Oracle Life Sciences Site Activate

Information for Configuration Designer Users

Release 23.3
F93384-01
February 2024

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Contents

Preface

This preface contains the following sections:

- Documentation accessibility
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- Access to Oracle Support

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

Product 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.

1 About Configuration Designer

Configuration Designer is an Oracle Site Activate component used to create, manage, and deploy business process configurations.

Configurations

Configurations are either custom or predefined templates (processes) that define:

- Documents, contracts, and submission items (**artifacts**) needed for each study country and study site
- Key dates (**milestones**) to track in a study
- Activities required to process each document, contract, or submission (**lifecycles**)
- Permissions (**roles**) that a team member must have to perform each activity
- Activities that must be complete before other activities begin (**dependencies**)

When deployed to Oracle Site Activate and applied to a study, a configuration guides the study's team members to complete and track document, submission, and other activities based on your organization's standard business practices as well as country-specific requirements.

Configuration development is a team effort

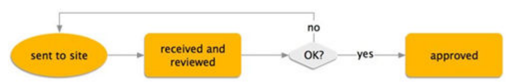
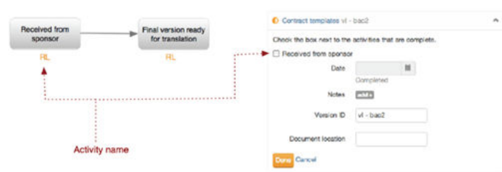
Configuration review and development will involve multiple stakeholders including members of the study team and an assigned configuration lead. Study team members may review available configurations to select a baseline and evaluate changes needed (for example, to ensure the proper artifacts exist at the country level). A representative from Oracle may also take part in certain configuration reviews or specific update types, like configuring lifecycles.

Business role permissions granted to your individual Oracle Site Activate user account will determine your ability to view or change the various attributes of a configuration. As a lead configuration designer user, you:

- Understand your organization's baseline configurations and change control process
- Can communicate how configuration changes will affect the project team
- Have used and understand Activate features and can evaluate the pros and cons of modeling configurations to support current processes
- Are a stakeholder who can make decisions as needed to deploy configurations that support overall business objectives

Key terms and concepts

The table below defines some key terms to help you better understand how to manage configurations.

Term	Definition
Artifact	Artifacts are distinct items like documents, contracts, packages, and submissions that study team members track and complete in Oracle Site Activate. Use Configuration Designer to add, change, or delete artifacts. See instructions in View and change configurations.
Collection	Groups of artifact workflows, also known as scenarios, which are managed together. Collections make it easier to automatically create groups of related artifacts. Oracle provides default collections of study, study country, principle investigator, and staff items.
Lifecycle	Activities your organization uses to track artifacts. To get you started, we offer a variety of lifecycles based on known submission requirements and common industry practices for documents, contracts, packages, and submissions in a wide range of countries. Artifact lifecycles can also have decision options that cause the collection to branch based on the choices your team members make. 
Dependencies	As team members complete activities, Oracle Site Activate alerts the individual(s) assigned to perform the next activity. Oracle Site Activate allows tasks to begin after the completion of all prerequisite tasks. 
Trigger	An event that causes a collection (see above) to run. Oracle Site Activate collections can automatically run when certain triggers happen. For example, a trigger event could be when a team member adds a study country, adds a staff member, or changes the investigator.
Category	Groups of document, contract, submission, and package activities. These help you have different regional or project-specific processes but track their status globally.

Term	Definition
Milestone	An action or event that marks a significant change or stage in a development. You can define and track as many milestones as you want in reports. Up to 50 milestones show on study country and site timelines. Oracle Site Activate milestone timelines show the baseline (original projection), planned (reprojected), and actual dates. Define study country and site milestones that your organization tracks globally.
Role	Role assignment controls who can perform activities in Oracle Site Activate. As you work with configurations, you can specify which role can carry out a task. Study team members have one or more role assignments that grant them permission or the responsibility to perform activities.

2 View and change configurations

In Configuration Designer, you can see your organization’s baseline configuration and others that were created based upon that configuration.

Use the procedures detailed in this section to add, change, and delete documents or create a new configuration. You'll also find a procedure to create a Master Configuration Specification report that helps you design and track configurations.

- View available configurations
  Access Configuration Designer from the link in the Oracle Site Activate "More" menu. When selected from the menu, Configuration Designer opens in a new browser tab. If you don't see the Configuration Designer option in the More menu, contact your super user to request the appropriate business role permission.
- View artifact details
  The Artifacts tab is where you can access a configuration's documents, contracts, and submission items and view details for each item like level, lifecycle, etc.
- View dependencies and triggers
  Some artifacts shouldn't be started until others reach a specified state. On the Dependencies tab, you'll see all artifacts that are prerequisites for others. The grid shows you the prerequisite artifact's name and the required activity (e.g., complete, upload, etc.). You'll also see the successor (downstream) artifact and activity.
- View milestones and report categories
  You'll find a configuration's defined milestones on the Milestones tab and the activity that, when complete, causes the milestone to be met. On the Categories tab, you'll see a list of categories.
- View roles
  On the Roles tab, you can view the list of roles to which activities can be assigned. Role names and descriptions reflect those that have been created for your organization's Oracle Site Activate account.
- Change configurations
  If you have the appropriate business role permission to change configurations in Configuration Designer (instead of view-only permission), you can clone an available (baseline) configuration to create a new one.
- Manage lifecycles
  Lifecycles define the activities required to process a document and the role(s) study team members must have to perform the activities.
- Bulk association and bulk delete
  To simplify configuration and management of multiple countries in a configuration, you have the ability to associate and delete Artifacts, Dependencies, and Milestones in bulk.
- Master Configuration Specification (MCS) report
  Configuration Designer users who create and maintain configurations can export a Master Configuration Specification (MCS), which provides a report of an individual configuration’s components/settings and can be used for compliance and design purposes.

View available configurations

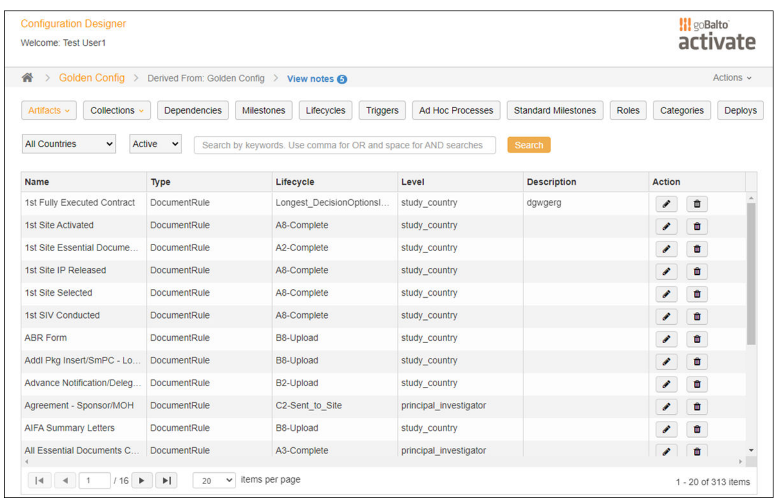
Access Configuration Designer from the link in the Oracle Site Activate "More" menu. When selected from the menu, Configuration Designer opens in a new browser tab. If you don't see the Configuration Designer option in the More menu, contact your super user to request the appropriate business role permission.

After opening Configuration Designer, you can explore available configurations on the home page, and you can return to the list on the home page at any time; click "Configuration Designer" at the top left on any page to return.

When you select a specific configuration to view, that configuration's name displays at the top of the grid's header panel. If the configuration is derived from another, the name of that configuration also displays in the grid's header panel with "Derived From: …" text.

Notes help you track a configuration's updates over time and communicate those changes to other Configuration Designer users. When notes exist for a configuration, an enumerated "View notes" link (View notes 1) displays to the right of the configuration name. Click to display the notes page where you can add a new note (10,000 character max.) and review all saved notes ordered from newest to oldest.

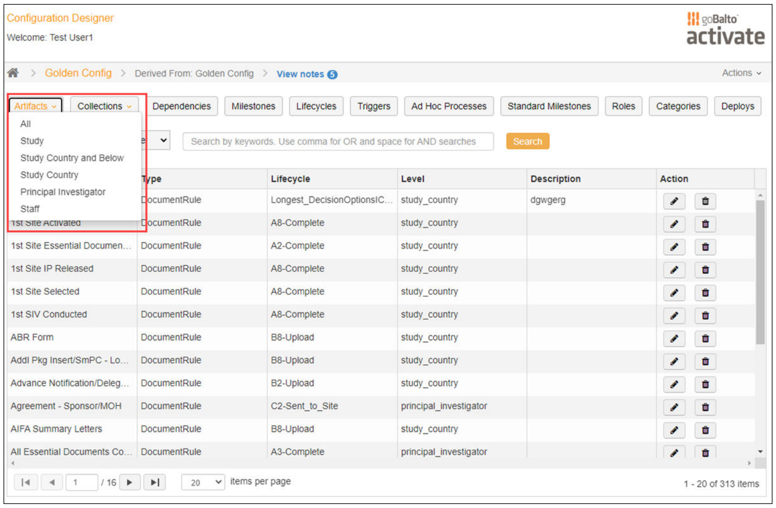
When you view a selected configuration, the grid changes to the reflect that configuration's contents. Click the tabs above the grid (e.g., Artifacts, Collections, Dependencies, etc.) to filter the grid to that content type. Use the pagination controls below the grid to adjust the number of items shown per page and advance from page to page. Note that all columns that contain alphanumeric data are sortable; click the column header to sort.



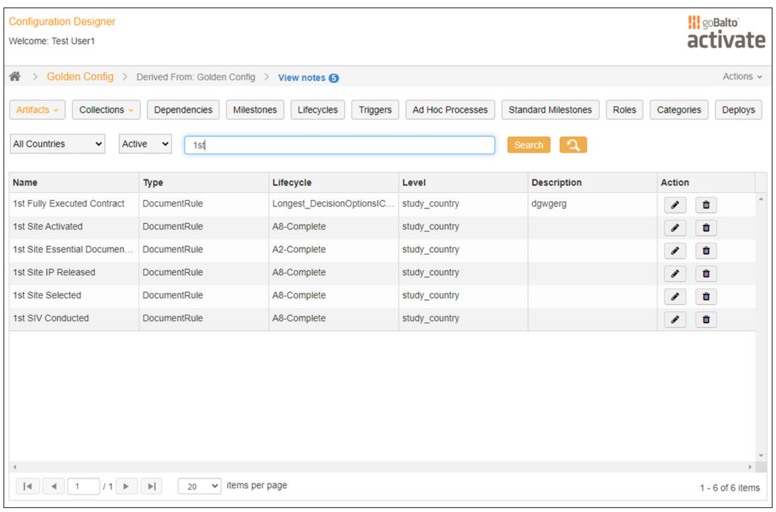
View artifact details

The Artifacts tab is where you can access a configuration's documents, contracts, and submission items and view details for each item like level, lifecycle, etc.

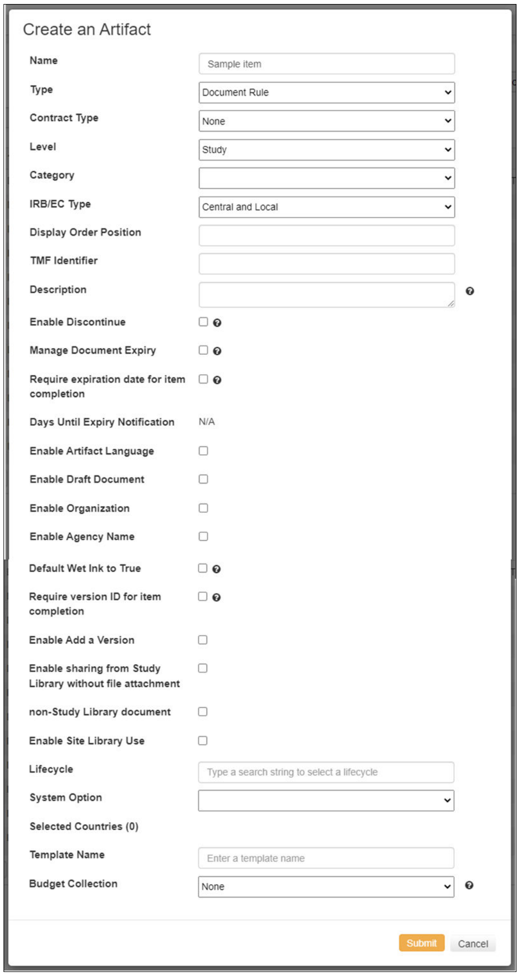
On the Artifacts tab, you'll see items tracked in the configuration. You can filter the displayed artifact level. Click the Artifacts tab to select your preferred view level from the drop-down menu.



On the Artifacts tab, you can search for a specific item. Enter a term in the search field above the grid and click Search to view the results in the grid. The Type column indicates if the item returned in the search is a document, submission, or package. The Level column indicates if the item is tracked for the study, study country, investigator, or staff.



In the Actions drop-down menu at the upper right of the page, click Create to create a new artifact in the Create an Artifact form shown below. In the grid, click the pencil icon next to any item to edit the item in the Customize an Artifact form. These forms are where you'll manage artifact details, such as displayed fields and artifact availability in Oracle Site Activate.

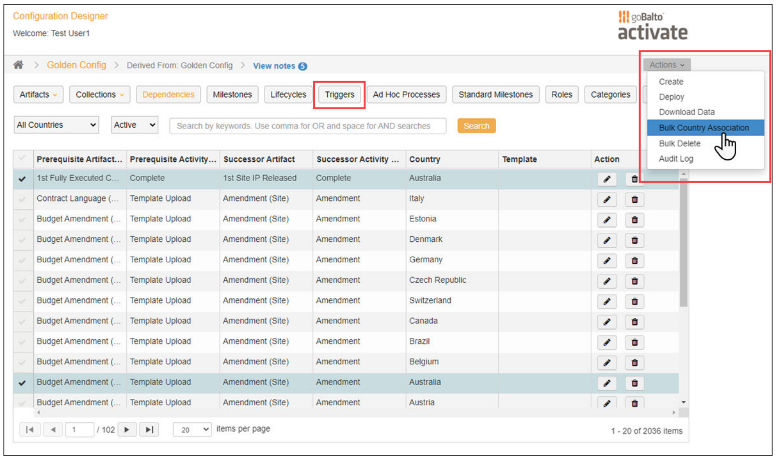


View dependencies and triggers

Some artifacts shouldn't be started until others reach a specified state. On the Dependencies tab, you'll see all artifacts that are prerequisites for others. The grid shows you the prerequisite artifact's name and the required activity (e.g., complete, upload, etc.). You'll also see the successor (downstream) artifact and activity.

You can filter, search, and sort the Dependencies grid to easily locate a specific dependency at the study or country level. Use the filters to the right of the search field to refine the list. For instance, select All, Study, All Countries, or a specific country and/or dependency state (e.g., Active, Changed, Deleted) filters. Use the search field to locate dependencies by one or more comma-separated keywords. Click any column header to sort the column and further refine the grid display.

- Select one or more dependency rows in the grid and then click the Triggers tab above the grid to see a list of items that, when they occur, cause collection for other items to run.
- Edit ( ) or delete ( ) a dependency; click the appropriate icon under the Actions column in the grid
- If you need to associate one or more dependencies with one or more countries, you can do that after you select the dependency rows and choose Bulk Country Association from the Actions drop-down menu.



View milestones and report categories

You'll find a configuration's defined milestones on the Milestones tab and the activity that, when complete, causes the milestone to be met. On the Categories tab, you'll see a list of categories.

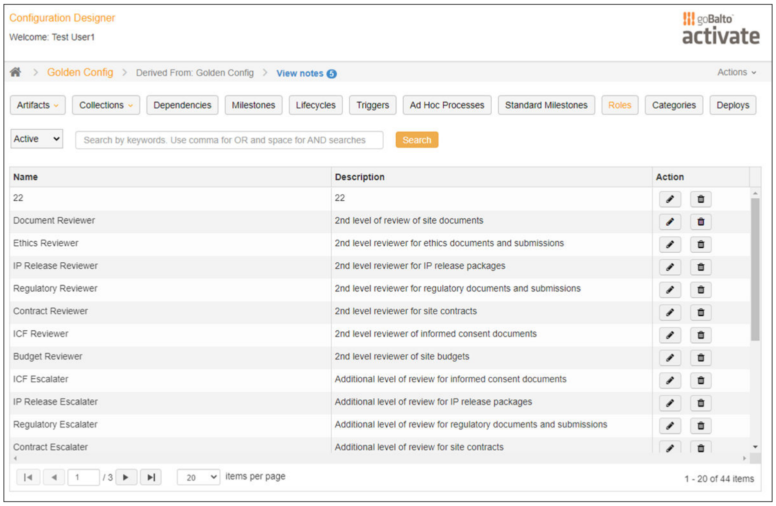
A milestone is an action or event that marks a significant change or stage in the study. Use the Milestones tab to view the list of milestones already saved in the configuration and optionally create a new milestone. Define and track as many milestones as you want to plan and report on.

Categories drive the logic used to group documents and submissions in reports and allow you to track the status of different artifacts across different regions or countries. Click the Categories tab to view a list of categories in the current configuration.

View roles

On the Roles tab, you can view the list of roles to which activities can be assigned. Role names and descriptions reflect those that have been created for your organization's Oracle Site Activate account.

The Roles tab includes all roles available to be assigned to an activity. A study team member must have the specified role to access or complete the activity in Oracle Site Activate. You can edit the role name and description, and you can delete the role if it has not been associated to any lifecycles.



Note:

Over time, your account's configurations may include multiple similar roles (i.e., three administration roles labeled "Admin," "Super user," and "Admin2,"), and these roles can be consolidated via script into a single, existing role. Use of the role consolidation script is optional. When run, the script updates all configurations in the account and automatically deletes old roles from all configurations. Please get in touch with your Oracle services representative to discuss scheduling, requirements, and the impact of script use for your account.

Change configurations

If you have the appropriate business role permission to change configurations in Configuration Designer (instead of view-only permission), you can clone an available (baseline) configuration to create a new one.

When you clone a configuration, the original configuration is the “parent” and the new one is the “child.” Changes that you make to the parent automatically propagate to children and are visible when you publish the configuration. You can add notes to configurations to help you track updates and comments over time.

Next, select the artifact in the configuration that you want to change. For example, a common change you might make is to modifiy the name of an artifact. See the Edit an artifact procedure for details about fields and options.

Run an audit report when you need to know about specific configuration changes. Configuration Designer audits create, update, and delete actions; the report also identifies the user who made the changes. See the View audit log procedure for instructions.

- Create a child configuration
  A child configuration is a copy of a baseline configuration. Once you've created the child, use that as the version you modify.

- Add or view configuration notes
  Configuration notes help you to track configuration changes over time and other Configuration Designer users can also view the notes you create.
- Add a new document artifact
  When you change a configuration and need to add a new document artifact, you'll define the artifact and attributes in a simple form.
- Edit an artifact
  When you edit an artifact you'll have access to a wide variety of artifact attributes. The attributes you can edit depend on the document, submission, or package artifact type.
- Delete an artifact
  If an artifact hasn't been deployed yet, you can still delete it from one or more countries.
- Remove an artifact from a country
  If a document artifact is not currently tracked in a production environment configuration, use this procedure to delete it.
- Change artifact list display order
  Complete this procedure if you want artifacts to display in Oracle Site Activate drop-down menus in a specific order rather than the default alphabetical order.
- Change a document artifact name
  One of the most common configuration changes you'll make is to change the name of a document artifact. Use this procedure to quickly complete this task.
- Add a dependency
  Define an activity that must be completed before the next activity can begin.
- Export configuration data to a .csv file
  Learn how to create a tab level data export (e.g., Artifacts, Collections, etc.) in Configuration Designer.
- View audit log
  You can view and optionally download a configuration level audit log that shows All, Create, Update, or Delete actions for up to 30 days.

Create a child configuration

A child configuration is a copy of a baseline configuration. Once you've created the child, use that as the version you modify.

1. On the home page, find a configuration you want to use as your baseline.
2. In the Actions menu, click **Create**.
3. At Name, enter a name for the new configuration.
4. At Base Configuration, select the baseline configuration.
5. Click **Submit**.

When you copy a configuration, the copy initially displays in the home page grid in a disabled (grayed out) state while the copy process is underway. The copy name displays in italicized, non-hyperlinked format, with “copy in progress” appended to the name. Additionally, the Action column does not display edit, copy, and delete options.

When Configuration Designer creates the copy and you refresh the page, the link in the home page grid returns to an active, hyperlinked state. You can then interact with the configuration as desired.

Add or view configuration notes

Configuration notes help you to track configuration changes over time and other Configuration Designer users can also view the notes you create.

1. On the home page, select the configuration for which you will enter or view notes.
2. Click View notes (View notes 1) in the configuration's header bar. If notes exist, the icon includes the total note count.
3. On the notes page, you can review existing notes ordered from newest to oldest.
4. To add a new note, enter your note text in the **Add note details...** field. Maximum character count in this field is 10,000.
5. Click **Save Note**.

Add a new document artifact

When you change a configuration and need to add a new document artifact, you'll define the artifact and attributes in a simple form.

1. On the home page, click the name of the configuration you want to change. The Artifacts tab automatically displays.
2. In the Actions menu, click **Create**.
3. At Name, enter the document name.
4. At Type, select Document rule.
5. At Level, indicate if the document is tracked for a study, study country, principal investigator, or staff. If you selected Staff, at Staff title select a title (e.g. sub investigator).
6. At Category, select the category in which you want to track the document. If this is a site document, at IRB type, optionally select the type.
7. Check boxes to enable any of the check box options listed at the end of this procedure, and note that options are dependent upon the "Level" type set above. Then return to procedure step 8 below.
8. At Lifecycle, enter a name of a lifecycle you will use to manage the document. As you enter characters, the names of applicable lifecycles appear on a list so you can select one.
9. At System Option, select Creation to have Oracle Site Activate automatically create the document when a study country or site is created.
10. At Countries, select the countries in which the document should be tracked. **Tip**: If all countries do not display, check Show all Countries. To select multiple countries, hold the Shift key as you select additional ones; see them appear on a list of selected countries below.
11. At Template name, enter the name of the template with which to group the document.
12. To associate the artifact with a budget collection, at Budget collection select one.
13. To associate the artifact with a submission collection, at Submission collection select one.

14. To associate the artifact with a package collection, at Package collection select one.
15. Click **Submit**.

Check box options

Enable Discontinue	Allows team members to discontinue the document
Manage Document Expiry	Allows team members to enter and track the document's expiration date
Manage Contract Expiry	Allows team members to enter and track expiry on contract, sub-contract, and contract amendment artifacts
Require expiration date for item completion	If checked, users must enter expiry date to compete the item
Days Until Expiry Notification	If Manage Document Expiry or Manage Contract Expiry is checked, allows you to enter the number of days before expiration that the study team is notified (default 90 days)
TMF Identifier	Associate an artifact for your TMF reference model
TMF sub type	Available if the TMF identifier field above contains a value
TMF sub sub type	Field available if the TMF identifier and TMF sub type fields above both contain a value
Enable Artifact Language	Enables an end user to denote the artifact as language specific
Enable Draft Document	Enables an end user to denote the artifact as a draft
Enable Organization	Enables an end user to denote the artifact as associated to a specific organization
Enable Agency Name	Enables an end user to denote the artifact as associated to a specific Agency
Default Wet Ink to True	Sets wet ink to True in Oracle Site Activate
Require version ID for item completion	Version ID must be entered before the item can be completed in Oracle Site Activate
Enable Add a Version	Artifact will display an Add a Version button
Enable Site Library Use	Artifact will be included in the Smart Site Library modal and available to reuse files attached to this artifact from previous studies.

non-Study Library document	Makes the document available on the Oracle Site Activate study home page rather than the Study Library.

Edit an artifact

When you edit an artifact you'll have access to a wide variety of artifact attributes. The attributes you can edit depend on the document, submission, or package artifact type.

1. On the home page, click the name of the configuration you want to edit. The Artifacts tab automatically displays.
2. Select the level of the artifact you want to change (study, study country and below, or all).
3. Click **Edit** next to the artifact you want to change.
4. Change any of the artifact options in the table below, then click **Submit** and refresh the page to view the new display order.

Name	This is the name that displays in Oracle Site Activate and in reports for the artifact.
Type	Choose document, submission, or package.
Contract type	Choose contract, budget, contract language, or contract amendment.
Level	Choose study, study country, principal, investigator, or staff.
Staff title	If you chose the staff level, choose sub investigator, pharmacist, coordinator, lab director, deputy, or all.
Category	Select the category in which you want to include information about this artifact.
IRB/EC type	If the artifact is associated with an IRB type, choose central and local, central, or local.
Display order position	Enter a number which determines the order in which the item appears on lists in Oracle Site Activate (lower numbers display first).
TMF identifier	Available to associate an artifact for your TMF reference model.
TMF sub type	Field available if the TMF identifier field above contains a value.
TMF sub sub type	Field available if the TMF identifier and TMF sub type fields above both contain a value.
Meeting dates enabled	Check this if you want meeting dates to display for a submissions artifact.
Pre IP release review	Includes the artifact on the site-level Pre-IP release review list (for the green light package).
Enable discontinue	Allows team members to discontinue the document.
Manage document expiry	Allows team members to enter and track the document's expiration date.
Manage contract expiry	Allows team members to enter and track expiry on contract, sub-contract, and contract amendment artifacts
Require expiration date for item completion	Sets expiration date as a required field in Oracle Site Activate to complete the artifact .

Name	**This is the name that displays in Oracle Site Activate and in reports for the artifact.**
Days until expiry notification	If Manage Document Expiry or Manage Contract Expiry is checked, allows you to enter the number of days before expiration that the study team is notified (default 90 days)
Submission classification	On submission artifacts, optionally choose Regulatory, Ethics, or Other as the Submission classification value. Classification is a different value from Type and Category values. When you deploy the configuration, the selected classification value populates in Oracle Site Activate for the relevant artifacts.
Enable Artifact Language	Available to enable an end user to denote the artifact as language specific.
Enable Draft document	Available to enable an end user to denote the artifact as a draft.
Enable Organization	Available to enable an end user to denote the artifact as associated to a specific organization.
Enable Agency Name	Available to enable an end user to denote the artifact as associated to a specific Agency.
Default Wet Ink to True	Sets Wet Ink to True in Oracle Site Activate.
Require version ID for item completion	Sets version ID as a required field in Oracle Site Activate to complete the artifact.
Enable Add a Version	Artifact will display Add a Version button.
Enable Site Library Use	Artifact will be available for reuse in the Oracle Site Activate Smart Site Library
non-Study Library document	Makes the document available on the study home page rather than within Study Library. Document will not use any Study Library functionality (e.g., Auto-share).
Lifecycle	Enter the name of a lifecycle to use to manage the document. As you enter characters, the names of applicable lifecycles display on a list so you can select one. Your Oracle Project Manager or Oracle Support can provide detailed lifecycle descriptions.
System option	• Creation, to have Oracle Site Activate automatically create the document when a study country, site or staff member is created • User, to have the document's collection available to run using the workflow wizard • User Protocol, to have the document's collection available on the workflow wizard list for specific protocols
Countries	Select countries in which the document should be tracked. **Tip:** To select multiple countries, press and hold the Ctrl key on a PC or the Cmd key on a Mac as you select additional countries; see them appear on a list of selected countries below.
Template name	The template name
Budget collection	Associate the artifact with a configured budget collection.

Name	This is the name that displays in Oracle Site Activate and in reports for the artifact.
Subcommittee collection	The collection to run when a subcommittee is added to a submission
Package collection	Associate the artifact with a configured package collection.

Delete an artifact

If an artifact hasn't been deployed yet, you can still delete it from one or more countries.

1. Display the details page of the configuration containing the artifact.
2. Specify the countries for which you want to delete the document by selecting them from the country list above.
3. Click **Edit**, next to the artifact, then deselect each country for which you want to remove it.
4. Click **OK** to confirm.

Remove an artifact from a country

If a document artifact is not currently tracked in a production environment configuration, use this procedure to delete it.

1. On the home page, click the name of the configuration. The Artifacts tab automatically displays.
2. Search for the document to delete by entering the name into the search box, or find it on the list.
3. On the document artifact grid row, click **Delete**.

> **Note:**
>
> If the artifact is in a collection or has a dependency assigned to it, you have to remove those associations before you can delete the artifact.

4. Click **OK**.
5. Deploy the configuration to a test environment to validate the deletion.

Change artifact list display order

Complete this procedure if you want artifacts to display in Oracle Site Activate drop-down menus in a specific order rather than the default alphabetical order.

1. On the home page, click the name of the configuration you want to work with. The Artifacts tab automatically displays.
2. Select the level of the artifacts you want to change (study, study country and below, or all).
3. Click **Edit** next to the artifact you want to change.

4. At Display order position, enter a number (where lower numbers appear first on lists).
5. Click **Submit**.
6. Refresh the page to see the new display order.

Change a document artifact name

One of the most common configuration changes you'll make is to change the name of a document artifact. Use this procedure to quickly complete this task.

1. On the home page, click the name of the configuration you want to change. The Artifacts tab automatically displays.
2. Search for the document you want to rename by entering the name into the search box, or find it on the list.
3. In the far right column of the grid, click **Edit** next to the document.
4. At Name, enter a new name, and click **Submit**.
5. Deploy the configuration to a test environment to validate the change.

Add a dependency

Define an activity that must be completed before the next activity can begin.

The dependency you define must be unique. Configuration Designer will prevent you from creating duplicate dependencies within a configuration.

1. On the home page, select the configuration for which you will add the dependency.
2. Click the **Dependencies** tab.
3. At the upper right of the page, click the **Actions** menu and choose **Create** to open the Create a Dependency form.
4. If the dependency will apply only at the study level, check the **Study Level Only Dependency** check box.
5. If the dependency does not apply only at the study level, select a country from the **Country** drop-down list.
6. If the dependency is pertains to a Successor or Prerequisite artifact, check the **Content Dependency** check box and complete the **Successor Artifact** and **Prerequisite Artifact** fields.
7. Enter the item name in the **Template Name** field.
8. Click **Submit**.

Export configuration data to a .csv file

Learn how to create a tab level data export (e.g., Artifacts, Collections, etc.) in Configuration Designer.

1. On the home page, click the name of the configuration.
2. Click the tab for which you would like to export data (Artifacts, Collections, etc.).
3. Click the **Actions** menu, then click **Download Data**.

View audit log

You can view and optionally download a configuration level audit log that shows All, Create, Update, or Delete actions for up to 30 days.

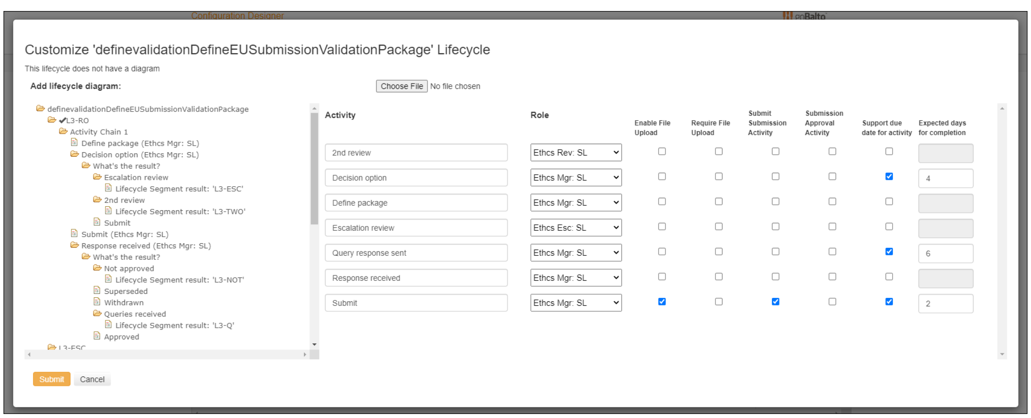
1. On the home page, click the name of the configuration.
2. Click the tab for which you would like to generate a log. Audit is supported in all tabs except Deploys.
3. In the Actions drop-down, choose **Audit Log**.
4. Select a date range (maximum 30 days).
5. Optional: Select an action type (All, Create, Update, Delete).
6. Click **View Audit Log**.
7. Optional: When Configuration Designer finishes generating the log, click **Download Audit Data** to download the log in .csv format.

Manage lifecycles

Lifecycles define the activities required to process a document and the role(s) study team members must have to perform the activities.

You can copy or edit lifecycles at the level where they were created (parent versus child). When you edit a lifecycle, you can change the names that appear for lifecycles, the roles that can perform the activity, as well as other activity specific options, like file upload and due dates. These changes take effect for your study team the next time you deploy the configuration.

You can also copy an available lifecycle and use the copy as the basis for a new lifecycle.



- Edit a lifecycle
  You can easily edit a lifecycle but pay special attention to any displayed warnings. Configuration Designer will warn you if any of the changes you want to save will invalidate a milestone or dependency.
- Copy a lifecycle
  Copy an available lifecycle to save time and effort in configuration updates.

Edit a lifecycle

You can easily edit a lifecycle but pay special attention to any displayed warnings. Configuration Designer will warn you if any of the changes you want to save will invalidate a milestone or dependency.

1. On the home page, click the name of the configuration.
2. Click the **Lifecycles** tab.
3. Click **Edit** next to the lifecycle you want to change. To change the name, at Activity, enter a new name.
4. To change the role that can perform the activity, at **Role** select a new one.
5. Optional: Enable or disable file upload, submission activity, and due date options using the check boxes to the right of the activity. If you enable due date, specify the **Expected days for completion**.
6. Click **Submit**.

You will receive a warning if an edit to an artifact's lifecycle will result in invalid milestones or dependencies. When you click Submit (above), Configuration Designer reviews the artifact's list of milestones and dependencies to determine the impact, and if no milestones or dependencies will be invalidated by the changes, the changes are saved and the artifact list displays as it did before.

If one or more milestones and/or dependencies will be invalidated by the changes, a confirmation modal displays that identifies the lifecycle name and lists all affected milestones and/or dependencies. The confirmation provides action options for you to:

- **Cancel** – This option cancels the lifecycle change and closes the modal.
- **Submit** – This option confirms the lifecycle change and closes the modal. Affected milestones and dependencies are then invalidated but not deleted. Non-deletion allows you to update the affected item as desired.
- **Copy to Clipboard** – This option copies the list of affected milestones and dependencies to your clipboard so you can paste and save it in a preferred editor (e.g., Notepad, Microsoft Word, etc.). This option does not close the modal or save artifact lifecycle changes. Instead, the you will click **Cancel** or **Submit** to close the modal

Copy a lifecycle

Copy an available lifecycle to save time and effort in configuration updates.

1. On the home page, click the name of the configuration.
2. Click the **Lifecycles** tab.
3. Next to the lifecycle you want to copy, click **Copy**.
4. At Root Segment Name enter a name for the new segment.

5. At Business Name enter a business name.
6. Click **Submit**.

Bulk association and bulk delete

To simplify configuration and management of multiple countries in a configuration, you have the ability to associate and delete Artifacts, Dependencies, and Milestones in bulk.

Access bulk options from the Actions drop-down menu on the Artifacts, Dependencies, and Milestones tabs after you select one or more items in the Artifacts, Dependencies, or Milestones grid.

> **Note:**
>
> For Artifacts, only those at the “Study Country and Below” level are supported for bulk deletion at this time; study level artifact bulk deletion is not supported.

- Associate artifacts to countries in bulk
  When you want to associate an artifact to multiple countries in a configuration, you can save time by performing this action in bulk.
- Delete items in bulk
  You can bulk delete any artifact that can be associated in bulk. If you bulk delete artifacts in a parent configuration, Configuration Designer automatically applies those deletions to the child configuration, and if a deleted artifact was part of a Collection, it will be removed from that Collection once deleted.

Associate artifacts to countries in bulk

When you want to associate an artifact to multiple countries in a configuration, you can save time by performing this action in bulk.

1. On the home page, click the name of the configuration you want to work with. The Artifacts tab automatically displays. Select the Dependencies or Milestones tab if the item to be associated is a dependency or milestone.
2. Check the box next to each item you want to associate with the country or countries. Click the **Actions** menu, then click **Bulk Country Association**.
3. Enter the names of the countries with which you want to associate the artifact, or click **Select All** if you want to associate an artifact to all countries in a configuration.
4. Click **Associate Countries**.

Delete items in bulk

You can bulk delete any artifact that can be associated in bulk. If you bulk delete artifacts in a parent configuration, Configuration Designer automatically applies those deletions to the child configuration, and if a deleted artifact was part of a Collection, it will be removed from that Collection once deleted.

1. On the home page, click the name of the configuration you want to work with. The Artifacts tab automatically displays. Select the Dependencies or Milestones tab if the item to be deleted is a dependency or milestone.
2. Check the box next to each item you want to delete from with the country or countries. Click the **Actions** menu, then click **Bulk Delete**.
3. In the pop-in, confirm the items to be deleted are correct.
4. Click **Delete Item**.

Master Configuration Specification (MCS) report

Configuration Designer users who create and maintain configurations can export a Master Configuration Specification (MCS), which provides a report of an individual configuration's components/settings and can be used for compliance and design purposes.

The Master Configuration Specification (MCS) report includes only that data associated with countries currently scoped to the configuration. The export is also not affected by any search terms or country filters selected prior to generating the report.

The option to download the CSV format report is available in the Actions menu on the Artifacts tab, and the naming convention for the completed report file is: [configurationName]_MCS_date.csv.

- Run Master Configuration Specification (MCS) report
  Create a configuration-level report to assist with future configuration designs or to document a configuration for compliance purposes.

Run Master Configuration Specification (MCS) report

Create a configuration-level report to assist with future configuration designs or to document a configuration for compliance purposes.

1. On the home page, click the name of the configuration for which you will run the MCS report. The Artifacts tab automatically displays.
2. Click the Actions drop-down menu and choose **Export MCS Data**.
3. Select a location to save the MCS report file.

3

Test and deploy configurations

If you change a configuration, deploy it to a test environment so that you and your study team can test the updated configuration without impact to studies that are in progress. Once you are satisfied with the configuration, deploy it to the production environment where actual studies are run.

Deploy to a subset of countries

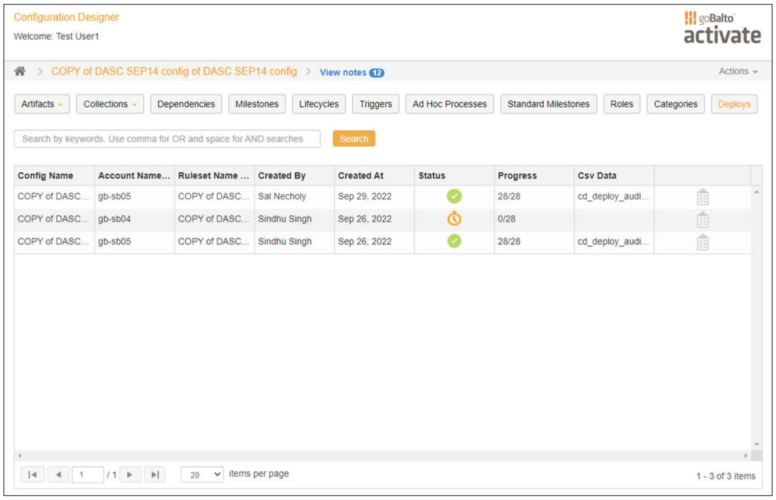
If the configuration involves many countries, it may take multiple hours to see the configuration appear in the target environment. You can optionally deploy to one or to a limited number of countries so that you don't need to wait until all country configurations are finalized before you start end-to-end validation across Configuration Designer and Oracle Site Activate.

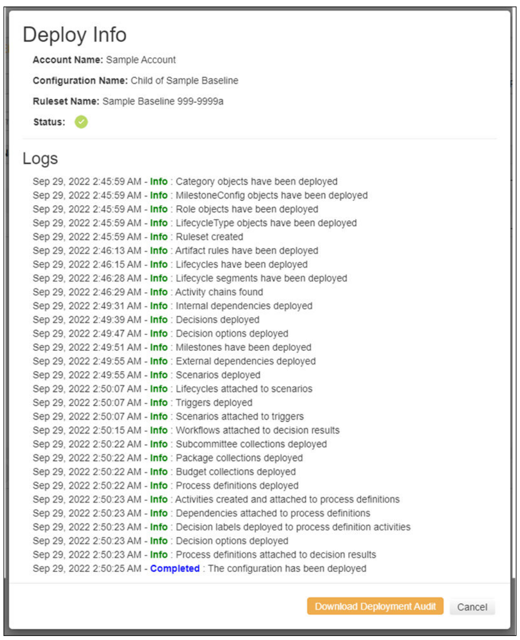
The Deploy Configuration modal includes a "Deploy to all countries in configuration" check box, which is checked by default. In this state, the configuration deploys to all countries included in the configuration. If you uncheck the check box, a list of all countries included in the configuration displays, and you can then select one or more countries for a subset deployment model. Selected countries display below the country list; click "X" to remove a selected country. When you select at least one country, the number of artifacts to be deployed for the country also displays in the modal. When you click Deploy, the configuration deploys only those items that are relevant to the selected country(ies) into the Oracle Site Activate environment with the associated ruleset name.

Deployments of child configurations, copy configurations, and differential deployments behave similarly when you complete a country-specific configuration deployment. For example, if you complete a differential deployment for a subset of countries, into an available process in Oracle Site Activate, only the selected subset of countries will be updated with any new data from the configuration.

View current deployment status

If you initiated the deployment of a configuration, a progress indicator displays at the lower left hand of the page, below the data grid.





Deployment audit report

Configuration Designer users responsible for configuration deployments can download a .csv format report that contains a full audit of all data deployed to the Oracle Site Activate environment. This audit is available for deployments that successfully complete and those that fail part way through. The file is not available while a deployment is actively underway.

The audit report captures all data inserted into the Oracle Site Activate database as part of the deployment and includes these data points:

- Item type
- Item name
- Item ID
- Country affected by the insert or update
- Operation type (insert or update)

You can access the audit report under the Deploys tab, in the deployment's log. The action button, "Download Deployment Audit," displays to the left of the Cancel button when the report is complete and available for download (see Deployment Info image above).

The audit report has a specific file name convention to make it easier to differentiate multiple reports when used in the deployment validation process. The convention is: <config name><ruleset_name>Deployment <account name>_<date time stamp>.csv.

These are the elements of the file name variables:

- **config name**: configuration name – visible in the Name column on the Configuration Designer homepage
- **ruleset name**: ruleset name – visible in the Ruleset Name column of the Deploys tab
- **account name**: Oracle Site Activate account to which the configuration was deployed - visible in the Account Name column on the Deploys tab
- **date time stamp**: deployment day of the week abbreviated, month abbreviated, day, year, hour_min_sec in the user's local timezone (i.e., Mon Jan 03 2022 14_16_33 GMT).

> **Note:**
>
> You can download audit logs for up to one year prior to release 22.3 (September 2022) by clicking the Deploy info modal's "Download Deployment Audit" button. However, for historical deploys older than one year, the Download Deployment Audit button is disabled. This is expected behavior and does not apply to future (post 22.3 release) deploy audit logs, which will be available indefinitely.

- View completed or failed deployments
  If you are not the individual who initiated a configuration's deployment, or if you would like to see the status of a configuration's completed or failed deployments, you can find this information on the Deploys tab.

View completed or failed deployments

If you are not the individual who initiated a configuration's deployment, or if you would like to see the status of a configuration's completed or failed deployments, you can find this information on the Deploys tab.

1. On the home page, click the name of the configuration.
2. Click the **Deploys** tab. You'll see the deployment status in the Status column. To review the deployment log details, click the clipboard icon in the far right column in the grid.
3. Optional: Optionally, click the **Download Deployment Audit** button to download a .csv format report containing a full audit of all data deployed to the Oracle Site Activate environment.