Oracle® Life Sciences Clinical One Platform

Release Assessment Environment Guide

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Oracle Life Sciences Clinical One Platform Release Assessment Environment Guide, Release 24.1.1

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Contents

Preface

This preface contains the following sections:

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

About the Release Assessment Environment

The Oracle Clinical One Platform **Release Assessment Environment**, managed by Oracle, allows customers to evaluate new features included in an upcoming minor release before they are released into a Production environment. Access is included with the purchase of a Production instance of the Oracle Clinical One Platform.

> **WARNING:**
>
> Production study subject data should never be entered or used in the Release Assessment Environment.

Before a new version of the Oracle Clinical One Platform is released to Production, customers can use the Release Assessment Environment for the following activities:

- Test new features before implementing them in existing and future studies.
- Determine if updates are needed in SOP's or other process documentation.
- Train end-users on new features.

For each minor release of the Oracle Clinical One Platform, Oracle posts announcements to the Oracle Life Sciences Support Cloud.

> **Note:**
>
> For more information on a release's announcements and how you can subscribe, see Subscribe to release announcements.

2

Studies in the Release Assessment Environment

The Release Assessment Environment includes both pre-configured and blank studies. Study access is controlled by Oracle when an active contract is in place.

All customers receive two (2) studies

Here's what's included with the purchase of a production Oracle Clinical One Platform service.

- One (1) Oracle-built template study (pre-configured), which includes the basic study structure with no subjects.
- One (1) blank study consisting of an empty study container with no pre-configured design, allowing customers to build a study to meet specific needs.
- Customers can request up to three (3) additional blank studies.

Studies are made available in draft and test modes, with one (1) being pre-configured by Oracle in test mode. The customer is responsible for all other configuration.

> **Note:**
>
> Customers, if needed, can promote the study to production or training mode but should be aware that they are responsible for all configurations.

3

Accounts, user roles, and environment access

The Release Assessment Environment comes with pre-defined study roles so you can easily review new features using multiple roles.

Accounts and user roles

> **Note:**
>
> For new study designer accounts it is a best practice to request both the **Assessment Designer** and **Assessment Tester** roles be associated to the account. This will allow the study designer to verify their study design prior to having other users start testing.

> **Tip:**
>
> Refer to the ***Ticketing details*** section below to see how to complete a request.

Create tickets in the Oracle Life Sciences Support Cloud to request the following:

- Access to the Release Assessment Environment (RAE)
- Additional user accounts
- Change a study role for a user
- Terminate a user account.

> **Caution:**
>
> It is the customer's responsibility to ensure active user accounts in the Oracle Clinical One Platform Release Assessment Environment are terminated should a member of your team leave your organization.

Accessing the Release Assessment Environment

Users receive the following emails the Release Assessment Environment as **Customer Release Assessment** and include a reference to the tenant used in the environment, **CUSTREL**.

The account details in the emails are different or separate from the account details tied to your organizations-specific tenant. The credentials in these emails only allow you to access the Release Assessment Environment.

- Users receive an email with the subject, ***Oracle Life Sciences Cloud – New Account in Customer Release Assessment***. This email contains their Oracle Life Sciences single sign-on (SSO) account log in name and instructions to setup a password.

> **Note:**
>
> If you need to reset your password after the initial setup, use the ***Trouble Signing In?*** link that is available when you first log in to the Release Assessment Environment.

- The Release Assessment Environment URL is provided in a separate email with the subject, ***Access Information for the xxxx study in Clinical One***. This email contains the link, ***Sign in to your study***.
- If you experience any issues logging in after following the steps above, refer to section 5 Support in this guide for details opening a Support Request (SR).

Ticketing details

1. Log in to Oracle Life Sciences Support Cloud.
2. Click **Create Request** in the upper-right corner, then select **Support Request**.
3. Complete the fields as defined below:

Table 3-1 Ticketing information

Field	Description
Summary for environment access	Requesting initial access to the Release Assessment Environment
Description for environment access	Include first name, last name, email address and the desired study role for each Study Mode (Design, Testing, Production and Training). **Note:** Study role names can be found in the table below.
Summary for additional accounts	Requesting additional Clinical One Release Assessment Environment user accounts
Description for additional accounts	Include first name, last name, email address and the desired study role for each Study Mode (Design, Testing, Production and Training).
Summary for a study role change	Requesting a change in study role for the Clinical One Release Assessment Environment
Description for a study role change	Include first name, last name, email address, new study role to be assigned for each Study Mode (Design, Testing, Production and Training), and the study(s) in which the role should be changed.
Summary for user termination	Requesting user termination for the Clinical One Release Assessment Environment
Description for user termination	Include first name, last name, email address, and the termination date (effective immediately or scheduled date) for the user to be terminated.
Severity	3 - Medium
Issue Category	User Roles and Privileges

Table 3-1 (Cont.) Ticketing information

Field	Description
Customer	Customer name
Product	Clinical One
Business Service	Clinical One - customer name
Environment	Assessment

Roles and permissions

- Permissions cannot be added or removed.
- Roles with the *View Role Assignments for Study Users* permission can view the permissions assigned to each role.

Table 3-2 Default roles and permissions

Clinical One Study Roles	Permissions assigned
Assessment Clinical Research Associate (CRA)	• Answer Assigned Queries • Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Close Queries • Create and Manage SDV Strategies • Create and Manage Sites • Create Candidate Queries • Create Queries • Create Shipments to DDF • Delete Candidate Queries • Edit Classified Subject Data Only • Edit Regions • Edit Study Settings • Manage Archives Settings • Manage Signature Settings • Move a Study Design to Testing or Production • Perform Source Data Verification and Reconcile Inventory • Perform Supplies Reconciliation at Site • Receive Rule Failure Notification for Locked Data • Receive Site has been Updated Notification • Receive the Code Break Notification • Receive the Pending Signatures Notification • Receive the Study Limits Notifications • Receive the Subject Number Update Notification • Receive the Subject Transferred Notification • Receive the Subject Withdrawal Notification • Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation • Run and download Site Confirmation and Download Log audit reports • Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Kits Dataset • Run the Study Query Dataset • Run the Study Roles Report • Run the Study Rules Report • Run the Subject Data Extract • Run the Subject Data Report

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the User Assignment Report • Transfer subjects between sites • Update Subject Number after Creation • Verify subject data entered at a site • View Blinded Dispensation Details with Calculated Doses • View Classified Subject Data Only • View Depots • View Form Data for Subjects • View Queries • View Regions • View Role Assignments for Study Users • View Shipments to Sites • View Site Inventory • View Sites • View Study Design • View Study Settings

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
Assessment Clinical Supply Manager (CSM)	• Answer Assigned Queries • Assign a Resupply Strategy to a Depot • Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Manage Depots • Create and Manage Dispensation Exceptions • Create and Manage Lots • Create and Manage Sites • Create Manual Shipments • Create Manual Shipments (Unblinded) • Create Shipments to Depots • Edit Classified Subject Data Only • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Manage Randomization Lists • Manage Study Inventory for Unblinded Users • Move a Study Design to Testing or Production • Receive and Reconcile Shipments at the Depot • Receive New Shipments at the Depot • Receive Notification of Depot Shipments • Receive Notification of Shipments • Receive Site has been Updated Notification • Receive the Quarantined Depot Shipment Notification • Receive the Quarantined Site Shipment Notification • Receive the Released from Quarantine Notification (Depot) • Receive the Study Limits Notifications • Receive the Unblinded Dispensation Notification • Release Shipments from Quarantine • Reveal the Treatment Arm for a Subject, or Code View • Run the Blinded Chain of Custody Report • Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Kits Dataset • Run the Study Query Dataset

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• Run the Study Roles Report • Run the Study Rules Report • Run the Subject Data Extract • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the Unblinded Kits Dataset • Run the Unblinded Randomization Report • Run the Unblinded Subject Events Dataset • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report • Run the User Assignment Report • Update Inventory Lists **WARNING:** Users with this permission can make supply updates that may be detrimental to your study. For more information, see Descriptions of permissions in Clinical One. • Update Supplies after Design Approval **WARNING:** Users with this permission can make supply updates that may be detrimental to your study. For more information, see Descriptions of permissions in Clinical One. • Update the Shipment Order Form • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View All Queries • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• View Depots • View Form Data for Subjects • View Regions • View Role Assignments for Study Users • View Shipments to Sites • View Site Inventory • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
Assessment Data Manager (DM)	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Answer Assigned Queries • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Close Queries • Create and Add Labs to a Site • Create and Manage SDV Strategies • Create Candidate Queries • Create Queries • Delete Candidate Queries • Edit Classified Subject Data Only • Freeze subject data entered at a site • Lock subject data entered at a site • Receive the Study Limits Notifications • Receive the Subject Completion Notification • Receive the Subject Number Update Notification • Receive the Subject Rollover Notification • Receive the Subject Withdrawal Notification • Receive the Unscheduled Visit Notification • Run and download Site Confirmation and Download Log audit reports • Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Kits Dataset • Run the Study Query Dataset • Run the Study Roles Report • Run the Study Rules Report • Run the Subject Data Extract • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the User Assignment Report • Schedule Reports to Run • Unfreeze subject data entered at a site

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Depots • View Form Data for Subjects • View Queries • View Regions • View Role Assignments for Study Users • View Shipments to Sites • View Site Inventory • View Sites • View Study Design • View Study Settings
Assessment Designer	• Assignment Report (Design Mode) • Design Clinical Supplies Form • Design Forms • Design Randomization • Design SDV Properties on Forms • Design Supplies and Dispensation • Design Visits and Events • Manage Study Code Lists • Run the Analytics Study Codelist Dataset • Run the Data Collection Design Dataset • Run the Draft Study Design Report • Run the Kits and Randomization Design Dataset • Run the Study Roles and User • View Design

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
Assessment Tester	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Approve and Sign Assigned Data Only • Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Add Labs to a Site • Create and Manage Depots • Create and Manage Lots • Create and Manage SDV Strategies • Create and Manage Sites • Design Custom Rules • Dispense Kits with Calculated Doses • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit General Study Settings • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Edit Visit Dates • Manage Randomization Lists • Manage Signature Settings • Manage Study Inventory for Unblinded Users • Move a Study Design to Testing or Production • Publish Custom Rules • Randomize Subjects • Receive and Reconcile Shipments at the Depot • Receive Notification of Shipments • Receive Site has been Updated Notification • Receive the Code Break Notification • Receive the Dispensation Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Pending Signature Notification • Receive the Randomization Notification • Receive the Study Limits Notifications • Receive the Subject Screening Notification • Receive the Subject Transferred Notification • Receive the Subject Visit Notification • Receive the Subject Withdrawal Notification • Receive the Unblinded Dispensation Notification • Receive the Unblinded Pharmacist Dispensation Notification • Receive the Unblinded Randomization Notification • Re-run Rules • Reveal the Treatment Arm for a Subject, or Code View

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation • Run and download Site Confirmation and Download Log audit reports • Run the Blinded Inventory Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Kits Dataset • Run the Study Query Dataset • Run the Study Roles Report • Run the Study Rules Report • Run the Subject Data Extract • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Randomization Data Extract Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the Unblinded Kits Dataset • Run the Unblinded Randomization Report • Run the Unblinded Subject Events Dataset • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report • Run the User Assignment Report • Skip Visits • Test Custom Rules • Unblind the Treatment Arm for a Subject, or Code Break • Update Inventory Lists **WARNING:** Users with this permission can make supply updates that may be

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	detrimental to your study. For more information, see Descriptions of permissions in Clinical One. • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View All Queries • View Blinded Dispensation Details with Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries • View Role Assignments for Study Users • View Shipments to Sites • View Site Inventory • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • View Unblinded Pharmacist Kits

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
Assessment PI Role	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Answer Assigned Queries • Answer Queries • Approve and Sign Assigned Data Only • Approve and sign subject data • Confirm download of Archival PDFs and content • Create and Add Labs to a Site • Create Shipments to DDF • Dispense Kits with Calculated Doses • Dispense Kits without Calculated Doses • Download Archival PDFs, and Audit Reports • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit Visit Dates • Randomize Subjects • Receive Notification of Shipments • Receive Shipments and Update Site Inventory • Receive the Code Break Notification • Receive the Dispensation Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Pending Signature Notification • Receive the Quarantined Site Shipment Notification • Receive the Randomization Notification • Receive the Released from Quarantine Notification (Site) • Receive the Subject Number Update Notification • Receive the Subject Screening Notification • Receive the Subject Transferred Notification • Receive the Subject Visit Notification • Receive the Subject Withdrawal Notification • Run Archival PDFs for your site(s) • Run the Blinded Inventory Report • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Subject Data Report • Run the Subject Events Report • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the User Assignment Report • Skip Visits • Unblind the Treatment Arm for a Subject, or Code Break

Table 3-2 (Cont.) Default roles and permissions

Clinical One Study Roles	Permissions assigned
	• View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries • View Shipments to Sites • View Site Inventory
Assessment Unblinded Site User	• Create Manual Shipments • Create Shipments to DDF • Edit Classified Subject Data Only • Perform Supplies Reconciliation at Site • Receive Notification of Shipments • Receive Shipments and Update Site Inventory • Receive the Code Break Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Quarantined Site Shipment Notification • Receive the Released from Quarantine Notification (Site) • Receive the Subject Number Update Notification • Receive the Unblinded Pharmacist Dispensation Notification • Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Subject Data Report • Run the Subject Events Report • Run the Titration Summary Report • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Shipments to Sites • View Site Inventory • View Unblinded Pharmacist Kits

Related Topics

- Descriptions of permissions in Oracle Clinical One Platform

4

Integrations

The Release Assessment Environment is a different environment outside your Production environment where you create and manage your live studies as an organization.

Because the Release Assessment Environment is used strictly for assessment purposes, any integrations you may have configured in your current Production environment will not work in the Release Assessment Environment. This also includes any APIs being used to interact with production study data and access Oracle Clinical One Platform services.

However, you will be able to generate **Oracle CRF Submit** archives. Additionally, you can also generate reports and dashboards in Oracle Clinical One Analytics, based on the data entered in your studies in the Release Assessment Environment.

5
Support

While you are fully in charge of reviewing new features in the Release Assessment Environment, you can always contact Oracle Life Sciences Support to help with any issues that arise during your assessment process.

Ticketing details

Enter a Support Request using the following details.

1. Log in to Oracle Life Sciences Support Cloud.
2. Click **Create Request** in the upper right corner, then select **Support Request**.
3. Complete the fields as defined below.

Table 5-1 Ticketing information

Field	Description
Summary	Provide a brief summary of the issue.
Description	Provide all necessary issue details to aid the support engineers. This should include your first name, last name, email address and current study role assigned as well as any other relevant details.
Severity	3 - Medium
Issue Category	Select the category that best describes your issue.
Customer	Customer name
Product	Clinical One
Business Service	Clinical One - customer name
Environment	Assessment

If you would like to implement new features in your Production studies work with your study build team to make changes once this Oracle Clinical One Platform release is available.

If you require additional studies, above the standard Release Assessment Environment offering a separate tenant can be purchased. For more information please reach out to your Oracle sales representative.

6
Documentation and resources

We offer a variety of resources to aid in your review of new features in the Release Assessment Environment.

For more information, visit the Oracle Help Center (OHC) after the upgrade completes. You can find updated release notes, user guides and other release documentation here.

Table 6-1 Documentation release time lines

Document/Resource	Availability
Draft Release Notes	Available upon request two (2) weeks before the Release Assessment Environment upgrade. To request a draft version of the Release Notes, reach out to your Oracle point of contact.
All other release documentation	Available after the Release Assessment Environment upgrade completes. This includes updated user and reference guides and all other release related content that is posted to the Oracle Help Center (OHC). **Note:** This may include an updated version of the Release Notes, check the revision history.
Product Verification Package (PVP)	Available after the Release Assessment Environment upgrade completes. For more information, see About the Product Verification Pack (PVP).

Table 6-1 (Cont.) Documentation release time lines

Document/Resource	Availability
Final Release Notes	Available after the Production upgrade completes. **Note:** The Release Notes is a living document that can change from the initial draft release until the Production upgrade completes. Check the revision history in the Release Notes at any time to view the document history.

7 Revision history

Date	Part number	Description
09-July-2024	F93085-05	The following permission was added to the Assessment Tester study role as a part of the 24.1.1 release. • *Run the Subject Randomization Data Extract Report*
May 2024	F93085-04	Consolidated information related to the announcement strategy included in About the Release Assessment Environment. For more information related to the announcement strategy for releases, see Subscribe to release announcements .
May 2024	F93085-03	Created this new version to add missing information to the Revision history topic.
May 2024	F93085-02	Updated the following topic to describe the new release announcement strategy: • About the Release Assessment Environment
May 2024	F93085-01	Original version of this document.