

Oracle® Health Sciences Clinical One Platform

Icon Reference



Release 22.1

F54347-01

April 2022

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

ORACLE®

Oracle Health Sciences Clinical One Platform Icon Reference, Release 22.1

F54347-01

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

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You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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1

Kit statuses and their meanings




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) and Kit Inventory (Unblinded) reports in Oracle Clinical One Platform


Status icon	What it means	How a kit reaches this status
 Available	Available 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 Available: <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	Damaged 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 Damaged.
 Damaged by Subject	Damaged by subject 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 Damaged by Subject during the kit reconciliation process. If a kit replacement occurs and the user marks the kit as Damaged, the status of the kit will change to Damaged by Subject.


Status icon	What it means	How a kit reaches this status
 Destroyed	<p>Destroyed 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 Destroyed. • 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 Destroyed.
 Dispensed	<p>Dispensed The kit was dispensed to a subject during a dispensation visit.</p>	<p>The kit's status automatically changes to Dispensed after a site user dispenses it to a subject.</p>

 **Note:**



Only Pending Destruction kits can be marked as Destroyed.

Status icon	What it means	How a kit reaches this status
 Expired	Expired The investigational product exceeded its expiration date.	The system automatically updates the status of the kit to Expired when it exceeds its expiration date.
 In Transit	In Transit The kit is being shipped from a depot to a site.	A shipment request was made by a site or sponsor user for that kit, and the ship date has been provided.
 Lost by Subject	Lost by Subject 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.	A site user marks the kit as Lost by Subject during the kit reconciliation process. If a kit replacement occurs and the user marks the kit as Lost, the status of the kit will change to Lost by Subject.

Status icon	What it means	How a kit reaches this status
 Misallocated	<p>Misallocated 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 Misallocated.</p>

 **Note:**

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

Status icon	What it means	How a kit reaches this status
		<p>me nt kit, the site use r wo n't be abl e to dis pen se a repl ace me nt kit.</p>
 Missing	<p>Missing 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 Missing.</p>
 New	<p>New 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 New.</p>





Status icon	What it means	How a kit reaches this status
 Not Dispensed to Subject	<p>Not Dispensed to Subject 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 Not Dispensed to Subject.</p>



 **Note:**

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

Status icon	What it means	How a kit reaches this status
○ Not in Use	<p>Not in Use 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 Not in Use. 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 Not in Use or has just been uploaded to Production.</p>
🗑 Pending Destruction	<p>Pending Destruction The kit is ready to be destroyed.</p>	<p>Typically, the Clinical Research Associate (CRA) verifies the kit and then marks it as Pending Destruction. The user must provide a reason for the status update.</p>

before dispensing a replacement kit, the site user won't be able to dispense a replacement kit.

Status icon	What it means	How a kit reaches this status
 Pre-quarantined	<p>Pre-quarantined 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 Available. If the kit can't be dispensed, the kit's status is updated to Quarantined so that it isn't considered part of the site's inventory anymore.</p>	<p>The sponsor user marks the kits as Pre-quarantined.</p> <div style="border-left: 2px solid #0070C0; padding-left: 10px; margin-top: 20px;"> <p> Note:</p> <p>A pre-quarantined kit is counted in a site's inventory.</p> </div>
 Quarantined	<p>Quarantined A kit failed to comply with the shipment or storage requirements, and it was damaged as a result. A Quarantined 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 Quarantined.</p>
 Received for Destruction	<p>Received for Destruction 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>





Status icon	What it means	How a kit reaches this status
 Returned to Site	Returned to site 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.	A site user changes the status of the kit to Returned to Site and indicates the number of returned and missing units.
 Temporarily Unavailable	Temporarily Unavailable A kit is temporarily on hold and can't be dispensed or shipped.	A site or sponsor user marks the kit as Temporarily Unavailable.

2

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> Note: 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.</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 Ruler Publisher.</p>

Rule status icon**What it means****Published**

Represents a rule that has been published by a Rule Publisher.

 **Note:**







A rule will automatically return to Draft status if Edit is selected.

3


Signing, verifying, and freezing icon descriptions


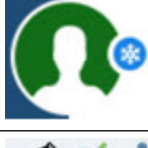
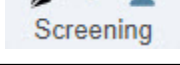
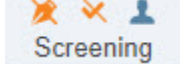
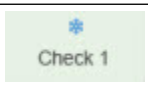
Learn about the different icons that represent signing, verifying, and freezing data.

Each sign, verify, or freezing 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 a subject's icon.
	This icon appears whenever a site user in the study updates question or visit data on a completed 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 a subject's icon.
	This icon appears whenever a Clinical Research Associate verifies a question.
	This icon appears whenever a site user in the study updates question or visit data on a completed 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 data is frozen on a completed or incomplete form, and the subject's data becomes read-only. It appears on subject visit cards and next to every question and form associated with a visit.
	This icon appears on the visit tile and next to each question that is unfrozen by a data manager on a completed or incomplete form.

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.






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


4

Shipment statuses and icons

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

Shipment status	Description	Shipment status icon
Cancelled	<p>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 Cancelled 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>	 Cancelled
Confirmed	<p>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 Confirmed.</p>	 Confirmed
Destroyed	<p>The kits in the shipment have been destroyed.</p> <p>A shipment's status is updated to Destroyed by a clinical supply manager or depot user, after all kits in the shipment have been destroyed during the depot return process.</p>	 Destroyed
In Transit	<p>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 In Transit:</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.	 In Transit

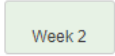

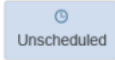
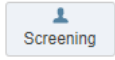


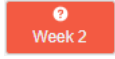
Shipment status	Description	Shipment status icon
Invalid	<p>The shipment request could not be processed.</p> <p>A shipment's status is updated to Invalid:</p> <ul style="list-style-type: none"> Automatically: when a an issue occurs with the shipment request, for an integration with the Almac Global Depot Network. Or when Catalent Clinical Supply Services cancel a shipment request during an integration with their system. 	 Invalid
Lost	<p>The shipment has been lost while being on its way to the site.</p> <p>A shipment's status is manually updated to Lost, typically by a clinical supply manager, when they have received notice that the shipment might be lost during its transit.</p>	 Lost
Pending	<p>The shipment has just been created in the system and it is pending an update. This is a shipment's first status.</p> <p>A shipment's status is updated to Pending:</p> <ul style="list-style-type: none"> Automatically: when a shipment is automatically created through an integration. Manually: when a clinical supply manager creates a new shipment for a site. 	 Pending
Pending Destruction	<p>The kits in the shipment are ready to be destroyed, whether at a site or depot facility.</p> <p>A shipment's status is updated to Pending Destruction once it has been marked as Pending Destruction 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>	 Pending Destruct
Received	<p>The shipment is received by the site.</p> <p>A shipment's status is updated to Received the moment a site user registers the shipment in the site's inventory.</p>	 Received




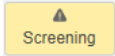


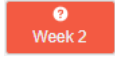

Shipment status	Description	Shipment status icon
Received for Destruction	The kits in the shipment have been confirmed and received for destruction by the depot facility. A shipment's status is updated to Received for Destruction after a depot user confirms each kit in the shipment they received for destruction.	 Received For Des




5

Visit statuses and icons

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.

Status	Description	Labels
Complete	<p>The subject has attended this visit and all forms are completed.</p> <p>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.</p>	<p>Figure 5-1 Scheduled Visit</p> 
	<p>Note:</p> <p>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.</p>	<p>Figure 5-2 Unscheduled Visit</p> 
		<p>Figure 5-3 Screening Visit</p> 
		<p>Figure 5-4 Failed Screening Visit</p> 
Complete with errors	<p>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.</p>	<p>Figure 5-5 Complete Visit with Queries</p> 

Status	Description	Labels
Incomplete	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.	Figure 5-6 Incomplete Scheduled Visit 
	Note: A subject can fail screening before completing the visit, leaving unanswered questions. In this case the visit is displayed as <i>Incomplete</i> and <i>Failed Screening</i> . This visit is displayed in a red tone.	Figure 5-7 Incomplete Unscheduled Visit 
		Figure 5-8 Incomplete visit label of Withdrawn subject 
		Figure 5-9 Failed Screening Visit 
Incomplete with errors	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.	Figure 5-10 Incomplete Visit with Queries 
Optional	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.	Figure 5-11 Optional Visit 

Status	Description	Labels
Skipped	<p>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.</p>	<p>Figure 5-12 Skipped Visit</p> 
Not Started	<p>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 5-13 Not Started Visit</p> 

 **Note:**

A skipped visit cannot be populated by a Data Intake integration. To resolve, undo the skipped visit and re-import the file.

 **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, and freezing icon descriptions](#).










Related Topics

- [What actions impact subjects?](#)

6

Form icons and their meanings

Learn more about the icons associated with forms.

Icon	What it means
	Indicates the form is locked.
	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.
<div data-bbox="1122 997 1458 1283"><p> Tip:</p><p>You can hover over the icon to reveal the study the form was copied from and when it was last modified.</p></div>	
	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.