title of the notification, for example, Shipment released from quarantine (Depot) or Shipment released from quarantine (Site).</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Shipment ID	Indicates a shipment's ID assigned at creation.



Field	Description
Temperature Excursion ID	Indicates the tracking number associated with the kit(s) that experienced a temperature excursion and have been released from quarantined.
Kit Number / Lot Number	Indicates the number of the specific kit(s), or quantity of non-serialized kits, that have been released from quarantine.
	For example,Lot Number: ABC345 (4).
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Destination	Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>
Shipping Address	Indicates the address of the shipment destination.
Date of Transaction (UTC)	Indicates the exact date and time the kits were released from quarantine. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the quarantine release.

# Pending shipment notification

This notification is sent when a shipment has not yet been registered at a site within the time span specified in the supply settings.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Pending shipment notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The title of the notification, for example, Pending Shipments.</li> </ul>



Field	Description
Study Name	Indicates a study's name, as specified by the global study creator when they created the study.
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Shipment ID	Indicates a shipment's ID assigned at creation.
From Depot ID	Indicates a short identifier for the depot the shipment left from.
To Site ID	Indicates a site's ID, as specified by the site manager who created the site, that the shipment is being sent to.
Date Shipment Left Depot (UTC)	Indicates the exact date and time the shipment left the depot. For example: 10-Nov-2022 08:07 AM.

### Randomization update notification

This notification is sent when the randomization limit is reached for a study, site, country, or cohort; or a percentage of the randomization limit is reached for a study, site, country, or cohort.

### Permissions required to receive this notification

Assign the *Receive the Randomization Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the Randomization update notification.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The title of the notification.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Site Name	Indicates the name of the site where the unscheduled visit took place. The name is displayed as it was specified by a site manager when they created the site.
Site ID	Indicates a site's ID as specified by the site manager who created the site.
Subject ID	Indicates the number of the subject who just completed the dispensation or randomization visit.
Visit Name	Indicates the name of a dispensation or randomization visit.



Field	Description
Date of Transaction (UTC)	Indicates the exact date and time of the randomization. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the randomization.

# Replace kits notification

This notification is sent when a kit has been replaced for a subject.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification.

### **Field descriptions**

The table below describes all fields and details in the **Replace kits notification**.

Field	Description
Title	The title of the notification, for example, Replace Kits.
Subject number	A system message followed by the subject's number whose kit is being replaced.
Kit number	Indicates the number of the kit the previous kit is being replaced with.

### Shipment cancellation notification

This notification is sent every time a shipment is cancelled.

#### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Shipment cancellation notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>
	<ul> <li>The title of the notification, for example, Shipment Cancellation Request.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.



Field	Description
Destination ID	Indicates a facility's ID as specified by the user who created the facility in the study. For example:  • For a site, it indicates a site's ID as specified by a site manager.
	<ul> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>
Destination	<ul> <li>Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates the site's title as specified by a site manager.</li> <li>For a depot, it indicates a depot's title as specified by a clinical supply manager.</li> </ul>
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Shipment ID	Indicates a shipment's ID assigned at creation.
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction
Date of Transaction (UTC)	Indicates the exact date and time of the shipment cancellation. For example: 10-Nov-2022 08:07 AM.
Performed By	Indicates the user who performed the cancellation of the shipment.

# Shipment failure notification

This notification is sent when a shipment can't be created, such as because of lack of inventory.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Shipment failure notification**.

Field	Description
Title	The title is comprised of two distinct elements:  The study's ID. For example, a study's ID can be P01-123-A3.
	<ul> <li>The reason for a shipment's failure. For example, that reason can be Insufficient kits when creating shipment.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.



Field	Description
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>
Destination	<ul> <li>Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates the site's title as specified by a site manager.</li> <li>For a depot, it indicates a depot's title as specified by a clinical supply manager.</li> </ul>
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Date of Transaction (UTC)	Indicates the exact date and time of the shipment failure. For example: 10-Nov-2022 08:07 AM.

# Shipment for destruction created notification

This notification is sent when a new shipment for destruction is generated.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Shipment for destruction created notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The title of the notification, for example, Shipment for destruction created.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.



Field	Description
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as</li> </ul>
Destination	specified by a clinical supply manager.  Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.
Date of Transaction (UTC)	Indicates the exact date and time the shipment for destruction was created. For example: 10-Nov-2022 08:07 AM.

# Shipment for destruction not received notification

This notification is sent when a depot doesn't confirm that they received one or all kits in a shipment.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **Shipment for destruction not received notification**.

Field	Description
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The title of the notification, for example, Shipment for destruction not received.</li> </ul>
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.



Field	Description	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.	
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction	
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> </ul>	
	<ul> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>	
Destination	<ul> <li>Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates the site's title as specified by a site manager.</li> <li>For a depot, it indicates a depot's title as specified by a clinical supply manager.</li> </ul>	
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.	
Date of Transaction (UTC)	Indicates the exact date and time the shipment for destruction was logged as not received. For example: 10-Nov-2022 08:07 AM.	

# Shipment Quarantined notification

This notification is sent when a shipment has been quarantined.

### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Quarantined Depot Shipment Notification: Includes details on the quarantined shipment associated with the depot.
- Receive the Quarantined Site Shipment Notification: Includes details on the quarantined shipment associated with the site.

### **Field descriptions**

The table below describes all fields and details in both the **Quarantined depot shipment** and **Quarantined site shipment notifications**.



Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The shipment ID.</li> <li>The title of the notification, for example, Shipment Quarantined.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.	
Shipment ID	Indicates a shipment's ID assigned at creation.	
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.	
Destination	Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.	
Destination ID	Indicates a facility's ID as specified by the user who created the facility in the study. For example:  For a site, it indicates a site's ID as specified by a site manager.  For a depot, it indicates a depot's ID as specified by a clinical supply manager.	
Shipping Address	Indicates the address of the shipment destination.	
Temperature Excursion ID	Indicates the tracking number associated with the kit(s) that experienced a temperature excursion and have been quarantined.	
Date of Transaction (UTC)	Indicates the exact date and time of the shipment quarantine. For example: 10-Nov-2022 08:07 AM.	
Performed By	Indicates the user who performed the shipment quarantine.	

### Shipment Released from Quarantine notification

This notification is sent when a shipment has been released from quarantine.

### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Released from Quarantine Shipment Notification (Depot): Includes details on the shipment released from quarantine at the associated depot.
- Receive the Released from Quarantine Notification (Site): Includes details on the shipment released from quarantine at the associated site.



### Field descriptions

The table below describes all fields and details in both the **Shipment released from quarantine (Depot)** and **Shipment released from quarantine (Site) notifications**.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> </ul>	
	<ul> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Shipment released from quarantine (Depot) or Shipment released from quarantine (Site).</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.	
Shipment ID	Indicates a shipment's ID assigned at creation.	
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.	
Destination	Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.	
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>	
Shipping Address	Indicates the address of the shipment destination.	
Temperature Excursion ID	Indicates the tracking number associated with the kit(s) that experienced a temperature excursion and have been released from quarantined.	
Date of Transaction (UTC)	Indicates the exact date and time the shipment was released from quarantine. For example: 10-Nov-2022 08:07 AM.	
Performed By	Indicates the user who performed the quarantine release.	



# Shipment request notification

This notification is sent when a site requests a shipment, and when a new shipment is generated. The notification is created for both automatic and manual shipments.

### Permissions required to receive the notification

Assign the *Receive Notification of Shipments* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### Field descriptions

The table below describes all fields and details in the **New shipment request notification**.

Field	Description	
Title	<ul> <li>The title is comprised of two distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The title of the notification, for example, New Shipment Request.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.	
Destination ID	<ul> <li>Indicates a facility's ID as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates a site's ID as specified by a site manager.</li> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>	
Destination	Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:  • For a site, it indicates the site's title as specified by a site manager.  • For a depot, it indicates a depot's title as specified by a clinical supply manager.	
Origin(s)	Indicates the name of the depot facility that is packaging and shipping the depot for its destination. The name appears as specified by a clinical supply manager when they created the depot.	
Shipment ID	Indicates a shipment's ID assigned at creation.	
Shipment Type	Indicates a shipment's type, as requested by the depot user, the site user, or the clinical supply manager. The following types can be displayed:  Manual  Shipment for Destruction	
Date of Transaction (UTC)	Indicates the exact date and time of the shipment request. For example: 10-Nov-2022 08:07 AM.	
Performed By	Indicates the user who created the new shipment request.	



### State of a site has changed notification

This notification is sent when a site changes status, such as going from New to Active.

#### Permissions required to receive the notification

Assign the *Receive Site has been Updated Notification* permission to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **State of a site has changed notification**.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The site's ID and name.</li> <li>The kit's ID.</li> <li>The title of the notification, for example, Site Status Change Alert.</li> </ul>	
Details	Provides information on the site's status change.	

### Study inventory notification

This notification is sent when available kits at a site or depot are marked as Quarantined.

#### Permissions required to receive the notification

Assign all or one of these permissions to anyone who wants to receive this notification:

- Receive the Quarantined Depot Shipment Notification: Includes details on Depot inventory kits that have been marked as Quarantined.
- Receive the Quarantined Site Shipment Notification: Includes details on Site inventory kits that have been marked as Quarantined.

### **Field descriptions**

The table below describes all fields and details in **Study Inventory notification**.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>The shipment ID.</li> </ul>	
	<ul> <li>The title of the notification, for example, Study Inventory Quarantined.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Destination ID	Indicates a facility's ID as specified by the user who created the facility in the study. For example:  For a site, it indicates a site's ID as specified by a site manager.	
	<ul> <li>For a depot, it indicates a depot's ID as specified by a clinical supply manager.</li> </ul>	



Description	
<ul> <li>Indicates the destination of the shipment, as specified by the user who created the facility in the study. For example:</li> <li>For a site, it indicates the site's title as specified by a site manager.</li> <li>For a depot, it indicates a depot's title as specified by a clinical supply manager.</li> </ul>	
Indicates the address of the shipment destination.	
Indicates the tracking number associated with the kit(s) that experienced a temperature excursion and have been quarantined.	
Indicates the number of the specific kit(s), or quantity of non-serialized kits, whose statuses have been updated.	
For example,Lot Number: ABC345 (4).	
Indicates the exact date and time of the inventory quarantine. For example: 10-Nov-2022 08:07 AM.	

# Unblinded dose hold performed notification

This notification is sent once a site user performs a dose hold.

### Permissions required to receive the notification

Assign the *Receive the Unblinded Dose Hold Notification* to anyone who wants to receive this notification. Users receive notifications for only the sites that they're assigned to.

### **Field descriptions**

The table below describes all fields and details in the **Unblinded dose hold performed notification**.

Field	Description	
Title	<ul> <li>The title is comprised of three distinct elements:</li> <li>The study's ID. For example, a study's ID can be P01-123-A3.</li> <li>A subject's number. For example: MUHC22.</li> <li>The title of the notification, for example, Unblinded dose hold performed.</li> </ul>	
Study ID	Indicates a study's ID again, as specified by the global study creator when they created the study.	
Study Mode	Indicates the study mode associated with this notification. Displayed values can be Test, Active, or Training.	
Site Name	Indicates the name of the site as specified by a site manager when they created the site.	
Site ID	Indicates a site's ID as specified by the site manager who created the site.	
Subject ID	Indicates the number of the subject.	
Treatment Arm	Indicates the corresponding treatment arm.	
Visit Name	Indicates the name of the visit the subject has just completed.	

Field	Description	
Number of Dose Holds	Indicates the total number of dose holds performed.	
Kit Type	Indicates the description of the kit.	
Date of Transaction (UTC)	Indicates the exact date and time of the dose hold. For example: 10-Nov-2022 08:07 AM.	
Performed By	Indicates the user who performed the dose hold.	

# User management notifications

Bulk User Upload notifications
 This notification is sent after the user upload process completes.

# Bulk User Upload notifications

This notification is sent after the user upload process completes.

### Permissions required to receive these notifications

A user associated to a role that includes the *Upload Users in Bulk* permission, receives this notification after processing the bulk upload.

### **Field descriptions**

The table below describes all fields and details in the Bulk User Upload notification.

Field	Description		
Title	The title is comprised of two distinct elements:  The organization's tenant.  A statement about user upload performed.  For example: User upload performed in customer-tenant in Clinical One		
Study Title	Indicates a study's ID, as specified by the global study creator when they created the study.		
Uploaded at	Indicates the date and time at which the user upload was processed.		
Updated by	Indicates the user who performed the user upload import.		
User Uploaded	Indicates the number of non-Oracle users included in the template that were uploaded and did not encounter a validation error upon import. Users are counted even if no changes were applied to them.		
User with error	Indicates the number of users that encountered a validation error upon import. This count always includes Oracle users records as they are not supported by the bulk user updates feature.  All the records for users with errors are included in the User Upload Error report.		
Comment	Displays comments entered during the upload process, if any.		

### **Related Topics**

- Manage study users in bulk
- User Upload Error report
- Report is ready notification

This notification is sent when a report is ready.



# Oracle CRF Submit notifications

Email and in-application notifications can be customized to notify sponsor and site users about the status of PDF and report requests and inform sponsor users about site-level PDF requests, downloads, and confirmation activities.

The system can even notify you if the Oracle CRF Submit storage limit is reaching capacity. For more information about these notifications and how to configure them, see Email and inapplication notifications.



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# **Revision history**

Date	Part number	Description
18-March-2025	G16749-03	Made the following updates:  Included the following new topics:  Subject undo completion notification  Subject undo screen failure notification  Subject undo withdrawal notification  Modified the following topics:  Permissions for subject notifications  Subject completion notification  Subject withdrawal notification  Subject screening notification (with error)
27-February-2025	G16749-02	Included information on how to proceed when a user receives the Auto-lock failure notification. For more information, see Auto-lock failure notification.
17-January-2025	G16749-01	Original version of the document.

