

Oracle® Life Sciences Clinical One Platform

Icon Reference Guide



Release 24.1.1

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

ORACLE®

Oracle Life Sciences Clinical One Platform Icon Reference Guide, Release 24.1.1

F95738-03

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
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- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

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Kit status descriptions






Learn more about the different icons that represent kit statuses.

Have you ever wondered what each kit status really means for how you manage shipments in your study? Here's a list of every status a kit might have in Oracle Clinical One Platform and their descriptions.

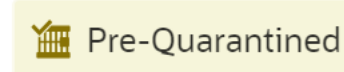
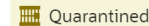

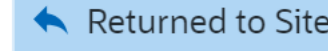
 **Tip:**

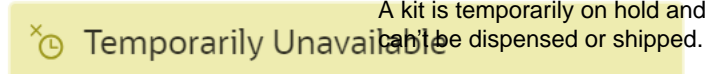
Depending on your role and the permissions assigned to it, you can see a kit's changed status at either a site or depot, on the **Inventory** and **Kit Reconciliation** tabs, or in **Subject History**. Information about all kit statuses in your inventory can also be found in the Kit Inventory (Blinded) report and Kit Inventory (Unblinded) report in Oracle Clinical One Platform.

Status icon	What it means	How a kit reaches this status
 Available	<i>Available</i> The kit is ready to be dispensed to subjects at a site, or ready to be shipped from a depot.	A kit's status is updated to <i>Available</i> : <ul style="list-style-type: none">• Automatically: when kits are created or uploaded.• Manually: when a sponsor user releases kits to a depot for Production or Training mode.
 Damaged	<i>Damaged</i> A kit was physically deteriorated at a site or depot. For example, a kit might have been damaged as a result of being dropped.	A site user or sponsor user marks the kit as <i>Damaged</i> .
 Damaged by Subject	<i>Damaged by subject</i> A kit was physically deteriorated after it was dispensed to the subject. In this case, the subject needs to return it to the site to be destroyed. Usually, if the kit is damaged by the subject, after returning it to the site, a new one is dispensed.	A site user marks the kit as <i>Damaged by Subject</i> during the kit reconciliation process. If a kit replacement occurs and the user marks the kit as <i>Damaged</i> , the status of the kit will change to <i>Damaged by Subject</i> .

Status icon	What it means	How a kit reaches this status
 Destroyed	<p><i>Destroyed</i> The kit was destroyed during the kit reconciliation process. Most kits are destroyed after the subjects return them to site. Additionally, a kit is destroyed if it was damaged, it expired, or wasn't dispensed to a subject at all.</p>	<p>Typically, before destruction, a Clinical Research Associate (CRA) verifies the kit and marks it as being ready for destruction. The next step depends on the location of the drug destruction facility:</p> <ul style="list-style-type: none"> • If a site is drug destruction capable, the site user destroys the kits and changes the status of the kits to <i>Destroyed</i>. • If a site can't destroy drugs on site, either the CRA or someone at the site sends the kits that are ready for destruction to a depot that is a drug destruction facility. After the kit is destroyed, its status is updated to <i>Destroyed</i>. <p><i>Only Pending Destruction kits can be marked as Destroyed.</i></p>
 Dispensed	<p><i>Dispensed</i> The kit was dispensed to a subject during a dispensation visit.</p>	<p>The kit's status automatically changes to <i>Dispensed</i> after a site user dispenses it to a subject.</p>
 Expired	<p><i>Expired</i> The investigational product exceeded its expiration date.</p>	<p>The system automatically updates the status of the kit to <i>Expired</i> when it exceeds its expiration date.</p>
 In Transit	<p><i>In Transit</i> The kit is being shipped from a depot to a site.</p>	<p>A shipment request was made by a site or sponsor user for that kit, and the ship date has been provided.</p>
 Lost by Subject	<p><i>Lost by Subject</i> The kit went missing after being dispensed to a subject. Usually, if the kit is lost by a subject, a new one is dispensed to them.</p>	<p>A site user marks the kit as <i>Lost by Subject</i> during the kit reconciliation process. If a kit replacement occurs and the user marks the kit as <i>Lost</i>, the status of the kit will change to <i>Lost by Subject</i>.</p>

Status icon	What it means	How a kit reaches this status
 Misallocated	<p><i>Misallocated</i></p> <p>A kit was dispensed in error. There are several reasons why a kit can be dispensed in error. For example, someone at the site might have given a subject a kit that was different from the kit that Oracle Clinical One Platform said to dispense, and the subject left the site with it; or someone at the site might have entered data in the wrong subject's visit and dispensed a kit.</p>	<p>A site user manually updates a kit's status to <i>Misallocated</i>.</p> <p><i>A site user must dispense a replacement kit before marking the kit as Misallocated. If a site user marks a kit as Misallocated before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.</i></p>
 Missing	<p><i>Missing</i></p> <p>A kit hasn't been dispensed yet and has gone missing from the site or depot.</p>	<p>A site user or sponsor user manually updates a kit's status to <i>Missing</i>.</p>
 New	<p><i>New</i></p> <p>The kit has just been uploaded and is going to be manufactured and made ready for use.</p>	<p>A site user or sponsor user manually updates a kit's status to <i>New</i>.</p>
 Not Dispensed to Subject	<p><i>Not Dispensed to Subject</i></p> <p>The dispensed kit was never distributed. A subject might not receive a kit for various reasons. For example, they accidentally left the kit at the site after their visit, or the site user intentionally chose not to distribute the kit to them.</p>	<p>A site user marks the kit as <i>Not Dispensed to Subject</i>.</p> <p><i>A site user must dispense a replacement kit before marking the kit as Not Dispensed to Subject. If a site user marks a kit as Not Dispensed to Subject before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.</i></p>
 Not in Use	<p><i>Not in Use</i></p> <p>The kit can't be dispensed or shipped, or it has just been uploaded to production. Think of this status as an "emergency brake". Whenever users want to prevent a kit from being dispensed or shipped they mark it as <i>Not in Use</i>. For example, they would use this status if a kit needs to be moved from one depot to another.</p>	<p>The site user or sponsor user marked the kit as <i>Not in Use</i> or has just been uploaded to Production.</p>
 Pending Destruction	<p><i>Pending Destruction</i></p> <p>The kit is ready to be destroyed.</p>	<p>Typically, the Clinical Research Associate (CRA) verifies the kit and then marks it as <i>Pending Destruction</i>. The user must provide a reason for the status update.</p>

Status icon	What it means	How a kit reaches this status
	<p><i>Pre-Quarantined</i> The kit failed to comply with the shipment or storage requirements. For instance, it could have suffered a temperature or humidity excursion. After the kit is pre-quarantined, a clinical supply manager determines whether the kit can still be dispensed or not. If it can be dispensed, the kit changes its status to <i>Available</i>. If the kit can't be dispensed, the kit's status is updated to <i>Quarantined</i> so that it isn't considered part of the site's inventory anymore.</p>	<p>The sponsor user marks the kits as <i>Pre-Quarantined</i>. <i>A pre-quarantined kit is counted in a site's inventory.</i></p>
	<p><i>Quarantined</i> A kit failed to comply with the shipment or storage requirements, and it was damaged as a result. A <i>Quarantined</i> status marks the end of life for a kit. Quarantined kits can no longer be dispensed to subjects, and aren't counted in a site's inventory. Multiple quarantined kits from the same depot might be a sign of issues with a shipping procedure.</p>	<p>A clinical supply manager marks the kit as <i>Quarantined</i>.</p>
	<p><i>Received for Destruction</i> The site user or Clinical Research Associate (CRA) has shipped the kit to a drug destruction depot and a depot user confirmed they received the kit for destruction at their facility. For instance, if a kit suffered some sort of irreversible damage, the site user might send it back to the depot facility to destroy it.</p>	<p>A depot user confirms a receipt per kit that they have received it at the depot.</p>
	<p><i>Returned to site</i> The subject returned the kit to the site. Subjects are required to bring any used and unused investigational products to their next dispensation visit. For instance, if the subject received three blisters of pills, and at his next dispensation visit they're left with three pills, they're required to return both the empty blisters and remaining pills to the site.</p>	<p>A site user changes the status of the kit to <i>Returned to Site</i> and indicates the number of returned and missing units.</p>

Status icon	What it means	How a kit reaches this status
 Temporarily Unavailable	<i>Temporarily Unavailable</i> A kit is temporarily on hold and can't be dispensed or shipped.	A site or sponsor user marks the kit as <i>Temporarily Unavailable</i> .

2

Library object statuses and icons




Learn about the different icons that represent object statuses in a library study.




Depending on how a library user modifies an object in their library study, that object might have a different status each time.



Note:

An object's status can be updated irrespective of the state of its associated study version. For example, you can mark an object as Approved even though its associated study version is still in the Testing container.

Object status icon	Description
 Draft	<p>Indicates the new version of an object. By default, when you create an object, that object has a Draft status. When an object has a status of Draft, you can edit or delete it. You can also edit its description and associated tags.</p> <p>An object with a status of Draft cannot be imported into a live study.</p>
 Ready to Test	<p>Indicates that an object is ready to be tested. After you create an object, you can mark it as Ready to Test. When the object is marked as Ready to Test, its status is updated to Testing. During this phase of the lifecycle, if the object fails testing, then its status can be updated to Rejected.</p> <p>An object with a status of Testing cannot be imported into a live study.</p>
 Rejected	<p>Indicates that an object did not pass testing. An object in a state of Rejected can be moved back to Ready to Test or Draft.</p> <p>An object with a status of Rejected cannot be imported into a live study.</p> <p>You cannot update a published object's status to Rejected. You must first move its status back to Approved before you can reject the object.</p>





Object status icon	Description
 Approved	<p>Indicates that an object has passed testing and can be published in a live study version.</p> <p>After you successfully test an object, you can mark it as Approved. An approved object can be further published or sent back to Testing, or you can change its status to Rejected.</p> <p>An object with a status of Approved cannot be imported in a live study, but you can publish it in your library.</p> <p>You can create a new version of an object in a state of Approved and further modify and test the new version of the same approved object.</p>
 Published	<p>Indicates that an object is eligible for importing it into a live study.</p> <p>Once an object is published, it has a unique system-generated object ID that is not displayed on the UI.</p> <p>You can create a new version of an object that is published and further modify and test it. You can also update a published object to a status of Archived or Approved.</p>
 Archived	<p>Indicates that an object is archived.</p> <p>You can update an archived object's status to Draft or Published again.</p> <p>If you create a newer version of an object, you can always mark that previous version as Archived.</p>

3

Rule status descriptions

Learn about the different icons that represent rule statuses.

Each rule status assigned by the Rules Programmer has a corresponding icon that allows you to easily distinguish it in the user interface.


Rule status icon	What it means
	<p>Draft Represents a newly created rule that can be edited by a Rule Designer. A rule with the status UAT or Approved must be moved back to Draft in order to modify it.</p> <p><i>Rules in Test mode that are moved to Draft will not affect the status of the rule in Production. In order to disable the rule, you must update the status of the rule in Production or else it will continue to run until an updated version is published.</i></p>
	<p>UAT Because rules statuses are assigned by the Rules Designer, you can create your own criteria for UAT status. However, it is recommended for this status to represent a rule with no syntax errors and is ready to be tested by a Rule Tester.</p>
	<p>Approved Because rules statuses are assigned by the Rules Designer, you can create your own criteria for Approved status. However, it is recommended for this status to represent a rule with no syntax errors, has the expected results and is ready to be published by a Rule Publisher.</p>
	<p>Published Represents a rule that has been published by a Rule Publisher.</p> <p><i>A rule will automatically return to Draft status if Edit is selected.</i></p>




4

Signing, verifying, freezing, and locking icon descriptions




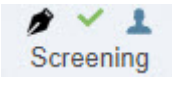
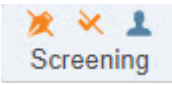
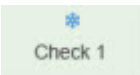
Learn about the different icons that represent signing, verifying, freezing, and locking data.

Each sign, verify, freeze, or lock action has an impact on the study data. Learn more about what each icon means.

Icon	What it means
	This icon appears whenever a principal investigator signed a subject's data. It typically appears on a visit card, next to every question on a form, and on a subject's icon.
	This icon appears whenever data that requires more than one signature does not have all required signatures applied. When applicable, it typically appears on a visit card, next to every updated question on a form, and on a subject's icon.
	This icon appears whenever a site user in the study updates a question on a complete or incomplete form, and the subject's data becomes unsigned. It typically appears on a visit card, next to every updated question on a form, and on a subject's icon.
	This icon appears whenever a Clinical Research Associate verifies a question. It typically appears on a visit card, next to every verified question on a form, and on a subject's icon.
	This icon appears whenever a question requires verification. It typically appears on the visit title.
	This icon appears whenever a site user updates questions or visit data on a complete or incomplete form, and the subject's data becomes unverified. It typically appears on a visit card, next to every updated question and form, and a subject's icon.
	This icon appears whenever questions have been marked as Critical Variables, but the subject has not been selected for the SDV pool. It typically appears next to questions marked as Critical Variables. <i>For this icon to appear, SDV Override must be turned on for the study. For more information, see Understanding Source Data Verification</i>
	This icon appears whenever a Clinical Research Associate (CRA) or data manager freezes data in a complete or incomplete form, and the subject's data becomes read-only. It appears on a visit card and next to every question and form associated with a visit.

Icon	What it means
	This icon appears whenever a Clinical Research Associate (CRA) or data manager unfreezes data in a complete or incomplete form. It appears on the visit tile and next to each question that is unfrozen.
	This icon appears on a subject's visit card and next to each question that is locked by a sponsor user.
	This icon appears on a subject's visit card and next to each question that is unlocked by a sponsor user.






Additionally, these icons can appear together if a subject is both signed and verified, or both unsigned and unverified. This also applies to visit cards.






Icon	What it means
	Both of these icons appear next to a subject whenever their data is both signed and verified.
	Both of these icons appear next to a subject whenever their data is both unsigned and unverified.
	This icon appears next to a subject whenever all of their visits have been frozen.
 Screening	Both of these icons appear in a visit card, whenever data in that visit is both signed and verified.
 Screening	Both of these icons appear in a visit card, whenever data in that visit is both unsigned and unverified.
 Check 1	This icon appears in a visit card, whenever all forms in that visit are frozen.

5

Shipment status descriptions

Learn more about each status a shipment might have in the application.


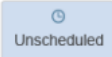
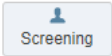

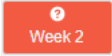
Shipment status icon	Description
 Cancelled	<p><i>Cancelled</i> This means that the shipment is cancelled and is no longer sent to the site or depot.</p> <p>A shipment's status is updated to <i>Cancelled</i> by a clinical supply manager when the kits in the shipment are no longer required or damaged. A destruction shipment can be cancelled if necessary.</p>
 Confirmed	<p><i>Confirmed</i> The shipment request has been acknowledged by the depot.</p> <p>When a shipment is automatically received at a site through an integration, its status is updated to <i>Confirmed</i>.</p>
 Destroyed	<p><i>Destroyed</i> The kits in the shipment have been destroyed.</p> <p>A shipment's status is updated to <i>Destroyed</i> by a clinical supply manager or depot user, after all kits in the shipment have been destroyed during the depot return process.</p>
 In Transit	<p><i>In Transit</i> The shipment has left the depot (warehouse) and it is on its way to the site.</p> <p>A shipment's status is updated to <i>In Transit</i>:</p> <ul style="list-style-type: none">• Automatically: when a shipment is automatically created and its ship date and tracking link is automatically set through an integration.• Manually: when a shipment's ship date is manually updated by a clinical supply manager.
 Invalid	<p><i>Invalid</i> The shipment request could not be processed.</p> <p>A shipment's status is updated to <i>Invalid</i>:</p> <ul style="list-style-type: none">• Automatically: when an issue occurs with the shipment request, for an integration with the Almac Global Depot Network. Or when Catalent Clinical Supply Services cancel a shipment request during an integration with their system.



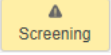


Shipment status icon	Description
 Lost	<p data-bbox="922 247 971 268"><i>Lost</i></p> <p data-bbox="922 275 1455 327">The shipment has been lost while being on its way to the site.</p> <p data-bbox="922 338 1455 449">A shipment's status is manually updated to <i>Lost</i>, typically by a clinical supply manager, when they have received notice that the shipment might be lost during its transit.</p>
 Pending	<p data-bbox="922 470 1013 491"><i>Pending</i></p> <p data-bbox="922 497 1455 581">The shipment has just been created in the system and it is pending an update. This is a shipment's first status.</p> <p data-bbox="922 592 1370 613">A shipment's status is updated to <i>Pending</i>:</p> <ul data-bbox="922 619 1455 735" style="list-style-type: none"> <li data-bbox="922 619 1455 672">• Automatically: when a shipment is automatically created through an integration. <li data-bbox="922 678 1455 735">• Manually: when a clinical supply manager creates a new shipment for a site.
 Pending Destruction	<p data-bbox="922 751 1143 772"><i>Pending Destruction</i></p> <p data-bbox="922 779 1455 831">The kits in the shipment are ready to be destroyed, whether at a site or depot facility.</p> <p data-bbox="922 842 1455 987">A shipment's status is updated to <i>Pending Destruction</i> once it has been marked as <i>Pending Destruction</i> at the site and the depot is being used as a destruction facility. The Update & Ship prompt will appear when users update the kit status.</p>
 Received	<p data-bbox="922 1003 1029 1024"><i>Received</i></p> <p data-bbox="922 1031 1305 1052">The shipment is received by the site.</p> <p data-bbox="922 1062 1455 1150">A shipment's status is updated to <i>Received</i> the moment a site user registers the shipment in the site's inventory.</p>
 Received For Destruction	<p data-bbox="922 1167 1192 1188"><i>Received For Destruction</i></p> <p data-bbox="922 1194 1455 1247">The kits in the shipment have been confirmed and received for destruction by the depot facility.</p> <p data-bbox="922 1257 1455 1344">A shipment's status is updated to <i>Received For Destruction</i> after a depot user confirms each kit in the shipment they received for destruction.</p>




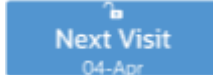
6

Visit status and icon descriptions

When you open the study, on the Subjects tab, you are able to view the visit board displaying attended visits in the **Previous Visits** column. Each visit is displayed in a specific color according to its status and type.

Labels	Description
Figure 6-1 Scheduled Visit 	<i>Complete</i> The subject has attended this visit and all forms are completed. A complete scheduled visit label is displayed in a light green color. Screening and unscheduled visit labels are displayed in a light blue tone when complete. <i>If a subject completes the screening visit but does not meet the criteria to join the study, the visit is displayed as Failed Screening with an X icon next to the screening icon (👤❌) and the visit is displayed in a red tone.</i>
Figure 6-2 Unscheduled Visit 	
Figure 6-3 Screening Visit 	
Figure 6-4 Failed Screening Visit 	
Figure 6-5 Complete Visit with Queries 	<i>Complete with errors</i> A complete visit that has open queries associated with it. A visit with errors label contains a question mark icon (❓) and is displayed in a red tone.

Labels	Description
<p>Figure 6-6 Incomplete Scheduled Visit</p> 	<p><i>Incomplete</i> The visit was completed at one point, but there are now one or more required questions that are unanswered due to clearing a question's response or adding a new form or question. The visit label contains a warning icon (⚠) and is displayed in a yellow color. <i>A subject can fail screening before completing the visit, leaving unanswered questions. In this case the visit is displayed as Incomplete and Failed Screening. This visit is displayed in a red tone.</i></p>
<p>Figure 6-7 Incomplete Unscheduled Visit</p> 	
<p>Figure 6-8 Incomplete visit label of Withdrawn subject</p> 	
<p>Figure 6-9 Failed Screening Visit</p> 	
<p>Figure 6-10 Incomplete Visit with Queries</p> 	<p><i>Incomplete with errors</i> An incomplete visit that has open queries associated with it. A visit with errors label contains a question mark icon (❓) and is displayed in a red tone.</p>
<p>Figure 6-11 Optional Visit</p> 	<p><i>Optional</i> Depending on how a study is set up, you might be able to skip a visit that a subject misses. You can always skip an optional visit.</p>

Labels	Description
<p>Figure 6-12 Skipped Visit</p> 	<p><i>Skipped</i> The visit has been skipped and this can be due to the following reasons:</p> <ul style="list-style-type: none"> • Not Scheduled • Visit Canceled • On Vacation • No Show • Investigator Correction • Data Not Available • Not Required per Protocol • Other <p>This visit label contains an X icon (✖) and is displayed in a light purple color. <i>A skipped visit cannot be populated by a Data Intake integration. To resolve, undo the skipped visit and re-import the file.</i></p>
<p>Figure 6-13 Not Started Visit</p> 	<p><i>Not Started</i> When data is automatically loaded in a future visit, out of chronological order, through a Data Intake integration, previously not started visits are displayed with a dotted outline and a (Not Started) label. For more information review How do visits display in subject listings view, when integrations populate a future visit?</p>
<p>Figure 6-14 Locked Visit</p> 	<p><i>Locked</i> The visit has been locked.</p> <p>A locked visit contains a closed padlock icon (🔒).</p>
<p>Figure 6-15 Unlocked Visit</p> 	<p><i>Unlocked</i> The visit has been unlocked.</p> <p>An unlocked visit contains an open padlock icon (🔓).</p>



Note:

Each of these visit labels may display additional icons depending on whether the data is signed, unsigned, verified, unverified and/or frozen. See [Signing, verifying, freezing, and locking icon descriptions](#).








Related Topics

- What actions impact subjects?

7

Form icon descriptions in study design

Learn more about the icons associated with forms in study design.

Icon	What it means
	Indicates it is a lab form.
	Indicates that a question in the form is used for calculating doses in a kit type.
	Indicates the form has been copied from another study. <i>You can hover over the icon to reveal the study the form was copied from and when it was last modified.</i>
	Indicates the form has been copied from another study with some or no rules.
	Indicates a question in the form has been used in a rollover study.
	Indicates a question in the form is used to stratify subjects at randomization.
	Indicates that a question in the form is used to assign subjects to a branch.

8

Form status icon descriptions




Learn more about the form status icons displayed next to a form's title, on the **Forms** sidebar.

These icons are only visible for forms in a Production, Testing, or Training study. For the form icons displayed in a study's design, see [Form icon descriptions in study design](#).

 **Note:**

For repeating forms and two-section forms, consider the following:

- For a repeating form, the form status icon displayed on the sidebar indicates the cumulative status of all repeating form instances.
- For a two-section form, the form status icon displayed on the sidebar indicates the cumulative status of all two-section form instances. On the **Forms** sidebar, you can expand a two-section form and see the status of an individual form instance.

Icon	Description
	Indicates that a form is complete after all of its required questions were answered without any validation errors.
	Indicates when a form is incomplete. This may happen when at least one required field is incomplete.
	Indicates when at least one field in a form contains a validation error.

9

Revision history

Table 9-1 Revision History

Date	Part Number	Description
01-July-2024	F95738-03	A new topic was created to include updated form status icons displayed for visits in a live study. For more information, see Form status icon descriptions .
10-May-2024	F95738-02	Formatting updates were made throughout the publication.
02-May-2024	F95738-01	Original version of the document.