Oracle® Health Sciences Clinical One Platform

Assessment Environment Guide

Release 22.2

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Oracle Health Sciences Clinical One Platform Assessment Environment Guide, Release 22.2

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Part I Revision history

Preface

This preface contains the following sections:

- Documentation accessibility
- 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.

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 of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

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

About the Assessment Environment (AE)

The Oracle Clinical One Platform **Assessment Environment (AE)**, created by the Oracle team allows you to evaluate new features included in each quarterly release.

Intended Audience: This is the first version of the Clinical One Assessment Environment (AE) guide. The initial version of the guide is being released to align with Clinical One Platform version 21.4 coming in Jan2022. This version of the guide is specifically being released for the **Customer Release** area and will be updated with future releases of the Clinical One Platform in order to accommodate additional, future use of the Assessment Environment (AE) for other purposes.

The Assessment Environment (AE) will be upgraded two weeks prior to the production upgrade. Accessing the Assessment Environment (AE) will allow you to gain an understanding of each feature to determine if you want to utilize the new feature(s) in your study design/management practices, and to plan for study changes prior to the new features being released into Production.

For each release of the Oracle Clinical One Platform, that include new features, customers will receive notifications from the Oracle team about Assessment Environment (AE) availability and the production upgrade. The following notifications will be made available on Oracle Health Sciences Support Cloud under Notifications.

- The **first announcement** will be posted two weeks prior to Assessment Environment (AE) availability and will include,
  - Details about the upcoming Assessment Environment (AE)
  - Production release upgrade dates
- The **second announcement** will be posted upon successful completion of the Assessment Environment (AE) upgrade to the new release informing customers that the Assessment Environment (AE) is now available.
  - The Oracle team will post the release documentation on the Oracle Help Center (OHC) to aid in your review process.
  - The announcement will also include the production release upgrade dates.
- The **third announcement** will be posted upon successful completion of the production upgrade to the new release.

2

Studies in the Assessment Environment (AE)

The Assessment Environment (AE) will contain pre-configured and blank studies that can be used to assess the new features.

- One study will be **pre-configured** containing study design basics such as, visits, forms, questions, kits, etc. as a starting point.
- Other studies will be **blank**, allowing you to design studies, including the new features to further assess if and how the features can be utilized to fit your specific study design needs.
- **Production study subject data** should never be entered or used in the Assessment Environment (AE).
- **Codelists** created in the Assessment Environment (AE) will be visible in other customer studies. If codelists need to be created, carefully consider the content to ensure no company information is contained in a codelist.
- The Assessment Environment (AE) should only be used for reviewing new features with your study design or overall Sponsor teams to prepare for the release. If you want to train site users, you must do so in the Training mode of your Production environment once the features are released.

3

Accounts, user roles, and environment access

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

Accounts and User Roles

You can enter tickets at Oracle Health Sciences Support Cloud, using the ticketing details provided below.

- To request access to the Assessment Environment (AE).
- To request additional user accounts.

> **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.

- To request a change of Study Role for an existing user.
- To terminate an Assessment Environment (AE) user account.

> **Note:**
>
> It is your responsibility to ensure active user accounts in the Clinical One Assessment Environment (AE) are terminated by Oracle should a member of your team leave your organization.

Accessing the Assessment Environment

> **Note:**
>
> The following emails refer to the Assessment Environment as, **Customer Release Assessment**, and will include a reference to the tenant used in the environment, **CUSTREL.**The account details in the emails are different/separate from the account details tied to your organizations specific tenant. The credentials in these emails will only allow you to access the Assessment Environment.

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

- 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 Assessment Environment.
- The Assessment Environment URL will be 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: Log into Oracle Health Sciences Support Cloud to create a Support Request using the details below.

> **Note:**
>
> You can include multiple requests in the same ticket.

- **Customer:** Customer name
- **Product:** Clinical One
- **Business Service:** Clinical One - <customer name>
- **Oracle Internal:** No
- **Environment:** Assessment
- **Severity:** 3-Medium
- **Issue Category:** User Roles and Privileges
- **Summary example 1:** Requesting initial access to the Assessment Environment
- **Description Details:** Include first name, last name, email address and the desired study role for each Study Mode (Design, Testing, Production and Training).
- **Summary example 2:** Requesting additional Clinical One Assessment Environment user accounts
- **Description Details:** Include first name, last name, email address and the desired study role for each Study Mode (Design, Testing, Production and Training).
- **Summary example 3:** Requesting a change in study role for the Clinical One Assessment Environment
- **Description Details:** 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 example 4:** Requesting user termination for the Clinical One Assessment Environment
- **Description details:** Include first name, last name, email address, and the termination date (effective immediately or scheduled date) for the user to be terminated.

Table 3-1 Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
Assessment CRA	• Run the Study Roles Report • Run and download Site Confirmation and Download Log audit reports • Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation • Edit Classified Subject Data Only • Verify subject data entered at a site • View Blinded Dispensation Details with Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries • Run the Subject Data Extract • Perform Supplies Reconciliation at Site • View Shipments to Sites • View Site Inventory • Receive Site has been Updated Notification • Receive the Code Break Notification • Receive the Study Limits Notifications • Receive the Subject Transferred Notification • Receive the Subject Withdrawal Notification • 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 Rules Report • 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 • Answer Assigned Queries • Close Queries • Create Candidate Queries • Create Queries

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• Create Shipments to DDF • Delete Candidate Queries • Perform Source Data Verification and Reconcile Inventory • Transfer subjects between sites • Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Manage SDV Strategies • Create and Manage Sites • Edit Regions • Edit Study Settings • Move a Study Design to Testing or Production • View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
Assessment Clinical Supply Manager	• Run the Study Roles Report • Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • Run the Subject Data Extract • Create Manual Shipments • Receive and Reconcile Shipments at the Depot • Update Supplies after Design Approval • View Shipments to Sites • View Site Inventory • Receive Notification of Shipments • Receive Site has been Updated Notification • Receive the Study Limits Notifications • Receive the Unblinded Dispensation Notification • 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 Rules Report • 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 Randomization Report • Run the Unblinded Subject Events Dataset • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• Run the User Assignment Report • Answer Assigned Queries • View All Queries • 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 Lots • Create and Manage Sites • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Move a Study Design to Testing or Production • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Manage Randomization Lists • Manage Study Inventory for Unblinded Users • Reveal the Treatment Arm for a Subject, or Code View • Update Inventory Lists

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
Assessment Data Manager	• Run the Study Roles Report • Run and download Site Confirmation and Download Log audit reports • Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation • Add a Lab to a Site • Add and Update Lab Normal Ranges • Create and Add Labs to a Site • Edit Classified Subject Data Only • Freeze subject data entered at a site • Unfreeze subject data entered at a site • 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 • Run the Subject Data Extract • View Shipments to Sites • View Site Inventory • Receive the Study Limits Notifications • Receive the Subject Withdrawal Notification • 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 Rules Report • 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 • Answer Assigned Queries • Close Queries

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• Create Candidate Queries • Create Queries • Delete Candidate Queries • Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Manage SDV Strategies • View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings
Assessment Designer	• Design Forms • Design Randomization • Design SDV Properties on Forms • Design Supplies and Dispensation • Design Visits and Events • Run the Draft Study Design Report • Run the Study Roles and User Assignment Report (Design Mode) • View Design

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
Assessment Tester	• Run the Study Roles Report • Run and download Site Confirmation and Download Log audit reports • Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation • Add a Lab to a Site • Add and Update Lab Normal Ranges • Create and Add Labs to a Site • Dispense Kits with Calculated Doses • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit Visit Dates • Randomize Subjects • Skip Visits • Take Action on Connected Devices • Unblind the Treatment Arm for a Subject, or Code Break • View Blinded Dispensation Details with Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries • Run the Subject Data Extract • Receive and Reconcile Shipments at the Depot • View Shipments to Sites • View Site Inventory • View Unblinded Pharmacist Kits • 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 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 • Run the Blinded Inventory Report • Run the Blinded Subject Events Dataset

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• 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 Rules Report • 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 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 • Design Custom Rules • Publish Custom Rules • Re-run Rules • Test Custom Rules • View All Queries • 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 Lots • Create and Manage SDV Strategies • Create and Manage Sites • Edit General Study Settings • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Move a Study Design to Testing or Production • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View Role Assignments for Study Users

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Manage Randomization Lists • Manage Study Inventory for Unblinded Users • Reveal the Treatment Arm for a Subject, or Code View • Update Inventory Lists

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
Assessment PI Role	• Confirm download of Archival PDFs and content • Download Archival PDFs, and Audit Reports • Run Archival PDFs for your site(s) • Add a Lab to a Site • Add and Update Lab Normal Ranges • Answer Queries • Approve and sign subject data • Create and Add Labs to a Site • Dispense Kits with Calculated Doses • Dispense Kits without Calculated Doses • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit Visit Dates • Randomize Subjects • Skip Visits • Unblind the Treatment Arm for a Subject, or Code Break • 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 • Receive Shipments and Update Site Inventory • View Shipments to Sites • View Site Inventory • Receive Notification of Shipments • Receive the Code Break Notification • Receive the Dispensation Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Randomization Notification • Receive the Subject Screening Notification • Receive the Subject Transferred Notification • Receive the Subject Visit Notification • Receive the Subject Withdrawal Notification • 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 Study Kits Dataset • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Dataset

Table 3-1 (Cont.) Review the table below to familiarize yourself with what each study role can do

Clinical One Study Roles	Clinical One Rights
	• 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 • Answer Assigned Queries • Create Shipments to DDF
Assessment Unblinded Site User	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • Create Manual Shipments • Perform Supplies Reconciliation at Site • Receive Shipments and Update Site Inventory • View Shipments to Sites • View Site Inventory • View Unblinded Pharmacist Kits • Receive Notification of Shipments • Receive the Code Break Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Unblinded Pharmacist Dispensation Notification • 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 Study Codelist Dataset • Run the Study Query Dataset • 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 Titration Summary Report • Create Shipments to DDF

Related Topics

- Descriptions of permissions in Oracle Clinical One Platform

4
Integrations

The Assessment Environment (AE) is a different environment that exists outside of your Production environment which is where you create and manage your live studies as an organization.

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

5
Support

While you are fully in charge of reviewing new features in the Assessment Environment (AE), you can always contact Health Sciences Support to help you with any issues that may come up during your assessment process.

You can enter a support ticket in Oracle Health Sciences Support Cloud using the following details.

> **Note:**
>
> Remember, it is your responsibility to ensure active user accounts in the Clinical One Assessment Environment are terminated by Oracle should a member of your team leave your organization. To do this refer to Accounts and user roles in this guide for specific ticketing details.

Support Request Ticketing Details:

- **Customer:** Customer Name
- **Product:** Clinical One
- **Business Service:** Clinical One - <customer name>
- **Oracle Internal:** No
- **Environment:** Assessment
- **Severity:** 3-Medium
- **Issue Category:** Select the category that best describes your issue.
- **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.

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 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 you a variety of resources to aid you in your review of the new features in the Assessment Environment (AE) for each release.

To browse the latest documentation for reviewing new features in your Assessment Environment (AE), go to the Oracle Help Center (OHC) page dedicated to the Oracle Clinical One Platform users: Oracle Help Center.

> **Note:**
>
> For this Assessment Environment release (21.4), the **Product Verification Package (PVP)** will not be available, but will be made available as part of the Production release.

Part I
Revision history

Date	Part number	Description
December 2021	F48969-01	Original version of the document.
January 2022	F48969-02	Republished the document for the Production release.
January 2022	F48969-03	Republished the document, updated Section 3.
July 2022	F60124-01	• Generated a new part # for the 22.2 release. • Updated the Description Details content (x3) under Accounts, user roles, and environment access.