Oracle Life Sciences Site Activate

Information for CRO and Sponsor Users

Release 23.2
F84099-01
September 2023

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Contents

Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- 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.

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About Oracle Site Activate

Oracle Site Activate gives study team members real-time, anywhere access to study startup status, metrics, and data. Sponsors, CROs, and sites use this application to collaborate, manage, and track site activation activities.

Workflows

Workflows reflect your standard operating procedures and drive the work

Oracle Site Activate workflows guide you to complete and track the specific documents and activities required for any country, investigator, or study based on your organization's standard operating procedures. If your requirements change, a member of your organization can update the workflows accordingly.

Activities guide the work

Oracle Site Activate automatically records when each activity starts and ends. No need to compile status reports — now everyone sees real-time study progress. The default configuration manages these common scenarios:

- Track documents and submissions for a study country or site (for an initial protocol)
- Protocol amendments

The study team and the study configuration

In Oracle Site Activate, multiple individuals make up the study team, and these individuals from your organization and Oracle work together to define the appropriate configuration for each study. Some common activities by team and role are:

Study team

1. Review existing configurations and determine if an existing configuration meets the requirements (e.g., same sponsor, similar study type, etc.).
2. If an existing configuration isn't available, identify one to use as a baseline and determine any changes needed.
3. Document requirements, changes to baseline configuration, and plan for internal review and approval.
4. Hand off configuration design and requirements to the designated Configuration Lead.

Configuration lead

1. Based on documented requirements, assess changes required.
2. Meet with your Oracle Project Manager to review and plan changes.
3. Make document artifact changes in the Oracle Site Activate Configuration Designer component.
4. Email the Oracle Project Manager for configuration review.

Oracle project manager

1. Assess changes made by the configuration lead.
2. (Optional) Make additional changes required for the configuration.
3. Email study team to confirm changes are complete.

Study team

1. Create new study and apply the configuration.
2. Track investigator and staff-specific documents with Oracle templates that define:
   - Documents and submissions required in each study country
   - Activities required to process each document or submission
   - Business roles and permissions that a team member must have to complete each activity
   - Activities that must be complete before others start (dependencies)

Get study status in real time

Oracle Site Activate shows everyone on your study team which sites have started or completed documents and submissions and how long it took to complete them.

Team members see the status of sites, documents, submissions, and notes in one place. All team members see status at a glance.

See activities when it's time to complete them

Once your workflows are defined, they automatically create the activities required to track documents and tasks you care about.

You can use the Workflow Wizard at anytime to create new activities. For example, when there is a protocol amendment, you can use the Workflow Wizard to specify the country or investigator documents that are impacted; Oracle Site Activate will create the activities required to track them. You can also use Workflow Wizard to generate study-level documents and submissions, when appropriate.

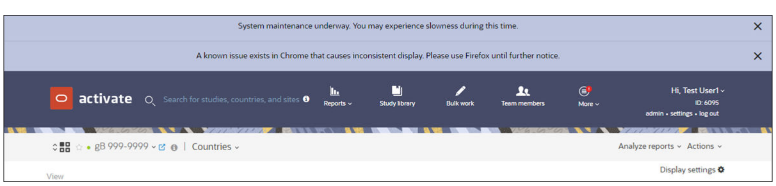
Add ad hoc documents as needed

At initial setup, workflows are configured for all the documents your organization wants to track, but sometimes you need to track others you did not expect. You can easily add new documents and select from several preconfigured workflows to track them.

Navigation

Communications banners

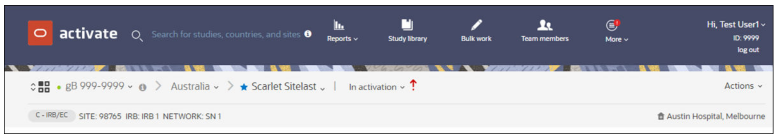
If configured, and active, for your organization's account, you may see up to two communication banners at the top of the page. These banners are intended to provide you with important broadcast messages from Oracle administrators or your organization. For instance, the banner(s) may communicate a known browser issue or an upcoming upgrade window. When active, banners display each time you log in, but you can dismiss them for your current session by clicking the X at the far right of the banner.



Global and persistent navigation

The global (top) navigation bar allows easy access to major functional areas in Oracle Site Activate from any page. Hover over the drop-down menu items to expand them and click any item to navigate to that page. For instance, to access your study document library, click the **Study library** menu item. You can also click the Oracle Site Activate logo at the upper left to return to the home page at any time.

Oracle Site Activate also features a persistent header, just below the global navigation bar, which displays partner, study, country, and site information. Use the study drop down to search by study, CRO ID, or protocol. You can also use the study, country, and site drop-down menus in the persistent header to quickly navigate to any corresponding page that you have business permission to access.



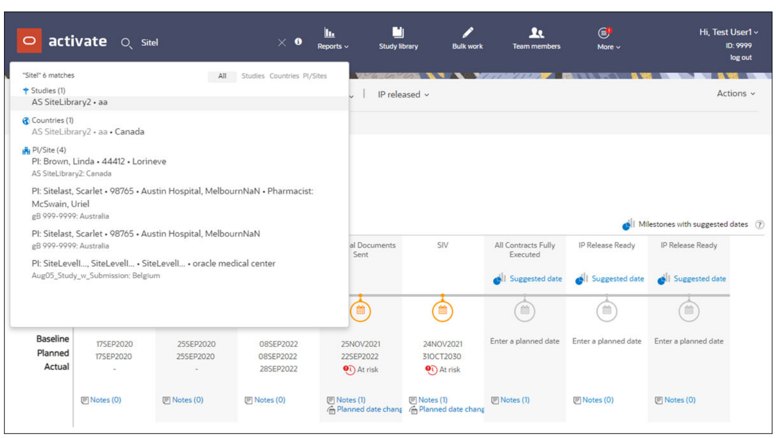
Global search

Use the global search feature, located to the right of the Oracle Site Activate logo, to navigate to any study, country, or site page. Study sites can be queried by the institution name, site number, or a PI/staff member name associated to that site.

You can also refine queries by typing multiple keywords into the search box, separated by spaces. Click on a search result to navigate to that page, or use arrow keys and press Enter on your keyboard to select a page to view.

To use Global Search, enter the leading characters of your study name, country name, PI name, institution name, or CRO ID (e.g., Study name: Contract test, you can search starting with Con). Your search term must start with the leading characters of a string of text within any of the above fields.

You can also search with leading characters directly after a separator (e.g., CRO ID 1234/5678 - you can search for 1234 or 5678 because the space and the forward slash (/) are separators).



Getting around in Oracle Site Activate

Familiarize yourself with a few basic screens to understand how to navigate from one page to the next.

- Home page

- Country details page
- Site details page

To get back to the home page at any time, click the logo at the top left of any screen.

Home page

On the Home page, you can access studies, manage activities, plan milestones in bulk, and view alerts across studies and sites.

The Home page has four distinct views, which are accessible by tabs at the upper left:

1. **Study work** – This tab displays a study level milestone timeline.
2. **Dashboard** – This tab displays the country milestone dashboard Timeline, and if at least one site milestone has been configured as a Summary Milestone, a Tabular option displays as well.
3. **Country progress** – This tab displays a bar chart of document progress by country.
4. **Notes** – This tab displays a study level notes view.

You can set any of the four views above as your preferred default. Use the "Display settings" control at the upper right of the Home page. You can change the preference setting at any time.

Below the four views, you'll see tabs to adjust the worklist view to "Your tasks," "Planning," or "Corrections." Note that you'll see the Corrections tab only if you have a business role that includes corrections permissions.

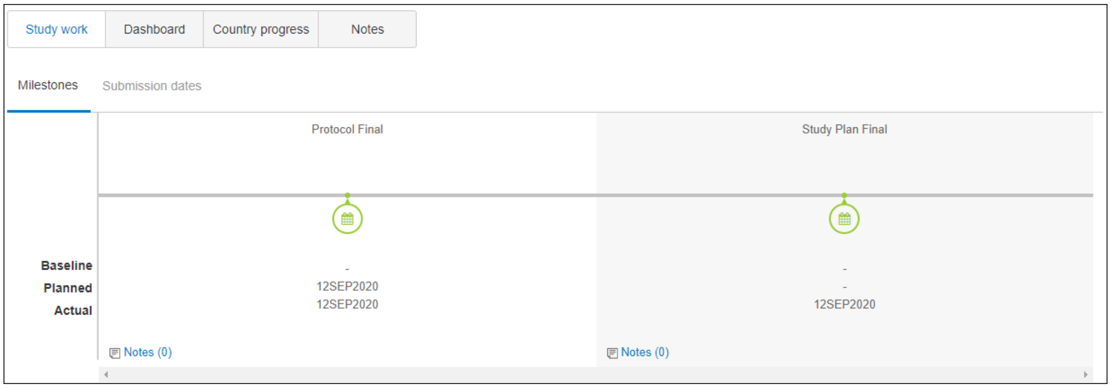
When viewing activity alerts on the study home page, you'll see multiple filters as well as the option to "Save Filters," if preferred. For instance, filters include:

- Documents, Submission: Both of these filters default to All
- Assigned to: Defaults to All my roles
- Sort by: (Most past due, Alphabetical, Newest to Oldest, Oldest to Newest) Defaults to Most past due
- Status: (All, Not started, In progress) Defaults to All
- Show: (All, Not assigned, Assigned to external business partner) Defaults to All
- Category: (All, and all configured study document categories) Defaults to All

The study home page filter area also includes a search field.

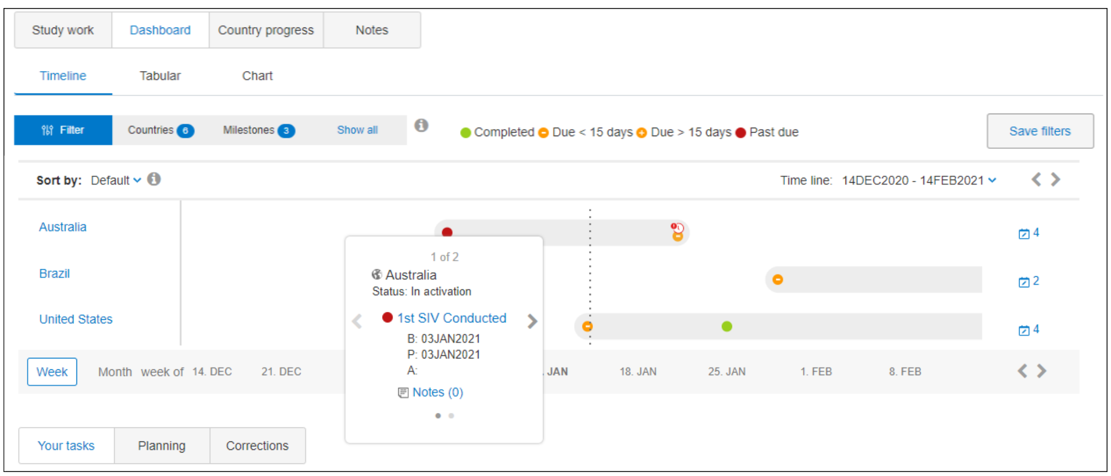
Study milestone timeline

The image below is a sample of a home page on the "Study work" tab. This tab shows the study milestone timeline.



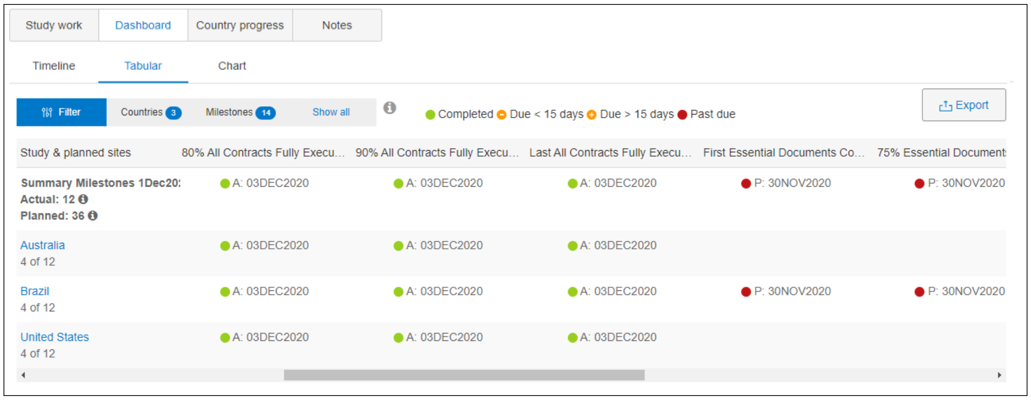
Country Milestone dashboard

The image below shows an example of a home page that is set to display the Country Milestone Dashboard on the Dashboard tab. This dashboard is highly interactive and allows for on-the-fly changes to the view. You can quickly add, remove, and optionally save filters for countries and milestones; enable/disable display of milestone statuses; select dates or a date range for the timeline; and toggle from month to week view.



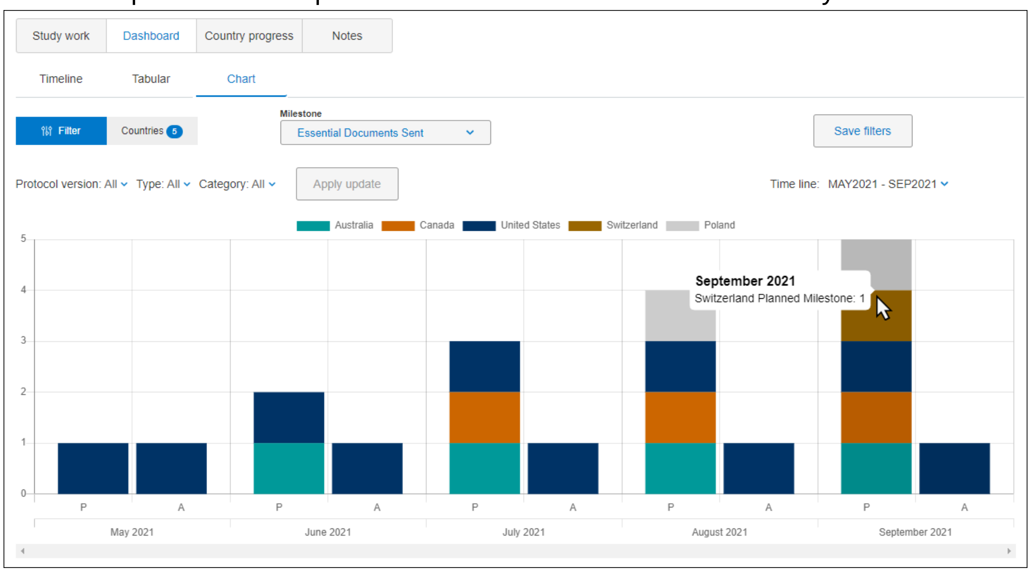
Summary Milestone dashboard

You can choose to view the Summary Milestone dashboard while on the home page Dashboard tab. Click the Tabular subtab to access this dashboard view. When the study has at least one site milestone configured as a Summary Milestone, this dashboard will help you understand progress toward completion of that site level milestone across multiple sites.



Summary milestone dashboard bar chart

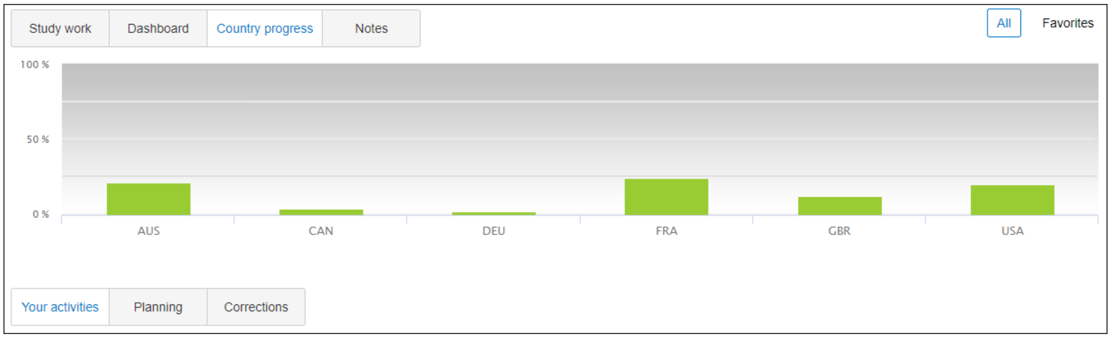
The Dashboard tab's Chart subtab shows Summary milestones as a bar chart visualization. Use this view to evaluate progress toward completion of configured Summary milestones for one or more study countries. Note that each month in the bar chart view includes two bars, P=Planned and A=Actual, with each bar segmented to filtered countries. When you hover over a bar segment, tooltip text displays the number of planned or completed milestones for the associated country and month.



Country progress dashboard

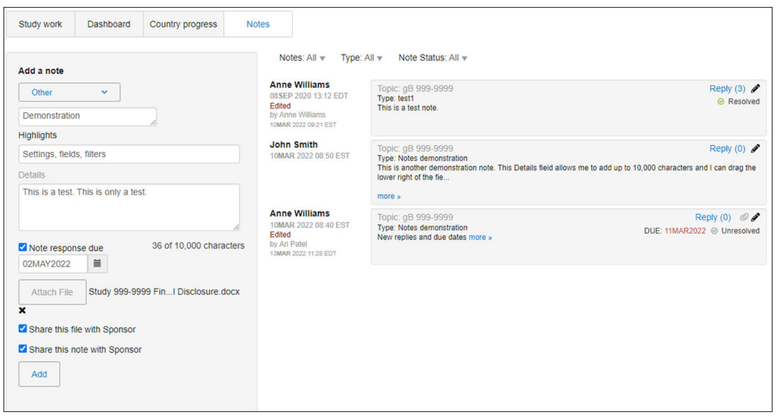
The image below shows an example of a home page that is set to display the Country progress dashboard, which shows document progress. To navigate to the country details page, click the country bar chart or the three-letter country code label beneath it; you can also click Actions, then click View study country and site details, and select the country.

When viewing the document dashboard, you can hover over a country bar to view document progress as a percentage of a total number of documents. You can also navigate directly to the country page by clicking the country bar.



Study Level Notes

This is an example of the study level notes view on the study home page. Here you can compose and/or review notes for the entire study. In the note form, you'll have the option to set a response due date, if preferred. If enabled for your organization's account, you'll also see the option to share the note and any file attachment with the study sponsor. The historical note list, if any, displays to the right. You can filter these notes as preferred, and reply, edit, and resolve notes as appropriate.

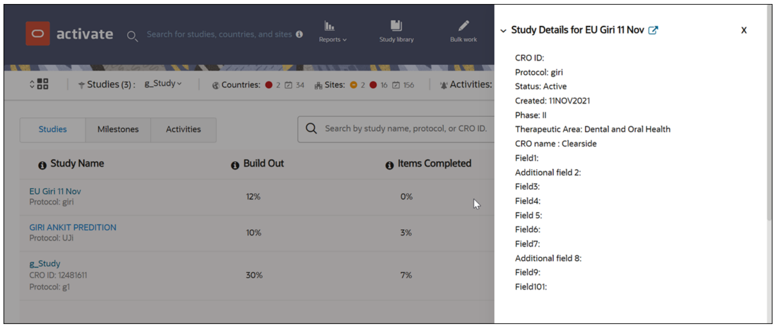


Tracking assigned studies

You can track your assigned studies on the Studies tab on the Account Overview page. This tab includes a grid with your active assigned studies (with CRO ID and Protocol identifiers, if available) and related progress metrics for each listed study. Sort the grid by the Study Name column and click the hyperlinked study name to open that study's home page in a new browser tab. Click a study row to view its Study Details panel on the right.

For each study, the grid displays a percentage value for the following metrics, which provide you with a live and accurate status update of your assigned studies:

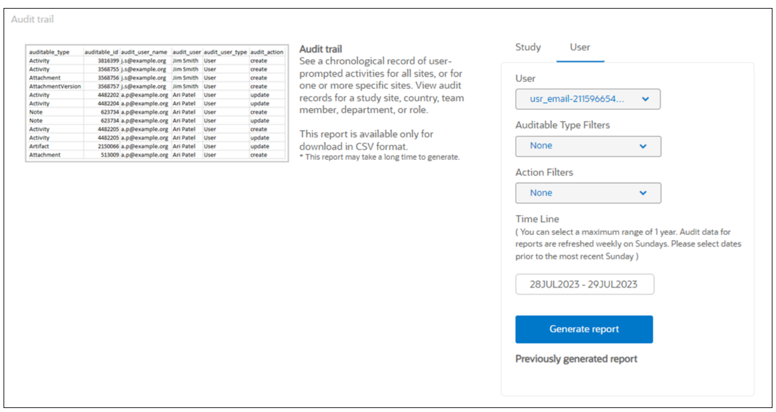
- Build Out – Represents the percentage of active sites/number of planned sites. Active site statuses are: In feasibility, In activation, IP Released, In screening, and Activated.
- Items Completed – Represents the percentage of completed items/number of created items. Items include Submissions, Packages, Contracts, and Documents from the study, active countries, and active sites. The calculated percentage excludes discontinued, on hold, and terminated items.
- IP Released – Represents the percentage of IP released and Activated sites/number of active sites. Active site statuses are: In feasibility, In activation, IP Released, In screening, and Activated.



Audit reports

When you have permission to create audit reports, you can do so at the study or individual user level. Both report types provide a variety of filter settings, like filter type (i.e.,Activity, Amendment, Artifact, etc.) and Action (i.e., Create, Update, All).

The Time Line filter is required, and it allows you to create a report that spans a maximum of one year. Audit data refreshes every Sunday, so when you create reports, it's important to select dates prior to the most recent Sunday so the reports will include the most recent data.



- Run an audit trail report
  Create a study-level or user-level CSV export that includes audit records of user-prompted activities.

Run an audit trail report

Create a study-level or user-level CSV export that includes audit records of user-prompted activities.

To create the report with a manual date range, know the report dates you need. Audit data refreshes weekly on Sundays. Select dates prior to the most recent Sunday. You can select a maximum range of one year.

> **Note:**
>
> Your user account must have audit report access enabled to complete this procedure.

1. In the top navigation bar, click **Reports** and choose **Audit report**.
2. The report's page defaults to the **Study** tab. If preferred, click the **User** tab to create a user-level report instead.
3. If you chose the **Study** tab, the **Study** drop-down list defaults to the current study. Click the drop-down to select a different study, if preferred. If you chose the **User** tab, search for and enter the user's email address in the **User** field.
4. Optionally select one or more Auditable Type Filters (e.g., Activity, Artifact, Note, etc.).
5. Optionally select Action Filters (i.e, Create, Update, or both).
6. Click the **Time Line** field to enter a specific date range of up to one year, or choose from the predefined options of Past month, Past 3 months, or Past 6 months.
7. Click **Generate report**.

   The Generate report button changes to “Report generating…” and a refresh option displays to the right of the button.

Depending upon the size of the study and number of audit activities, this report may take a long time to generate but it is not necessary to stay on the Audit trail report page to create the report. When completed, the "Report generating" button returns to “Generate report,” and a report link displays below the button.

2
About your user login and profile

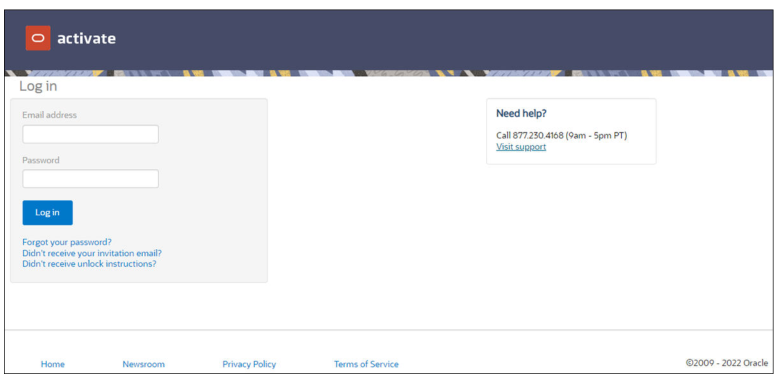
Access methods

Oracle Site Activate supports two types of access - manual login and Single Sign On (SSO) from a customer's configured Identity Provider (IDP) application (usually this is the customer organization's portal). If your organization has configured SSO access to Oracle Site Activate, login and password sections below will not apply to you, as all login activity and password management will be handled through your organization's IDP.

Logging in to Oracle Site Activate

If users in your organization do not access Oracle Site Activate via SSO, you'll be required to log in to protect and control access to your study data. You, along with each study team and site member, will use a unique user name and password.

To make sure that access to data is properly protected and to ensure that activities performed by you are properly attributed to your user account, do not share your user name or password with others.



Terms of Service and Privacy Policy

All Oracle Site Activate users, including site experience users, must review and then either accept or decline the Terms of Service and Privacy Policy.

The Terms of Service and Privacy Policy display immediately after your first authentication. This applies if you authenticate via manual login with credentials or via single sign-on (SSO). Site users who complete tasks via email and do not directly log in to Oracle Site Activate will not be required to accept or decline the terms in that flow. However, if at any time site users do attempt to log into the system, they must accept the terms to gain access.

If you choose to:

Accept terms - you will be automatically logged into Oracle Site Activate (or site experience, as applicable). Oracle Site Activate retains a database audit record of the “Accept” action, and you will not be asked to accept the terms again unless a new or updated version requires your acceptance.

Decline and sign out - you will be redirected back to the login page and will not have access to any page in Oracle Site Activate except the login page and the Terms of Service acceptance page. Oracle Site Activate retains a database audit record of the “Decline” action.

If you initially decline, you can return to the Oracle Site Activate login page at any time to enter your credentials and review and accept the Terms of Service and Privacy Policy.

Automatic logout

If Oracle Site Activate detects that you are inactive longer than the allotted time defined by your organization, it will warn you that you will automatically be logged out unless you choose to continue. This is a compliance requirement that helps prevent unauthorized access should you leave your computer unattended.

Managing your password

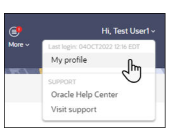
Unless your organization has set up single sign on (SSO) to Oracle Site Activate, you will be asked to change your password the first time you log into Oracle Site Activate and every 90 days thereafter. The following password management requirements apply:

- Passwords are required to include one uppercase character, one lowercase character, one special character, and one number
- New passwords may not be the same as the previous 10 passwords
- Passwords must be reset by user if issued for the first time or reset by customer support
- User accounts will be locked out after three unsuccessful attempts

If you forget your password, click **Forgot your password?** on the Oracle Site Activate login page; we will send an email with instructions for creating a new one.

Accessing your profile

At the upper right of any Oracle Site Activate page, hover over the "Hi, <your name>" drop-down menu and click **My profile** to see your profile. Here, you can change your email address, manage email reminders, see your password expiration date, or create a new password.



Adding team member accounts

There are two ways to add new team member accounts to Oracle Site Activate:

1. If your organization has integrated Oracle Site Activate (i.e., via API), new user accounts may automatically be created.
2. Manually add new user accounts in the Oracle Site Activate Team Members area.

Newly added team members will receive an email that includes instructions for logging in.

Controlling access with team and role assignments

After new user accounts are created, you will need to assign business roles to new team members and grant them access to studies. Until you assign roles, team members will see an empty dashboard when they log in to Oracle Site Activate.

During initial go-live of Oracle Site Activate, your company representatives worked with the Oracle Project Team members to determine which business roles can perform specific activities in Oracle Site Activate. You were then granted one or more of these roles that reflects the type of work you do and determines what you can see and do in the system. You can be granted different roles for different studies.

For your roles, you may be designated the “primary assignee” for certain study countries or sites so that when activities are due for the role, you are the person expected to complete them.

> **Note:**
>
> You are only able to access studies for which you have been granted a specific role, for viewing activities, completing them, or both.

Below are some typical business roles; however, your organization is unique and may use different role names or have additional roles:

- Study lead
- Contract manager
- Project manager
- Startup specialist
- Administrator (super user)

3
About study countries

Tracking study country status

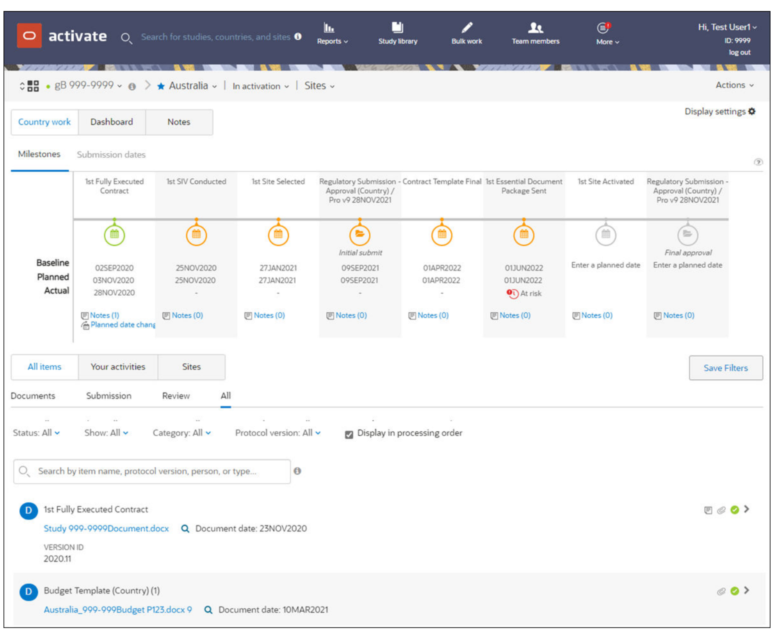
Each study country has a details page where you'll see the information you need to manage and track all the country’s documents and submissions. You can access the study country details page by clicking on a country code or bar in the bar graph on the home page.

Once the country's details page displays, you can optionally "favorite" the country as shown below (blue star to the left of the country name). When you favorite a country, you can use the toggle control on your home page to toggle the country document bar graph display to all countries or favorite countries.

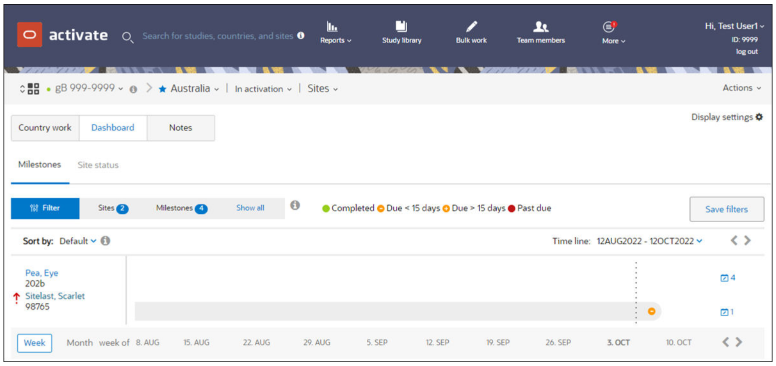
Country status labels display in the persistent header if this option has been enabled for your organization's account. Oracle Site Activate users who have appropriate permissions may edit a country’s status label if necessary.

Country pages include primary tabs that allow you to access distinct views. The tabs display at the upper left of the page. The primary tabs are:

1. **Country work** – this view is the country page with item activities displayed below the milestone timeline.
2. **Dashboard** – this view is the site milestone dashboard
3. **Notes** – this view provides notes functionality. The note form displays to the left and any previously saved notes display to the right.



The image above shows the **Country work** tab view with the milestones timeline. You can also evaluate site status and milestone progress on the country details page. Click the **Dashboard** tab for the site milestone dashboard view shown below.



You can set either Country Work (country tab) or Site dashboard as your default view. Use the "Display settings" control at the upper right of the view to select your preferred default.

Details	What you'll find on the country details page
overall country status	If enabled for your organization's account, country status labels display in the persistent header. Preconfigured status labels include: Planning, Submitted, Dropped, Approved, In activation, On hold, Completed/ Maintenance, and Closed. When configuring Oracle Site Activate, your organization may have preferred to use alternate display values and those values will display instead. On the site status tab, you'll see the percentage of sites in the country by status (activation, activated, on hold, or dropped).
key milestones	You'll see the baseline planned and actual dates for the milestones your organization tracks. The baseline date is the original date you or another team member estimated that the milestone will be met. Enter a new projected date and it appears as the planned date on the milestone timeline. If you re-plan a date, you are asked to enter a reason. When the activity associated with the milestone is complete, the actual date automatically appears on the timeline.
notes & communications	Each time you or another team member enters a note while completing an activity, that note appears on the **Notes** tab. You can also enter notes without activities by entering them directly on the tab.
all items	The all items tab lists all of the country's Document, Submission, and Review items.
your activities	This tab lists all of the items for this country that have been assigned to a user with your business role.

sites	Here you'll find a list of sites in the study country. Click the Actions column to view other options available to you depending on your business role permissions (e.g., Remove a site, Export completed documents, etc.) Click the site name to view the site milestone dashboard.

Deleting a study country

Occasionally it may be necessary to delete a study country and associated study sites from a study. To do so, you must have the "Enable study country deletion" business role permission. When you have the permission, you'll see "Delete study country" as an option in the country level Actions menu.

When you choose to delete a study country, you must enter a deletion Reason and check the acknowledgment check box to enable the deletion button in the confirmation modal. If the study country has any associated study sites, the modal will also show the number of sites that will be removed.

> **WARNING:**
>
> Please be sure you want to delete the country and any associated study sites. You cannot undo this action.

- View study country details
  Quickly access a list of countries included in a study and the count of sites included per country.
- Favorite a study country
  When you favorite a country, you can use the toggle control on your home page to toggle the bar graph display to all countries or favorite countries.
- Add a new study country
  If necessary, you can add a new country to your study and specify a configuration process at the same time. If you have a business role permission that allows you to set country status, you can also specify the country status when adding a country to a study.
- Edit number of planned sites for a country
  If you have the appropriate business role permissions, you can enter or edit the number of sites planned for a study country.
- Delete a study country
  You can delete a study country from an existing study when necessary. This procedure also removes associated study sites.

View study country details

Quickly access a list of countries included in a study and the count of sites included per country.

- On the home page, from the **Actions** menu, select **View study country and site details**.

Favorite a study country

When you favorite a country, you can use the toggle control on your home page to toggle the bar graph display to all countries or favorite countries.

1. On the home page, from the **Actions** menu, select **View study country and site details**.
2. Click the star to the left of the country name.

   The country now displays a blue star next to the country name.

Add a new study country

If necessary, you can add a new country to your study and specify a configuration process at the same time. If you have a business role permission that allows you to set country status, you can also specify the country status when adding a country to a study.

1. On the home page, from the **Actions** menu, select **Add new study country**.
2. Choose a new country from the **Country** drop-down menu.
3. Select a **Country status** from the drop-down menu. Status defaults to "In activation."
4. At **Process**, select the process (configuration) you want to use.
5. Enter the number of sites planned for the new country.
6. Optional: If enabled for your account, you can enable/disable electronic signature for the new study country, if preferred.
7. Click **Done**.

Edit number of planned sites for a country

If you have the appropriate business role permissions, you can enter or edit the number of sites planned for a study country.

1. On the study country details page, from the **Actions** menu, select **Edit study country**.
2. At **Number of planned sites**, enter a new number.
3. Click **Done**.

Delete a study country

You can delete a study country from an existing study when necessary. This procedure also removes associated study sites.

You must have "Enable study country deletion" business role permission to complete this procedure.

> **WARNING:**
>
> This action cannot be undone. Please ensure you want to remove all data for the country and associated study sites before completing this procedure.

1. On the country home page, choose **Delete study country** from the **Actions** menu.
2. In the confirmation modal, enter a **Reason** for removing the country and any associated sites from the study.
3. Check the **I acknowledge that all study country data will be deleted** check box.
4. Click **Yes, delete this study country**.

4
About study sites

Multiple ways to track site activities

You can manage and track site activities in Oracle Site Activate as follows:

1. Track documents on behalf of sites (you mark activities complete to indicate that the site performed them).
2. Invite sites to exchange documents and complete activities in Oracle Site Activate.
3. Invite sites to exchange documents in Oracle Site Activate LITE via email without the site user needing to log in.
4. Sites may review and upload documents directly from an email via site email integration.
5. Sites may complete tasks via email integration without sending an attachment.

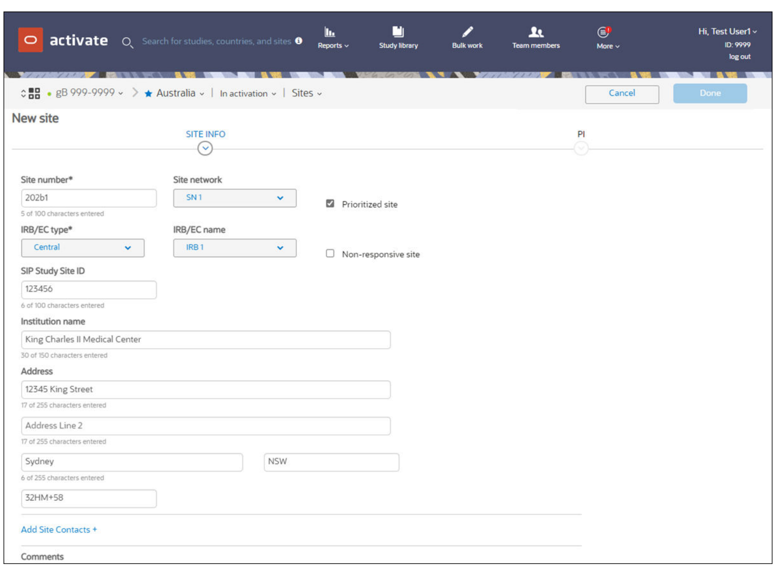
Managing sites and site personnel in Oracle Site Activate

To get started:

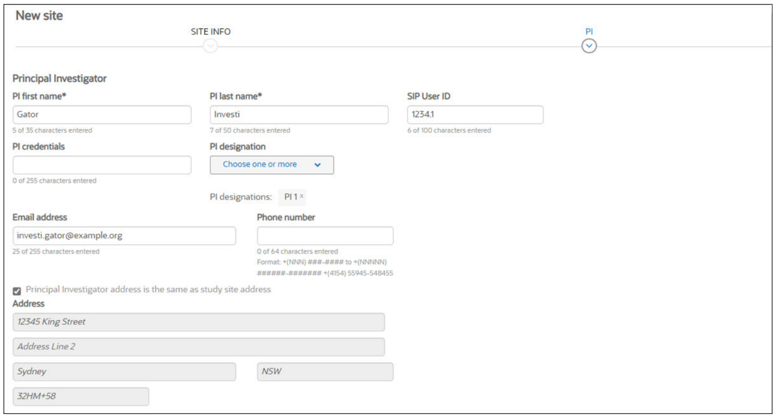
- Your Oracle Site Activate administrator or super user sends your site list to Oracle and we set up sites in Oracle Site Activate for you.
- A member of your study team then adds site personnel (e.g., Sub-investigator, Lab director, etc.) on the **Staff** tab of the site's details page.
- Oracle Site Activate automatically creates the activities that track site CVs, medical licenses, financial disclosure forms, and other required documents.

If you need to add a new site after initial study setup by Oracle, click the **Add study site** button on the country details, Sites tab.

Start with the "SITE INFO" section on the left and complete all required form fields. You can also add up to 10 staff members at the bottom of the form.

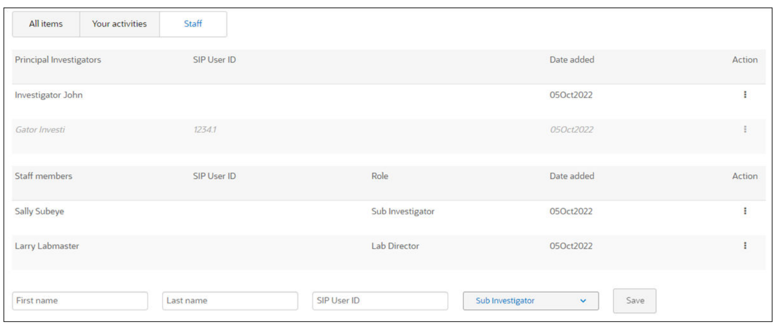


Once you've added all the SITE INFO fields, click **PI** at the upper right of the page so you can add in PI information and save the new site.



If you will collaborate with sites in Oracle Site Activate, at least one person at the site is issued an Oracle Site Activate login (even if the site will use Oracle Site Activate LITE, which enables sites to exchange documents without logging in).

You can change information about site staff; however, if you add or remove staff or change names in a way that impacts documents, Oracle Site Activate automatically regenerates the documents so you can get them changed.



Marking a site as Prioritized or Non-responsive

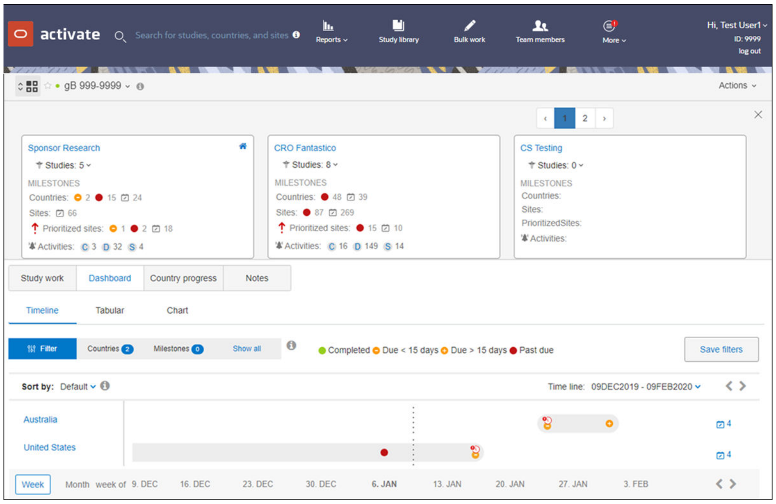
When adding or editing a site in Oracle Site Activate, you can manually flag a site as Prioritized and/or Non-responsive. Sites that have the "Prioritized site" flag enabled are made more prominent and easily accessible within the Oracle Site Activate user interface. Conversely, sites that have the "Non-responsive site" flag can have their work deprioritized (within your organization's standard operating procedures) until the non-responsive flag is removed.

Prioritized and non-responsive flags apply at the study level (i.e., a site may be prioritized in one study but not in another). A prioritized or non-responsive site may also be a "Favorite" site, as favorites are applied at the individual user level.

Oracle Site Activate indicates a Prioritized site with a red up arrow (↑). This arrow displays, to the left of the site name, in the following areas:

- Site Milestone Dashboard
- Country page, Sites tab
- Activity Overview page
- Account cards

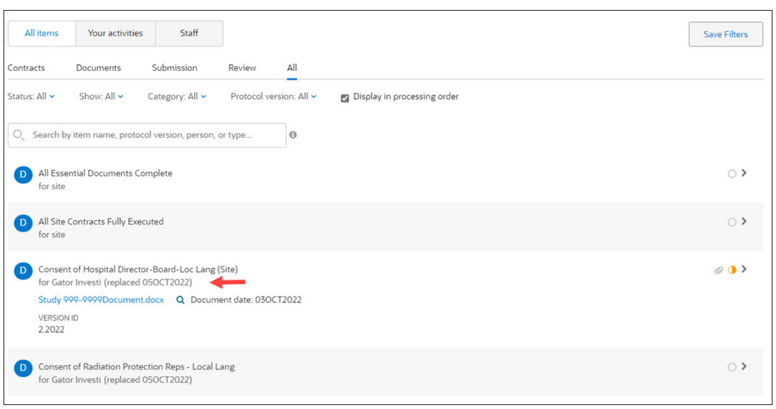
Prioritized sites are also in the persistent header that displays when viewing partner accounts as well as the account card when the account panel is open. The entry in the header and cards indicates the number of due, past due, and unplanned milestone items for prioritized sites, as applicable.



Replacing a principal investigator

If you have the appropriate permissions to replace a PI, you can enter information about the new investigator and Oracle Site Activate automatically generates the activities required for the new PI.

To help you focus your work on active investigators, activities for replaced PIs are noted on activity lists.



If necessary, you can reinstate the PI. This action is available on the Staff tab in the Action drop-down list. If you reverse the PI replacement, the following reinstatement behaviors apply:

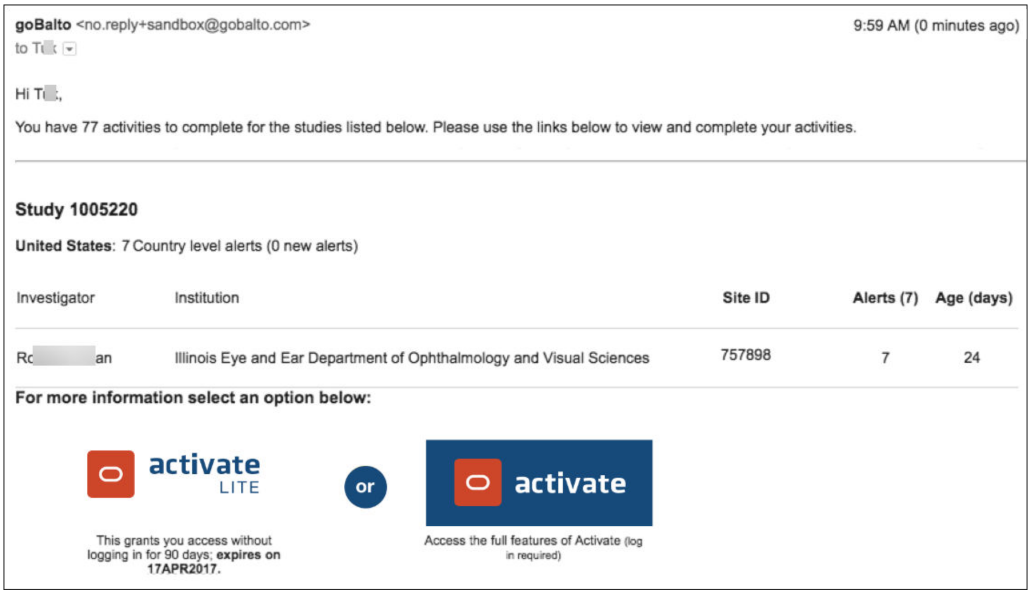
- Documents for the reinstated PI that were marked as "For replaced PI" will be marked as “Active.”
- The PI being replaced (by the reinstated PI) will go through the normal PI replacement process, and documents associated with the replaced PI will be marked as “For replaced PI.”
- On the Staff tab, the reinstated PI is marked as “Active” with the original Added date, and the replaced PI will be marked as replaced.

Tracking activities on behalf of sites

When it is time for the site to submit a document, you will receive an alert on behalf of the site. When documents are complete, just mark the activities complete in Oracle Site Activate.

Collaborating with sites in Oracle Site Activate

If your organization configures Oracle Site Activate for site collaboration, as sites are added, they receive an email invitation to collaborate with you in Oracle Site Activate. The site coordinator clicks a link in the email or the Oracle Site Activate logo button to gain secure access to the system.



goBalto <no.reply+sandbox@gobalto.com> 9:59 AM (0 minutes ago)
to T

Hi T,

You have 77 activities to complete for the studies listed below. Please use the links below to view and complete your activities.

Study 1005220

United States: 7 Country level alerts (0 new alerts)

Investigator	Institution	Site ID	Alerts (7)	Age (days)
Rc an	Illinois Eye and Ear Department of Ophthalmology and Visual Sciences	757898	7	24

For more information select an option below:

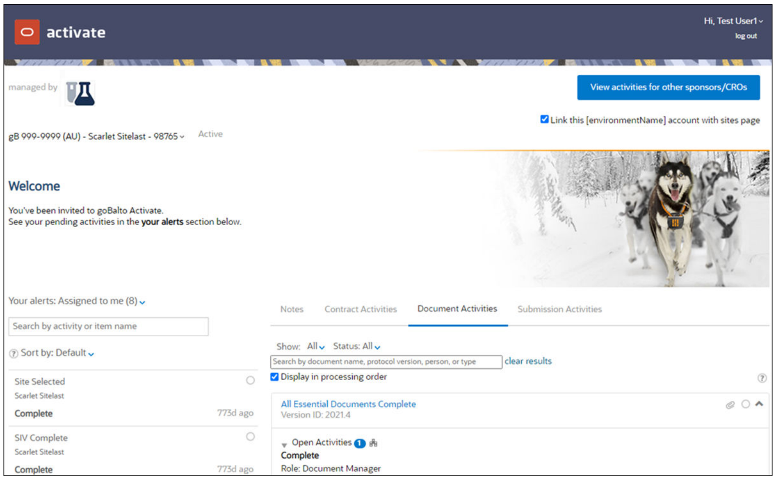
This grants you access without logging in for 90 days; **expires on 17APR2017.**

Access the full features of Activate (log in required)

Sites have their own Oracle Site Activate dashboard that shows only information about their site and the studies in which they are involved. They see activities that are due for them on the home page and they complete all activities there. They also see a running list of all communications and documents so they will know the current status of the work they do with you.

With sites participating in Oracle Site Activate, they can upload their documents into Oracle Site Activate. You and other members of your study team receive alerts to review and approve the documents.

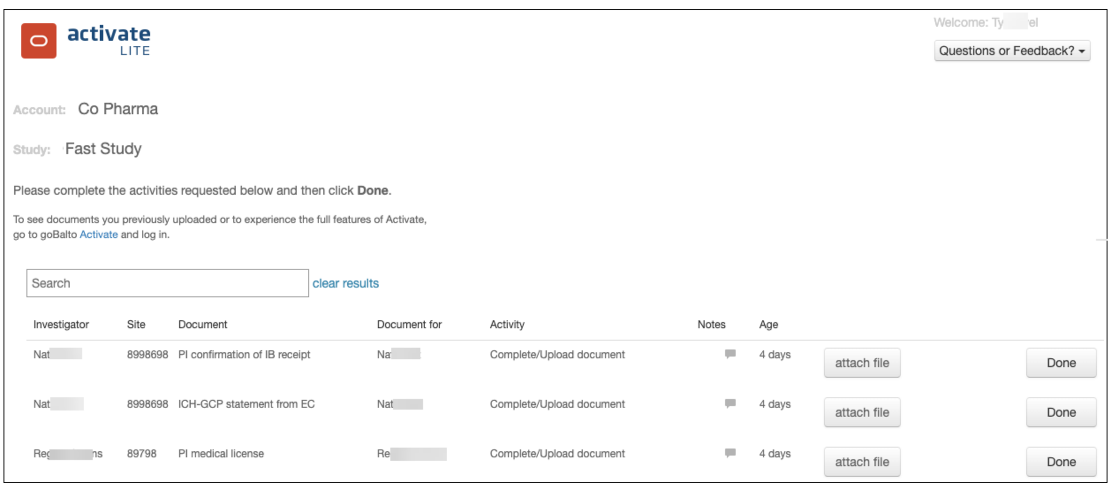
If your organization uses the optional contracts module, your sites will also see a **Contract Activities** tab.



Collaborating with sites using Oracle Site Activate LITE

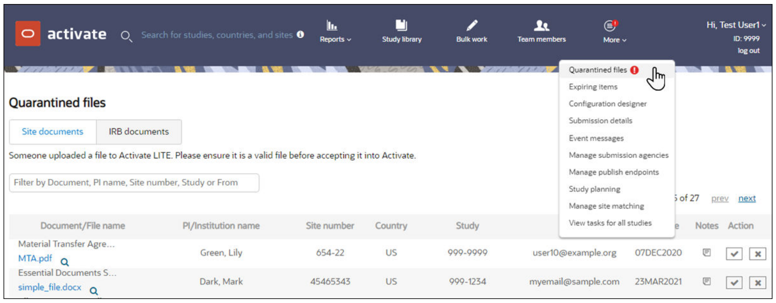
If your organization allows sites to access Oracle Site Activate LITE, they receive an email notification with a link to a web page where they can exchange documents with you without logging in.

The files sites upload in Oracle Site Activate LITE are placed in a quarantined area of Oracle Site Activate until a member of your study team reviews the files before accepting them into the system. This allows you to address any security and compliance concerns about documents uploaded by sites who have not logged into Oracle Site Activate and prevents inappropriate documents from entering into your secure study workspace



The quarantine indicator displays when there are files in the quarantine area for you to review and accept into Oracle Site Activate.

Site users who use email integration can also complete tasks without sending an attachment. If the site replies with a note (e.g., to acknowledge the task), the note goes into the Quarantine area (in the same way an attachment would) to be accepted by an Oracle Site Activate user. When accepted, the activity completes – regardless of any accompanying note or attachment.



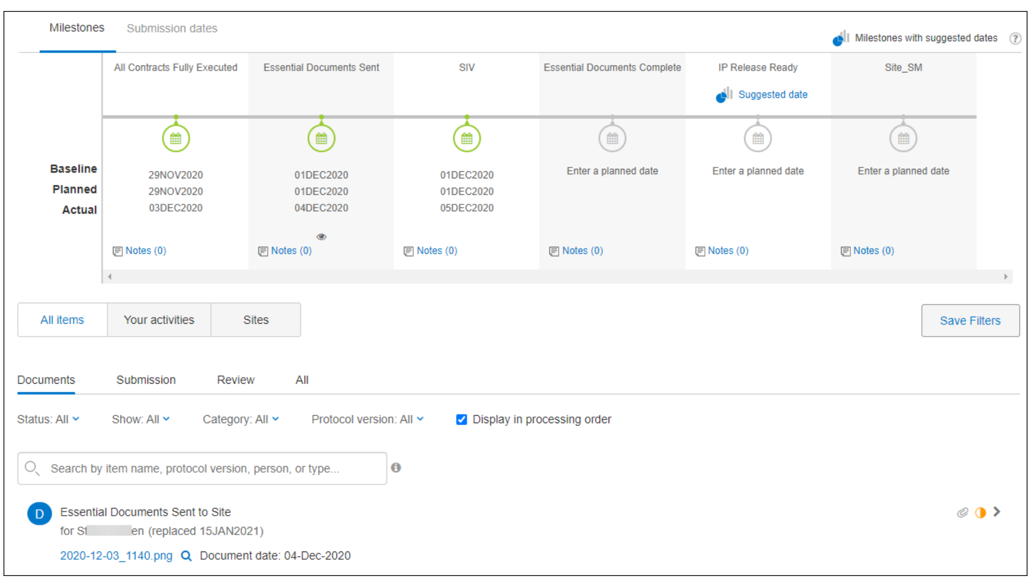
Tracking site status

In Oracle Site Activate, each site has a site details page where you will see all their documents and submissions, and view or change the site's activation status. You'll access the site details page from the **Sites** tab of the study country details page or from an alert on the home page.

You can observe the site's status (e.g., "In activation") in site details page persistent header. If you choose to favorite a site by clicking the star to the left of the site name, you'll see a blue star next to the site on site lists. Additionally, the favorite site will display at the top of site lists, and you can also filter site lists to display only favorite sites. Favorites apply at the individual user level; sites you favorite may not be favorites of others on your study team.

Below the site page milestone timeline, you'll see secondary tabs that simplify access to the activity placeholder list and site/staff list. The secondary tabs are:

- **All items** – displays a filterable list of all parent item placeholders
- **Your activities** – displays a filterable work list of activities where you have one or more assigned role
- **Staff** – displays the list of site staff, including the current PI and any previous (replaced) PI



Details	What you'll find on the site details page

site details	You'll see the site number, institution name, primary investigator, study country, and IRB type. If configured for your account, you'll also see the IRB name and/or Network.
site status	You'll see the site status. As the status changes, you can select a new status from the drop-down in the persistent header. If enabled for your organization's account, certain country statuses automatically "flow down" to sites to update status as follows: • When an Oracle Site Activate user changes a country status to "On hold," all statuses of the sites in that country change to "On hold" unless already in IP release • When an Oracle Site Activate user changes a country status to "Closed," all statuses of the sites in that country change to "Closed" unless already in IP release • When an Oracle Site Activate user changes a country status to "Dropped," all statuses of the sites in that country change to "Dropped" unless already in IP release • When an Oracle Site Activate user changes a country status back to "In activation" from "On hold," the statuses of the sites that were not already "Closed," "On hold," or "Dropped" before the country status change will change back to "In activation" • When an Oracle Site Activate user changes a country status back to "In activation" from "Closed" or "Dropped," the statuses of the sites remain "Closed" • If a country status is "Dropped," "On Hold," or "Closed," Oracle Site Activate users **will not**be able to change the site status. Users will see a tool tip noting that the country status needs to change to allow changing of site status
key milestones	You'll see the baseline planned and actual dates for the milestones your organization tracks. The baseline date is the original date you or another team member estimated that the milestone will be met. Enter a new projected date and it appears as the planned date on the milestone timeline. If you re-plan a date, you are asked to enter a reason. When the activity associated with the milestone is complete, the actual date automatically appears on the timeline. If you re-plan a milestone date and the change impacts downstream activity due dates, Oracle Site Activate warns you so that you can notify others who are impacted by the change.

notes & communications	Each time you, another team member, or a site enters a note while completing an activity, that note appears on the **Notes** tab. You can also enter notes without activities by entering them directly on the tab.
documents	You'll see the status and history of documents tracked on the **Document Activities** tab. If you are managing document files in Oracle Site Activate, you will also see those files.
submissions	You'll see the status and can manage site-level submissions tracked on the **Submissions Activities** tab.
staff	You'll see the list of site staff and their roles.
alerts	You'll see the list of alerts for this site. Filter the list to see alerts intended for your role or just you.

- Add a new site
  If a new site needs to be added to your study, you can add the site individually and Oracle Site Activate automatically creates non-protocol related activities for the site.
- Add multiple new sites
  Send your list to your super user. If your organization does not have a designated super user, contact Oracle Support.
- View site details
  Among the details displayed at the top of the site details page are the site number, institution name, primary investigator, study country, and IRB/EC type. If configured for the account, you'll also see the IRB/EC name and/or Network.
- Favorite a site
  If you favorite a site by clicking the star to the left of the site name, an blue star displays next to the site on site lists. The favorite site will display at the top of site lists, and you can also filter site lists to display only favorite sites.
- Change a site's status
  Note: If a country's status is “Dropped,” “On Hold,” or “Closed,” and country status display is enabled for your organization's account, you will not be able to change the site status. Tool tip text notes that the country status needs to change to allow changing of site status.
- Change a site's information
  If necessary, you can change a site's institution information, site number, IRB/EC type, and more. To change an investigator's name, see the Replace the principal investigator instructions (related topic link below) for details.
- Add site staff
  This procedure shows how to quickly record the names and roles of study site staff members.
- Edit staff contact details
  When necessary, you can edit a staff member's demographic details to update assigned IDs, email address, phone number, and more.

- Replace the principal investigator
  If you need to replace a principal investigator and you have the appropriate permissions, you can enter information about the new investigator and Oracle Site Activate automatically generates the activities required for the new PI.
- Reverse PI replacement
  When appropriate you can reinstate a Principal Investigator and save time by using data already saved for that investigator instead of manually recreating the data.
- Change site staff names
  You can quickly update site staff names to ensure that the correct individual is on record for specific study site roles (e.g., sub-investigator, deputy, etc.).
- Review quarantined files uploaded by sites
  If you have the appropriate business role permissions, you can access the quarantine area to review and then accept or reject files uploaded to Oracle Site Activate by sites.
- Track ad hoc documents
  If you need to track a document that you didn't originally plan for, you can add the document at the study country or site level.

Add a new site

If a new site needs to be added to your study, you can add the site individually and Oracle Site Activate automatically creates non-protocol related activities for the site.

1. On the country details page **Sites** tab, click **Add study site**.
2. On the New site page under the **Site info** section, enter the **Site number**.
3. If your organization's account is configured to capture site network, select the **Site network** from the drop-down list.
4. Select an **IRB/EC** type from the drop-down list.
5. If your organization's account is configured to capture **IRB/EC name**, select the name from the drop-down list, or select Other and type in the IRB/EC name.
6. Optional: If work for this site should be prioritized among team members, check the **Prioritized site** check box. Alternatively, if the site is not expected to respond to communications and requests, you can check the **Non-responsive site** checkbox.
7. At **Institution name**, enter the name of the organization working on the study.
8. Enter the institution's address.
9. Optional: Click **Add Site Contacts** to add PI staff contact information. Select a contact type (role), then add name email, and phone number. You can repeat this step up to 10 times.
10. Optional: Enter comments for the site, if appropriate.
11. At the upper right, click the **PI** toggle.
12. Enter the Principal Investigator's first and last name.
13. If your organization's account is configured to capture **PI credentials**, enter the credentials.
14. If your organization's account is configured to capture **PI designation**, select one or more designation(s) from the drop-down list, and click **Done**.
15. Enter the PI's **Email address** and **Phone number**.

16. If the PI's address information is the same as the study site address (the institution added at step 8 above), click the "Principal Investigator address is the same..." checkbox. Otherwise add the PI's address in the fields provided.
17. At the upper right of the page, click **Done**.

After completing the procedure steps above, the investigator’s name displays on the sites list, and Oracle Site Activate creates the activities needed to track the required non-protocol related documents (such as CVs, medical licenses, and financial disclosure forms).

Add multiple new sites

Send your list to your super user. If your organization does not have a designated super user, contact Oracle Support.

View site details

Among the details displayed at the top of the site details page are the site number, institution name, primary investigator, study country, and IRB/EC type. If configured for the account, you'll also see the IRB/EC name and/or Network.

- On the home page, click the site’s name on an activity, or from the country details page, click the **Sites** drop-down in the persistent header and click the site's name.
- You can also access the site details page by clicking on the site name in the country milestone dashboard.

Favorite a site

If you favorite a site by clicking the star to the left of the site name, an blue star displays next to the site on site lists. The favorite site will display at the top of site lists, and you can also filter site lists to display only favorite sites.

1. On the home page, click the site’s name on an alert, or from the country details page, click the **Sites** tab.
2. Click the star next to the site name.

Change a site's status

Note: If a country's status is “Dropped,” “On Hold,” or “Closed,” and country status display is enabled for your organization's account, you will not be able to change the site status. Tool tip text notes that the country status needs to change to allow changing of site status.

1. On the site details page, click on the status option at the right of the site name.
2. Select a new status (In activation, IP released, on hold, dropped or closed).

Change a site's information

If necessary, you can change a site's institution information, site number, IRB/EC type, and more. To change an investigator's name, see the Replace the principal investigator instructions (related topic link below) for details.

1. On the country details page, click the **Sites** tab, then select **Actions** next to the investigator's information you would like to edit.
2. In the **Action** column, click edit ( ).
3. Change the investigator's institution, site number, IRB/EC type, etc. as necessary.
4. Optional: Enter comments for the site.
5. At the upper right, click **Done**.

Related Topics

- Replace the principal investigator
  If you need to replace a principal investigator and you have the appropriate permissions, you can enter information about the new investigator and Oracle Site Activate automatically generates the activities required for the new PI.

Add site staff

This procedure shows how to quickly record the names and roles of study site staff members.

1. On the site details page, click the **Staff** tab.
2. At the bottom of the tab, enter the staff member's **First name** and **Last name**.
3. Select the staff member's role from the list: Sub Investigator, Pharmacist, Coordinator, Lab Director, or Deputy.
4. Click **Save**.

Edit staff contact details

When necessary, you can edit a staff member's demographic details to update assigned IDs, email address, phone number, and more.

1. On the site details page, click the **Staff** tab.
2. To the right of the staff member's name, under **Actions**, click the menu control and click **Edit**.
3. Update any field as necessary.
4. Click **Done**.

Replace the principal investigator

If you need to replace a principal investigator and you have the appropriate permissions, you can enter information about the new investigator and Oracle Site Activate automatically generates the activities required for the new PI.

1. On the site details page, click the **Staff** tab.

2. Next to the PI’s name, click **Actions** and select **Replace PI**.
3. Enter the new PI’s information.
4. Click **Done**.

The new PI's name displays in the principal investigator's list, and the previous PI's name displays below in italics.

Reverse PI replacement

When appropriate you can reinstate a Principal Investigator and save time by using data already saved for that investigator instead of manually recreating the data.

1. On the site details page, click the **Staff** tab.
2. Next to the replaced PI's name, click **Actions** and select **Reinstate PI**.
3. In the confirmation dialog, click **Confirm**.

When confirmed, the following reinstatement behaviors apply:

- Documents for the reinstated PI that were marked as "For replaced PI" will be marked as “Active.”
- The PI being replaced (by the reinstated PI) will go through the normal PI replacement process, and documents associated with the replaced PI will be marked as “For replaced PI.”
- On the Staff tab, the reinstated PI is marked as “Active” with the original Added date, and the replaced PI will be marked as replaced.

Change site staff names

You can quickly update site staff names to ensure that the correct individual is on record for specific study site roles (e.g., sub-investigator, deputy, etc.).

1. On the site details page, click the **Staff** tab.
2. Under the staff member's name, click **Actions** and select **Edit**.
3. Change the staff member first and last name as necessary.
4. Click **Save**.

Review quarantined files uploaded by sites

If you have the appropriate business role permissions, you can access the quarantine area to review and then accept or reject files uploaded to Oracle Site Activate by sites.

1. From the top navigation bar, click or hover on **More**, then select **Quarantined files**.
2. Optional: To filter the list by name or sender, enter a term into the search box.
3. To view a file, click the file name to download it, and open the file from your computer.
4. Optional: If enabled for your account, click preview ( ) to view the file before downloading.

5. All files are checked for viruses when they are first uploaded to Oracle Site Activate. Check the document to make sure it is valid.
6. In Oracle Site Activate, check the box next to the file name.
7. To allow the file to stay in Oracle Site Activate, click accept ( ). Otherwise, click reject ( ) and enter an explanation for the rejection. The text will be entered in the document's note history and the site will receive a note explaining the rejection. The sender will receive an email with a link to upload a different file. Click **Send message to site** if rejecting the file.
8. Optional: To view the history of document notes, click ( ) in the **Notes** column.

Track ad hoc documents

If you need to track a document that you didn't originally plan for, you can add the document at the study country or site level.

1. Display the study country or site details page for the country or site for which you will track the document.
2. From the **Actions** menu, select **Add an ad-hoc document**.
3. Under **Or add a new ad-hoc document for one or more sites**, enter a unique document name.
4. Select the document type from the drop-down menu.
5. If the document should be tracked with a specific protocol version, indicate which one.
6. Select the workflow to use when processing the document.
7. Click **Next**.
8. Indicate the site(s) or country(ies) for which the document will be tracked.
9. Confirm or edit your selections, and click **Done**.

5

About activity alerts

Oracle Site Activate automatically alerts you when there is a pending activity. Alerts are for activities that you, or someone with your role, need to complete. You can stay informed of outstanding alerts by receiving a daily or weekly email notification, and if you have the appropriate business role permission, you can also pause your alerts for an item.

Activity alerts

When you click an alert in Oracle Site Activate, the corresponding work area opens and you can complete the assigned action (e.g., review, upload document, etc.). Once you complete the associated activity, it disappears from the alerts list. There are two types of alerts:

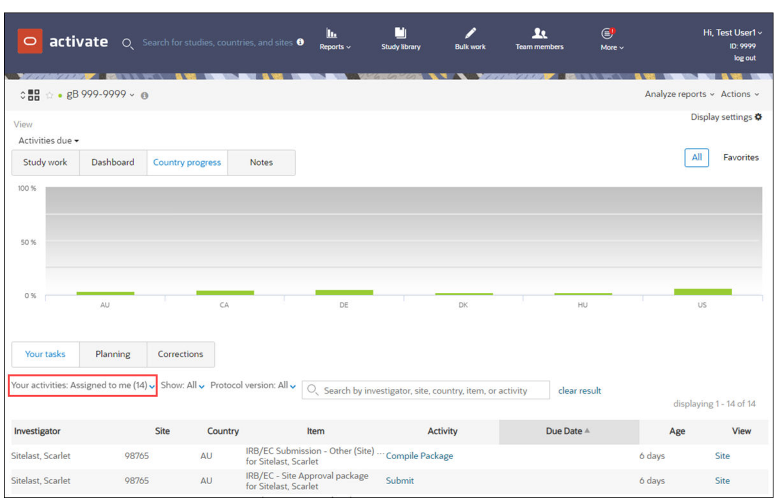
1. **Alerts assigned to me** – alerts for study countries or sites to which you are specifically assigned and at the study, country, or site level you're viewing
2. **Alerts for all my roles** – alerts for all of your business roles and the number of alerts per role

Alerts will display when:

- An activity is due for a document activity or submissions activity
- You are assigned to the site or study country associated with the alert
- The alert is to be addressed by someone with your business role

By default, all activities assigned to you display on your alerts lists; however, you can filter the list to show activities that are due for your role. You'll see alerts on the home page and on the study country and site details pages associated with the activities.

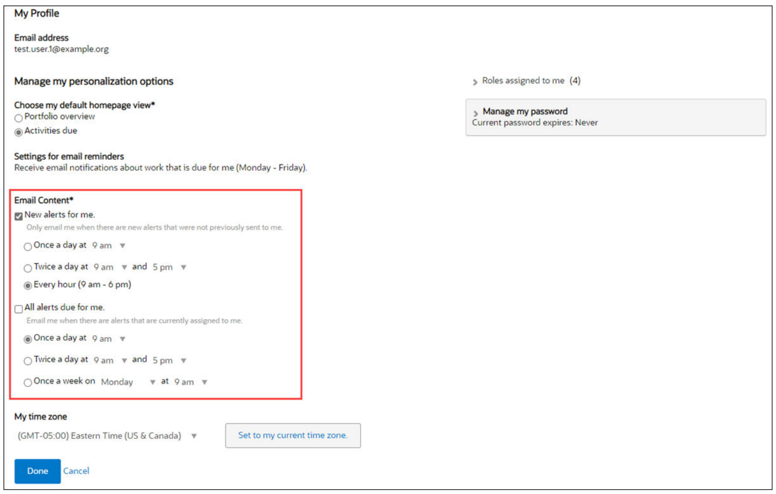
On country, site, and study pages, "Assigned to me" and "All my roles" display at the top of the list, followed by specific roles. By design, roles sort by those with the most activities assigned to them (greatest to least) and alphabetic secondary sort. On the Account overview page, "Assigned to me" is the first option at the top of the list, followed by specific roles. These roles also sort by most activities assigned and alphabetic secondary sort.



Getting notifications by email

You'll receive an email indicating there are new activities that require attention. The activities listed in the email are separated by study and site to help you see which alerts require immediate attention.

Customer organizations can work with Oracle Support to enable or disable notifications for all study team members and customize the message that study team members and sites see in the email. As an individual team member, you can control how often you receive an email notification and the time of day that emails are sent. You'll configure your preferred settings in your profile.



If you receive an email notification, click the link in the email. If you are not already logged in to Oracle Site Activate, the login page displays. The country or site details page associated with the alert displays if you are logged in.

> **Note:**
>
> To ensure you receive relevant communications, Oracle Site Activate stops sending email notifications for activities over 6 months (180 days) old. Additionally, email alert notifications are not generated for sites that are in "On hold" status.

Pause your alerts for individual items

When you have the "Enable pausing email alerts" business role permission, you can temporarily pause email alerts asking you to complete an item. You'll find the"Pause email alerts for this item" option on the Info tab of any item you can access when that item has not yet been completed. When you pause an alert, that pause applies only to you and will not affect alerts received by other users.

The feature is a temporary pause, so when you enable it, specify your preferred date to resume the alerts. Activate will resume email alerts when the date is reached, and the pause alert switch on the Info tab will reset to disabled. Activate will then send only new email alerts for the item; alerts that would have been triggered while on pause will not be sent.

When you pause an item's alerts, your email notifications will not include the specific paused item but will include any other alerts for items that have not been paused. In the user interface, the paused item will display a snooze ( ) icon in the item list and item modal. Use the "Items with notifications paused" option in the Show filter on the All items tab to find the items you currently have paused. Note that If contract sub items and submission sub items have notifications paused, but the main item does not, the grouping of the items appears in the filtered list for items with notifications paused.

Using your to-do list to access incomplete activities

On the home page, you'll see all of your activities for the currently-selected study. Filter the list to see just the items you want or sort to view the oldest or newest items first. You can then go directly to the country or site details page to complete the activities listed or click Bulk to complete multiple activities simultaneously.

To view your to-do list:

- Filter the list to show alerts for your roles.
- Refine the list by entering a term in the search box and hitting the **Enter** key on your keyboard.
- Click **Country** or **Site** in the View column to go to the appropriate page, where you can complete the work.

Filtering the work by role and assignment

On your home, study country, and site details pages, you will only see those activities intended for your role(s). You can further filter the list to only see those activities for study countries and sites you are specifically assigned to manage. For example, if you are a contract specialist and are granted the “contracts” role:

- You will only see activities on your activities list that someone who has the contracts role can complete. However, on the **Document Activities** tab, you can still see documents and information managed by other roles.
- If you are also assigned responsibility for one or more study countries or sites, you can filter your activities list to see only contract activities that are assigned to you.

- View your alert list
- Respond to alerts
- Complete individual alerts
- Customize alert email notifications
- Pause your alerts for an item
  You can temporarily pause email alerts that ask you to complete a specific item and resume alerts for that item on a date you specify.
- Complete activities in bulk

View your alert list

1. From your home page, below the milestone timeline or dashboard, click the **Your Tasks** tab.
2. Filter your activities by **Assigned to me**, **All my roles**, or by a specific role.
3. Your list of activities displays. To refine the list, enter a term into the search box and press the return key on your keyboard.
4. In the **View** column at the far right, click **Country** or **Site** to see the associated country details or site details page where you can complete the work. You can also click the hyperlinked action in the **Activity** column (e.g., Upload, Compile package, Sent to site, etc.) to open the modal where you can complete the work.

Respond to alerts

1. If you receive an email notification, click the link in the email, which will redirect to the country or site details page after you log in.
2. If you are already working in Oracle Site Activate, you can access a list of alerts on your home page or on the study country or site details pages for the activities.
3. Click the alert to display the document or submission widget that shows details about the activity you need to complete.

Complete individual alerts

1. From the study home page, scroll down and click the **Your tasks** tab.
2. Filter the Your activities: list to **Assigned to me**, **All my roles**, or by each role.
3. Your list of alerts displays. To refine the list, enter a term into the search box and press the return key on your keyboard.
4. In the **View** column to the far right, click either **Country** or **Site** to be taken to the associated country details or site details page, where you can complete the work. You can also click the hyperlinked action under the **Activity** column to open the modal and complete the work.

Customize alert email notifications

1. From the top navigation bar, hover over your name then select **My profile** to see the **Email Content** section on the left.
   - To receive notifications only for new alerts (that were not contained in any previous notification email), check the box next to **New alerts for me**.
   - To receive notifications for all alerts (including new and incomplete), check the box next to **All alerts due for me**.
2. Select how frequently you want to receive alerts and the time of day you want to receive them.
3. To receive notifications in a time zone other than Pacific Standard Time (PST), at **My Time zone**, click **Set to my current time zone**, or select a time zone from the list.

4. Click **Done**.

Pause your alerts for an item

You can temporarily pause email alerts that ask you to complete a specific item and resume alerts for that item on a date you specify.

You must have the "Enable pausing email alerts" business role permission to complete the steps in this procedure, and the item must not be in Complete status.

1. Open the item modal and click the **Info** tab.
2. Click the **Pause email alerts for this artifact** toggle switch.
3. Select a date for the required **Resume email alerts for this artifact on** field.
4. Navigate away from the tab as preferred.

Complete activities in bulk

1. If your Oracle Site Activate user account has the Bulk work page enabled, click **Bulk work** in the top navigation bar.
2. Verify that the **Activities** toggle is selected at the top of the page before filtering activities.
3. Filter your activities based on **study**, **country**, and **site**.
4. If desired, filter your activities based on **role**, **item type**, and **activity type**.
5. Use the check boxes in the left column to select activities that you would like to perform in bulk.
6. If you would like to remove activities from your selected set, you can uncheck the box in the filtered grid, or you can click the **X** to the left of the activity in the summary table at the top of the page.
7. Once you have selected all of the desired activities, update any of the fields beneath the summary table at the top of the page.

   The following fields are supported for bulk updates:

   - **Notes**
   - **Version ID**
   - **Attached files** (only for applicable activities)
   - **Completed date** (if Completed date is not entered, activities will be updated but not completed)
8. Click **Done** to update the selected activities in bulk.

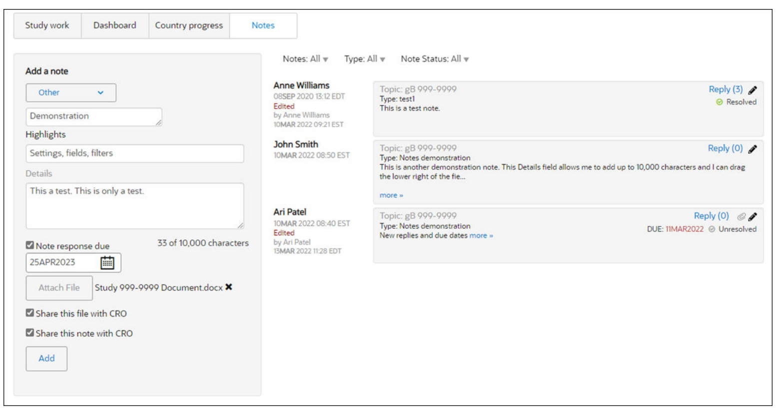
6 About notes

Notes allow the study team to optionally share comments and documents for the study, a country, or an individual item.

Notes functionality provides Oracle Site Activate users, sites, and CROs/Sponsors with an optional way to share comments of up to 10,000 characters among study team members. Certain notes features, like sharing document attachments and note Type selection, can also be enabled at the account level.

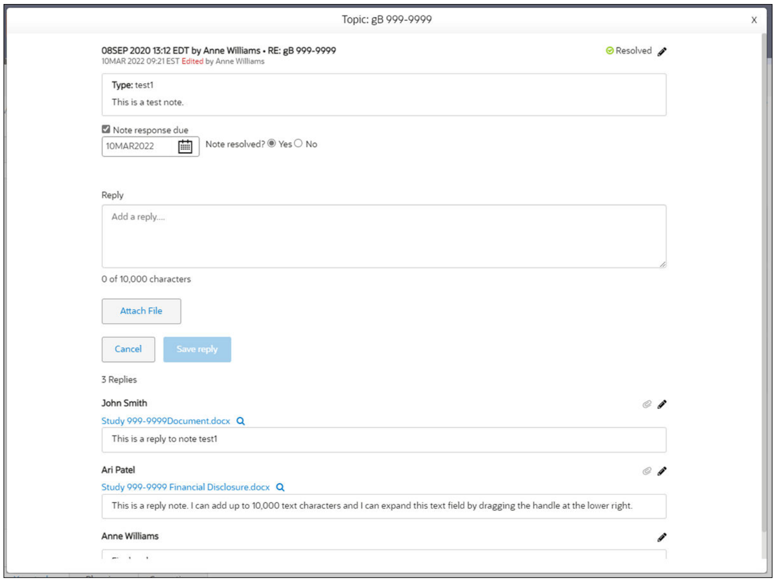
You can optionally track a note with a due date. The date you set for **Note response due** displays with the note in the user interface, and the date displays in red for an overdue response.

The study, country, and site level Notes tabs display saved notes in activity order, with the newest note or newest reply note at the top of the list. You can filter saved notes by author, type, or note status. On the study, country, and site level Notes tabs, each saved note has a **Reply (#)** link that opens a new reply modal. The link reflects the current number of saved replies starting at 0; the count increments with each saved reply. Notes also indicate "Resolved" or "Unresolved" if a user applied the resolution setting when editing or replying to a note.



> **Note:**
>
> Note and note replies can be restricted from editing if this option is enabled for your organization's account. If restricted, you will have the option to edit only those notes and note replies that you authored. You will not see the edit ( ) option on notes you did not author.

In the reply modal (accessed from the study, country, or site level Notes tabs), the original note and any previous replies are in read-only mode. Previous replies display at the bottom of the modal in chronological order (oldest to newest). In addition to creating reply text, you can add a file attachment if preferred. If the note has a response due date set and you're adding a reply, you can enable or disable that setting, modify the date if enabled, and mark the note as resolved if appropriate. These elements update the note listed on the study, country, or site level Notes tabs.



Site Experience users can view replies for notes shared with them and reply to specific notes. Site Experience Note functionality is similar to the Oracle Site Activate functionality described above, such as note ordering, Reply(#) links, Due date formatting (red font if overdue), etc. In a new note reply modal, the Site Experience user can view the original shared note and any existing replies in read only mode. Site Experience users do not have the ability to:

- Edit any reply shared with them by a CRO/Sponsor user
- Add a due date to a new note or note reply
- Mark a note resolved/unresolved

Site Experience users may edit any note they create, and they may reply to any note they create, as well.

- Add a note
  Notes allow you to add a free-text comment with an associated file attachment, and you can indicate a response due date as well. If enabled for your account, you can also optionally share the note with CRO or sponsor users.
- View a previous item note
  View notes you or your team members have saved that relate to a specific item.
- Change a note
  If you need to correct or update a saved item note or reply, you can do so anywhere notes are used throughout the application. After you change the note, it displays an Edited flag with your name.

Add a note

Notes allow you to add a free-text comment with an associated file attachment, and you can indicate a response due date as well. If enabled for your account, you can also optionally share the note with CRO or sponsor users.

1. From a country details or site details page, click the **Notes** tab.

2. In the **Add a note** form, **Select a type** from the drop-down list. Choose a note type or select **Other** to enter free text.
3. Enter optional note **Highlights** (e.g., one or two words or a brief summary phrase).
4. In the **Details** free text field, enter the note (10,000 characters maximum).
5. If preferred, check **Note response due** and choose a due date.
6. Click **Attach File** to upload a file.
7. If you attached a file, and if enabled for your account, click the **Share this file with Sponsor / CRO** check box.
8. If enabled for your account and appropriate to the note, click the **Share this note with sponsor / CRO** or check box.
9. Click **Add**.

View a previous item note

View notes you or your team members have saved that relate to a specific item.

1. From a country details or site details page, click the **Documents**, **Submission**, **Review**, or **All** tab to view the item placeholder list.
2. Filter the list and click the item's placeholder to open the modal.
3. In the modal, click the **Notes** tab to view any notes saved for that item.

Change a note

If you need to correct or update a saved item note or reply, you can do so anywhere notes are used throughout the application. After you change the note, it displays an Edited flag with your name.

If your organization's account settings allow it, you may change any note or reply authored by any user; however, if your organization restricts note changes, you will be able to change only those notes or replies you authored. If you have the option to change a note, you will see the edit icon and you can complete the steps in the procedure below.

1. Click the **Notes** tab on the home page or in an open country or site level item placeholder.
2. Next to the note you want to change, click edit ( ) and edit the note as preferred.
3. Click **Save note** or **Save reply**.

7 About documents

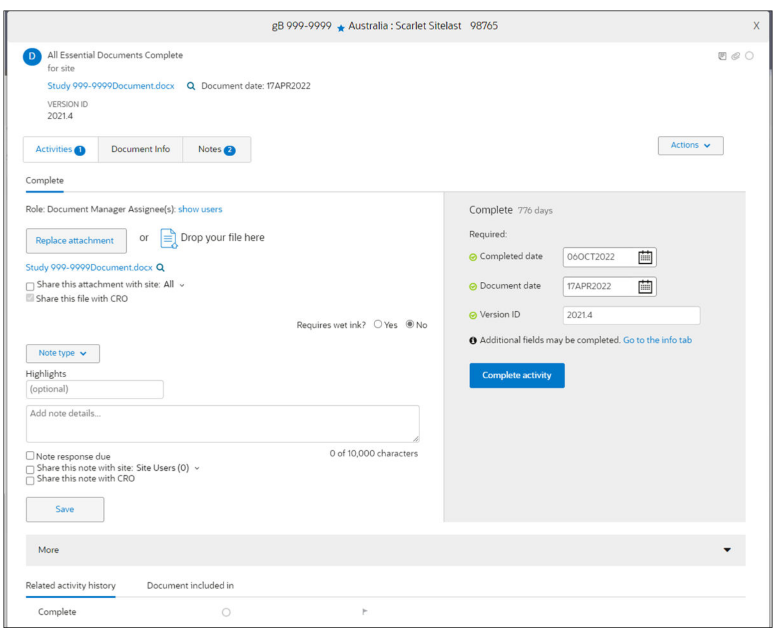
The documents modal

At the top of document modals, you'll see the study name, country (for country or site level documents), and site information (PI and site number) if the item is a site level document. Document modals also display item metadata and other familiar Oracle Site Activate icons in a static header section at the top. The lower section of the modal supports vertical scrolling when appropriate.

Oracle Site Activate groups related items together for ease of access (e.g., a single contract modal may include tabs for the contract, budget, contract language, etc.). You can navigate to the related items by clicking the tabs at the top of the modal. If the modal includes more tabs than can be displayed within the standardized modal width, a navigation control displays at the top right to allow you to advance to the additional tabs.

You'll also Activities, Information, and Notes tabs at the bottom of the header section. Activities is the default tab. The label on the Information tab is specific to the item you are viewing (e.g., Contract Info, Document Info, etc.).

In the modal's Activity tab, in the shaded section to the right, you must address any “Required” items and you may optionally address any “Important” items. Required vs. Important fields vary based on your organization's requirements and SOPs, and these fields are configured for each item. Oracle Site Activate enables the “Complete Activity” button in the shaded section only when you complete ( ) all “Required” items.



The static header section in the sample document modal image above includes a hyperlink to an attached file, and icons displayed at the right side of the header indicate the file attachment as well as the presence of at least one saved note. Depending upon a document's configuration, displayed metadata might include filename, version, document date, or due date. The Activities, Document Info, and Notes tabs in the header section allow you to easily navigate to document information. The "Actions" button in the header includes options that are specific to the document modal type (e.g., "Discontinue this version" and "Add a new version").

In the sample image above, the lower section of the modal's Activities tab reflects one required activity (Complete), underlined in blue. If additional activities exist for this item, they align with the Complete item, and you can click through the subsequent activities; your selected activity would then be underlined in blue. You may see additional document controls (e.g., file upload, electronic signature request, wet ink control, etc.) if enabled for your organization's account.

The lower section of the modal (the "More" section) is collapsed by default. Open the panel to view tabs for Related activity history, Blocked activities, and Document included in (for documents included in Submission or IP release packages). The additional tabs display only if appropriate for the Activity and item.

The Document Info tab displays additional information about this item. On this tab, you can update metadata (e.g., Version ID and document Expiration Date), access file details and options for current and previously uploaded files, and complete fields for any configured TMF data. What data you see depends upon previous activities for the item, the document configuration, and any applicable account settings.

On the Notes tab, you can review, add, reply to, resolve and/or edit any notes related to this document item.

When you complete all required fields or actions for this document, Oracle Site Activate enables the blue "Complete Activity" button within the gray panel on the right side of the modal. This panel is intentionally shaded – to draw your attention to Required and any configured Important items, as well as the Complete Activity button.

Document lifecycles and alerts

Oracle Site Activate automatically generates activities to complete documents. Your organization determined the appropriate lifecycle to track, for example, how a document is created or collected from the site, reviewed, approved, and rejected (and needs to be redone). Activities will become available once the prerequisite activities are completed. You will receive an alert when it's your turn to perform an activity related to a document.

File storage and file size limits

File storage is not limited at the account level; individual file size is limited. The maximum accepted file size is 150 MB.

Manage files or track completion

Depending on your team’s process and your role, you may only track document completion dates, or you might upload documents into Oracle Site Activate. You may also preview and annotate documents and exchange them with sites in Oracle Site Activate (using the eTMF, artifact, or activity APIs).

Marking documents complete individually or in bulk

You will complete activities in the document modal or in bulk from the home page. You might complete documents in bulk, for example, when:

- You receive central IRB approval for multiple sites and want to mark them as being approved as a group

- You send a document to multiple sites on the same day

You'll see what you need to do in the modal's Activities tab. You may need to post a document in Oracle Site Activate or review and approve it. If the activity is to approve a document, you may need to provide a document version number or name. If you need to indicate a completion date, be sure it isn't in the future. Oracle Site Activate will prevent you from adding future dates for completion. This is by design.

Tracking document expiration dates

Some site personnel documents expire during the course of a study. If your organization configures Oracle Site Activate to track the expiration date for these documents, you will see the expiration date in the document's modal.

You can enter the expiration date as you accept the document or at any time later. Then, depending on how Oracle Site Activate is configured, you will see the document appear on the expired documents list.

Managing Document Due Dates

Documents configured to support due dates include a "Due Date" field in the following areas:

- Country and site items
- Site experience items
- Overview page items

When configured to display for an item, the default Due Date that displays in the field is based on the date the item was created, plus a preconfigured number of days for expected completion (if known at the time of configuration). You can modify the item's due date if you have a role assigned to any activity in the item's lifecycle and if the item is not yet completed. Site users do not have the ability to edit due dates.

What to do when document activities are blocked

Oracle Site Activate workflows drive activities to be completed in the order dictated by your organization's standard operating procedures. As a result, some activities may be blocked (or cannot be completed) because prerequisite activities are not yet complete.

In the document's modal, you can see if an activity is blocked and which document activities are blocking it. Oracle Site Activate will also indicate if the blocking item is "actionable," meaning that it is not blocked and therefore can be completed. You can view the item's level, who is currently assigned to complete it, and the status so you can follow up with the person who is responsible for completing the activity.

Sharing document notes with your team and sites

You can add notes about a document to help your study team view a complete history of communications about the study country or investigator. A list of Note categories available to you may be configured for your organization's account.

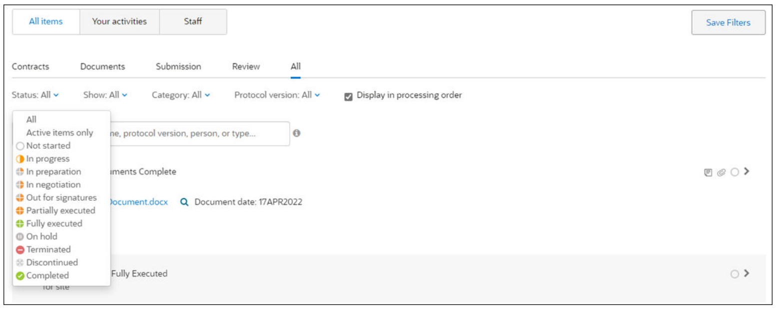
In the document modal, the **Notes** tab includes all notes previously saved for the document and a form to create a new note. If you collaborate with sites or sponsors in Oracle Site Activate, you can also share notes with sites/sponsors if configured for the document. You can also optionally set a response due date for any note and mark a note as resolved, if appropriate. You can edit saved notes if assigned activities to manage the document.

Replacing a document with a new version

You may want to replace a document with a new version to start from the beginning and re-run all the document's activities. You might do this, for example, if you began to process an FDA Form 1572 and the site sends a new one that needs to be processed from the beginning. You can add the new version and discontinue the activities for the original version; Oracle Site Activate will run the document's workflow only on the new version or complete both documents.

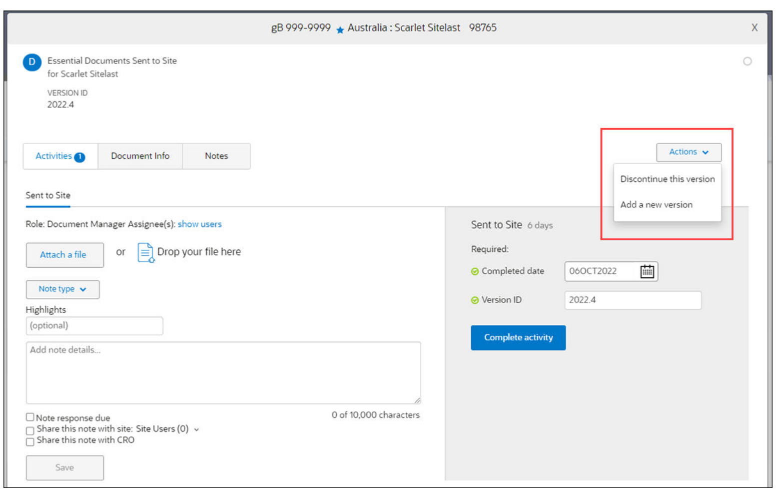
In the document modal, you will only see active documents; however, you can view discontinued documents by selecting **View discontinued items** at the top of the **Document Activities** tab.

To help you locate incomplete and unstarted items, use the "Status" quick filter. This filter includes choices appropriate to the current tab and pairs these choices with familiar Oracle Site Activate icons. Status filter options display as follows:



Discontinue a document if it has no activity yet, or discontinue those completed in error. If you have at least one role that is part of an item's lifecycle, you can discontinue an item in "Complete" status, and can reinstate the item if appropriate.

> **Note:**
>
> The Actions menu, which includes Discontinue and Add a new version action options, displays only if you have at least one role assigned for at least one activity in the item's lifecycle. If you do not see the Actions menu, contact your super user.

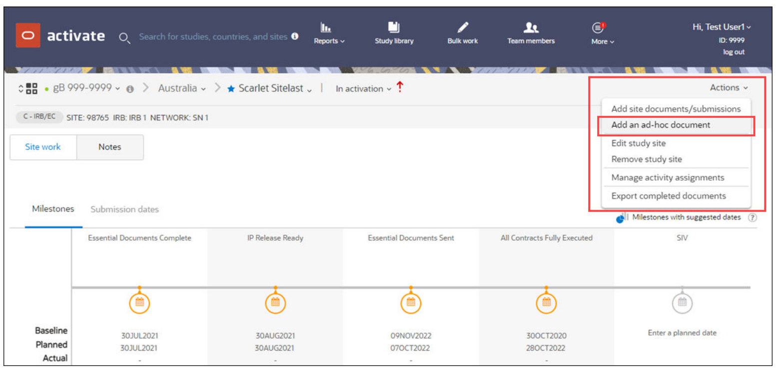


Managing ad hoc documents

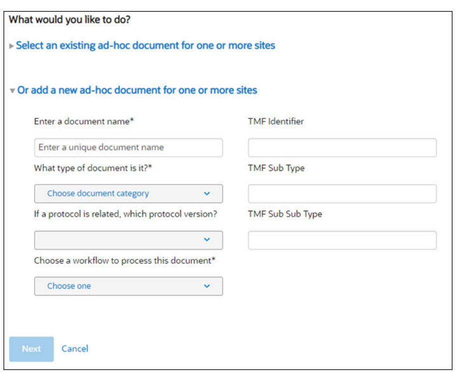
Oracle Site Activate workflows are configured for all the documents your organization wants to track, but sometimes you need to track a document you did not expect to track. You can add these new, “ad hoc” documents to Oracle Site Activate and choose a preconfigured workflow (document collection) that creates the activities you'll need.

> **Note:**
>
> For more substantial changes, such as changes in regulations that affect a country process, you can contact Oracle Support.

You can add an ad hoc document for the study, or for one or more study countries or sites. Before you add a document, check the "view existing" list and descriptions of documents that are already managed in Oracle Site Activate — this helps prevent duplication and ensures you are using the right workflow for the document you want to add.



Review the list of existing documents in the first section, then if necessary, define the ad hoc document.



If you are adding an ad hoc document at the study country level, select one or more countries for which the document is applicable. If adding at the site level, select sites.

Managing documents after IP release

Once you reach the IP release milestone, you can continue to work on certain documents. You can filter the document list by post IP release documents and see a special indicator on all documents processed post IP release.

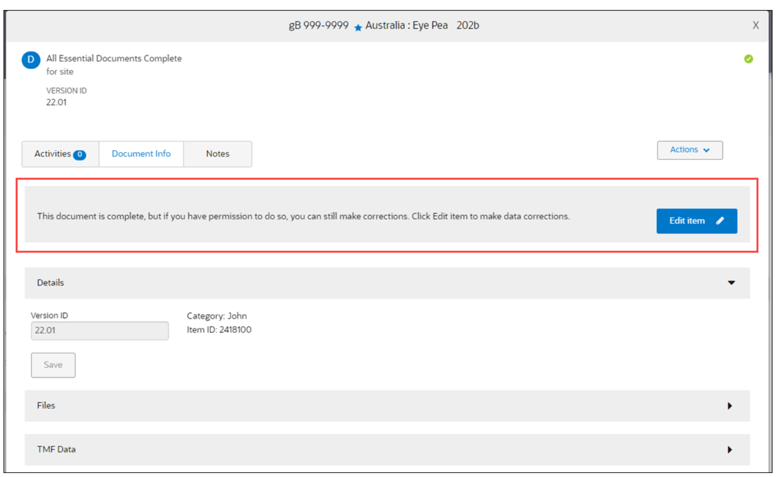
Exporting documents from Oracle Site Activate

Export a group of files for a study country, site, submission, or IP release package. For submission or IP release packages, the name of this file includes the name of the package, protocol version number and version ID. If your organization uses Oracle Site Activate APIs, completed documents can be exported to your eTMF.

Correcting mistakes

If you have a user role with data correction permission, or if your organization has enabled an optional account setting that allows the user who completed a document or contract item to make post-completion edits, you can correct errors within the document modal, when the document is complete but not yet approved in an IP package. Under these conditions, you can correct the following fields, and you may be required to enter a correction reason (if required by your organization):

- Version ID
- Language
- Document Date
- Expiry Date
- Due Date
- Draft Document
- Organization
- Translation Type



If you experience one of the following, a team member with the corrections role can correct the mistake (depending on your organization's policies and assigned role permissions):

- **Upload the wrong document** – From the Corrections tab on the home page, disable incorrect files and optionally replace them with a new one. Files you disable are “soft deleted’, so they don’t appear as the current, valid file. You can always see that they existed and access them; if necessary, you can restore them by re-enabling them.
- **Enter the wrong completion date** – You can correct document completion and milestone dates. You will be asked to provide a reason for your changes; these become part of the item’s permanent record so that others can track the changes.

If the document is associated with a submissions package or in IP release review, Oracle Site Activate warns you so that you can determine the correct action.

If you have the required permissions, you'll see the Corrections tab and Work and Planning tabs on your study Home page, just below the milestone dashboard or document dashboard.

Self-service inline corrections

If enabled for your organization's account and if you have the appropriate permission you can edit ( ) completed dates you entered for document, contract, and submissions activities.

If you have the appropriate permission (and if enabled in your organization's account) you may also "un-complete" activities by blanking out completed dates. Due to downstream consequences, this feature does not allow for blanking out dates for any of the items listed below. However, alerts, placeholder statuses, and the audit trail will reflect un-completed (blanked) activity dates accordingly.

These items may not be un-completed:

- Completed placeholders (document, submission, package, review contract)
- Activity dates that include decision options
- Activity dates tied to milestones
- Placeholders originating from the quarantine area

Additionally, activity dates with completed successor activities may not be blanked out, but successors can be displayed and blanked out in reverse order.

Smart Site Library

The Smart Site Library feature allows for document reuse. When enabled for your organization's account, Oracle Site Activate proactively identifies sites, institutions, Principal Investigators, and staff members who previously participated in studies and who may have essential documents that could be reused for the current study.

Smart Site Library provides a flexible solution that allows your organization to choose the items that are included in the library. Customer Administrative users and Configuration Designer users have the ability to flag document and contract items individually within the Oracle Site Activate Settings and Configuration Designer features. A file will be available for optional reuse if it meets the following criteria:

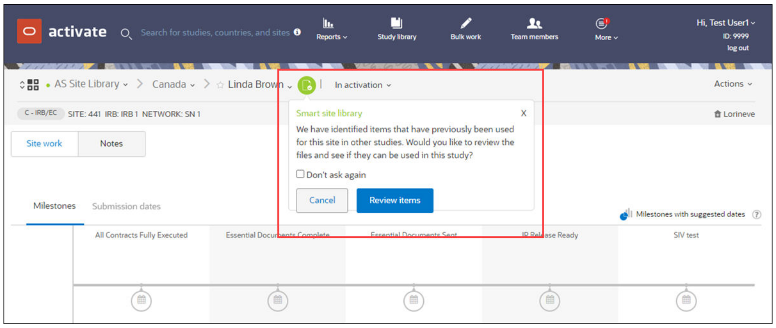
- The item has been configured to be a part of the Smart Site Library.
- The file's document or contract name match. This does not include contract type, document revision number, or protocol version number (e.g., “PI Medical License” and “PI Medical License (3)” are considered a match).
- The file is the most recent version of the attachment on the item.
- The item is in a complete status.

When Oracle Site Activate identifies a site, institution, PI, or staff member that may have items available for reuse, and when you have "Enable site library use" permission, you'll see a Smart Site Library icon ( ) displayed next to the site name in the persistent header.

The icon displays a notification modal to inform you that:

- Items may be available for reuse. In this case, you can select from previous files to complete items in the current study. You can review the identified items, dismiss the modal, or check a box that will dismiss the Smart Site Library notifications on your subsequent visits to the site page.

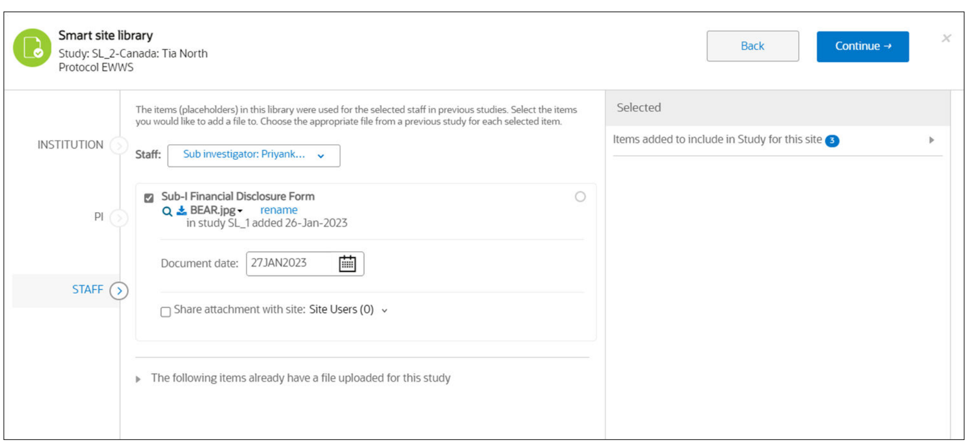
- There are no open items in your site library. You can review completed items, dismiss the modal, or check a box that will dismiss the Smart Site Library notifications for this site on your subsequent visits to the site page.



If you choose to "Review items" to complete open items on behalf of the site, the list of the site's item placeholders displays. To help you understand the full scope of completed and open items, the list includes all items – including those that are available for action, complete, and blocked. Some items may appear grayed out if you don't have the required business permissions to act upon the item. This is by design, and tool tip text displays if this is the case.

Within the library, you can select the item to use in the current study. The file selection drop-down menus include one or more files that you can review to confirm an item meets study requirements. For example, the drop-down list allows you to download the item or preview the item (if preview is enabled for the account). Additionally, each item identifies the source study, the date it was added to that study, the document date, and the expiration date if any.

If you select a file from the drop-down menu, Oracle Site Activate automatically displays additional fields to specify a document date, attachment sharing, and wet ink requirement. You can also rename the item, if preferred. To use a file in the current study, check the box to the left of the placeholder name. When checked, the item displays in the "Selected" panel to the right.



- [Generate document and submission activities](#)
  If a country is added after study-level documents have been shared, run the country-level protocol workflow from the workflow wizard on the country details page.

- Run workflow to generate document activities
  When necessary, you can run a workflow to create country and/or investigator document and submissions activities.
- Generate protocol amendment activities
  When a study has a protocol amendment, you can run a workflow to add the protocol and add the appropriate investigator and/or country activities.
- Complete document activities individually
  Document modals are the containers where you'll upload file attachments, set preferred options for the file (e.g., sharing and signature requirements), and add notes that you can optionally share outside of your study team. After entering all required fields, you can complete a document activity in the document modal.
- Upload document files for an individual activity
  You can either browse for a file or drag and drop a file directly into the document modal to upload.
- Replace file attachment
  To replace an existing file attachment for an item that is not yet completed, you can either browse for a replacement file or drag and drop a file directly into the document modal.
- View document information
  The document modal "Document info" tab includes helpful metadata about a document and related file attachment(s). You'll find version ID, Category, and Item ID (if configured) as well as file attachment details and TMF data, if appropriate.
- Add a document expiration date
  When a document isn't intended to be valid indefinitely, it may be configured with an expiration date field.
- Manage expiring documents and submissions
  When you complete the procedure below, you'll see a list of documents without an expiration date; click the Principal Investigator name to access the document's work area.
- Add a new document version
  When necessary, you can add a new version of a document, even when the original version exists in one or more packages.
- Discontinue a document
  You may not discontinue a completed document. If a document is not necessary for a trial to conduct, it is best practice to discontinue it. For document updates during study startup, use the Document version feature.
- Disable an incorrect document
  You must have corrections permission associated with your user account to complete this procedure. If you do not have the permission to correct files, contact your team lead or super user for assistance.
- Reenable a document
  You must have corrections permission associated with your user account to complete the procedure below. If you do not have the permission to correct files, contact your team lead or super user for assistance.
- Delete a document placeholder
  You must have corrections permission associated with your user account to complete this procedure. If you do not have permission to correct files, see your team lead or super user for assistance. Be sure you want to delete the document; document deletions cannot be undone.

- Change a document completion date
  You must have corrections permission associated with your user account to complete this procedure. If you do not have permission to correct files, contact your team lead or super user for assistance.
- Set dates for multiple documents
  When you first enter a baseline date, Oracle Site Activate automatically makes the planned date the same. After a baseline date is entered, it cannot be changed.
- Add an ad hoc document
  Oracle Site Activate workflows are configured for the documents your organization wants to track, but sometimes you need to track a document you did not expect to track. You can add these “ad hoc” documents and choose a preconfigured workflow (document collection) that creates the activities you need to track.
- Manually export documents and add a new section
  Depending upon your organization's preferred configuration, you can export individual files or a zipped file that includes all completed documents as well as a file manifest.
- Preview a document
  If the document preview feature is enabled for your organization's account, you can preview csv, doc(x), msg, odt, pdf, rtf, txt, xls(x), xml, ppt(x), bmp, gif, jpeg, png, psd, and tif(f) format document without downloading. Preview also displays document metadata (name, version, upload date, etc.) in the right panel.
- Annotate a document
  If the document preview and annotation feature is enabled for your organization's account, while previewing documents, you can add annotations in pdf, doc(x), ppt(x), jpeg, png, gif, and bmp document types. Other users in your account may annotate responses or add new comments as desired.
- Correct document item metadata
  When you need to correct a document item's metadata (e.g., Version ID, Document date, Expiry date, etc.), you can do so within the document modal when the document is complete but not yet approved in an IP package.

Generate document and submission activities

If a country is added after study-level documents have been shared, run the country-level protocol workflow from the workflow wizard on the country details page.

1. From a country details or site details page, click **Actions** and click **Add [site or country] documents/submissions**.
2. Select the action you’d like to take, and click **Next**.
3. Select the existing protocol version, and click **Next**.
4. Indicate whether you’re tracking activities for a country, investigators, or both; click **Next**.
5. Select the investigators that the protocol impacts and click **Next**.
6. Select the documents and submissions you’d like to track, and click **Next**.
7. Confirm your selections, and click **Done**.

Oracle Site Activate generates the documents and submissions to track.

Run workflow to generate document activities

When necessary, you can run a workflow to create country and/or investigator document and submissions activities.

1. From the study country or site detail page's **Action** menu, select **Add documents and submissions**.
    a. If the document is tracked with a specific version of the protocol, click the protocol to select, and click **Continue**, specify the protocol version, then click **Next**.
    b. If the document is tracked with a different protocol version, select **Add a new protocol version reference**, enter the Protocol version, then click **Save and Continue**.
2. Indicate if you want to generate activities for one or more investigators, the country, or both. Click **Continue**.
3. Select the document collection that will generate the desired activities, then click **Continue**. If the collection contains documents that already exist, those documents will not be duplicated.
4. Review the list, then click **Done**.

Generate protocol amendment activities

When a study has a protocol amendment, you can run a workflow to add the protocol and add the appropriate investigator and/or country activities.

1. From the study country detail page's Action menu, select **Add country documents/ submissions**.
2. Select **Add a new protocol (and track activities)**.
3. Enter the protocol version and click **Next**.
4. Indicate if you want to generate activities for one or more investigators, the country, or both.
5. In the **For the protocol** section, review the list of country-level document collections for which activities can be generated, select a collection, then click **Next**.
6. Select sites for which you want to generate document activities and click **Next**.
7. In the **For the protocol** section, review the list of site-level document collections for which activities can be generated, select a collection and click **Next**.
8. Review the list, then click **Done**.

Complete document activities individually

Document modals are the containers where you'll upload file attachments, set preferred options for the file (e.g., sharing and signature requirements), and add notes that you can optionally share outside of your study team. After entering all required fields, you can complete a document activity in the document modal.

1. Display the country details or site details page for the document activity you want to complete.

2. On the **Your activities** tab, click **Documents**.
3. Filter the document list using the **Assigned to**, **Sort by**, **Status**, **Show**, and/or **Category** options.
4. Click the document placeholder to open the document modal.
5. On the left side of the modal's **Activities** tab, browse and **Attach a file** or drag and drop a file to attach, if appropriate. If enabled for your organization's account, you can optionally click the check box below the file name to share the attached file with the site and/or CRO/sponsor, as appropriate.
6. Optionally enter a Note for this document. If you do so, click **Save**. If enabled for your organization's account, you can optionally click the check box below the note text box to share the note with the site and/or CRO/sponsor, as appropriate.
7. Set the preferred electronic signature and/or wet ink options, as appropriate.
8. On the modal's **Activities** tab, view the shaded area on the right to evaluate and complete the configured Required and/or Important activities (e.g., attach a file, add a document completed date, review file, add Version ID). Activities are unique to your organization's configuration.
9. Click **Complete Activity**.

Upload document files for an individual activity

You can either browse for a file or drag and drop a file directly into the document modal to upload.

1. From a country details or site details page, click the **Documents** tab, then click the placeholder for the file you’d like to upload.
2. The document modal opens. On the left side of the modal, click **Attach a file** to browse and choose a file from your computer. Or, you can choose a file from your computer and then drag and drop the file directly into the open document modal on the Activities tab.
3. You can optionally indicate an electronic signature request (if appropriate for the document and enabled for your organization's account). You can also indicate if the document requires a wet ink signature.
4. If enabled for your organization's account, you can check the boxes below the file attachment to share the file with sites and/or CRO/sponsor users, as appropriate.
5. Click **Save**.
6. In the modal, expand the **Document Info** tab's Files section to see the new document listed for the activity.

As the file is uploading, you will see a progress bar that indicates a file upload virus check is underway. When completed, Oracle Site Activate displays a confirmation that the file was successfully saved. If you upload an incorrect file, click **Replace attachment** to replace it. If the file is rejected due to virus scan outcome, contact Oracle support.

Replace file attachment

To replace an existing file attachment for an item that is not yet completed, you can either browse for a replacement file or drag and drop a file directly into the document modal.

The document modal must be opened to complete this task. Dragging and dropping files into the placeholder list view is not supported.

1. With the document modal opened, click **Replace attachment** to browse for and select the replacement file, or drag a file into the outlined file drop zone.
2. Click **Save**.

View document information

The document modal "Document info" tab includes helpful metadata about a document and related file attachment(s). You'll find version ID, Category, and Item ID (if configured) as well as file attachment details and TMF data, if appropriate.

1. From a country details or site details page, click the **Documents** tab.
2. Filter the list of documents, and click a document placeholder to open the modal.
3. Click the **Document Info** tab and expand the **Details**, **Files**, and/or **TMF Data** sections to view more information about this document.
4. To download an attached file, click the file name.

Add a document expiration date

When a document isn't intended to be valid indefinitely, it may be configured with an expiration date field.

1. From the site details page, click the **Documents** tab.
2. Filter the documents list and click the document's placeholder to open the modal.
3. At **Expiration date**, select a date using the calendar control.
4. Click **Done**.

Manage expiring documents and submissions

When you complete the procedure below, you'll see a list of documents without an expiration date; click the Principal Investigator name to access the document’s work area.

1. From the top navigation menu, hover over **More** and click **Expiring items**.
2. Select the study name, if necessary.
3. Click the appropriate tab to display desired results:
   a. **Not specified**: documents for which an expiration date has not been assigned
   b. **Expired**: expired documents, including the date they expired
   c. **Expiring**: documents that will be expiring in the next 30, 60, 90, 120, or more than 120 days (or whatever intervals your organization has configured).

4. At **Item**, select **Documents** or **Submissions**.
5. At **Show**, select **Active** or **Addressed**.
6. To specify or update an expiration date for a listed document, click the PI name. The document work area displays. Enter an expiration date and click **Done**.
7. To filter the list, enter a country, site, investigator, or document name into the search box, and then hit your computer’s return key.

After completing the procedure above, if you receive an updated document, add a new version of it with a new expiration date. Remove the expiration date from the old document by clicking **X** next to the date.

Add a new document version

When necessary, you can add a new version of a document, even when the original version exists in one or more packages.

1. From a country details or site details page, click the **Documents** tab.
2. Filter the list and click the document's placeholder to open the modal.
3. At the far right, click **Actions** and select **Add a new version**.
4. If the document exists in a package, you are required to specify the preferred action for the old document. Choose a radio button for: add this document to the package and leave old document as well, add this document to the package and replace the old document, or do not add this document to the package and leave old document.
5. Click **Confirm**.

The new document version displays on the Documents tab with version number in parentheses.

Discontinue a document

You may not discontinue a completed document. If a document is not necessary for a trial to conduct, it is best practice to discontinue it. For document updates during study startup, use the Document version feature.

1. From a country details or site details page, click the **Documents** tab.
2. Filter the documents list and click the document's placeholder to open the modal.
3. At the far right, click the **Actions** drop-down menu and click **Discontinue this version**.
4. Select a discontinuation reason and click **Done**.

Disable an incorrect document

You must have corrections permission associated with your user account to complete this procedure. If you do not have the permission to correct files, contact your team lead or super user for assistance.

1. From the home page, click the **Corrections** tab, then click **Items**.

2. Use the Item drop-down menu to specify item type (Documents, Submissions, or Packages).
3. In the item's **Actions** column, click edit ( ).
4. In the item modal, click **Attach File**. Browse for the correct file and double click to attach the replacement file.
5. At the bottom of the modal, click **Disable** next to the document you want to disable. Select or enter a **Reason** for disabling the original document, and click **Done**.
6. Click **Save**.

Reenable a document

You must have corrections permission associated with your user account to complete the procedure below. If you do not have the permission to correct files, contact your team lead or super user for assistance.

1. From the home page, click the **Corrections** tab, then click **Items**.
2. Use the Item drop-down menu to specify item type (Documents, Submissions, or Packages).
3. In the item's **Actions** column, click edit ( ).
4. At the bottom of the item modal, click **Enable** next to the document you want to reenable. Select or enter a **Reason** for enabling the document, and click **Done**.
5. Click **Save**.

Delete a document placeholder

You must have corrections permission associated with your user account to complete this procedure. If you do not have permission to correct files, see your team lead or super user for assistance. Be sure you want to delete the document; document deletions cannot be undone.

1. From the home page, click the **Corrections** tab, then click **Items**.
2. Use the **Item** drop-down menu to specify item type (e.g., documents, submissions, or packages).
3. Click delete ( ) in the **Actions** column for the document placeholder you want to delete.
4. Enter a reason for the deletion, and click **Done**.

Change a document completion date

You must have corrections permission associated with your user account to complete this procedure. If you do not have permission to correct files, contact your team lead or super user for assistance.

1. From the home page, click the **Corrections** tab, then click the **Activities** sub-tab, if necessary.
2. In the item's **Actions** column, click edit ( ).
3. Under **Completed Date**, select a new date from the calendar control.
4. In the **Reason** field, enter a free-text reason for the date change.

5. Click **Done**.

Set dates for multiple documents

When you first enter a baseline date, Oracle Site Activate automatically makes the planned date the same. After a baseline date is entered, it cannot be changed.

1. From your home page, click **Planning**.
2. Select one or more documents for which you would like to set a date. To select all documents, click the box next to Investigator.
3. Optional: (Optional) To remove an item from the list, click **X** to the right of it.
4. Enter a baseline or planned date for the selected documents. Baseline date is the date by which you would like the activity to be completed; the default is the current date. Planned date is a new date to be entered as plans change. To enter a planned date only, delete the baseline date by clicking the X to the right of it.
5. Click **Done**.

Add an ad hoc document

Oracle Site Activate workflows are configured for the documents your organization wants to track, but sometimes you need to track a document you did not expect to track. You can add these “ad hoc” documents and choose a preconfigured workflow (document collection) that creates the activities you need to track.

1. Display the study home, study country or site details page for the study, country or site for which you will track the document.
2. From the **Actions** menu, select **Add an ad-hoc document**.
3. At **Select an existing ad-hoc document...**, review the list of existing documents to see if the document is already managed in Oracle Site Activate. If it is on the list, select the document and click **Next**.
4. If the document is not already managed in Oracle Site Activate, expand the **Or add a new ad-hoc document...** section then specify the document name, type, protocol version (if applicable) and select a workflow to process the document.
5. Click **Next**.
6. If the document you want to add is a country-level document, select the countries for which you are adding this document, and click **Next**.
7. Review your selections. If you need to make changes, click **Back** to return to the selection and change it.
8. Click **Done**.

The new document displays on the **Document Activities** tab for the study, study country, or site.

Manually export documents and add a new section

Depending upon your organization's preferred configuration, you can export individual files or a zipped file that includes all completed documents as well as a file manifest.

- From either country details, site details, IP release package or submission packages, select the Actions option to**Export completed documents**.

If files were not uploaded, a “No documents to export” message displays. If configured, files will be downloaded individually instead of a single .zip format file. The file name contains the study name and two-letter country code or the package name, protocol number and version ID. The 000 file is an index of all documents included in the export. In this index, files are listed in numerical order based on a three-number prefix Oracle Site Activate assigns during export.

Preview a document

If the document preview feature is enabled for your organization's account, you can preview csv, doc(x), msg, odt, pdf, rtf, txt, xls(x), xml, ppt(x), bmp, gif, jpeg, png, psd, and tif(f) format document without downloading. Preview also displays document metadata (name, version, upload date, etc.) in the right panel.

Your user account must be enabled for document preview in order to complete this procedure.

1. On the File history section of the document’s modal, preview the document by clicking the **magnifying glass** icon.
2. Preview the document and select options to **Print** or **Download**, as desired.

Annotate a document

If the document preview and annotation feature is enabled for your organization's account, while previewing documents, you can add annotations in pdf, doc(x), ppt(x), jpeg, png, gif, and bmp document types. Other users in your account may annotate responses or add new comments as desired.

1. When previewing a document type that is available for annotations, select the annotate icon at the upper right of the preview window.
2. Select anywhere in the document to leave an annotation and click the option to **Post** to leave a user specific comment with a time date stamp.

Correct document item metadata

When you need to correct a document item's metadata (e.g., Version ID, Document date, Expiry date, etc.), you can do so within the document modal when the document is complete but not yet approved in an IP package.

You must have a business role with data corrections permission to correct document metadata.

1. Open the completed document item modal, and click the **Document info** tab.
2. Click **Edit item**.
3. Make the desired correction.
4. If enabled for your organization's account, you may be required to select or specify a **Reason** for the correction.
5. Click **Save changes**.

8

About document editing

The document editing feature provides permisioned users with an efficient way to edit documents without the need to download and edit documents locally.

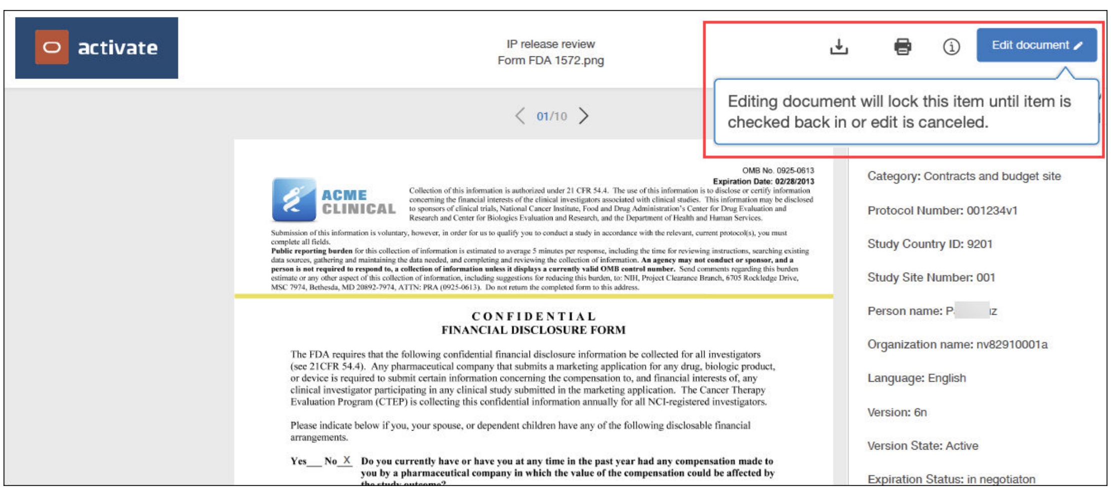
Role permissions

To use document editing, a user must have:

1. "Enable digital document preview annotation/editing capabilities" setting turned on for the user account.
2. A role assignment that allows the user to access at least one activity for the item. A user who does not have a role assigned cannot edit a document using the document editing feature.
3. Box Tools for document editing installed on the user's local machine. If necessary, users can view a video with installation instructions. Users can launch the installation instruction video from the document's Preview mode.

Editing flow and document locking

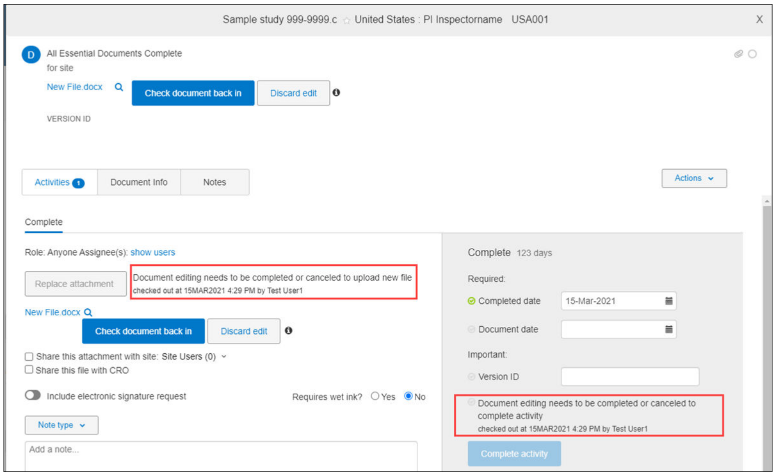
Users access the editing flow within an item modal using an edit icon ( ) or from document Preview ( ) mode using an "Edit document" button. The editing feature allows permissioned users to edit any Microsoft Office Word, Excel, or PowerPoint document.



When a user opens a document for editing, Oracle Site Activate automatically locks the item. This lock prevents other users from making edits, adding/replacing the file attachment, or completing the activity. When a lock is active, the item modal displays the following text next to the "Attach a file" button and in the modal's Required panel: "Document editing needs to be completed or canceled to upload a new file." The note also indicates the date and time of document check out and the name of the user who checked out the file for editing.

Oracle Site Activate users who have "Allow for cancel of document editing" business role permission can cancel in-progress document editing. Canceling discards any changes made by the user who checked the document out for editing and unlocks the activity in Oracle Site

Activate so that it can be completed. Note that the editing user has the option to cancel editing and discard changes, as preferred, with no additional permission required.

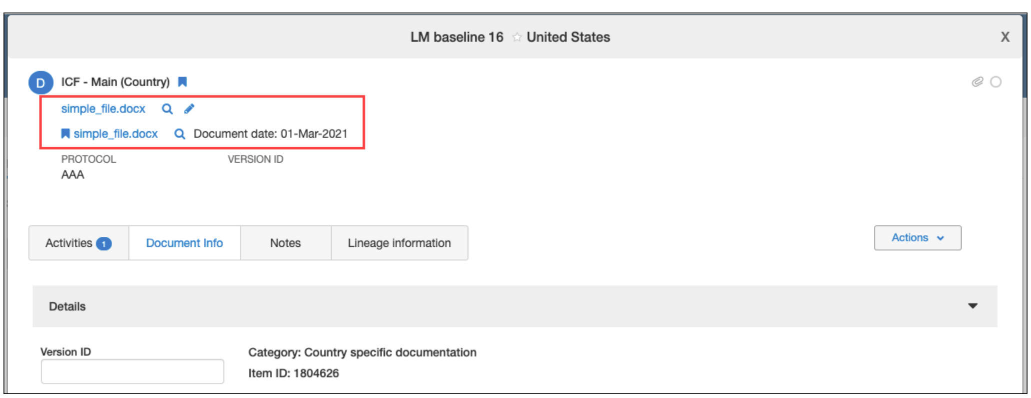


Oracle Site Activate automatically refreshes the item modal or grid when the user takes an action on the Preview screen (e.g., check out/check in, save or discard edits, etc.). This refresh ensures that the modal view reflects the user's actions when the Preview screen is open in a separate tab or different browser.

When the editing user completes the desired edits and finalizes the editing flow, Oracle Site Activate saves both the original document version and the new document version in the modal's Files section. Oracle Site Activate also lifts the file lock, and users can complete activities in the modal as necessary – including editing the document again if desired.

Editing lineage documents

Management of lineage documents is one of the best examples of how the editing feature improves Oracle Site Activate users' efficiency. Using the document editing feature, users can create a copy of a country or site level lineage document, edit the copy as necessary, and check in the edited copy as the document attached to the activity. This process uses the lineage document as the "starting point" and creates the document attachment while preserving the lineage file; the lineage file itself may not be edited and continues to be the original document.



- Install Box Tools for document editing
  To edit documents in Oracle Site Activate, you must install the Box Tools app to make edit functionality accessible to you on your machine.

- Edit a document
  With the document editing feature, you can open a Microsoft Office document from Oracle Site Activate, make your desired changes in the document's default application, and save the updated document back to Oracle Site Activate.

Install Box Tools for document editing

To edit documents in Oracle Site Activate, you must install the Box Tools app to make edit functionality accessible to you on your machine.

> **Note:**
>
> You need to complete this installation task only if you have the document editing permission applied to your Oracle Site Activate user account. If you require the editing permission, please contact your Oracle Site Activate administrator.

1. Access the Box Downloads web URL at: box.com/resources/downloads
2. On the Desktop & Mobile apps page, in the Box Tools section, click the link to download the proper app version for your Mac or Windows operating system.
3. An executable file (i.e., BoxToolsInstaller.exe) downloads to your local machine. Click the file and follow the on-screen instructions to install Box Tools to your machine.
4. Access the following Box Developer Guides web URL: developer.box.com/guides/embed/ui-elements/custom-domains/
5. On the Boxdev Safelisting on Windows page, click the “here” link that immediately follows this text on the page: “Before starting the domain safelisting installation, please download the required scripts from the provided .rar.

   When you click "here" the download automatically begins.
6. Extract the downloaded script files to your preferred machine location (e.g., a folder on your C drive).
7. Access the location to which you extracted the script files. Using a text editor application, open the following file: Add_OpenWith_WhiteListed_Domain.reg
8. Replace the file's placeholder domain text with accurate text that identifies the last part of your organization's valid Oracle Site Activate domain. For example, replace the file's “*.exampleDomain.net” with "*.MyOrganizationNameActivateProd.org". You must enter the appropriate name for your organization's Oracle Site Activate instance, which may also identify the environment (i.e., UAT, PROD, etc.).
9. Close the text file and save your changes when prompted.
10. Open a Command Prompt with Administrator privileges, and enter the following command: "reg import Add_OpenWith_WhiteListed_Domain.reg".

When the Command Prompt window displays a success message, close the window. You have completed this task.

Edit a document

With the document editing feature, you can open a Microsoft Office document from Oracle Site Activate, make your desired changes in the document's default application, and save the updated document back to Oracle Site Activate.

> **Note:**
>
> To complete this task, you must have the Box Tools application installed on your local machine. You must also have a document annotation and editing business role permission in Oracle Site Activate, and you must be assigned to the activity.

1. Open the document, contract, or submission modal and see the item has an attached file.
2. Click the pencil ( ) and then click **Approve** to open the file in its default application (i.e., Microsoft Word, Excel, or PowerPoint).

   (Optional)
   When you edit a document, that locks the item. This means that the activity prevents more edits, further attachments, and activity completion.
3. Make the necessary edits and close the document.
4. Click **Save**.
5. Click **Check document back in** to save your edits, or click **Discard edits** to remove any changes.

   If you checked in, the newly edited document is unlocked, has a new version, can be edited again, and the activity is ready for completion. If you discarded edits, the document is unlocked with no changes.

9

About study library

Accessing documents and required permissions

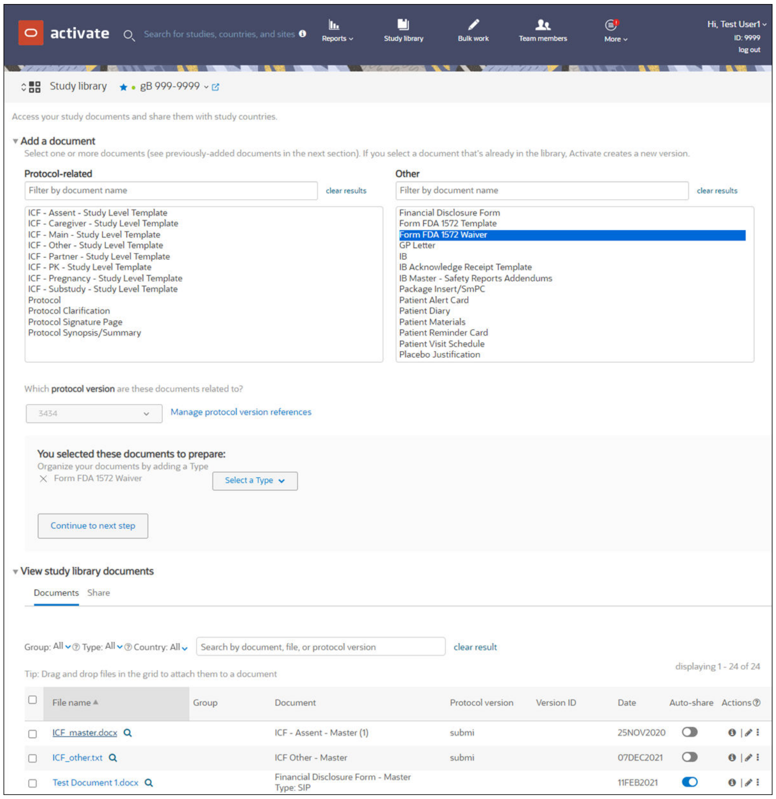
The Study library feature allows you to post study level document files such as protocols, protocol amendments, ICFs, and templates to the library and share them with the entire study team.

> **Note:**
>
> If your organization doesn't use the library, country leads will retrieve the documents from another repository and then run a workflow to generate the activities required to process them.

Country leads receive an alert to complete activities and a link to the document. Other team members assigned to the study can see study documents at any time; however, only team members with permission can add them.

On the study library page, you will select from a list of preconfigured document types (e.g., protocol). If the document is related to a protocol, you can specify which one. You will also edit the document to add a description and version ID, then upload the file. You can then share the document with study countries.

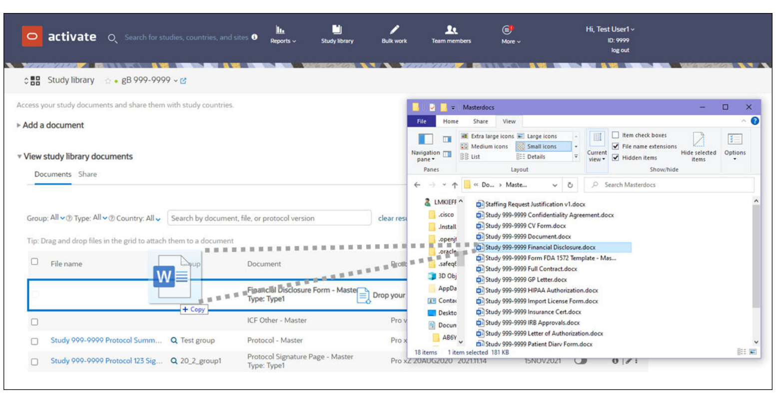
If you have a business role with "Enable document grouping in Study library" permission, you can organize documents into groups on the document tab. Document groups are account-specific, meaning you'll choose from a preconfigured list of groups. If necessary, you can add and remove a document group to meet your organization's unique needs.



Add a file to a document

If you have a business role that allows you to upload documents to Study Library, there are two options to add a file to a document on the **Documents** tab:

1. Click edit (✏) in a document's Action options to upload (or replace) a file in the document modal. If you're replacing a file, you can simply drag and drop a file into the edit modal.
2. Drag and drop the file to an empty document row. Because each document allows one file attachment, you'll receive a warning if you attempt to drop a file on a row with an existing attachment or attempt to drop multiple files to a document row at one time. When you drop the file on an available row, the document modal displays, and the user can specify document metadata as preferred (e.g., Document Date, Responsible Party, Description, etc.) before clicking "Done" to save the file attachment.



Sharing without file attachment

Document items can be configured to allow sharing from Study Library without a file attachment. Oracle Site Activate creates the downstream placeholder(s) when a study document is shared without a file attachment. If a file is subsequently attached to the item in the library, then it will appear within the lineage section of its downstream placeholders.

In line with standard behavior, the study item will become enabled for sharing again if new countries/sites are added for which downstream items are configured.

Documents that are not configured for share without attachment functionality require file attachment before they are available in the Share tab.

Using document Types

Study Library makes it easy to keep a standard document configuration and then customize it to the needs of the study. For example, having just one ICF or patient material item and then delineating between those with unique content using the Type field (100 character max) to specify what sort of ICF or patient material.

When adding a document, users with the appropriate business role permission can add a new Type (if enabled for the account) or select from a Type list that contains all Types previously created for that study or the account. You can create up to 25 additional instances of the document and differentiate the documents by selecting or adding a unique document + Type combination. To prevent duplicates, Oracle Site Activate will not allow you to specify a Type that has already been selected for a different instance of the document.

The Documents and Share tabs allow you to filter the document grid by Type. When saved for a document, the Type value displays as a second line below the document name. A document's associated Type value also displays throughout Oracle Site Activate anywhere that document is available (e.g., Workflow Wizard, document placeholders at site and country levels, Corrections area, etc.).

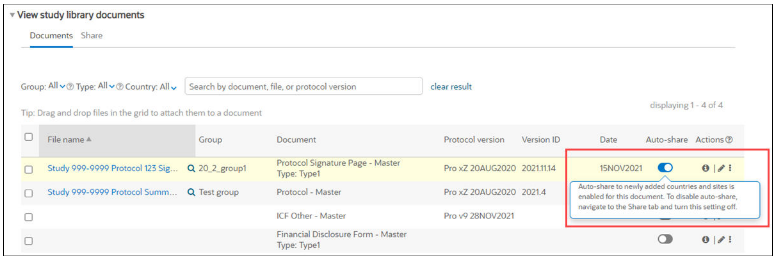
Automatic document distribution

Study Library allows for automatic document sharing when the optional auto-sharing feature is enabled for your organization's account. This feature allows you to configure auto-sharing on an individual document basis from within Study Library and reduces time and effort related to sharing documents.

When a document has auto-share enabled, Oracle Site Activate automatically shares out to the lineage items tied to that document any time a new country or site is added to the study based on the document's configuration. For example, if only country level documents are tied to the study level item, auto-share occurs only when new countries are added and not when new sites are added. Additionally, documents that have auto-share enabled continue to auto-share when new countries or sites are added until the auto-share setting for the document is manually disabled; auto-share occurs even if new versions of the item are available.

With this feature enabled, you'll see auto-share status toggles in several Study Library areas. Some of these controls are view only, and others allow you to enable or disable auto-share for the document. View only and editable toggles are the same type of control – this is by design to provide a consistent user experience. For all toggles, blue indicates enabled status and gray indicates disabled status. When a toggle is view only, hover over text displays to provide status context and instructions on how to change the status.

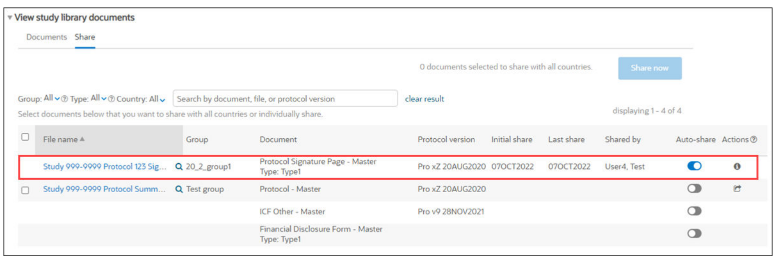
On the Documents tab, an "Auto-share" column displays view only auto-share status indicators for each document in the grid.



On the Documents tab, when you click information ( ) or edit ( ) under a document's Actions, the modals include the view-only status indicator and hover-over text as well.

The Share tab also has the Auto-share column, and this is where auto-share status is editable. Just click the blue or gray status indicator and enable the setting in the resulting modal or by respond Yes to confirm disabling the setting.

If a shareable artifact has auto-share enabled, it is not manually shareable via the individual share modal or the "Share now" bulk share button. Additionally, the Actions column displays an information icon ( ), which displays an information modal for that document when clicked.

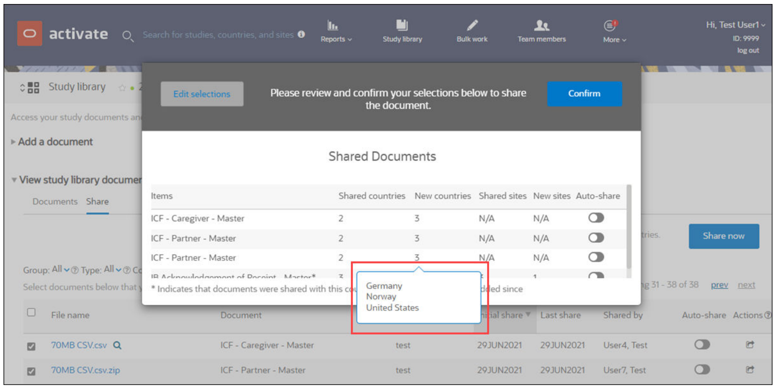


Sharing tool tips

Study Library uses hover-over tool tips in bulk sharing and individual sharing modals to surface the detailed information you need to make document sharing decisions and help you understand why sharing for specific documents isn't available.

For example, when you hover over a numeric value for any country or site column in the bulk sharing confirmation modal, a tool tip shows the list of countries or sites that make up that value. The tool tip shows up to 10 countries or sites, and you can click through to additional pages if there are more than 10 entities making up the total value.

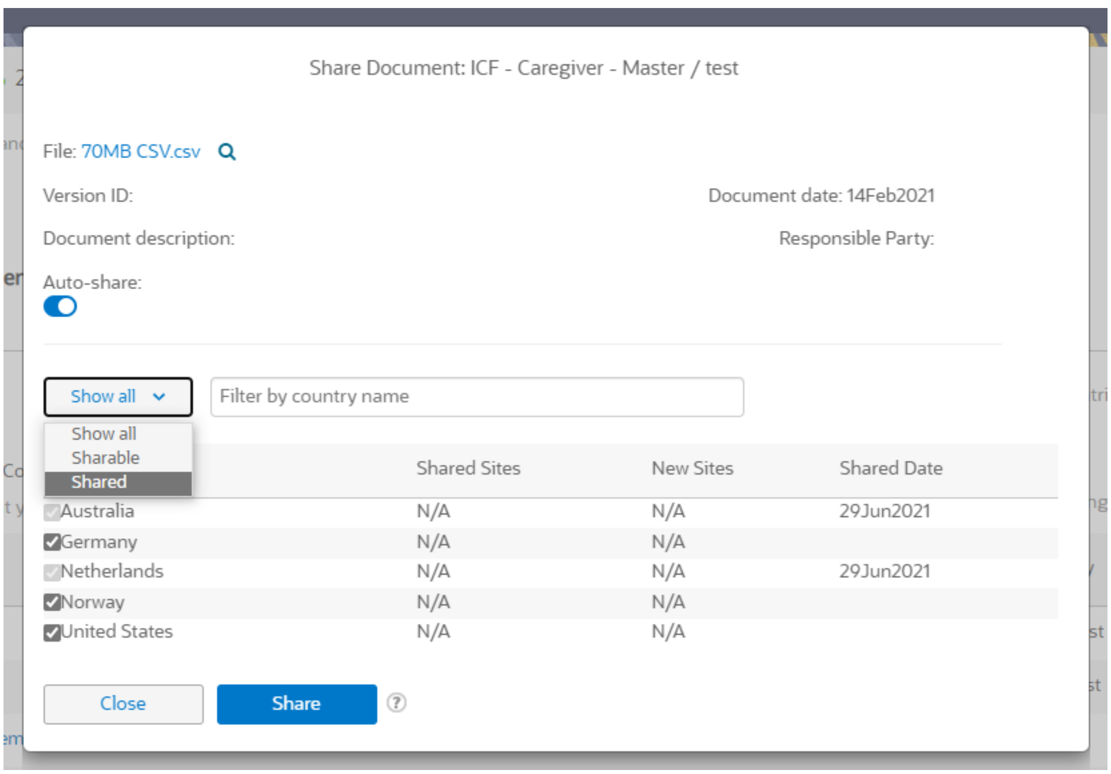
When a document is not configured to be shared with countries or sites, it displays "N/A" in the country or site column. Tool tips specify the reason for displaying "N/A" for the country or site. For example, if the country value is "N/A," the tool tip message is: "This document is not configured to be shared with countries in this study."



Confirming a document was shared from the library

The first time you share a document from the library, it is shared with existing country leads. If new countries are added to the study, you can re-share the documents with just the new countries. If you think you made a mistake or need to make sure a document was shared, you can see which countries received the shared document from the **View study library documents** section at the bottom of the Study library page.

On the study library page, click **View** next to the study document name to see where and when it was shared.



If a document is shared in error or does not apply to a country (and if Oracle Site Activate has been configured to discontinue versions), you can click **Discontinue this version** on the document's widget. This action removes it from document lists, stops all alerts related to the document, and removes it from document counts.

Users who view a document artifact at the country and/or site level that has already been added via Study Library will see a tool tip next to the **Add a new document version** button.

The tool tip text is: "Versions added at this level will override additional lineage document versions shared from the Study Library."

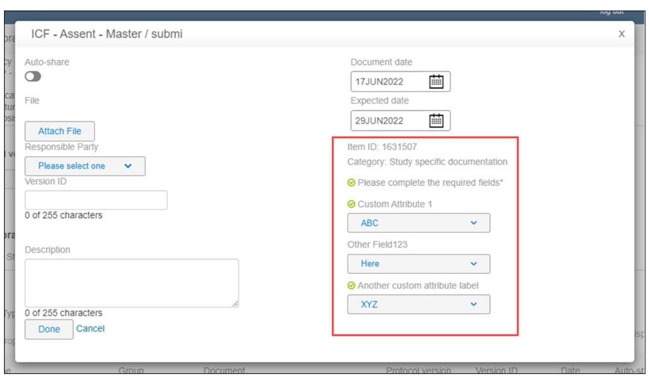
Editing library documents

You can replace files you upload into the library. You can also change the document's attributes like Version ID, document date, and description. If the account has been enabled to capture the "Responsible Party" (the individual or organization responsible for creating the study document(s) that will be distributed to countries or sites), you can also specify the responsible party by choosing the appropriate entry from a preconfigured drop-down list.

To access the edit modal below, from the **Documents** tab, click edit ( ) to the far right of the study document name. Use the options in the modal to modify Version ID, document date, description, etc.

Custom eTMF attributes are available in the Study Library document edit modal when configured for an item. You can see the Item ID and Category and view and edit attributes associated with the Category, as preferred. Within the modal, custom eTMF attributes configured as required display the incomplete/complete required field icon ( ). You must complete any required fields to enable the modal's **Done** button. When you share the study document with countries/sites, the created lineage document will not have values set into its custom attribute fields.

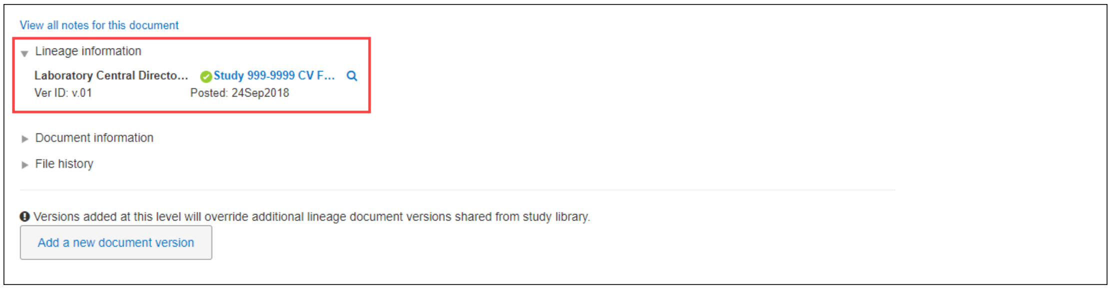
Custom attributes will be included in eTMF Publish messages when a Study Library document is included in an IP release package. Custom attributes for Study Library documents will also be available on Artifact Publish messages and GET responses.

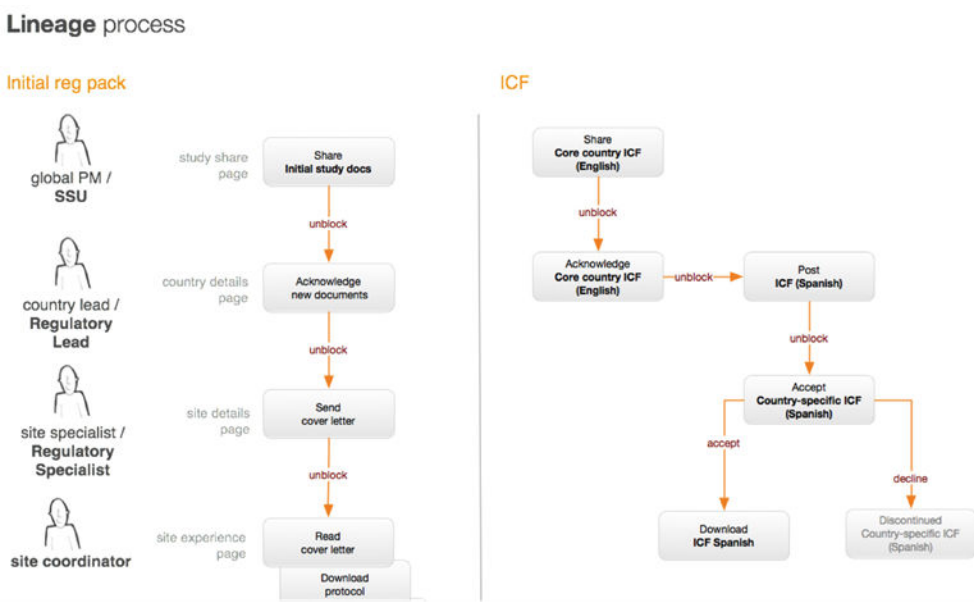


Document lineage - identifying the parent library file

There are three ways you can determine the parent study library file on which a document is based:

1. By looking at the file name: depending on your organization's standard naming procedures, you may see the name of the parent document in the file name.
2. You can see a lineage icon at the upper right side of the document widget.
3. On the document's widget, under the **Lineage information** section.





Sharing protocol amendments from the library

Managing protocol amendments is a three step process:

1. A member of your team shares the amended protocol and any associated document files from the study library.
2. Oracle Site Activate automatically generates activities for the country leads so they can accept the amended protocol.
3. Depending upon how Oracle Site Activate is configured for your organization, country leads use Oracle Site Activate workflow wizard (available from the study country **Actions** menu) to generate activities that track the protocol and additional country documents, activities, and submissions that need to be redone.

If a country did not receive the initial release of the amended protocol, share it again with just that country from the Study Library.

- Share study level document with all study countries
  Do you need to add a new study level document to the library and share it with all existing study countries? Learn how to quickly share the document using this procedure.
- Share study level document with newly added countries
  When a study has one or more new countries added, you can manually share study level documents with the new countries.
- Enable/disable automatic document distribution from library
  When this feature is enabled for the account, you can save time and effort by enabling automatic document distribution in study library. This optional, document-specific setting

allows enabled documents to be shared automatically with newly added study countries and sites.

- View countries with which a document is shared
  When you need to confirm that a document has been shared or plan for sharing, you can quickly review the list of countries that have already received the document.
- Find existing protocol versions
  When adding a new document to the Study library, you might need to specify a protocol version. Learn how to find protocol versions for the study.
- Share and reshare individual documents with countries
  When automatic document sharing isn't enabled for a document, you can manually share and reshare that document with one or more countries.
- Organize study files with document groups
  You can add and remove a document group, provided your user account has a business role with the "Enable document grouping in Study library" permission.
- Remove unshared documents
  When a document isn't needed and hasn't been shared yet, remove it from the document list to avoid confusion.

Share study level document with all study countries

Do you need to add a new study level document to the library and share it with all existing study countries? Learn how to quickly share the document using this procedure.

1. Click **Study library** in the top navigation bar.
2. If necessary, select the study name in the persistent header.
3. In the **Add a document** section, select the documents you want to share.
4. If the document is related to a protocol, choose or enter the protocol version.
5. Select or add a document **Type**. If necessary, you can add up to 25 unique document + Type instances. Click **+** (plus sign) to create additional instances.
6. Click **Continue to next step**.
7. In the **View study library documents** section, click the **pencil** icon to the far right of the document you want to share.
8. If your organization stores files on a shared drive, enter the complete path to the file location, for instance http://myfiles.ICF.doc. Otherwise, if your organization stores files in Oracle Site Activate, click **Attach File** and upload the file.
9. If enabled for your organization's account, select a **Responsible party** from the drop-down list.
10. Optional: (Optional) Enter the document’s **version ID** and **description**, then change the date, if necessary.
11. Click **Done**.
12. Click the **Share** tab, select documents you want to share, then click **Share now**.
13. Review selections, and click **Confirm**.

Share study level document with newly added countries

When a study has one or more new countries added, you can manually share study level documents with the new countries.

1. Click **Study library** in the top navigation bar.
2. If necessary, select the study name in the persistent header.
3. Expand the **Add a document** section and select one or more files to share.
4. If the selected documents are protocol-related, select the protocol version number.
5. Select or add a document **Type**. If necessary, you can add up to 25 unique document + Type instances. Click **+** (plus sign) to create additional instances.
6. Click **Continue to next step**.
7. Confirm your selections, and click **Continue to next step**.
8. Click the **Share** tab, select documents you want to share, and click **Share now**.
9. Review selections, and click **Confirm**.

Enable/disable automatic document distribution from library

When this feature is enabled for the account, you can save time and effort by enabling automatic document distribution in study library. This optional, document-specific setting allows enabled documents to be shared automatically with newly added study countries and sites.

1. Click **Study library** in the global navigation bar.
2. On the **Share** tab, use the filters and search field to locate the document you want to enable for automatic sharing. In the document's **Auto-share** column, click the enable/disable toggle.
3. If auto-share is available, a share document modal opens. Confirm the auto-share toggle is enabled (blue state is enabled, gray state is disabled), and click **Share**.
4. On the confirmation modal, click **Confirm**.

View countries with which a document is shared

When you need to confirm that a document has been shared or plan for sharing, you can quickly review the list of countries that have already received the document.

1. Click **Study library** in the top navigation bar.
2. If necessary, select the study name in the persistent header.
3. Expand the **View study library documents** section.
4. Under Actions, click information (ℹ) to open the document details modal.

Find existing protocol versions

When adding a new document to the Study library, you might need to specify a protocol version. Learn how to find protocol versions for the study.

- From the country details page's **Actions** menu, select **View protocol versions**.

Share and reshare individual documents with countries

When automatic document sharing isn't enabled for a document, you can manually share and reshare that document with one or more countries.

1. Click **Study library** in the top navigation bar.
2. If necessary, select the study name in the persistent header.
3. Expand the **Share** tab of the View study library documents section.
4. Click the icon at the far right to individually select countries to share or re-share documents, if those documents have been configured.
5. Click **Done**.

Organize study files with document groups

You can add and remove a document group, provided your user account has a business role with the "Enable document grouping in Study library" permission.

1. On the Documents tab, click the document's ellipses option (⋮) under Actions. Choose **Add to a group**.
2. Select from the preconfigured Groups list, or add a new value under **Other**, then click **Save**.
3. Filter to find study library documents associated with your selected document group by selecting the group from the **Group** drop-down.
4. **Remove group** names by clicking on the **Actions** drop-down list when filtering by document group names.

Remove unshared documents

When a document isn't needed and hasn't been shared yet, remove it from the document list to avoid confusion.

To complete this procedure, your user account must have a business role permission that allows for removing documents from Study library.

1. On the Documents tab, click the check box to the left of the document to be removed.
2. Under Actions, choose **Remove document**.

10 About electronic signature

Oracle Site Activate users can tag documents and contracts for electronic signature and electronically sign documents and contracts when requested.

Integration with Adobe Sign

To speed the study startup process and reduce the amount of time required to gather signatures for contracts and essential site documents, Oracle Site Activate supports integration with electronic signature vendor, Adobe Sign.

If enabled for your organization's account, the electronic signature feature allows document managers to tag documents for signature and document receivers to sign important documents, in an FDA-compliant manner, within Oracle Site Activate and via mobile device. Because the signature is digital, electronically signed documents can also be transmitted into eTMF systems if this integration is enabled for the account.

> **Note:**
>
> Only Oracle Site Activate users have the ability to sign documents using the electronic signature feature; the feature is not available to site users who do not log in to Oracle Site Activate.

Understanding electronic signature permissions

The electronic signature feature must be enabled at the account level. Please contact your Oracle Project Manager or Account Manager for details.

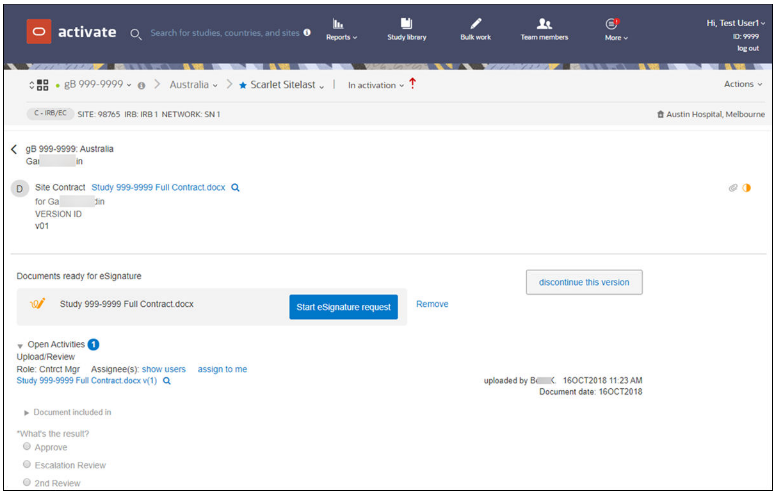
Once enabled at the account level, Administrative users who have permissions to add and edit studies/countries can enable or disable electronic signature functionality at the country and study levels.

Additionally, this feature has two associated business role permissions:

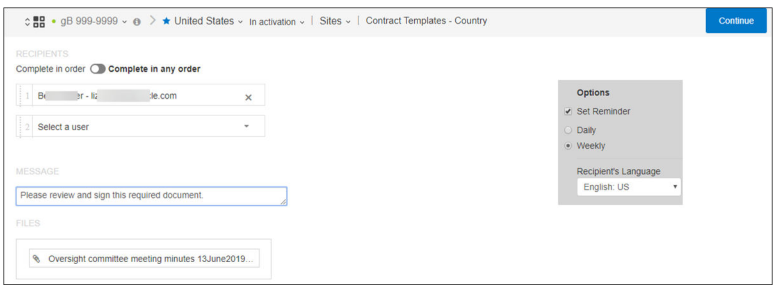
1. Enable management of electronic documents - allows the user to specify the user(s) who will sign the document and tag the document for electronic signature (i.e., indicate where in the document the signature, initials, etc. are required).
2. Enable signing of electronic documents - allows the user to electronically sign a document via Adobe Sign

Tagging items for electronic signature

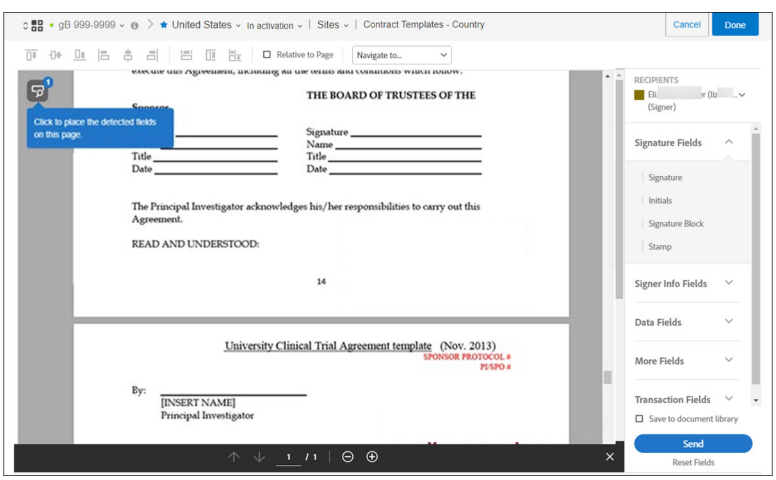
After uploading an item to Oracle Site Activate, users who have tagging permissions can assign one or more users as signers, order the list of required signatures (if more than one signer), and set reminders and notification email languages. The document tagger will also indicate where in the document the signature, initials, etc. are required before sending the electronic signature request.



Add one or more signer(s) for the request. If you have multiple, you can specify the order of signatures required. You can also add a message that will display in the email notification sent to all signers you specify. If appropriate, you can also set reminders and specify the recipient notification language.



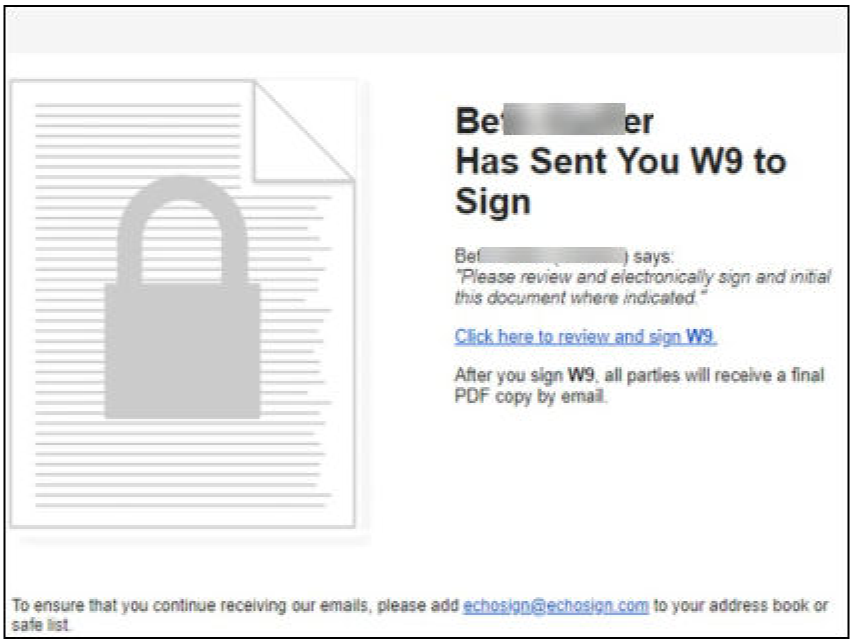
Once you confirm the recipient list, Oracle Site Activate processes the file with Adobe Sign and displays the item for tagging. If signature fields were automatically detected during processing, an icon displays at the upper left. Click the icon to automatically place the signature fields. You can also drag and drop additional fields into the item as necessary. Just select them from the panel on the right.



Once you've sent an item out for signature, Oracle Site Activate displays icons to indicate completed or outstanding electronic signatures in the widget's File history section. For example:

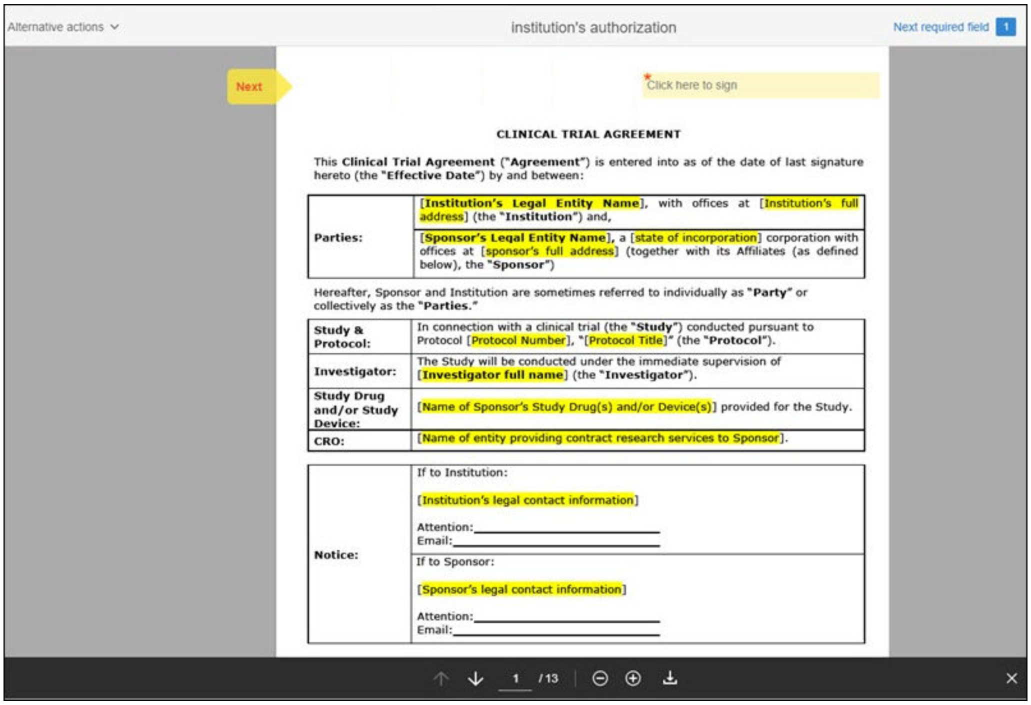
The electronic signature feature is not tied to configured study workflows; alerting functionality identifies needed activity outside of workflows. Oracle Site Activate users who have electronic signature requests assigned to them will find the requests in their alert list as "Electronic Signature request." These users also receive an email from Adobe Sign (sender: echosign@echosign.com) notifying them of the request and providing an Adobe Sign login link.

Email notification sample



Accessing the item from the alert or email notification

In Adobe Sign, flags indicate were in the document signature or other items (dates, initials, etc.) are required and the total number of required fields also displays at the upper right.



- [Enable or disable electronic signature at the country level](#)
  When electronic signature can be used in one country but not another, study administrators can enable the feature for only the applicable country.
- Enable or disable electronic signature at the study level
  Users who manage study attributes can enable or disable electronic signature for the entire study with just one click.
- Tag document or contract for electronic signature
  Tagging shows the signer(s) where to input signature(s).
- Sign items in Adobe Sign - Oracle Site Activate
  Oracle Site Activate users can quickly access items that require their electronic signatures from within activity lists.
- Sign items in Adobe Sign - email notification
  If preferred, document signers can add their signatures while viewing the document or contract within the Adobe Sign application.

Enable or disable electronic signature at the country level

When electronic signature can be used in one country but not another, study administrators can enable the feature for only the applicable country.

You must have a business role that has "Enable management of electronic documents" permission and an active Adobe Sign account to complete the procedure below. Please contact your administrator or super user to adjust permissions, if necessary.

1. On the home page, click the **Actions** menu.
   a. To edit an existing country, choose **View study country and Site details**. Click the **Action** menu for a country, and click **Edit study country**.
   b. To add a new country, click **Add new study country**.

2. Scroll down the country page. At **Enable electronic signatures for this study country** click the toggle control to enable/disable electronic signatures for the country.
3. Click **Done**.

Enable or disable electronic signature at the study level

Users who manage study attributes can enable or disable electronic signature for the entire study with just one click.

You must have a business role that has "Enable management of electronic documents" permission and an active Adobe Sign account to complete the procedure below. Please contact your administrator or super user to adjust permissions, if necessary.

1. On the home page, click the **Actions** menu.
2. To edit an existing study, choose **Edit study** or to add a new study, click **Add new study**.
3. Scroll down the page. At **Enable electronic signatures for this study**, toggle to enable/disable electronic signatures for the study.
4. Click **Done**.

Tag document or contract for electronic signature

Tagging shows the signer(s) where to input signature(s).

You must have a business role that has "Enable management of electronic documents" permission and an active Adobe Sign account to complete the procedure below. Please contact your administrator or super user to adjust permissions, if necessary.

1. Open document or contract widget. Under **Open Activities** click **Attach File**.
2. Click the toggle above **Include electronic signature request**.
3. Click **Complete Activity**.
4. Oracle Site Activate automatically performs a virus scan on the file. When finished, click **Start eSignature request**.
5. Under **Recipients**, click **Complete in order** if the item requires multiple signers who must sign in succession. Click **Complete in any order** if the item requires one or more signers, but the order of signatures isn't fixed.
6. At **Select a user**, begin typing an Oracle Site Activate user's name or email. Click the user's name when found.
7. If adding additional signers, search for the next Oracle Site Activate user's name or email and select the user. Drag and drop the signer list into the preferred order. Repeat until all signers are selected and ordered.
8. In the **Message** section, enter a message to the signers (e.g., "Please review and electronically sign where indicated in this document.").
9. In the **Options** section, set a daily or weekly reminder for the recipient. The recipient will receive the reminder by email either daily or weekly until he or she completes the signature request or opts out of reminder messages.
10. In the **Options** section, choose the recipient's language. This is the language that will be used in the notification email.
11. Click **Continue**.

12. Review the list of recipients. If correct, click **Confirm**.
13. After processing, the item displays. To tag the item, drag and drop signature, initial, date, etc. fields from the right panel into the appropriate location(s) or click the form fields icon at the upper left of the page to automatically place fields.
14. Click **Send**.

You will receive an email notification (sender: echosign@echosign.com) that confirms the item has been sent for signature, and the notification includes a link to the item. Sign in to your Adobe Sign account to view.

Sign items in Adobe Sign - Oracle Site Activate

Oracle Site Activate users can quickly access items that require their electronic signatures from within activity lists.

You must have a business role that has "Enable signing of electronic documents" permission and an active Adobe Sign account in order to complete the procedure below. Please contact your administrator or super user to adjust permissions, if necessary.

1. In Oracle Site Activate, under **Your activities**, click the Electronic Signature request alert. The associated widget opens.
2. At the top of the widget, click **Complete signature request**.
3. Sign in to Adobe Sign. The document or contract displays.
4. Adobe Sign flags the fields that require your signature and displays a counter at the upper right indicating the number of fields you need to complete. Click where indicated to sign and click **Apply**.
5. Review the Signature Preview pop-in, enter a **Signing Reason**, and click **OK**.

Sign items in Adobe Sign - email notification

If preferred, document signers can add their signatures while viewing the document or contract within the Adobe Sign application.

You must have a business role that has "Enable signing of electronic documents" permission and an active Adobe Sign account in order to complete the procedure below. Please contact your administrator or super user to adjust permissions, if necessary.

1. In the email notification message, click the hyperlinked document or contract name.
2. Sign in to Adobe Sign. The document or contract displays.
3. Adobe Sign flags the fields that require your signature and displays a counter at the upper right indicating the number of fields you need to complete. Click where indicated to sign and click **Apply**.
4. Review the Signature Preview pop-in, enter a **Signing Reason**, and click **OK**.

11
About submissions

> **Note:**
>
> This section describes working with non-EU submissions. To see detailed information about creating and managing study level, EU submissions, see About study level submissions.

The submissions modal

The submissions modal makes it easy for you to complete required and important activities. The modal (see image below) includes a static header that identifies the study and country as well as scrolling modal body design.

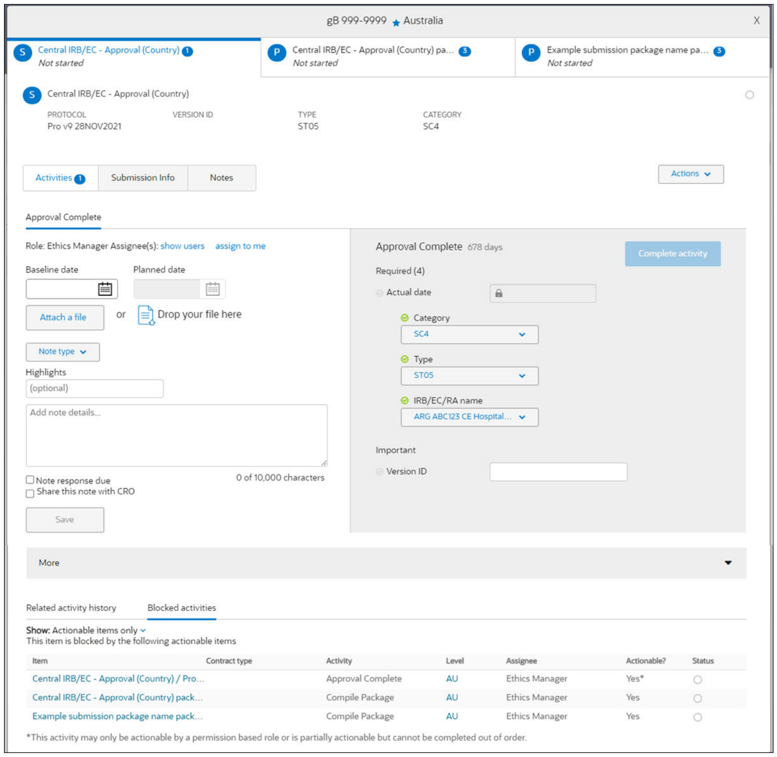
When appropriate, Oracle Site Activate groups related submission activities in a single, tabbed modal. For instance, a submission modal may include the submission tab, as well as one or more package and/or subcommittee tabs when these items exist for that submission. The Actions menu in the header section of the Submissions modal includes options to discontinue or reinstate the submission and add additional packages, when necessary.

The Activities tab is the default view, and required activities are listed horizontally below the Activities tab. You can easily navigate from one activity to another by click, and your selected activity will be underlined in blue.

The modal's “Info” tabs include a Details area where you can enter data into configured metadata fields (e.g., Version ID, reason, description, agency, etc.). Below the Details area is a Submission dates area where you can plan smart submission milestones and adjust the eye button to display/hide milestones on the milestone calendar. The Info tab also includes sections for Files and any configured TMF data.

Within the modal body, you'll have date, file attachment, and notes options to the left. The shaded panel, to the right, includes an enumerated list of Required actions, as well as any Important fields.

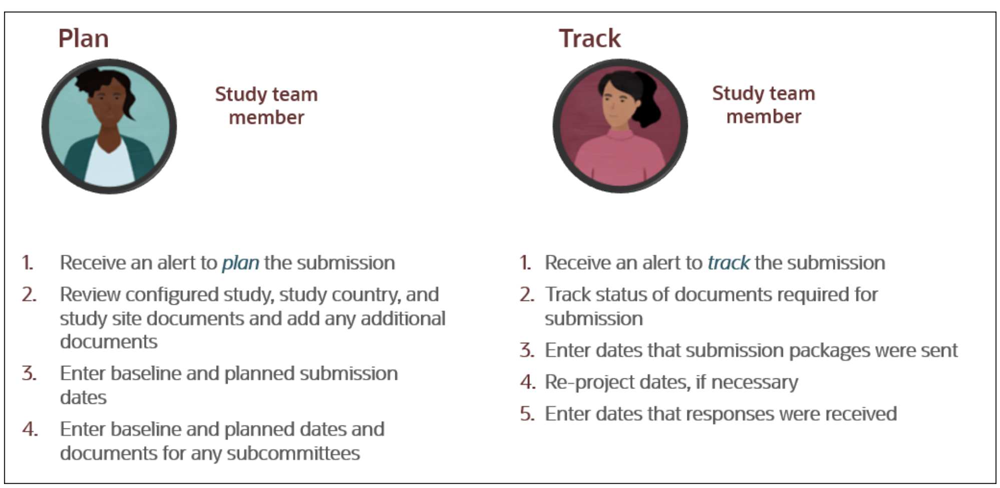
The lower section of the modal includes Related activity history and Blocked activities sections, if applicable.



Using workflow wizard and submission activity widget

Oracle Site Activate is configured to create activities that help your study team manage and track study country and site submissions. During initial setup, your organization worked with Oracle to identify required submission documents based upon known regulatory requirements and your organization’s standard processes.

You'll use the workflow wizard to generate the activities required to track and manage each submission. Then you'll use the submission activity widget to record key dates and track the list of required documents.



Planning submissions

You or another member of your study team may receive an alert to plan the submission. Start by defining key dates, for example package date is required. The package date can be edited, if necessary, and Oracle Site Activate prompts the user who is updating the date to enter a reason for the date change.

Submissions can be configured to have expiration dates, which may be set to required, if desired by your organization. Submission expiry notification (default 90 days) may optionally be set as well. If expiration does not apply, Oracle Site Activate users may check a “no expiration date” check box within the Submission modal. Once the submission is completed, the expiration date field is no longer editable.

At any time, you can view the submissions widget **Planning** or **Tracking** tabs and see the status of documents being tracked for the package.

If you need to replan a submission, and you attempt to remove one or more documents that are in first review or final approval status, Activate will display a warning message. The submission package planning page displays the warning if you:

- uncheck a document that is already in an approved status. The message is: "This document is in first review or final approval for this package. Are you sure you want to remove this document?"
- click the deselect all check box at top of the page, and one or more of the previously selected items is already in an approved status. The message is "One or more of the below documents is in first review or final approval for this package. Are you sure you want to remove this document?"

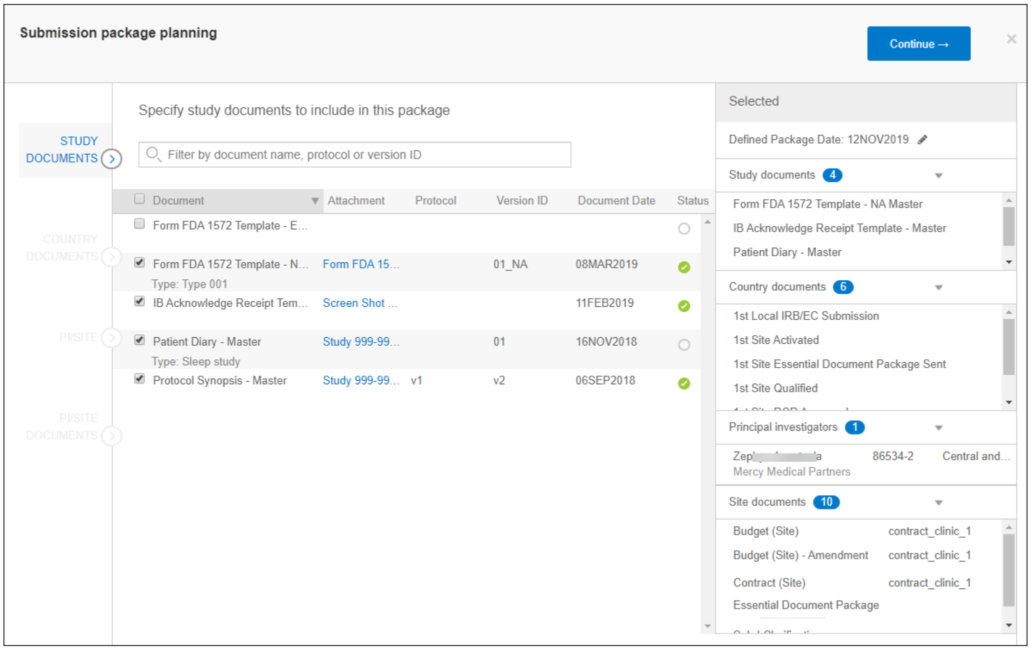
Within the warning message pop-in, you can confirm removal by clicking "Yes," or "Cancel" the removal action.

Creating additional packages and adding subcommittees

If you need to submit additional documents later, create a new submission package to track them. To define the new package, you will repeat the steps you performed to create the initial package.

To help you differentiate and track key dates and documents for subcommittees, you can also add a submissions widget to help you track those submissions.

In the packages section, click "plan this submission package" to define a package date and select study, country, PI/site, and PI/site documents as appropriate to the new package.



Tracking submissions

Immediately after planning is complete, you or another team member who is responsible to track the submission receives an alert as a reminder to mark the date that the package was submitted. That alert remains on your to-do list until you enter a completion date.

During planning, you or another team member entered a baseline date for each of the submission's activities. If you learn that a submission date changes, you can re-plan the submission date. You can re-project dates as many times as needed. From the submission Tracking tab's Submission information section, you can specify the submission type (e.g., initial, amendment, etc.), version ID, and reason why the submission is being made.

If your organization configures Oracle Site Activate to do so, you can upload the submission approval letter so that it can be stored with the submission in Oracle Site Activate.

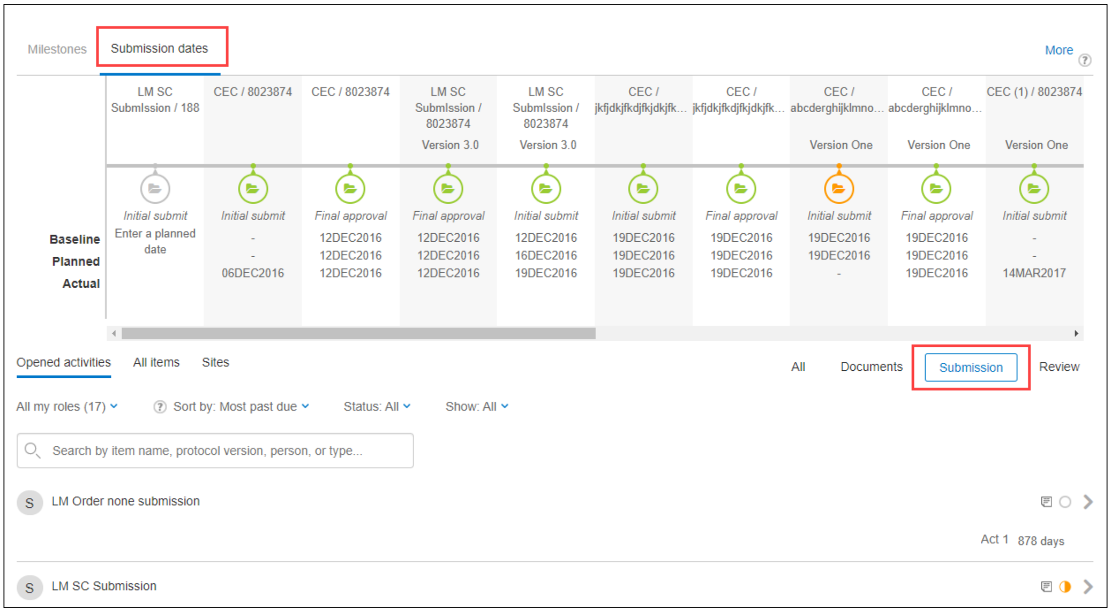
Tracking submission dates

To easily track key submission dates, you can also enter baseline, planned and actual submission dates on the widget and at the top of study country and site detail pages.

The newest milestones sort to the left on the timeline and oldest sort to the right. Date and sort order are determined as follows:

1. If an Actual Date is present on a submission, that date will be used as the sort date for that submission.
2. If no Actual Date is present on a submission, the Planned Date will be used as the sort date for that submission.
3. Submissions with no planned dates will display at the far left of the timeline. A maximum of 50 submissions will be displayed in the timeline. Submission milestones will be removed from timeline display based on the date and sort order described above. The oldest planned submission milestones (i.e., those that sort

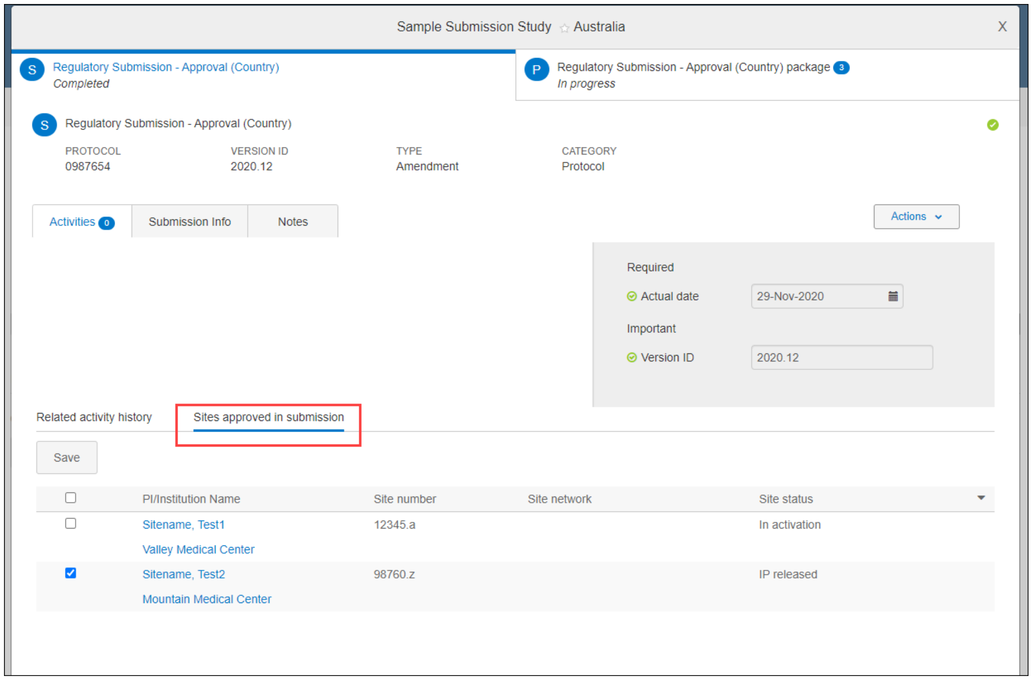
to the far right on the timeline) will be removed from display first as new milestones are added.



Correct sites included in a submission

If you have a role with data corrections permission, you can correct the sites included in a submission. After a submission has been approved, a new “Sites approved in submission” subtab lists all sites that were included in the submission’s “Define package” step. The site grid lists PI/Institution name, as well as the site number, site network, and status.

While the new tab is visible to all users after submission approval, only those users who have data corrections permission may uncheck sites to remove them from the submission approval. After site removal, the site will still be included in the initial submission and will still have an associated milestone; however, the site will no longer be approved for this submission.

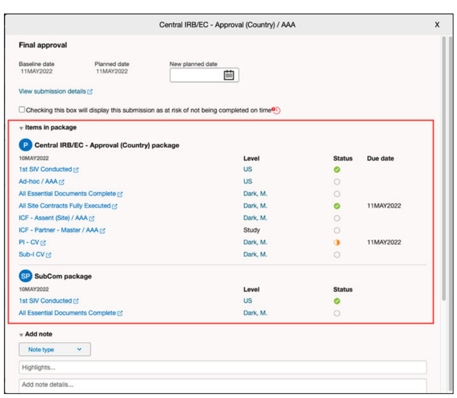


Submission milestone modals list Items in package

You can quickly access a list of all items included in a submission package using the "Items in package" section in the Final Approval and Initial Submit submission milestone modals. Expand the section to view:

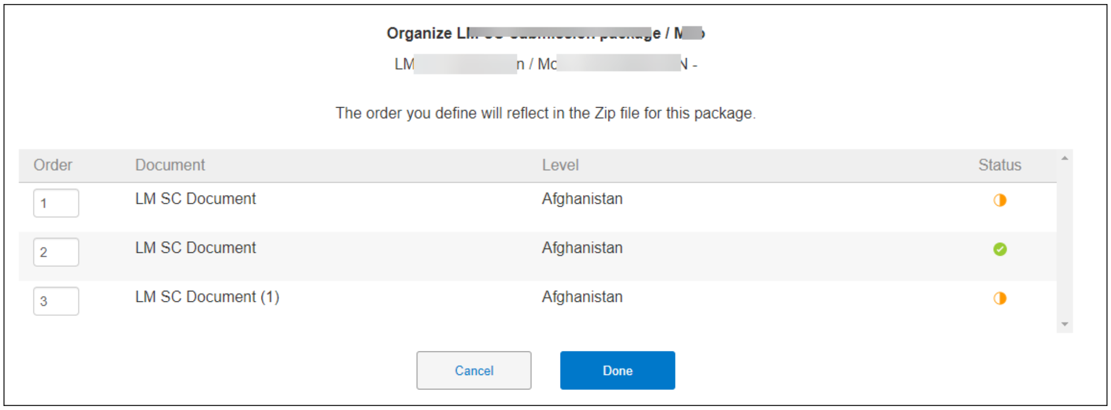
- Submission package name
- Item name
- Item level (study, country, or site)
- Item status
- Item due date, if a date exists. This column displays only if one or more items have a due date.

Item names, as well as country and site names, provide hyperlinked navigation. For example, you can click an item name to open the document modal or click the country code to navigate to the country page.



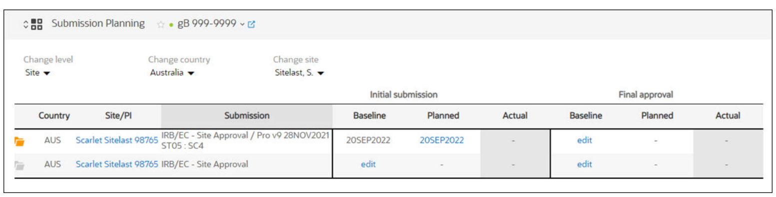
Submission package file ordering

When planning a submission package, you can order the files included in the package export ZIP file. In the package placeholder, the “Define order for this package” hyperlink displays a pop-in where you can manually number file order. Each number can be used once, and when an item has no number, it will be ordered in the ZIP file alphabetically on item name and then by item number. The file will be ordered by manually numbered items first, followed by alphabetized items (e.g., 123ABC).



Using smart submission management

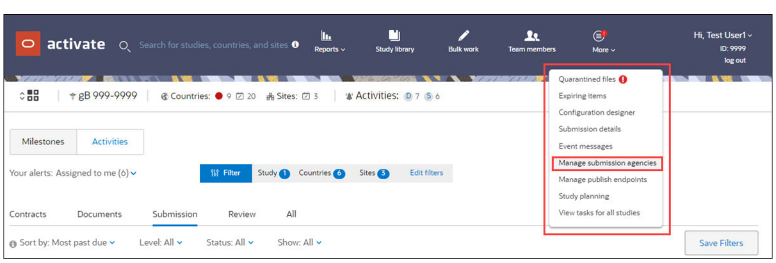
You can quickly view and update submission dates from the submissions details page; in the top navigation bar, click or hover over **More**, then select **Submission details**. Click **edit** to enter baseline and planned (re-projected) submission dates.



Managing a submission agencies list

Your organization has the option to upload a CSV format file containing the different submission agencies you may work with across countries. When uploaded, the agencies are available for users to select in an “IRB/EC/RA” type-ahead selection field in country and site level submissions.

You must have the appropriate business role permission to upload the CSV agency file. When you have this permission, the top navigation’s **More** menu includes a **Manage submission agencies** option.



The CSV upload file must include three columns in the following order:

1. **agency_id** - (100 character maximum)
2. **display_name** (255 character maximum)
3. **active** (true/false)

Note that agency_id is a unique ID for each submission agency. If the ID already exists in Oracle Site Activate, the existing record will be updated (i.e., update either/both display_name and active). If the ID does not already exist, Oracle Site Activate creates a new agency record.

To determine the agencies that already exist in the system, you can download the current list to a CSV using the Export to CSV option on the Manage submission agencies page.

- Add submission packages
- Add submission subcommittees
- Order submission package files
- Track submission status
- Set submission Type and Category
- Track planned submission dates
- Plan submission dates in bulk
  Save time by planning submission dates for multiple submissions at one time. You can plan submissions in bulk at the country or site level.
- Mark submission activities complete
- Enter submission dates in bulk
  If appropriate, you can enter a single date for multiple submissions.
- Generate document and submission activities
  If a country is added after study-level documents have been shared, run the country-level protocol workflow from the workflow wizard on the country details page.
- Include sites for submission to a central authority
- Export submission package documents
  Once the final activity for a submission package or sub-committee is complete, Oracle Site Activate automatically initiates a process to export all completed package documents and a manifest to a .zip file.
- Upload or download submission agency CSV
  If you have the appropriate business role permission, you can upload and download a submission agency list in Oracle Site Activate. If you do not see "Manage submission agencies" in the **More** menu item, please contact your administrator or super user.

Add submission packages

1. In the submission modal, click **Actions** and select **Add a submission package**.
2. Enter a package **Name**.
3. Click **Done**.

Add submission subcommittees

1. In the submission modal click **Actions** and select **Add a subcommittee package**.
2. Click **Add a new subcommittee**.
3. Enter the subcommittee package **Name**.
4. Click **Done**.

Order submission package files

1. In the submission modal, under the **Compile Package** activity, click **Define order for this package**.
2. For each listed file, enter the preferred **Order** number.
3. Click **Done**.

Track submission status

1. From the country or site details page, click the **Submission** tab.
2. Expand the main submissions, subcommittee, or package submissions placeholder.
3. At the top of the placeholder, you'll see key dates and notes.
4. Click the **Submission Info** to see the status of activities and documents.

Set submission Type and Category

1. From the country or site details page, click the **Submission** placeholder to expand.
2. Click the Submission (S) tab.
3. Click the **Submission Info** sub-tab. To the right, at **Type** select a new type (e.g., “Amendment”).
4. At **Category** select a category.
5. Click **Save**.

Track planned submission dates

1. On the country or site details page, click the **Submission dates** tab just below the persistent header.
2. For the date you want to enter or update, click the folder icon.
3. To enter the baseline (your first projected) date, click the date icon, select a date, and click **Done**.
4. To re-project a date, click the date icon and at **New planned date** select a date. At **Reason**, enter a reason for the change.
5. Click **Done**.

Plan submission dates in bulk

Save time by planning submission dates for multiple submissions at one time. You can plan submissions in bulk at the country or site level.

1. From the top navigation bar, hover over **More** and select **Submission details**.
2. At Change level, choose **Country** or **Site** from the drop-down.
3. At Change country, select the country.
4. To enter a baseline date, click **edit** and select the date.
5. To re-project a date, at **planned**, click **edit** (if the date has never been replanned), or click the date. Select a new date from the calendar and enter a reason for the change.
6. Click **Done**.

Mark submission activities complete

1. From the country or site details page, click the **Submission** tab.
2. Expand the main submissions, subcommittee, or package submissions placeholder.
3. On the **Activities** tab, complete the activity(ies) in the shaded section to the right. You may optionally complete any "Important" activities (such as completing a Version ID field, if configured).
4. Click **Complete Activity**.

Enter submission dates in bulk

If appropriate, you can enter a single date for multiple submissions.

1. On the home page, click the **Planning** tab, then click **Submissions**.
2. Check the box next to each investigator whose submissions dates you want to enter. You'll see the investigator name display in the section above.
3. Enter the dates.
4. Click **Done**.

Generate document and submission activities

If a country is added after study-level documents have been shared, run the country-level protocol workflow from the workflow wizard on the country details page.

1. From a country details or site details page, click **Actions** and click **Add [site or country] documents/submissions**.
2. Select the action you'd like to take, and click **Next**.
3. Select the existing protocol version, and click **Next**.
4. Indicate whether you're tracking activities for a country, investigators, or both; click **Next**.

5. Select the investigators that the protocol impacts and click **Next**.
6. Select the documents and submissions you'd like to track, and click **Next**.
7. Confirm your selections, and click **Done**.

Oracle Site Activate generates the documents and submissions to track.

Include sites for submission to a central authority

1. When working in the submission package planning modal, select option to **include site** for all sites that should be included in the country submission package.
2. Once the submission package planning is complete, the submission milestone for "Initial submit" will automatically be created for selected sites.
3. Once the country submission is approved, approval dates will be automatically populated for the sites.

Export submission package documents

Once the final activity for a submission package or sub-committee is complete, Oracle Site Activate automatically initiates a process to export all completed package documents and a manifest to a .zip file.

1. From the site or country details page, click the **Submission** tab and select the submission's placeholder to expand.
2. Click the **Submission Info** tab.
3. Click **Export to zip** to download the prepared .zip file.

Upload or download submission agency CSV

If you have the appropriate business role permission, you can upload and download a submission agency list in Oracle Site Activate. If you do not see "Manage submission agencies" in the **More** menu item, please contact your administrator or super user.

The CSV files you upload must use ASCII or UTF-8 encoding. When exporting and importing, you should save any additions or edits you make to the exported CSV as "CSV UTF-8 (Comma delimited) (.csv)" file format.

1. In the top navigation bar, hover over **More**, and click **Manage submission agencies**.
2. To upload a new CSV file, click **Upload CSV**.

   If the CSV was properly formatted and imported, Oracle Site Activate displays a success message and the screen refreshes to show the number of Agencies created and the number of Agencies updated (if any).
3. To download the existing agency list, click **Export to CSV**.

12 About study level submissions

> **Note:**
>
> This section describes how to work on study level submissions (a.k.a. EU submissions) in Oracle Site Activate. If you need information about working on regular, non-EU submissions please refer to About submissions instead.

Create and manage study level submissions

Oracle Site Activate supports submissions to the European Union (EU) Clinical Trials Information System (CTIS). Supporting features include the definition of study level submissions and packages, the ability for one EU member state to submit on behalf of other EU member states, as well as use of activity level due dates.

EU Submissions you to manage study level submission packages that have been deployed to Oracle Site Activate with one of the following activity types:

- Define EU Submission Validation Package
- Define EU Submission Part 1
- Define EU Submission Part 2

Validation, Part 1, and Part 2 submission packages each have unique package definition requirements, and Oracle Site Activate includes definition modals that provide all appropriate fields for completion.

After study level submissions have been defined for your study, you'll see the study level submission milestones on the study and site level milestone timelines. Additionally, study level submission milestones displayed on countries and sites include the associated study submission or submission package as a read-only item.

Defining an EU submission validation package

When you open a study level submission modal and click “Plan the Submission Package,” the planning modal opens the validation package’s define step, where you'll enter or select values for the following fields:

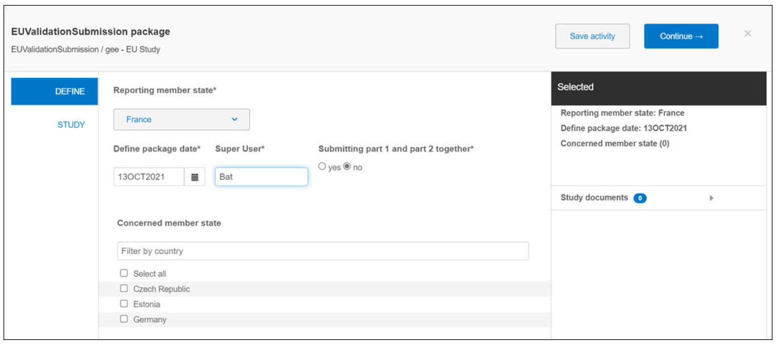
- Reporting Member State (the drop-down list includes the 27 EU Member countries)
- Define Package Date
- Super User
- Submitting part 1 and part 2 together (Yes / No option)
- Concerned member state (with a search field, multiselect, and Select All options)

As you define the Reporting member state, Define Package Date, and Concerned member state(s), the modal’s “Selected” panel updates with your selections.

The definition modal allows multiple users to define the package. When a group of users works together to define the validation package, any user can click “Save activity” at any time to save their progress without completing the activity, and that user can return to the package modal later to finish package planning. When multiple users are planning the package, they'll also see the name of the user who last made updates displayed in the Selected panel.

When a user clicks the modal's Continue button, the modal saves and automatically advances to the Study document selection area. As the user chooses individual study-level documents, the Selected panel also updates to reflect the chosen documents.

When a user clicks the package's "Done" button, a confirmation request displays, and when confirmed, the activity is completed, and the completion date is the date selected from the "Define Package Date" date picker.



Defining an EU submission Part 1

When the validation package definition has been completed as described above, you can define the EU submission Part 1 and mark states as Ready for submission, as appropriate. Like the Validation Package definition, the center panel of the Part 1 definition includes fields for:

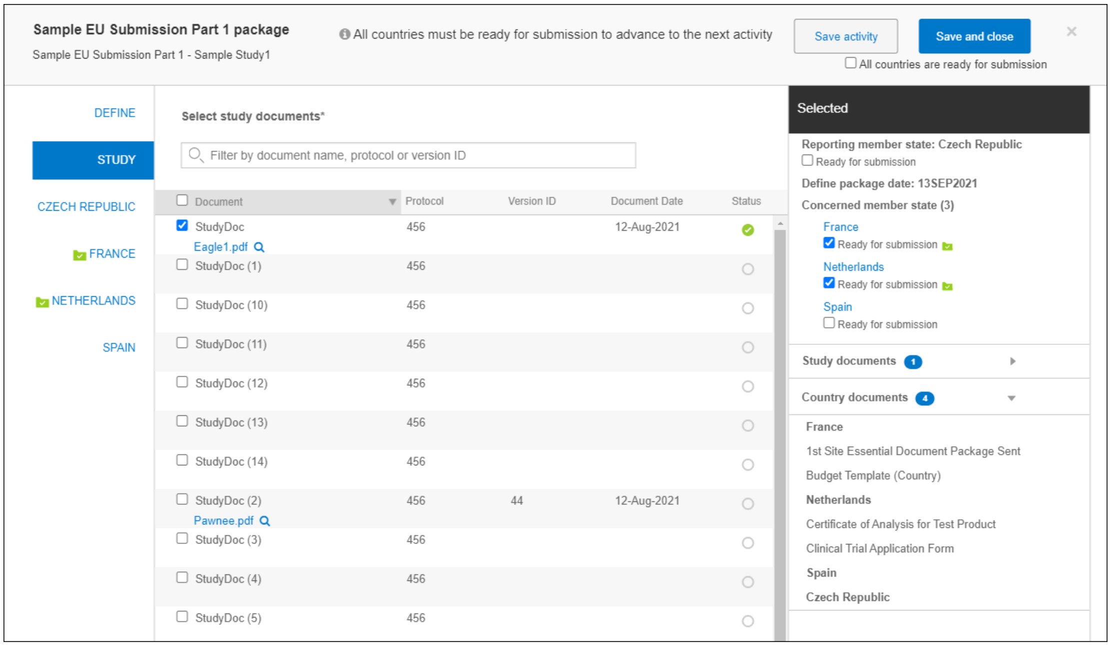
- Reporting member state
- Define package date
- Concerned member state

For both the Reporting member state and Concerned member state(s) the value(s) automatically populate from the associated Validation package, if available. You can edit these values as necessary.

You can then select Study level and then Country level documents using the links in the far left panel or by clicking "Continue" in the modal header to advance to the next step in the definition process, study level document selection. Again, if you're working with a group of users to create the definition the modal header's Save activity button will allow any one of the users to optionally save their progress on the definition without completing the activity. When the user enters the flow of study and country document selection, the modal header replaces the "Continue" button with a "Save and close" button.

Define package date, and chosen member state values, study documents and country documents populate the Selected panel to the far right. When appropriate, users can also check the country level "Ready for submission" check boxes in the Selected panel, or apply the ready setting to all countries in the submission package at once by checking "All countries are ready for submission" in the modal header.

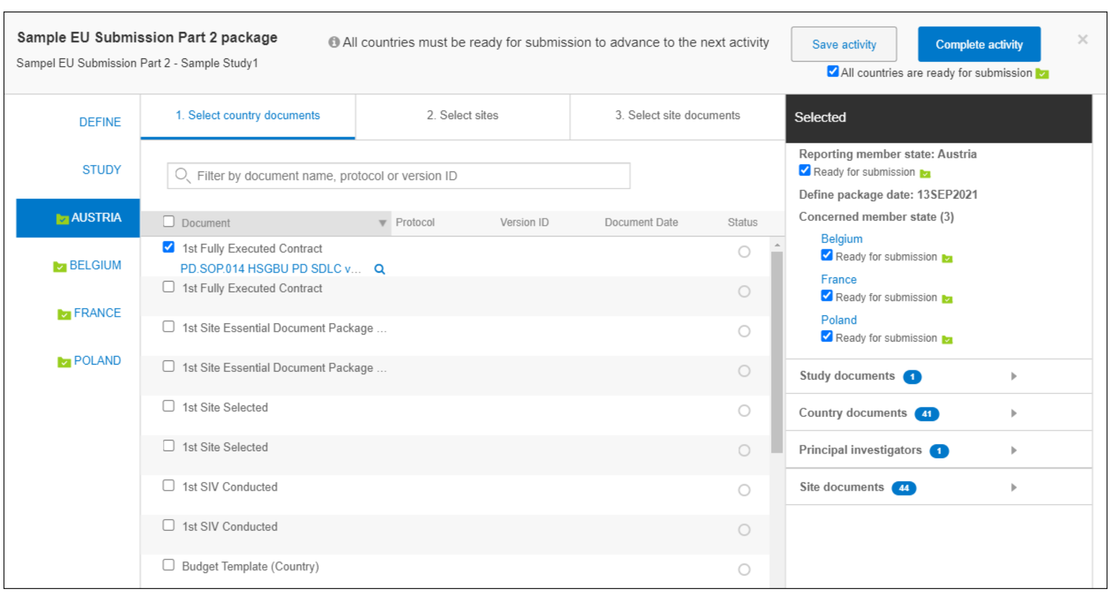
When all countries are marked as ready for submission, the modal's "Save and close" button will be replaced by a "Complete activity" button. When the user confirms the completion, the completion date for the activity is the value entered in the Define package date field.



Defining an EU submission Part 2

The Part 2 definition process includes a flow and user interface functionality similar to the Part 1 definition, but after selecting Study level documents, Part 2 allows users to select country documents, sites, and site documents. Users will access these selections from the modal's center panel, divided into three tabs.

After selection, the modal functions in the same manner as the Part 1 definition, including the ability complete the activity after all countries have been marked as ready for submission.

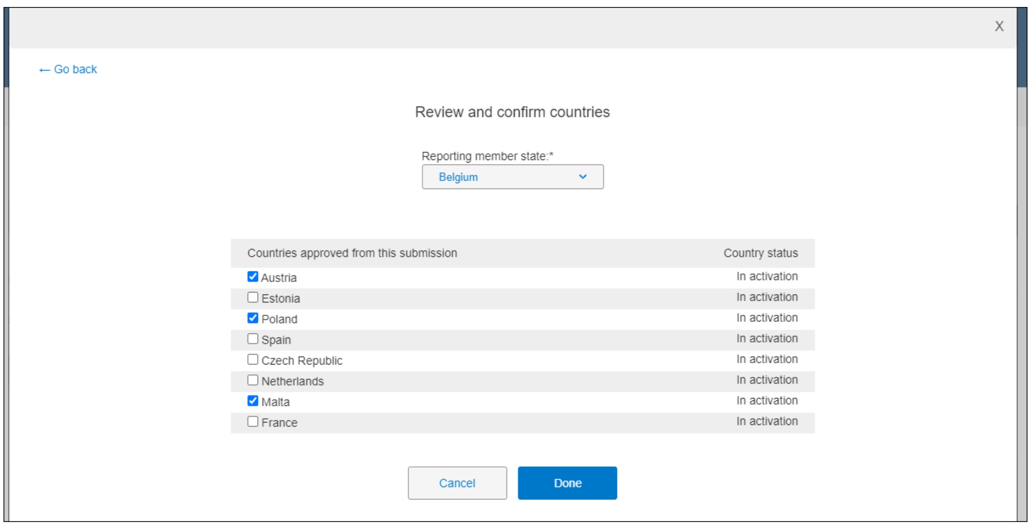


Submission approval confirmation steps

Study level submission approval activities require you to review and confirm approved countries and sites to complete the activity. Approval requirements for the available package types are as follows:

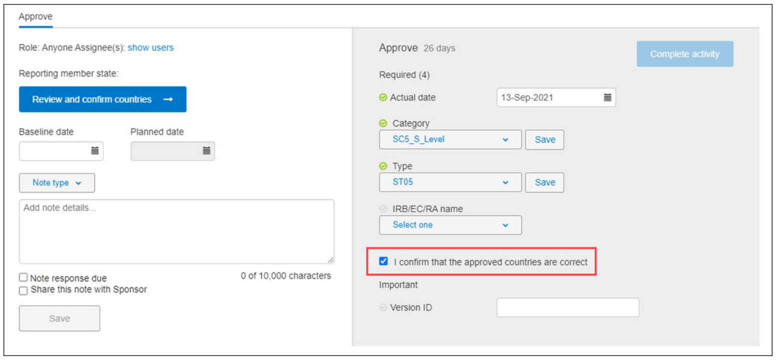
Validation package and Part 1 package – The package's Approval Complete activity includes a **Review and confirm countries** button. When clicked, a modal displays a required **Reporting member state** field, followed by a list of all countries in the package. You'll select a value for Reporting member state, review and click the check boxes as appropriate for approved countries, and click **Done** to save and close the modal.

To complete the approval activity, upon return to the submission package modal, you'll check the **I approve confirmed countries are correct** check box in the activity completion panel. You must check the box, and complete any other required fields, to enable the Complete activity button.



Part 2 package – This package's Approval Complete activity is similar to the Validation package and Part 1 package design; however, the button under Activity Complete is labeled **Review and confirm countries and sites**. When clicked, a similar review modal displays, but in this use case, you do not have the ability to update the Reporting member state. Instead, for each reporting member state, you'll review the sites approved and check/uncheck the sites as applicable. Approvers also have the ability to remove and add a selected member state along with the state's associated sites.

When you complete the review, the package modal displays an **I confirm that approved countries and sites are correct** check box in the activity completion panel. Again, you must check the box, and complete any other required fields, to enable the Complete activity button. When the check box is checked but other required fields are incomplete, the Complete activity button remains inactive.



Filter documents in the submission modal Documents in package tab

When you need to view the study, country, sites, or site documents included in a study level submission package, you can filter the package modal's **Documents in package** tab to view your preferred list organized by country. The country filter defaults to the first country included in the package, by alphabetical sort. The filter list also indicates the package's Reporting member state.

When filtered, the tab lists read-only results as follows:

- Related study documents in this package
- Related study country documents in this package
- Related study site documents in this package
- Related study sites in this package

If preferred, you can also export the package's documents using the **Export to zip** button.

Document export follows a defined folder structure that separates study, country, and site documents into separate folders. The folder structure is:

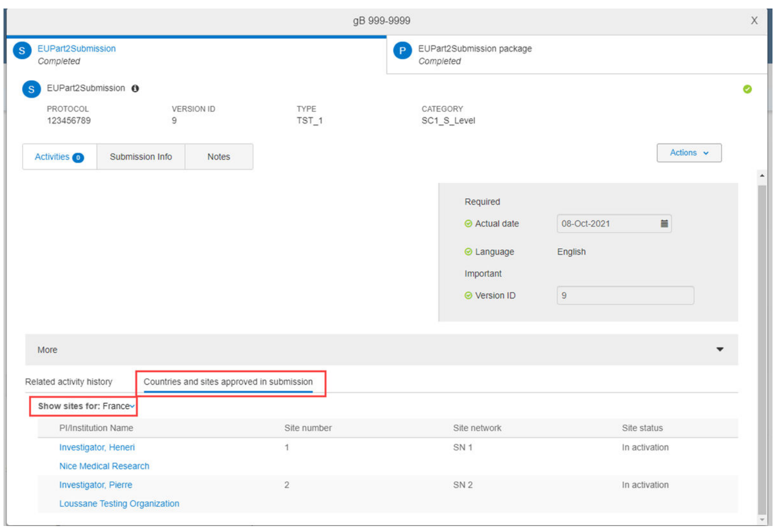
- **Part 1 package** – export file is a zip file that includes the manifest file. Within the zip file are:
  - A study level folder that includes the study level files
  - Separate folders for each country in the package that include the country documents for each country
- **Part 2 package** – export file is a zip file that includes the manifest file. Within the zip file are:
  - A study level folder that includes the study level files

- Separate folders for each country in the package that include the country documents for each country. Within each country folder are:
  - Separate PI name sub-folders for each site that include the documents from the sites

See the countries and sites approved in the package

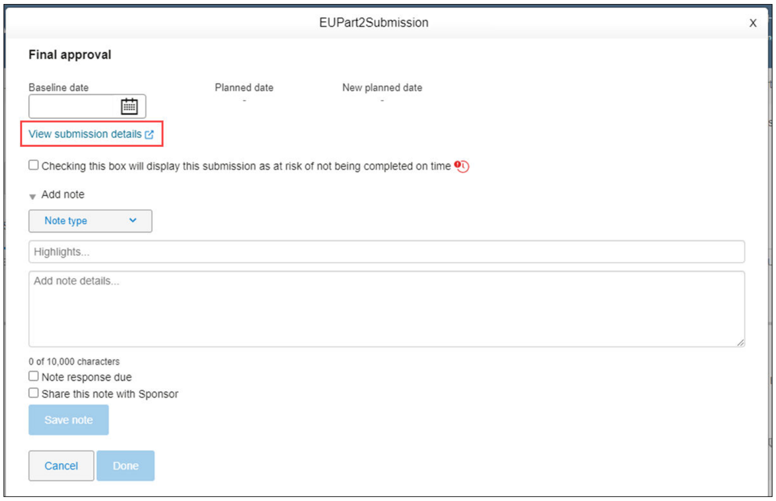
Completed study level submissions associated with a Validation package, Part 1 submission package, or Part 2 submission package include a tab in the submission modal's More section that displays country and site information as follows:

- **Validation and Part 1 submissions** – include a "Countries approved in submission" tab that displays the approved countries as links that open the country details page in a new browser tab. The list of approved countries also indicates which country is the Reporting member state.
- **Part 2** – submissions include a "Countries and sites approved in submission" tab that displays a list of approved sites filtered by approved country. Approved sites listed in the PI/Investigator column are links that open the site details page in a new browser tab. The "Show sites for" country filter indicates which country is the Reporting member state.



View submission details

At all levels, submission milestone modals include a View submission details link. The link displays just below the Baseline date field, and when clicked, the related submission modal opens in a new tab where you can see the countries, sites, and documents included in the submission.



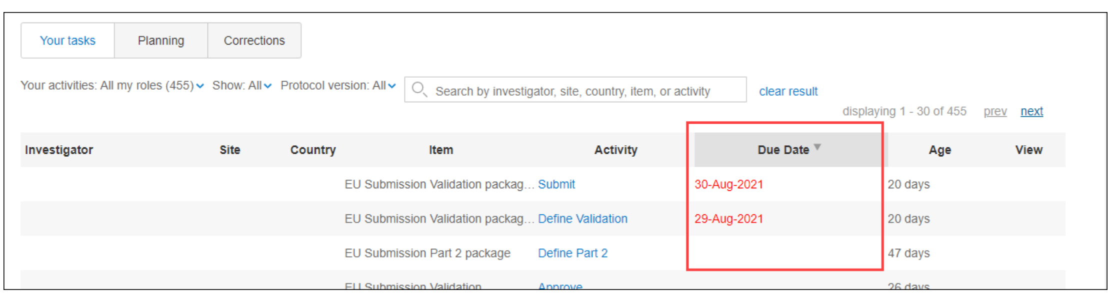
Activity level due dates and activity sorting

Regulations related to submission to the EU portal enforce specific timelines, and Oracle Site Activate supports activity level due dates. Note that this functionality is not limited to EU submission activities; activity due dates can be configured for any activity. For any configured activity, the Due date field displays in the item modal's Activity completion panel, in the "Important" section.

Sort logic considers activity level due dates as well. The "Most past due" sort logic uses the activity due date as the primary sort, followed by the previously existing sort logic. For example, Study work – Your tasks uses activity due date as the primary sort order (activities with due dates that are most past due descending down to activities with farthest away due dates), followed by secondary sort on milestones that are most past due, and tertiary alphabetical sorting). These filters use activity level due date in sorting logic:

- Study work - Your tasks tab
- Country level - Your activities tab
- Site level - Your activities tab
- Account overview - Activities tab

Additionally, on the study Home page's Your tasks tab, you'll find a sortable Due Date column that displays due dates for items configured for activity due date.



- [Define an EU submission validation package](#)
  To create and manage study level EU submissions in Oracle Site Activate, begin by defining the validation package.

- Define an EU submission Part 1
  Define Part 1 after defining the EU submission validation package. In Part 1, you'll select study and country level documents to include in the package and mark member states as ready for submission, as applicable.
- Define an EU submission Part 2
  Define Part 2 after defining Part 1. When defining Part 2, you'll choose study and country level documents, sites (Principal investigators), and site level documents.
- Filter documents in an EU submission package
  Submission packages can include many documents. To make it easier to evaluate the list, you can filter the Documents in package tab to view documents by country.
- Review and confirm countries for EU submission validation or Part 1 package
  Study level submission approval activities for both the EU submission validation package and the Part 1 package require users to review and confirm approved countries.
- Review and confirm countries and sites for EU submission Part 2 package
  EU submission Part 2 approval activities require review and confirmation of the member state countries and sites included in the submission.

Define an EU submission validation package

To create and manage study level EU submissions in Oracle Site Activate, begin by defining the validation package.

1. Open an EU submission validation package modal and click **Plan the Submission Package** to open the planning modal.
2. Select the **Reporting member state** from the drop-down list.
3. Select a date for **Define package date**.
4. Enter the name of the **Super User**.
5. Select **yes** or **no** for **Submitting part 1 and part 2 together**.
6. At **Concerned member state**, choose the member state(s) to include in the validation package. You can filter the list to search for a specific state, select all, or multi-select several states.
7. Click the **Save activity** button to save your progress without completing the activity. Click the **Continue** button to save all selections and display the study level document options.
8. If you clicked **Continue**, the package planning modal's **Study** section displays. Choose the study documents you want to include in the validation package. Confirm that the **Selected** panel to the right lists the documents you chose.
9. Click **Done** and click **Confirm**.

Define an EU submission Part 1

Define Part 1 after defining the EU submission validation package. In Part 1, you'll select study and country level documents to include in the package and mark member states as ready for submission, as applicable.

1. Open EU submission Part 1 modal and click **Plan this Submission Package** to open the planning modal.

2. The **Reporting member state** and **Concerned member state** information automatically populate the package's **Define** section from the associated validation package. You may edit the values as necessary and the **Selected** panel will update to reflect your new selections.
3. Select a value for **Define package date**.
4. Click the **Save activity** button to save your progress without completing the activity. Click the **Continue** button to save all selections and display the study level document options.
5. If you clicked **Continue**, the **Study** section displays. Use the check boxes to select the study level document(s) you want to include in the EU submission Part 1.
6. Click the **Save activity** button to save your progress without completing the activity. Click the **Continue** button to save all selections and display the country level document options.
7. If you clicked **Continue**, on the left side of the screen, click the country you want to define. Use the check boxes to select the country document(s) you want to include in the EU submission Part 1. The **Selected** panel on the right side of the screen updates to reflect your selections.
8. If the country you defined is ready for submission, in the **Selected** panel, click the **Ready for submission** check box for that country.
9. Repeat steps 7 and 8 for each country, as applicable. If appropriate, click the **All countries are ready for submission** check box below the **Save and close** button.
10. When all countries are marked as ready for submission, the modal's **Save and close** button will be replaced by a **Complete activity** button.
11. Click **Complete activity** and click **Confirm**.

Define an EU submission Part 2

Define Part 2 after defining Part 1. When defining Part 2, you'll choose study and country level documents, sites (Principal investigators), and site level documents.

1. Open EU submission Part 1 modal and click **Plan the Submission Package** to open the planning modal.
2. The **Reporting member state** and **Concerned member state**s automatically populate the package's **Define** section from the associated validation package. You may edit the values as necessary and the **Selected** panel updates reflect your new selections.
3. Select a value for **Define package date**.
4. Click the **Save activity** button to save your progress without completing the activity. Click the **Continue** button to save all selections and display the study level document options.
5. If you clicked **Continue**, the **Study** section displays. Use the check boxes to select the study level document(s) you want to include in the EU submission Part 2.
6. Click the **Save activity** button to save your progress without completing the activity. Click the **Continue** button to save all selections and display the country level document options.
7. If you clicked **Continue**, on the left side of the screen, click the country you want to define. In the center panel, click the **Select country documents** tab, if necessary. Use the check boxes to select the country document(s) you want to include in the EU submission Part 2. The **Selected** panel on the right side of the screen updates to reflect your selections.

8. In the center panel, click the **Select sites** tab and use the check boxes to select the principal investigators (sites) you want to include in the EU submission Part 2.
9. In the center panel, click the **Select site documents** tab and use the check boxes to select the site level documents you want to include in the EU submission Part 2.
10. If the country you defined is ready for submission, in the **Selected** panel, click the **Ready for submission** check box for that Reporting or Concerned member state country.
11. Repeat steps 7 and 8 for each country, as applicable. If appropriate, click the **All countries are ready for submission** check box below the **Save and close** button.
12. When all countries are marked as ready for submission, the modal's **Save and close** button will be replaced by a **Complete activity** button.
13. Click **Complete activity** and click **Confirm**.

Filter documents in an EU submission package

Submission packages can include many documents. To make it easier to evaluate the list, you can filter the Documents in package tab to view documents by country.

1. Expand the **More** section in the submission package modal.
2. Click the **Documents in package** tab.
3. Use the **Show documents for:** drop-down list to view documents for a specific country. The drop down list indicates the reporting member state, while all other countries on the list are concerned member states.

Review and confirm countries for EU submission validation or Part 1 package

Study level submission approval activities for both the EU submission validation package and the Part 1 package require users to review and confirm approved countries.

1. Open the EU submission validation or Part 1 modal and click **Review and confirm countries**.
2. The **Review and confirm countries** modal opens and displays the **Reporting member state** in a drop down list and countries approved from the submission in a check box list.
3. The **Approve reporting member state** check box will be checked (enabled) by default. If this is incorrect, uncheck the check box.
4. Check or uncheck the check boxes for each country listed under **Countries approved from this submission**. A country with a checked box is approved, while a site with an unchecked box is not.
5. Click **Done**.

Review and confirm countries and sites for EU submission Part 2 package

EU submission Part 2 approval activities require review and confirmation of the member state countries and sites included in the submission.

1. Open the EU submission validation or Part 2 modal and click **Review and confirm countries and sites**.
2. The **Review and confirm countries and sites** modal opens and displays the **Reporting member state** as a read-only field.
3. Choose a country to confirm from the **Select a member state** drop down list.
4. Optional: Optional: To remove the selected member state, check **Remove selected member state** check box.
5. If the member state should remain in the submission, continue by checking or unchecking the check boxes for each site listed under **Sites approved from this submission**. A site with a checked box is approved while a site with an unchecked box is not.
6. Repeat the steps above for each approved member state and associated sites, as appropriate.
7. Click **Done**.

13 About milestones

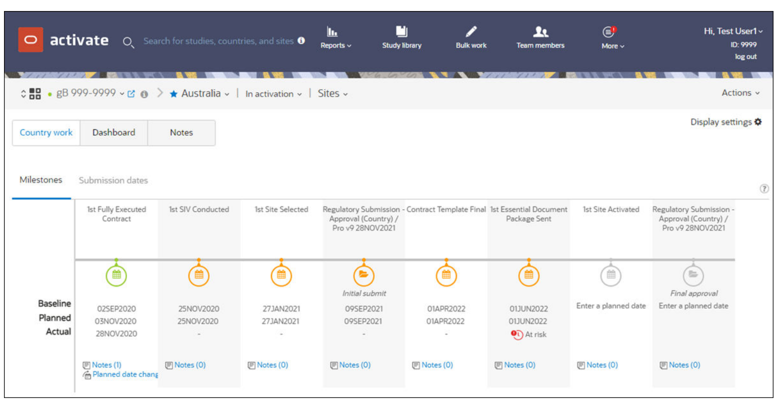
Milestones and milestone dates

A milestone is an important business accomplishment used to track progress towards a larger goal. In Oracle Site Activate, your organization's milestones are tied to the completion of an activity specified during the Oracle Site Activate configuration process.

With milestones, you can enter a **Baseline** (projected completion) date. If that projection changes, adjust the **Planned** date — this helps you to keep a record of how much your projection has changed since you entered the original baseline date. The **Actual** date is the date that the activity tied to the milestone is actually completed; this date is automatically entered when the activity is marked complete by you or another team member.

Milestone prediction functionality can also help you improve planning accuracy. When you plan or replan a site level milestone that is mapped to a global milestone, you will have the option of using a suggested milestone date. Milestone prediction functionality passes study-site factors through a data model derived from historic cross-customer data to determine the most realistic suggested date for the milestone. Suggested dates are available (i.e., for the specific milestone type) in all Oracle Site Activate areas where you can plan or replan site milestones and any user with the permission to plan milestones will see the suggestion.

If you re-plan a milestone date and that change impacts other milestones, Oracle Site Activate will show you which items will be at risk.



Smart milestones

Milestones configured as "smart" milestones will automatically create another instance of the milestone when you create a new version of the item that has the final activity the Smart Milestone is dependent upon. The date populated in the created milestone's Actual Date is taken from the item that has the activity to which the milestone is tied.

Oracle Site Activate differentiates the automatically created milestones as follows:

- Display of an item version number everywhere the milestone displays.
  - Example: If the item is PI CV (1), the milestone displays (1) at the end of the milestone name.

- If tied to a contract milestone, display of contract Type appended to the end of the milestone name, when a Type value has been saved for the item.
  - Example: If contract Type is “Institution” the milestone displays Institution at the end of the milestone name. If multiple versions of an institution contract exist, the milestone also displays version number (2) after Type.
- Milestones dependent upon a protocol version item display the protocol version.
- Contract amendment milestone names follow same naming convention defined above, with the addition of the word "Amendment"

Automatically planned successor milestones

Oracle Site Activate allows for automated planning for milestones configured with a predecessor milestone. For customers with established base timelines, this optional configuration can eliminate manual user steps in milestone planning and ensure the correct entry of baseline milestone dates.

For your organization's account, your Oracle representative can configure a milestone with a single "predecessor" milestone. The predecessor must be within the account and on the same level (e.g., Country level milestone 1 as the predecessor to Country level milestone 2 would be scoped to that study country and would not cross countries). In addition, the predecessor may optionally specify a due date in number of days.

If the predecessor does not have a due date in number of days, the created dependency will be used in the existing "Determine Impact" functionality. This means the milestone modal's existing Determine impact functionality continues to work with legacy milestone dependencies when milestones dependencies are set in this new way.

For created milestones, when the predecessor milestone is initially planned (i.e., baseline date entered), the successor milestone is planned with the date of the predecessor's milestone baseline date + the length of days entered in the configuration. Note that there will be no change to the successor milestone date if the successor is already completed or planned or if the predecessor is updated.

This functionality also allows for automated successor planning for Smart Milestones. Oracle Site Activate will use the same baseline date + length of days model described above for the planned successor date. However, for created Smart Milestones, only the first version of the successor milestone will be automatically planned. Only Version zero predecessor will trigger automatic planning and only Version zero successor milestone will be able to get a planned date.

Predecessor milestone update indicator

There is no automatic update to the successor milestone in response to an updated predecessor planned date. In this case, the successor milestone modal and milestone timeline display an information (ℹ) icon and helper text to inform you of the update so you'll know that the successor milestone may also require an update. The helper text is "Your predecessor milestone "<milestone name>" has a new planned date. Please review." The icon and message no longer display when you update the successor milestone.

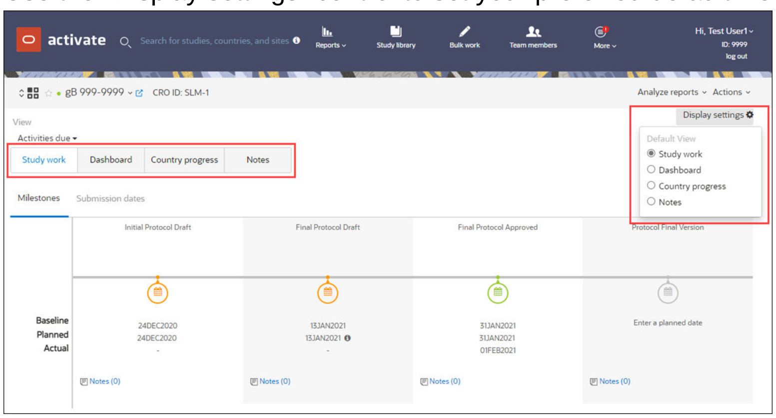
The milestone timeline also uses the information icon to help you identify and understand automatically planned successor milestones. The icon's tooltip text is: "This milestone was automatically planned based on the predecessor milestone "<milestone name>." The information icon displays only if Oracle Site Activate automatically planned the successor milestone; no icon displays if a you manually planned the milestone. In addition, the information icon will no longer display after a you manually updates the baseline or planned date.

Study level milestones

You can access milestone information from the Oracle Site Activate home (study) page. Primary tabs included on the home page are:

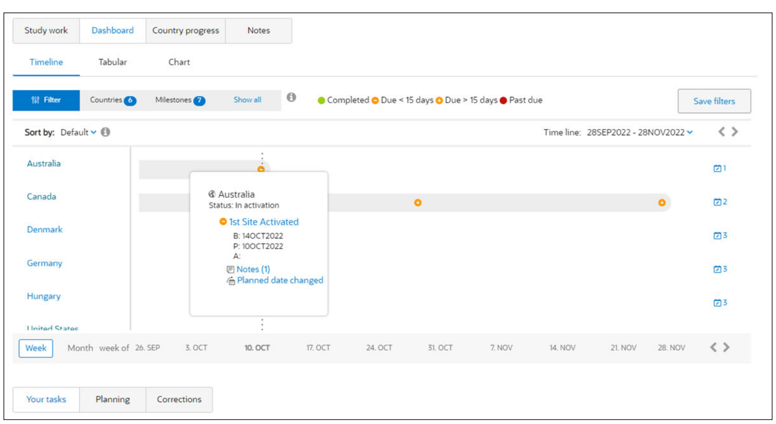
- **Study work** – This tab provides a study level milestone timeline.
- **Dashboard** – This tab displays the country milestone dashboard Timeline, and if at least one site milestone has been configured as a Summary Milestone, a Tabular option displays as well.
- **Country progress** – This tab includes a bar chart of document progress by country.
- **Notes** – This tab displays the study level notes view.

Use the "Display settings" control to set your preferred default view.



Country milestone dashboard

The home page country milestone dashboard view allows team members to better understand the status of a study at a glance and quickly pinpoint areas where they are falling behind. The dashboard displays milestones and submissions made visible on the country timeline.



The country milestone dashboard is highly interactive and allows for on-the-fly changes to the view. You can quickly add, remove, and optionally save filters for countries and milestones; enable/disable display of milestone statuses; select dates or a date range for the timeline; and toggle from month to week view.

Most data points on the dashboard are interactive:

- Country names and all circles along a country's timeline bar link to the country level page.
- Status circles in the icon key above the dashboard are clickable to enable/disable. Disabled status(es) do not display in the dashboard view.
- For unplanned milestones, a calendar icon at the far right of the country timeline bar indicates the number that are unplanned per country. You can click this icon to view the unplanned milestone(s) and click a pencil icon to display the planning pop-in.
- When you hover over a status circle in the dashboard, an overview tool tip displays:
  - country and country status
  - number of milestones (e.g., 1 of 5) if multiple milestones are set for the same date
  - milestone name (opens the milestone modal) and dates
  - If applicable, the name of the user who added a note about a replanned milestone and note(s) icon. Click the note icon to view the replan note text or add a note.

Summary milestone dashboard

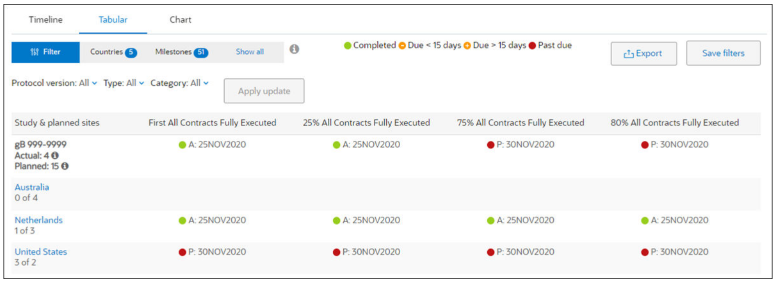
You can also view the summary milestone dashboard while on the home page Dashboard tab. When the study has at least one site milestone or submission milestone configured as a summary milestone, this dashboard will help you understand progress toward completion of that site level milestone across multiple sites. The "Tabular" option, under the home page Dashboard tab, summarizes milestones at the study and country levels and allows you to view planned or actual dates to hit key summary milestones including First complete, 25% complete, 50% complete 75% complete, and Last complete. For summary submission milestones summaries are: First, 25%, 50%, 75%, 80%, 90%, and Last.

Tabular dashboard view

When viewing the dashboard, you can filter the data by selecting one or more countries and one or more milestones for display. The dashboard displays only planned milestones that match both the selected country and milestone filter values.

Like the milestone timeline view, you can show and hide Summary Milestones in the tabular view, as preferred, by selecting/deselecting milestone status icons on the legend above the table.

The first row in the table summarizes milestones at the study level. At the far left, bolded text indicates the study name, actual number of sites created in the study, and planned number of sites for the countries in the study. Below this summary row, the dashboard displays a row for each country selected in the dashboard filter with the actual number and planned number of sites (e.g., "2 of 8").



When at least one site level submission milestone has been created in the study, the filter panel includes the submission milestone(s), and the timeline displays all appropriate submission milestones, including central submission milestones generated/populated when a user adds a site as part of approval in the country level central submission.

The summary milestones feature bases submission summaries on configuration item names, which means the IRB/EC submission rules from the configuration group together based on the name. This expected behavior allows all submissions across countries to roll up and display together.

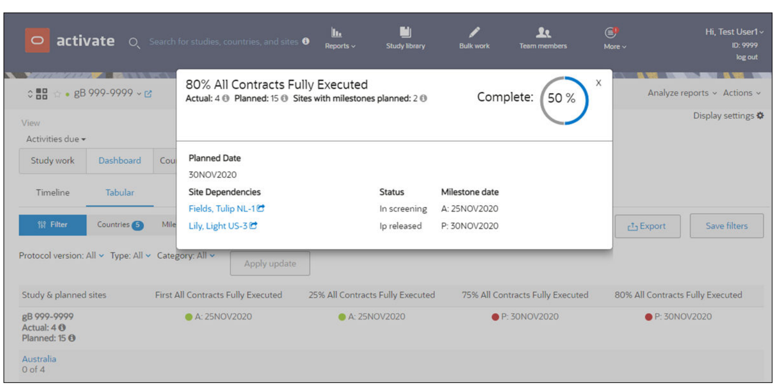
To act on a displayed submission, users can access the submission modals from the Summary detail modal. For site level submissions, users click the site name to display the site submission modal. For Central submissions, users click the "Country dependencies" link to open the country level submission modal in a new tab.

Summary milestone status detail

Milestone details display when you click on a milestone date. This action opens a modal that includes:

- Summary milestone name (and country, if applicable)
- Actual number of sites
- Planned number of sites
- Sites with milestones planned
- Milestone percentage complete (calculated as number of completed sites included in the summary milestone and divide by the total number of sites included in the summary milestone)

Below, the details modal shows the planned or actual date for the milestone, as well as the list of included sites. For each listed site, the modal also displays the milestone Planned or Actual date. You can quickly update the date by displaying the milestone planning modal. When updated, the planning modal closes, and the details modal reflects the update.



Export to CSV

You may optionally export Summary Milestone dashboard's tabular view to a CSV format file using the "Export" option at the top right of the table. When exported, the CSV file includes all data present in the tabular view at that time.

Summary milestone dashboard bar chart view

You can also evaluate progress toward completion of configured Summary milestones using the Summary milestone bar chart visualization.

You have multiple options to filter the bar chart to a preferred view, and you may optionally save a filtered view. When saved, the filtered view displays by default the next time you view the bar chart. Available filters are:

- **Country** – Select one or more from the Filter modal
- **Milestone** – Select one from the Milestone drop-down list. The list includes only configured Summary milestones.
- **Protocol version** – Quick filter
- **Type** – Quick filter
- **Category** – Quick filter
- **Timeline** – Specify month range or select a quick filter for Past or next 3, 6, or 9 months

When you filter the bar chart and later change any of the above filter settings, the "Apply update" button is enabled. When clicked, milestone data recalculates, and the page refreshes to show the updated chart.

Each month in the bar chart view includes two bars, P=Planned and A=Actual, with each bar segmented to filtered countries. When you hover over a bar segment, tooltip text displays the number of planned or completed milestones for the associated country and month.

Configuration options

Any site level milestone within an account can be configured to display one or more of the values listed below.

- First (first site completed milestone within a country or study)
- 25%
- 50%
- 75%

- 80%
- 90%
- Last (last site completed milestone within a country or study)

Additionally, your organization may choose one or more of the following site statuses to be included in Summary Milestone calculations:

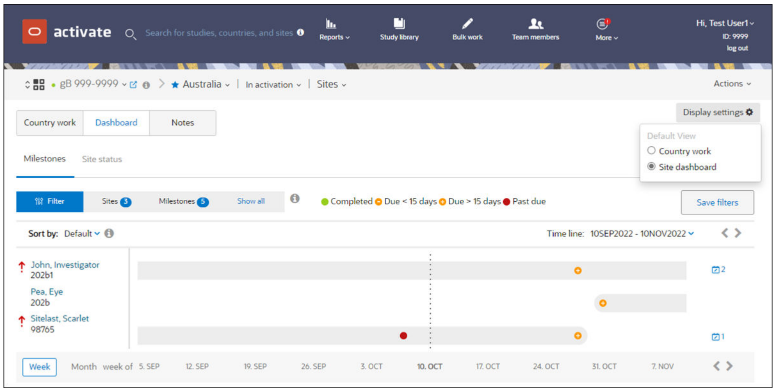
- In screening country on hold
- In feasibility country on hold
- Country on hold
- Closed
- Dropped
- On hold
- IP released
- In Activation
- In screening
- In feasibility
- Activated

Oracle Site Activate calculates the planned and actual Summary Milestones when you visit the page and when you update the site status filter.

> **Note:**
>
> Discontinued milestones are not included in calculations in the Tabular and Chart views. When a Summary milestone has been discontinued, Oracle Site Activate automatically recalculates the milestones for that study (excluding the discontinued milestone), and if a Summary milestone is later reinstated, Oracle Site Activate will again automatically recalculate to include the reinstated milestone.

Site milestone dashboard

The site milestone dashboard provides the same type of high-level overview and interactive navigation that available in the country milestone dashboard, described above. The site dashboard, which is accessible from the country details page, displays milestones and submissions made visible on the country timeline. Using the "Country work" and "Dashboard" tabs, you can toggle to view either the milestone dashboard or the document dashboard on the country page; set your preferred default view using the Display settings control at the upper right.



Just like the country milestone dashboard, the site milestone dashboard is highly interactive and allows for on-the-fly changes to the view. You can quickly add, remove, and optionally save filters for sites and milestones; enable/disable display of milestone statuses; select dates or a date range for the timeline; and toggle from month to week view.

Most data points on the dashboard are interactive:

- Site names and all circles along a site's timeline bar link to the site level page.
- Status circles in the icon key above the dashboard are clickable to enable/disable. Disabled status(es) do not display in the dashboard view.
- For unplanned milestones, a calendar icon at the far right of the site timeline bar indicates the number that are unplanned per site. Click the calendar to view the unplanned milestone(s) and click a pencil icon to display the planning pop-in.
- When you hover over a status circle in the dashboard, an overview tool tip displays:
  - site and site status
  - number of milestones (e.g., 1 of 5) if multiple milestones are set for the same date
  - milestone names and dates
  - note icon with name of user who added a note about a replanned milestone. Click the note icon to view the note text.

Milestone Dashboard Sorting

To prioritize work, use the “Sort by” filter on the Country Milestone Dashboard or Site Milestone Dashboard. Like other available filters on the dashboards, the Sort by setting can be saved permanently.

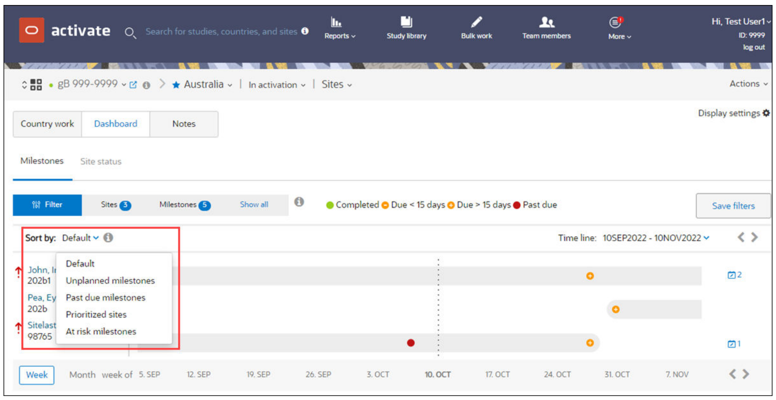
Country Milestone Dashboard Sort Options

- Default (alphanumeric order)
- Unplanned milestones (sorts countries with the most unplanned milestones to the top in alphanumeric order)
- Number of sites (sorts countries with the most sites to the top in alphanumeric order)
- Past due milestones (sorts countries with the most past due milestones to the top in alphanumeric order)

- Prioritized sites (sorts countries with the most prioritized sites to the top ordered greatest to fewest)

Site Milestone Dashboard Sort Options

- Default (alphanumeric order)
- Unplanned milestones (sorts sites with the most unplanned milestones to the top in alphanumeric order)
- Past due milestones (sorts sites with the most past due milestones to the top in alphanumeric order)
- Prioritized sites (sorts the prioritized sites to the top in alphanumeric order)
- At risk milestones (sorts milestones flagged as at risk to the top in alphanumeric order)

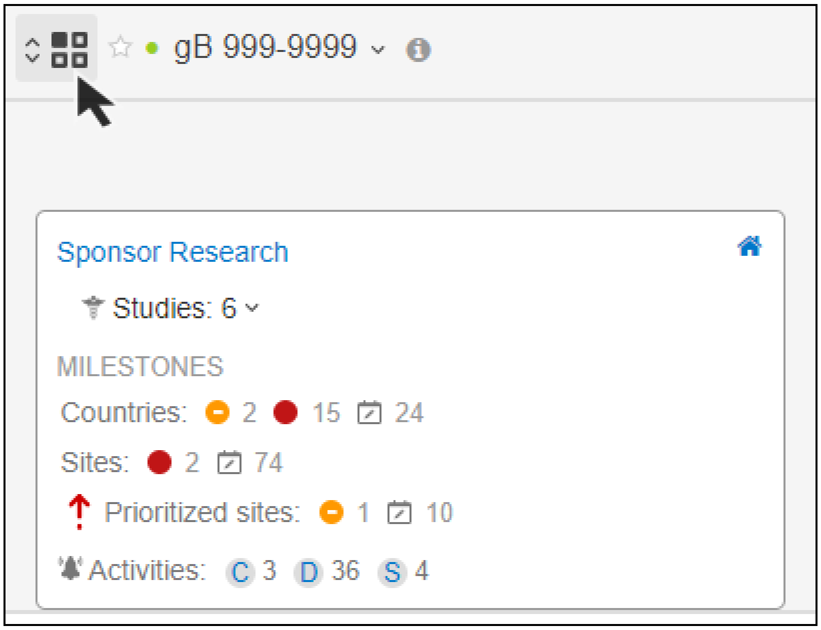


Account-level milestone overview

When enabled for your organization's account, you'll see a “four-square” in the persistent header just to the left of the study name. When clicked, a panel displays below the header that includes an account-level milestone overview card.

By design, you must be assigned to a study in order to see the milestones; the “Access to all studies” individual user account setting does not control access to the milestone overview feature.

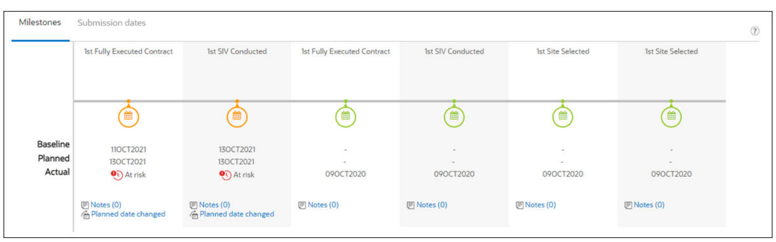
The account card is an at-a-glance view of studies to which you have access; the card raises visibility of your actionable items. The card provides a searchable study list (including total study count) as well as country and site milestone counts. Studies that have past due, due soon, or unplanned milestones will have numerated status icons within the searchable study list. When you click a status icon, the Country Milestone Dashboard view or Document dashboard view displays, depending upon your preferred Display settings (described in the Country milestone dashboard section above).



Milestone timeline

The milestone timeline automatically displays when a study country or site is added to Oracle Site Activate. Timelines for your specific country or site do not appear until the protocol version workflow has been run at the country or site level. You can scroll to the right to see any milestones not visible.

Once a country and its sites are added in Oracle Site Activate, from the Action menu you can select Track documents and submissions and then run a protocol workflow at the country level. This creates the protocol-related tracking items at the country level. You should also run the appropriate protocol-related workflow for sites, which can be done in bulk using the workflow wizard.



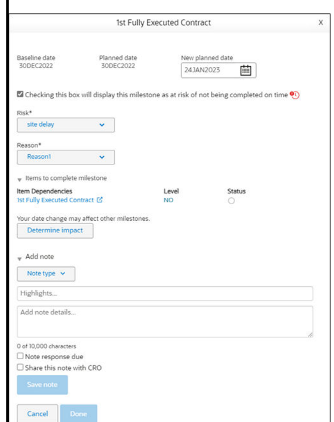
Notes: If you are working on a site and are missing milestones, first check with your study lead to see if the protocol workflow has been run for your country.

- If you are granted permissions, you can show and hide milestones on the timeline.
- Your study may be configured with an IP release review milestone. After reaching this milestone, all activities are identified as post IP release activities.

If you are granted permissions, you can remove a milestone from the timeline. Click the question mark at the upper right of the timeline to see what permissions you have related to managing milestones.

The timeline shows the following for each milestone:

baseline	This is the date that you or another study team member projected that the milestone

	will be met. Once you enter this date, you can change it only if you have the permissions to correct information in Oracle Site Activate; without that permission, you can only replan the date. If the milestone is associated with a submission, you can also enter the baseline and planned dates from the submissions widget.
planned	This is the date that you or another team member re-planned the milestone. You can re-plan dates as often as desired; each time you are asked the reason for the change. If you re-plan a date and it causes a downstream milestone to be late, Oracle Site Activate warns you so that you can warn your team members who are impacted, or keep the projected date. At **Milestone details**, you can also see the status of activities on which the milestone is dependent. 
actual	When a document or submissions activity associated with a milestone is complete, Oracle Site Activate automatically enters the date on the timeline. Your team specifies which activity triggers completion of the milestone during configuration.

If configured for your organization's account, you can track activities and milestones before and after site IP release. With this feature enabled, milestones automatically show or hide on the milestone timeline, based on the following optional settings:

- Pre-IP Release milestone: Once a site reaches IP release and the status changes to IP release, completed milestones (green status) automatically hide from the timeline. By design, the milestones display on the Planning tab, where they can be manually unhidden using the eye ( ) toggle. Additionally, the milestones are accessible on the bulk page. If you have permission to access to the bulk page, you can use bulk actions to manually unhide the milestones, if preferred.

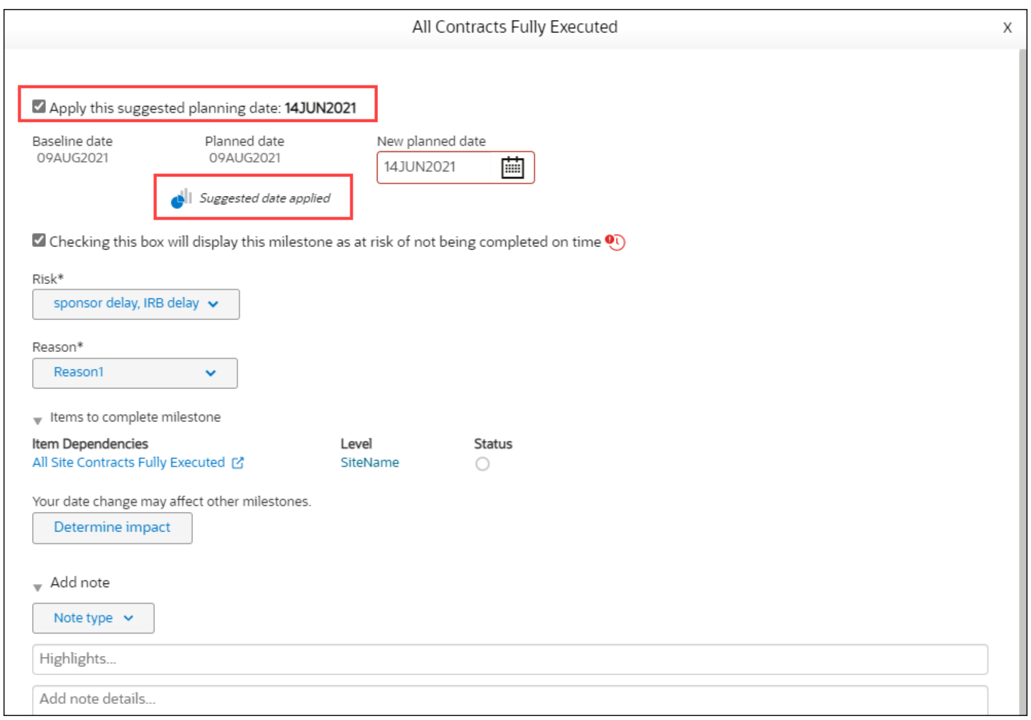
- Post-IP release milestone: Once a site reaches IP release and the status changes to IP release, these milestones automatically display on the milestone timeline. By design, prior to IP release, these milestones are available on the Planning tab and the bulk tab.

Suggested milestone dates

Oracle Site Activate milestone prediction functionality present suggested milestone dates when you're planning or replanning a site level milestone that is mapped to a global milestone. You can improve planning accuracy by using a suggested milestone date. This option is available in the following areas where you have the ability to plan or replan site milestones:

- Site milestone timeline
- Site milestone dashboard
- Bulk milestone planning

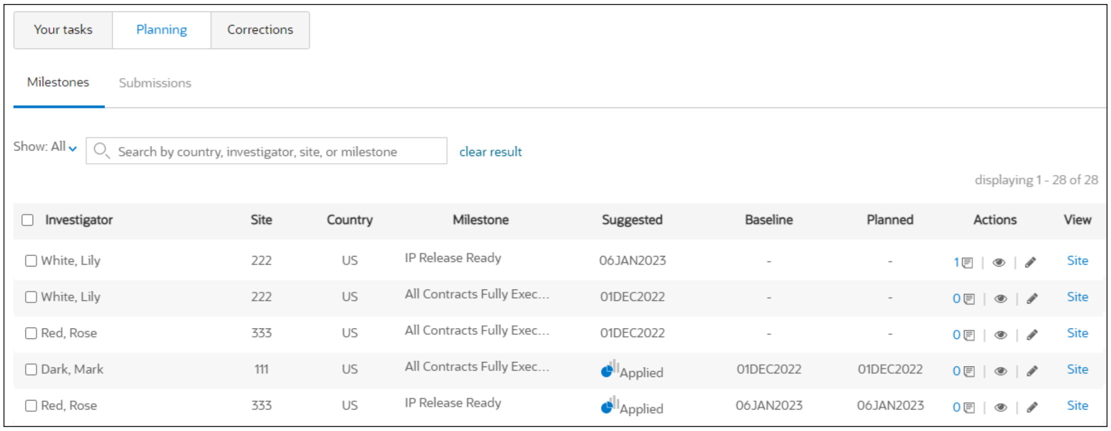
When a you plan or replan an individual site IP release ready milestone and a suggested date is available, a check box option displays at the top of the planning modal. The check box option identifies the suggested planning date in bold text. If you click the check box, a suggested date applied icon (*Suggested date applied*) displays in the modal. If you're replanning the milestone, be sure to enter a reason.



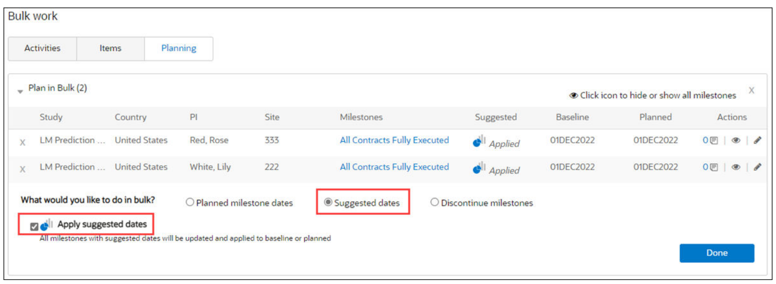
Activate also informs you when a new prediction date is available after a milestone or submission prediction retriggers or recalculates. When you complete an activity that triggers or retriggers a prediction, a "Prediction is available due to new data" text prompt displays below the new suggested date in the milestone modal. The prompt text remains until you or another user applies the new suggested date.

On the study Planning tab, you'll also see a “Suggested” date column. Here, you can quickly identify items available for individual or bulk planning with suggested dates:

- When a suggested date is available but has not yet been applied, the date displays in the Suggested column
- When a milestone has already had the suggested date applied, Applied (Applied) displays in the column



You can also use suggested dates when bulk planning. Toggle to “Suggested dates” and click the check box for “Apply suggested dates.” If you selects a site milestone to include in bulk planning with suggested dates, but that milestone does not have a suggested date (i.e., no date available, not a supported milestone for prediction, etc.), Oracle Site Activate will simply take no action on that milestone and it will remain as it was before selection.



Nulled actual dates remove calculated Suggested dates

When a milestone's actual date changes via the Corrections flow, Oracle Site Activate recalculates any suggested dates on other milestones that had been predicted based on the actual date. Oracle Site Activate also reflects changes for nulled actual dates.

When a corrections user blanks (nulls) an actual date on a prediction start milestone (Initial Protocol Received/Sent or Essential Docs Sent to Site), Oracle Site Activate removes the opportunity to view and apply suggested dates based on that milestone. However, any Suggested date based on that milestone that has already been applied by a user will remain.

To help you understand the effect of nulling a date, the Suggested date check box tool tip text is: "When blanking out the actual date, only related milestones (and not activities) will be updated. Any milestone suggested dates predicted from this milestone will disappear."

Predicted date triggers

Milestone suggested dates (predictions) for milestones do not require the completion of an associated milestone activity. For example, you can complete the milestone via the corrections tab, or a milestone can be completed via API without a completed activity and predictions will trigger as expected. Predictions will use the Actual Date from the milestone as the start point.

For studies with a completed Initial Protocol Received/Sent milestone, predictions trigger and be available for every newly added site in the study. Additionally, predictions for the site retrigger if any of the following study attributes change throughout duration of the study:

- Number of countries
- Sites in study
- Phase
- Therapeutic area
- Country code
- Region code
- Sites in country
- PI counts
- IRB EC type
- Start month

Completing either a study level milestone mapped to Initial Protocol Sent/Received or a site level milestone mapped to Essential Docs Sent to Site will trigger the prediction for Initial Submission for the site if the submission was already generated.

The Initial Submission predicted milestone allows more than one starting point (i.e., Initial Protocol Received/Sent and Essential Docs Sent to Site). If two milestones are enabled for predictions, the following prediction trigger behaviors apply:

- **Essential Docs Sent to Site** milestone completion triggers Initial Submission prediction for the site. When Initial Protocol Received/Sent completes after Essential Docs Sent to Site completes, this triggers Initial Submission prediction for all sites in the study -- except for those sites that already have Initial Submission predicted from Essential Docs Sent to Site completion. This exception is by design and ensures that Activate does not overwrite existing Essential Docs Sent to Site predictions.
- **Initial Protocol Received/Sent** milestone completion triggers Initial Submission prediction for all sites in the study. Then, when the site level milestone mapped to Essential Docs Sent to Site completes, this triggers prediction again for that site, which will override the prediction by Initial Protocol Received/Sent.

When a user adds a new submission to a site that does not yet have one, predictions display as follows:

- When Initial Protocol Received/Sent is not completed and Essential Docs Sent to Site is completed at the site, predictions are based on Essential Docs Sent to Site
- When Initial Protocol Received/Sent is completed and Essential Docs Sent to Site is not completed at the site, predictions are based on Initial Protocol Received/Sent
- When Initial Protocol Received/Sent is completed and Essential Docs Sent to Site is completed at the site, predictions are based on Essential Docs Sent to Site
- When Initial Protocol Received/Sent is not completed and Essential Docs Sent to Site is not completed at the site, no predictions are displayed for the site

Just like for other predicted milestones, the prediction for the initial submit milestone will retrigger if any of the attributes listed below changes, or if the start milestone dates changes. This includes changes made via corrections or API:

- Therapeutic area
- Study Phase
- Number of countries in study
- Country of site
- Number of sites in country
- Number of sites in study
- Region of site
- IRB/EC type of site
- Month of start milestone

Additionally, the prediction for initial submit retriggers if Initial Protocol Received/Sent or Essential Docs Sent to Site completed dates are updated via correction or API. Oracle Site Activate also generates an additional prediction from Contract Executed to IP Release once the milestone mapped to Contract Executed is completed. This greatly improves the accuracy of the prediction as it takes account of more recent information and keeping the IP release prediction adaptive.

The model described above predicts only initial submission at the site level. A second or later submission added to the site will not get any prediction. Additionally, the prediction will apply to only the first created submission if a site has multiple submissions. If the submissions have the same submission created date/time, the prediction will apply only to the submission with version 0.

Oracle Site Activate also creates a submission to approval prediction. When the Initial submit activity is completed for site-level submissions, the Final approval gets a suggested date on the "Submission dates" tab. You'll see the Suggested date symbol on the Final approval when a prediction becomes available. This new prediction triggers only when both Initial submit and Final approval activities exist for the submission artifact. If only one is configured, no prediction occurs.

Milestone prediction timeline

You can easily evaluate a predicted milestone's history. Click the Suggested dates icon on the Milestone timeline to view a vertical timeline with the milestone prediction trigger or change reason along with the associated date. You can access the timeline via the Suggested dates icon, even after the milestone has been completed and no new predictions are available.

In the timeline, you'll see the prediction's trigger/change reason to the left and prediction dates and other milestone dates to the right. Depending upon the milestone's status, the timeline may reflect one or more of the following triggers or change reasons:

- Number of countries in the study changed from <number_of_countries> to <number_of_countries>
- Number of sites in the study changed from <sites_in_study> to <sites_in_study>
- Study phase changed from <phase> to <phase>
- Study therapeutic area changed from <therapeutic_area> to <therapeutic_area>
- Site country changed from <country> to <country>

- Site region changed from <region> to <region>
- Number of sites in the country changed from <sites_in_country> to <sites_in_country>
- PI study experience changed from <pi_counts> to <pi_counts>
- IRB/EC type changed from <irb_ec_type> to <irb_ec_type>
- Start month changed from <start_month> to <start_month>

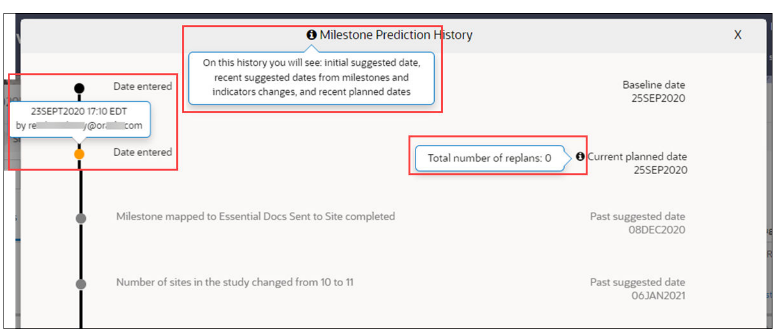
When Essential Docs Sent to Site or Initial Protocol Received/Sent completes or updates a mapped milestone, the modal's text prompt for that event shows which initially triggered or retriggered the prediction:

- **Initial trigger Initial Protocol Received/Sent completed**: "Milestone mapped to Initial Protocol Received/Sent completed"
- **Initial trigger Essential Docs Sent to Site completed**: "Milestone mapped to Essential Docs Sent to Site completed"
- **Initial trigger Essential Docs Sent to Site completed after Initial Protocol Received/Sent completed**: "Milestone mapped to Essential Docs Sent to Site completed"
- **Retrigger Essential Docs Sent to Site date update (via correction or API)**: "Milestone mapped to Essential Docs Sent to Site completed"
- **Retrigger Initial Protocol Received/Sent date update (via correction or API)**: "Milestone mapped to Initial Protocol Received/Sent completed"

The modal displays the above information with the following dates, as appropriate to the event. Date sequence in the timeline is based on date availability (not based on the suggested/planned/baseline/actual dates.):

- Past suggested dates (gray text) – The modal displays up to five from the four most recent suggested date changes. When two or more suggested dates occur back to back and are the same, the modal displays the oldest suggested date and change reason
- Current suggested dates
- Planned date
- Baseline date
- Actual date

Users see a unique entry for up to five most recent planned dates (four past most recent and current Planned date). The text prompt label for initial planned dates is "Date Entered" and for any later replanned dates, the text prompt is "Replanned".



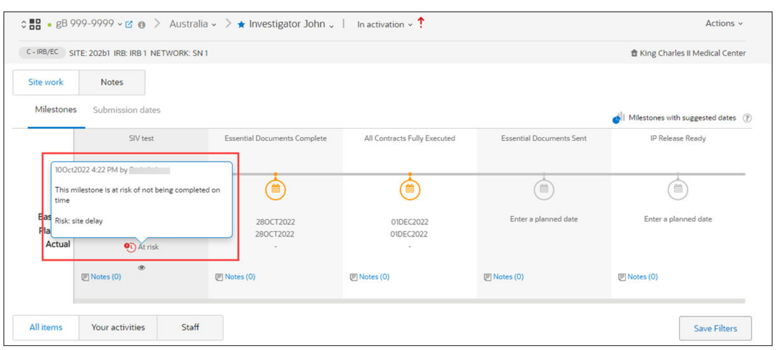
Flagging a milestone or submission as "At Risk"

If enabled for your organization's account, you can indicate if a milestone or submission is at risk of not being completed on time and specify the "Risk" value by selecting from a preconfigured list or entering a free text "Other" value. This milestone functionality is available in the following areas:

- **Milestones**
  - milestone dashboard (site and country)
  - study planning – milestones
  - study corrections – milestones
  - milestone timeline on site page
  - milestone timeline on country page
  - all above areas when submission is added to milestone timeline
- **Submissions**
  - milestone dashboard (site and country)
  - study planning – submissions
  - submission timeline on site page
  - submission timeline on country page

When you, or someone else on your study team flags a milestone or submission as at risk, the item displays a "risk" icon ().

On hover over, the icon displays details about when the risk was flagged, by whom, and why. If a member of your team replans the at risk milestone, Oracle Site Activate automatically removes the icon.



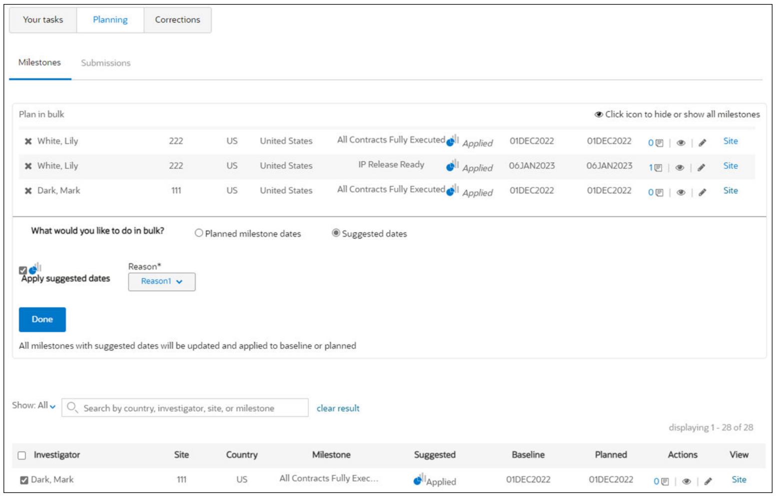
High-level milestone status indicators

The calendar icons on the milestone timeline indicate current milestone status.

- Green calendar = Completed
- Orange calendar = In Progress
- Gray calendar = Not Started

Managing milestone dates in bulk

You can plan and update milestones in bulk, directly from the study home page. Filter your milestones list by country, then select a baseline or planned date to apply to all of them. You can also enter planned dates for individual milestones. When you manage milestones in bulk, for instance if you apply Suggested dates in bulk, you'll need to indicate a Reason for the date change if at least one of the selected milestones already has a baseline date.

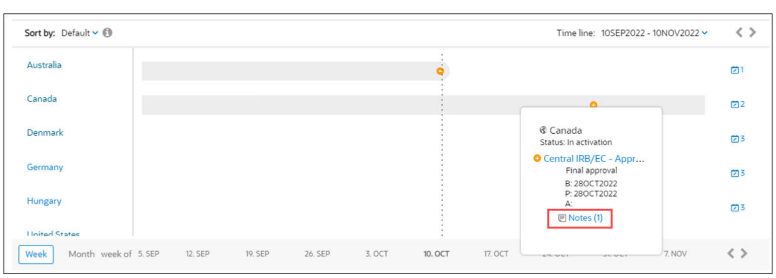


Milestone notes

Milestone notes will help you to communicate with your study team members as well. Notes are supported as follows for milestones and submissions:

- Milestones
  - Milestone dashboard (country and site)
  - Milestone timeline (country and site)
  - Study home page Planning tab, Milestones sub-tab
- Submissions:
  - Milestone dashboard (country and site) – if the submission was added to the milestone calendar
  - Milestone timeline (country and site) – if the submission was added to the milestone calendar
  - Submission timeline (country and site)
  - Study home page Planning tab, Submissions sub-tab

When viewing a milestone from a dashboard or timeline listed above, the note option displays as a hyperlinked icon (Notes) accompanied by a note count. If notes exist for the milestone, when you hover over the note icon, the name of the last person who entered a note displays.



When you click (Notes) the note modal opens to display the milestone's entire note history. When no previous milestone notes exist, you can add a new note of up to 10,000 characters. Notes also allow you to specify Type, Highlight, and Due date. You can also Reply to a note, if necessary, and mark a note as Resolved, if appropriate.

On the Study home page Planning tab, Milestones and Submissions sub-tabs, click note ( ) in the Actions column to add or review milestone notes. The edit ( ) planning modal includes the ability to add milestone notes as well.

- Set milestone dates from country and site details pages
  When necessary, you can change milestone dates from country and site details pages and determine the impact of the change on downstream activities before you make the change.
- Set and change milestone dates from the home page
  Quickly set or change dates for one or more milestones from the Planning tab on the home page.
- Correct a baseline milestone date
  If you have the appropriate corrections permissions in Oracle Site Activate, you can correct a baseline milestone date if it was entered incorrectly. If you do not see a Corrections tab, contact your super user or administrator.
- Replan milestone dates
  If you do not have a business role permission to correct a projected date, you can replan a projected date instead. You can replan the date as often as necessary.
- Determine impact of milestone date change
  If you re-plan a milestone date and the change will cause a downstream milestone to be late, Oracle Site Activate warns you so that you can notify your team members who are impacted, or keep the projected date.
- Show or hide milestones on the timeline
  If you have the appropriate business role permission, you can adjust the milestone timeline view to show or hide specific milestones.
- Mark a milestone at risk
  From any area where milestones and submissions display, you can easily add a visual indicator to let your team members know when a milestone may be at risk of not being completed on time.
- View Summary Milestones
  On your study home page, view the Summary Milestone dashboard or bar chart to evaluate progress toward the completion of site level milestones and submissions across multiple sites in your study.
- Export Summary Milestones
  You can optionally export milestones included in the Summary Milestone dashboard to a CSV format file.

Set milestone dates from country and site details pages

When necessary, you can change milestone dates from country and site details pages and determine the impact of the change on downstream activities before you make the change.

1. From the study country or site details page, click the calendar icon.
2. Select a date.
3. Select a Reason (required).

4. Click **Determine impact**, to see if the re-projected date will cause downstream milestones to be missed. Expand **Milestone details** to see the status of activities on which the milestone is dependent.
5. If the impact causes other milestones to be missed, you can click **Cancel** and keep the original projected date.
6. Enter the reason for the re-projection.
7. Click **Done**.

Set and change milestone dates from the home page

Quickly set or change dates for one or more milestones from the Planning tab on the home page.

1. From the home page, click the **Planning** tab.
2. Refine the list of displayed items using the search field and/or column sorting. You can also filter by All, Country, and Site items using the **Show** drop-down menu.
3. To the left of one or more items in the list, click the checkbox(es) to select.
4. Selection(s) display in a panel above the list.
5. Select a baseline and planned date, or the planned date you want to update.
6. If you are changing a date, select or enter a reason for change at the bottom of the calendar date selector, and click **Done**.
7. In the panel above the list, click **Done**.

Correct a baseline milestone date

If you have the appropriate corrections permissions in Oracle Site Activate, you can correct a baseline milestone date if it was entered incorrectly. If you do not see a Corrections tab, contact your super user or administrator.

1. From the home page, click the **Corrections** tab, then click **Milestones**.
2. In the **Actions** column for the activity, click the edit icon.
3. Enter a new date and select a reason for the change.
4. Click **Done**.

Replan milestone dates

If you do not have a business role permission to correct a projected date, you can replan a projected date instead. You can replan the date as often as necessary.

1. From the home page, click the **Planning** tab.
2. In the Actions column for the activity whose date you want to change, click edit ().
3. On the **New planned date** calendar, select or enter new date.
4. Use the **Reason** drop-down menu to select or enter a reason for the change and click **Done** to close the menu.
5. Click **Done**.

The above procedure describes one method to replan milestone dates. Alternatively, you can replan a milestone directly on the country or site milestone timeline by clicking the calendar, setting a new plan date, and entering a reason.

Determine impact of milestone date change

If you re-plan a milestone date and the change will cause a downstream milestone to be late, Oracle Site Activate warns you so that you can notify your team members who are impacted, or keep the projected date.

1. From the study country or site details page, click the calendar icon.
2. Select a date.
3. Select the reason for re-projecting the date.
4. To see if your date change affects other milestones, click **Determine impact**.
5. If there is an impact, on the home page **Planning** tab, go to the milestone (on the country or site details page) and change the milestone date as needed.
6. Click **Done**.

Show or hide milestones on the timeline

If you have the appropriate business role permission, you can adjust the milestone timeline view to show or hide specific milestones.

> **Note:**
>
> If the milestone has already been completed, it will not be available in the Planning tab and can be found by permissioned users in the Corrections tab instead. Users can then show/hide the milestone from the Corrections tab, as appropriate, using the eye described below.

1. From the home page, click the **Planning** tab.
2. If you don't see the milestone you want to add or remove from the timeline, enter the name of the milestone in the search box.
3. To show or hide the milestone on the timeline, click show/hide ( ). If the milestone is currently in a hidden state, the eye displays in light gray.

Mark a milestone at risk

From any area where milestones and submissions display, you can easily add a visual indicator to let your team members know when a milestone may be at risk of not being completed on time.

1. Click a milestone or submission item to edit.
2. In the milestone or submission modal, check the **Checking this box will display...** check box.
3. Use the **Risk** drop-down menu to select or enter a reason why the milestone may not be completed on time.

4. Click **Done**.

When milestones and submission milestones are completed or re-planned, they automatically have At risk () removed in the user interface, and the milestone is no longer marked as at risk in the Oracle Site Activate database. However, the fact that the milestone was marked at risk and the duration that it was marked at risk remain reportable.

View Summary Milestones

On your study home page, view the Summary Milestone dashboard or bar chart to evaluate progress toward the completion of site level milestones and submissions across multiple sites in your study.

To display the Summary Milestone dashboard or chart, the study must have at least one site milestone configured as a Summary Milestone.

1. On the study home page, click the **Dashboard** tab and select the **Tabular** tab to view the dashboard or select the **Chart** tab to view the bar chart.
2. Use the filter options above the dashboard or chart to filter the view by country and/or milestone.
3. You can optionally filter displayed milestones by **Protocol version**, **Type**, and/or **Category**. Click **Save filters**, if this is your preferred data subset.
4. In the dashboard view, click any milestone date to view details (e.g., actual/ planned sites, percentage complete, status, etc.) in a modal. In the bar chart view, hover over any point in the chart to view country milestone information.

Export Summary Milestones

You can optionally export milestones included in the Summary Milestone dashboard to a CSV format file.

To display the Summary Milestone dashboard, the study must have at least one site milestone configured as a Summary Milestone.

1. On the study home page, click the **Dashboard** tab and select the **Tabular** tab.
2. Use the filter panel above the dashboard to filter the view by country and/or milestone. The exported file includes only those countries and milestones included in the current view.
3. At the upper right of the dashboard, click **Export** to create and download a CSV format file.

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About contracts

The contracts modal

At the top of contract modals, you'll see the study name, country (for country or site level documents), and site information (PI and site number) if the item is a site level contract. Contract modals also display item metadata and other familiar Oracle Site Activate icons in a static header section at the top. The lower section of the modal supports vertical scrolling, when appropriate.

The Contracts modal will group related items within a single, tabbed modal (i.e., the modal includes navigation tabs along the top for Contract (Site), Budget (Site), and Contract Language (Site)) when appropriate. In the example image below, the Budget (Site) tab is active. Any new additional budgets will also display with the tabs along the top of the modal. Because the items relate to a site, in addition to the study name, the country, PI name, and site number display above the grouped tabs. The static header panel for the Budget (Site) tab shows an attached file for which a Document date has been saved, as well as the budget's saved Version ID. To the right, the static header displays familiar icons to indicate a file attachment and item status.

Each tabbed item in the grouped modal includes an "Info" tab (Contract Info, Budget Info, or Contract Language Info) that includes additional information appropriate to the item. For instance, when viewing the Budget Info tab, you can enter Version ID, budget metadata fields enabled for the account, or view files attached to the modal.

When viewing a Budget or Contract Language tab, the modal's Actions button includes only those actions applicable to the Budget and Contract Language item (based on configuration):

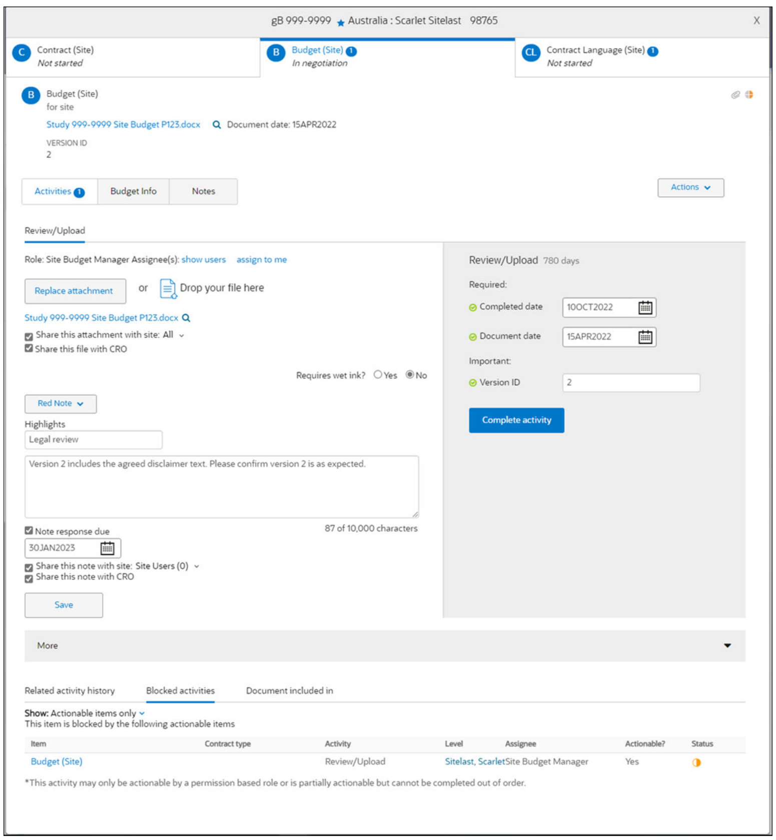
- Discontinue
- Reinstate
- Terminate
- Put on hold

In contrast, when viewing the Contract tab, the Actions button includes options specific to the Contract item type. For instance, on the Contract tab, users can click the "Actions" button to access the following options (based on configuration):

- Add an amendment
- Add an amendment to all contracts within country
- Add a budget
- Terminate contract
- Put contract on hold
- Discontinue
- Reinstate

In the example modal below, on the right side of the modal's scrolling body, Oracle Site Activate has enabled the "Complete Activity" button in the shaded panel because all Required fields have been completed for the Budget activity (i.e., Completed date, Document date, and Version ID). "Required" and any "Important" fields included in this shaded panel are unique to your organization's account settings. If required fields under the "Info" tab have not yet been completed, the Complete Activity button will be disabled, and you'll see a message directing you to review the Info tab fields for missing information.

When appropriate, the bottom section of the modal body includes sections for (1) Related activity history, which shows the status of created activities, who created them, and how they were created, (2) Blocked activities, and (3) Document included in, which provides package details if the document is included in a Submission or IP review package. You can toggle from one area to another by clicking the section name, and the active section is underlined in blue. If necessary, use the edit ( ) function edit the date and enter a reason for the change.



Contract activities

The optional Oracle Site Activate contract management module:

- Helps study team members better identify activities and manage contract processes separate from regulatory documents
- Displays amendments and budgets separately to make it easier to see the relationship between the contract and related budget and amendment items
- Enables team members to enter and see amendment reasons

If you see the **Contracts** tab, your organization has enabled the optional contract management module. If you do not see the tab, you'll manage contracts on the **Documents** tab.

Generating contract activities

When you add a study site, Oracle Site Activate automatically generates activities to manage contracts. Like document activities, each contract-related document is configured with a lifecycle that defines the required activities. If you have a role that requires you to interact with contract documents, and it's your turn to perform an activity related to a contract document, you'll receive an alert.

Contract activities can also be configured to auto-complete immediately after a predecessor activity has been completed. Contact your Oracle Project Manager to discuss including auto-complete activities in your contract lifecycles.

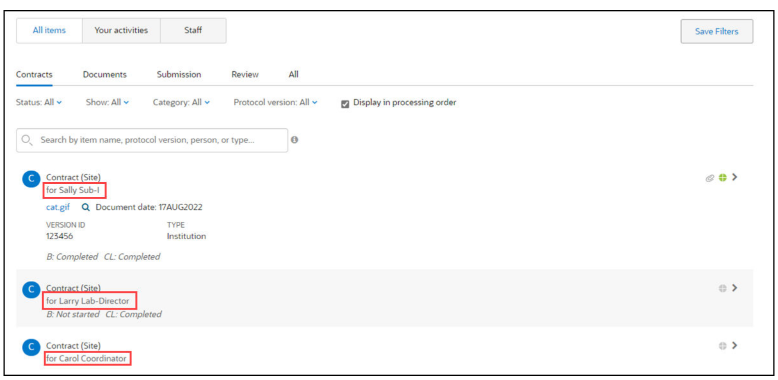
If your organization enables the Oracle Site Activate site collaboration feature, study sites will also see a **Contract Activities** tab in their version of Oracle Site Activate, as well as alerts for their contract-related activities.

Depending upon your team’s process, you may track only document completion dates, or you may upload documents into Oracle Site Activate or exchange them with sites. Using Oracle Site Activate to manage files makes it the repository for incomplete documents; once they are approved and complete they can automatically be transferred to an eTMF (using the standard Oracle Site Activate APIs). Your organization may also enable an Oracle Site Activate feature that enables you to track the location of a shared drive or other repository.

Staff level contracts

Oracle Site Activate also allows for creating and managing staff level contracts. This allows you to create contracts and associated amendments that are unique to individual staff members. Contract and amendment items configured at the staff level function the same way these items work at the Principal Investigator/Site level. For example:

- The items display in Oracle Site Activate under the Contracts tab
- Contract Language and Budget items nest under the main contract item
- Items are associated with the staff member, whose name displays with the items



Managing contract language and budgets

By default, the contract modal displays with tabs for the contract language (which appears with the “CL” identifier) and a budget (which appears with the identifier “B”). In instances where you may have multiple contracts with a site, you can easily see which items are related to each contract. Click a budget or contract language tab in the contracts modal to see and complete open activities, enter a version ID, and to see the history of that item’s related activities.

If you need to create a new budget version, you can do so under Actions on the Budget tab. You'll see the new budget appear as a separate tab. To help you track multiple budgets, any new versions appear with an indicator (V1, V2, etc.).

Managing amendments

When you need to process a contract amendment, click **Add an amendment** under Actions in the contract modal. You can choose:

- **to this contract** – amendment added within the contract itself
- **to all contracts within [country name]** – amendment added within Bulk work

Depending upon how your organization configures Oracle Site Activate, you can choose to add a:

- **one way amendment**: where only one party signs the amended agreement, or
- **two-way amendment**: where both parties sign the document

You are also prompted to provide a version ID.

If your organization configured Oracle Site Activate to capture amendment reason, you can select a reason from a preconfigured list.

Also note that if the contract has a Type value set, the amendment automatically inherits the contract Type. This applies to amendments created individually and in bulk.

Discontinuing and terminating items

If a budget or contract is no longer needed, you can discontinue it from the item's **Action** menu.

You can also place items on hold to temporarily suspend alerts for them. If you need to resume work on the item, you can reinstate them as well from the **Actions** menu and have processing resume where it ended when you discontinued or placed the item on hold.

Managing notes

You can add notes about the contract language, budgets, or amendments to help your study team view a complete history of communications.

Important:

- The notes you enter on the **Contract activities** tab will not display on the **Notes** tab (where notes from document and submissions activities appear); this is by design and allows you to keep contract-related notes confidential.
- When you enter notes into the contract, budget, and contract language sections, you can view them only in those sections (e.g., notes entered into the budget section are not visible in the contract language section).

Exporting files

When you need to get contracts out of Oracle Site Activate you can:

- Download individual files from the document widget
- Export a group of files for a study country or site

If your organization uses the Oracle Site Activate eTMF API, completed documents are automatically exported to your eTMF.

- Complete contract activities
  If your organization uses the optional Contracts feature, you'll complete assigned activities within a contract modal.
- Add a contract or budget note
  If your organization uses the optional Contracts feature, you can compose and save notes for contracts and budgets to keep your study team informed of progress and updates.
- View and edit contract or budget notes
  If your organization uses the optional Contracts feature, you can access notes saved for a contract, contract language, or a budget when needed. You'll also have the ability to edit a note, if necessary.
- Process a contract amendment
  If your organization uses the optional Contracts feature, you can add a new amendment widget when you need to track documents, activities, and dates for a contract amendment.
- Manage expiring contract items
  You can easily create a list of contract, contract language, budget, and amendment items that have been configured for and are nearing expiration.
- Discontinue or reinstate a contract item
  If your organization uses the optional Contracts feature, and you need to discontinue a contract item, you can do so in the contract widget. If you need to reinstate the item later, you can also complete this action within the widget.
- Export contract documents
  If your organization uses the optional Contracts feature, and you want to download contract documents, Oracle Site Activate will create a .zip file that contains the most current, completed versions of all documents, if there are documents available.

Complete contract activities

If your organization uses the optional Contracts feature, you'll complete assigned activities within a contract modal.

1. Display the site details page for the contract.
2. On the **Your activities** tab, click the **Contracts** filter.
3. Use the Assigned to filter to refine the displayed list of contract items. You can also sort and filter the list using the controls above the search field, or you can search for a specific contract item using the search field.
4. Click the contract, budget, or contract language placeholder to open the contract modal.
5. With the modal displayed, click the **Contract**, **Budget**, or **Contract Language** tab at the top of the modal.
6. On the **Activities** tab, review the list of Required/Important activities in the shaded area to the right. Complete all Required activities to enable the **Complete Activity** button.
7. Click **Complete Activity**.

Add a contract or budget note

If your organization uses the optional Contracts feature, you can compose and save notes for contracts and budgets to keep your study team informed of progress and updates.

1. From the site details page, click the contract item's placeholder to display the contract modal.
2. Click the **Contract**, **Budget**, or **Contract Language** tab at the top of the modal.
3. Click the **Note** tab and enter the note.
4. Click **Save**.

View and edit contract or budget notes

If your organization uses the optional Contracts feature, you can access notes saved for a contract, contract language, or a budget when needed. You'll also have the ability to edit a note, if necessary.

1. From the site details page, click the contract item placeholder to display the contract modal.
2. Click the **Contract**, **Budget**, or **Contract Language** tab at the top of the modal.
3. To see all saved notes, click the **Notes** tab.
4. To edit a note, click **Edit** next to the entry you want to change.
5. After editing, click **Save**.

Process a contract amendment

If your organization uses the optional Contracts feature, you can add a new amendment widget when you need to track documents, activities, and dates for a contract amendment.

1. From the site details page, on the **Your activities** tab, click the **Contracts** filter.
2. Filter the contract items list and click the contract placeholder to display the contract modal.
3. On the **Contract** tab, click the **Actions** drop down list and select "Add an amendment to this contract," or "Add an amendment to all contracts within [Country Name]."
4. (Optional) Enter the Version ID.
5. If configured for your account, select an amendment **Reason**.
6. If configured for your account, at **Method**, select one or two-way.
7. Click **Done**.

Manage expiring contract items

You can easily create a list of contract, contract language, budget, and amendment items that have been configured for and are nearing expiration.

1. From the top navigation menu, hover over **More** and click **Expiring items**.
2. Select the study name, if necessary.
3. Click the appropriate tab to display desired results:
    a. **Not specified**: documents for which an expiration date has not been assigned
    b. **Expired**: expired documents, including the date they expired
    c. **Expiring**: documents that will be expiring in the next 30, 60, 90, 120, or more than 120 days (or whatever intervals your organization has configured).
4. At **Item**, select **Documents**.
5. At **Show**, select **Active** or **Addressed**.
6. To specify or update an expiration date for a listed contract item, click the PI name. The document work area displays. Enter an expiration date and click **Done**.
7. To filter the list, enter a country, site, investigator, or document name into the search box, and then Enter on your keyboard.

After completing the procedure above, if you receive an updated document, add a new version of it with a new expiration date. Remove the expiration date from the old document by clicking **X** next to the date.

Discontinue or reinstate a contract item

If your organization uses the optional Contracts feature, and you need to discontinue a contract item, you can do so in the contract widget. If you need to reinstate the item later, you can also complete this action within the widget.

1. From the site details page on the **Your activities** tab, click the **Contracts** filter.
2. Filter the contract items list to locate the item you want to discontinue or reinstate. Click the item's placeholder to open the contract modal.
3. Click the **Contract**, **Budget**, or **Contract Language** tab at the top of the modal.
4. From the item’s **Actions** menu, select **Discontinue this version** or **Terminate this version** (contract language only).
5. To reinstate the item, from the item’s **Actions** menu select **Reinstate this version**.

Export contract documents

If your organization uses the optional Contracts feature, and you want to download contract documents, Oracle Site Activate will create a .zip file that contains the most current, completed versions of all documents, if there are documents available.

1. From a country details or site details page, under **Actions**, click **Export completed documents**. If no files were uploaded, a “No documents to export” message displays.
2. Oracle Site Activate creates and downloads a .zip file. The file name includes the study name and two-letter country code.
3. Open the .zip file to see all completed document versions.

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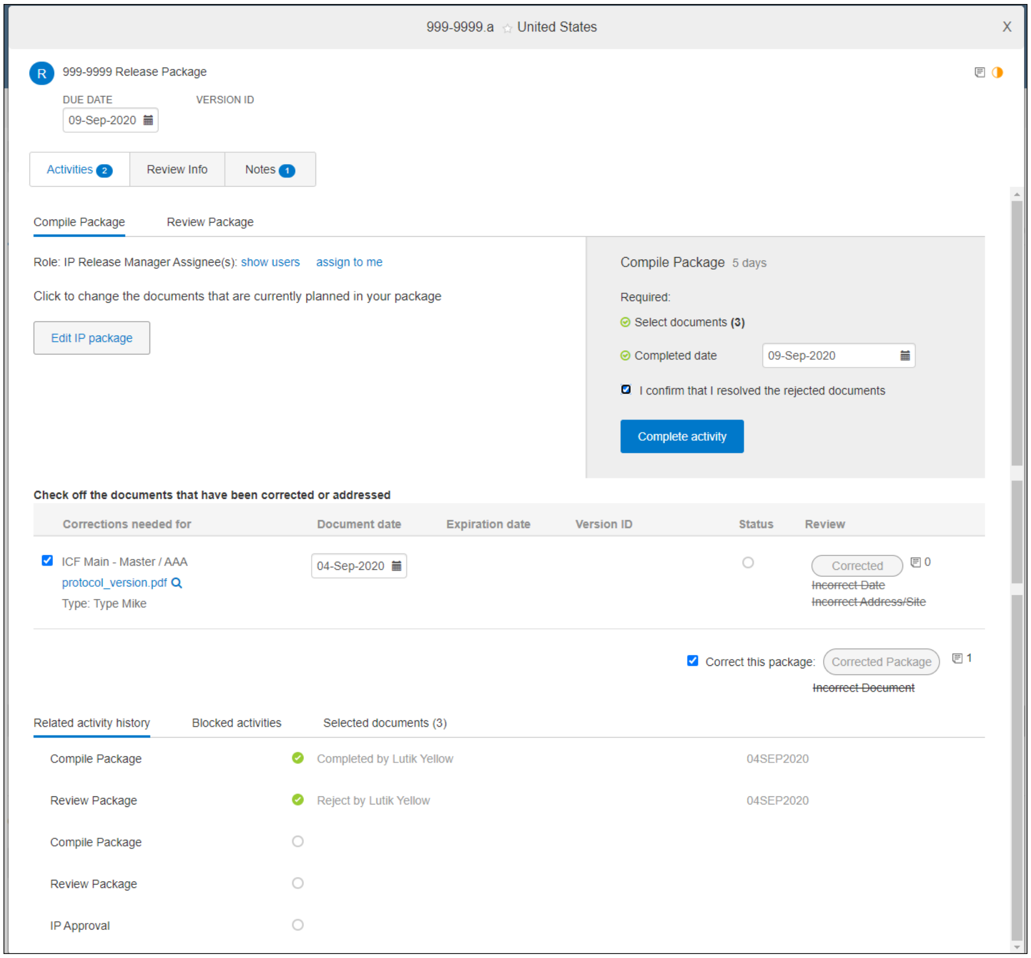
About IP release

The IP package modals

The IP package modal (see image below) includes a static header that identifies the study and country as well as scrolling modal body design. The left side of the modal header displays the name of the IP Release package, and if configured, the Due Date and Protocol Version display below the package name. Version ID displays in the header as well; if no value has been saved, the Version ID label displays with no additional value (this is by design). The modal also displays appropriate icons on the right side of the static header (e.g., urgency, note, status, etc.).

In the example modal image below, two activities display just below the Activities tab: Compile Package (underlined in blue) and Review Package. You'll click the activity name to change the current view within the modal and complete the Required actions/fields in the shaded panel on the right side of the modal body. Where necessary, you'll check boxes to select documents for the activity. The modal indicates this requirement using bold text. The lower section of the redesigned modal gives you access to additional information in three sections, with the currently displayed section underlined in blue:

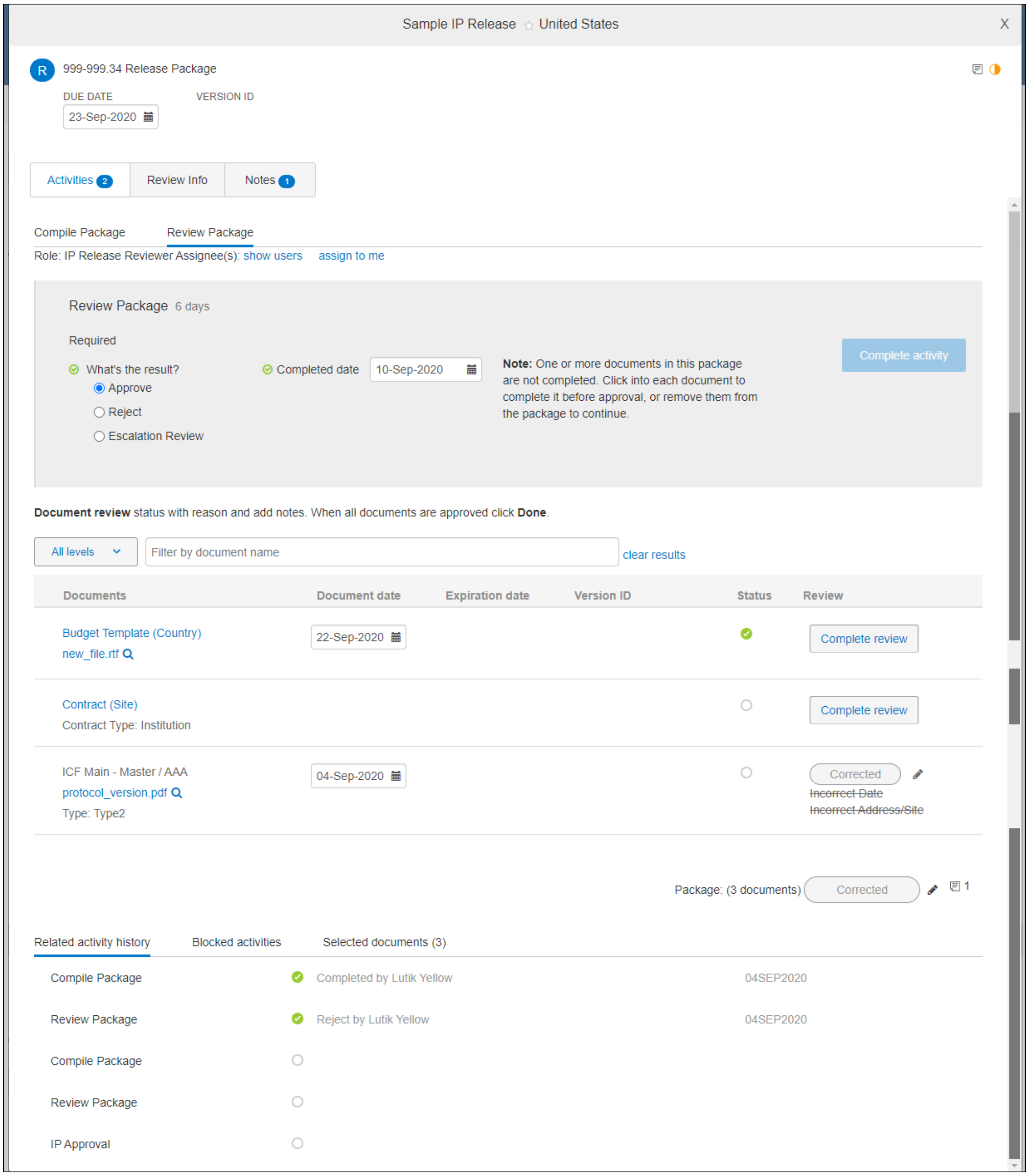
1. Related activity history
2. Blocked activities
3. Selected documents



The Review Package activity area of the IP release package modal uses a slightly different layout designed to maximize use of horizontal space. For example:

- The shaded activity completion area displays above the list of documents for review
- Each document in the review list uses the full width of the modal
- Complete Review buttons also launch pop-ins that use the full horizontal width of the modal

This review design makes it easy for you to evaluate item details while performing the review. Item names display as hyperlinks, and you can click a link to open an item in a new browser tab. You can also easily switch between package review on the original tab and the modal containing an item's details on the new tab.



If enabled for your organization's account, IP modals indicate the protocol version so that study team members are aware of the version to which the package applies. When this feature is enabled, the package's Required panel includes a “Protocol version” drop-down selection field.

The Protocol version field includes all available versions. If the IP package is already tied to a protocol version through workflow wizard, the field shows that protocol version as preselected. If the package is not tied to a version, the study team member must select one from the list to complete that required entry. When selected, the protocol version displays at the top of the modal and the item placeholder list.

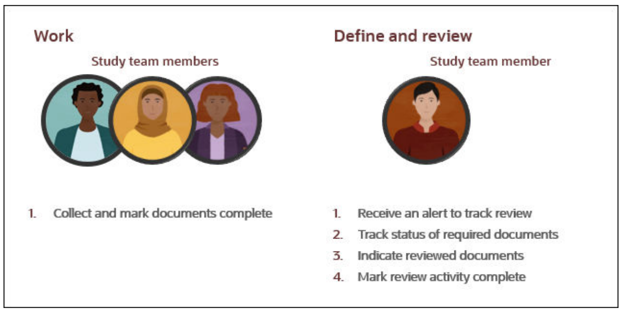
At any point before IP package approval, the study team member may update the Protocol version associated with the package item by editing the selection in the modal’s Required panel. At the final approval activity, Oracle Site Activate displays a prompt to confirm the selected protocol version. The text, “Please confirm that the selected protocol is accurate before completing this activity.” displays next to the “Complete activity” button.

IP release readiness

Oracle Site Activate helps you track your team's progress towards achieving IP release. Your organization has configured the system to track documents required for IP release and to specify a group of documents to review and approve for IP release. When it is time to conduct the review, you or another study team member will receive an alert to define the list of documents to review.

If you have the "reviewer" role, once all required docs are complete, team members can send their package for you to review. When it is time to conduct the review, you will receive an alert to review the documents. As you review documents, you can indicate which ones were reviewed; that way if you cannot finish in one session, you will know where to start when you return.

If you find that one or more documents are not completed correctly, contact the person responsible for the document and ask them to make the necessary corrections. When all documents are complete, indicate that the review activity is done. If your milestones are so configured, Oracle Site Activate automatically updates the Actual completion date for the IP release approved milestone. In addition, on all IP release review activities, a user can accept or reject a document and provide a reason for doing so.



Country and site IP release review

Oracle Site Activate allows for both country-level and site-level IP release review. The country-level **Review Activities** tab provides the same functionality as the site-level **Review Activities** tab.

When country-level document approval is complete, users will see an icon on the site-level Review Activities list and the Define IP Release Package pages at the study and country document levels.

Managing documents after IP release

You can continue to work on documents after IP release approval without impacting the IP release status of sites if post-IP release activities are enabled by your organization.

Downloading and viewing documents

You can download multiple documents in a zip file format, or click an individual document's name to download just that document. To preview a document, click the magnifying glass icon. When certain metadata has been saved for a document, preview includes this information in the Details pane on the right side of the page. Metadata fields include Document Date, Uploaded by, Status, Protocol version, Study name, Principal Investigator, and more.

Define activities

Oracle Site Activate walks you through the process of selecting study, country, and site documents to include in the review, starting at the Define tab. Click **select documents** to begin selection.

After you define the documents, Oracle Site Activate displays the document status. At any time, you can display this list to determine review readiness. Additionally, because you are likely to review documents over an extended period of time, you can save your work and return later to complete it.

Review activities

Define and conduct the IP release review on the modal's **Review Package** tab. When it's time to conclude your review, click **Complete review**. You can then **Approve** or **Reject** the document.

If you click **Approve**, select **First review** or **Final approval**.

If you click **Reject**, a list of reasons displays and you may choose one or more. The contents of the rejection list are configurable.

Reviewers can also optionally enter a review note for the approval or rejection and categorize the note Type (Review, Contract, Submission, General, or Internal). An incremented note history is available on the **Review** tab for the individual item.

Once you've completed the review activities described above, you can view a list of items you've reviewed and whether you've accepted or rejected them. To sort the documents to your preferred view, click the **Documents**, **Status**, or **Review** heading.

Users with “Enable package update” business permission can replace package documents provided the documents are not in either First Review or Final approval status. If a document has either of these statuses, and the user selects “Add a new document version,” a pop-in will provide the following action options:

- add this document to the package and leave old document as well
- do not add this document to the package and leave old document

If enabled for your organization's account, Oracle Site Activate will allow package approval if all items are in either First Review or Final Approval status. Conversely, your organization may have enabled the option to allow IP approval only if all documents are both complete and approved. Contact your organization's super user to discuss the approval option enabled for your organization.

Also note that Oracle Site Activate prevents corrections users from changing a document or contract item after it has been approved in IP release review (i.e., First Review or Final Approval). When corrections users attempt to change an approved document, Oracle Site Activate displays the following message: “This document is included in a review package. This document cannot be edited as it has already been accepted in the document review process."

Document and package notes

Oracle Site Activate users can easily add and review notes throughout the IP release review process.

On the **define** tab, users viewing activity for a rejected document can enter a note for that rejected document. A note icon next to the document opens a pop-in where the user can view previous, timestamped notes, as well as note author and category. The user can then choose a note category and add a response note.

On the **review** tab, if a document has one or more associated notes, a note icon displays next to the name of the document. When clicked, a pop-in displays all activity and item notes, note author(s), note timestamps, and whether the note is in response to the item or activity.

The **review** tab also displays individual notes for each document (separate from review notes). A note icon displays with each document only when the individual document has one or more notes.

eTMF systems and notes

Saving notes for the entire IP package review process may be required by some eTMF systems. If enabled for your organization's account, when the package is completed, Oracle Site Activate creates a PDF format document containing all of the notes on the individual documents within the IP review process, as well as all the notes on the package itself.

Within IP review, the PDF file displays under the section, "Documents included in this review" with the file name and document title "IP Review Notes - [Package Name + Principal Investigator]. The PDF will be part of the document export if the export is updated after completion of the package. The document will also be published to the eTMF system.

IP release item urgency

To increase visibility of high-priority items, Oracle Site Activate allows users to indicate the urgency of an item included in the review. If enabled for your account, users who have business role permission to perform IP Release reviews can indicate, via radio button, if the review item is "Urgent."

Two radio buttons (Urgent and Not urgent) display below the header in the **Review Activities** widget when the placeholder is expanded. By default, when the feature is enabled, IP Release items are "Not urgent."

When a user selects the "Urgent" radio button and clicks "Save" in the widget, the text label and the icon for "Urgent" display to the left of the item's status icon:

- in the placeholder header on site or country view and on the Account Overview page
- in the alerts widget on site or country view and on the Account Overview page

To help you quickly focus on Urgent IP release package activities in alert lists, sorting on the account Overview, country, and site pages includes an "Urgency" sort option. When you select this sort option, alerts display an alphabetized list of Urgent items first, followed by an alphabetized list of Not urgent items. For example:

- Urgent – A IP release activity
- Urgent – D IP release activity
- Not urgent – B activity
- Not urgent – F activity

- Compile an IP release package
  Create the bundle of documents that will be included in the IP release package.

- Review an IP release package
  When it's time to review an IP release package, you'll review the document(s) and either approve or reject each item.
- Download an IP release package
  Once a site has completed IP release, Oracle Site Activate automatically initiates a process to export all completed documents of the package and a manifest to a .zip file. You can then download the .zip file.
- Add or replace a document version
  If you have the appropriate permissions, you can add or replace documents in IP Release packages that have been defined, but not completed.

Compile an IP release package

Create the bundle of documents that will be included in the IP release package.

1. From the site details page or country details page, on the **Your activities** tab, click the **Review** filter.
2. Filter the list of review items as preferred. Click the item's placeholder to open the IP Package modal.
3. On the Activities tab, click **Plan this IP package**.
4. In the Study documents, Country documents, and/or PI/Site documents sections, check the documents you want to include in the package (click **Continue**, at the upper right, to advance through sections).
5. Enter the date you compiled the package (defaults to today's date).
6. Confirm the **Protocol version** (if required for your organization's account).
7. Click **Complete activity**.

You can see the list of selected documents and status in the **Documents review** section.

Review an IP release package

When it's time to review an IP release package, you'll review the document(s) and either approve or reject each item.

1. From the site or country details page, on the **Your activities** tab, click the **Review** filter.
2. Filter the list of review placeholders as preferred, and click a placeholder to open the IP release package review modal.
3. On the Activities tab, under the **Review Package** activity, scroll down to access the list of documents included in the review. Click a document name to open the document.
4. For each document, click **Complete review** as you progress through the list of documents, and click **Approve** or **Reject** for the document. If rejecting the document, select from one or more of the reasons or enter a different reason by selecting **Other**. You can add notes as needed. Click **Done** for each approval/rejection.
5. When all documents have been approved/rejected, below the document list, click **Package review**, and either **Approve** or **Reject** the package. You can add a note as needed.
6. Click **Done** to complete the package review.

7. Above the document list, review the Required activities in the shaded area. When all required activities are completed (e.g., you indicate a package decision option, select a completed date, confirm protocol version (if required for your organization), etc.), the **Complete activity** button will be enabled. Click **Complete activity**.

If the review is associated with a milestone, Oracle Site Activate automatically updates the status of the milestone.

Download an IP release package

Once a site has completed IP release, Oracle Site Activate automatically initiates a process to export all completed documents of the package and a manifest to a .zip file. You can then download the .zip file.

1. From the site or country details page, click the **Review** tab.
2. Filter the Review placeholder list and click a placeholder to open the IP Package Review modal.
3. Click **Export to zip** to download the prepared .zip file.

Add or replace a document version

If you have the appropriate permissions, you can add or replace documents in IP Release packages that have been defined, but not completed.

1. From the site details page, on the **Your activities** tab, click the **Documents** filter.
2. Click the document's placeholder to open the document modal.
3. At the right, click the **Actions** drop-down list and select **Add a new version**.
4. If the document exists in one or more packages, a pop-in displays. Choose:
   - add this document to the package and leave old document as well
   - add this document to the package and replace the old document (this option is available only if the document is not in First QC passed or Approved state)
   - do not add this document to the package and leave old document
5. Click **Confirm**.

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About bulk actions

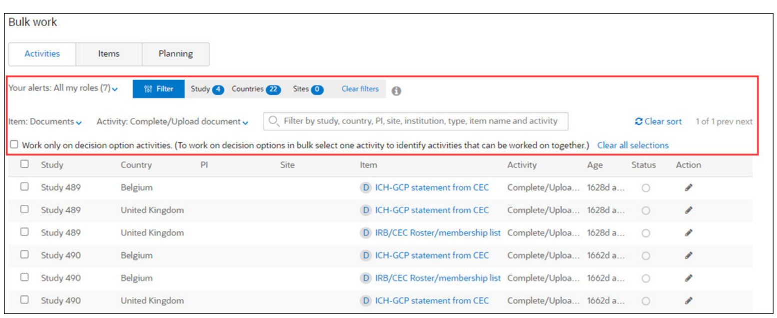
Access bulk work

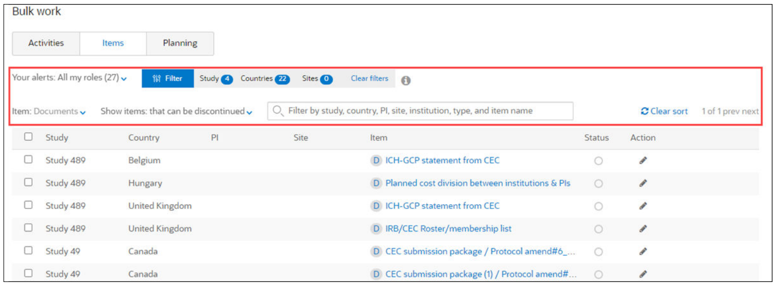
Working in bulk saves time and effort when completing items or updating item attributes. You can access Bulk work from the menu item in the global navigation bar and complete your assigned document, contract, package, and submission activities in bulk. You can also add notes, attachments, and version IDs to those items as appropriate. Document items also allow you to complete some specific actions in bulk like: discontinuation, reinstatement, and setting expiration dates.

You'll need a special business permission to complete activities in bulk across multiple studies at once. Without this permission, you can complete bulk actions on activities and document items for a single study at a time. Contact your study super user or administrator to request this permission. Regardless of permission levels, you will only be able to see and complete actions on those studies, countries, and sites to which you have been granted access in Oracle Site Activate.

Bulk work provides multiple filter and sort options under both the Activities tab and the Items tab. Begin your bulk work activities by filtering and/or sorting to create a targeted list. As you refine the list of available items or activities, matches move to the top of the screen to make them easily visible and allow you to quickly make updates.

> **Note:**
>
> Bulk work excludes any activity with a file that is still pending acceptance in the Quarantine area. This ensures that Bulk work does not present activities to you that you are unable to complete. After file acceptance in Quarantine, the activity displays in Bulk work, and you can manage the activity as preferred.





Apply decision options in bulk

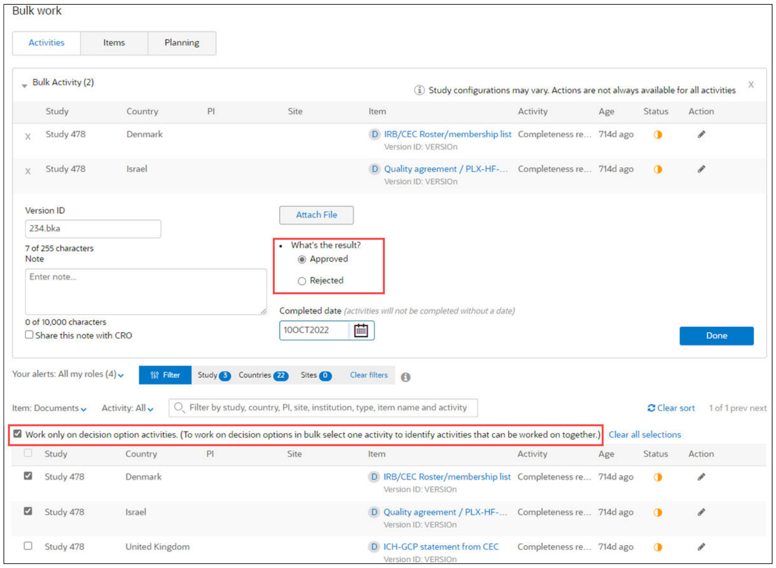
You can take action on decision option activities in bulk for documents, sub-contracts, submission packages, and subcommittee packages. The Activities grid includes a "Work only on decision option activities…" check box that you can check to enable if you want to use this functionality.

The new check box option can be checked only if you have not selected any item in the Activities grid. If you select non-decision option activities in the grid before checking the check box (i.e., leave the check box unchecked), an information tooltip directs you to clear all selections to enable the option. When the box is checked, that also disables the Activities grid "select all" option, and the grid filters to display only decision option activities. Then, when you select one decision option activity in the grid, the list filters again to display only the same activities with the same decision option label and decision options (i.e., the same configuration lifecycle).

> **Note:**
>
> Bulk work restricts completing an activity in bulk when it is the final item activity and the item has incomplete required fields (e.g., custom metadata, budget metadata, type, category, etc.). Activities that cannot be completed will display in the grid with an information icon (?) instead of a selection check box. To proceed, edit the activity and complete required fields.

When the grid displays the results, you can then select activities to complete. The top panel displays a single view of the available decision options. Once you edit the item (e.g., to select a decision option and Completed date) and click Done, all selected activities complete, and the decision option you selected in the top panel will be applied to all the selected activities.

By design, Bulk work clears all selections if you uncheck the "Work only on decision option activities…" check box before clicking Done in the top panel. Except to persist any selected study, country, or site filters, the Activities grid will return to its original state.



Plan milestones and submissions in bulk

The Bulk work area's Planning tab replicates many of the features of the study home page planning tab but allows you to plan study level milestones and submissions, across studies.

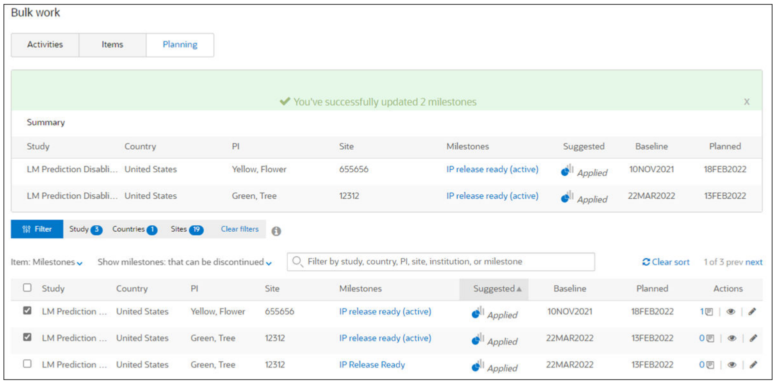
Discontinue and reinstate milestones

On the Planning tab, if you have "Enable user to discontinue milestones" business role permission, you can discontinue milestones that have not yet been completed. When you have this permission, the bulk planning panel displays "Discontinue milestones" as an action option. If selected, you must enter a reason for discontinuing before the bulk panel's "Done" button will be enabled for use. Discontinued milestones will no longer display on milestone timelines (study, country, or site) or on the study home page Planning or Corrections tabs.

When you have the "Enable user to discontinue milestones" business role permission, you can also reinstate discontinued milestones. The Planning tab's "Show milestones" menu includes a "that can be reinstated" option, which lists discontinued milestones. When you choose to proceed, Oracle Site Activate displays a warning message that all selected milestones will be reinstated, and you must select a reinstatement reason to enable the bulk panel's "Done" button. After reinstatement, the milestones display normally on the milestone timelines (study, country, or site) or on the study home page Planning or Corrections tabs.

Apply Suggested dates

If prediction functionality has been enabled for your organization's account, you can also optionally apply Suggested dates when planning milestones in bulk. With milestones selected on the Planning tab, the Plan in Bulk panel displays the Suggested dates option. When selected, check the “Apply suggested dates” check box and Oracle Site Activate will update Baseline dates for unplanned milestones and update Planned dates for already planned milestones.



Actions not supported in bulk

It's important to understand what you can't do in bulk work. By design, the bulk work area does not permit the following actions, either in bulk or against individual activities or items:

- Scheduling dates for contracts
- IP release review
- Submission package planning

- Navigate to bulk work and filter by items or activities
  When enabled for your account, the Bulk work option displays in the top navigation bar. Save time and effort by using this feature to update document items and activities in bulk.
- Filter items or activities by study, country, and site
  When enabled for your organization's account, you can simplify management of items and activities in bulk work with study, country, and site filters. These filters help target the list of available items or activities you can modify.
- Filter items or activities by role, item type, activity type, or text search
  When bulk work is enabled for your organization's account, secondary filters like role, item type, activity type, and text search help restrict the list of items and activities you'll manage with bulk actions.
- Perform actions on individual document items
  When bulk work is enabled for your account, filtering items in bulk and completing actions on them one-by-one can save significant time, compared with navigating to each study-country or study-site to perform actions.
- Perform bulk actions on filtered document items
  When Bulk work is enabled for your account, you can save time by performing actions in bulk on a filtered list of document items.
- Perform bulk actions on individual activities
  When bulk work is enabled for your account, filtering activities in bulk and completing actions on them one-by-one can save significant time, compared with navigating to each study-country or study-site to perform actions.
- Perform bulk actions on filtered activities
  When Bulk work is enabled for your account, you can save time by performing actions in bulk on a filtered list of activities.

- Plan milestones and submissions in bulk
  The Bulk work area to includes a Planning tab that replicates many of the features of the study home page Planning tab but allows users to plan study level milestones and submissions, including discontinue and reinstate milestone actions, across studies.

Navigate to bulk work and filter by items or activities

When enabled for your account, the Bulk work option displays in the top navigation bar. Save time and effort by using this feature to update document items and activities in bulk.

1. Click **Bulk work** in the top navigation bar.
2. To begin filtering activities in the grid on the Bulk work page, no change to the toggle is needed. **Activities** is the default selection for the toggle each time you navigate to Bulk work.
3. To begin filtering document items into the grid, select **Items** in the toggle near the top of the page.

Filter items or activities by study, country, and site

When enabled for your organization's account, you can simplify management of items and activities in bulk work with study, country, and site filters. These filters help target the list of available items or activities you can modify.

1. Click **Bulk work** in the top navigation bar.
2. Click the **Filter** button to open the filter modal.
3. Select a study from the set of available studies (you can search by study name to narrow the results). **Note**: To select more than one study at a time, you must have a business role permission that allows you to access multiple studies.
4. Optional: Click **Countries** at the top of the filter modal to proceed to the country selection step. If you do not specify one or more countries, only study level items or activities display in the grid.
5. Select one or more countries (you can search by country name to narrow the results). **Note**: To filter site-level documents or activities, you can select just one country at a time. If you select multiple countries, only country-level activities or documents can be filtered (the **Sites** step is disabled in this case).
6. If you selected only one country, click **Sites** in the filter modal to proceed to the site selection step.
7. Select one or more sites (you can search by site name to narrow the results).
8. Click **Apply filters**.

Note: If you click outside of the modal before clicking **Apply filters**, no new filters are applied. Once you have applied your filters, you can click **Clear filters** at any point to clear your filters.

Filter items or activities by role, item type, activity type, or text search

When bulk work is enabled for your organization's account, secondary filters like role, item type, activity type, and text search help restrict the list of items and activities you'll manage with bulk actions.

1. Once you have applied study, country, and/or sites filters in the filter modal (described in the Filter items or activities by study, country and site procedure), you can click the selection next to **Your alerts** to filter results by any of your Oracle Site Activate business roles.
2. You can click the selection next to **Item** to filter results by different item types.
3. You can click the selection next to **Activity** to filter results by different activity types.
4. You can also type into the search bar to filter results by study, country, PI name, site, institution, item name, or activity (where applicable).

Perform actions on individual document items

When bulk work is enabled for your account, filtering items in bulk and completing actions on them one-by-one can save significant time, compared with navigating to each study-country or study-site to perform actions.

1. Click **Bulk work** in the top navigation bar.
2. Verify that the **Items** toggle is selected at the top of the page before filtering items.
3. Filter items based on study, country, and site.
4. Depending on which action you want to complete, from the **Show documents** menu, select one of the following: **Documents that can be discontinued**, **Documents that can be reinstated**, or **Documents that require expiration date**.
5. Once you have applied these filters, click Edit ( ) in the **Action** column of the grid to perform the selected action on any filtered item individually.
6. Update the required fields in the modal and click **Done**.

Perform bulk actions on filtered document items

When Bulk work is enabled for your account, you can save time by performing actions in bulk on a filtered list of document items.

1. Click **Bulk work** in the top navigation bar.
2. Verify that the **Items** toggle is selected at the top of the page before filtering items.
3. Filter your activities based on study, country, and site.
4. Filter your activities based on role (if desired) and based on the action you would like to perform.

5. Use the checkboxes in the left column to select items that you would like to perform in bulk.
6. To remove activities from your selected set, you can uncheck the box in the filtered grid, or you can click **X** to the left of the activity in the summary table at the top of the page.
7. Once you have selected all desired items, update the fields beneath the summary table at the top of the page.
8. Click **Done** to update the selected document items in bulk.

If Completed Date is not entered, activities will be updated but not completed.

Perform bulk actions on individual activities

When bulk work is enabled for your account, filtering activities in bulk and completing actions on them one-by-one can save significant time, compared with navigating to each study-country or study-site to perform actions.

1. Click **Bulk work** in the top navigation bar.
2. Verify that the **Activities** toggle is selected at the top of the page before filtering activities.
3. Once you have applied filters in the filter modal, click Edit ( ) in the **Action** column of the grid to perform supported actions on any filtered activity individually.
4. Update any of the available fields in the modal and click **Done**.

Perform bulk actions on filtered activities

When Bulk work is enabled for your account, you can save time by performing actions in bulk on a filtered list of activities.

1. Click **Bulk work** in the top navigation bar.
2. Verify that the **Activities** toggle is selected at the top of the page before filtering activities.
3. Filter activities based on study, country, and site.
4. If desired, filter your activities based on role, item type, and activity type.
5. Use the checkboxes in the left column to select activities that you would like to perform in bulk.
6. If you would like to remove activities from your selected set, you can uncheck the box in the filtered grid, or you can click **X** to the left of the activity in the summary table at the top of the page.
7. Once you have selected all of the desired activities, update any of the fields beneath the summary table at the top of the page. The following fields are supported for bulk updates: Notes, Version ID, Attached files (if applicable for the activity), and Completed date. Note that if you don't include Completed date, activities will be updated but not completed.
8. Click **Done** to update the selected activities in bulk.

Plan milestones and submissions in bulk

The Bulk work area to includes a Planning tab that replicates many of the features of the study home page Planning tab but allows users to plan study level milestones and submissions, including discontinue and reinstate milestone actions, across studies.

To discontinue or reinstate uncompleted milestones in the Bulk planning area, you must have a business role with "Enable user to discontinue milestones" permission.

1. Click **Bulk work** in the top navigation bar.
2. Click the **Planning** tab.
3. **Filter** the list by study, country, and or sites.
4. Use the **Item:** and **Show:** drop-down lists to refine the milestones or submissions displayed in the grid. You can also search for a specific study, country, PI, site, institution, or milestone.
5. In the resulting list, select the item(s) you want to plan by clicking the check boxes to the left of the item(s).
6. The selected items display in a panel at the top of the page. Use the options in the **Actions** column to edit the item, view a note, or show/hide the item on the milestone timeline. You can also option the item modal by clicking the item's hyperlink.
7. For milestones: In the **What would you like to do in bulk?** area, choose **Planned milestone dates**, **Suggested dates**, or **Discontinue milestones**. If you choose to plan dates, select the new dates from the calendars. If you choose to use Suggested dates, check the **Apply suggested dates** check box. If you choose to discontinue, **Select a reason** for discontinuing. After completing your chosen bulk action, click **Done**.
8. For submissions: In the **What would you like to do in bulk?** area, select **Initial submission** and/or **Final approval** dates, and click **Done**.

17 About partner collaboration

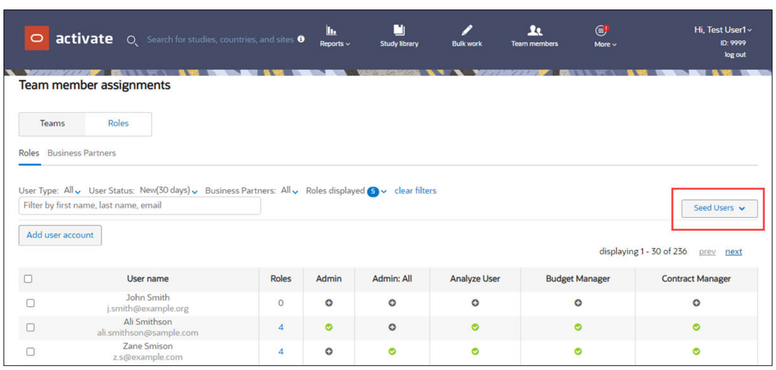
Establishing partnerships in Oracle Site Activate

To facilitate collaboration and status updates between study team and sponsors, you can grant partners, such as sponsors who also use Oracle Site Activate, the ability to log in and see study status. When the relationship is no longer desired, you can dissolve the partnership in Oracle Site Activate.

To get started, ask Oracle Support to establish the partnership. If your partner accepts, you can grant partner team members access to only view study status, or grant them access to fully collaborate with you and complete activities. When partner team members have assigned activities, they receive a email notification that includes a summary of the assignments. The email also includes a link to the Oracle Site Activate log in page where the user can log into his or her own Oracle Site Activate account and complete the activities using business partner collaboration functionality.

Seeding partner team members and managing access

If a list of partner users already exists, you can "Seed" (add) your partner's team members to your Oracle Site Activate environment. Click the Seed Users button, then select the partner from the drop-down menu.



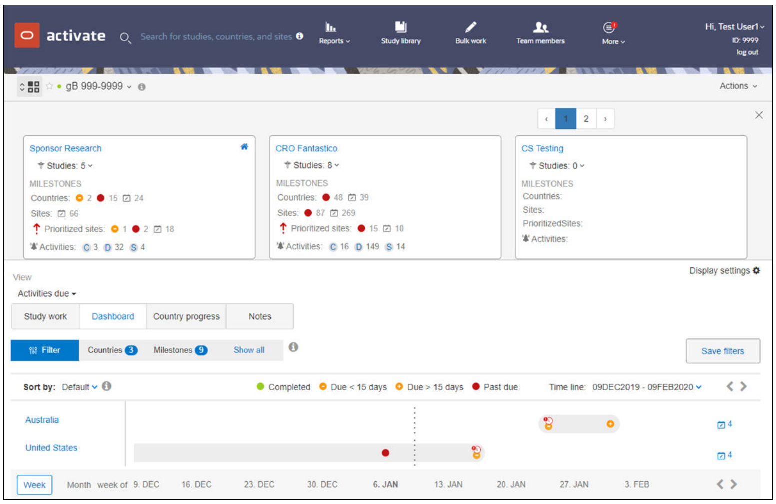
Once you've seeded users, you'll see the partner's team members on the list of users you can assign to roles. Use the filters above the table to choose user type, status, business partner and select up to 10 roles to view at one time. Once the role is assigned, you can grant the partner access to studies, study countries, and sites. What they can do is controlled by the activities that are assigned to the role during configuration.

Account-level milestone view

If your organization has established CRO/Sponsor collaboration relationships you will have access to a new account-level view where you can see progress across all studies/accounts to which you have access with milestone views of all studies.

> **Note:**
>
> Use of the milestone feature requires that your organization AND your partner's organization have the feature enabled at the account level.

Click the four-square in the persistent header, to the left of the study name, to expand a panel under the persistent header and view account cards for all studies to which you have access. Cards display in the following order: your account first (at the far left), followed by partner account cards in alphabetical order

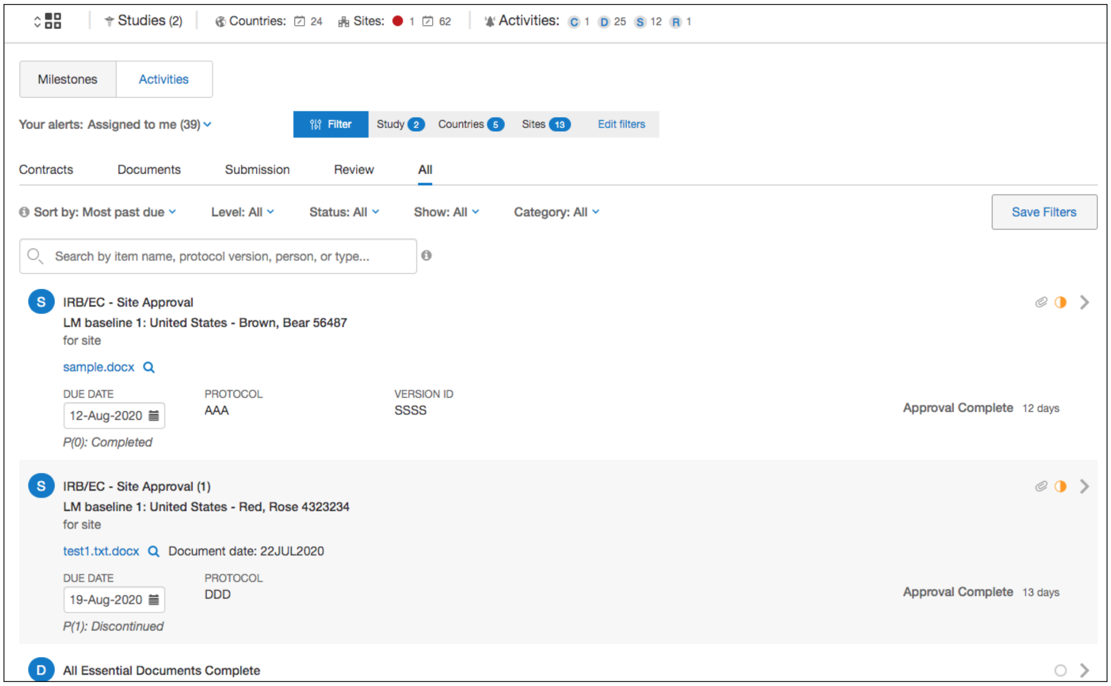


Account Overview cards provide an at-a-glance view of your actionable work, across partner accounts. Use the studies drop-down(s) in the cards to search specific studies within your or your partner's accounts. If you are responsible for milestone tasks in the accounts, you'll see numerated icons that will link to the milestone dashboard on your home page.

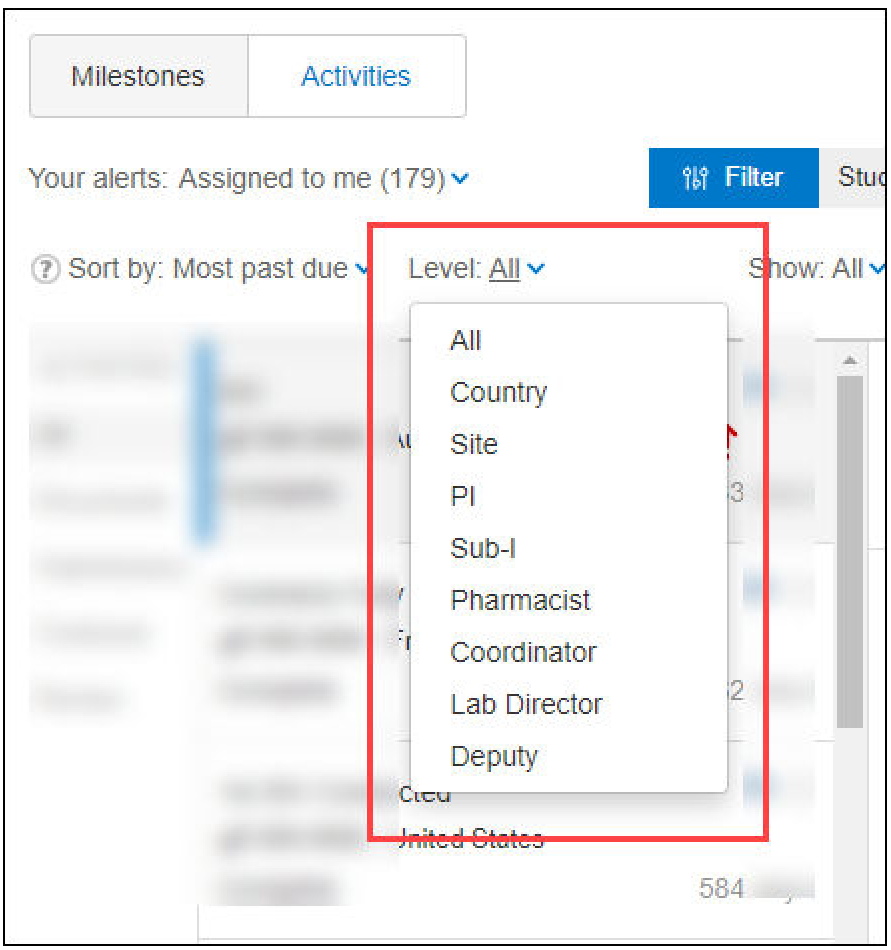
When enabled for your organization's account, an information icon also displays at the study, country, and site levels in the persistent header. The icon displays when the study being viewed has been shared with a sponsor partner for oversight. Oracle Site Activate users who have the appropriate permissions to edit studies can make the study viewable to partners using a control on the add/edit study page. When users in shared studies hover over the icon, tooltip text displays the sponsor name.

Account-level Overview

The Account Overview page allows users to easily view, filter, sort, and search for their work and activities across all studies/accounts to which they have access. Account details with activity and milestone counts and icons display above the overview page in the sticky header.



The oversight Level filter shown below allows CROs and sponsors to easily subset activities based on country, site, principal investigator, sub-investigator, or other staff types (e.g., pharmacist, lab director, etc.).



> **Note:**
>
> Users who have the "IP reviewer" business role permission will view a consolidated list of IP Review activities, across studies, on the overview page. For these users, the page defaults to the IP reviewer role configured for the account, and IP review activities are pre-selected. By design, the users may not choose other activity types to view.

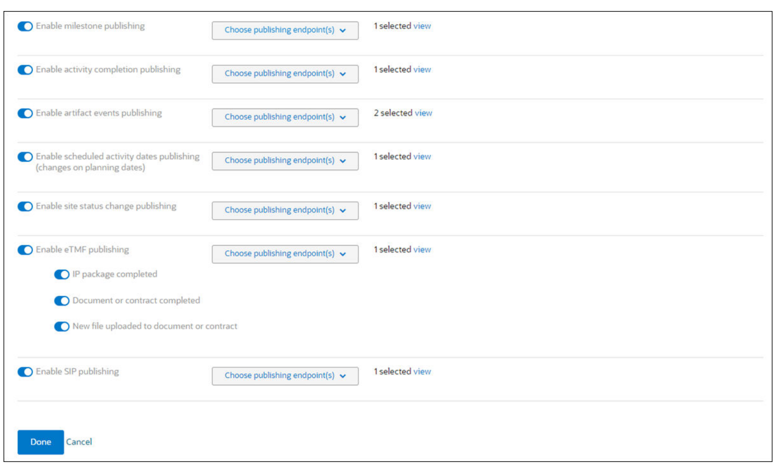
If configured, item and milestone descriptions display on the overview page and in other areas of Oracle Site Activate.

To ensure that users access actionable activities, sites or countries that are in the system statuses Dropped, On Hold, or Closed will not have any activities display on the overview page, and counts of activities will not be impacted by these sites or countries.

Sharing data via API

To ensure that the appropriate data can be shared between CROs and sponsors, administrative users can select the types of API messages to be published outbound to the sponsor, as well as the endpoint URL, on the Add a study/Edit study page in Oracle Site Activate. The following message types are supported:

- milestones
- activity completion
- artifact events (create/complete)
- scheduled activity dates (changes on planning dates)
- site status change
- eTMF publishing
- SIP publishing



Partners and URL endpoints displayed on the **Add a study** or **Edit study** page must be enabled at the account level. Please contact your Oracle Project Manager to discuss requirements.

Additionally, the user choosing message types and partner URL endpoints on the Add a study/Edit study page must also have the business role permission, “Enable user to create business partner relationships,” enabled for his or her account.

Hover over tooltips and Open Activity icons

If enabled for your account and your partner account, you'll see hover over tooltips for items and milestones and Open Activity icons.

Tooltips

Because similar items and milestones could have different uses or use cases between partner accounts, hover-over tooltips help users understand what an item or milestone actually represents within the account. Oracle Site Activate users who have “Enable user to manage study configuration” permission can add descriptions of up to 500 characters to items and milestones in Oracle Site Activate Configuration Designer. Tooltips display when you or a partner user views:

- a milestone on the country milestone dashboard
- an item or milestone on the country page
- an item on the site page or Oracle Site Activate LITE page
- a milestone on the site page
- an item on the bulk page
- an item on the study library page

Open Activity icons

When at least one activity in an item is assigned to a business partner or a site, new icons display within the item at the country or site level, at the “Open Activities” heading. When you or a partner hover over one of these icons, a tooltip displays the site or business partner name, assignee name, activity required (e.g., review or upload), and the date assigned.

- Establish a partner relationship
  To facilitate collaboration and status updates between study team and sponsors, you can grant partners, such as sponsors who also use Oracle Site Activate, the ability to log in and see study status.
- Accept a request to establish a partner relationship
  Your organization and your partner will both consent to a business partner relationship. You will accept requests, and once your partner responds and consents to participate, you can grant their study team members access to your studies.
- Set Portfolio overview as your default view
  Portfolio overview facilitates collaboration and status updates between the study team and sponsors.
- Dissolve a partner relationship
  When an existing partner relationship is no longer required, you can remove the partner's access to your account.
- Seed external users
  If you have a business role that allows you to manage users, you can "seed" a partner's users into your account so that the study team member names appear on Team members and assignments page. This will allow you to then assign them to studies, study countries, sites, and roles.

- Assign a partner View Only access
  If you have a business role that allows you to modify user permissions, you can grant external partners View Only access into your studies.

Establish a partner relationship

To facilitate collaboration and status updates between study team and sponsors, you can grant partners, such as sponsors who also use Oracle Site Activate, the ability to log in and see study status.

1. From the top navigation bar, select **Team Members**.
2. Click the **Business Partners** tab.
3. Click **Establish Partnership**.

Once your partner responds and consents to participate, you can grant their study team members access to your studies. If you change your mind, click **Cancel Request**.

Accept a request to establish a partner relationship

Your organization and your partner will both consent to a business partner relationship. You will accept requests, and once your partner responds and consents to participate, you can grant their study team members access to your studies.

1. From the top navigation bar, select **Team Members**.
2. Click the **Business Partners** tab.
3. Click **Establish Partnership**.

Set Portfolio overview as your default view

Portfolio overview facilitates collaboration and status updates between the study team and sponsors.

1. From the top navigation bar, click on your name in the top right, and then select **My Profile**.
2. At Choose my default home page view, select **Portfolio overview**.
3. Click **Done**.

Dissolve a partner relationship

When an existing partner relationship is no longer required, you can remove the partner's access to your account.

1. From the top navigation bar, select **Team Members**.
2. Click the **Business Partners** tab.
3. Next to the partner’s name, click **Dissolve Partnership**.

Seed external users

If you have a business role that allows you to manage users, you can "seed" a partner's users into your account so that the study team member names appear on Team members and assignments page. This will allow you to then assign them to studies, study countries, sites, and roles.

1. From the top navigation bar, select **Team Members**.
2. Click the **Business Partners** tab.
3. Click **Seed Users**, then click **OK**.

Assign a partner View Only access

If you have a business role that allows you to modify user permissions, you can grant external partners View Only access into your studies.

1. From the top navigation bar, select **Team Members**.
2. Click the **Roles** tab.
3. For the partner you want to grant access, click **Assign Role**, then select the role your organization has configured for read-only access by external partners.

18
About study setup

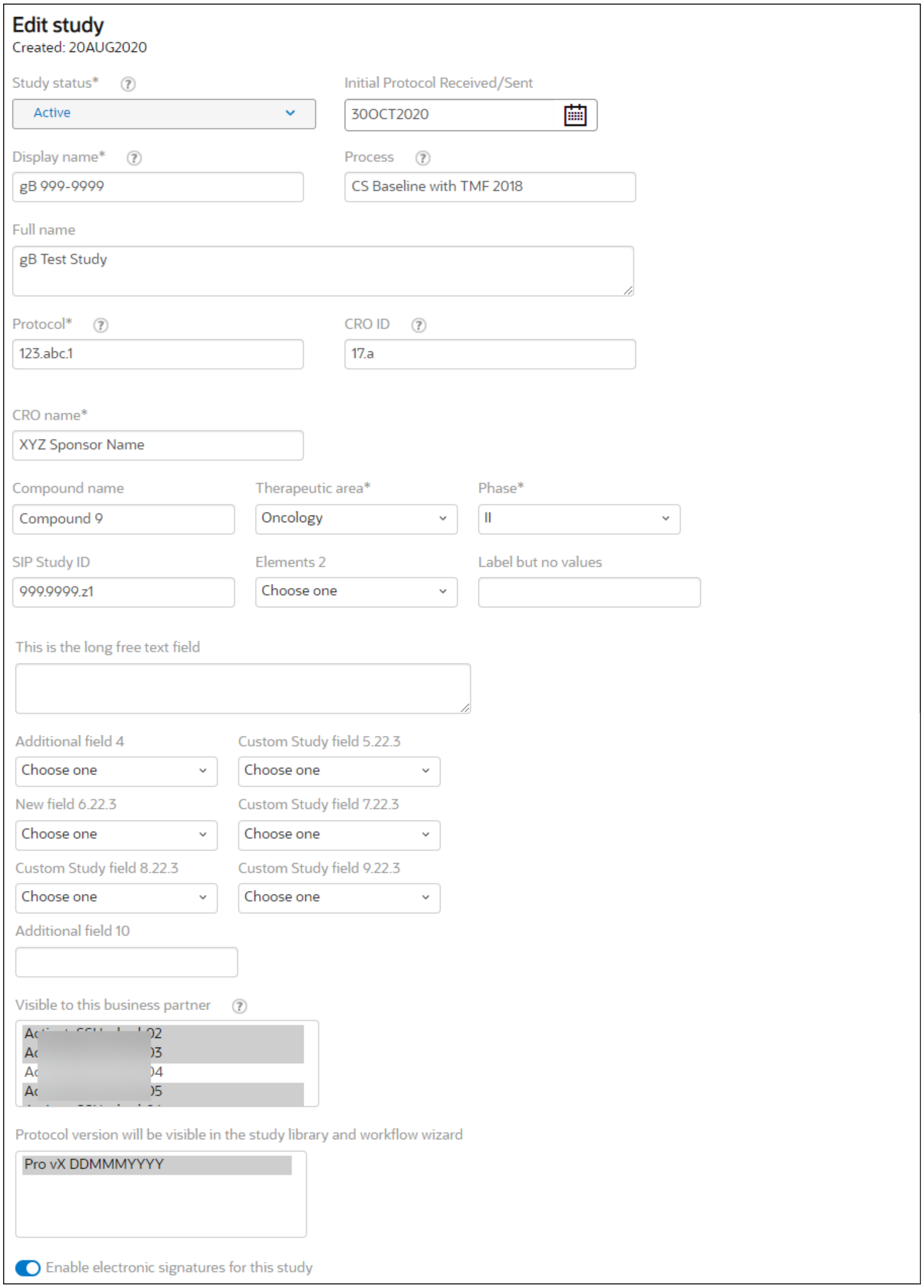
As you progress through the study start up process, you might need to add new studies or modify attributes of studies that have already been added to your account.

Initial study setup and modifying study attributes

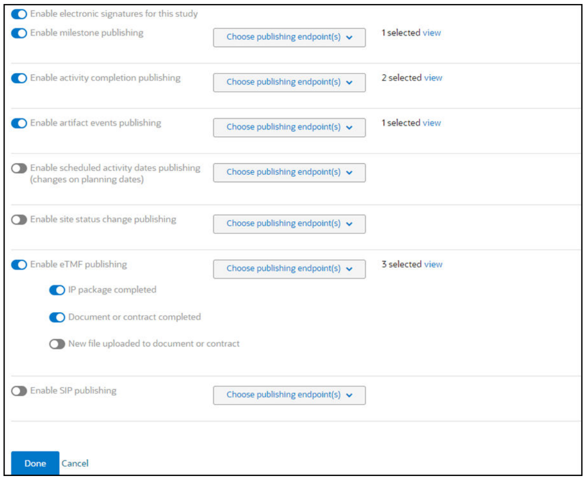
When it is time to add a new study to Oracle Site Activate, contact your organization's designated party who has the appropriate business role permissions to create new studies. After the study is set up, if you have the proper permissions, you can change certain attributes:

- Study status (choose from “Active,” “Not in use,” “Canceled,” “Closed,” “Closing out,” and “On hold,” or other labels that are unique to your organization)
- Study ID
- Number of sites planned for a study country
- Site status (choose from “Active,” “Not in use,” “Canceled,” “Closed,” “Closing out,” and “On hold,” or other labels that are unique to your organization)

On the Add or Edit study page shown below, you'll also see 10 additional fields. These fields will have labels and content unique to your organization's needs and may allow you to enter free text or make a selection from a predefined drop-down list.



The lower section of the Add or Edit Study page allows permissioned users to enable configured integrations. For example, electronic signature can be enabled at the study level here, and users who manage data integration can select and enable integration endpoints.



- Add new studies
  If you have the appropriate business role permission, you can add new studies to your account. If you do not, please contact your super user. If your organization does not have a designated super user, contact Oracle Support.
- Set study status
  If you have a business role with permission to view and edit study information, you can update a study's status. If you do not have this permission, please contact your organization's super user for assistance.
- Edit study attributes
  After the study is set up, if you have the proper business role permissions, you can change default attributes like study display name, full name, and protocol name, etc. You'll see additional attributes that you can change if custom attributes have been enabled for the account.
- Favorite a study
  With one click, you can favorite any study to which you have access. Favorites are tied to your user account and don't affect how your team members view studies.
- Generate study level items
  When you need to generate non-Study Library documents and submissions at the study level, you can do so using the workflow wizard flow.

Add new studies

If you have the appropriate business role permission, you can add new studies to your account. If you do not, please contact your super user. If your organization does not have a designated super user, contact Oracle Support.

1. On the home page, click **Actions**, then click **Add new study**.
2. Enter, at minimum, all required fields.
3. Click **Done**.

Set study status

If you have a business role with permission to view and edit study information, you can update a study's status. If you do not have this permission, please contact your organization's super user for assistance.

1. From the home page, in the persistent header, confirm the correct study name displays or use the drop-down list to select another.
2. From the **Actions** menu, select **Edit study**.
3. At **Study status**, select a new status.
4. Click **Done**.

Edit study attributes

After the study is set up, if you have the proper business role permissions, you can change default attributes like study display name, full name, and protocol name, etc. You'll see additional attributes that you can change if custom attributes have been enabled for the account.

1. From the home page, in the persistent header, confirm the correct study name displays or use the drop-down list to select another.
2. From the **Actions** menu, select **Edit study**
3. Enter a new display name, full title, or adjust other available study attributes as required. Note that you may not update a study's Process. Contact your super user for assistance with this type of change.
4. Click **Done**.

Favorite a study

With one click, you can favorite any study to which you have access. Favorites are tied to your user account and don't affect how your team members view studies.

1. View the study's home page.
2. In the persistent header, click the favorite star to the left of the study name ( ). The inactive state is gray.

   When enabled, the favorite star is blue ( ). You can disable the favorite setting at any time by clicking the star again.

When you navigate to a study home page and hover over the study name drop-down menu, favorite studies display at the top of the list in alphanumeric order.

Generate study level items

When you need to generate non-Study Library documents and submissions at the study level, you can do so using the workflow wizard flow.

1. On the study home page **Actions** drop-down menu, click **Add study documents/ submissions**.
2. Choose a protocol version, and click **Continue**.
3. Click the check box to the left of the documents/submissions you want to generate. Selected items display in the panel to the right of the Collections list
4. Click **Done**.

19 About user accounts, roles, and permissions

Understanding roles

Oracle Site Activate roles dictate the privileges for a specific user or a group of users, and roles are categorized into **System roles** and **Business roles**.

System roles – System roles are not configurable and are given to users individually to specify the user's access level in Oracle Site Activate. System roles apply only to CRO/ Sponsor experience users and Associate experience users, they are not applicable to site experience users. System roles are:

- **Administrative access** – Provides the user with access to all inherent functions in Oracle Site Activate and allows the user to add studies and remove sites. To create new studies in Oracle Site Activate, a user's individual account must have this setting enabled as well as "Enable access to all studies in account" user account flag.
- **Participatory access** – Provides the user with the same access as Administrative (above), except Participatory users cannot add studies or remove sites. This system role applies to most, but not all, Oracle Site Activate users. With business role permission, users with Participatory access can also add a study country.
- **View access** – Provides the user with "read only" capabilities. The user may not add, edit, or manage documents/activities or run workflows.

Business roles – Business roles are configurable, as they relate to a customer's specific process configuration, and are associated to completion of specific activities. Your Oracle project team creates and configures business roles and will make configured roles available in the **Team Members** area of Oracle Site Activate. Then, you can assign team members to one or more studies, study countries, or study sites and designate one or more business roles that determine what the team members can do.

Below are sample roles and activities. Note that your organization may choose to use different labels for the role names or associate different activities with business roles.

Role	Activities
Manager or lead	• Change the planned number of sites • Add protocols • Add study sites • Add staff members • Assign team member responsibilities for study countries and site
Startup specialist	• Track documents • Track submissions • Receive email alerts for sites (regardless of assignment)

Administrator	• Add studies • Add study countries • Change study names • Track submissions • Receive email alerts for sites (regardless of assignment)

Optional business role consolidation

Over time, your organization may create more business roles than needed. Oracle offers an optional consolidation script that consolidates one or more roles into a single existing role and copies permissions and user assignments as appropriate.

When run, the consolidation script updates all configurations in the account. Please contact your Oracle services representative to discuss scheduling, requirements, and the impact of script use for your account.

Understanding business role permissions

When your Oracle project manager creates and configures a business role for use in the **Team Member Assignments** area, part of that process is defining the associated business role permissions. Business role permissions provide the granular control necessary to ensure that the right users can access the right Oracle Site Activate features to complete required activities.

Often, Oracle Site Activate features enabled at the customer account level also impact decisions about which roles require which permissions. Your Oracle Project Manager or Account Manager will work with you or another representative of your organization to adjust role permissions as necessary and in relation to your organization's Master Services Agreement.

Functional area	Permission	Description
Activities	Enable self-assignment of activities	Allows the user who has at least one role with this permission to view an **assign to me** link for self-assignment of unblocked document, contract, submission, submission package, and IP package activities on the Account Overview, country, and/or site pages.
Alerts	Enable pausing email alerts	At the item level, allows the user to temporarily pause email alerts asking them to complete the item. Applies only to the permissioned user and does not pause alerts for other users.
API integration	Enable endpoint management	Allows the user to manage publishing endpoint for the account and for each study if they have access to the "edit study" page.
API integration	Enable user to view event messages	Allows the user to view the event message log through the **Event messages** link in the **More** menu. This permission is needed only if the customer account is configured for API integration.

Functional area	Permission	Description
API integration	Place user in eTMF message	When this permission is assigned to a role in a country, and an eTMF message is generated for a country-level document in that country, the name of the user who has Primary Assignment for the role in that country is included in the document_owner field in the message. This permission applies to sites in the same way. When the permission is assigned to a role for a site, and an eTMF message is generated for a site-level document in that site, the name of the user who has Primary Assignment for the role in that site is included in the document_owner field in the message.
API integration	Enable access to IRB documents queue	Allows users to review incoming IRB documents in the quarantine section and accept matching documents into the country/site.
API integration	Enable user to view Activate-Select links	Allows user to see launch site and study in Select links in the persistent header. Requires additional configuration. Please contact your Oracle services representative.
Bulk activities	Allows bulk activities across multiple studies	Allows the user to complete activities in bulk across multiples studies. "Enable bulk page access" feature must be enabled at the account level.
Business partner relationships	Enable user to create business partner relationships	Allows access to the **Business Partners** tab in **Team Member Assignments** to initiate a partnership between two customers. This permission also allows the user to select preconfigured partner endpoint and URLs on the add/edit study page. When configured, users can enable publishing for the following message types: milestones, activity completion, artifact events, scheduled activity dates (changes on planning dates), and site status change.
Business partner relationships	Enable user to assign roles to business partners' users	Allows the user to assign roles to business partner users who have been seeded in from partner environments.
Business partner relationships	Enable user to be visible to business partners for role assignment	Allows the individual user account to be seeded into business partner environments. The user will be part of the next user seeding activity initiated by the business partner.
Business partner relationships	Enable user to assign roles to sensitive users	Allows the user to assign business roles to any user that is flagged as a "sensitive user" and assign those users to studies, countries, and sites.

Functional area	Permission	Description
Business partner relationships	Make user the Main Contact	If using CRO/Sponsor Partnership, users with this permission will be shown in the **Contact** section for the study in the **Portfolio Overview** page.
Business partner relationships	IP reviewer	View a consolidated list of IP review activities, across studies, on the **Overview** page. IP review activities are preselected; by design, the user may not view any other type of activity. Customers may enable this permission on *one role* for their account.
Configuration Designer	Enable user to manage study configuration	Allows the user to access Configuration Designer through the **Configuration Designer** link in the **More** menu. Users with this permission can add, edit, deploy and delete configurations.
Configuration Designer	Enable user to view study configuration	Allows the user to access Configuration Designer through the **Configuration Designer** link in the **More** menu. Users with this permission can view configuration details, but may not make changes.
Contract management	Enable user to interact with contracts	Allows the user to view the **Contracts** tab in Oracle Site Activate. Contract management feature must be enabled at the account level.
Corrections	Enable data change users with this role to correct metadata	Allows the user to modify document, contract, and budget metadata fields. Prerequisite individual user account settings: Administrative or Participatory system role and "enable access to corrections page (data change)" individual user account flag. Prerequisite account settings (for contract and budget metadata): "Enable contract management" feature and individual contract metadata fields enabled for the account. Metadata available to the user for correction is dependent upon the metadata enabled for the account (such as wet ink, document date, etc.) and metadata configured within an item (such as agency name or artifact language - there are many other metadata fields).

Functional area	Permission	Description
Corrections	Enable data change users with this role to correct attachments	Allows the user, if they also have the data correction system role flag, to replace files through the Attachments tab under Corrections on the home page. Prerequisite individual user account settings: Administrative or Participatory system role and access to corrections page (data change) enabled for user account. Oracle personnel manage these prerequisite user account settings.
Corrections	Enable data change users with this role to delete documents	Allows the user, if they also have the data correction system role flag, to delete placeholders in Oracle Site Activate. Prerequisite individual user account settings: Administrative or Participatory system role and access to corrections page (data change) enabled for user account. Oracle personnel manage these prerequisite user account settings.
Corrections	Enable blanking activity completed date (when user has access to correct completed activities)	Allows the user to blank out ('undo') activities for all artifact types: documents, submissions, packages, reviews, and contracts. Corrections users can undo activities in any study they have access to in the **Corrections** tab. Non-corrections users can only blank out dates for activities that they completed in the placeholder. Self-serve correction feature needs to be enabled, at the account level, for non-corrections users to blank out their dates.
Country management	Enable country status change	Allows the user to change the status of individual countries in studies to which the user has access.
Document management	Enable access to quarantine files	Allows the user to access the **Quarantine** page to accept files received from sites through Oracle Site Activate LITE or via email integration through the **Quarantines files** link in the **More** menu.
Document management	Enable manual doc export	Allows the user to manually generate a new package export if the original package has been replanned or recently completed.
Document management	Enable access to Expiring documents list	Allows the user to access the expiring documents page through the **Expiring Items** link in the **More** menu.
Document management	Enable management of electronic documents	Allows the user to tag a document for electronic signature. Electronic Signature feature must be enabled at the account level.

Functional area	Permission	Description
Document management	Enable signing of electronic documents	Allows the user to electronically sign a document via Adobe Sign. Electronic Signature feature must be enabled at the account level.
Document management	Allow for cancel of document editing	Allows the user to cancel in-progress document editing. Canceling discards any changes made by the user who checked the document out for editing and unlocks the activity in Oracle Site Activate so that it can be completed.
Help	Enable access to Oracle Help Center	Enables the user to access product documentation on the Oracle Help Center from a link in the Oracle Site Activate Support menu.
IP release	Enable package update	Allows the user to replace documents in packages that have been defined, but not completed.
Milestones	Enable user to hide milestone and submission dates from calendar	Allows the user to show and hide milestones on the milestone timeline. Add and remove: document and submission milestones from the Oracle Site Activate homepage **Planning** and **Corrections** tabs and/or initial submission and final approval dates from the submission widget. This business permission is independent of the "Enable users to plan milestones" permission below.
Milestones	Enable user to plan Milestones	Allows the user to plan country and site level milestone dates on the milestones timeline or in the **Planning** tab on the home page.
Reports	Enable Analyze custom reports	Allows the user to access Oracle Health Sciences Analyze using the **Analyze Reports** link in the Oracle Site Activate **Reports** menu.
Reports	Enable access to Data Export Utility	Allows the user access to the Data Export Utility option from the Reports drop-down menu, and allows user to create exports from the available data cubes.
Site library	Enable site library use	Allows the user to access the site library feature if two sites have a matched profile and artifacts are configured for site library use.
Site management	Enable change Principal Investigator	Allows the user to initiate the Replace PI feature to change an investigator after the start-up process has begun.
Site management	Enable site status change	Allows the user to change the status of individual sites in studies to which the user has access.

Functional area	Permission	Description
Study library	Enable document upload, removal, and Type management in Study Library	Allows the user to upload to and remove documents from the Study Library. Also allows the user to add, edit, and remove document Types in Study Library. Without this permission, the team member can see files that have been posted in the library but cannot upload or edit the files or manage document Types.
Study library	Enable document grouping in study library	Allows the user to create, edit, and delete document groups in the Study Library.
Study setup	Enable study participants to add study country	Allows the user access to the **Add new study country** option in the **Actions** drop-down menu. User must have either Administrative system role, or both the Participatory system role and the business permission to Enable study participants to add study country.
Study setup	Enable study participants to manage sites and staff	Allows participatory users to add or edit a site/principal investigator and/or staff, delete a site, and replace a principal investigator and/or staff. Note: If the account creates sites only via API integration (site creation disabled in the Oracle Site Activate user interface), users with the new permission will **not** have the ability to add a site from within Oracle Site Activate. Users must also have the “Enable change Principal Investigator” business role permission in to replace a Principal Investigator and the “Enable site status change” permission to edit the site’s status.
Study setup	Enable edit planned number of sites	Allows participatory users to edit the planned number of study sites.
Study setup	Enable study country deletion	Allows user to delete countries and associated study sites from existing studies.
Submissions	Enable managing agency upload	Allows the user to access the **Manage submission agencies** option in the **More** menu and upload a CSV file of agencies.
Team member assignments	Enable managing team members	Allows the user to assign team members to roles in studies, countries, and sites through the **Team members** menu item.
Team member assignments	Enable managing user roles	Allows the user to assign/unassign business roles to individual users through the **Team members** menu item

Functional area	Permission	Description
Team member assignments	Enable manage user accounts	Allows the user to provision, lock, and unlock individual user accounts within the enabled user's Oracle Site Activate account.

Assigning roles to team members

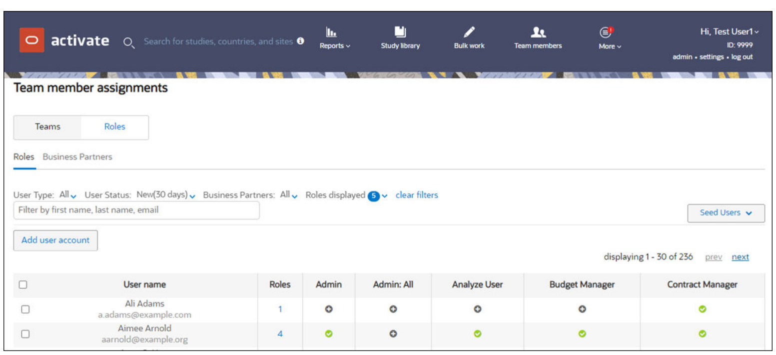
If you have "Enable managing team members" business role permission, you can add and remove business roles for team members, including sites and business partners, if applicable. Access the Team member assignments area using the Team Members option in the top navigation bar.

The Team member assignments **Roles** tab filter panel (above the grid) provides filtering options that allow you to filter data displayed in the grid by:

- User Type (All, CRO/Sponsor, Site, Associate)
- User Status (All, Users without roles assigned, Inactive (90 days), New (30 days)
- Business Partners (select from list)
- Roles Displayed (up to 10 roles can be displayed in the grid at one time)
- Individual first name, last name, or email

Using a combination of the above filters, examples of use cases are:

- Perform alphanumeric sort on User name and Roles columns
- Select one, multiple, or all users to view in a summary table at the top of the Roles tab to optionally add roles in bulk for the selected users
- View the number of roles assigned to an individual user. When one or more roles have been assigned, the number will be hyperlinked (in the Roles column) to a pop-in that lists the user's role(s) and the date(s) of assignment.
- Add or remove roles with just one click when a role has been added to the tab's filters. Click the green check mark or gray plus sign to add/remove roles



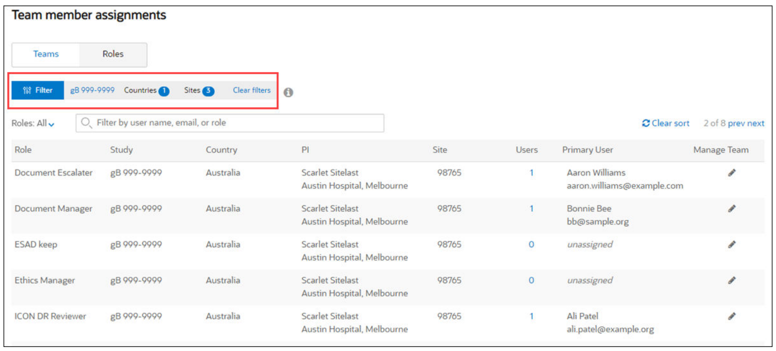
> **Tip:**
>
> The **Roles displayed** filter allows you to save selected roles for automatic display in the team members grid. Choose the roles you'd like to display by default, click **Save**, and your selected roles display each time you return to the page.

Managing teams

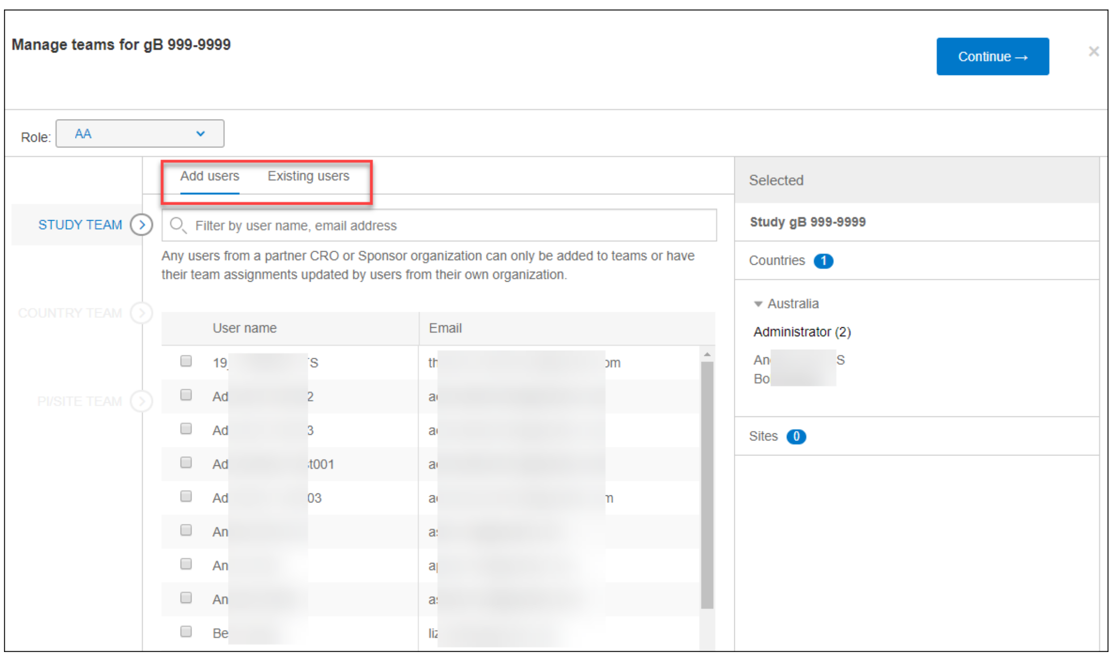
The Teams tab displays role assignment information in a filterable grid layout, with one team per row. If you manage teams in Oracle Site Activate, you can quickly review and modify team assignments at the study, country, or site level.

The filter panel, above the teams grid, allows you to define the content of the grid by:

- Study, Country, and Sites
- Role
- Individual user



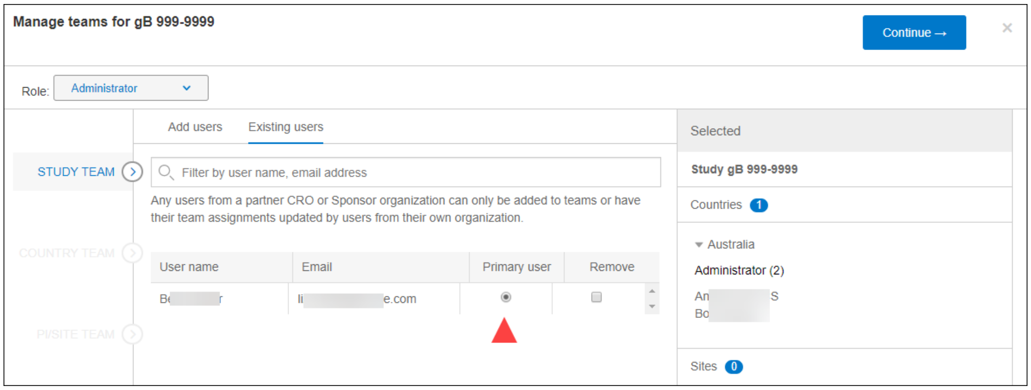
When you click the numeral in the Users column or click the pencil icon above, you can then select unassigned users to add to the team at the study, country, and team levels in the interface shown below. The summary table to the right shows the selections you make on the Add users tab. To view currently assigned users and make adjustments (for instance, to change or remove the primary assignment), click the Existing users tab.



Primary assignments

When you assign multiple people to the same role for a study country or site, you can designate one person to be the primary assignee. That person's name appears in Oracle Site Activate and on reports as the person who's ultimately responsible for completing activities assigned to the role (although others also assigned to the role can still complete them). This helps team members know who to contact for status updates and who can help unblock activities.

If one person is assigned to a role, by default, that person becomes the primary assignee.



Viewing assignee by activity

Oracle Site Activate allows all users to view the assigned role and assigned user(s) for unblocked document, contract, submission, submission package, and IP package activities on the Overview, country, and/or site pages.

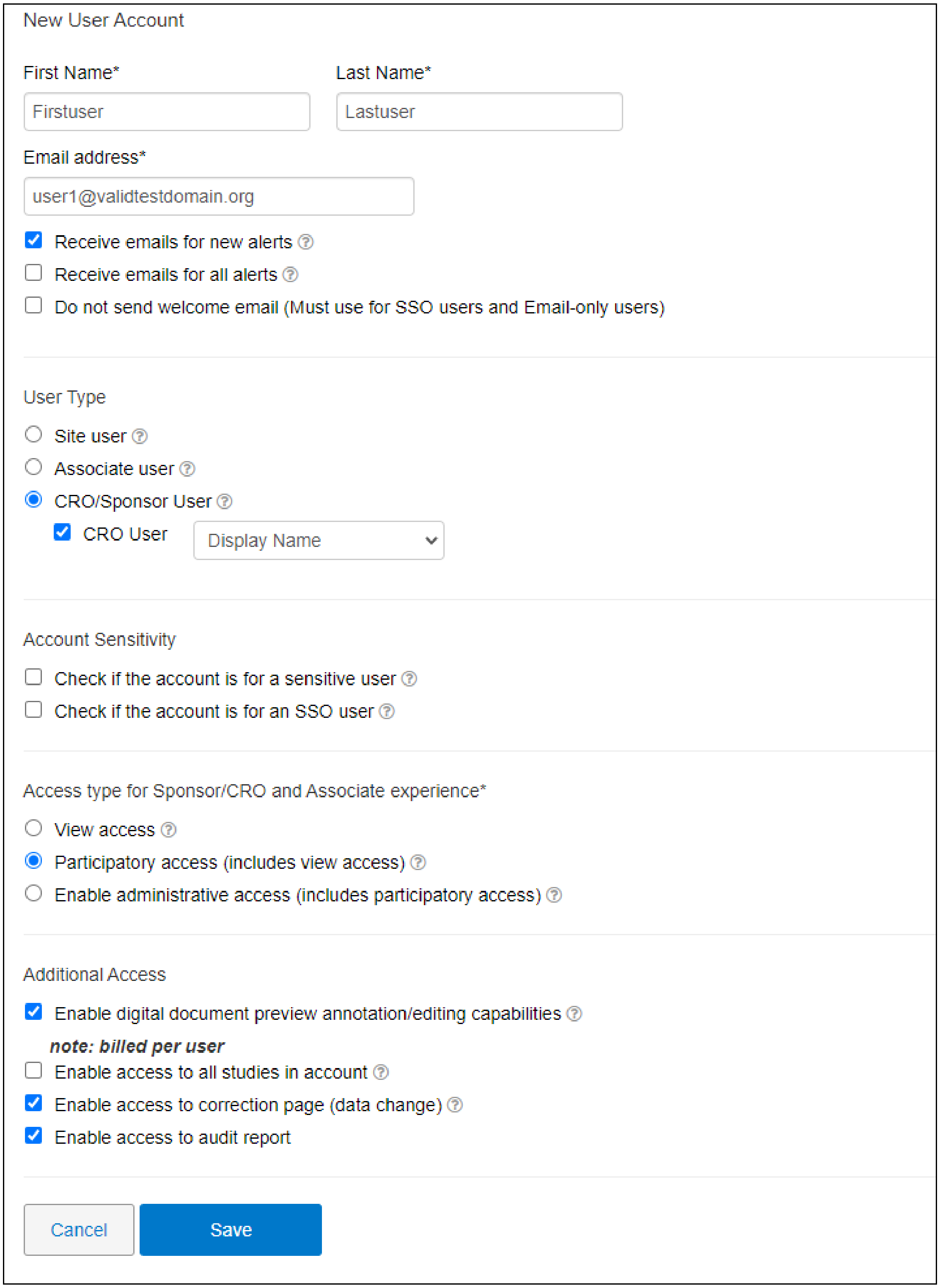
Users who have at least one role with the "Enable self assignment of activities" business role permission can view an "assign to me" link for self-assignment of the unblocked activity. When a permissioned user assigns an activity to himself or herself at the country or site level, that user will automatically be assigned to that site or country as the role of the activity.

> **Note:**
>
> When an activity has a role of "Anyone," no Assignee(s) will be listed and the **assign to me** link does not display.

Creating new user accounts

Oracle Site Activate supports creating user accounts by two methods. User accounts can be created via API integration, or a designated user in your organization can create a user account manually from within Oracle Site Activate. To discuss API user account creation, please contact your Oracle Project Manager or Account Manager.

Oracle Site Activate users who have a the business role permission, “Enable manage user accounts,” can create and edit individual user accounts and manage individual user account settings within the team member assignments area.



Account options dynamically display depending upon the selected “User Type.” For instance, if user type “Site User” is selected, only those options relevant to site users display. Below are the available settings, by user type.

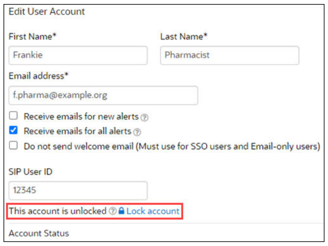
When the User Type selected is "CRO user" or "Associate user," you'll also have the ability to specify a CRO/Sponsor value that has been saved for your organization's account. This selection controls the user's access to certain study/site data, meaning Oracle Site Activate prevents assignment of a CRO or Associate user to a study, country, or study site if the external CRO or sponsor value saved for the user’s account does not match that of the study. This logic also prevents assignment when no sponsor or CRO setting exists for the study.

Type	Setting	Site User	Associate User	CRO or Sponsor User
Alerts	Receive emails for new alerts	yes	yes	yes
Alerts	Receive emails for all alerts	yes	yes	yes
Alerts	Do not send welcome email (must use for SSO users and email-only users)	yes	yes	yes
Account sensitivity	Check if the account is for a sensitive user	yes	yes	yes
Account sensitivity	Check if the account is for an SSO user	yes	yes	yes
Access type	View access	yes	yes	yes
Access type	Participatory access	yes	yes	yes
Access type	Administrative access	no	yes	yes
Additional access	Enable digital document preview annotation/editing capabilities (billed per user)	yes	yes	yes
Additional access	Enable activity completion by email	yes	no	no
Additional access	Email access only	yes	no	no
Additional access	Enable access to all studies in account	no	yes	yes
Additional access	Enable access to correction page (data change)	no	yes	yes
Additional access	Enable access to audit report	no	yes	yes

Locking and unlocking user accounts

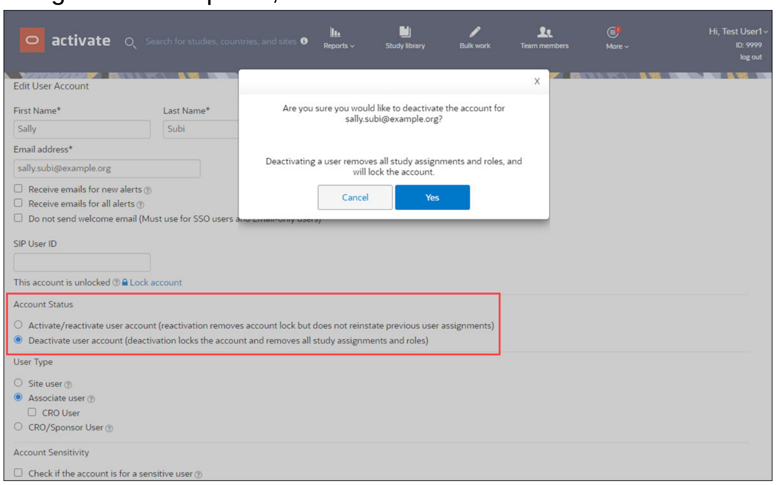
Users with the “Enable manage user accounts” business permission can lock and unlock user accounts in the team member assignments area, on the edit user page.

User accounts automatically lock when a user enters incorrect credentials three consecutive times. Customers can unlock these accounts without Oracle intervention.



Deactivating and reactivating user accounts

If you have permission to manage user accounts and you need to deactivate an account, you can do so from the Add/Edit User Account page. When you acknowledge the deactivation activity, Activate removes all study assignments and roles from the account and locks the account as well. Activate prevents role assignment for deactivated accounts. If role assignment is required, the account must be reactivated.



You can also reactivate accounts from the Add/Edit User Account page. When you reactivate an account, Activate removes the account lock but does not reestablish any previous study assignments or roles. This expected behavior allows you to evaluate any access changes that may have occurred during the time the individual user account was deactivated.

> **Note:**
>
> when a user's account has been deactivated, that user no longer has access to Oracle Site Activate reports in Oracle Site Analyze. Deactivation in Oracle Site Activate does not automatically remove access to Oracle Site Select reports if the user had report access from both applications. However, if the user account is reactivated, the account must be reassigned report access permission to provide access to Oracle Site Activate reports inOracle Site Analyze.

- Assign or unassign a role for one team member
  Learn how to quickly add or remove a role for an individual team member.
- Assign team members for study, country, and site
  When necessary, you can add new team members to the study team at the study, country, and/or site level.

- Self-assign an activity
  If an unblocked item includes an activity you can complete, you can self-assign the activity.
- Change an assignment
  Learn how to change an assignment or the primary assignee for a task.
- Add new team member accounts
  As your study team changes over time, you can create user accounts for new team members, when necessary.
- Deactivate or reactivate a user account
  Learn how to deactivate and reactivate Oracle Site Activate accounts for users in your organization.

Assign or unassign a role for one team member

Learn how to quickly add or remove a role for an individual team member.

To complete this task, you must have a user role permission that allows you to manage user accounts. If you do not have the appropriate permission, contact your administrator/super user or Oracle support.

1. From the top navigation menu, select **Team members**.
2. Click the **Roles** tab.
3. In the filter panel, use the **Role** filter to identify the role you want to add or remove for the team member.
4. To find the team member, in the **Filter by. . .** field, and enter some or all of the team member's name or email address.
5. In the role grid under the Role column, click the gray plus sign to add the role for the user, or click the green check mark to remove the role for the user.
6. Click **Done**.

Assign team members for study, country, and site

When necessary, you can add new team members to the study team at the study, country, and/or site level.

To complete this task, you must have a user role permission that allows you to manage user accounts. If you do not have the appropriate permission, contact your administrator/super user or Oracle support.

1. From the top navigation bar, select **Team members**.
2. Click the **Teams** tab.
3. Filter the Teams tab to the preferred study, country, and site(s).
4. In the **Study team** section, under the **Add Users** tab, enter the name of the user, and click the check box to select.
5. At the upper right, click **Continue** to advance through the study, country, and site flows.
6. Click **Done**.

If configured for your account, Oracle Site Activate supports the ability to differentiate between internal and external team assignments. Users who have been designated as “sensitive” are differentiated with a label of "external” and may only be assigned by those users with a specific business role, although all users would have the ability to view all external user assignments.

Self-assign an activity

If an unblocked item includes an activity you can complete, you can self-assign the activity.

To complete this task, you must have a user role permission that allows you to self-assign activities. If you do not have the appropriate permission, contact your administrator/super user or Oracle support.

In an unblocked document, contract, submission, submission package, or IP package placeholder modal on the Account Overview, country, and/or site page, click **assign to me**.

Change an assignment

Learn how to change an assignment or the primary assignee for a task.

To change an assignment or primary assignee assignment, on the site level page, click **Edit** next to the role name.

Add new team member accounts

As your study team changes over time, you can create user accounts for new team members, when necessary.

To complete this task, you must have a user role permission that allows you to manage user accounts. If you do not have the appropriate permission, contact your administrator/super user or Oracle support.

1. From the top navigation bar, select **Team Members**.
2. Click the **Roles** tab.
3. Click **Add user account**.
4. Enter the user's **First name**, **Last name**, and **Email address** (required fields).
5. Select the appropriate account options (e.g., alerts, user type, access type, etc.). For CRO/Sponsor and Associate user types, select the CRO/Sponsor value from the drop-down menu.
6. Click **Save**.

Deactivate or reactivate a user account

Learn how to deactivate and reactivate Oracle Site Activate accounts for users in your organization.

To complete this task, you must have a user role permission that allows you to manage user accounts. If you do not have the appropriate permission, contact your administrator/super user or Oracle support.

1. From the top navigation bar, select **Team Members**.

2. Click the **Roles** tab.
3. Enter the team member's name or email address in the search field.
4. In the result list, hover over the team member's name, and click edit ( ).
5. Deactivate account: In the **Account Status** section, click the **Deactivate...** radio button. Click **Yes** in the confirmation modal. Scroll to the bottom of the page, and click **Save**.
6. Reactivate account: In the **Account Status** section, click the **Activate/ reactivate...** radio button. Scroll to the bottom of the page, and click **Save**.

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About API Integration

If you are responsible for integration and endpoint management, you'll find details in this chapter. Links include task-based instructions for monitoring API messages on the Event Messages page and for configuring endpoints with common authentication methods (e.g., Standard, OAuth, etc.).

- Access API documentation
  API documentation provides the message detail your organization will need for data integration with Oracle Site Activate.
- View event messages
  Evaluate API message activity in the Event Messages area to see individual message detail and actions.
- Retry a single failed event message
  Filter the event message list to quickly locate a single failed event message so that you can retry sending it.
- Retry failed event messages in bulk
  Learn how to efficiently manage failed event message retries by filtering the message list and initiating the retry in bulk.
- Retry successful event message
  Under certain circumstances, you may want to retry an event message that was originally successful. This procedure describes how you can optionally filter the event messages list to find the successful message.
- Download event messages to CSV
  When you want to view event messages outside of the application, you can export the list to a comma separated values (.csv) format spreadsheet.
- Create publishing endpoint with standard authentication
  When you create an endpoint with standard authentication type, it displays on the left side of the Publishing to an Outside API page, and the endpoint and "view" pop-in details are also available for selection on the Edit Study page.
- Create publishing endpoint with basic authentication
  Using the steps in this procedure, you can quickly create a publishing endpoint with username and password authentication type.
- Create publishing endpoint with OAuth 2.0 authentication
  Learn the steps required to create a publishing endpoint that uses the industry-standard OAuth 2.0 authentication method.
- Edit an existing endpoint
  If you need to update attributes for an existing endpoint, use this procedure. When you finish making your updates, the endpoint details will be updated on the Edit Study page as well.
- Delete an endpoint
  Sometimes you'll need to delete an endpoint so that it isn't available for selection. Use this procedure to ensure that messages stop flowing to the endpoint.

- Configure custom eTMF attributes
  Create up to 10 custom fields to capture document data and send that data in an eTMF publish message.
- Review files in IRB documents queue
  If you have a role that allows you to access the IRB approval documents queue, you can quickly evaluate files received via API from IRB integration partners.
- Match an IRB file or add new item
  If you have a role that allows you to access the IRB approval documents queue, you can attempt to match a file in the queue to an existing placeholder item or add a new item if no match is found.

Access API documentation

API documentation provides the message detail your organization will need for data integration with Oracle Site Activate.

> **Note:**
>
> You must have a business role with “View event messages” permission to complete this procedure.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. On the Event Messages page, click **API Documentation** at the upper right.

   API documentation opens in a new browser tab.

View event messages

Evaluate API message activity in the Event Messages area to see individual message detail and actions.

> **Note:**
>
> You must have a business role with “View event messages” permission to complete this procedure. Success messages remain in the database for 7 days and Failed messages remain for 14 days after which the messages are automatically removed from the database.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. Optional: Adjust the available filters (**Display Messages From**, **Status**, **Type**, etc.) and/or search a text string (**Message Contains**) and click **Find**.
3. To view message details, on a message row, click **Message & Response**.

Retry a single failed event message

Filter the event message list to quickly locate a single failed event message so that you can retry sending it.

> **Note:**
>
> You must have a business role with “View event messages” permission to complete this procedure.
> Also note, Failed event messages are available for 14 days. After 14 days, the messages are automatically removed from the database.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. (Optional) Use the **Display messages from**: menu at the upper left of the page to specify a date range. Use the **Status** filter to select **Failed**. Use the **For failed Messages from the past**: menu at the upper right of the page to display failed messages from the past Hour (default), Day, 3 Days, or Week.
3. (Optional) Adjust the message list using the **Message Contains** (search), **Show**, and/or **Type** filters.
4. Locate the message row for the failed message you want to retry. At the far right, click **Retry**.

Retry failed event messages in bulk

Learn how to efficiently manage failed event message retries by filtering the message list and initiating the retry in bulk.

> **Note:**
>
> You must have a business role with “View event messages” permission to complete this procedure.
>
> Also note, Failed event messages are available for 14 days. After 14 days, the messages are automatically removed from the database.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. (Optional) Use the **Display messages from**: menu at the upper left of the page to specify a date range. Use the **Status** filter to select **Failed**. Use the **Endpoint** filter to choose a specific endpoint where messages have failed. Use the **For failed Messages from the past**: menu at the upper right of the page to display failed messages from the past Hour (default), Day, 3 Days, or Week.
3. (Optional) Adjust the message list using the **Message Contains** (search), **Show**, and/or **Type** filters.

4. (Optional) If you filtered the list to a subset of messages, and the list now includes successful and failed messages, check the **Only Retry Failed** check box at the upper right.
5. At the upper right, click **Retry**.

Retry successful event message

Under certain circumstances, you may want to retry an event message that was originally successful. This procedure describes how you can optionally filter the event messages list to find the successful message.

> **Note:**
>
> You must have a business role with "View event messages" permission to complete this procedure. Also note, Success messages remain in the database for 7 days. After 7 days the messages are automatically removed from the database.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. (Optional) Use the **Display messages from**: menu at the upper left of the page to specify a date range. Use the **Status**: menu to select **Success**.
3. (Optional) Adjust the message list using the **Type**, **Endpoint**, **Message Contains** (search), and/or **Show** filters.
4. Locate the message row for the successful message you want to retry. At the far right, click **Retry**.

Download event messages to CSV

When you want to view event messages outside of the application, you can export the list to a comma separated values (.csv) format spreadsheet.

> **Note:**
>
> You must have a business role with "View event messages" permission to complete this procedure.

1. From the top navigation menu, hover over **More** and click **Event messages**.
2. Optional: Adjust the available filters (**Display Messages From**, **Status**, **Type**, etc.) and/or search a text string (**Message Contains**) and click **Find**.
3. When the list displays your preferred messages, click **Download CSV** at the upper right of the page.

Create publishing endpoint with standard authentication

When you create an endpoint with standard authentication type, it displays on the left side of the Publishing to an Outside API page, and the endpoint and "view" pop-in details are also available for selection on the Edit Study page.

You must have a business role with “Enable endpoint management” permission to complete this procedure. All fields in this procedure are required.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. At the upper left, at **Publishing endpoints**, click **+** to add a new endpoint.
3. Enter a **Publishing endpoint** name.
4. Enter a **Publishing endpoint URL**.
5. Choose a Vendor from the **Vendor Mapping** drop-down list.
6. Use the **Authentication type** drop-down menu to select **Standard**.

   The page refreshes to display required standard fields.
7. In the **Token** field, enter the authentication Token.
8. If preferred, enter a **Custom token name**. If valued, this field will be sent in outbound messages, paired with the key name set in the configuration.
9. Click **Save**.

The configured endpoint displays on the left side of the Publishing to an Outside API page. The endpoint and "view" pop-in details are also now available for selection on the Edit Study page.

Create publishing endpoint with basic authentication

Using the steps in this procedure, you can quickly create a publishing endpoint with username and password authentication type.

You must have a business role with “Enable endpoint management” permission to complete this procedure. All fields in this procedure are required.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. At the upper left, at **Publishing endpoints**, click **+** to add a new endpoint.
3. Enter a **Publishing endpoint** name.
4. Enter a **Publishing endpoint URL**.
5. Choose a Vendor from the **Vendor Mapping** drop-down list.
6. Use the **Authentication type** drop-down menu to select **Basic authentication**.

   The page refreshes to display required basic authentication fields.
7. In the **Username** field, enter the username associated with the endpoint.
8. In the **Password** field, enter the password associated with the username.
9. Click **Save**.

The configured endpoint displays on the left side of the Publishing to an Outside API page. The endpoint and "view" pop-in details are also now available for selection on the Edit Study page.

Create publishing endpoint with OAuth 2.0 authentication

Learn the steps required to create a publishing endpoint that uses the industry-standard OAuth 2.0 authentication method.

You must have a business role with “Enable endpoint management” permission to complete this procedure. All fields in this procedure are required.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. At the upper left, at **Publishing endpoints**, click **+** to add a new endpoint.
3. Enter a **Publishing endpoint** name.
4. Enter a **Publishing endpoint URL**.
5. Choose a Vendor from the **Vendor Mapping** drop-down list.
6. Use the **Authentication type** drop-down menu to select **OAuth 2.0**.

   The page refreshes to display required OAuth 2.0 fields.
7. In the **Access Token URL** field, enter the access token.
8. In the **Token name** field, enter the token name.
9. In the **Client ID** field, enter the client ID.
10. In the **Client Secret** field, enter the client secret.
11. Use the **Grant Type** drop-down menu to select either **Client Credentials** or **Password Credentials**.
12. If you selected Client Credentials, use the **Client Authentication** drop-down menu to select either **Send as Basic Auth Header** or **Send Client Credentials in the Body**.
13. If you selected Password Credentials, enter the **Username** and **Password**.
14. Click **Save**.

The configured endpoint displays on the left side of the Publishing to an Outside API page. The endpoint and "view" pop-in details are also now available for selection on the Edit Study page.

Edit an existing endpoint

If you need to update attributes for an existing endpoint, use this procedure. When you finish making your updates, the endpoint details will be updated on the Edit Study page as well.

> **Note:**
>
> You must have a business role with “Enable endpoint management” permission to complete this procedure.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. From the list on the left side of the page, click the endpoint you want to edit.
3. Edit as necessary. All fields are required.
4. Click **Save**.

The updated endpoint and "view" pop-in details are now available for selection on the Edit Study page.

Delete an endpoint

Sometimes you'll need to delete an endpoint so that it isn't available for selection. Use this procedure to ensure that messages stop flowing to the endpoint.

> **Note:**
>
> You must have a business role with “Enable endpoint management” permission to complete this procedure. If the endpoint you intend to delete is included in one or more configurations, remove the endpoint before completing the steps below.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. From the list on the left side of the page, click the endpoint you want to remove.
3. Click **Delete endpoint**.
4. A confirmation message displays. Click **Yes, delete endpoint** to remove the endpoint, or **Cancel** to cancel the removal procedure.

If you confirmed endpoint deletion, the endpoint is removed from the Publishing to an Outside API page, the endpoint and "view" pop-in details are no longer available for selection on the Edit Study page, and messages will no longer be sent to the endpoint.

Configure custom eTMF attributes

Create up to 10 custom fields to capture document data and send that data in an eTMF publish message.

You must have a business role with “Enable endpoint management” permission to complete this procedure. All fields in this procedure are required.

1. From the top navigation menu, hover over **More** and click **Manage publish endpoints**.
2. In the left navigation panel, click **Custom eTMF Attributes**.
3. Click **Add a new field +**.
4. Enter a unique **Display name** to display in the document modal and a unique **eTMF label** to include in the eTMF publish message.
5. If enabled for your organization's account, use the **Category** drop-down control to select one or more categories for the attribute.
6. At **Values separated by a comma**, enter a comma-separated list of acceptable field values.

7. Optional: If users should always complete this custom field, check the box for **Require this field be complete when saving an artifact**.
8. Click **Save**.

Configured custom TMF fields display in a document modal's TMF Data section in the order of field creation. On the last item activity, when a required custom field is incomplete, Oracle Site Activate displays a reminder note in the item's Activity completion panel, "Additional fields need to be completed. Go to the Info tab." The reminder includes a link that directs you to the current modal's Info panel (e.g., Document Info, Budget Info, Contract Info, etc.) where you can then complete the required custom field in the TMF Data section.

Where custom eTMF attributes exist and eTMF publishing is configured, the custom fields are sent with the publish message using the specified "eTMF label" field name and the value you selected. If the custom field is not required, and you do not select a value in the item modal's TMF Data section, Oracle Site Activate sends the specified "eTMF label" field name with a null value. When no custom fields are defined, the message includes the object: "custom_etmf_fields": null.

Review files in IRB documents queue

If you have a role that allows you to access the IRB approval documents queue, you can quickly evaluate files received via API from IRB integration partners.

1. In the Oracle Site Activate global navigation bar, hover over the **More** menu and click **Quarantined files**.
2. On the **Quarantined files** page, click the **IRB documents** tab.
3. Optional: Filter the queue by file name, site, country, study or source.
4. To download a file, click the file name. If enabled for your account, you can also preview ( ) the file, if preview is enabled for your account.
5. In the **Action** column, click edit ( ) to attempt to match the received file to a placeholder item or delete the file from the queue.

Match an IRB file or add new item

If you have a role that allows you to access the IRB approval documents queue, you can attempt to match a file in the queue to an existing placeholder item or add a new item if no match is found.

1. In the Oracle Site Activate global navigation bar, hover over the **More** menu and click **Quarantined files**.
2. On the **Quarantined files** page, click the **IRB documents** tab.
3. Optional: Filter the queue by file name, site, country, study or source.
4. In the **Action** column, click edit ( ) and select **Match file**.
5. In the **Match file to an item** modal, evaluate the potential matching items. Click the radio button for a matching item. If no matching item, skip to step 11.

   Potential matching items display colored status indicators (e.g. orange for in progress, green for complete, etc.). The status indicators are intended to help you see when a document has already been added to certain placeholder and perhaps the placeholder should not be used again.

6. Click **Continue**.
7. In the **Enter metadata** modal, enter a **Document date**.
8. If enabled for the item, you may optionally check the box for **Share with sites**. Use the **Site Users** drop-down menu to select individuals or All.
9. Click the **Requires wet ink** check box if the item requires a physical signature.
10. Click **Done**.
11. If no matching item was found, click the **No match – add new item** radio button.
12. In the **Add a new item** modal, use the drop-down menu to select the type of document.
13. If the document is protocol related, choose the protocol from the drop-down menu.
14. Click **Continue**.
15. In the **Enter metadata** modal, enter a **Document date**.
16. If enabled for the item, you may optionally check the box for **Share with sites**. Use the **Site Users** drop-down menu to select individuals or All.
17. Click the **Requires wet ink** check box if the item requires a physical signature.
18. Click **Done**.