Oracle Life Sciences Site Select

Information for CRO and Sponsor Users

Release 25.1
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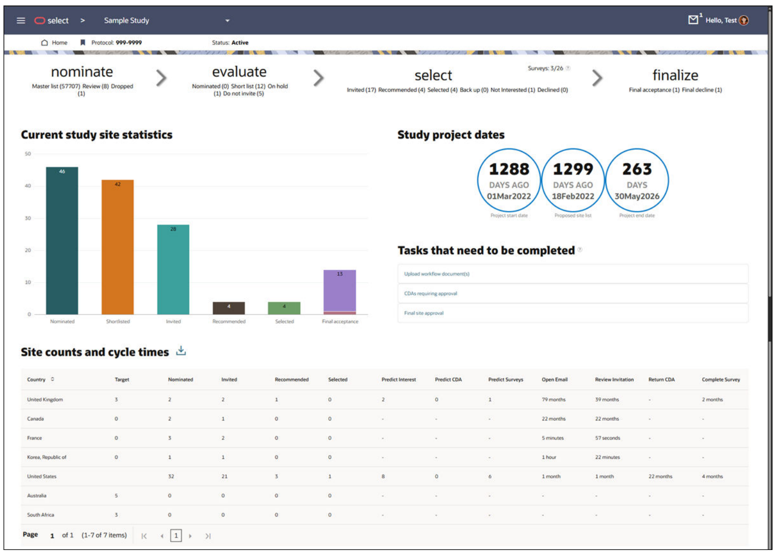
Contents

1 About Oracle Site Select

If you're new to Oracle Site Select, this guide will show you how this application uses evidence-based logic to help you find qualified study sites for your clinical trials. With custom workflows, Oracle Site Select helps you automate processes and refine the criteria required to identify, evaluate, and engage study sites.

Evaluate study and site progress and check your task list on the home page

The Oracle Site Select study home page provides an at-a-glance view of study and site statistics so you can quickly see study progress. A task list also shows those tasks that need your attention.

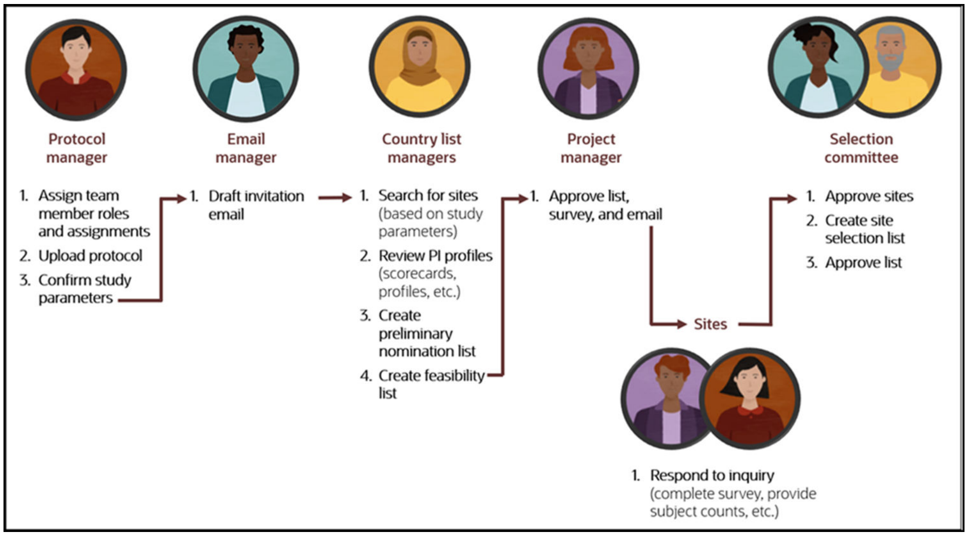


Intelligent, centralized site recommendations

Oracle Site Select can leverage your organization’s site list and curated datasources to help you create and manage a robust target site profile for evidence-based site selection. Our site recommendation engine helps identify sites with a proven track record of meeting enrollment dates and delivering quality subjects for the study's target population. Protocol matching technology also helps identify sites that meet your study eligibility parameters.

Your entire study team can collaborate online to define selection criteria and then evaluate candidate sites, select, and approve them. You won't need to create and maintain spreadsheets to manage and track site selection; the entire team sees the progress and results in Oracle Site Select in real time.

Using the site portal, site users can collaborate with you to complete tasks and return documents. If necessary, you can complete tasks in Oracle Site Select on behalf of sites.


Protocol manager
1. Assign team member roles and assignments
2. Upload protocol
3. Confirm study parameters
Email manager
1. Draft invitation email
Country list managers
1. Search for sites (based on study parameters)
2. Review PI profiles (scorecards, profiles, etc.)
3. Create preliminary nomination list
4. Create feasibility list
Project manager
1. Approve list, survey, and email
Sites
1. Respond to inquiry (complete survey, provide subject counts, etc.)
Selection committee
1. Approve sites
2. Create site selection list
3. Approve list

2

Navigation

This section, which is intended for all user roles, describes how to navigate in Oracle Site Select and provides helpful tips for managing your profile and password.

- Get around in Oracle Site Select
  The application provides global menus, links, and dashboards that allow you to transition between views and pages.
- Manage your profile and login credentials
  Oracle Site Select allows you to customize some elements of your user profile (e.g., display name, signature, profile picture, and more) with your preferred settings.

Get around in Oracle Site Select

The application provides global menus, links, and dashboards that allow you to transition between views and pages.

The page header provides several navigation options:

- Menu ☰ opens the global navigation menu drawer on the left side of your screen. Click again to close it, or use the collapse/expand ‹ toggle at the bottom to collapse the menu and pin it to the left or expand it. Your available menu options depend on your role and the permissions granted to you, so you may see some or all of the following options:
  Dashboards
  - My Dashboard
  - PSV Tracker
  - Email invitations
  - Data Export

  Study
  - Communications
  - Document submissions
  - Data source query
  - Study site matching

  Setup
  - Study details
  - Study data sources
  - Master list criteria
  - Site scoring
  - Email templates
  - Workflow configuration
  - Workflow documents

- Feasibility survey
- Milestones
- Manage reasons for study exclusion/disinterest

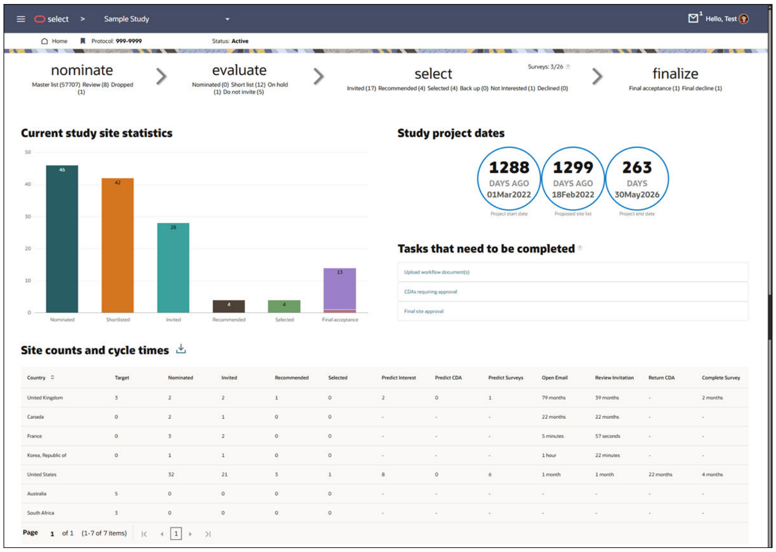
Account

- General
- Account data sources
- Disinterest and exclusion
- Email templates and config
- Study email history and status
- Integrations
- Event notification history and status
- Library documents
- Networks
- Note labels
- User and access
- Workflow templates

- The Select logo will navigate to the My Dashboard feature, which lists all your studies with your favorite(s) on top and key information about CDA status and site communications.
- The study picker supports type-ahead search. If you have user permission to view other studies, use the study picker's drop-down list to choose a different study. Again, studies you favorite are at the top of the list. You can also control the status of the studies that show in the drop-down list (e.g., if you prefer not to view Closed or Cancelled studies or want to view only Active studies). To specify the status(es) of studies you want in the list, use the Filter study list option in your user profile.
- At the right side of the page header, a message icon shows the number of new messages across your studies. When you have no unread messages, or if unread messages exist only in your current study, clicking the message icon opens the Site communications page for your current study. If unread messages exist in other studies, the icon displays a badge with the total number of unread messages. Click the icon to open a drop-down list of studies that also shows the number of unread messages in each study. Studies are listed in order of oldest unread message first. Click a study name to open its Site communications page.
- Your circular avatar, “Hello, <yourname>,” opens a new menu with access your profile, help, a link to API documentation, and a link to log out.

The persistent header, just below the page header, groups study related actions and information. For the chosen study, the Home icon returns you to the study home page with one click. Additionally, the persistent header shows the Favorite bookmark, study Protocol, and study Status.

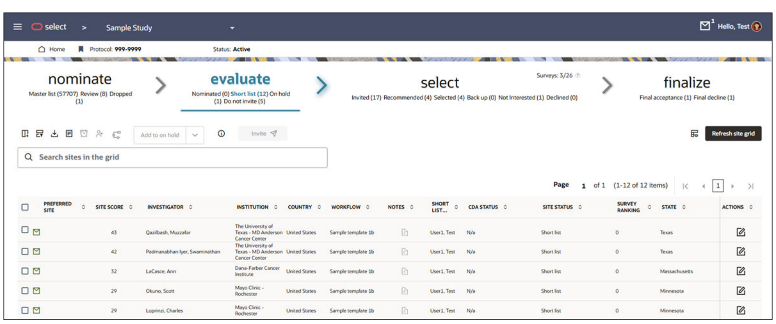
The study home page includes bar charts, milestone visualizations, tabular site count data, and a task list to help you track study progress and tasks you need to complete. The bucket state bar charts show the aggregate number of study sites placed in each represented bucket state over time. Recommended, Selected, and Final Acceptance bar charts display stacked values when available. Hover over the bar charts to see detail.



The study home page also includes Site count and cycle times detail, which you can download, if preferred. The table shows the real-time status of site enrollment and site counts as study team members and sites complete tasks. Compare progress across countries, evaluate the following for your study:

- Number of sites nominated, screened, selected, and invited
- Number of sites predicted to be interested in the study, complete their CDA, and complete their survey
- Average number of days that it takes sites to open and review the invitation email, return the CDA, complete surveys, and complete the survey and prestudy visit
- Target number of sites by country
- Number of sites nominated, screened, selected, and invited by country
- Average cycle time for the invitation, survey, study visit, and selection processes

If you perform site selection tasks, you can quickly switch between nominate, evaluate, select, and finalize buckets by clicking the bucket name or one of the individual bucket states. You'll see the bucket navigation options at the top of the study home page and above all bucket site grids. When navigating among site grid buckets, a blue underline indicates the current bucket and bold, blue text indicates the current bucket state (for example, in the image below, the current view is the Short list bucket state in the evaluate bucket).



Manage your profile and login credentials

Oracle Site Select allows you to customize some elements of your user profile (e.g., display name, signature, profile picture, and more) with your preferred settings.

At the top right of any Oracle Site Select page, click your circular avatar, and click the " my profile" menu option. On your User profile page, you can change your first name, last name, and job title to your preferred display values. Your email address displays; however, the email field is not editable in this view. Please contact your Oracle Site Select administrator or super user if your email address needs to be modified.

If you are responsible for one or more study setup tasks, you can optionally enable email reminders for these tasks using the toggle control just below the email address field.

On the right side of the profile page, you can optionally upload your photo or other image. If you choose to do so, the photo replaces the circular initial icon in the page header. Accepted images are:

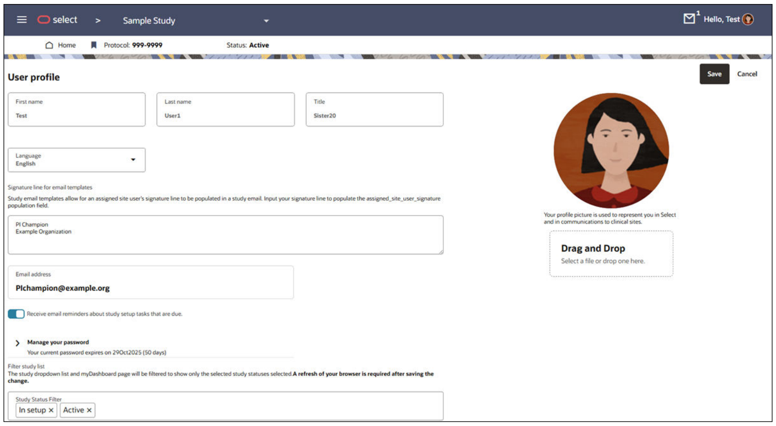
- Up to 10 MB file size
- JPEG, GIF, TIF, or PNG file type (you can crop JPEG, TIF, and PNG images. GIF file cropping is not currently supported.)

The image will also be attached to emails that are sent to sites to help personalize site communications.

Periodically, you'll need to change your application password. At the profile's lower left, you'll see how many days remain before automatic password expiration. However, you can change your password at any time using the fields in the Manage your password section.

> **Note**
>
> If your organization has configured single-sign on (SSO) integration with Oracle Site Select, you won't manage your password in your profile. Instead, your user ID and password will be managed by your organization's identity provider application (e.g., an employee portal or other organization-managed site).

You can optionally specify the study status(es) you prefer to view in the Oracle Site Select study selector in the page header and on your My Dashboard page. For example, if you only want to see your permissioned studies that are in Active status, you can filter for only Active studies using the Filter study list control at the bottom of the profile page.



- [Log in to Oracle Site Select](#)
  You'll manually provide your log in credentials only if your organization has not configured Single Sign On (SSO) integration with Oracle Site Select.
- [Reset your password](#)
  Use this procedure if you've forgotten your password. If you want to change your password, use the "Change your password" procedure instead.
- [Change your password](#)
  If your user account allows you to log in by manually supplying your user ID and password credentials, you can update your password at any time using the option in your Oracle Site Select user profile.

Log in to Oracle Site Select

You'll manually provide your log in credentials only if your organization has not configured Single Sign On (SSO) integration with Oracle Site Select.

> **Note**
>
> If your organization has configured a Single Sign On (SSO) integration with Oracle Site Select, you won't log in manually using the procedure below. If you're already logged in to your organization's IDP (identity provider application - often an employee portal), you'll be logged into Oracle Site Select automatically.

1. Using your web browser, display the Oracle Site Select login page.
2. At **Email address**, enter your email address.
3. At **Password**, enter your password, then click **Log in**.

Reset your password

Use this procedure if you've forgotten your password. If you want to change your password, use the "Change your password" procedure instead.

> **Note**
>
> This procedure does not apply if your user account has been configured with Single Sign On (SSO) integration to Oracle Site Select.

1. Using your web browser, display the Oracle Site Select login page. On the right, click **Forgot your password?**
2. At Email address, enter your email address, then click **Done**.
3. Check your email inbox for a message sent from "no.reply.select@oracle.com, and follow the password reset instructions included in the email.

Change your password

If your user account allows you to log in by manually supplying your user ID and password credentials, you can update your password at any time using the option in your Oracle Site Select user profile.

> **Note**
>
> This procedure does not apply if your user account has been configured with single sign on (SSO) integration to Oracle Site Select.

1. If you are already logged into Oracle Site Select, at the far right of the page header, click your circular avatar, then click **my profile**.
2. At **Manage your password** click > to expand the section.
3. At **Current password**, enter your current password.
4. Enter your new password at **New password**. Password requirements are:
   - must be at least 8 characters
   - must contain at least one each of an upper-case letter, a number, and one of the symbols !, @, #, $, %, ^, &, *
   - must not reuse any of the previous five passwords
5. **Re-enter new password** to confirm.
6. Click **Update password**.

> **Note**
>
> Passwords automatically expire after 180 days.

3 Dashboards

Oracle Site Select includes dashboards that provide tools for navigating, tracking, and analyzing your sites and your studies.

> **Note**
>
> Your user role permissions determine your access to each dashboard. If you need access to one of the options below and you do not see it in the Dashboards menu, please contact your account administrator.

The **My Dashboard** feature lets you access a personalized overview of your assigned studies. From here, you can view a study grid showing site progress, study communications, and pending CDAs, and easily navigate to any study's home page. You can also mark studies as favorites to keep them sorted at the top of your list for quick access.

The **PSV Tracking** dashboard, available to those with *PSV Dashboard* permission, allows you to monitor site visits before finalization by listing sites that have reached at least the Recommended bucket; the dashboard will display these sites even after they have moved beyond this stage.

The **Email invitations dashboard**, available with *View Dashboards* permission, offers graphical and tabular insights into the status of a study's invitations, including a funnel chart for site responses and a bar graph for invitation rounds, along with a table tracking all invitation and re-invitation dates for invited sites.

The **Data Export** option, for those with *Data Export Management* permission, provides access to the self-service Data Export Utility, where you can design and download custom CSV extracts of key study data, including site feasibility, survey responses, notes, and study site users.

- My Dashboard
  The study level My Dashboard feature gives you multiple options to access and navigate your studies.
- PSV Tracker
  Use the Pre-study visit tracking dashboard to track site visits prior to site finalization.
- Email invitations
  The Email invitations dashboard provides a convenient place to review the status and outcome of a study's invitations in graphical and tabular formats.
- Data Export
  The Data Export dashboard option opens the self-service Data Export Utility (Oracle Site Analyze required).

My Dashboard

The study level My Dashboard feature gives you multiple options to access and navigate your studies.

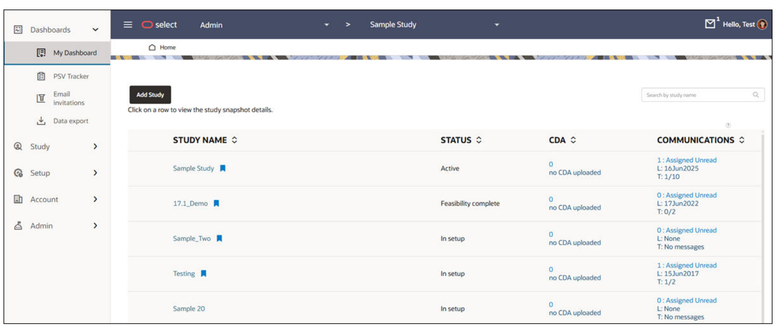
In the global menu Dashboards section, you'll see a My Dashboard option. You can also access your My Dashboard view by clicking the logo select in the page header.

Your My Dashboard page is specific to your study assignments. It includes a study grid with quick views into the progress of sites in the study and insight into study communications and pending CDAs. Click any linked study name to navigate to that study's home page. You can interact with that study as usual and favorite the study if preferred. Your favorite studies sort to the top of the study grid (alphabetically among any other favorite studies).

Your user account permissions also affect the display of other menu or action items on your My Dashboard page. For example:

- If you have an account administrator permission (such as user management), you can see the global "account" menu, and the menu has all items you have permission to use.
- When you have *Account study creation* permission, you'll see an Add Study action button above the study list. Just enter a unique study name and ID to create the study within the account, and you'll see a confirmation when successful. After creation, the new study's home page displays and includes a "Manage study details" task link to provide quick access to the first step in new study setup.

Additionally, you can control which studies display based on Status. For instance, you can choose to display only those studies in Active or In setup status and filter out all others. You'll set this option in your "my profile" page (click the circular avatar at the upper left of any page) using the Filter study list control. Please note that this setting will also affect the studies returned in the page header's study picker.



A sortable CDA column shows the count of actionable CDAs (those in Requires review or Final review status) and the date of the last CDA uploaded for a site assigned to you. The CDA column design brings higher visibility to these documents, as they can be challenging to track as they progress from submission to approval.

Check the Communications column to see if unread messages might need to be addressed. This column reflects multiple totals, and the stacked numbers are:

number = the total unread communications from sites assigned to you for the study

L = Date last message received from a site in the study

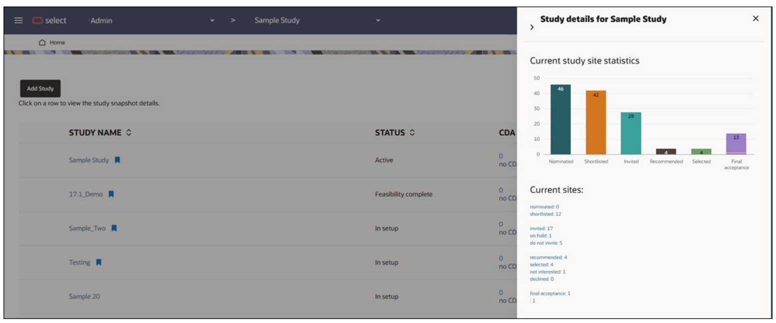
T = Total unread messages from sites in the study / Total messages received from sites in the study.

My Dashboard also includes a study details drawer component that opens from the right side of the page when you click on a study row. From top to bottom, the drawer displays:

- Study details, which is an expandable accordion list of values saved on the Study details page. This section can display:

- Study ID
- Protocol number
- Study type
- Study sponsor
- Study internal description
- Study internal ID
- Study internal status
- Study owner
- Study partner ID

- Study site statistics (the same progress visualization you see on that study's home page)
- Current site counts by bucket state. Click to navigate directly to any listed bucket state.



PSV Tracker

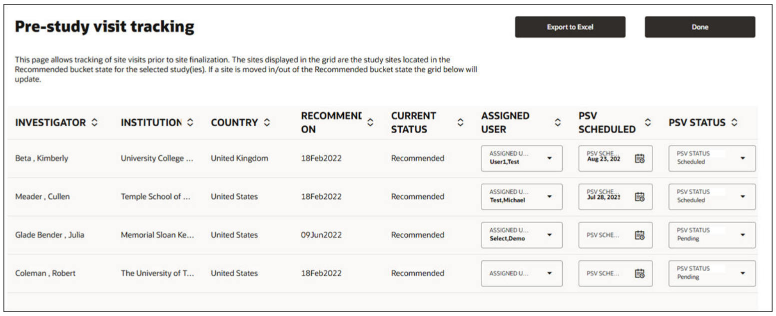
Use the Pre-study visit tracking dashboard to track site visits prior to site finalization.

If you have a role with *PSV Dashboards* permission, you'll see the PSV Tracker option in the global menu's Dashboards section. The dashboard lists sites in the current study that have progressed to at least the Recommended bucket state, and by design, the grid displays sites even when they have moved out of Recommended.

The Current Status column indicates the site’s current bucket state. Editable columns in the grid allow you to update values for:

- Assigned user – Lists users in the account who have PSV dashboard permission
- PSV scheduled – Date and time input
- PSV status – Pending, Scheduled, or Completed

If preferred, you can export the list of sites to Microsoft Excel. Just click the "Export to Excel" button at the upper right.

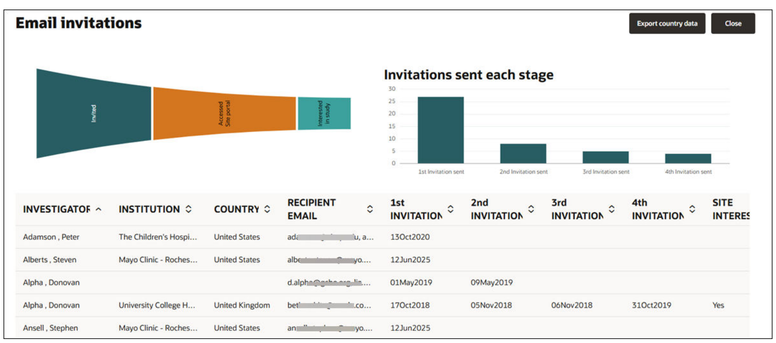


Email invitations

The Email invitations dashboard provides a convenient place to review the status and outcome of a study's invitations in graphical and tabular formats.

If you have a role with *View Dashboards* permission, you'll find the Email invitations dashboard in the global menu's ☰ Dashboards section. The dashboard includes a funnel chart that shows invited sites, sites accessing the portal, and sites expressing interest. The funnel chart has a clear legend and hover text for each section. a list of sites that received study invitation emails, the date the initial and subsequent invitations were sent, and if the site indicated interest in participation.

You'll also see a bar graph at the upper right that shows the number of invitations sent per stage (i.e., 1st, 2nd, 3rd, and 4th invitation) and a table listing invited sites with their invitation and re-invitation dates (i.e., track up to four invitations total). At the upper right, click the "Export country data" button to export the table data to CSV, and click "Close" to return to the study home page.



- [View a site's invitation status](#)
  The Email invitations dashboard lets you track up to four invitation attempts for a site in your study.
- [Resend study invite to one or more site(s)](#)
  Use the Resend Invite option in the site grid's Invited bucket state to resend a study invite to selected site(s).
- [Resend study invite to site or representative](#)
  Use the resend option in a site's details drawer to send another study invite to the site or their representative.

View a site's invitation status

The Email invitations dashboard lets you track up to four invitation attempts for a site in your study.

You must have a role with *View Dashboards* permission to complete this task.

1. Click menu ☰ in the page header.
2. Open the **Dashboards** menu and click **Email invitations**.

   The dashboard displays:

   - Dates that the first and subsequent invitations were sent to each listed site
   - If the site has indicated interest in participation (Yes or blank for no response)

Resend study invite to one or more site(s)

Use the Resend Invite option in the site grid's Invited bucket state to resend a study invite to selected site(s).

1. Navigate to the site grid's **Invited** bucket state in the **select** bucket.
2. In the site grid, check the box next to each site that you want to receive another invitation, then click **Resend Invite**.
3. In the Resend study invitation to selected site(s) modal, click **Send to unresponsive sites** or **Send to all sites**.
4. Click **Done**.

Resend study invite to site or representative

Use the resend option in a site's details drawer to send another study invite to the site or their representative.

1. In any **select** bucket state (e.g., Invited, Recommended, Selected, etc.), click the date listed in the site's **INVIT. RCVD.** column.
2. The site details drawer opens on the **Invitation and site status** tab. On the row for the site or other representative you want to resend the invitation to, click **resend** in the **Resend invite** column.

   A confirmation message displays.

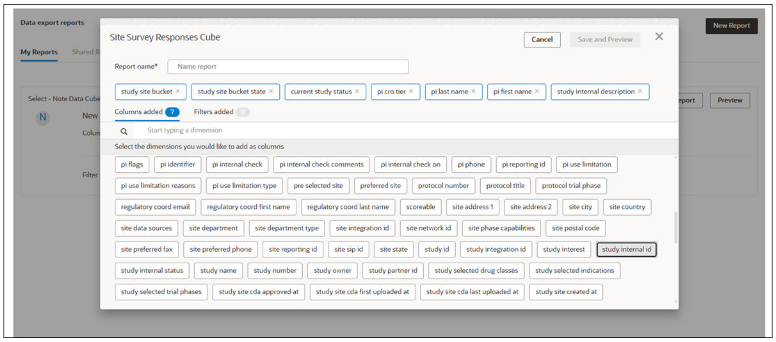
Data Export

The Data Export dashboard option opens the self-service Data Export Utility (Oracle Site Analyze required).

If you have a role with *Data Export Management* permission, you'll see the Data Export option in the global menu's ☰ Dashboards section. Data Export Utility for Oracle Site Select is a self-service tool that lets you design a CSV extract with specified data columns and filters. Currently, the extract includes data columns for site feasibility, survey response, notes, and study site users.

The Data Export Utility allows you to create new extracts based on:

- Cube (a multidimensional array of data) – The available data cubes are Note data, Site survey responses, Study site data, and Study-site users. You select one cube per extract.
- Columns (dimensions) – For example, PI Name, PI email address, Country, Study, etc. You can add columns in any order.
- Filters – For example, Study name, Country, etc. You can also add filters in any order and specify an operator (e.g., contains, equals, is null, etc.) for each filter.



The utility includes a preview mode that allows you to view a previously-created report. Preview mode provides pagination controls and page count to ensure acceptable response time for high-volume reports. Each page can include up to 10,000 rows, and the preview page displays the first 100 records. A "Total records" value displays to the left of the pagination controls to show you the total records returned based on the report's filters.

You can optionally share reports you've created with other users in your account who have permission to access the Data Export Utility. Shared reports are read only for all users except the report author, who has full access to edit, delete, etc. When non-authors view shared reports, they do not have the option to edit or delete; however, they can Preview and Export shared reports as preferred.

4

Study

This section introduces the Site communications tool and offers detailed guidance on managing study documents linked to a site's workflow. You will also find information about Investigator and Trial data source queries, along with an overview of the Study site matching tool.

- Site communications tool
  Send and receive site messages within the Oracle Site Select application.
- Document submissions
  Submitted study documents that require action are available on the Document submissions page under the Study menu. Depending upon your permissions, you can view a document's full history, download it, upload a new version, and more. You can also use the page to manage Survey submission PDF history documents.
- Study site matching
  The Oracle Site Select data disambiguation match resolution feature surfaces possible matching records that require human review and intervention to resolve.
- Targeted investigator and trial searches
  With the appropriate user permissions, you can find and add investigators and trials directly to the Nominate bucket.

Site communications tool

Send and receive site messages within the Oracle Site Select application.

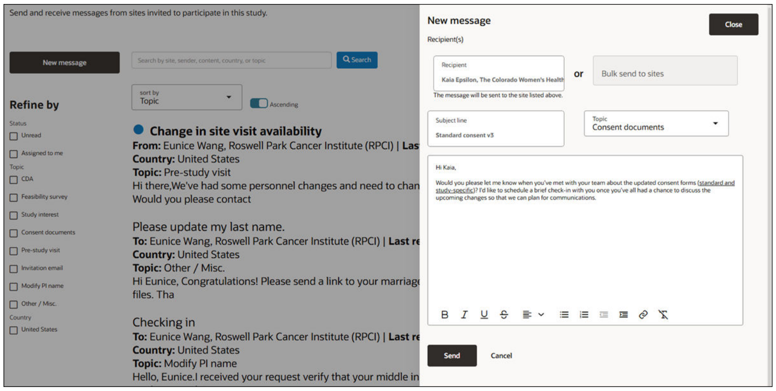
Within the Oracle Site Select application, you can use the Site communications tool to send and receive messages from sites that have been invited to participate in a study. Site communications provides a simple messaging alternative to email communications, and it does not use account level or study level email templates.

There are several ways to access the Site communications tool:

1. Click the new message icon in the page header; it shows you how many new messages you have across your studies. When you have no unread messages, or if unread messages exist only in your current study, clicking the message icon opens the Site communications page for your current study. If unread messages exist in other studies, the icon displays a badge with the total number of unread messages. Click the icon to open a drop-down list of studies that also shows the number of unread messages in each study. Studies are listed in order of oldest unread message first. Click a study name to open its Site communications page.
2. In the global Study menu, choose Communications.
3. When you have the *Site nomination, Evaluation and Selection* user role permission, you can also access the Site communication tool from the site details drawer. At the top of the drawer next to the site name, click message

   to open the Site communications page. The page opens filtered to that site (i.e., the site’s name is in the search bar). If preferred, you can click the Clear filters button to remove the site from the search and any other filters you might apply. By design, you'll see the Clear filters button only when filter conditions exist.

When you click New message in the Site communications area, the drawer opens to provide authoring functionality like single or bulk messaging, topic selection, and rich text formatting.



Site communications supports sending bulk messages to all sites in a specific bucket as well. Open a New message, and select the preferred bucket from the Bulk send to sites list. You can send the message to sites that are in any of the post-invitation bucket states:

- Back up
- Declined
- Final acceptance
- Final decline
- Invited
- Not interested
- Recommended
- Selected

By design, Oracle Site Select deactivates the single recipient (To) field when you choose one or more buckets in the “Bulk send to site” list. The bulk bucket selection list is deactivated if you’ve added a site or institution in the To field.

Oracle Site Select sends your bulk message to all sites in the selected bucket states as individual messages. Each site receives a copy of the message, but there isn’t an indication on the message itself that it was created as a bulk message. Sites can read and reply to the message, and a reply will also behave as an individually-sent message.

For existing messages, the tool lets you:

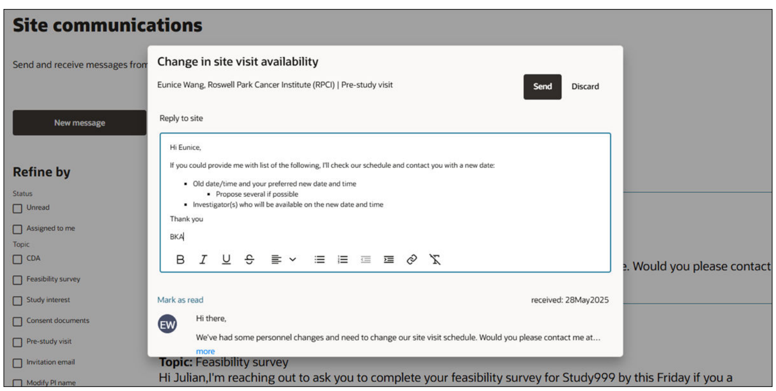
- see all message threads for the study
- filter, search, and sort message threads
- read an incoming message
- reply to a site message
- compose a new message to a site
- mark a message as unread
- toggle the read status of the message to unread

Click a message row to open a modal with the conversation's subject line as the title and the PI name, institution, and message type as a subtitle. The message modal lists threaded messages in reverse chronological order, showing whether each was sent or received, along with the date. By design, messages are truncated to two lines, with options to expand or collapse using "more" or "less" links. When you open or expand a new message, it will be marked as read, and you can manually toggle the read status back to unread for the most recent message.

If the most recent message in a thread is your message to the site, the message's Reply button is disabled, with a tooltip explaining that follow-ups must be sent as new messages. The reply button is available only when a message from the site is the most recent thread. When the Reply option is available, the response modal will include a "Reply to site" heading and rich-text enabled text input area at the top of the modal. To send the message, you'll click Send and then click Yes to confirm. Users with read-only permissions can view threads but cannot reply or perform other actions.

If you have the existing *Read only site communications view* permission, your interactions in the Site communications tool are restricted and you can't compose or reply to a message or mark a message as unread. You can:

- see all message threads for the study
- see, open, and read emails sent to and received from sites
- filter, search, and sort message threads
- read an incoming message
- see unread messages (does not toggle the read status of the message to Read)



Document submissions

Submitted study documents that require action are available on the Document submissions page under the Study menu. Depending upon your permissions, you can view a document's full history, download it, upload a new version, and more. You can also use the page to manage Survey submission PDF history documents.

Managing submitted documents

When you have any of the following user role permissions, you can access the Document submissions page from the Study > Document submissions menu item:

- *Negotiation for assigned CDA/Document submissions only*
- *Review and Approve All CDA/Document Submissions*

- *Review and Approve Assigned CDA/Document Submissions Only*
- *Read only document management view*

You can also use the page to manage Survey submission PDF history documents. You'll need *Site nomination, Evaluation, and Selection* permission to do so, and we've described this enhancement below.

The documents table lists the following document types, which you can search by Investigator or Institution (fuzzy search, full word/string match):

- CDA task
- Generic document (approval)
- Feasibility survey submission (if Include Feasibility surveys check box is enabled)

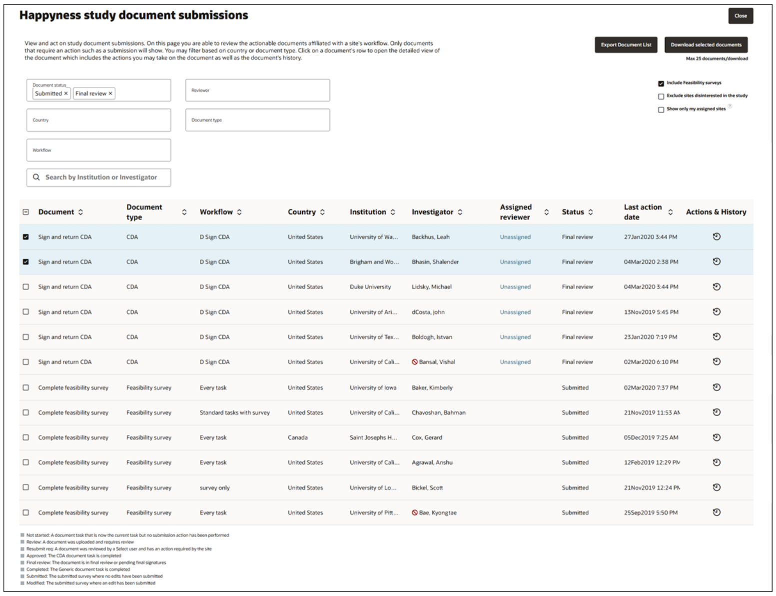
You can apply one or more of the filters below. Note that when you use multiple filters, they'll use AND logic to return matching documents:

- Document type
- Workflow
- Country
- Assigned reviewer
- Document status

To filter the documents further, you can check the Exclude sites disinterested in the study, and/or the Show only my assigned sites check boxes. If you don't exclude disinterested sites, any site that has expressed disinterest in the study will have a disinterest icon before the investigator's name.

You'll also see two export options on the Document submissions page:

1. **Export document list**: Exports a CSV format file with the contents of the current document table and with any filters you've applied to the view
2. **Download selected documents**: Downloads the latest document version for each site selected. Maximum 25 documents per download. For CDAs, the download will include the most recent CDA submission file, not the document reviewer file. This is expected behavior.



On this Document submissions page, you'll find document history and actions features in a history and actions drawer. Click a document's row to open the drawer from the right. At the top of the drawer, the Actions section provides available actions based on the document type and the document workflow task status. These are:

- **Not started**: Document task is not started, and helper text directs you to the Site details, Workflow tab if you want to act on behalf of the site.
- **Review**: Includes response options applicable to a CDA or Generic document (approval required). You can also add comments, upload a file, and submit after choosing a response option.
- **Resubmit required**: You can complete the task by uploading a response and providing a comment.
- **Final review**: Review the submission, provide a response, with an optional document upload.
- **Completed/Approved CDA**: You can recall the document using the link in the History section and return the CDA task to incomplete status.
- **Completed/Approved Generic document (approval required)**: The document is complete, and no actions are available to you.

The History section, located at the bottom of the Document History and Actions drawer, displays a full version history for each document update. Each version is listed with a version number (e.g., V1, V2), a download link for the uploaded file, the upload date and user, and approval details, when applicable. For CDA and Generic document: Approval required tasks, the approval date and the approving user are also shown. A colored status badge reflects the latest version status: green for completed or downloaded, orange for pending, red for resubmission required, and blue for not started or for download.

For CDA tasks, there is also a Recall option for the most recent version. When used, the document reverts to its previous status. If a final approved CDA is recalled, the task becomes uncompleted and reappears as the current required workflow task.

Assigning a CDA reviewer

Recently, we modified requirements for assigning a CDA reviewer. This now requires a file uploaded with the reviewer assignment. Note that you should expect different behavior in the document history drawer for old studies where the review was assigned without a file. The comments to the reviewer will show on the CDA history row before the action.

With this change, the document history drawer will show a separate row for the assignment of a document reviewer (i.e., “DR” instead of “V”). This will visually separate the reviewer and CDA document histories. This change does not affect Generic documents since they do not have reviewer functionality.

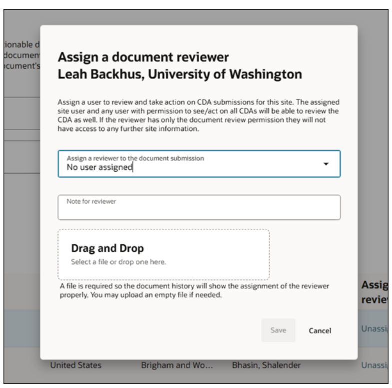
You can assign a CDA document reviewer directly from the Document submissions table. Click the linked name (or an Unassigned link) in the Assigned reviewer column to open the Assign reviewer modal. By design, the Assigned reviewer link will be disabled if the document is in Requires site submission or Final approved status.

In the assignment modal, choose a reviewer, optionally add a note (shown in the document history and stored with CDA comments in site notes data), and upload a file. File upload is required to show the reviewer assignment correctly in the document history. You may upload an empty file if preferred.

Assigned site users can always view documents for their sites, even if a document is reassigned to another reviewer. If they have permissions such as "Review/Negotiate all CDAs," "Approve all CDAs," or "Approve only assigned CDAs," they can review and, when applicable, approve or deny the CDA. These users can also reassign a document at any time, even if it’s no longer reviewer-assigned to them, and have the option to add a comment with the reassignment.

Forwarded users who aren't assigned to a site can only see documents directly forwarded to them. They can view associated comments but won’t see site details unless they have site grid or nomination permissions. All reassignments are recorded in the document’s review history, and a new history entry is added for each reviewer update. However, the site view remains unchanged; its status stays “Pending,” and site users don’t see reviewer changes. Once reassigned, the new reviewer will find the document added to their study homepage task list.

Finally, after reassignment, the GET workflow details API will display the most recent assigned_user_email field, populated with the email of the newly assigned user.



CDA lifecycle and outputs

Below you'll see a full CDA document lifecycle scenario with the expected outputs in Oracle Site Select and the site portal. In this scenario:

- The user has the *Review and Approve All CDA/ Document Submissions* permission
- The recall button only shows on the most recent CDA version history
- The table below shows the version history (i.e. V1, V2, etc.) as each step is performed

Action	Document submissions page	Document submission version history () drawer	Site portal documents > Study documents tab
The site downloads the CDA template	No change: "Not started" status	V1, the document file name as a download link, badge "Downloaded"	Template shows as V1
The site uploads a file with comment	Status changed to "Review" (on page reload)	V2, the document the site uploaded file name as a download link Updated on/by information *Comments from site user <site user's name first last>: <comment> Badge = "Pending review" Recall button added (removed later)	V2 added with file from site user Comment included Ability to delete document
Reviewer is assigned, comment for reviewer added, file for reviewer added	Status remains Assigned reviewer column updated	The V2 history status remains "Pending review" A new "DR" row added to the history. Badge "Reviewer assigned." Reviewer assigned: <first name> <Last name> | <email>Reviewer assigned on: <datetime of the update> by: <select user who made the assignment> Comments for reviewer: <comments associated with the review> File uploaded for reviewer: if a file is uploaded display as link| no change - reviewer actions do not show on the Site portal	No change - reviewer assignments do not show on the Site portal

Action	Document submissions page	Document submission version history ( ) drawer	Site portal documents > Study documents tab
Oracle Site Select reviewer/user sends back to site "Requires resubmission" with comments and file	Assigned reviewer Status "Resubmission req"	The V2 history status remains "Requires resubmission" with a red background since it was rejected Rejection reasons: (comma sep) (added to V2 since that is the document that was rejected) V3 added File: if file uploaded when rejecting then display filename as link to download. If no file uploaded then display the last CDA file (v2) as download link Updated on/by badge "Requires resubmission" (gray on v2) Recall button moved to this Version row	V3 added with file from Oracle Site Select user On the workflow task's document history view the file and comment are included
Site uploads a response with comments and file	Assigned reviewer Status "Review"	V4, the document the site user uploaded file name as a download link Uploaded on/by information Comments from site user <site (from site user's profile) user>: <comment> Badge "Pending review" Recall button moved to this Version row	V4 added with file from site user Ability to delete document File and comment included in the workflow task document history modal
Add review, no file but with comment	N/A	Not supported. File is required.	N/A
Change reviewer to 3, no file	N/A	Not supported. File is required.	N/A

Action	Document submissions page	Document submission version history () drawer	Site portal documents > Study documents tab
Oracle Site Select user marks the CDA as Final approved with comment but no new file	Status = "Approved"	V4 badge updated to "Approved" with green background V5 not added Updated on/by Signed CDA comments from <select user first last name>: (for comments made by an Oracle Site Select user on Final approval the word "Signed" is added) Badge "Approved" in green Recall on this Version row	V5 added with file from Oracle Site Select user Comment included
Oracle Site Select user Recalls finalized CDA	Status = Review	V4 badge returned to "Pending review" Recall button put on V4	Final approved comment removed from workflow task document history popover CDA is back in pending status for site Site can delete file or wait for Oracle Site Select user to act
Oracle Site Select user sends CDA to site for "Requires site signature" with comment and file	Resubmit req	V5 entry added Badge = Pending signatures File: filename as link to download, if no file then use the previous version file CDA comments from <select user first last name>: Updated on/by Recall button moved to this Version row	New version added with the file and comment sent back to site
Site returns CDA with comment and file	Final review	V6 entry added Badge = Final review File: filename as link to download, if no file then use the previous version file Comments from site user <site user's name>: <comments> Updated on/by Recall button moved to this Version row	New version added with file Site can delete file or wait for Oracle Site Select user to act

Action	Document submissions page	Document submission version history () drawer	Site portal documents > Study documents tab
Oracle Site Select user marks the CDA as Final approved with comment but no new file	Status = "Approved"	V4 badge updated to "Approved" with green background File: filename as link to download is the same file uploaded by the site in V4 Updated on/by Signed CDA comments from <select user first last name>: Recall button moved to this Version row	Comment added to history on workflow task document history modal

CDA and Generic document (Approval) cycles and permissions

Below are lifecycle scenarios for a CDA document and an Approval type Generic document with the expected outputs in the study's Document submissions table and version history drawer, and in the Site details drawer accessed from the site grid. In these scenarios:

- You'll see important behavior differences between when you're assigned a site vs. assigned as CDA document reviewer
- If you have the *Review and Approve Assigned CDA/Document Submissions Only* permission, you will only see CDAs for which you are assigned as the CDA reviewer AND/OR assigned in the site grid as the site-assigned user.
- Generic Document Approval types do not have reviewers
- In the scenario below, a full CDA document lifecycle occurs using four users with the different CDA-related permissions and no permission
- In the scenario below, a full Generic document - Approval lifecycle occurs using three users with the different generic document-related permissions and no permission
- In the scenarios below, assume the user doesn't have the *Complete as not required* permission unless noted

User permission(s)	Assigned a site?	Document submissions table	Document submissions version history	Site grid > Site details drawer > Documents tab
Negotiation for assigned CDA/ Document submissions only	No assigned sites	No sites should load	N/A	Can't see the site grid
Negotiation for assigned CDA/ Document submissions only	Cannot be assigned to a site	No sites should load	N/A	Can't see the site grid
Negotiation for assigned CDA/ Document submissions only	Assigned as document reviewer only	See CDA for the assigned site, cannot see Generic doc approval	Can take all actions except Final approval	Can't see the site grid

User permission(s)	Assigned a site?	Document submissions table	Document submissions version history	Site grid > Site details drawer > Documents tab
Negotiation for assigned CDA/ Document submissions only, Site nomination permission	Assigned as document reviewer only	See CDA for the assigned site, cannot see Generic doc approval	Can take all actions except Final approval	Can see all sites in the site grid Can see the workflow tab and all workflow tasks for sites in the site grid The Action menu is enabled for CDAs only and allowed to Review CDAs for only the sites assigned to me as a document reviewer
Negotiation for assigned CDA/ Document submissions only, View assigned sites, Site nomination	Assigned a site	See CDA for the assigned site, cannot see Generic doc approval	Can take all actions except Final approval	Can see only the site assigned, can see the workflow drawer and tasks, can Act on the CDA except finalize
Review and Approve Assigned CDA/Document Submissions Only, Site nomination, Complete task as Not Required	Assigned a site, Can Complete task as Not Required	See CDA for the assigned site, cannot see Generic doc approval	Can take all actions including Final approval	Can see all sites in the site grid Can see the workflow tab and all workflow tasks for sites in the site grid Can CDA Action > Complete Not Required for all tasks even on not-assigned site. Cannot do this for Generic doc approval Req tasks The Action menu is enabled and allowed to Review and Approve CDAs for only the sites assigned to me from the site grid
Review and Approve Assigned CDA/Document Submissions Only, View assigned sites only	Assigned as document reviewer only	See CDA for the assigned site, cannot see Generic doc approval	Can take all actions including Final approval	Can see only the site assigned, can see the workflow drawer and tasks, can Act to review and finalize the CDA
Review and Approve All CDA/ Document Submissions	Nothing	See all CDAs, cannot see Generic doc approval	Review and approve all CDAs	Can't see the site grid

User permission(s)	Assigned a site?	Document submissions table	Document submissions version history	Site grid > Site details drawer > Documents tab
Review and Approve All CDA/ Document Submissions, View assigned sites only, Site nomination	Assigned a site	See all assigned CDAs, cannot see Generic doc approval	Review and approve all CDAs	Can only see assigned site, can review and finalize CDA via the Actions menu
Review and Approve All CDA/ Document Submissions, Site nomination	Nothing	See all CDAs, cannot see Generic doc approval	Review and approve all CDAs	Can review and finalize all site CDAs via the Actions menu
Review and Approve Generic Document Submissions for assigned sites Only	No assigned sites	No sites should load	N/A	Can't see the site grid
Review and Approve Generic Document Submissions for assigned sites Only,View assigned sites, Not required permission, Site nomination	Assigned a site	Should only see Generic doc approval for the assigned site, no CDAs show	Can take all actions	Can see only the site assigned, can see the workflow drawer and tasks and act on the Generic doc. Can mark any task as Not required.
Review and Approve Generic Document Submissions for assigned sites Only, Site nomination, Complete task as Not Required	Assigned a site, Complete task as Not Required	Should only see Generic doc approval for the assigned site, no CDAs show	Can take all actions including Final approval	Can see all sites in the site grid Can see the workflow tab and all workflow tasks for sites in the site grid Can Action > Complete Not Required for all tasks even on not-assigned site The Action menu is enabled for Generic doc approval req tasks and user is allowed to Review and Approve Gen Docs for only the sites assigned to me from the site grid
Review and Approve All Generic Document Submissions	Nothing	See all Generic doc approvals, no CDAs	Can take all actions including Final approval	No site grid access

User permission(s)	Assigned a site?	Document submissions table	Document submissions version history	Site grid > Site details drawer > Documents tab
Review and Approve All Generic Document Submissions, Review and Approve All CDA/ Document Submissions, Site nominate permission	Nothing	See all CDAs and Generic doc approvals	Can finalize all CDAs and Generic doc approvals	See all sites, can finalize all CDAs and gen doc approvals
Review and Approve Generic Document Submissions for assigned sites Only,View assigned sites, Review and Approve Assigned CDA/Document Submissions Only, Completed not required	Assigned to site1, assigned as a CDA reviewer for site2 so site2 has a Generic doc but the user is not site-assigned	See 2 CDAs, 1 Generic doc (assume both sites have a Generic doc approval task) Do not see the Generic doc for site2 because user is not site-assigned to site2's Generic doc	Can finalize 2 CDAs and 1 Generic doc approval	See site1 in the site grid, can approve the CDA and Generic doc, can mark any task as not required Cannot see site2 in the site grid

Manage survey submission PDF history documents

When you have *Site nomination, Evaluation, and Selection* permission, it's easy to view and manage feasibility survey documents, especially when working with multiple workflows and surveys across sites. You can access and download (including bulk download) survey documents from the study's Document submissions page. To view survey submissions in the document grid, click the "Include Feasibility survey" check box.

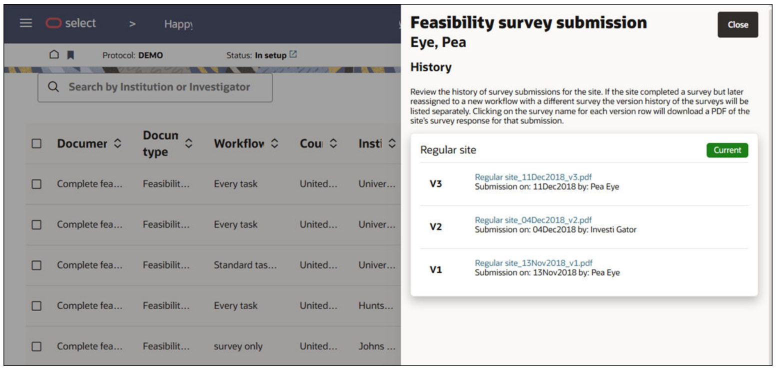
When you've enabled viewing feasibility surveys in the document grid, you'll have the following survey-specific filters:

- A Feasibility survey Document type filter is available when any submissions exist.
- The Status filter includes "Submitted" and "Modified" if those types are present.

Please note that filters work across all document types, so if you select "CDA" Document type and also have the Include Feasibility surveys check box option checked, the document table will only show CDA entries. This is expected behavior.

To view a submission document's history, including any version history, click in the Actions & history column. The history drawer shows the survey(s), version(s), individual PDF file download links, and submission information (date submitted and the name of the submitter). If you want to download survey submission PDF documents in bulk, select the rows in the document table instead, and then click Download selected documents at the top of the Document submissions page. You can also download a Microsoft Excel file with the filtered list of submission documents. Click Export document list at the top of the Document submissions page. Maximum 25 documents per download.

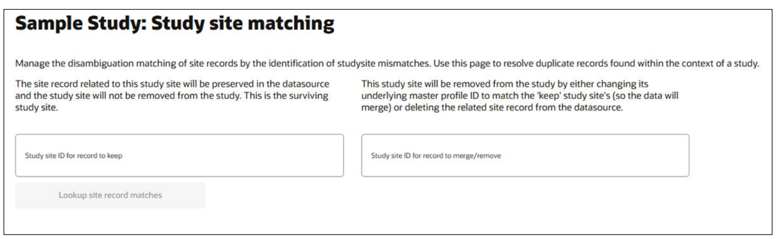
The *Site nomination* permission also grants access to the study's Document submissions page. If Site nomination is your only user role permission, the document table will be empty on initial load; however, you can check the "Include Feasibility survey" check box to view survey submission documents.



Study site matching

The Oracle Site Select data disambiguation match resolution feature surfaces possible matching records that require human review and intervention to resolve.

While Oracle Site Select automatically identifies and merges strongly matched records within an account's private datasources, potential matches pending intervention are viewed as individual site records in the Master List. Records identified as matches by a user in your account who has *Data Source Management* permission are then merged so the Master List reflects only the single master record.



- Merge or remove duplicate site records

Merge or remove duplicate site records

You must have a role with *Data Source Management* permission to complete this procedure. Additionally, you will need the Study site ID for the records you want to keep and merge/remove. You can find this information in the site's history drawer in the site grid.

> **Note**
>
> This procedure applies only to regular datasources. If your organization will use composite datasources, please contact your Oracle Project Manager for assistance.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Study** and choose **Study site matching**.
3. On the **Study site matching** page, in the **Study site ID for record to keep** field, enter the site ID.

4. In the **Study site ID for record to merge/remove** field, enter the site ID.
5. Click **Lookup site record matches**.
6. If the records match, click **Yes** to resolve the potential match and display the merged record in the master list.
7. If the records do not match, click **No** to remove the pair from the potential matches list. Two separate records will continue to display in the master list.

Targeted investigator and trial searches

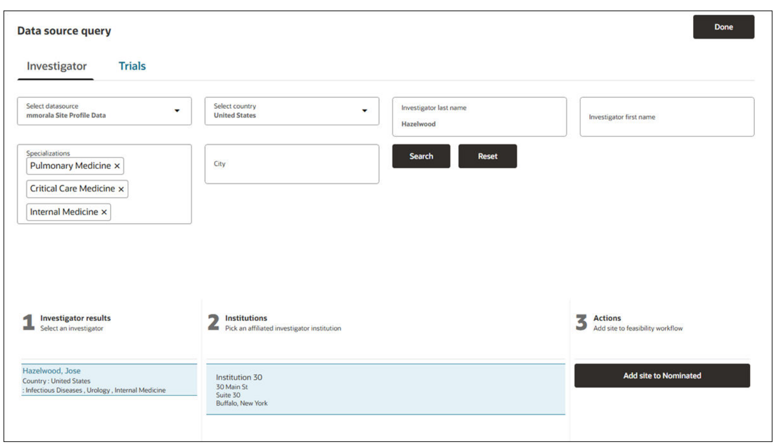
With the appropriate user permissions, you can find and add investigators and trials directly to the Nominate bucket.

Oracle Site Select If you have a role with *Perform a targeted data source search* permission, you can search for investigators or trials that are not included in a study's datasources and add an investigator or trial from the results list directly to the Nominate bucket state.

To perform the search, you must identify the datasource for the search as well as the investigator's country. Datasources are limited to those attached to the study. To refine the search, you can include additional criteria, such as Investigator first name, last name, city, and specialization(s).

Search results include a three step process to help you identify the correct investigator or trial to add to the study. The steps are:

1. **Investigator/Trials results** – at the lower left of the screen, select an investigator or trial from the results list
2. **Institutions/Sites** – from the lower middle column, choose the investigator's affiliated institution for investigator searches, or for trial searches, choose investigator sites
3. **Actions** – if both the investigator name and the institution, or trail and sites are as expected, add the investigator/trial to the Nominated list. Note: you will not be able to nominate a site if the site is already found in the study.



Sites that don't align with study parameters but are added to the Nominated bucket state via targeted search on the Data source query page are included in all reporting. These sites:

- are included in all CSV downloads within Oracle Site Select where site grid filters do not filter out the site
- included in all Oracle Site Analyze reports for the study

- display as a possible country filter in the Oracle Site Select site grid
- display as a possible country filter in all applicable Oracle Site Analyze reports

- Perform a targeted investigator search
  Search for investigators who aren't included in your study's datasources and add an investigator from the results list directly to the site grid's Nominate bucket state.
- Perform a targeted trial search
  Search for investigators in trials that aren't included in your study's datasources and add one or more investigator(s) from the results list directly to the site grid's Nominate bucket state.

Perform a targeted investigator search

Search for investigators who aren't included in your study's datasources and add an investigator from the results list directly to the site grid's Nominate bucket state.

You must have *Perform a targeted data source search* permission to complete this procedure.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Study** and click **Data source query**.
3. On the Data source query page, click the **Investigator** tab if necessary, then complete at least the **Select datasource** and **Select country** fields. All other fields are optional, but entering data into the available fields may reduce the number of results.
4. Click **Search**.
5. In the lower portion of the page, at **1 Investigator results**, select an investigator from the results list.
6. At **2 Institutions**, choose the investigator's affiliated institution.
7. If both the investigator and institution are as expected, at **3 Actions**, click **Add site to Nominated**. Note: you will not be able to nominate a site if the site is already found in the study.
8. Click **Done**.

Perform a targeted trial search

Search for investigators in trials that aren't included in your study's datasources and add one or more investigator(s) from the results list directly to the site grid's Nominate bucket state.

You must have *Perform a targeted data source search* permission to complete this procedure.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Study** and click **Data source query**.
3. On the Data source query page, click the **Trials** tab, then complete at least the **Study Data Source** field and one other field of your choice. All other fields are optional; however, entering data into the available fields may reduce the number of results.
4. Click **Search**.
5. In the lower portion of the page, at **1 Trials**, select a trial from the results list.
6. At **2 Sites**, pick the site(s) you want to import into the study workflow.
7. At **3 Actions**, click **Add site to Nominated**. Note: you will not be able to nominate a site if the site is already found in the study.

8. Click **Done**.

5

Study setup

This section, intended for study administrators and those responsible for study documents, describes how to set up and manage studies.

- Study details and site list criteria
  Permissioned users can set up studies in Oracle Site Select with attributes that help you and your team members track those studies based on various parameters. Parameters include protocol number and title, protocol phase and compound, study status and type, and more.
- Study data sources
  Choose the data sources that will be used to create the master list for the study. You can also set data source priority to determine outcomes of data merging.
- Site scoring (weighting)
  Turn site scoring off, or specify the formula used to determine how Oracle Site Select assigns a site score when turned on. Your site selection team can use the scores displayed in the site grid to determine which sites are most likely to meet key study criteria.
- Study email templates
  Study level email templates can be configured with default and study country specific settings, if necessary. Specify preferred settings for salutation, login options, and more for all non-system site email notifications.
- Workflows and workflow documents
  Defining a study's workflows involves detailed planning around the order in which sites complete individual workflow tasks, required documents, and site communication. Some organizations define workflows using account level templates, which are available to you at the study level when you choose to Add a new workflow.
- Feasibility Surveys
- Milestones
  Define study milestones when you set up your study to help ensure your team stays on track with key study accomplishments like site enrollment targets.
- Reasons for study exclusion/disinterest
  When an Oracle Site Select user excludes a site from the feasibility process or a site indicates that they aren't interested in study participation, they may need to provide a reason. An administrator in your account can define a list of reasons, and you can modify that list as necessary for your study.

Study details and site list criteria

Permissioned users can set up studies in Oracle Site Select with attributes that help you and your team members track those studies based on various parameters. Parameters include protocol number and title, protocol phase and compound, study status and type, and more.

Study setup requires two explicit permissions:

1. *Study details management*: This role-based permission allows a user to set and modify most study details within their account. Exceptions are the study's "status" and " type"

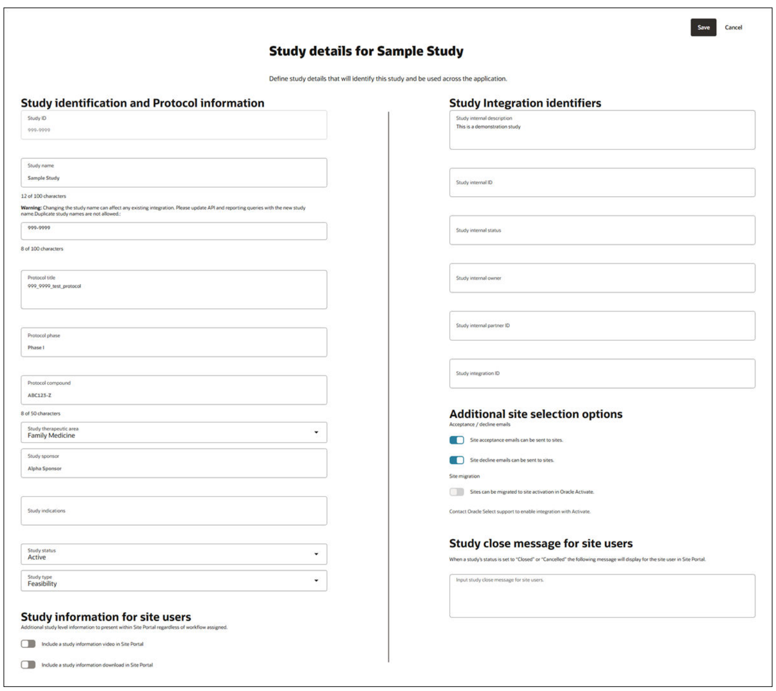
values. Users granted *Study setup management* permission should also have *Study details management* permission.

2. *Study administration*: This role-based permission allows users to set and modify a study's status and type values – in addition to the functionality available with the *Study details management* permission.

Study details page

Users who have a role with *Study details management* or *Study administration* permission access the Study details page from the global "Setup" menu. Fields defined on the page identify the study at the highest level (such as study name and ID, protocol, sponsor, etc.), and the values are used across the application and in reporting. When viewing the Study details page for one study, you can navigate to the details page for a different study by selecting the other study from the study picker in the page header.

> **Note**
>
> If you want to edit a study's name, you must have a user role with *Study details management* and *Study administration* permissions.



If you have a role with *Study administration* permission, you can set a study status for studies within the account. When set, the status value (Active, Closed, etc.) displays in the study picker in both Oracle Site Select and the site portal. You can select one of the following statuses from a drop-down list:

- In setup
- Active
- Feasibility complete
- On hold

- Closed
- Cancelled

Oracle Site Select also includes study type values. If you have a role with *Study administration* permission, you can set a study type for studies within your account. Currently, the available types are:

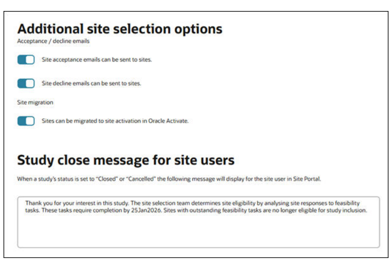
- Feasibility (default)
- Internal insights
- Investigator outreach
- Pre-award

Other optional study level settings on this page allow for configuration of a study information video embed link, study information document download, enabling of site acceptance/decline emails and indication of site migration to Oracle Site Activate.

Your Oracle administrator will work with you to enable a study-level information video, if desired. When configured on the Study details page, sites can access the video from a link in a Generic workflow task in the site portal. This configuration has explicit access restrictions and your organization will obtain and maintain the Content Delivery Network (CDN) service account. Please contact your Oracle representative to discuss specific requirements.

On the Study details page, you can also optionally add a study-level information document that will be available to site users on the site portal home page in the study information panel. Importantly, access to the document in the site portal is **not** restricted at the task level. Please do not configure this option for any document that should be available to a site only after completion of a specific task or with a signed legal agreement (for instance, a protocol document that has restricted access).

At the account level, your administrator can also turn on a setting that will hide studies in Closed or Cancelled status from Oracle Site Select users. When that setting is on, you can create a message to display to site portal users to inform them that the study is no longer available. Look for this section under the "Study close message for site users" heading on the Study details page.



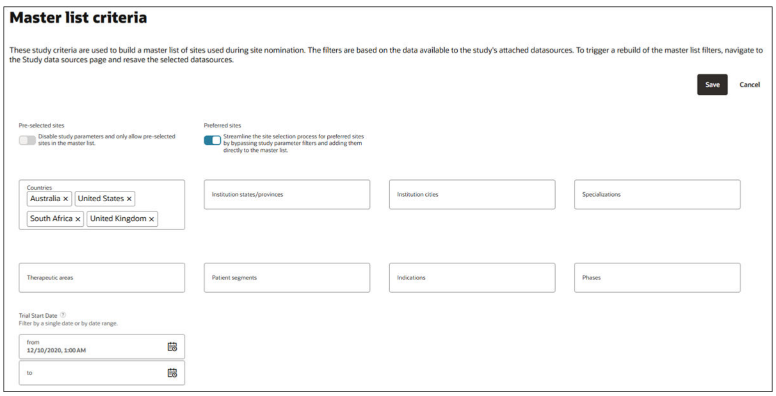
Master list criteria page

If you have *Study setup management* permission assigned via role, you can access a study's Master list criteria page from the option in the global "Setup" menu. This page provides multiple options to restrict the study's Master list to a specific subset of countries, specializations, therapeutic areas, etc., or to populate the master list with only pre-selected sites or preferred sites.

Caching functionality allows the page to display only those filters and filter values found in the study's attached datasource(s). Caching applies to all master list filters except Trial Start Date.

The Master list criteria page displays a filter only if the attached study datasources have the filter's data columns available and populated with at least one value. Updating the datasources attached to a study will remove/rebuild the cached master list filter values. If a filter displays because there is a value found in one datasource, and a Datasource manager removes that datasource, the filter will no longer display on the Master list criteria page. Similarly, if a filter includes a value found only in one datasource, and a Datasource manager removes that datasource, that value will no longer be available in the filter.

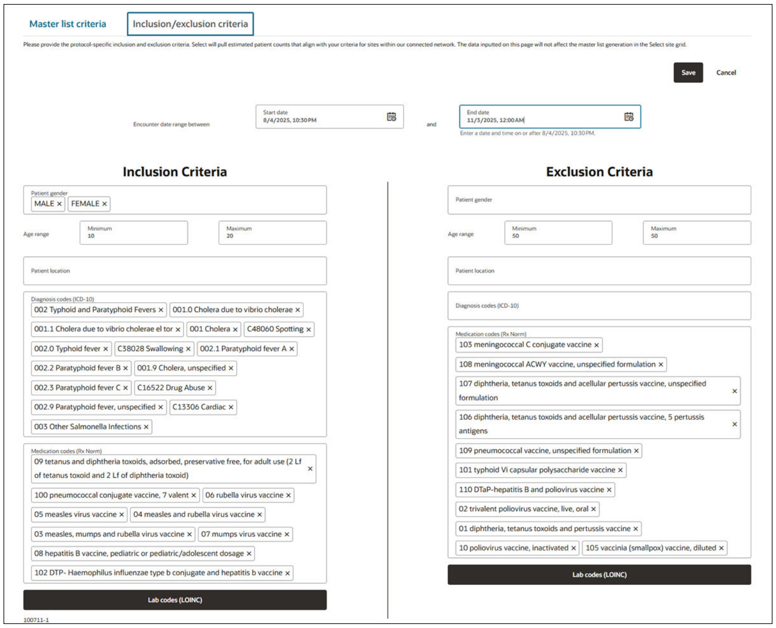
If a filter has a selected value that exists in only one datasource, and that datasource is removed while other datasources still provide values for the same filter, the selected value remains when the you return to the master list criteria page. If you don't remove the selected value, the master list will be built based on that filter. However, if you remove the filter value, it will not be added back to the available filter values.



When your organization has enabled Oracle Learning Health Network integration, the Master list criteria page will be split into two tabs, Master list criteria and Inclusion/exclusion criteria.

In this case, functionality on the Master list criteria tab is as described above. The Inclusion/exclusion criteria tab will allow you to specify protocol inclusion/exclusion criteria, including an encounter date range and protocol-specific inclusion and exclusion criteria (e.g., patient gender, age range, diagnosis and lab codes, etc.). The inclusion/exclusion criteria tab will show a message while the Diagnosis code and Medication code filters are populating with the available options and the related inclusion and exclusion input fields are disabled. The user interface will refresh to remove the message once the last of the codes load and inputs are available for your use. The message is, “Population of inclusion/exclusion codes is processing. The code selectors will be available as each is completed.”

The Learning Health Network will respond with estimated patient counts that align with the study’s criteria for network sites.



> **Note**
>
> Data inputted on the Learning Health Network patients tab does not affect the master list generation in the Oracle Site Select site grid.

- [Set up study details](#)
  All studies created in Oracle Site Select have a study details page where you'll specify the study's unique attributes that will be used across the application.
- [Set up master list criteria](#)
  Master list criteria (e.g., countries, specializations, therapeutic areas, and more) determine the studies included in the site nomination master list.
- [Set up Learning Health Network criteria](#)
  Specify protocol-specific inclusion and exclusion criteria so the Learning Health Network (LHN) can provide estimated patient counts that align with the study criteria.

Set up study details

All studies created in Oracle Site Select have a study details page where you'll specify the study's unique attributes that will be used across the application.

You must have *Study administration* or *Study details management* permission to define the details of a study. To set study status and study type, you must have *Study administration* permission. To update the name of an existing study, you must have *Study details management* and *Account study creation* permissions.

> **Note**
>
> Some fields below are available only if a composite datasource is attached to the study.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Study details**.
3. Edit any of the following fields:
   - **Study name** (required, 100 character maximum)
   - **Protocol number** (required, 100 character maximum)
   - **Protocol title** (required)
   - **Protocol phase** (required)
   - **Protocol compound** (50 character maximum)
   - **Study therapeutic area**
   - **Study sponsor**
   - **Study indications**
   - **Study status** (required, Study administrator users only)
   - **Study type** (required, Study administrator users only)
   - **Study internal description**
   - **Study internal ID**
   - **Study internal status**
   - **Study internal owner**
   - **Study internal partner ID**
   - **Study integration ID**
4. At **Study information for site users**, see or enable:
   - **Include a study information video in Site Portal**: By design, this control is not actionable. Contact your Oracle administrator to enable the video option. When enabled, the Study details page shows the control toggled on so you can validate the video link.
   - **Include a study information download in Site Portal**: Toggle on to enable and upload a study-level document in DOC, DOCX, PDF, or ZIP format.

   > **Warning**
   >
   > Access to the file download is not restricted based on the site portal user's current workflow task. Please do not configure documents for download that should be available to a site user only after they have completed a specific task or signed a legal agreement. For instance, do not configure a protocol document for download as it will be available to site users prior to signing a CDA.

5. At **Additional site selection options**, see or toggle:
   - **Site acceptance emails can be sent to sites**
   - **Site decline emails can be sent to sites**
   - **Sites can be migrated to site activation in Oracle Activate**: By design, this control is not actionable. Contact Oracle Support to enable site data migration into Oracle Site Activate during the Finalize step. When enabled, this control will display as toggled on on the Study details page.

6. At **Study close message for site users**, optionally enter a brief message to display in the site portal when a study is no longer accessible to site users (i.e., study is in Closed or Cancelled status). Note that your account administrator must also enable a separate Authentication setting to hide studies in Closed or Cancelled status.
7. Click **Save**.

Set up master list criteria

Master list criteria (e.g., countries, specializations, therapeutic areas, and more) determine the studies included in the site nomination master list.

You must have *Study setup management* permission to set master list criteria.

1. Choose the study from the study drop-down list in the page header.
2. Click menu in the page header. Then open **Setup** and choose **Master list criteria**.
3. If displayed, click the **Master list criteria** tab. The tab displays only when your organization has enabled query for Oracle Learning Health Network patient counts. Otherwise, go to step 4.
4. Except for `Trial Start Date`, the page will display only those filters and filter values found in the study's attached datasource(s). Enter or change any of the following **bold** attributes (for fields, click into a field to display a selection list):
   - **Pre-selected sites**: allows sites to bypass study parameter filters. If toggle enabled, only pre-selected sites display on the master list. This option requires upload and mapping of a CSV format file with pre-selected sites. Please contact your site identification and/or feasibility specialist for more information.)
   - **Preferred sites**: If toggle enabled, allows CRO preferred sites to bypass study parameter filters and move into the master list. This option requires upload and mapping of a CSV format file with CRO preferred sites. Please contact your site identification and/or feasibility specialist for more information.
   - **Countries**: Enter a portion of the country name. If found in the attached study datasource(s), choose a country from the list. To remove a country, click **X** next to the country name.
   - **Institution states/provinces**: Enter a portion of the state or province name. If found in the attached study datasource(s), choose the item from the list. To remove a selection, click **X** next to the state or province name.
   - **Institution cities**: Enter a portion of the city name. If found in the attached study datasource(s), choose the city from the list. To remove a selection, click **X** next to the city name.
   - **Specializations**: Enter a portion of the specialization. If found in the attached study datasource(s), choose one from the list. To remove a specialization, click the **X** next the specialization.
   - **Therapeutic areas**: Enter a portion of the therapeutic area. If found in the attached study datasource(s), choose one from the resulting list. To remove a therapeutic area, click **X** next to the item.
   - **Patient segments**: Enter a portion of the patient segment type. If found in the attached study datasource(s), choose the item from the list. To remove a selection, click **X** next to the patient segment name.
   - **Indications**: Enter a portion of the indications relevant to the study. If found in the attached study datasource(s), choose one from the resulting list. To remove a filter indication, click **X** next to the item.

- **Phases**: Enter a portion of the phase relevant to the study. If found in the attached study datasource(s), choose one from the resulting list. To remove a phase, click **X** next to the item.
- **Drug classes**: Enter a portion of the drug classes relevant to the study. If found in the attached study datasource(s), choose one from the resulting list. To remove a drug class, click **X** next to the item.
- **Trial Start Date**: Specify **from** and **to** date range values; the site list includes sites associated with the study sites when the trial start date falls within the specified date range, and excludes any sites whose trial-sites do not have trial start date data. If both date range fields for the filter are empty, the site list includes all sites except those excluded by other filter criteria.

5. Click **Save**.

   Warning:
   The site grid will experience degraded performance when loading very large datasets. If this occurs, please check your master list filters and apply more stringent criteria

Set up Learning Health Network criteria

Specify protocol-specific inclusion and exclusion criteria so the Learning Health Network (LHN) can provide estimated patient counts that align with the study criteria.

Your organization's account must be configured to use Learning Health Network and you must have *Study setup management* permission to set Learning Health Network criteria.

1. Choose the study from study drop-down list in the page header.
2. Click menu in the page header. Then open **Setup**, and choose **Master list criteria**.
3. Click the **Inclusion/exclusion criteria** tab.
4. At **Encounter date range**, enter **Start date** and **End date**.
5. Under the **Inclusion Criteria** section on the left, click the **Patient gender** field and choose **Male**, **Female**, and **Other** as preferred.
6. At **Age range**, enter a number greater than 0 for both the **Minimum** and **Maximum** fields.
7. Click the **Patient location** field, and choose the appropriate location(s) (i.e., In patient, Out patient, etc.).
8. Click the **Diagnosis codes (ICD-10)** field, search by code or display name, and choose one or more codes.
9. Click the **Medication codes (Rx Norm)** field, search by code or display name, and choose one or more codes.
10. Click the **Lab codes (LOINC)** button, to view a lab codes modal. Click **Add new lab criteria**.
11. Click the **LOINC lab code** field, search by code or display name, and choose a code from the drop-down list. Click the **Lab result type** field, and choose **Range** or **Result**. If **Range**, enter **Min** and **Max** values. If **Result**, choose **Positive** or **Negative**.
12. Click **Update** to close the modal and return to the criteria page, or click **Add new Lab criteria** (upper left) to specify additional LOINC codes. If necessary, you can delete a code by clicking **X** at the far right of its row.
13. For the **Exclusion Criteria** section, repeat steps 5-12 above.
14. Click **Save**.

Study data sources

Choose the data sources that will be used to create the master list for the study. You can also set data source priority to determine outcomes of data merging.

Choosing a study's datasources

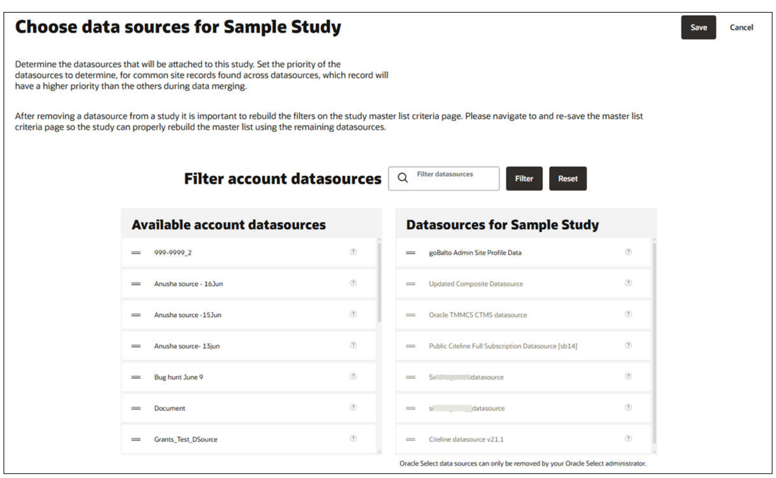
The Choose data sources for study page lists the account data sources available for use in the study and those that are already applied. The page allows for simple drag and drop from the available list at the left to the selected list on the right. Click and hold the handle ═ to the left of a data source name, then drop the data source in the preferred list.

You can also use the handle to reorder (prioritize) data sources, with the highest priority in the highest list position. You can move the site profile datasource up or down in priority against other chosen study datasources. Priority (i.e., higher or lower in the list of the study's attached datasources) determines the data displayed in the site grid. For example, study site "Joshua Johnston" (no "e") exists in the Site Profile datasource, and "Joshua Johnstone" (with "e") exists in another datasource titled Preferred Sites. The site grid displays the name "Joshua Johnston" (no "e) when the Site Profile datasource is prioritized above the Preferred Sites datasource. If the Site Profile datasource is reprioritized lower than the Preferred Sites datasource, the site grid displays "Joshua Johnstone" (with "e").

Please note: When the study's attached Site Profile datasource has a lower priority than other attached datasources, the site profile could display information that does not match the site grid (e.g., the site name could be different). This is expected behavior.

> **Note**
>
> If you remove a datasource or reprioritize the existing data source list, please navigate to the Master list critera page and save it again to ensure the site grid will properly build the master list using the new list of study data sources.

Oracle Site Select offers a study datasource with the full Citeline subscription. If your organization has this subscription level, you can request that an Oracle administrator add the curated Citeline datasource to one or more of your studies and you can prioritize it as preferred in the study datasources list. Please contact your Oracle project manager for subscription details.



Discontinued records

Oracle Site Select users who manage datasources can upload a source that includes records flagged as “discontinued” at the institution, investigator, or site levels. When flagged as discontinued, Oracle Site Select filters all sites correlated to the institution/investigator/site/trial-site from master list generation, except as described below.

When multiple datasources exist for a study, datasource priority as well as record updates (e.g., changing a discontinued setting from “true” to “false”) may affect the display of a discontinued site in the master list/nominate bucket. The following list details expected behaviors for this feature:

- A site currently in the nominate bucket that later has the discontinue flag set to true remains in the nominate bucket unless another action, such as changing the priority of study datasources, triggers the rebuild of the master list.
- If the discontinue flag for the institution/investigator/site record is false and the site is nominated and moved beyond the nominate bucket, and later the discontinue flag is updated to true, Oracle Site Select will maintain the site record in the site grid and preserve the underlying data that contributes to the site record from the originating datasources (regardless of site profile record). In this case the site's investigator name will be formatted in maroon text with an accompanying alert icon () displays in the grid.

> **Note**
>
> A site profile record that shares a master profile ID with an institution/investigator/site will be filtered based on the criteria above only when a datasource with the discontinue flag set to true is attached to the study.

- The master list will not automatically regenerate if an attached datasource has the institution/investigator/site discontinue flag set to true and the flag is later updated to false. However, if an Oracle Site Select user triggers master list regeneration (e.g., by changing the priority of study datasources) the site will be filtered according to the expected behavior described above.
- When two datasources are attached to a study and the higher priority datasource has the discontinue flag set to true, the site **is** filtered from nomination/master list along with any associated site profile record. However, when two datasources are attached to a study and the higher priority datasource has the discontinue flag set to false, but the lower priority datasource has the flag set to true, the site/site profile record **is not** filtered from nomination/master list.
- A site record with preferred and/or preselected site set to true and discontinue set to true will be included in the master list provided the preferred site and/or preselected site check box setting is enabled on the study parameters page. The record from the CSV where preferred_site=true and/or preselected_site=true will be the record that persists. Again, in this case, the site's investigator name will be formatted in maroon text with an accompanying alert icon () displays in the grid.

These records provide hover over tool tip text and display the discontinue reason, if available. Users can also optionally include an institution/investigator/site discontinue reason column in the grid, if preferred.

- [Set up study datasources]()

Set up study datasources

You must have a role with *Data Source Management* permission to complete this procedure.

> **Note**
>
> This procedure applies to regular datasources. If your organization will use composite datasources, please contact your Oracle Project Manager for assistance.

1. Select the study from the study drop-down list in the page header.
2. Click menu ≡ in the page header. Then open **Setup**, and choose **Study data sources**.
3. From the available datasources list on the left, drag and drop datasources you want to use in the study into the list at the right.
4. To modify datasource ranking in right side list, drag and drop datasources to the preferred order.
5. Click **Done**.

   If you removed a datasource, remember to navigate to and re-save the master list criteria page. This step will ensure that the master list uses only the remaining datasources.

> **Note**
>
> Oracle administrators manage sources that display in light gray. If you need to remove an Oracle datasource from the **Selected** list, please contact your Oracle Project Manager.

Site scoring (weighting)

Turn site scoring off, or specify the formula used to determine how Oracle Site Select assigns a site score when turned on. Your site selection team can use the scores displayed in the site grid to determine which sites are most likely to meet key study criteria.

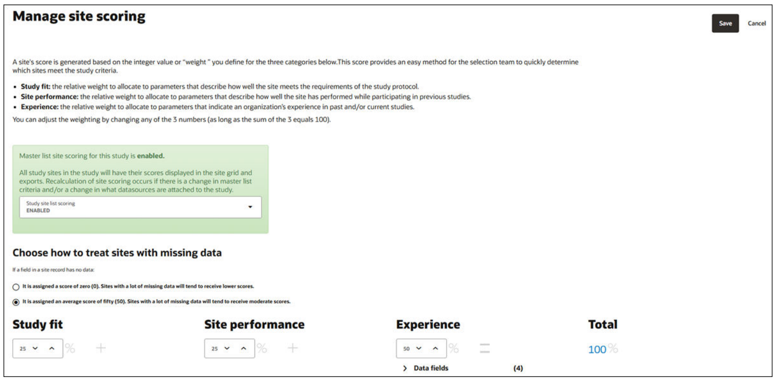
If your organization doesn't use site scoring for your existing studies, you can turn it off for your existing studies to improve site grid loading time. New studies will have site scoring turned off by default, and you can turn it on if preferred. The master list scoring control has a yellow highlight when study site scoring is disabled and a green highlight when enabled.

When you have site scoring turned on, Oracle Site Select bases site scoring on the "weight" (a whole number) of the following, which must add up to 100%:

- **Study fit**: the relative weight to allocate for patient demographic parameters (ontological terms) that were defined for the study
- **Site performance**: the relative weight to allocate to a metric that indicates how well a site delivers patients compared to what was promised
- **Experience**: the relative weight to allocate a metric that indicates an organization's experience in past and/or current studies

By default, a site record field with no data scores 0 for that field. If preferred, you can change the radio button setting (above the percentage fields) to assign empty fields a score of 50.

> **Note**
>
> Master list creation is independent of the site scoring process, so you can proceed with your work on the master list while site scoring runs in the background. Look for a **Master list created** timestamp at the upper left of the grid to see the last time the master list was built.



- Set up site scoring parameters (weighting)
  The value or "weight" defined for Study fit, Site performance, and Experience categories determines a site's score. This score provides an easy method for the selection team to quickly determine which sites meet the study criteria.

Set up site scoring parameters (weighting)

The value or "weight" defined for Study fit, Site performance, and Experience categories determines a site's score. This score provides an easy method for the selection team to quickly determine which sites meet the study criteria.

You must have *Study Setup Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open the **Setup** menu and choose **Site scoring**.
3. Confirm study site list scoring is **Enabled**, or change the drop-down option from **Disabled** to **Enabled**. When enabled, the section turns green.
4. For empty data fields in site records, using the radio button, assign a score of 0 or 50.
5. At **Study fit**, **Site performance**, and **Experience**, indicate the relative importance of each criteria. The sum of the weighting you assign to all three categories must equal 100%.
6. Click **Save**.

Study email templates

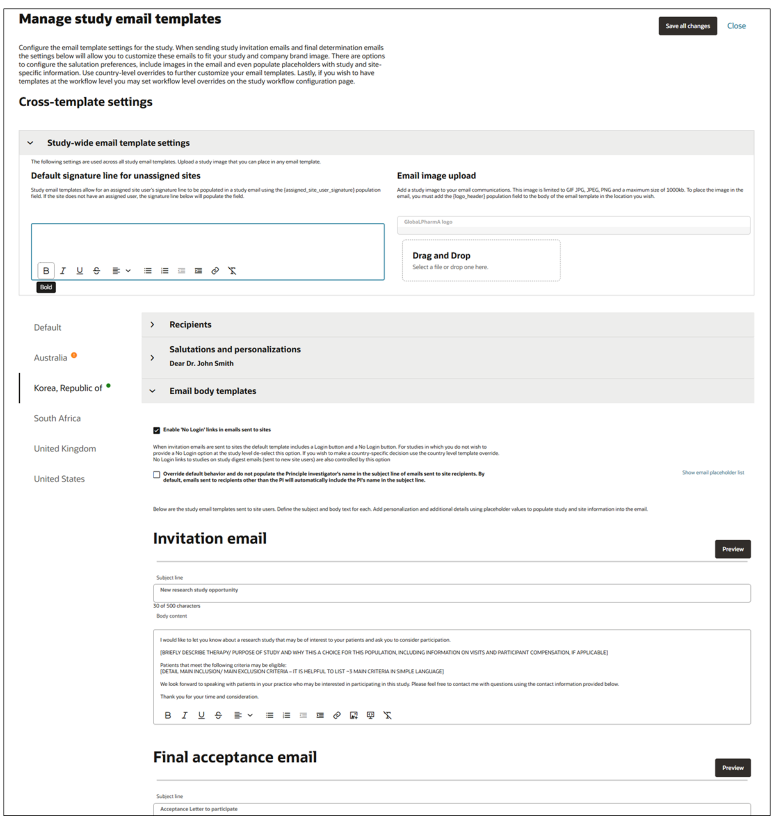
Study level email templates can be configured with default and study country specific settings, if necessary. Specify preferred settings for salutation, login options, and more for all non-system site email notifications.

Default and country specific template options

When you have *Email template management* permission, you can access the Study email templates page from the Setup menu. The Manage study email templates page gives you options to set up templates that fit your study and organizational branding while ensuring your study messages reach the intended recipients.

If you are the email manager, you will receive a notification to set up the templates before study invitation emails are sent to sites. You can define:

- Sender email address, recipient type, salutation, and personalization
- Message attributes (e.g., message copy, no login link, study logo)
- Study invitation subject and text
- Acceptance and decline message subject and text



Template settings and attributes

The Manage study email templates page organizes related settings in sections you can open and close using accordion controls. Click a section's toggle to open or close that section.

At the top of the configuration area, open the Study-wide email template settings section to configure a Default signature for unassigned sites and an Email image, as preferred. The settings in this section apply across all study email templates (i.e., Default and all country-specific templates).The signature and image options will fill placeholders you define.

> **Note**
>
> You must define a study logo and email salutation settings for all new studies. These attributes are not recreated automatically when you set up a new study.

Default signature: The default signature will populate the {assigned_site_user_signature} placeholder for sites that don't have an assigned user. Use the rich text controls at the bottom of the signature field to apply formatting.

If, instead, you add the {assigned_user_signature_line} placeholder in the study email template, the outbound email includes the signature line configured in the assigned user's Oracle Site Select profile, if any. That signature is not configured within the "Manage study email template" page.

Email image upload: When you upload a study image file it populates the {logo_header} placeholder in the body of any email template. For each new study, add a logo image on the Default tab. You'll find the control for browse and select or drag and drop at the section's top right. You can upload an image that is:

- Up to 1000KB file size
- JPEG, GIF, or PNG file type (you can crop JPEG and PNG images but not GIF images)
- Up to 40 pixels high (the template automatically resizes the image to 40 pixel maximum)

A vertical navigation menu allows you to navigate to settings for the Default template and the country-specific templates for this study. Each menu item includes three accordion sections that group related settings:

1. **Recipients**: General (like default sender email address), Site network delegates, and Archived copies sections allow for the configuration of those respective study settings. For country templates, the Recipient section also includes the Override default settings check box. See below for more details above email template attributes. If you check the Override check box, and you customize the required fields for that template section, the country displays a green dot badge in the vertical menu to indicate a complete setup. If fields for that country are not completed as required, the country will display an orange attention badge .
2. **Salutations and personalizations**: Fields in this section let you configure how site users will be greeted in the study invitation and final determination emails. You can also specify the template's default signature line (Default and country-specific) in this section.
3. **Email body templates**: Select your preferred behavior to enable no login links and the use of the Principal investigator's name in the email subject line. You'll also configure the Invitation, Final acceptance and Final decline body text in this section. Click Show email placeholder list to open the list in a drawer at the right. The drawer remains open until you click Close, allowing the list to be available to you as you compose the body text. We encourage you to Preview each of your email templates to ensure they reflect the formatting and text you intend to send. Previews populate email placeholder values with sample site data. Data is not related to an imported site.

When final acceptance and/or final decline emails are disabled at the study level, inputs for these fields are also disabled on the Study email templates page. In this case, the inputs show the following message on hover: “This email template is disabled at the study level. Please review the configuration on the Setup > Study details page.”

Email template attributes

You can optionally turn on an override setting to send all study emails from the address listed in the Default tab's "Default Sender Email" field. When turned on, all emails to site and Oracle Site Select users, including study template emails (e.g., Invitation to participate, Acceptance and Decline, CDA approval, etc.) and Oracle Site Select user notification emails (i.e., CDA submission notification), will have the sender's email pulled from the Default Sender Email input, not the assigned user's or any other user's email.

With the override setting enabled, there is no change to the sender's name, only the email address. The following example behaviors are by design:

- If the email address listed on the default tab is: no-reply@example.com (or similar), the site is not assigned to a Oracle Site Select user, and the user who invites the site to the study is "John Smith," then the site user(s) who receive the invitation email will receive the email from "John Smith" with the email address no-reply@example.com
- If the email address listed on the default tab is: no-reply@example.com, the site is assigned to the Oracle Site Select user "Brandon Smith" with the email brandon.smith@cro.com, and the user who invites the site to the study is "John Smith," then the site user(s) who receive the invitation email will receive the email from "Brandon Smith" with the email address no-reply@example.com
- If a site user "Jane Doe" whose email address is jane.doe@site.com submits a CDA to the site portal, and the email address listed on the default tab is: no-reply@example.com then the Oracle Site Select user who invited the site (there is no Oracle Site Select user assigned to the site) will receive the CDA submission notification email from "Jane Doe" with the email no-reply@example.com
- If a site user "Jane Doe" whose email address is jane.doe@site.com submits a CDA to the site portal, and the email address listed on the default tab is: no-reply@example.com, then the Oracle Site Select user assigned to the site will receive the CDA submission notification email from "Jane Doe" with the email no-reply@example.com

Additionally, when the Default tab's email override setting is on, the Default Sender Email input field on the country level tabs will be disabled - even when the country level override setting is enabled.

System emails that are not related to a study (e.g., locked user account, password reset, etc.), and thus will not use the study-specific override address defined on the study email template's Default tab.

If required by your organization, you can also enable a feature that will forward a copy of all site emails to an account manager or other specific email address. This setting is controlled by "Send a copy of all site communications to" on the default template, and this control is also available on each country-level tab and can be overridden from the default level. Enter one email address in the field provided with the control; multiple addresses are not supported. If your organization requires email copies sent to multiple addresses, enter a distribution list address in the field.

The duplicated email will include an identifier that prepends the email subject line of the originating email. Note that site users will not see this prepended identifier, nor will site users have any indication that a copy of the email is sent to another email address. The prepended identifier includes the following information: "Archived <study_id>; <PI_lastname>, <PI_firstname>: <original subject line>".

Additionally, site portal links in the following email types are disabled in the copy sent to the specified address:

- Welcome
- Resent invitation
- CDA notification

If your organization prefers to have some or all site users log in to the site portal to complete tasks, you can enable and disable the "No login" links in site emails. You'll find the option in the template Default tab, as well as on the individual tab for each country included in the study.

You can also set multiple email personalization options to define western or eastern salutation convention and follow the salutation with additional text or specific punctuation. Optionally, you can disable the option to apply salutation, personalization and additional text options to the digest email sent to users added to a site's profile.

Email message text and placeholders

When creating or modifying message text for the invitation, acceptance, or declination email templates, you can optionally customize the message using any of the study and user placeholders listed below.

Placeholder	Description
{account_image_<number>}	The outbound email message will include the image saved for the account image placeholder, if any. Up to five images can be saved at the account level. Replace <number> in the placeholder with numeral 1-5 for the preferred image.
{assigned_user_email}	From the assigned site user's profile. Blank if site is not assigned
{assigned_user_first_name}	From the assigned site user's profile. Blank if site is not assigned
{assigned_user_full_name}	Concatenated first and last name from the assigned site user's profile. Blank if site is not assigned
{assigned_user_last_name}	From the assigned site user's profile. Blank if site is not assigned
{assigned_user_signature_line}	A user configures their signature by editing their Oracle Site Select user profile. The signature field supports HTML for added design support.
{assigned_user_title}	From the assigned site user's profile. Blank if site is not assigned.
{compound}	Compound
{inst_address1}	Institution address 1
{inst_address2}	Institution address 2
{inst_city}	Institution city
{inst_country}	Institution country
{inst_department}	Institution department
{inst_full_address}	Institution full address
{inst_name}	Institution name
{inst_state}	Institution state
{inst_zip}	Institution ZIP/postal code
{logo_header}	From the uploaded logo on the manage email templates page

Placeholder	Description
{pi_address1}	Investigator's address 1
{pi_address2}	Investigator's address 2
{pi_city}	Investigator's city
{pi_country}	Investigator's country
{pi_degree}	Investigator's degree
{pi_department}	Investigator's department
{pi_first_name}	Investigator's first name
{pi_full_address}	Investigator's full address
{pi_full_name}	Investigator's full name
{pi_last_name}	Investigator's last name
{pi_middle_name}	Investigator's middle name
{pi_npi}	Investigator's NPI
{pi_state}	Investigator's state
{pi_suffix}	Investigator's suffix
{pi_title}	Investigator's title
{pi_zip}	Investigator's ZIP/postal code
{protocol_number}	Current study protocol name from the "Study details for <studyname>" page, Protocol number field
{protocol_title}	Current study protocol title from the "Study details for <studyname>" page, Protocol title field
{reasons_decline}	Comma separated list of declination reasons chosen for declining a site
{reasons_exclude}	Comma separated list of exclusion reasons chosen for declining a site
{salutation_header}	Email template salutation header
{study_description}	Study description saved upon study creation
{study_id}	Current study ID from the "Study details for <studyname>" page, Study ID field
{study_indications}	Indication name from the "Study details for <studyname>" page, Study indications text field
{study_information}	The study information text that is input on the site's assigned workflow
{study_name}	Study name saved upon study creation for the current study
{study_sponsor}	Sponsor name from the "Study details for <studyname>" page, Study sponsor text field
{today_date}	US date format MM/DD/YYYY
{today_date_eu}	EU numeric date format DD/MM/YYYY
{today_date_eu_mon}	EU abbreviated month date format DD/MON/YYYY (abbreviated month)
{today_date_us_long}	Long format US date Month DD, YYYY
{today_date_us_verbose}	Verbose US date DD(st/nd) of Month, YYYY
{trial_phase}	The study's phase
{user_study_list}	The list of comma-separated studies (including this study) the email recipient has access to associated with this account

> **Tip**
>
> Preview each template to validate that placeholders in the template heading and body display as expected and ensure that curly braces are not displayed by mistake.

- Set up study level email templates
  Use the settings on the Manage study email templates page to define the messaging, routing, and branding used in the study's emails. You can set Default options and optionally configure specific settings for the countries included in your study. The settings apply to your study's invitation, final acceptance, and final decline emails.
- Set up custom logo for study email templates
  Configure a custom logo to populate an image placeholder in your study templates. The image will be used across the study's Default and country-specific study templates.
- Send copy of email to a specific CRO/Sponsor address
- Set up No login links in emails
  Optionally enable or disable Site portal No login links in study emails sent to sites or their representatives You can also configure this setting for one or more study countries, if appropriate.

Set up study level email templates

Use the settings on the Manage study email templates page to define the messaging, routing, and branding used in the study's emails. You can set Default options and optionally configure specific settings for the countries included in your study. The settings apply to your study's invitation, final acceptance, and final decline emails.

You must have a role with *Email Template Management* permission to complete this task.

If preferred, you can include study and user placeholder fields in a template's subject and/or body, and if available, the placeholder's value automatically populates outgoing study email notifications. On Default and country tabs, click **Show email placeholder list** to access the full list of placeholders and formatting requirements.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open the **Setup** menu and click **Email templates**.
3. Open the **Study-wide email template settings** section using the open/close section toggle ›.
4. At **Default signature line for unassigned sites**, enter the preferred signature. You can optionally format the signature using the rich text controls at the bottom of the text field.
5. Optionally, at **Email image upload**, click **Drag and Drop** to navigate to a storage location to select an image file. Use a JPEG, GIF, or PNG file type up to 1000KB max file size.When uploaded, complete the text field above the file name. This alt text is available to users who use assistive technology text readers.
6. At the left side menu, click the **Default** tab. If necessary, toggle open the **Recipients** section. Under **General recipient settings**, enter a **Default sender email address** (the address of the person who will be sending the email). Optionally check the **Override and send all emails...** check box, and use the drop-down field to choose the **Recipients of study email from the site's profile**.
7. At **Site network delegates**, use the drop-down field to choose the **Site network user preference**.

8. At **Archived copies of study emails**, optionally check **Send an archived copy of all site communication emails to the site-assigned Select user**. Click the **Send an archived copy of all site communications to** field to enable field editing and enter a single email address in the field. Click **Add** to create an additional email address field. These fields also accept distribution list addresses to allow groups to receive copies, if necessary.
9. (Optional) toggle open the **Salutations and personalizations** section. If you want to personalize emails with default and country-specific salutations, use the options below. The section header will update to show you the current settings as you set the following:
    a. Under **Salutation format**, select how to display the recipient's first and last names. Western convention options are First name, Last name, or First name + Last name. Eastern convention is Last name + First name. You can also choose No personalization, if preferred.
    b. To add a custom salutation, at **General salutation** enter a message (e.g, "Dear").
    c. (Optional) add custom text or punctuation (e.g., add a colon or comma) after the salutation in the **Enter text or punctuation** field.
    d. To add a title to the salutation, enter a title, such as "Dr.," in the **Personalize title prefixed to Principal Investigator names** field.
    e. (Optional) Check **Apply salutation, personalization and additional text options to the digest email sent to users added to a site's profile**.
10. Toggle open the **Email body templates** section. Optionally check the **Enable 'No Login' links in emails sent to sites** check box. Optionally check the **Override default behavior and do not populate the Principal Investigator**... check box.
11. Click **Show email placeholder list** to open a drawer where you can view all available placeholders. You can leave the drawer open while you complete the following steps.
12. In the **Invitation email**, **Final acceptance email**, and **Final decline email** sections:
    a. At **subject line** enter the subject you want sites to see when viewing the email in their inboxes. You can use placeholders as preferred.
    b. At **body content**, enter the message. You can use placeholders as preferred.
13. Click **Preview** the configured template to confirm the content and appropriate use of placeholders, if any.
14. At the top of the **Manage study email templates** page, click **Save all changes**.

    If necessary, you can configure country-specific email templates. To do so, click the country name at the left side of your screen. Under the **Recipients** section, click **Override default settings**. Then complete the settings as necessary for that specific country. Remember to return to the top of the **Manage study email templates** page to click **Save all changes** when you're done.

Set up custom logo for study email templates

Configure a custom logo to populate an image placeholder in your study templates. The image will be used across the study's Default and country-specific study templates.

You must have a role with *Email Template Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open the **Setup** menu and click **Email templates**.
3. Open the **Study-wide email template settings** section using the ›.

4. In the **Email image upload** section, click **Drag and Drop** to navigate and choose an image of your company logo from your hard drive or other storage location. The image must be 1000KB or less and must be GIF, JPG, JPEG, or PNG format.
5. Above the uploaded file name, optionally add alternative text to display for screen readers.
6. Click **Save all changes** to save the image to the study email template.

Send copy of email to a specific CRO/Sponsor address

You must have a role with *Email Template Management* permission to complete this task.

> **Note**
>
> You can configure this setting for one or more study countries, if appropriate. If you choose to do so, click the "Override default settings" option on each country tab.

1. In the top navigation bar, hover over **setup** and select **email templates**.
2. On the default tab, in the **Communication settings** section, check the box for **Send a copy of all site communications to:**
3. Below the check box, enter a single email address. To create another individual email address field, click **Add** and enter the second address. Repeat as necessary, or enter a distribution list address to send the email to a defined group.
4. Click **Done** to save your changes to your email template.

Set up No login links in emails

Optionally enable or disable Site portal No login links in study emails sent to sites or their representatives You can also configure this setting for one or more study countries, if appropriate.

You must have a role with *Email Template Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu in the page header. Then open the **Setup** menu and click **Email templates**.
3. Click the **Default** tab at the left and toggle open the **Email body templates** section. Check or uncheck the box for **Enable "No login" links in emails sent to sites**.
4. (Optional) to configure this option by country, click the country tab at the left. Toggle open the **Recipients** section, check the **Override default settings** check box. This enables editing the country-specific templates. Toggle open the **Email body templates** section. Check or uncheck the box for **Enable "No login" links in emails sent to sites** as necessary.
5. At the top of the **Manage study email templates** page, click **Save all changes**.

Workflows and workflow documents

Defining a study's workflows involves detailed planning around the order in which sites complete individual workflow tasks, required documents, and site communication. Some organizations define workflows using account level templates, which are available to you at the study level when you choose to Add a new workflow.

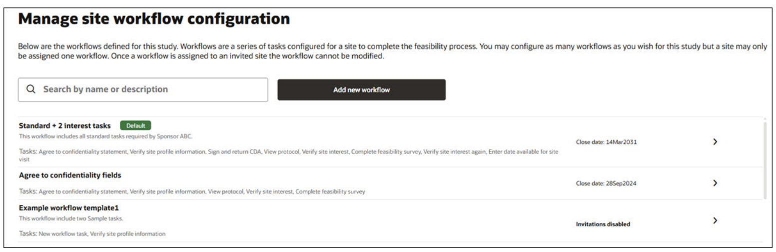
Study workflows

Depending on your role, you may be responsible for defining the tasks that sites complete and the order in which the tasks are made available to sites.

The Manage site workflow configuration page shows an alphabetical list of all saved workflows, with the default pinned to the top. In addition to the workflow name, you'll see more details, if available:

- Description
- A "Default" badge, if applicable
- Workflow close date or "Invitations disabled" text, if applicable
- Task list (ordered by the task display name in the user interface

To help you find what you need faster, you can search for a workflow by name or description. You can also click Add new workflow to create a new workflow from scratch or use an existing account level template.



When you add a new workflow or open an existing one, the configuration page makes it easy to navigate by organizing the Details, Email templates, and Tasks settings into separate tabs. By default, when you open the configuration page, you'll land on the Details tab. A blue line under the tab name shows you which section you're viewing. Each tab has its own Save button that saves only the changes you made in that section. There's also a Save all changes button to save everything across all tabs.

> **Note**
>
> Tabs don't auto-save, so be sure to save your changes regularly.

On the Details tab, you'll define:

- Workflow name (must be unique to the study and no more than 31 characters)
- Workflow close date
- Workflow description (for internal use, up to 250 characters)
- Study workflow information (visible to sites, up to 3,000 characters)
- Completed workflow message (visible to sites, no character limit)

You'll also see a Make default button and an option to delete the workflow. The Delete workflow button is disabled if the workflow has already been assigned to an invited site. If the button is enabled and you choose to delete, you'll confirm that action in a modal before the workflow is removed.

On the Email templates tab, you'll have a dedicated control to enable or disable study invitation emails and all the setting options you'll need to set up workflow-specific email templates. If you enable workflow-specific email templates, you'll define the Invitation, Final acceptance, and Final decline text. These templates do support placeholder fields, so please preview each template to ensure it displays as expected.

The Tasks tab lets you manage the individual tasks that make up a site workflow. You can add, edit, reorder, and remove tasks unless the workflow has already been assigned to an invited site. In that case, task changes are disabled.

When tasks are enabled, you can:

- View all existing tasks under the Workflow tasks section
- Click Create new task to add a task at the bottom of the list
- Reorder tasks by dragging them into a new position
- Click the trash can icon to delete a task
- Optionally enable Allow digital signatures on CDA documents by checking the box

Click any task to open its details drawer, where you can make edits or enter information for a new task. Task detail fields and options include:

- Task type (required): Choose from available task types. Task types already used in this workflow will not appear again, except for Generic document tasks.
  - Document task types include a document type picker
  - Survey includes a survey picker
  - Generic document task includes a task type picker
  - Agree to confidentiality task includes an option to require inputs
- Task display name (required) This name shows in Select and in the Site portal.
- Task information (optional): Add up to 2,000 characters of rich text.
- The next task becomes due after this task is completed (check box)
- When you're done working in the drawer, click Done to keep your changes, or click Cancel to discard any changes to that task.

Some tasks include unique functionality. For instance, if you choose to include "Verify site interest," "Verify site interest again," and/or "Agree to confidentiality statement" workflow tasks, and a site answers No for any of those tasks, the site will be prevented from previewing or moving to the next task unless they change their response to Yes. This is by design.

When sites answer No, the workflow task's progress icon in the Oracle Site Select site grid and in the site portal updates to a red "Discontinued" icon: When a site portal user answers "No" to a task, that action then removes them from consideration (Verify site interest, Confidentiality statement, or Verify site interest again), and the following message displays "Your response to the current task is preventing you from continuing on with this study. If you would like to resume participation, please accept the terms of the current task."

If you include the Sign and return CDA task, you can optionally enable a "Send the finalized CDA as an attachment to all study contacts" check box. When the task setting is enabled and the CDA is fully executed, Oracle Site Select sends the CDA as an attachment to the completed CDA email notification in the same document format as the finalized CDA. The document attachment will also be included in the site communication copy (archive) email if this option is enabled in the study email template settings.

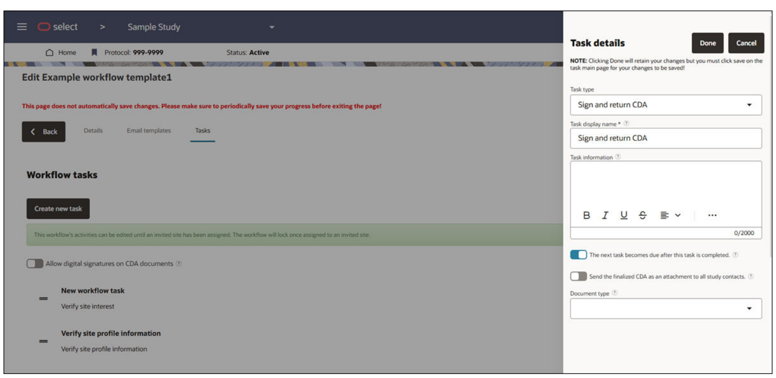
When you include a Generic document task, specify one of the Action Types below. To help you choose the appropriate type, Oracle Site Select displays related subtext depending upon the value selected:

- **Download required** (default) – Use this action type to provide information to the invited site. A document template will be provided to the site. The task only requires the site user to download the file then click Done to complete the task.
- **Approval required** – Use this action type to require an uploaded document from the invited site. A document template will be provided to the site. The task requires the site user to download the file, then upload a file in response. The task will complete when a Select document reviewer approves the uploaded file. A rejection will require the site to upload a new file.
- **Choose response** – Use this action type to require the site to review a document and choose a response. The task requires the site user to download the file and choose their affirmative or declination response. Either response will complete the task.
- **Attestation required** – Use this action type to require the site to review and attest to a document. A document template will be provided to the site along with attestation text. The task requires the site user to download the file, review the attestation text and choose their affirmative or declination response. An affirmative response is required to move on to the next task if the option "The next task becomes due after this task is completed" is selected.

The "Internal workflow task" is another with special functionality. A site assigned to a workflow with an Internal workflow task will see the task in their site portal task list, and their workflow will be paused when they reach it. The task's configured "Site display information" displays during this pause, and that message will be removed when an Oracle Site Select user completes the task.

Please note, if the site reaches their Internal workflow task but also has an ungated Generic document task pending completion, the site portal shows both task's information with the Generic document task below the Internal workflow task. The internal task will halt the workflow, but the site can still complete the Generic document task.

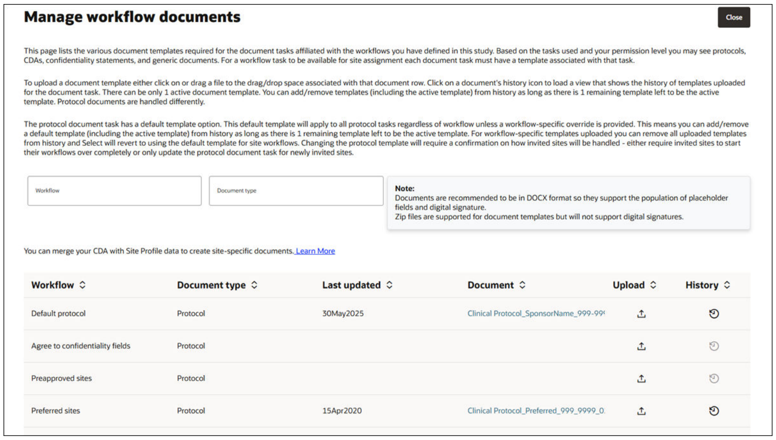
In Oracle Site Select, a site's details drawer shows the Workflow tasks in the configured order. When a Oracle Site Select user completes the task on behalf of the site, a modal displays the task's configured "Task information" text. That user must include an entry in the modal's Task response text field before clicking Submit to complete the internal workflow task and allow the site to resume the workflow.



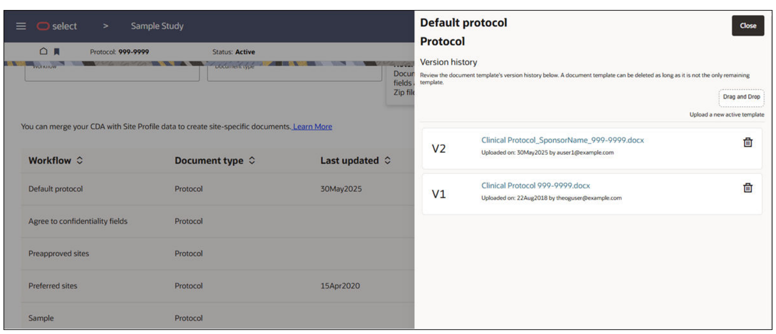
Workflow documents

The Manage workflow documents page is a repository for all document templates used in the study's document workflow tasks.

Your user role permissions determines your access to documents on the Manage workflow documents page. If you have *CDA/Document Template Upload* permission, you'll see CDAs, Confidentiality statements, and Generic documents. If you have *Study Setup Management* permission, you'll see protocol documents. If you have both, or the *Read-only Study Setup* permission, you'll see everything.



Only one template can be active at a time, but you can remove or replace templates as long as one remains active. Upload a new template by clicking the upload icon in the document row. Or, you can click history to view the Version history drawer where you can upload a new template, download the existing template, or delete a previous template (as long as one remains active). The history icon will be enabled if at least one template document has been uploaded for that workflow task.



Protocol templates work a little differently because the page supports both a default protocol template and workflow-specific protocol templates. If you remove a workflow-specific template, Oracle Site Select will automatically fall back to the default template. Changing a protocol template associated with a workflow that has invited sites will prompt you to specify whether the update should apply to new invitations only or restart workflows for already invited sites.

> **Note**
>
> As a best practice, Oracle recommends that you first upload a default protocol then upload any workflow-specific protocols.

The Manage workflow documents page also supports merging CDA templates with Site profile data. To see details about using placeholders in your document, click the **Learn more** link above the document table.

When you're finished viewing or updating documents on the Manage workflow documents page, click Close at the upper right to return to the study home page.

- Set up workflows for sites
  Set the workflow's attributes and close date and set up the tasks you need sites to complete and the order in which they must complete those workflow tasks.
- Set up workflow documents
  The Manage workflow documents page stores all document templates used in the study's document workflow tasks. For a workflow task to be available for site assignment, each document task must have an associated template. Use these instructions to upload and save the documents and optionally view the template upload history.

Set up workflows for sites

Set the workflow's attributes and close date and set up the tasks you need sites to complete and the order in which they must complete those workflow tasks.

You must have a user role with *Select Lite Workflow Configuration* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Workflow configuration**.
3. To create a new site workflow, click **Add new workflow**.
4. Choose to create a new workflow from scratch by clicking **Create new workflow** or Use an existing workflow template. If you choose to use (copy) an existing workflow, select it from the **Choose workflow template** drop-down list, and click **Use template to create workflow**. For copied workflows, update the copy as preferred to change field inputs, reorder or add tasks on the Tasks tab, etc.

   > **Caution**
   >
   > The workflow pages and task drawer DO NOT automatically save changes. Please make sure to periodically save your progress before exiting the page!

5. On the **Details** tab, add or edit the **Workflow name**, **Workflow close date**, and internal-only **Workflow description**.
6. Optionally complete/edit the **Study workflow information** and/or **Completed workflow message** fields. These messages display in the site portal.
7. At the top of the page, click the **Email templates** tab.
8. Click the on/off toggle control for **Send email invitations and collaborate with sites...** and/or **Override the default and country-specific email templates...** to set your email communication preferences for this workflow.
9. At the top of the page, click the **Tasks** tab.
10. If you copied an existing template to create this workflow, the tasks from that template will be listed on the **Tasks** tab and you can add, delete, or update each task as preferred. If you are creating a new workflow from scratch, the **Tasks** tab will show an alert until you

add the first task. Click **Create new task** to open a new task drawer to add a new one to your template copy or brand new workflow. Complete or update the fields below as applicable. You may see some or all of the following options depending on the task type(s) you add to your workflow:

a. At **Task type**, select the task from the drop-down list.
b. At **Task display name**, enter a different name or use the default. This name will show in Oracle Site Select and in the site portal.
c. Optionally un-check **The next task becomes due after this task is completed** if you do NOT want the task to be gated (i.e., completing this workflow task is not required to proceed in the workflow).
d. Optional – check **Send the finalized CDA as an attachment...** for CDA tasks.
e. Optional – choose a **Document type** for tasks that can be completed with a Document library document (CDA, Generic, etc.).
f. Optional – enable/disable toggles for required title, first and last name, and email address for Confidentiality statement tasks.
g. Optional – **Choose survey** for Complete feasibility survey tasks.
h. Optional – enable toggle for **Display study information video link...** for Generic Document tasks.
i. For Generic document tasks, update the document name fields as desired. Select an Action type. If you selected Choose Response or Attestation required, complete the additional text fields.
j. Click **Done** to return to the workflow page.

11. Repeat the **Create new task** steps above to add all tasks required for the new workflow. As you create the task list, you can continue to create more tasks, reorder them, and delete them as preferred. If you choose to delete a task, click to the far right of task name.
12. ***IMPORTANT***: Click **Save all changes** to save your changes. When you return to the study template list, the template's **Last edited on:** line will show today's date and your name.

Set up workflow documents

The Manage workflow documents page stores all document templates used in the study's document workflow tasks. For a workflow task to be available for site assignment, each document task must have an associated template. Use these instructions to upload and save the documents and optionally view the template upload history.

Access to documents on the Manage workflow documents page depends on your user role permissions. If you have *CDA/Document Template Upload* permission, you'll see CDAs, Confidentiality statements, and Generic documents. If you have *Study Setup Management* permission, you'll see protocol documents. If you have both, or the *Read-only Study Setup* permission, you'll see everything.

1. Select the study from the study drop-down list in the page header.
2. Click menu in the page header. Then open the **Setup** menu and choose **Workflow documents**.
3. Locate the document row where you want to add the document. You can filter by **Workflow** or **Document type** using the options above the list.

4. To upload a document template, either click on or drag a file to the drag/drop space associated with that document row. NOTE: the recommended file type is DOCX. You can also use ZIP, but it will not support digital signature.
5. Optional - click history to access template history drawer. You can add or remove templates using controls in the drawer, but you must leave at least one active template.

> **Note**
>
> Protocol documents are handled differently because the Workflow documents page supports both a default protocol template and workflow-specific protocol templates. If you remove a workflow-specific template, Oracle Site Select will automatically fall back to the default template. Changing a protocol template associated with a workflow that has invited sites will prompt you to specify whether the update should apply to new invitations only or restart workflows for already invited sites.
> As a best practice, Oracle recommends that you first upload a default protocol then upload any workflow-specific protocols.

6. Click **Close** to close the history drawer.
7. On the **Manage workflow documents** page, click **Close**.

Feasibility Surveys

This section describes how survey managers create, choose, and score feasibility surveys using the Alchemer tool and Oracle Site Select. Surveys you create in Alchemer will be configured in Oracle Site Select and communicated to sites via workflow task. You'll also learn about the total survey points and where you can see this information in Oracle Site Select.

Alchemer online survey tool and supported question types

If you have the Feasibility Survey Manager permission, you'll use Alchemer online survey tools to create and manage feasibility surveys in Oracle Site Select.

After creating a survey in using the Alchemer product, you can then associate that survey to a study and configure the survey name, flag it as the default, apply scoring and ranking as preferred from within Oracle Site Select. On a survey's Definition tab, you'll find a "View your Alchemer account surveys" link that will open the Alchemer login page in a new browser tab.

> **Tip**
>
> When creating an Alchemer survey, use sections to add and organize related content if another section heading is needed.

Alchemer offers many question types that allow your organization to create highly customized feasibility surveys. The following tables detail question types supported in Oracle Site Select and those that are not supported. The table also includes details about options and scenarios we've tested.

Question Type	Logic Tested with Oracle Site Select	Supported by Oracle Site Select	Scorable in Oracle Site Select	Tested As	Additional Conditions	Supported in Oracle Site Analyze
Textbox	Skip, Display	Yes	No	N/A	None noted in testing	Yes
Textbox List	This type does not allow additional logic	Yes	Yes	2, 4, 6, 8, 10	None noted in testing	No
Textbox Grid	This type does not allow additional logic	Yes	No	2x2, 4x4, 6x6, 8x8, 10x10, 20x20	None noted in testing	No
Slider	Skip, Display	Yes	No	N/A	None noted in testing	Yes
Rating (Likert Scale)	Skip, Display	Yes	Yes	6, 10, 20	None noted in testing	Yes
Radio Button Grid	Skip, Display	Yes	No	2x2, 10x10, 20x20	None noted in testing	No
Radio Button	Skip, Display	Yes	Yes See Additional Conditions	4x4, 10x10, 20x20	Scorable without customization. Using the custom response option, the data does NOT come into Oracle Site Select and therefore is not scored.	Yes
Percent	Skip, Display	Yes	Yes	N/A	None noted in testing	Yes
Number	Skip, Display	Yes	Yes	N/A	None noted in testing	Yes
Net Promoter Score (NPS)	Skip, Display	Yes	Yes	N/A	None noted in testing	Yes
Image Select (select one)	Skip, Display	Yes	Yes	3, 4, 5	Advanced logic not supported. Known behavior: Oracle Site Select PDF shows both "no answer" and list of image file names.	Yes

Question Type	Logic Tested with Oracle Site Select	Supported by Oracle Site Select	Scorable in Oracle Site Select	Tested As	Additional Conditions	Supported in Oracle Site Analyze
Image Select (multi- select)	Skip, Display	Yes	Yes	4, 7	Advanced logic not supported. Image file name included in PDF download and CSV export	No
Essay/ Long Answer	Skip, Display	Yes	No	N/A	None noted in testing	Yes
Email	Skip, Display	Yes	No	N/A	None noted in testing	Yes
Drop-down menu	Skip, Display	Yes	Yes	N/A	None noted in testing	Yes
Drag and Drop Ranking	This type does not allow additional logic	Yes	No	8x8, 20x20	None noted in testing	No
Date	Skip, Display	Yes	No	N/A	None noted in testing	Yes
Continuous Sum	This type does not allow additional logic	Yes	Yes	2x2, 6x6, 20x20	None noted in testing	No
Checkboxes	Skip, Display	Yes	Yes	4, 8, 10, 20	Oracle Site Select does not support the checkbox logic option "Other."	Yes
Checkbox Grid	Skip, Display	Yes	Yes	8x8, 10x10, 20x20	Known behavior: Does not work for reversioning of surveys; 8x8 option shows incorrect order in UI/PDF	No
Contact Form	Skip, Display	Yes	No	N/A	None noted in testing	No
Signature	This type does not allow additional logic	No	No	N/A	None noted in testing	No

Question Type	Logic Tested with Oracle Site Select	Supported by Oracle Site Select	Scorable in Oracle Site Select	Tested As	Additional Conditions	Supported in Oracle Site Analyze
File Upload	This type does not allow additional logic	No	No	N/A	None noted in testing	No
Star Rating Grid	Skip, Display	Yes	No	10x10, 20x20	Limited to 10x10 option. 20x20 can cause unexpected behavior.	No
Ranking Grid	This type does not allow additional logic	Yes	No	10x10, 20x20	None noted in testing	No
Slider List	This type does not allow additional logic	Yes	No	10x10, 20x20	Limited to 10x10 option. 20x20 can cause unexpected behavior.	No
Drop-down Menu List	Skip, Display	Yes	No	6x6, 10x10, 20x20	None noted in testing	No
Drop-down Menu Grid	Skip, Display	Yes	No	10x10, 20x20	Limited to 10x10 option. 20x20 can cause unexpected behavior.	No

The following table defines export for Alchemer question types listed above:

Question Type	Export from Select via PDF	Export from Select via CSV	Export from Analyze via CSV
Textboxes	Yes	Yes	Yes
Textbox List	Yes. Each option listed with input.	Yes. Each row exports as a column.	No
Textbox Grid	Yes	Yes. Each grid row exports as a separate column.	No
Slider	Yes	Yes	Yes
Rating (Likert Scale)	Yes	Yes	Yes
Radio Button Grid	Yes	Yes. Each grid row exports as a separate column.	No
Radio Button	Yes	Yes	Yes
Percent	Yes	Yes	Yes
Number	Yes	Yes	Yes

Question Type	Export from Select via PDF	Export from Select via CSV	Export from Analyze via CSV
Net Promotor Score (NPS)	Yes	Yes	Yes
Image Select (select one)	Yes	Yes	Yes
Image Select (multi-select)	Yes - selected file name	Yes - selected file name	Yes
Essay/Long Answer	Yes	Yes	Yes
Email	Yes	Yes	Yes
Dropdown Menu	Yes	Yes	Yes
Drag & Drop Ranking	Yes. Answers appended with -add.	Yes. Each grid row exports as a separate column.	No
Date	Yes	Yes	Yes
Continuous Sum	Yes. Shows options selected but not total value.	Yes. Each selected option exports as a column.	No
Checkboxes	Yes	Yes	Yes
Checkbox Grid	Yes	Yes. Each grid row exports as a separate column.	No
Contact Form	Yes	Yes. Each field exports as a separate column.	No
Signature	No	No	No
File Upload	No	No	No
Star Rating Grid	Yes	Yes. Each grid row exports as a separate column.	No
Ranking Grid	No	Yes. Each grid row exports as a separate column.	No
Slider List	Yes	Yes. Each grid row exports as a separate column.	No
Dropdown Menu List	Yes	Yes. Each row exports as a separate column.	No
Dropdown Menu Grid	Yes	Yes. Each grid row exports as a separate column.	No

The following Alchemer survey question types are not supported.

Question Type	Comments
Video Sentiment	This type requires additional cost for a higher license level and will not be supported.
Audio Sentiment	This type requires additional cost for a higher license level and will not be supported.
Text Highlighter	This type requires additional cost for a higher license level and will not be supported.

Question Type	Comments
User Data	This is data collected only on Alchemer users and will not be supported.
Cascading Drop-down Menu	This type requires additional cost for a higher license level and will not be supported.
Conjoint (Choice-Based)	This type requires additional cost for a higher license level and will not be supported.
Semantic Diff	This type requires additional cost for a higher license level and will not be supported.
Quick Sort	This type requires additional cost for a higher license level and will not be supported.
Max Diff	This type requires additional cost for a higher license level and will not be supported.
Image Heatmap	This type requires additional cost for a higher license level and will not be supported.
Grouping (Open Card Slot)	This type requires additional cost for a higher license level and will not be supported.
Grouping (Closed Card Slot)	This type requires additional cost for a higher license level and will not be supported.
Custom Table	This type requires multiple levels of logic and will not be supported.
Custom Group	This type requires multiple levels of logic and will not be supported.

Feasibility survey configuration

When you have the Oracle Site Select *Feasibility Survey Management* role permission, you can configure and manage your study's surveys on the Configure study feasibility surveys page. The page lists the study's saved surveys and includes distinguishing details on each survey row to provide more information at a glance. For instance, the list shows:

- Survey short name
- Survey Alchemer name
- Workflows: (assigned workflows list)
- Last updated: <date in DDMonYYYY>; Created: <date in DDMonYYYY>

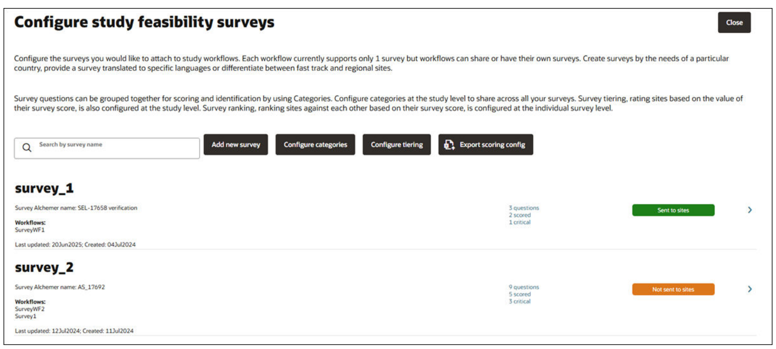
The list also shows question count details for each listed survey. Question counts are clickable links to the settings area for that detail line (e.g., the questions/scored/critical preview numbers on the survey list link to the scoring detail subtab for that survey). The links are:

- # questions
- # scored questions
- # critical questions (design may show unscored questions)
- Ranking enabled (displays only when enabled)

A badge displays on the far right of the survey row if a survey has a specific type (i.e., Default or Preferred site). Additionally, status badges show you whether the survey is Available, In setup, Sent to sites, or Not used.

The configuration list page provides additional functionality. For example:

- The search field above the studies list allows you to search for a specific survey by the survey short name or Alchemer name. This field is a “fuzzy” search that returns close matches and exact matches.
- Category, tiering, and export settings for surveys apply at the study level, and you can access these settings from the configuration page. Above the study list, click the Configure categories, Configure tiering, or Export scoring config buttons to open a settings drawer from the right side of your screen. Each of these configuration options open a separate settings drawer.
  - **Category**: Use the settings in the Define categories drawer to add new, unique categories (25 character max) and delete categories, if necessary. For an existing study with survey categories already defined, the previously-saved values will display in the category config drawer. If you attempt to delete a category that's already assigned to a question, an error displays and lists the surveys where the category is already used so you can assign a new category to the affected questions before attempting to delete again.
  - **Tiering**: Use the settings in the Define scoring tiers drawer to define ranges for each of the four survey tiers. For an existing study with existing tiering configured (other than the default) the previously-saved values will display on the tiering config drawer.
  - **Export scoring**: Use the settings in the Export survey scoring drawer to your preferences for the Microsoft Excel format export. You can choose your report format (either Questions as rows, Questions as columns, or Enhanced questions and criteria report) and your preferred reporting options (Only export questions marked scored and/or Export questions comments).
- If none of the surveys listed on the Configure study feasibility surveys page meet your study requirements, click the Add new survey button to navigate to the survey definition tab, where you can choose a survey from the list of the surveys configured in your connected Alchemer account and configure it as required for the study.



Preferred site surveys

When there is at least one preferred site in any datasource attached to the study, Oracle Site Select automatically adds a Preferred site survey to the survey list on the Configure study feasibility surveys page. The survey will have a white "Preferred site" badge. By design, Oracle Site Select won’t add a Preferred survey if there isn’t a preferred site in an attached datasource, and you may not create a survey with “Preferred site” as the short name.

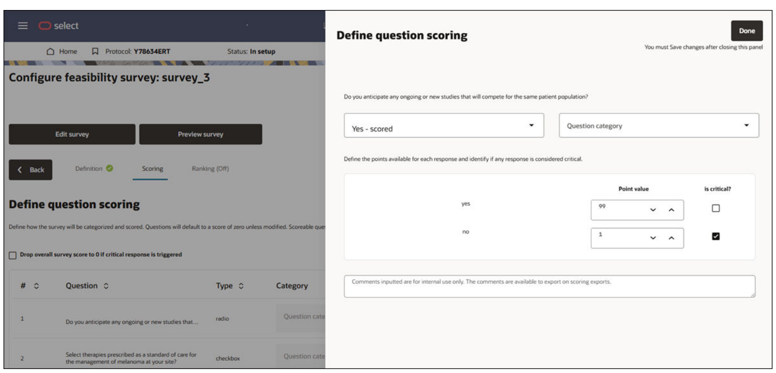
On the Preferred site survey’s Definition tab, below the Study survey short name field (which is not editable), you’ll see a check box option with the following label and helper text: “Disable this survey option so preferred sites receive the survey they are assigned in their workflow. Note: If this option is disabled you must select a survey below and save changes. All preferred sites in the study will receive this survey regardless of what survey is assigned in their study workflow. This may cause confusion with your study team.” By default, the check box is checked.

If there is a Preferred site survey and you configure it to be available for all preferred sites (i.e., the checkbox is unselected for “Disable this survey option….”), choose a survey and configure the survey specific settings on the Scoring and Ranking tabs. You can also create a Survey submission message for the Preferred site survey.

Survey definition settings

To adjust settings for an individual survey listed on the Configure study feasibility surveys page, click the arrow at the far right of the survey row to access the Configure feasibility survey, Definition tab. Here, you'll find settings for selecting a survey for the study and configuring it to your needs. Functionality like setting the survey's short name, marking it as the default, creating a survey submission message, etc. is also available on this page. Note that if you choose to update the submission message after already assigning the survey to sites, you'll need to click Update message to ensure the new message will be used going forward. Click Edit survey at the top left of the Definition tab to sign in to Alchemer and modify the selected short name survey, if necessary. Click Preview survey to view the survey in a new browser tab.

Click the Scoring tab to define the survey's question scoring. When defining scoring settings, you can update the Category and Scored? column values, in line, by clicking the applicable table cell (look for the down arrow that opens a list of values). If you need to update other values for the question, click edit to open the question's scoring drawer component. After making changes, click Done to close the drawer, and be sure to click Save on the Configure feasibility survey page to ensure your changes take effect.



> **Note**
>
> We recently made a change to scoring configuration to allow for saving and calculating a survey score without categorizing the scorable questions. With this change, the survey's Survey total score is based on the total points achieved from responses to scored scoreable questions divided by the maximum points available for each scored scoreable question in the survey.

You can optionally award score values to survey question responses based on a scale determined by how the response compares against all other inputted responses. These “Floating scale” scores apply only to textbox input questions with numeric and percentage inputs. When you choose Floating scale scoring, the drawer displays four ranking inputs, each having its own score input. If the question isn’t marked as scored, the ranking input configuration is disabled, but it will persist any inputted criteria. Please note that marking a range as critical is not supported for Floating scale scoring.

When you set up Floating scale scoring:

- For textbox list questions and continuous sum questions, each row of the question is considered a separate textbox input question. For example, a textbox list question with three rows is considered three separate textbox input questions, and you can apply a floating score to each.
- For textbox grid questions (with numeric or percentage validation), each row:column pairing is considered a separate textbox input question.

The site grid Survey analysis tab has a Rescore button that is enabled when any survey in the study has a question configured for float scoring. When clicked, Oracle Site Select ranks survey responses to the question marked for a floating scale and applies the point value corresponding to the percentile ranking for the site's question response. Each time a Oracle Site Select site grid user clicks the Rescore button, Floating scale scoring recalculates across every survey in the study.

IMPORTANT: Oracle Site Select considers the latest responses to a survey with floating point questions when scoring the survey across all sites that have submitted it. If a study site has been reassigned to a new survey, the previous latest response submission of the survey with a floating point question will still be considered in the scoring of all surveys with that floating point question. This is regardless of the fact that the study site is no longer assigned to that survey with the floating point question.

On the Configure feasibility survey page, click the Ranking tab to configure survey ranking to your preferences within the drawer component. Survey ranking is an optional feature that groups sites based on their performance against their peers. For example, when 10 site surveys are submitted, and Rank 1 is defined as the top 80% of sites, the 2 sites with the highest scores will receive a rank of 1. When survey ranking is configured, site grid users can add a Survey ranking column to the grid and the column can be included in data extracts, reports, etc. Chapter 12 Scoring surveys 12When Ranking has been enabled for the survey, you'll see a green check mark next to the Ranking tab.

Survey started at or by

Oracle Site Select records the survey as started when either an Oracle Site Select user or a Site portal user clicks the survey link for a particular site.

Survey started at/by values will be recorded as follows:

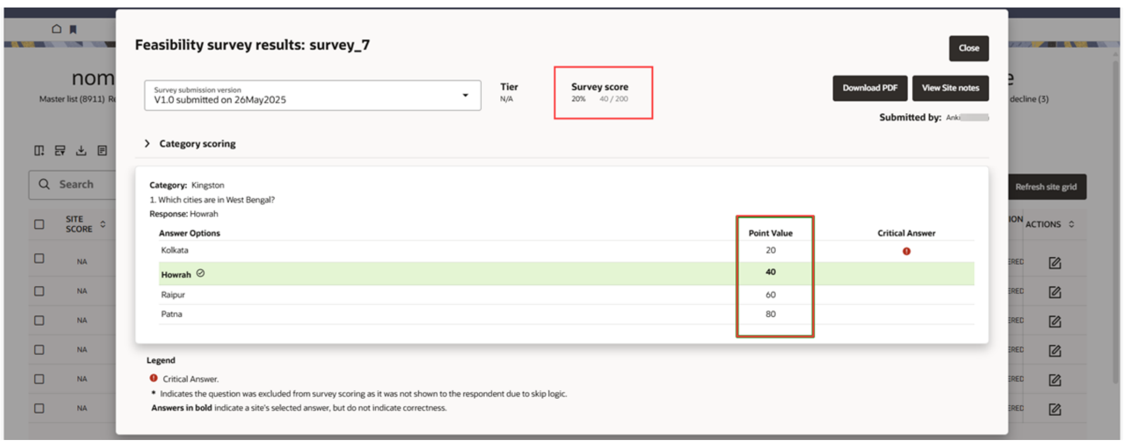
- When a Site portal user reaches the survey task, the survey is considered started, and the started at/by values are set based on the user who clicks the link to the survey from the Site portal survey task action.
- If an Oracle Site Select user completes the previous task, they are recorded as the user who ungated or unblocked the survey task. If the workflow's first task is the Survey task, the first user to access the Site portal and the time they first accessed it are recorded as the started at/by values
- If the survey started at/by values are not already populated and a Select user opens the survey via the site Workflow tab in the Site details drawer, that user will be recorded as the survey started at/by value.
- If a site starts a survey in one workflow (e.g., SurveyA), is reassigned to another workflow with a different survey (e.g., SurveyB), and then returns to the previous workflow (SurveyA), the started by/at values for SurveyA will be restored.
- Editing a survey does not update or change the started by/at values.

Total survey points

Total survey points improves visibility into feasibility survey scoring, and there are several options for you to view this important information. Using the column picker, you can optionally add the Total Survey Points column to see the total in the context of the site grid. The column displays the total possible points a site could have received on its most recent survey submission, taking into account skip logic, branching paths, and question type (single, multiple, or grid).

The score shown in the Survey score area of the survey response modal also shows Total survey points. You can see both the raw score and the possible score for all submitted survey versions. If a survey was submitted prior to Oracle Site Select release 25.1, resave the scoring configuration page to view the possible points. Resaving triggers recalculation and population of a new scoring field for that survey.

Survey percentage score and category-level scoring logic also use the actual possible points attained during survey completion. This ensures the percentage reflects only the questions that were shown and answerable by the site.



We created a total_possible_score column to the survey_response table to support this functionality. The name of the column aligns with the current column names and differentiates possible points from the existing "raw_score" column.

The total_possible_score column is also available in nightly CSVs files for reporting views in the study_sites and survey_responses, and as follows in REST API endpoints:

- workflow_details - added to the survey_response_details object array: For each submitted survey, will populate the total possible points calculated as "survey_total_possible_score" and will populate the total points earned by the site for the survey as "survey_total_points_scored"
- studysite_details - this api is a dump of the studysite table. It outputs only the most recent survey submission version possible points as "survey_possible_score"
- Set up feasibility survey
  Configure one or more feasibility surveys for use with a study. When a study has multiple associated surveys, at the workflow level, users can determine which survey to affiliate with which workflow.
- Set up tiering
  Survey tiering is based on the survey response total percentage score. The ranges can be updated as needed and tiers will be recalculated immediately for all survey submissions upon saving changes. Survey tiering is configured at the study level.

- Export survey scoring configuration
  If you have permission to set up feasibility surveys, you can optionally export a study's survey scoring configuration to a Microsoft XLSX file.
- Edit existing surveys
- Preview a survey
  Preview a survey to confirm expected layout and question formatting.

Set up feasibility survey

Configure one or more feasibility surveys for use with a study. When a study has multiple associated surveys, at the workflow level, users can determine which survey to affiliate with which workflow.

You must have a role with *Feasibility Survey Management* permission to complete this task, and your organization must have at least one survey created in your Alchemer account.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Feasibility survey**.
3. Click **Add new survey** to open the survey's **Definition** tab.
4. At **Study survey short name**, enter an abbreviated but recognizable survey name. It will be use in reporting and in the site's progress view.
5. Optionally click **Make default survey**.
6. Open the **Survey submission message** section, and review the default text. If preferred, update the message and format using the rich-text options in the text field. Click **Update message**.
7. At the bottom of the **Definition** tab, click a radio button to choose a saved survey. You can optionally filter the list by survey title, and optionally view only available surveys. Above the list, optionally click **View your Alchemer account surveys** to log in to Alchemer in a new browser tab.
8. The survey you chose now has a Selected label. If necessary, you can edit the survey in Alchemer. You can optionally preview the survey as well.
9. Click the **Scoring** tab. Above the questions table, optionally check the **Drop overall survey score to 0**... check box.
10. Questions default to a 0 score unless modified. For each question, you can adjust Category or Scored settings and add Comments in line if preferred. Alternatively, you can view all of the question's settings (e.g., Point values, Critical question flags, etc.) in the scoring drawer. Click edit to open the scoring drawer. In the drawer, use the drop-down controls at the top to specify **Yes-scored** or **No-not scored** and to set a question **Category**.
11. Define the **Point value** available for each response and identify if any response is considered **Critical**.
12. Optionally enter Internal comments, and click Done to save your changes and close the scoring drawer for that question. Repeat the scoring steps for each question as preferred.
13. Above the question table, click **Save**. If you do not need to set up Ranking, click **Save all changes**.
14. Optionally click the **Ranking** tab to configure grouping sites based on their performance against their peers. Click **Enable rank-based tiering** for this survey. For each of the four ranks, enter a percentage value. Click **Save**.

15. At the top of the page, click **Save all changes**.

Set up tiering

Survey tiering is based on the survey response total percentage score. The ranges can be updated as needed and tiers will be recalculated immediately for all survey submissions upon saving changes. Survey tiering is configured at the study level.

You must have a role with *Feasibility Survey Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Feasibility survey**.
3. Click **Configure tiering**.
4. For each of the four percentage fields, enter the preferred thresholds. Use descending integers between 0 and 100 (inclusive). Each rank you enter must be less than the rank above it (i.e., when Rank 1 is 80, Rank 2 must be 79 or below). If you input a rank of 0 in the Rank 1, 2, or 3 fields, the field(s) below that 0 entry will be disabled.

   The field's narrative description updates to reflect your entry as you enter rank values.
5. Click **Save**, and click **Close**.

Export survey scoring configuration

If you have permission to set up feasibility surveys, you can optionally export a study's survey scoring configuration to a Microsoft XLSX file.

You must have a role with *Feasibility Survey Management* permission to complete this task.

1. In the top navigation bar, hover over **setup** and select **feasibility survey**.
2. Click the **Export scoring config** button.
3. In the Export survey scoring drawer, click the radio button for your preferred export format (i.e., **Questions as rows**, **Questions as columns**, or **Enhanced questions and criteria report**.
4. Optional: Check the box for **Only export questions marked as scored** and/or **Export questions comments** as preferred.
5. Click **Export to Excel**.

   Oracle Site Select creates an export file with the following naming convention: <studyName>-surveyScoringConfig-<ddMONyyyy>.xlsx.

Edit existing surveys

You must have a role with *Feasibility Survey Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Feasibility survey**.
3. On the row for the survey you want to edit, click the right arrow › to navigate to the survey's configuration options.
4. Click **Edit survey**.

The Alchemer log in page opens in a new tab. After authenticating, you can edit and save changes to the existing survey. For detailed instructions on editing surveys within the Alchemer tool, please see the Alchemer documentation.

> **Note**
>
> To prevent a scenario where an updated Alchemer survey no longer matches the configured and scored survey in Oracle Site Select, you must now confirm the deletion of the previously saved scoring configuration if you update the survey definition in Alchemer. A new confirmation modal lets you Cancel or Proceed. If you click:
>
> - **Cancel**: the modal closes and restores the previously selected Alchemer survey without changing the saved scoring configuration.
> - **Proceed**: the updated survey replaces the previously selected survey, the previous survey's scoring configuration will be deleted, and the green check mark on the scoring configuration tab will be removed.

Preview a survey

Preview a survey to confirm expected layout and question formatting.

You must have a role with *Feasibility Survey Management* permission to complete this task.

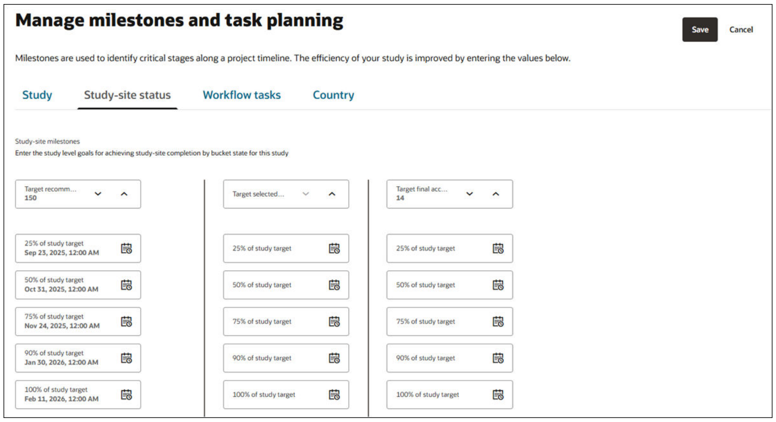
1. Select the study from the study drop-down list in the page header.
2. Click menu ☰ in the page header. Then open **Setup**, and choose **Feasibility survey**.
3. On the row for the survey you want to view, click preview.
4. If you've progressed to the survey's configuration options (e.g., Definition, Scoring, Ranking), click **Preview survey** at the top of the page.

Milestones

Define study milestones when you set up your study to help ensure your team stays on track with key study accomplishments like site enrollment targets.

Milestones will help you track the actual enrollment compared to the goals desired for number of sites and subjects, site activity completion dates, study-site and country response time targets by percentage, and more.

> **Note**
>
> The following study setup tasks must be completed prior to study milestone setup:
>
> 1. Manage study details
> 2. Set master list criteria
> 3. Manage site workflow configuration



- [Set up study, country, and site response time milestones](#)
  Milestones are used to identify critical stages along a project timeline. Use these instructions to set date, number, and percentage targets for specific study milestones.

Set up study, country, and site response time milestones

Milestones are used to identify critical stages along a project timeline. Use these instructions to set date, number, and percentage targets for specific study milestones.

1. Select the study from the study drop-down list in the page header.
2. Click menu in the page header. Then open the **Setup** menu and choose **Milestones**.
3. On the **Study** tab, for the **Project start date**, **Project end date**, and **Proposed site list finalized** fields, click the calendar to select a date, and enter a number in the **Target number of subjects** field.
4. On the **Study-site status** and **Workflow tasks** tabs, enter the goals for completion. You can optionally select dates that reflect the percentage (25, 50, 75, 90, 100) of study target completion for recommended sites, selected sites, and final acceptance sites.
5. On the **Country** tab, select start and end dates for each country in the study. Then, optionally enter country targets for final acceptance, sites selected, and recommended sites. You can also select dates that reflect the percentage (25, 50, 75, 90, 100) of study target completion for recommended sites, selected sites, and final acceptance sites. Complete all remaining country level milestone fields as preferred for each country.
6. Click **Save**.

Reasons for study exclusion/disinterest

When an Oracle Site Select user excludes a site from the feasibility process or a site indicates that they aren't interested in study participation, they may need to provide a reason. An administrator in your account can define a list of reasons, and you can modify that list as necessary for your study.

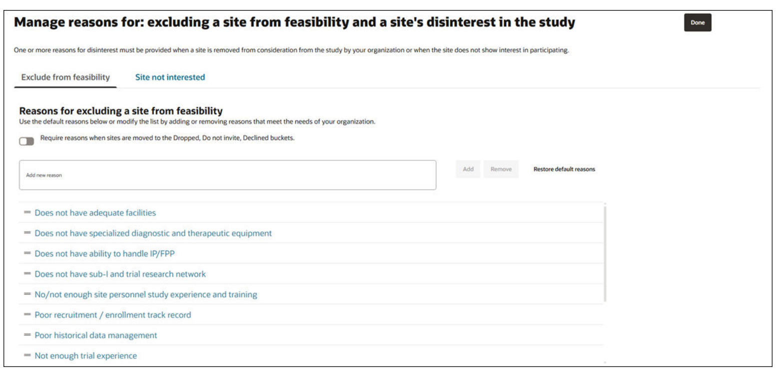
When disinterest and exclusion reasons have been defined at the account level, they automatically populate new studies in the order you set in the default list. Study administrators can adjust the pre-populated reasons while setting up a new study, and any changes made at the study level won't affect the saved account template.

To change Exclude from feasibility and Site not interested lists click the appropriate tab, then enter the reason in the Add new reason field (100 characters max.), drag-and-drop reasons to a new display order, and remove reasons as preferred by selecting and clicking "Remove."

> **Note**
>
> You can switch the "Require reasons..." toggle to enable/disable the required entry if appropriate to the study.

At the study level, you can add a new disinterest reason, or discard any changes to restore the default list and order. You can also drag and drop reasons to a new display order or remove a reason.

> **Note**
>
> You can add and remove "not interested" reasons, but you cannot update them. If a site has already selected a reason and you later add or remove options, the site's original selection will still display. Sites that have not yet accessed the verify site interest task will only see the new set of reasons. If a site selects a reason and you delete that reason, their original choice will continue to appear, even after removal at the study level. Additionally, if a site selects an original reason, you make changes, and the site returns to verify interest again, both the deleted and new reasons will be visible as options.



- [Set up study disinterest and exclusion reasons](#)
  Manage the list of available site study disinterest and site exclusion reasons shown in Oracle Site Select and site portal. Depending on the study, you can use the template reasons defined at the account level, use default reasons, add new reasons, reorder the reasons list, and delete reasons that don't apply.

Set up study disinterest and exclusion reasons

Manage the list of available site study disinterest and site exclusion reasons shown in Oracle Site Select and site portal. Depending on the study, you can use the template reasons defined at the account level, use default reasons, add new reasons, reorder the reasons list, and delete reasons that don't apply.

You must have a user role with *Study Setup Management* permission to complete this task.

1. Select the study from the study drop-down list in the page header.
2. Click menu in the page header. Then open the **Setup** menu, and click **Manage reasons for study exclusion/disinterest**.
3. If you are viewing the default **Exclude from feasibility** tab, optionally toggle the **Require reasons when sites are moved...** on/off switch to the preferred setting for this study. This switch does not apply to the **Site not interested** tab.
4. For both tabs: review the default list of reasons, and then:
   a. To add a new reason, enter the reason text in the **Add new reason** field (100 character max) and click **Add**.
   b. To delete any default reason, select any reason from the list to populate the reason field. Click **Remove**.
   c. To reorder the list, grab the handle to the left of any reason, drag the reason up or down the list to the preferred location, then drop the reason in place.
   d. To discard all changes, click **Restore default reasons**.
5. At the upper right, click **Done**.

6 Account management

Configure account specific settings as preferred for your organization.

- General settings
  Set display behavior for closed studies, default scoring behavior for new feasibility surveys, and optionally configure a custom support link for Oracle Site Select and site portal.
- Account data sources
  When you have *Data Source Management* permission, you can access the account data sources feature to define and manage composite and regular datasources.
- Disinterest and exclusion reasons
  When sites indicate they are disinterested in study participation or an Oracle Site Select user needs to exclude a site from the feasibility process, they may be required to provide one or more reasons. Administrators can configure a master list of reasons available to display to sites in the site portal or when Oracle Site Select users complete tasks on behalf of a site.
- Account level email templates
  Account level templates simplify application of your organization's branding in emails. Use the options in Oracle Site Select to create templates, image placeholders, and default internal task messaging. You can also define custom login/no login button text if preferred.
- Email history and status by study
  See the history and status of email sent to study sites and Oracle Site Select users. When necessary, you can also retry and resend messages.
- Integrations
  Oracle Site Select provides optional account integration solutions at access (user authentication), data (API), and application levels. Use settings on the Account integrations page to manage API tokens, configure PUSH event notifications, setup digital signature authentication, configure survey vendor authentication, and define preferred user authentication.
- Library document labels
  Document-related workflow tasks use your account's defined document labels to categorize Library documents and allow for versioning of similar documents affiliated with the same label.
- Network management
  Network functionality allows for the configuration of account level network profiles and the affiliation of a site to a network profile. Network functionality also allows your organization to leverage a site's affiliated network contact to override study invitation preferences and invite only the network contact.
- Note labels
  Note labels help to group and organize study site notes. When you have *Account note label configuration* permission, you can create and manage the labels to make them available across all studies in the account.
- Users, roles, and teams

- Workflow templates
  Configuring workflow templates at the account level simplifies creation of study level workflows and tasks. Templates you create are available to study administrators when they choose to add a new workflow.

General settings

Set display behavior for closed studies, default scoring behavior for new feasibility surveys, and optionally configure a custom support link for Oracle Site Select and site portal.

Display behavior for closed studies

The Account management: General settings page includes an optional setting to hide studies that are in Closed status. When you turn the setting on, Closed studies aren't visible to Oracle Site Select users, so they don't need to take any action to remove them from their study list and My Dashboard page.

The Study details page includes an optional "Study close message for site users" section where study managers can create a message to display in the site portal. A message saved in that section displays when the study's status is Closed or Cancelled and the account level setting described above is on.

Default feasibility survey scoring

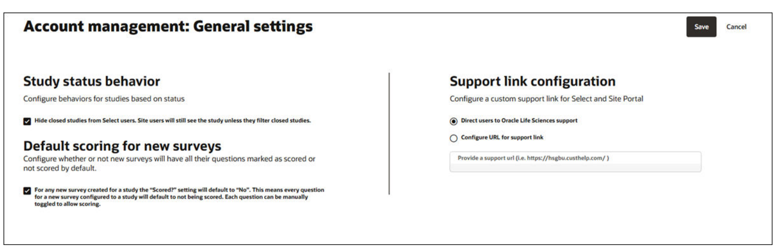
If preferred, you can enable an account level feature to default feasibility survey questions to either scored or not scored. When enabled, all questions in new surveys will be unscored. Study survey managers who configure new surveys can manually toggle individual questions to allow scoring if needed. The on the Account management: General setting page, the default scoring check box unchecked (off) by default. When the setting is off, a new survey added to the study will have the "Scored" option on each scoreable question set to "Yes" by default.

Support link configuration

If your organization prefers provide its own support for your Oracle Site Select and site portal users, you can configure a custom support URL to replace the Oracle Help Center URL. On the Account management: General settings page, input a valid URL in the Support link configuration section. When saved, the "visit support" links in Oracle Site Select and site portal navigation automatically redirect to the configured URL.

Note that the configured URL does not redirect for the following:

- In Oracle Site Select and the site portal, the "support" link in the page footer
- The error page returned with an SSO authentication issue occurs
- The error returned when survey authorization for an account has expired



- Configure closed study display behavior
  Optionally hide closed studies from Oracle Site Select users so they don't show in the study list or on a user's My Dashboard view.
- Configure new survey default scoring
  This account level setting controls whether or not new feasibility surveys will have all their questions default to scored or not scored.
- Configure custom support link
  If your organization prefers to direct users to a group other than Oracle Life Sciences for end user support, you can configure a custom support link that will display in the user navigation menu in Oracle Site Select and in the site portal.

Configure closed study display behavior

Optionally hide closed studies from Oracle Site Select users so they don't show in the study list or on a user's My Dashboard view.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **General** to open the **Account management: General settings** page.
2. Under **Study status behavior**, check the **Hide closed studies ...** check box to enable the setting.
3. At the upper right, click **Save**.

Configure new survey default scoring

This account level setting controls whether or not new feasibility surveys will have all their questions default to scored or not scored.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **General** to open the **Account management: General settings** page.
2. Under **Default scoring for new surveys**, check the **For any new survey created ...** check box to enable the setting.
3. At the upper right, click **Save**.

Configure custom support link

If your organization prefers to direct users to a group other than Oracle Life Sciences for end user support, you can configure a custom support link that will display in the user navigation menu in Oracle Site Select and in the site portal.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **General** to open the **Account management: General settings** page.
2. Under **Support link configuration**, click the **Configure URL for support link** radio button.
3. Enter a valid URL.

4. At the upper right, click **Save**.

Account data sources

When you have *Data Source Management* permission, you can access the account data sources feature to define and manage composite and regular datasources.

Understand composite and regular datasources

Composite datasources contain complex, structured data. With composite datasources, Oracle Site Select handles all five composite data entities that comprise a trial-site (sometimes called a study-site):

1. Investigator
2. Institution
3. Trial
4. site
5. trial-site

This means that the Oracle Site Select composite data model imports five unique files: investigator, institution, trial, site, and trial-site that Oracle Site Select combines internally to create a single site row.

Composite datasource benefits:

- Unique institution records combine with investigator records to form sites. Instead of having limited fields to import institution staff records, the investigator file can handle any number of institution staff in a nested structure of: first name, last name, email, phone, and role.
- The investigator file can import any number of investigator email addresses and is not limited to primary and secondary email.
- When creating a master list of sites for evaluation, if the datasource contains composite records, users can additionally filter by: therapeutic area, indication, drug class, and study phase.
- Oracle Site Select calculates an Investigator score for studies involving composite datasources. The score is the average of all site scores for the site's investigator, and it is listed for each of the investigator's sites.

> **Note**
>
> Oracle administrators manage composite datasources. Contact your Oracle Project Manager to manage configuration and import of data into these datasources.

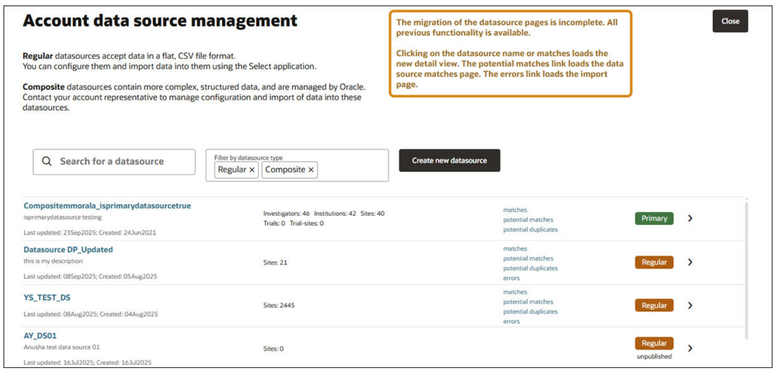
Regular datasources accept data in a flat, CSV (comma separated value) file format, such as an Excel spreadsheet. In this flat data model, each CSV row is a site and that row includes investigator, institution, and site data. You can configure regular datasources and import data into regular datasources using the Oracle Site Select application. Once you've imported data into a new datasource, contact your Oracle Project Manager who can associate the new datasource to your studies.

Preferred sites: This type of source allows CRO preferred sites to bypass study parameter filters and move into the Master List. This option requires upload and mapping of a CSV format file with CRO preferred sites. The source file must contain a column labeled "preferred_site" and must specify TRUE or FALSE for each row in the source.

Pre-selected sites: You can also upload study-specific, pre-selected site lists and have only those sites included in the datasource displayed on the Master List. To use this functionality, the datasource must include a is_pre_selected_site column, which must specify TRUE for all sites in the datasource.

Account datasource management

The Account data sources feature makes it easy to define and manage datasources. If you have the *Data Source Management* role permission, you can access this area from Account menu's Account data sources menu item.



The datasource list page includes search and filter options to help you locate the datasource you want to view. You can click a datasource name to access the details area, or click the right arrow. For each listed datasource, you'll see other details like a description (if populated), Last updated date, Created date, Number/type of records, and quick links to match and error tabs (published datasources only). You'll also see a badge that identifies the datasource as a Primary, Regular, or Composite, and if the datasource has not yet been published, you'll see the note "unpuplished" below the badge.

When you click Create new datasource, or open an unpublished datasource to access the "Definition" tab. Under the Manage data source definition section, for Step 1: Define datasource structure, lets you enter a unique name, optional description, and upload a sample CSV schema. Note that for unpublished datasources, the tabs for Records, Matches, Potential matches, and Errors remain disabled until the datasource is published.

For Regular/CSV datasources, the schema file upload supports files up to 500KB and gives feedback if errors occur. The Definition tab also displays a list of tips for successful uploads to help ensure your schema meets the minimum requirements. The datasource will be auto-saved once you provide a valid schema and datasource name. If a new schema is uploaded later, it will replace the current one after confirmation. The page autosaves changes and shows “Changes auto-saved: <DDMonYYYY HH:MM AM/PM>" in red text when updates are saved.

Upon import, Oracle Site Select validates institution country names against the Oracle Site Select standard country names. Import behavior is:

- **CSV import** – A site row with an invalid institution country errors and that site record is not imported, but it is included on the import error list. Because the CSV import utility streams each record, a site record with an invalid institution country will be skipped and the next record will be processed. The list of error sites displays after the import process has completed.

- **API import** – An import of an institution record with an invalid country errors and the institution record is not written. If one record in a batch errors, the entire batch fails.

For composite datasources and published CSV datasources, schema uploads are disabled, but you can still edit the name and description as preferred, and changes will autosave. Unpublished CSV datasources allow editing of name and description as well as replacement of the existing CSV schema file.

After naming the regular datasource and uploading a schema as described above, the Step 2: Map the imported columns to Oracle Site Select data columns section walks you through mapping the imported data columns to Oracle Site Select data columns. This includes selecting a unique ID column, matching fields via a drag-and-drop interface, de-linking mapped columns for an unpublished datasource, and creating custom columns when needed. For composite datasources or published CSV datasources, mapping is view-only and editing is disabled.

Custom column example: A custom column “Equipment list” is defined at the site level in two customer datasources as a string array. In datasource 1, it includes “fMRI” and “portable X-ray.” In datasource 2, it includes only “portable infusion pump” for the same site record. When both datasources are attached to a single study, and the column is defined to concatenate array values, the resulting site record will include “fMRI, portable X-ray, and portable infusion pump” for the data column “Equipment list.”

A column mapping tool lets you filter, review, and adjust how each imported column aligns with the Oracle Site Select data structure. You can also review each column’s properties, including filter options and site scoring configurations. Once your schema is mapped, Step 3: Publish the datasource prompts you to publish, which is required before any data can be imported. Publishing locks the schema, so a confirmation dialog ensures you're ready. The datasource you publish will be private to your account. After publishing, the Records, Matches, Potential matches, and Errors tabs become active. Additional options allow for disconnecting mapped fields and deleting unused custom columns, with safeguards in place to prevent accidental data loss across datasources. For any published datasource in your account, you can import additional records data in CSV format, if necessary.

> **Note**
>
> Column filters act as OR filters, for example, filtering on "string" and "Institution" will show all string columns and all institution columns. This is expected behavior.

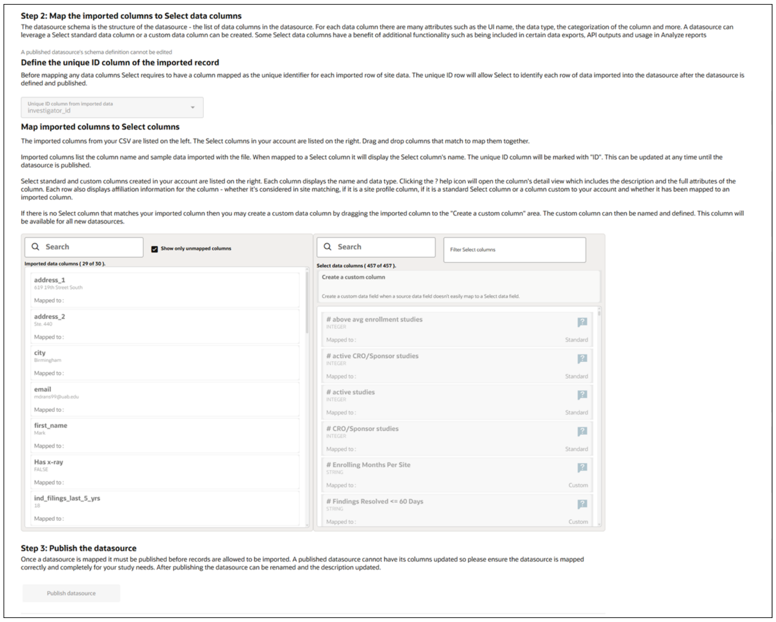
When creating a new custom column, the column definition drawer will open with the custom column already created. If you click Close, that does not remove the newly created custom column. You must click the Delete button. For example, if you drag an imported column to the Create custom column area, the Data column properties drawer opens. If you change your mind about creating the column, you must click the drawer's Delete button. Clicking Cancel will not revert creation of that column as it was created immediately and before the drawer opened. If you wish to keep a custom column for future use, but unlink the custom column and the imported column, simply click the unmap icon on the column list in line with the "Mapped to:" label.

Oracle Site Select provides the ability to define how data is merged when multiple customer datasources are attached to a study. For standard Oracle Site Select data columns, Oracle defines how each column will handle data merges. For custom data columns, customer datasource managers will define the method by which data is merged for a particular column. Available merge methods for custom columns are:

- concatenate data (string array)

- highest priority datasource wins (all data types)
- sum data (integer, real)
- average (integer, real)

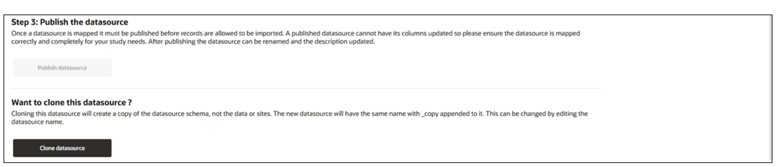
> **Note**
>
> Please contact your Oracle Project Manager to coordinate custom column merging methods prior to data load.



You can easily reuse an existing datasource setup. At the bottom of the Definition tab, below Step 3: Publish the datasource section, you'll find a section for cloning a datasource. This option is available for both published and unpublished datasources.

To use the feature, click the Clone datasource button. This will create a new datasource with the same schema but without any imported data or associated sites. The new datasource will automatically have "_copy "added to the name, which you can change by editing the name field. This cloning option makes it easier to start a new datasource using an existing configuration as your starting point. Note that cloning only copies the definition of the datasource but not the data within the original datasource. You can overwrite the file with a new CSV and modify fields and field mappings in the copy as preferred.

By design, the Records, Matches, Potential matches, and Errors tabs are disabled until you've successfully uploaded the schema CSV for the new datasource. Once you upload the schema CSV, the page updates to display the data source name and description in the title area, and the data source is saved as unpublished. Mapping columns also display after the schema upload is complete.



Viewing datasource records

For both regular and composite datasources, you'll see a "Records" menu item on the datasource details page above the records table. If applicable to the datasource, you can select a page or advance through the available pages using the pagination control at the lower left of the records table.

You can add or update records in a regular (flat) datasource via CSV upload on the Records tab, which includes a file upload control above the site records grid. Use this control to upload a CSV file to add new site records or update existing site records. The CSV file you upload will undergo standard processing validation (e.g., checking for valid country names, disambiguation, etc.). If errors are found, the Errors tab will show a numbered badge and a red exclamation mark to draw your attention to data issues you need to address. The tab lists each error message encountered when processing your CSV upload.

When you view a regular or composite datasource, you'll see all mapped data columns for that datasource with all rows of imported site records and the data imported for each site. For composite datasources only, use the Data entity filter (above the data table) to choose between the five composite datasource entity types (i.e., Investigator, Institution, Site, Trial, or Trial-site) and filter the data in the table to the selected type. For both regular and composite datasources, the unique ID column for each site row is the first column in the table. Where appropriate, you can hover over a cell to view a tooltip with the full content of the cell (e.g., long string array values).

You can also search the record grid. Enter a value in the search field, and Oracle Site Select performs a "fuzzy" search (approximate string match) as follows:

Regular datasource searches data available in the records table for the following columns:

- unique id column
- first_name
- last_name
- institution
- country
- pi_emails
- city
- npi
- master_profile_id

Composite datasource searches the following columns by entity:

- Investigator (unique id column, first_name, last_name, pi_emails, and npi)
- Institution (unique id column, institution, country, and city)
- Site (unique id column, investigator_id, institution_id, and master_profile_id)
- Trial (unique id column, protocol_title, and protocol_numbers)
- Trial-site (unique id column, site_id, and trial_id)

> **Note**
>
> To prevent performance issues, Oracle Site Select disables the search field when a flat datasource or composite datasource entity (i.e., investigators) has more than 50,000 records.

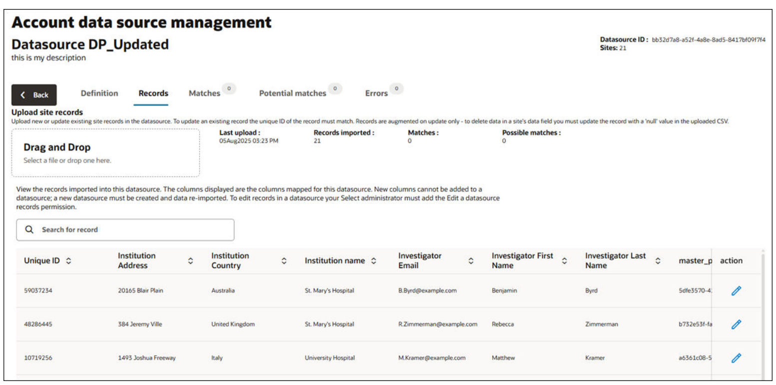
Viewing and modifying datasource records

Editing records

When you have *Edit a datasource record* permission, you'll see a fixed Action column with Edit and Discard action icons at the far right of the records table. Note that this permission is a user role permission that doesn't apply to Teams. The permission allows you to edit regular and composite datasource entity records of the following data types:

- String
- Boolean
- Datetime
- Integer and real (numeric)
- Text

To edit a record, click the Edit icon and click the column cell you want to update. You'll see a border around that editable cell. When you've finished the update(s), return to the Action column and click Save or Discard to revert unsaved updates(s) and return to view mode.



Managing potential record matches

Identifying matching sites to eliminate duplicate sites in Oracle Site Select and maintaining site history across studies is important, and you can manage these records on the Potential matches tab. Here, you can review the disambiguation potential matches and duplicates for sites you've imported into a datasource.

You must have the existing *Data Source Management* business role permission to access the tab and to use the functionality granted to you with this permission (i.e., some functionality is available only to Oracle administrators).

The Potential matches tab loads when you click on the number of potential matches for a datasource from the account datasource list page. You can also access the tab when you click the Potential matches tab on the datasource details page. The tab itself shows a badge with total actionable potential matches.

You'll see three subtabs displayed above the grid on the Potential matches tab:

1. **Total potential matches**: shows the number of records in the datasource that potentially matched a record in Oracle Site Select across all accounts. This tab is visible to you, but the content is enabled only for Oracle administrator use.
2. **Actionable potential matches**: shows the number of potential match records in the datasource that match against a datasource record within this account. This tab is enabled for your use and Oracle administrator use.
3. **Oracle-actionable potential matches**: shows the number of potential match records in the datasource that match against a datasource record outside this account. This tab is visible to you, but the content is enabled only for Oracle administrator use.

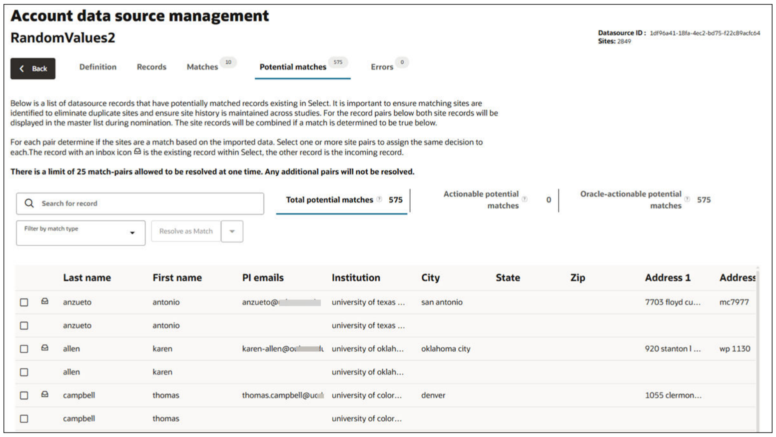
Only an Oracle administrator can see and act on potential matches or duplicates in a site profile datasource.

By default, the Potential matches grid shows both potential duplicates and potential matches (i.e., filtering is off). If preferred, filter the displayed records using the "Filter by match type" drop-down to select Potential or Duplicate. You can also search records in the list. Search will return string matches in any of the following grid columns:

- Last name
- First name
- PI email
- Institution
- City
- State
- Zip
- Address 1
- Address 2
- NPI
- Country
- Datasource
- Match type
- Master profile id

All records in the potential match grid are site records, and you'll see a double row for each. The top record is the current datasource record; the bottom is the record matched record. The row for the record existing in Oracle Site Select has an inbox icon.

The Actionable potential matches tab shows the message "No potential matches were found for datasource" instead of an empty grid if no potential matches or duplicates are scoped to the account. This is the case regardless of whether there are potential matches or duplicates with a record in another datasource.



Resolve potential matches

All records in the potential match grid are site records; you'll see a double row for each. The top record is the current datasource record, and the bottom is the record matched record. The row for the record existing in Oracle Site Select has an inbox icon.

Delete record for a potential duplicate match

To take action on a duplicate record, you may delete it from the datasource Records tab. You must have the existing *Edit Datasource Record* business role permission to delete one of the duplicate records.

Resolve a potential match

When you select at least one match pair in the grid, you can click the button above the table to Resolve as Match (default) or Resolve as Not a match.

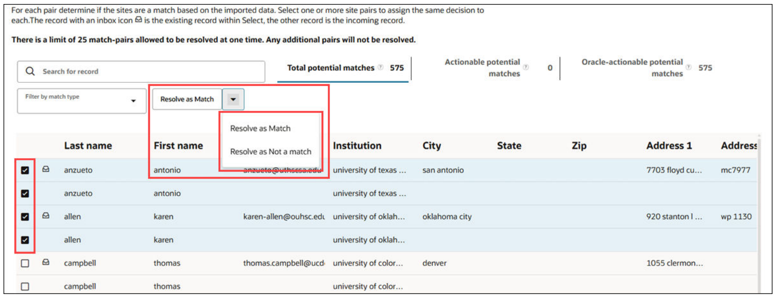
If you choose **Resolve as Match**, Oracle Site Select updates the records as it did previously, meaning:

- For potential matches: The master profile IDs of the individual sites are updated to match the existing site so that the inbound site matches the site existing in Select. The site pairs are marked as resolved, and the potential matches grid updates to remove the potential match pair.
- For potential duplicates: The master profile IDs of the individual sites are NOT updated. The pairs are marked as DUPLICATES of each other, and the potential matches grid updates to remove the potential duplicate pair.

If you choose **Resolve as Not a Match**, Oracle Site Select updates the records as it did previously, meaning:

- For both potential matches and potential duplicates: The master profile IDs of the individual sites are NOT updated. The site pairs are marked as resolved, and the potential matches grid updates to remove the potential match pair.

Note that you can resolve rows of sites as matches and not matches, alternating, without needing to reload the page. You can also use the Resolve as Match action to resolve potential matches and potential duplicates as matches at the same time. There is a limit of 25 match-pairs allowed to be resolved at one time. Any additional pairs will not be resolved.

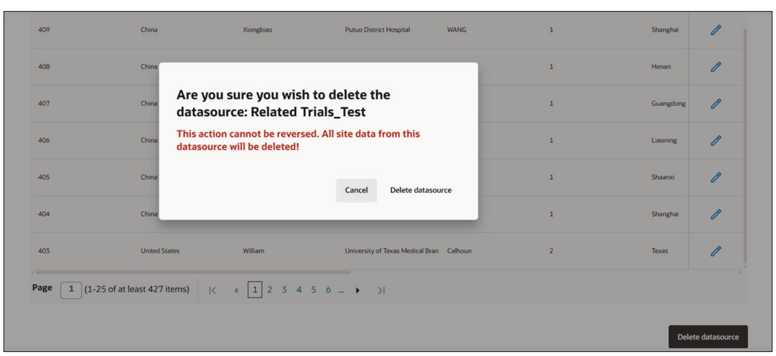


Delete a datasource

It is possible to delete an account datasource using the option available on the datasource Records tab. You must have *Edit a datasource record* permission to access the Delete datasource button at the bottom of the page. If you have only the *Data Source Management* permission, the button will be hidden from view.

When you click the "Delete datasource" button, it will be disabled to prevent multiple submissions, and a confirmation dialog displays. The dialog warns that the action is irreversible and all site data from the datasource will be deleted, and you will need to choose either to cancel or confirm the deletion. If you proceed, you will be redirected to the datasource list page, where you will see a notification that the delete process has started. The delete button remains disabled after a failed attempt until the page is refreshed, and a successful deletion updates the datasource list to remove the datasource and returns you to the summary list page.

While deletion is in progress, the affected datasource's list item will not have actionable links, and the datasource detail counts will display as zero. You will find the "Delete datasource" button at the bottom of the Records data grid on the details page, and its color will be gray. After the deletion attempt, a status message will inform you whether the deletion succeeded or failed.



- [Create a new regular datasource](#)
  Create a new datasource for any dataset that you want to import and merge into the Oracle Site Select site profile database. You will determine the unique identifier for the datasource and set up definitions for each field in the datasource.
- [Clone a datasource definition](#)
  Cloning a datasource creates a copy of the datasource schema, not the data or sites. The new datasource will have the same name with _copy appended to the name, and you can update the name as preferred.

- Import data for a published regular datasource
  Once a datasource is mapped it must be published before you can import records. To add records, upload a CSV that contains the same columns as the mapped datasource.

Create a new regular datasource

Create a new datasource for any dataset that you want to import and merge into the Oracle Site Select site profile database. You will determine the unique identifier for the datasource and set up definitions for each field in the datasource.

You must have a role with *Data Source Management* permission to complete this procedure.

> **Note**
>
> This procedure applies only to regular datasources. If your organization will use composite datasources, please contact your Oracle Project Manager for assistance.

1. Click menu in the page header. Then open the **Account** menu, and click **Account data sources**.
2. On the **Account data source management** page, click **Create new data source**.
3. On the **Definition** tab, at **Step 1: Define datasource structure**, enter a unique **Datasource name**, optional **Description**, and **Upload a CSV schema** file (max size 1MB).

   Once uploaded, the file name displays below the upload field, and the page auto-saves. You'll see the save timestamp to the right of the upload field.
4. At **Step 2: Map the imported columns to Select data columns**, use the **Unique ID column from imported data** drop-down to specify the unique ID column for the new datasource.
5. The left side includes the columns from the CSV upload. You can **Search** for a specific column, and optionally check **Show only unmapped columns** to filter the list. The right side includes Oracle Site Select standard data fields.
6. For each column on the left, find (optionally **Search**) a matching column on the right. You can drag and drop the field from the left to the right side or right side to left. When you've dropped the column to match it, the **Mapped to:** line in the field updates and mapped icon displays. Map all columns, including the unique identifier column.

   Click the column properties icon to open the Data column properties drawer where you can view, but not edit a Select standard column's definition and attributes.
7. Optional: If an imported column doesn't easily map to an Oracle Site Select standard column, drop it into the **Create custom column** field at the top of the right side column. In the **Data column properties** drawer, adjust drop-down entries for all applicable fields (Display name is required) and check filtering and scoring options as available/preferred. At the top of the drawer, click **Save**.
8. When you've completed mapping, at **Step 3: Publish the datasource**, click **Publish datasource**.
9. Review the statements in the confirmation window, and click **Proceed**.

Clone a datasource definition

Cloning a datasource creates a copy of the datasource schema, not the data or sites. The new datasource will have the same name with _copy appended to the name, and you can update the name as preferred.

You must have a role with *Data Source Management* permission to complete this procedure.

1. Click menu in the page header. Then open the **Account** menu and click drop-down menu, click **Account data sources**.
2. On the row for the datasource you want to clone, click the datasource name to navigate to the **Definition** tab.
3. Scroll to the bottom of the page and click **Clone datasource**.

Import data for a published regular datasource

Once a datasource is mapped it must be published before you can import records. To add records, upload a CSV that contains the same columns as the mapped datasource.

You must have a role with *Data Source Management* permission to complete this procedure.

> **Note**
>
> This procedure applies only to regular datasources. If your organization will use composite datasources, please contact your Oracle Project Manager for assistance.

1. Click menu in the page header. Then open the **Account** menu, and click **Account data sources**.
2. On the **Account data source management** page, click the name of the datasource you want to import data to.
3. Click the **Records** tab.
4. Click the **Drag and Drop** field, to select a CSV file or drop one in the field for immediate upload.

Once you complete the procedure above, you will see a progress indicator under the Date column. Once the data import is complete, the **Last upload:** date and timestamp to the right of the upload field will be updated.

The imported data records are displayed in the Records table. If there are any errors in the source file, the error messages are displayed in the Errors tab.

Disinterest and exclusion reasons

When sites indicate they are disinterested in study participation or an Oracle Site Select user needs to exclude a site from the feasibility process, they may be required to provide one or more reasons. Administrators can configure a master list of reasons available to display to sites in the site portal or when Oracle Site Select users complete tasks on behalf of a site.

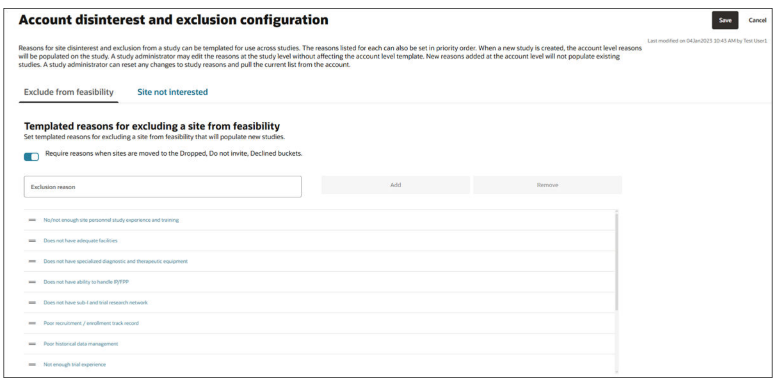
If you have the appropriate permission, you can standardize disinterest and exclusion reasons across studies using reason templates you configure at the account level in Oracle Site Select. Reason configuration at the account level lets you add and remove free text reasons, optionally switch on a setting to require reasons, and adjust default reasons to your preferred order.

Reasons configured at the account level automatically populate new studies in the order you set in the template. Study administrators can then adjust these pre-populated reasons while setting up a new study, and any changes made at the study level won't affect the saved account template. You can also add or remove reasons from account level templates at any time; these updates will not change the reasons for existing studies, but will apply to any new studies created after you save your changes at the account level.

By design, Oracle Site Select does not support configuring disinterest reason templates at the Teams level.

Defining the Exclude from feasibility and Site not interested lists is easy: Click the appropriate tab, then enter the reason in the Add new reason field (100 characters max.), drag-and-drop reasons to a new display order, and remove reasons as preferred by selecting and clicking "Remove." You can also optionally require the Oracle Site Select user to specify a reason when excluding a site from feasibility.

> **Note**
>
> By default, the "Require reasons..." toggle will be switched on. You can switch off the toggle to disable the required entry if appropriate to the study or your organization's standard operating procedures.



At the study level, study managers see the list you create and can add new disinterest reasons for each study or discard their changes to restore the default list and order. They can also optionally drag and drop reasons to change their display order or remove a reason if needed.

- Set up account level study disinterest and exclusion reasons
  You can create templates for site disinterest and exclusion reasons at the account level, and these configured reasons will automatically populate new studies in the order you define in the template. Study administrators can adjust the prepopulated reasons while setting up a new study, and any changes made will not affect the saved account template.

Set up account level study disinterest and exclusion reasons

You can create templates for site disinterest and exclusion reasons at the account level, and these configured reasons will automatically populate new studies in the order you define in the template. Study administrators can adjust the prepopulated reasons while setting up a new study, and any changes made will not affect the saved account template.

You must have *Account disinterest and exclusion configuration* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Disinterest and exclusion**.
2. If you are viewing the default **Exclude from feasibility** tab, optionally toggle the **Require reasons...** on/off switch to the preferred setting. This switch does not apply to the **Site not interested** tab. If you are viewing the **Site not interested** tab, optionally toggle the **Limit site responses**... on/off switch to your preferred setting. This switch does not apply to the **Exclude from feasibility** tab.
3. To add a custom reason, type the reason in the **Exclusion reason** or **Site disinterest reason** field. Click **Add**.
4. To delete any default or custom reason, click the reason in the list to populate the **Exclusion reason** or **Site disinterest reason** field above the list. Click **Remove**.
5. To reorder the list, grab the handle to the left of any reason, drag the reason up or down the list to the preferred location, then drop the reason in place.
6. At the upper right, click **Save**.

Account level email templates

Account level templates simplify application of your organization's branding in emails. Use the options in Oracle Site Select to create templates, image placeholders, and default internal task messaging. You can also define custom login/no login button text if preferred.

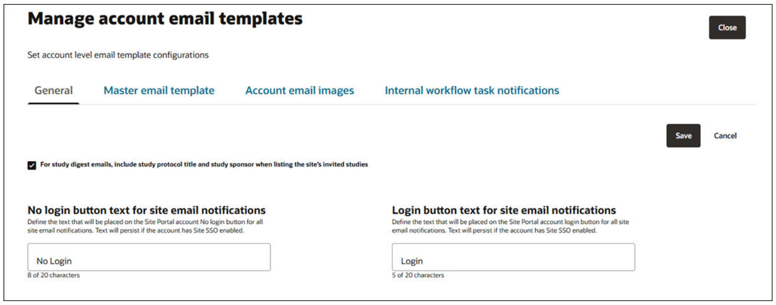
If you are an Oracle Site Select user with *Account email template management* role permission, you can access the access the Manage account email templates page to set account level email template configurations.

> **Note**
>
> The **Close** button exits the page but does not save any changes you make in the tabs, so click **Save** where needed.

General

On the General tab, you can control how study digest and invitation emails appear. You can:

- Show the study protocol title and sponsor in digest emails
- Set custom button labels for Login/No Login buttons in site email invites
- Click the Save button to apply your changes

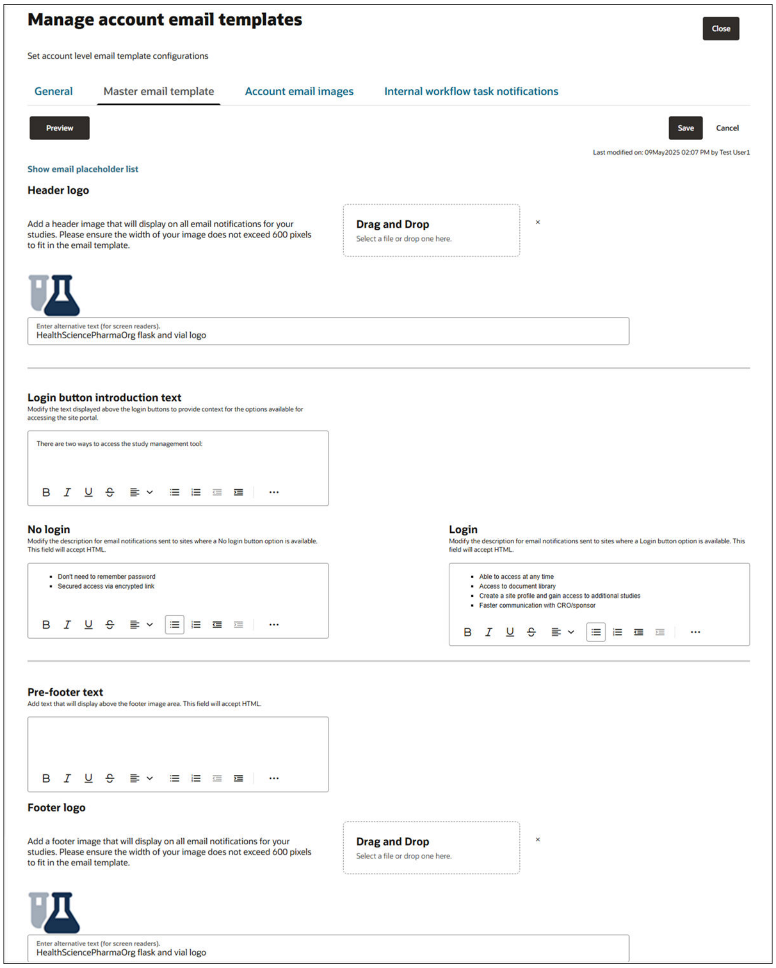


Master email template

Use the option on the Master email template tab to customize the look and feel of your emails. You can:

- Show the email placeholder list for dynamic content. The list opens a right-side drawer so the placeholders are visible as you configure your master template
- Configure header and footer logos (600 px width max, any resolution, 5MB max, and JPEG, GIF, or PNG file type)
- Complete the rich-text enabled fields below as required. All text input fields on the Master email template tab accept HTML; however, Javascript (i.e., "<script>" or "</script>" HTML tag) is not supported in any field.
  - Login button introduction text to display above the buttons in site emails
  - Login/No Login button descriptions
  - Pre-footer text to display above the footer image area
- Click Preview at the top of the page to confirm the email template meets your formatting and layout expectations
- Click the Save button to apply your changes

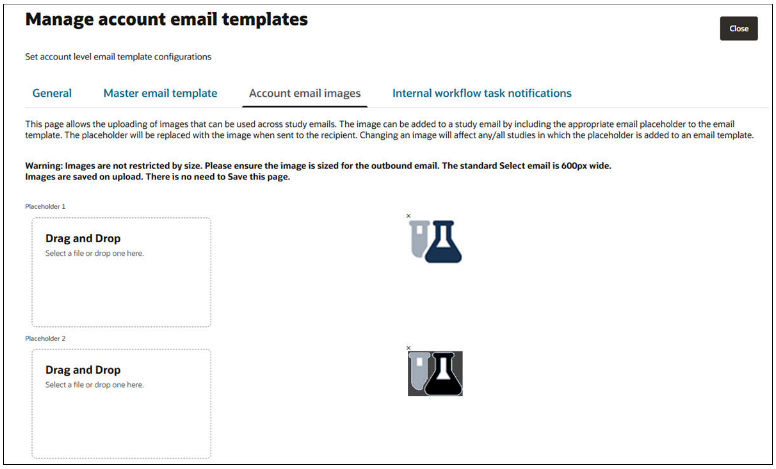
Oracle Site Select applies the configured account-level email template attributes (header logo, footer logo, login button intro text or no login/login text, and pre-footer text placeholder) to non-system email templates. For instance, a CDA Approval email includes all configured placeholders, while a system email (e.g., password reset) does not include any placeholders configured at the account level.



Account email images

Configure account level email image placeholders on the Account email images tab. This option allows you to upload up to five images that can be used across study emails when the study email template has the corresponding account-level image placeholder (i.e., {account_image_1}, {account_image_2, etc.}.

The Account email images section provides upload, preview, and remove functionality for up to five JPEG, GIF, or PNG images. Importantly, images are not restricted by dimension, but image file size may not exceed 10 MB. Please ensure any uploaded image is the appropriate size for the outbound email (standard Oracle Site Select emails are 600 pixels wide).

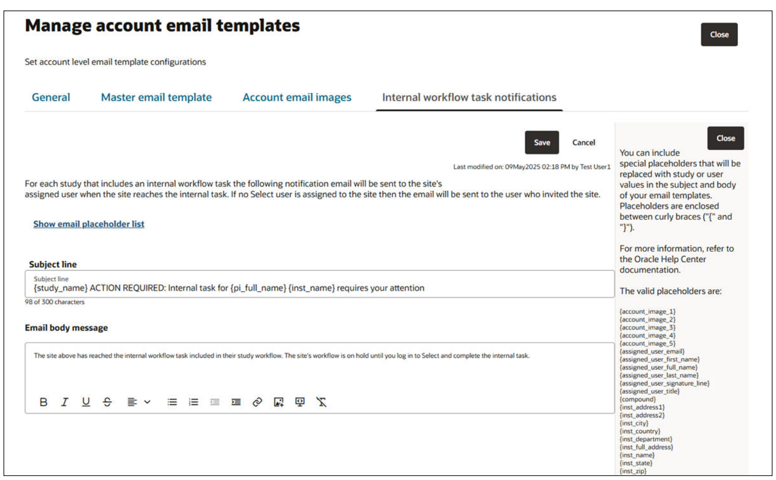


Internal workflow task notifications

If your organization uses Internal workflow tasks, you can create email notifications specific to those tasks. On the Manage account email templates page, Internal workflow task notifications tab, configure the template to include the preferred subject line and the rich-text enabled message body. Both areas support email placeholder values. Click Show email placeholder list above the Subject line field to see available placeholders in a drawer.

> **Note**
>
> When you've completed configuring the Subject line and message body, remember to click Save to apply your updates.

For each study that includes an internal workflow task, the configured notification email will be sent to the site's assigned Oracle Site Select user when the site reaches the internal task. If the site does not have an assigned user, the email will be sent to the user who invited the site.



- Configure study digest protocol and sponsor display
  You can optionally display the study protocol and study sponsor when listing the site's invited studies in study digest emails.

- [Configure custom login button labels for site email notifications](#)
  You can optionally specify text to replace the default "No login" and "Log in required" button labels in email notifications sent to sites.
- [Configure account master email template](#)
  Configure header and footer logos, login/no login button text, and additional prefooter text to display in non-system emails sent to sites. All configuration options are optional and independent of one another.
- [Configure account email images](#)
  If your organization prefers to use specific images in emails across studies, upload the files to the Account email images library. This option allows you to upload up to five images that can be used across study emails when the study email template has the corresponding account-level image placeholder (i.e., {account_image_1}, {account_image_2, etc.}.
- [Configure internal workflow task notifications](#)
  You can set up a unique email template to notify a site's assigned user when the site reaches an internal workflow task.

Configure study digest protocol and sponsor display

You can optionally display the study protocol and study sponsor when listing the site's invited studies in study digest emails.

You must have a role with *Account email template management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and view the **General** tab.
2. Check the **For study digest emails, include study protocol title and study sponsor when listing the site's invited studies**check box to enable.
3. Click **Save**.

Configure custom login button labels for site email notifications

You can optionally specify text to replace the default "No login" and "Log in required" button labels in email notifications sent to sites.

You must have a role with *Account email template management* permission to complete this task. Additionally, if updating the No login button label, the No login option must be enabled for your organization's account.

1. Click menu ☰ in the page header. Then open the **Account** menu, and view the **General** tab.
2. Under **No login button text for site email notifications**, enter up to 20 alphanumeric characters for the button label. Special characters are supported.
3. Under **Login button text for site email notifications**, enter up to 20 alphanumeric characters for the button label. Special characters are supported.
4. Click **Save**.

   Once configured and saved, the text persists even if the account has Site SSO enabled.

Configure account master email template

Configure header and footer logos, login/no login button text, and additional prefooter text to display in non-system emails sent to sites. All configuration options are optional and independent of one another.

If preferred, you can use placeholders in your template's subject and body. Click **Show email placeholder list** to open the list of available placeholders. If you use placeholders, remember to enclose them in curly braces ("{" and "}").

You must have a role with *Account email template management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Master email template**.
2. Under the **Header logo** section, click in the **Drag and Drop** field to browse and select a logo image, or drop a selected image directly into the field. The Image must be JPEG, GIF, or PNG file type and can be up to 600 pixels wide.
3. Below the logo image, enter alternative text for the Header logo. This text can be read by screen reader applications.
4. At **Login button introduction text**, optionally modify the text that will display above login buttons in site emails. If not modified, the text will be "There are two ways to access the study management tool:"
5. Under the **No login** section, modify the default description text that displays in email notifications when the no login button is available. The field supports rich text formatting and accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
6. Under the **Login** section, modify the default description text that displays in email notifications when login button is available. The field supports rich text formatting and accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
7. Under the **Pre-footer text** section, enter text to display above the footer image area. The field supports rich text formatting and accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
8. Under the **Footer logo** section, click **Upload image** and browse to locate a logo image that does not exceed the maximum of 600 pixels.
9. In the text field below **Upload image**, enter alternative text for the Footer logo. This text can be read by screen reader applications.
10. At the top of the page, click **Preview** to view the configured template to confirm the template meets your expectations. This is especially important if you used placeholders.
11. Click **Save**.

Configure account email images

If your organization prefers to use specific images in emails across studies, upload the files to the Account email images library. This option allows you to upload up to five images that can be used across study emails when the study email template has the corresponding account-level image placeholder (i.e., {account_image_1}, {account_image_2, etc.}.

You must have a role with *Account email template management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and view the **Account email images** tab.
2. At **Placeholder 1**, select or drop your image file into the **Drag and Drop** field. The image saves upon upload and displays to the right of the field.

   The maximum image width is 600px, which is the full width of the standard Oracle Site Select email.

   > **Note**
   >
   > Changing or adding an image will affect any/all studies in which the account image placeholder is added to an email template.

3. At **Placeholder 2**, repeat step 2 above as required. You can add up to five placeholder images to the library.

Configure internal workflow task notifications

You can set up a unique email template to notify a site's assigned user when the site reaches an internal workflow task.

If preferred, you can use placeholders in your template's subject and body. Click **Show email placeholder list** to open the list of available placeholders. If you use placeholders, remember to enclose them in curly braces ("{" and "}").

You must have a role with *Account email template management* permission to complete this task.

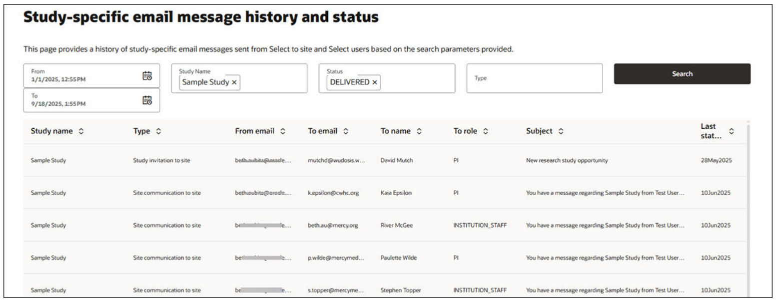
1. Click menu ☰ in the page header. Then open the **Account** menu, and view the **Internal workflow task notifications** tab.
2. At **Subject line**, enter up to 300 characters.
3. At **Email body message**, enter the message text. The field supports rich text formatting and accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
4. Click **Save**.

Email history and status by study

See the history and status of email sent to study sites and Oracle Site Select users. When necessary, you can also retry and resend messages.

When you have a role with *Account email message monitoring* permission, you can access the Study-specific email message history and status page. Use filter controls to search emails by preferred criteria (i.e., sending date range, study, status, and type). The page will also list archived copy emails sent for a study, if appropriate to the filter set.

For each email message row in the grid below the filters, you can either Resend a successful message or Retry an unsuccessful message (scroll to the right to see the available action button for each message). Both options re-queue the exact message to resend or retry. When you click to resend or retry the email message, the action button will be disabled, and the table will list the newly queued message as a separate row upon page refresh.



- [Retry or resend study email messages](#)
  Use the options on the Study-specific email message history and status page to either Resend a successful message or Retry an unsuccessful message.

Retry or resend study email messages

Use the options on the Study-specific email message history and status page to either Resend a successful message or Retry an unsuccessful message.

You must have a role with *Account email message monitoring* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Study email history and status.**
2. Adjust the **From** and **To** date, **Study Name**, **Status**, and **Type** filter fields to your preferred values and click **Search.**
3. In the message grid below the filters, locate the message you want to resend or retry. You can sort any grid column by clicking the column header.
4. If necessary, scroll right to view the **Actions** column. Click **Resend** or **Retry** to requeue the exact message.

   The Action button will be disabled after you click, and the grid will list the newly queued message as a separate row upon page refresh.

Integrations

Oracle Site Select provides optional account integration solutions at access (user authentication), data (API), and application levels. Use settings on the Account integrations page to manage API tokens, configure PUSH event notifications, setup digital signature authentication, configure survey vendor authentication, and define preferred user authentication.

Data Integration APIs

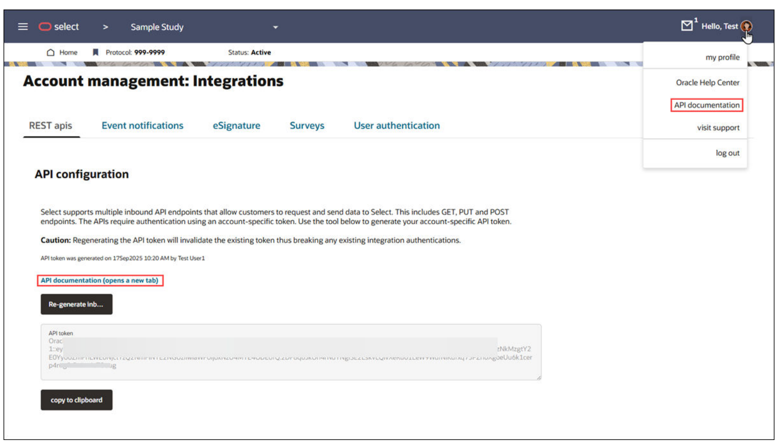
Oracle Site Select uses RESTful APIs, formatted as JSON objects, strings, and arrays to send information between systems. This is a well-understood and well-supported technology capable of handling complex and high-volume messages. The APIs accept requests as JSON objects encoded using the UTF-8 character set.

Oracle Site Select supports the following API routes:

- **Version GET** – Fetch the version and host name of the Oracle Site Select instance hosting the API
- **Datasource PUT** – Add datasources to a study by sending an array of IDs to identify all datasources that should be attached to the study

- **Datasource GET** – Fetch a list of datasources in an account
- **Datasource and Composite Datasource Counts GET** – Fetch the counts of entities in a flat or composite datasource
- **Datasource Records PUT, GET, and DELETE** – Imports one or more records into a datasource; returns a record from a datasource; or physically deletes an investigator, institution, or site record from a datasource
- **Composite Datasource Records PUT and DELETE** – Import one or more entity (investigator, institution, site, trial, or trial_site) records into a composite datasource; retrieves investigator, institution, site, trial, or trial_site record from composite datasource; or physically delete an investigator, institution, site, trial, or trial_site record
- **Datasource Clone** – Clone an existing composite or flat datasource within your organization's account and keep the existing data column mapping of the cloned datasource.
- **Study Put** and **GET** – Create a new or update an existing study, retrieve information about an existing study, or retrieve a list of studies within an account.
- **Study Sites in Study PUT, POST, and GET** – Invite a study site to a study; import a site record from a datasource into a study and create a study site; or fetch information related to a specific study site like bucket state, profile details, and more.
- **Document Library PUT, POST, and GET** – Upload, update, or download a document scoped to institution or investigator.
- **Document Download GET** – Download a workflow document with a specific document ID.

You can access API documentation with full Request/Response details for the APIs using the link above the API token field on the Integrations page. Alternatively, click the circular avatar at the far right of the page header, and choose **API documentation**. Both options open the API documentation page in a new browser tab.



The REST apis page also provides options to generate or regenerate the API token. Please use the regenerate option with care, as regenerating the inbound API token will invalidate the existing token, and you must confirm this action. Invalidating will break all existing integrations. If you proceed, please ensure to update all existing integrations with the new token. Click the "copy to clipboard" button to copy the new token.

Event notifications

Oracle Site Select offers an optional PUSH service that sends event messages to a customer's deployed and managed integration endpoint(s), such as a Clinical Trial Management System

(CTMS). When configured, the PUSH service sends a JSON format POST message for each site profile, site status, or investigator library document update event.

Site profile updates

The PUSH service sends a POST message to the configured endpoint(s) when an Oracle Site Select or site portal user saves the site profile, regardless of whether the user edits the profile and saves it. Updates to an investigator, institution, or site's datasource record do not initiate a POST message for a site profile change.

When pushed, the POST message for a site profile update event includes the following fields:

A-I	I-P	P-Z
• address_1	• investigator_status	• protocol_title
• address_2	• investigator_status_reason	• site_data_sources
• city	• irb_coord_email	• site_integration_id
• compound	• irb_coord_first_name	• site_last_verified_at
• country	• irb_coord_last_name	• specialties
• customer_last_updated_at	• irb_coord_phone_number	• state
• degree	• irb_type	• study_id
• department	• last_name	• study_indications
• fax_number	• middle_name	• study_name
• first_name	• npi	• study_phase
• institution	• oracle_master_profile_id	• study_sponsor
• institution_data_sources	• phone_number	• study_status
• institution_fax_numbers	• pi_address_1	• study_therapeutic_area
• institution_integration_id	• pi_address_2	• study_type
• institution_phone_numbers	• pi_central_irb_experience	• studysite_id
• institution_sip_id	• pi_city	• suffix
• institution_staff	• pi_country	• therapeutic_area
• institution_status	• pi_department	• title
• institution_status_reason	• pi_emails	• trial_coord_email
• institution_type	• pi_postal_code	• trial_coord_first_name
• investigator_data_sources	• pi_region	• trial_coord_last_name
• investigator_integration_id	• pi_state	• trial_coord_phone_number
• investigator_sip_id	• protocol_number	• zip

Site status

When configured for the account, the push service sends a site status change notification message each time a site has moved bucket states, provided the site is beyond Nominate Step 1 (i.e., Master list, Review, and Dropped bucket states). Messages are not sent for sites added to or moved within Step 1. This is expected behavior.

When pushed, the POST message for the site status change event includes the following fields:

A-I	I-P	P-Z
• address_1	• investigator_integration_id	• site_sip_id
• address_2	• investigator_sip_id	• specialties
• bucket_after	• last_name	• state
• bucket_before	• middle_name	• study_id
• bucket_state_after	• oracle_master_site_id	• study_indications
• bucket_state_before	• phone_number	• study_integration_id
• city	• pi_address_1	• study_name
• compound	• pi_address_2	• study_phase
• country	• pi_city	• study_sponsor
• department	• pi_country	• study_status
• first_name	• pi_emails	• study_therapeutic_area
• gb_additional_site_staff	• pi_postal_code	• study_type
• institution	• pi_state	• studysite_id
• institution_data_sources	• protocol_number	• suffix
• institution_integration_id	• protocol_title	• title
• institution_sip_id	• site_data_sources	• updated_at
• institution_type	• site_department	• updated_by_emal
• investigator_data_sources	• site_integration_id	• updated_by_full

The PUSH message also identifies the user who performed the status change (i.e., “updated_by”) as follows:

- If the create/update occurs as an action within Oracle Site Select, the PUSH message includes the user’s full name and email address
- If the create/update occurs as an action via API, the PUSH message includes the user's full name as "Site Import," and the user’s email will be <null>

On the Event notification configuration page, account administrators can optionally configure a list of email addresses that receive notification in the event of a event message failure. The administrator can configure the notification list separately for Site profile, Site status, or Library documents event notification messages.

An internal service checks for failed event messages every three hours. If an event message fails to send, each email address configured for that event message type receives a templated notification about the failure.

Investigator document library

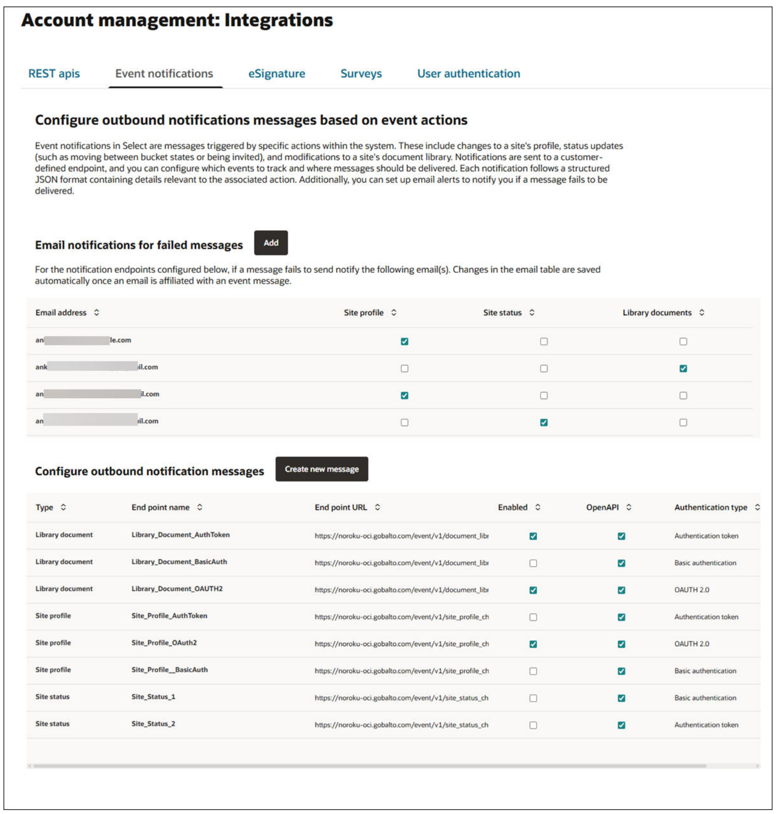
When an account has a primary composite datasource created, the account administrator can configure event notification messages that send each time an investigator library entry has been created or updated within Oracle Site Select, site portal, or via API. The PUSH service sends a message to the configured endpoint, and customers can use the message to keep their systems updated with changes to an investigator's document library.

The PUSH service does not send the document file itself, but rather the associated metadata. Customers that require the document can request it using the Document Library GET API described below.

When sent to the configured endpoint, the PUSH service notification message includes the following metadata, as appropriate:

A-D	D-I	I-Z
• accept_text	• document_type	• is_latest_version
• attestation	• invalid_reason	• response_accepted
• created_at	• investigator_id	• response_by_email
• created_by_email	• investigator_integration_id	• response_by_full_name
• created_by_full_name	• investigator_sip_id	• response_change_reason
• decline_text	• is_invalid	• response_on
• document_file	• is_invalid_by_email	• updated_at
• document_get_route	• is_invalid_by_full_name	• updated_by_email
• document_id	• is_invalid_on	• updated_by_full_name

When you have a role with *API and Authentication Management* permission, you can define Event notification endpoints for the Site status, Site profile, and Library document update event message types, as appropriate to the account. You can also set up email notifications for individuals who should receive notice of failed messages.

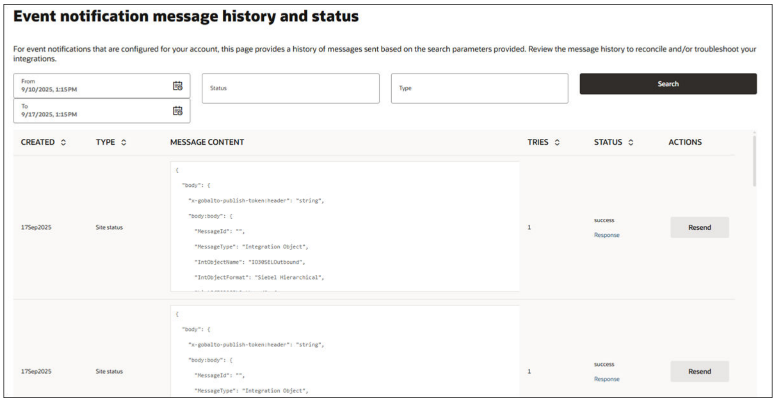


Event notification message history

When you have a role with the *API and Authentication Management* permission, you can track the status of messages sent via event notification message integration. The Event notification message history and status page, accessed from the Account menu, shows a list of matching event messages sent outbound based on your specified date range, status, and type search criteria. For instance, you can filter the list to see only Successful Document library event messages sent this week.

The sortable result list includes a scrollable message content field and other message details. Each row also includes a Response link (opens the response object in a modal window) and a

Resend or Retry action button. Resend and Retry will re-queue the exact message to resend or retry based on any updated integration settings (URL, security, etc.). If you click Resend or Retry, the original message's action button is disabled, and the table will list the newly queued message as a separate row upon page refresh.

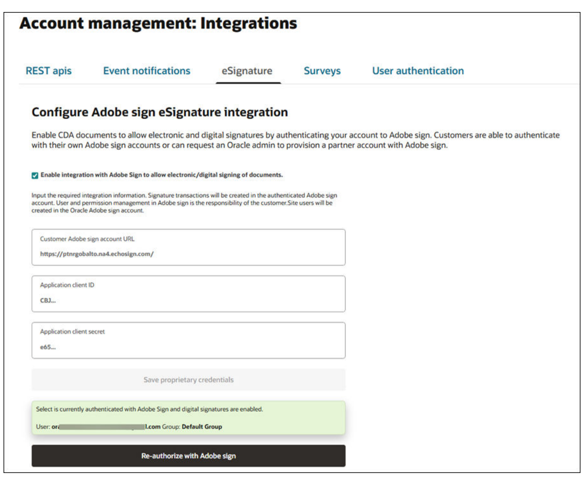


Digital signature configuration

When you have a role with *API and Authentication Management* permission you can configure electronic and digital signature authentication on your account's Account management: Integrations page. Your organization can use any contracted Adobe Sign account you prefer. User and permission management is the responsibility of your organization. Site users will be created in the Oracle Adobe Sign account.

To configure, you'll input your organization's proprietary account data for the following required fields:

- Customer Adobe sign account URL
- Application client ID
- Application client secret



When authenticated to Adobe Sign with your organization's account credentials, Adobe Sign creates signature transactions in your organization's account. For example, in an Oracle Site Select environment configured with customer-provided account credentials, the your organization can authenticate a user on a European Union (EU) server to activate digital signatures on the account, and signature transactions will be created in the your organization's EU Adobe Sign account.

In the customer-provided account credential model, your organization has responsibility for Adobe Sign user and permission management. For example, an EU user should be granted transaction creation/management permissions in Adobe Sign. Note that site user signature accounts are created only in the Oracle Adobe Sign account.

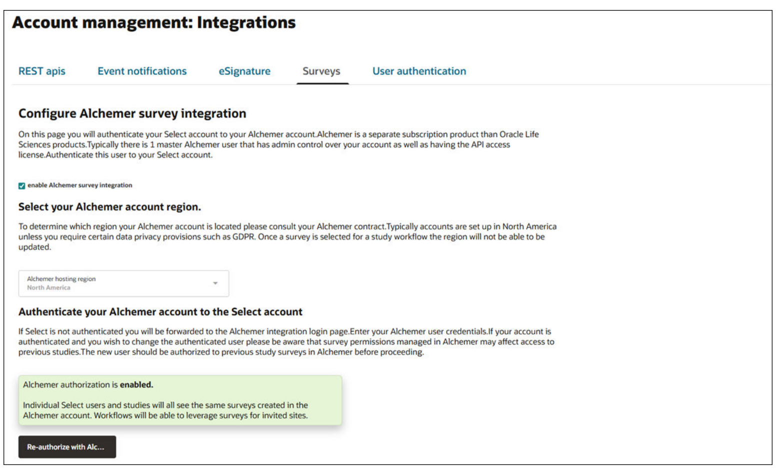
> **Note**
>
> Oracle Site Select creates a document sign transaction by specifying the email and name of the site user who will sign the document. If that site user needs to create an account, the site user will receive an email from Adobe Sign and Adobe Sign will manage the creation of the site user's account.

Survey vendor configuration

When you have a role with *API and Authentication Management* permission you can authenticate your Oracle Site Select account to your organization's Alchemer account.

Oracle Site Select customers outside of the United States can authenticate with the Alchemer European Union server if appropriate using the option in the Alchemer hosting region drop-down.

On the study Feasibility survey setup page, Oracle Site Select persists the chosen server region (e.g., EU) to the study level when Alchemer is set as the account survey vendor. When the account is configured to authenticate to the Alchemer EU region server, and the Oracle Site Select survey administrator visits the Feasibility survey page, the administrator must sign in to Alchemer to direct authentication to the Alchemer EU authentication page. All survey data for that study survey will reflect from the authenticated EU Alchemer account.



User Authentication

All Oracle Site Select customers use Oracle Identity Cloud Service (IDCS) for user authentication. Users can access Oracle Site Select and other licensed Oracle Identity Cloud Service applications using a single login portal when enabled and configured for the account. This authentication method also supports automatic, just-in-time user account provisioning in

Oracle Site Select to provision new users with a default user role. Oracle Identity Cloud Service also supports federation with a customer's existing identity management solution.

> **Note**
>
> An Oracle representative must enable integration with Oracle Identity Cloud Service at the customer account level. Please contact your Oracle client services representative to discuss requirements.

When your account has been enabled and if you have a role with *API and Authentication Management* permission, you can configure this authentication on the User authentication tab on the Account management: Integrations page. When enabled, the Oracle IDCS configuration section will include SSO URLs as well as several additional fields that let you specify:

- Entry point
- Issuer
- Default role
- IDCS logout URL
- IDP public certificate

If you disable authentication for an account where an IDCS configuration was enabled and saved, the saved configuration will persist should the authentication be re-enabled. This includes persisting the IDP public certificate. Additionally, for an account where IDCS integration is turned off, the configuration can still be provisioned or updated via API. The changes will persist should an Oracle Site Select user enable or re-disable the integration.

When enabled for the account, IDCS Test Mode allows users to authenticate to Oracle Site Select via ICDS or the configured local or IDP (SSO) method. If testing mode is enabled but IDCS is later disabled, an Oracle Site Select user cannot log in via IDCS and must use the configured local or IDP method. API administrators with access to the ICDS provisioning API can toggle the IDCS testing mode on and off via API.

You can optionally configure authentication method(s) specifically for Oracle Site Select testing purposes. Under the Select login test preference section specify an authentication type:

1. User name and password (standard local login)
2. Single Sign On (SSO)

User name and password

Manual login with user name and password is the default user authentication method in the testing authentication section. This option allows for periodic password changes and users can manually change their passwords at any time using a reset option in their user profiles. If you choose this authentication method, the Oracle Site Select login page displays upon either manual or timed logout.

Single Sign On (SSO) - Oracle Site Select users

Single Sign On (SSO) authentication requires integration between Oracle Site Select and your organization's trusted Identity Provider (IDP) system (e.g., an employee portal). When you choose this authentication method for testing, you will see URLs under the Authentication type drop-down that you will use to manage your account’s Oracle Site Select IDP configuration. You'll need to specify the Entry point URL, Issuer, Default user role, and upload the IDP public certificate in the appropriate fields.

The SSO integration you set up for testing will affect all users in the Oracle Site Select account. Once enabled, SSO authentication overrides the default user name and password authentication, and all users in the account must access Oracle Site Select via SSO.

Log in controls:

- The customer IDP or portal controls access to Oracle Site Select. Oracle Site Select will authenticate based on the customer's IDP settings.
- A user who is part of an account that has SSO enabled but attempts to login directly via the Oracle Site Select login page is redirected to the IDP instead.
- An SSO user will not be able to log in to Oracle Site Select directly using a SSO password and will not have the ability to change the SSO password in Oracle Site Select. The user will redirect to their IDP and must be authenticated via SSO.
- A user who attempts to access Oracle Site Select but does not have an active IDP session redirects to the account's IDP for login. Once authorized, the user will be redirected and logged into Oracle Site Select.

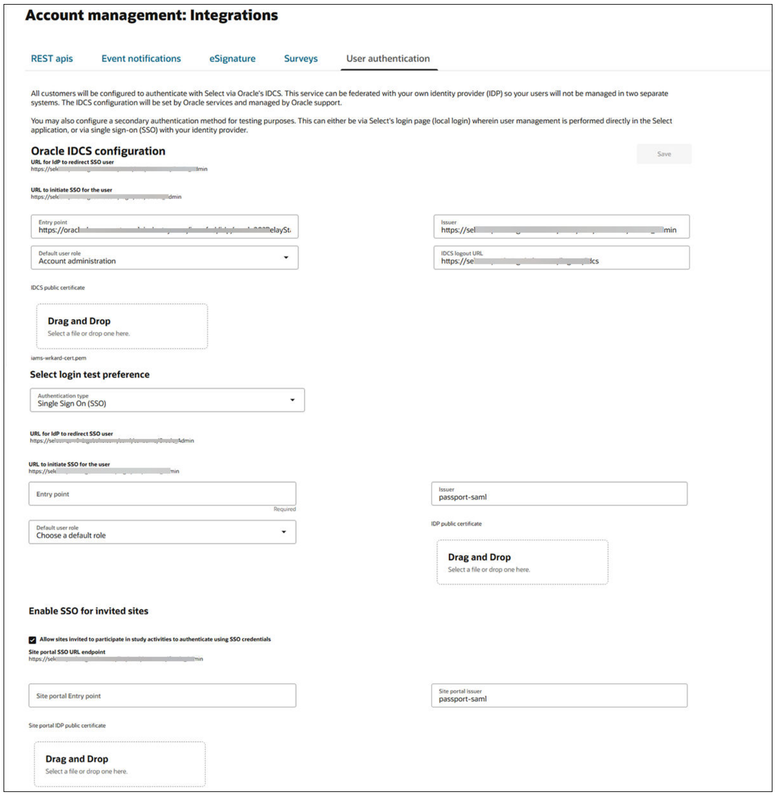
Oracle Site Select SSO uses the SAML authentication protocol and will accept the following properly formatted elements to authenticate an individual user:

1. Email address
2. First name
3. Last name

Upon log out, Oracle Site Select redirects the user to the IDP entry point URL configured for the account. If a user’s Oracle Site Select session times out, and if the user is still logged in to the IDP, the user will be able to log back in with a click of a button. When SSO users manually log out of Oracle Site Select, they will also be redirected to the IDP entry point URL configured for the account.

Single Sign On (SSO) - Site portal users

For testing you can also optionally configure SSO authentication for invited sites. When a site accesses the site portal via SSO authentication, studies to which the site has access are limited to those in which the site has been invited to participate within the logged-in account. By design, site users can log in manually to access studies in another account, if necessary. Upon timeout or manual log out, site portal users who logged in with SSO are redirected to their IDP.



- Access API documentation
  By design, you must be logged into the Oracle Site Select application to access the link to API documentation.
- Generate API access token
  When you need to generate an API access token for use with a Oracle Site Select API, you can do so with one click then copy the token to your clipboard for use.
- Regenerate API access token
  You can regenerate an API access token if one was already created for your organization's account and you need to replace it.
- Copy API access token
  Once you generate or regenerate an API access token, you can copy the token's text as needed.
- Enable event notifications
  The optional PUSH service sends a JSON format POST message for each site profile, site status, or investigator library document update event. The event messages transmit to one or more of your organization's deployed and managed integration endpoint(s), such as a Clinical Trial Management System (CTMS).
- Retry or resend event messages
  You can track the status of event history notification messages and resend or retry messages when necessary.
- Enable Adobe Sign Integration
  Administrative users can enable their document signature workflow to allow digital signatures using any contracted Adobe Sign account they wish. Oracle Site Select currently supports an integration with Adobe Sign for the CDA workflow only.

- Configure survey vendor integration
  Enable Alchemer survey integration and authenticate your Oracle Site Select account to your Alchemer account.
- Configure user authentication
  Your organization's account will be configured to authenticate with Oracle Site Select via Oracle's Identity Cloud Service (IDCS). This service can be federated with your own identity provider (IDP) so your users will not be managed in two separate systems. The IDCS configuration will be set by Oracle services and managed by Oracle support.
- Enable preferred test authentication method
  You may configure a secondary (non-Oracle IDCS) authentication method for testing purposes. This can either be via the Oracle Site Select login page (local login) wherein user management is performed directly in the application, or via single sign-on (SSO) with your identity provider.

Access API documentation

By design, you must be logged into the Oracle Site Select application to access the link to API documentation.

1. At the far right of the page header, click your circular avatar to open the menu.
2. Click **API documentation**.

The API documentation site opens in a new browser tab.

> **Note**
>
> If you have a role with *API and Authentication Management* permission, you can also reach API documentation using the link on the **Account management: Integrations** > **REST apis** page.

Generate API access token

When you need to generate an API access token for use with a Oracle Site Select API, you can do so with one click then copy the token to your clipboard for use.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations** page, view the **REST apis** tab.
3. Click the **Generate inbound API token** button.

   The token displays in the API token field.
4. Click the **copy to clipboard** button.

Regenerate API access token

You can regenerate an API access token if one was already created for your organization's account and you need to replace it.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations** page, view the **REST apis** tab.
3. Click the **Re-generate inbound API token** button.

   The new token displays in the API token field.
4. Click the **copy to clipboard** button.

Copy API access token

Once you generate or regenerate an API access token, you can copy the token's text as needed.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations** page, view the **REST apis** tab.
3. Below the API token field, click the **copy to clipboard** button.

Enable event notifications

The optional PUSH service sends a JSON format POST message for each site profile, site status, or investigator library document update event. The event messages transmit to one or more of your organization's deployed and managed integration endpoint(s), such as a Clinical Trial Management System (CTMS).

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations page**, view the **Event notifications** tab.
3. In the **Email notifications for failed messages** section:
   a. Click **Add** to add a new notification address.
   b. In the **Add notification email** drawer, enter the **Email address** (required).
   c. Click the on/off toggle controls for **Site profile**, **Site status**, and/or **Library documents** to specify the type of failed outbound notification that will trigger the email.
   d. Click **Save** to close the drawer, and view the new entry in the **Email notifications for failed messages** section.

   > **Note**
   >
   > If you need to modify or delete a notification address later, return to the **Email notifications for failed messages** section and click the email row to reopen the details drawer.

4. In the **Configure outbound notification messages** section:
   a. Click **Create new message** to add a new notification address.
   b. In the message settings drawer, enter the preferred **Endpoint name** and enter the customer-managed integration endpoint URL **Endpoint URL** (required).

c. Click the on/off toggle controls for **Site profile**, **Site status**, and/or **Library documents** to specify the type of failed outbound notification that will trigger the email.
d. At Notification type use the drop-down list to choose **Site profile updates**, **Site status changes**, or **Library document updates**.
e. Toggle the **Enable integration** control to the on (right side) position).
f. In the **CTMS Open API specification (Seibel integration)** section, optionally enable **Wrap message tag for Siebel OpenAPI Integration**. If enabled, complete thev required **OpenAPI object name** and **OpenAPI root** fields.
g. In the **Authentication** section, at **Authentication Type**, choose either **Authentication token**, **Basic authentication**, or **OAUTH 2.0**.
h. For Authentication token type, at **Authentication Token**, enter the authentication token for the Endpoint URL. For Basic authentication type, enter the **Username** and **Password**. For Outh 2.0 authentication, enter the **Access token URL**, **Token name**, **Client ID**, **Client secret**, **Scope**, **Grant type**, and **Client authentication** method
i. Click **Save** to close the drawer, and view the new entry in the **Configure outbound notification messages** section.

> **Note**
>
> If you need to modify or delete an endpoint later, return to the **Configure outbound notification messages** section and click the endpoint row to reopen the details drawer.

Retry or resend event messages

You can track the status of event history notification messages and resend or retry messages when necessary.

You must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Event notification history and status**.
2. Use the **Date** range, **Status** (i.e., Success, Processing, Failure, or Trying), and **Type** (i.e., Site profile, Site status, Document library) filters to refine the event messages list.
3. Click **Search** to reload the list.
4. Click a message to view sending details.
5. You can optionally view a message's response object details when necessary. In the **Status** column, click the **Response** link to see the object details in a modal window.
6. You can optionally **Resend** a successful message or **Retry** an unsuccessful message. Both options requeue the exact message to resend or retry based on any updated integration settings (URL, security, etc.).

   Once you click Resend or Retry on the original message, Oracle Site Select disables the action button, and the table lists the newly queued message as a separate row when you refresh the page.

Enable Adobe Sign Integration

Administrative users can enable their document signature workflow to allow digital signatures using any contracted Adobe Sign account they wish. Oracle Site Select currently supports an integration with Adobe Sign for the CDA workflow only.

An optional Adobe Sign subscription may be required to use this feature. Please contact your Oracle Project Manager for subscription details. Additionally, you must have a role with *API and Authentication Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations page**, click the **eSignature** tab.
3. In the **Configure Adobe sign eSignature integration** section, click the “**Enable integration with Adobe Sign**…” check box.
4. Enter the **Customer Adobe sign account URL**, **Application client ID**, and **Application client secret**.
5. Click **Save proprietary credentials**.
6. Click **Authorize with Adobe sign**.

Configure survey vendor integration

Enable Alchemer survey integration and authenticate your Oracle Site Select account to your Alchemer account.

You must have a role with *API and Authentication Management* permission to complete this task. Additionally, Alchemer is a separate subscription product than Oracle Life Sciences products, and typically, there is one master Alchemer user who has admin control over your account as well as having the API access license. Authenticate this user to your Oracle Site SelectSelect account.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations page**, view the **Surveys** tab.
3. Click the **enable Alchemer survey integration** check box.
4. In the **Select your Alchemer account region** section, use the **Alchemer hosting region** drop-down to authenticate with servers in either the **North America** or **European Union** region. Consult your Alchemer contract, which will specify the region.
5. Click **Authorize with Alchemer**.

   If Oracle Site Select is not authenticated you will be forwarded to the Alchemer integration login page. Enter your Alchemer user credentials. If your account is authenticated and you wish to change the authenticated user please be aware that survey permissions managed in Alchemer may affect access to previous studies. The new user should be authorized to previous study surveys in Alchemer before proceeding.

Configure user authentication

Your organization's account will be configured to authenticate with Oracle Site Select via Oracle's Identity Cloud Service (IDCS). This service can be federated with your own identity provider (IDP) so your users will not be managed in two separate systems. The IDCS configuration will be set by Oracle services and managed by Oracle support.

You must have a role with *API and Authentication Management* permission to complete this task. In addition, an Oracle administrator must enable integration with Oracle Identity Cloud Service at the customer account level. Please contact your Oracle client services representative to discuss requirements before completing this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations page**, view the **User authentication** tab. If your organization's account is enabled for IDCS, you'll see read-only URLs listed for IdP to redirect SSO users and Initiate SSO for the user.
3. At **Entry Point**, enter the entry point URL.
4. At **Default user role**, use the drop-down menu to select the default role assigned to users that don't already have a role in Oracle Site Select.
5. At **Issuer**, enter the URL for the instance.
6. At **IDP public certificate**, click **Drag and Drop**. Browse to the location where you've stored the certificate and click the file to upload.

Enable preferred test authentication method

You may configure a secondary (non-Oracle IDCS) authentication method for testing purposes. This can either be via the Oracle Site Select login page (local login) wherein user management is performed directly in the application, or via single sign-on (SSO) with your identity provider.

You must have a role with *API and Authentication Management* permission to complete the task below.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Integrations**.
2. On the **Account management: Integrations page**, view the **User authentication** tab.
3. In the **Select login test preference** section, use the Authentication type drop-down to choose **User name and password (standard local login)** or **Single Sign On (SSO)**.
4. If you chose local login, that is the default; click **Save**.
5. If you chose SSO, at **Entry Point** (required), enter the identity provider entry point URL.
6. At **Choose a default role**, use the drop-down menu to select the default role assigned to users that don't already have a role in Oracle Site Select.
7. At **Issuer**, enter the name of the certificate issuer. At **IDP public certificate**, click **Drag and Drop**. Browse to the location where you've stored the certificate and click the file to upload.
8. Click **Save** to save SSO authentication for Oracle Site Select users, or complete the following optional steps to also enable SSO authentication for site users.
9. Optional: In the **Enable SSO for Invited Sites** section, check the **Allow sites invited to participate in study activities...** check box. This will enable the following fields:
10. Optional: At **Site portal Entry point**, enter the identity provider entry point URL.
11. Optional: At **Site portal issuer**, enter the public certificate issuer.
12. Optional: At **Site portal public certificate**, click **Drag and Drop**. Browse to the location where you've stored the certificate and click the file to upload.

Library document labels

Document-related workflow tasks use your account's defined document labels to categorize Library documents and allow for versioning of similar documents affiliated with the same label.

Document labels

If you have *Account document configuration* permission, you can create account-level identifier labels for Document Library documents. For example, document labels might include “CDA” or “Data privacy agreement,” among others. Document label names must be unique (i.e., no duplicates), and they may include any alphanumeric character, spaces, emojis, and special characters (~!@#$ %^&*()_+-= []:";'<>,./?).

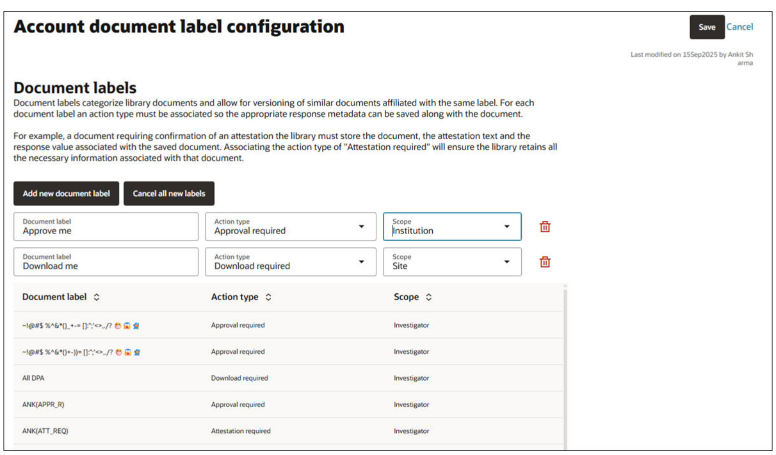
When creating a new label on the Account document label configuration page, you must also specify one of the following Action Types when adding a new document label:

- Download required
- Approval required
- Choose response
- Attestation required

Finally, you'll specify the document label's scope as Investigator, Institution, or Site.

> **Note**
>
> The account must have a primary composite datasource in order to create document labels scoped to Investigator or Institution. A primary composite datasource is not required to create document labels scoped to Site.

When you save the new document label to the list, you may not change or delete it; however, you can create a new document label if necessary.



- [Create document library labels](#)
  Create labels to organize Library documents and use the labels across all studies in the account.

Create document library labels

Create labels to organize Library documents and use the labels across all studies in the account.

You must have a role with *Account document configuration* permission to complete this task.

1. Click menu in the page header. Then open the **Account** menu, and click **Library documents**.
2. Click **Add new document label** to enable input fields.
3. Enter a unique **Document label** including any alphanumeric character, spaces, emojis, or special characters (~!@#$ %^&*()_+-= []:";'<>,./?).
4. Choose an **Action type** (Download required, Approval required, Choose response, or Attestation required).
5. Choose a **Scope** (Investigator, Institution, or Site). The account must have a primary composite datasource in order to create document labels scoped to Investigator or Institution.
6. Confirm your inputs and click **Save** to add a single label, or click **Add new document label** to add a new row of input fields, configure them, and then click **Save**. If you need to delete a row (before saving), click delete .

   After saving, you may not remove any label, but you can add a new, unique label to the list.

Network management

Network functionality allows for the configuration of account level network profiles and the affiliation of a site to a network profile. Network functionality also allows your organization to leverage a site's affiliated network contact to override study invitation preferences and invite only the network contact.

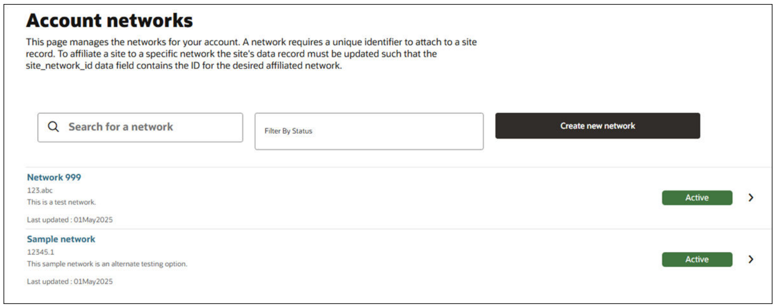
Account networks page

If you are an Oracle Site Select administrative user with *Network profile management* permission, you can configure and manage account-level site network profiles on the Account networks page. The page allows you to create the network with a name, identifier, and other metadata that defines the network as a unique entity within the account (such as Network group type, Affiliation scope and type, Network delegate contact information, Therapeutic area(s), etc.).

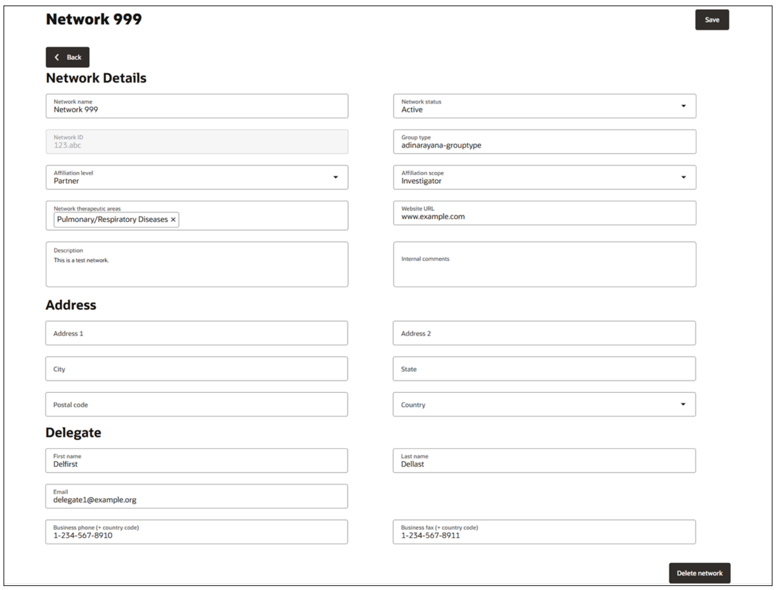
The Account networks page shows an alphabetical list of the account's saved networks and displays the following details for each saved network:

- Network name (required)
- Network ID (required)
- Description (optional)
- Last updated: <date>
- Status badge (i.e., Active, Pending review, or Inactive)

The Account networks page also includes a search field, so you can search for an existing network, and you can Create a new network if necessary.



In the existing networks list, to the right of the network's status badge, a right arrow navigates to the Network details page where you can update information for that network, as preferred. You can also access the Network details page by clicking the network name. Click the Back button on the Network details page to return to the Account network list.



Every network must have a name and an ID. All other fields on the Network Details page are optional. You can also delete an existing network, if necessary. You'll see this option at the lower right of the Network details page, and you must confirm deletion if you click Delete network.

> **Caution**
>
> **Account level Network deletion has significant impact**:
>
> - Network won't be considered for sites that have not yet been invited, and invitations proceed as if no network is assigned. When you or another Oracle Site Select user view the site's assigned network in the Site profile > Network page, the network will not be set.
> - For a network assigned to a site that has been invited and the network delegate is included in the invitation, then the network is deleted at the account level:
>   - The network delegate will still be listed as a study contact when viewing the study contacts tab. If you or another Oracle Site Select user re-invite the site, the network delegate will receive re-invitation and study-related emails, such as a CDA notification. The invitation received modal/information will maintain that the network delegate received an email.
>   - No network will be set when you or another Oracle Site Select user view the site's assigned network in the Site profile > Network page.
> - The Site profile > Network menu item will be disabled for a site affiliated with a now-deleted network (i.e., that affiliation will no longer exist).

Standard data column

A configured network profile's Network ID is an important value that must be unique across all networks in the account. When saved, Oracle Site Select users who manage data import can affiliate a site record to a network by including the ID in a new site_network_id data import column. The new Site network ID column is available as a:

- Standard Oracle Site Select site data column when creating a new composite or flat (CSV) datasource
- Column in the site grid column picker
- Column available for CSV export

The site_network_id data column will save data to the site's profile when the column is populated on import and the site's profile is saved.

Site profile Network tab

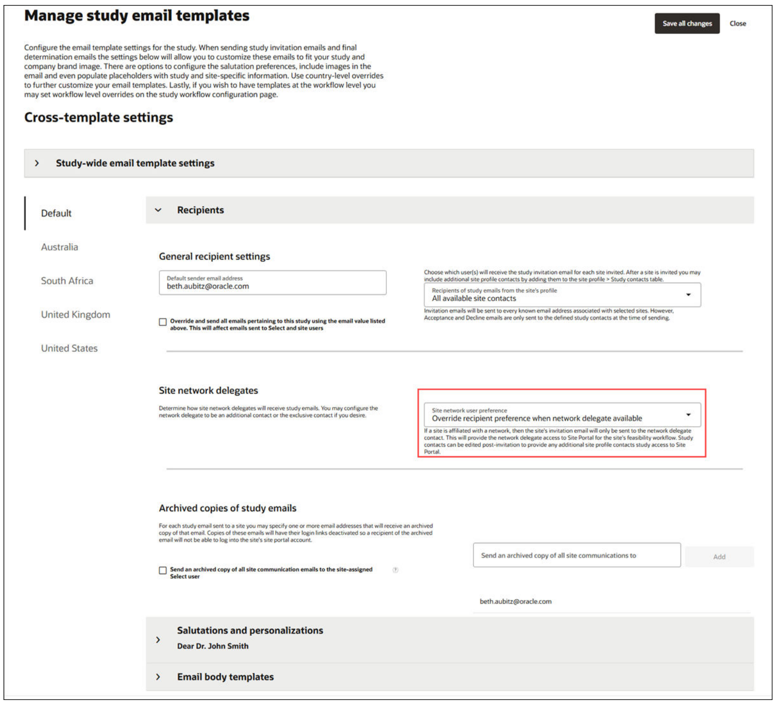
When an account has at least one saved network profile, the Site profile in Oracle Site Select and the Edit site profile page in the site portal include a Network sub-tab. If a site's record has been affiliated with a configured network in the account (i.e., the site record includes the site_network_id value), the tab displays the network profile in read-only format. Note that a configured network's "Network status" and "Internal comments" fields do not display in the site portal, as these fields are not intended for site users.

Networks and study invitations

The Manage study email templates page Default template tab includes a Site network delegates setting that lets you specify how site network delegates will receive study emails, if at all. The options and study invitation impacts are:

- **Do not include the network delegate**: If the site is affiliated with a site network the network delegate will not be automatically added as a site contact when the site is invited.

- **Include the site's affiliate network delegate as an email recipient**: If the site is affiliated with a site network then the network delegate affiliated with the site will also receive study emails along with the recipients defined. The user will be added to study contacts and can be removed later.
- **Override recipient preference when network delegate available**: If a site is affiliated with a network, then the site's invitation email will only be sent to the network delegate contact. This will provide the network delegate access to Site Portal for the site's feasibility workflow. Study contacts can be edited post-invitation to provide any additional site profile contacts study access to Site Portal.



- [Add, edit, or delete a site network profile](#)
  If your organization uses Network functionality, you can manage site network profiles at the account level by creating unique network records with a name, identifier, and other metadata. You can also update existing network profiles in your Account networks list or delete any profiles that are no longer needed.

Add, edit, or delete a site network profile

If your organization uses Network functionality, you can manage site network profiles at the account level by creating unique network records with a name, identifier, and other metadata. You can also update existing network profiles in your Account networks list or delete any profiles that are no longer needed.

You must have *Network profile management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Networks**.
2. On the **Account networks** page, complete one of the following:
   a. To add a network: Click **Create new network**. Enter the required **Network Name** and **Network ID**. Complete, as applicable, all remaining fields. Note that the **Network**

delegate contact section affects study invitations sent to sites associated with the network. When you're done, click **Save**.

b. To edit a network: Search, filter, or scroll to the network profile you want to Edit. Click the network name to open the **Network Details** page. Update any field as preferred (Network Name and Network ID fields are required and must have a value). Click **Save**.

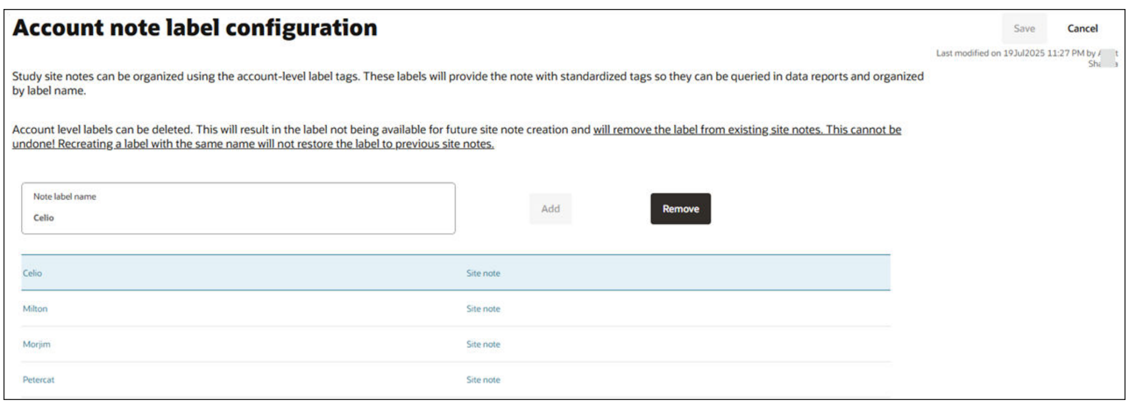
c. To delete a network: Search, filter, or scroll to the network profile you want to remove. Click the network name to open the **Network Details** page. At the bottom right, click **Delete network**. In the confirmation modal, click **Yes**.

Note labels

Note labels help to group and organize study site notes. When you have *Account note label configuration* permission, you can create and manage the labels to make them available across all studies in the account.

When you create a study site note, you can add a label to help find the note later. Configured at the account level, you can add and delete labels from the common list as necessary.

> **Warning**
>
> If you delete a label from the list it will become unavailable to add to a study site note and it will be removed from existing notes. This action cannot be undone, so be sure before you choose to delete an existing label. If you recreate the label later, the recreated label will NOT restore the label to previous site notes.



- Configure note labels
  Study site notes can be organized using the account level labels. Labels provide the note with standardized tags so they can be queried in data reports and organized by label name.

Configure note labels

Study site notes can be organized using the account level labels. Labels provide the note with standardized tags so they can be queried in data reports and organized by label name.

You must have a role with *Account note label configuration* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Note labels**.
2. To add a label: At the **Note label name** field, enter the preferred name and click **Add**. Repeat this step to create additional labels.
3. To delete a label: Click the row for the label you want to delete, and click **Remove**.
4. In the confirmation pop-in, click **Delete**.
5. Click **Save**.

> **Warning**
>
> Deleting a note label will result in the label not being available for future site note creation and will remove the label from existing site notes. This cannot be undone! Recreating a label with the same name will not restore the label to previous site notes.

Users, roles, and teams

This section, which is intended for users in a study administrator or study manager role, describes how to manage user accounts and access permissions in Oracle Site Select. You'll see the Users and access menu option in the Accounts menu if you have a role with *User and Role Management* permission.

Account users and access

The Account users and access page includes three action buttons:

1. **Add new user** – Specify the user's email address, first name, and last name. You can optionally specify the user's status (Active (default) or Inactive)
2. **Configure roles** – Use this option to create, modify, or delete a role. You'll specify the role name, description, and associated permissions to create a role. To modify an existing role, you can change the name or description and check or uncheck available permissions. If you Delete an existing role, it will be removed, and any user with that role will no longer have the associated permissions.
3. **Configure teams** – Use this option to create, modify, or delete a set of permissions limited to one or more studies. This configuration is similar to the available options for configuring a role, except you will specify (or modify) the studies included in the team. Again, removing a team will remove the associated permissions and study access for any user assigned to that team.

The Account users and access page also has a paginated grid of all active and inactive user records. Use the type-ahead search field to find user records that match any part of the last name, first name, or email address. You can also sort any column in the grid. Click a user's Last name, First name, or Email address field to open the Edit user modal, where you can update any of these fields or the Status (Active or Inactive) field.

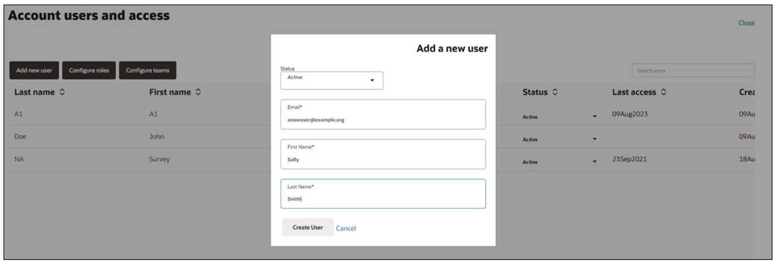
To manage an individual user's Roles or Team assignments, click edit in the user's Roles or Teams column. A drawer will open from the right side of your screen where you can select or unselect the roles or teams you want to add or remove for that user.

When you close the Account users and access page, you'll automatically navigate to the homepage for the last study you accessed.

Super user tasks

If you are your organization's designated Oracle Site Select super user, one of your common tasks is to add user accounts for other study team members when necessary. You'll use the Add new user option on the Account users and access page to do this. Each team member you add receives an email notification with a time-limited link to access Oracle Site Select.

After adding user accounts, you can assign team members to one or more roles that determine the tasks they can perform and the information they are allowed to view. You can also create a Team and assign users to one or more roles for various studies.



- Add new user
- Edit a team member's name and status
  You may need to manually update a user's name, user account status, or email address as part of regular business processes. Follow these instructions to make the necessary changes.
- Roles and permissions
  When you have *User and Role Management* permission, you can create or edit roles in Oracle Site Select. When you do so, you'll specify individual permissions associated with the new role or updated role.
- Study level (teams) permission

Add new user

You must have *User and Role Management* permission to add new users in Oracle Site Select.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **User and access**.
2. Click **Add new user**.
3. To make the new user inactive when their account is created, at **Status**, select **Inactive**.
4. Enter the user's **Email** address.
5. Enter the user's **First Name** and **Last Name**.
6. Click **Create User**.

After you've completed the steps above, the new user receives an email with a link to access Oracle Site Select.

Edit a team member's name and status

You may need to manually update a user's name, user account status, or email address as part of regular business processes. Follow these instructions to make the necessary changes.

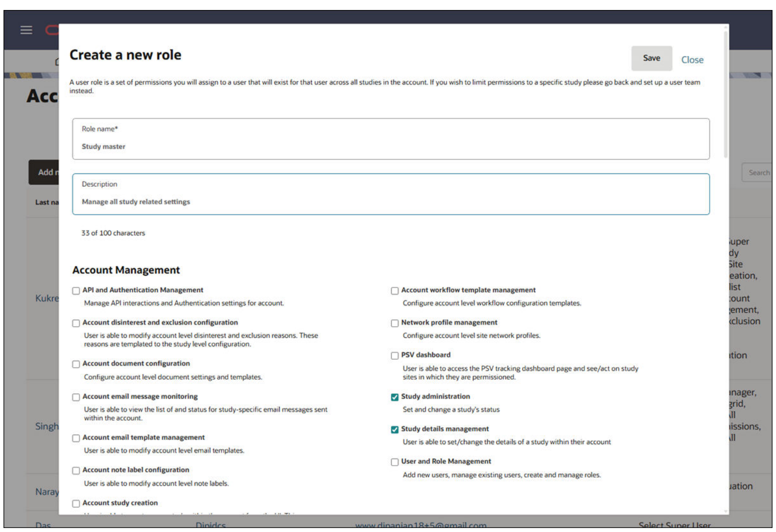
You must have *User and Role Management* permission to modify a user's details in Oracle Site Select.

1. Click menu in the page header. Then open the **Account** menu and click **Users and access**.
2. On the **Account users and access** page, search for or scroll to the user's record. Click the user's Last name.
3. In the **Edit user** modal, change the user’s **Status**, **Email**, **First Name**, and/or **Last Name**, as preferred.
4. Click **Update user**.

Roles and permissions

When you have *User and Role Management* permission, you can create or edit roles in Oracle Site Select. When you do so, you'll specify individual permissions associated with the new role or updated role.

Use the Configure roles option on the Account users and access page to create a new role or modify an existing one. You can add or edit the role name and description. Scroll down to choose the permissions you want associated with that role.



Available user permissions are grouped under the following section headings:

- Account management
- CDA/Document Management
- Data Source Management
- Read Only Permissions
- Reporting

- Site Grid
- Site Management
- Site Selection
- Study Management
- Survey Management
- Targeted Search

Below is the list of permissions you can add to a role in Oracle Site Select.

Permission	Description
Access study-specific Select Lite No Login links	View and copy the Login link from the site grid's Invitation email status modal or download a CSV file with study-specific Site portal login links.
Account disinterest and exclusion configuration	Configure a template containing disinterest and exclusion reasons at the account level that can be used across studies in that account. This permission is not supported for teams.
Account document configuration	Configure account level document settings and templates.
Account email message monitoring	Access the Study-specific email message history and status page to Retry or Resend an email message.
Account email template management	Configure account-level email template with placeholder values (logos, custom text, etc.).
Account study creation	Allows users who have *View Dashboards* permission to add a new study while viewing My Dashboard.
Account workflow template management	Create and manage account-level workflow templates.
Analyze reports	Access to Oracle Site Select reports in Oracle Site Analyze based on user's account and study permissions.
API and Authentication Management	Manage API interactions and Authentication settings for account.
CDA counter signer	Users assigned this permission are listed as available CDA counter signers if digital signature is configured for the account and enabled in the assigned workflow.
CDA/ Document Template Upload	Upload a study CDA/ document template.
Complete tasks as Not required	Close (complete) tasks that are not required in the workflow. User is able to mark a study site's workflow task with the status of Completed - Not required for workflow tasks except: Confidentiality statements, CDAs, and Feasibility surveys.
Complete task as Not required: Sign and return CDA	User is able to mark a study site's CDA task workflow task with the status of Completed - Not required.
Complete task as Not required: Feasibility survey	User is able to mark a study site's Feasibility survey task workflow task with the status of Completed - Not required.
Complete task as Not required: Confidentiality Statement	User is able to mark a studysite's Confidentiality Statement task workflow task with the status of Completed - Not required.

Permission	Description
Cross-study study-site view	Allows site grid users access to the "View site history" option in the Actions menu to see a site's cross-study performance and workflow completion in all studies in the account. This permission is not supported for teams.
Data Export Management	Allows access to self-service, tabular data export tool (Oracle Site Analyze required).
Data Source Management	Create and manage private datasources.
Edit Datasource Record	Edit and delete individual data source records from the data source details page, or delete an entire datasource.
Edit Site Profiles	Modify profile information for sites and verify site profile information on behalf of sites.
Edit/delete site note	Edit and Delete any saved note in the Notes History section and in the site grid drawer's Site Notes tab.
Email Template Management	Review, edit, and approve email templates.
Export Sites to Activate	Export sites from Oracle Site Select to Oracle Site Activate
Feasibility Survey Management	Configure feasibility survey and survey scoring for study.
Link to Activate study and studysite	Allows access to an Oracle Site Activate deep link for the current study or study site. Functionality requires Oracle Site Activate integration.
Negotiation for assigned CDA/ Document submissions only	Allows a document reviewer to view all CDA submissions in any status, but the user is prevented from performing the Fully executed document action in the approval workflow. Allows access to Document submissions page.
Network profile management	Add and manage an account's site network profiles.
Perform a targeted data source search	Enables the user to perform a targeted search on datasource to import specific site records.
PSV dashboard	Allows the user view and edit access to the Pre-Study Visit tracking dashboard.
Read only document management view	Allows auditor users access to the Document submissions page.
Read only notes/reasons dialog view	When combined with *Read only notes/reasons dialog view* permission, allows auditor users to access the Notes modal dialog from the site grid.
Read only site communications view	Allows auditor users access to the Site communications area from the "manage" menu.
Read only site grid view	Allows auditor users to view all site grid steps and bucket states.
Read only study set up view	Allows auditor users to access all study setup functional areas listed in the "setup" menu.
Revert site finalization	Return sites to the Select bucket from the Finalize bucket.
Review and Approve All CDA/ Document Submissions	View and approve all CDAs or Documents on the Document submissions page.
Review and Approve Assigned CDA/ Document Submissions only	Approve fully executed CDAs or Documents on the Document submissions page.

Permission	Description
Review generic document attestation submissions	Output details for a generic document attestation submission to a file in PDF format.
Review and Approve All Generic Document Submissions	Allows the user to view, review, and approve all generic document submissions.
Review and Approve Generic Document Submissions for assigned sites Only	Allows the user to view, review, and approve only the generic documents for sites assigned to them.
Select Lite Workflow Configuration	Configure Site portal workflow and upload documents on behalf of sites.
Site Nomination, Evaluation and Selection	Search for sites, add and reject sites for a study, put sites on hold.
- -Add sites to the short list during Evaluation	Add sites to the short list during Evaluation.
Site Selection Approval	Approve sites for invitation to participate and for activation.
Send CDAs for digital signature	Assign CDA signers and send a CDA for digital signature.
Study administration	Set and modify a study's Status and Type values in the study setup process.
Study details management	Set and modify most study details within the account in the study setup process. Exceptions are the study Status and Type values (see *Study Administration* above).
Study Setup Management	Upload study protocols, set study parameters, milestones and site score weighting.
Team management	In the teams feature, limit the users who have visibility into a study within an account.
User and Role Management	Add new users, manage existing users, create and manage roles.
View/Create study notes	Allows users to create study-level notes.
View Dashboards	View analytical dashboards and user level My Dashboard feature.
View/manage assigned sites only	Users with this permission will be restricted to a subset of sites within their permissioned studies. To be listed as a user available to assign to a site, users must also be: • granted at least the site nomination permission • permissioned to the study • a valid user within the account

- Add, edit, or delete roles
  If you need to add a new role, modify an existing role, or delete a role in the account, use these instructions to learn how to define the role and manage permissions associated to it.
- Assign a role to a user
  When your account has a role defined, you can assign it to an Oracle Site Select user and that user will have all permissions associated to that role for all studies in the account.
- Site level permission
- Oracle Site Analyze reports permission
- Read only permissions

Add, edit, or delete roles

If you need to add a new role, modify an existing role, or delete a role in the account, use these instructions to learn how to define the role and manage permissions associated to it.

You must have *User and Role Management* permission to add, edit, or delete roles in Oracle Site Select.

1. Click menu ☰ in the page header. Then open the **Account** menu and click **User and access**.
2. On the **Account users and access** page, click **Configure roles**.
3. On the **Configure roles** page:

   a. to add a new role, click **Create new role** and see step 4.

   b. to change an existing role, scroll to the existing role and click the role name and see step 4.

   c. to delete an existing role, scroll to the existing role and click **Delete role**. Read the statements in the confirmation modal, and if you want to continue with deletion, click **Proceed**.
4. At **Role name**, enter a unique name for the role or update the existing name.
5. At **Description**, enter a brief description or modify the existing description. If saved, descriptions display when you hover over more information on the Configure roles page.
6. Scroll down and check the box next to each permission you want to assign to/unassign from the role.
7. Click **Done**.

Assign a role to a user

When your account has a role defined, you can assign it to an Oracle Site Select user and that user will have all permissions associated to that role for all studies in the account.

You must have *User and Role Management* permission to assign a role to a user in Oracle Site Select.

1. Click menu ☰ in the page header. Then open the **Account** menu and click **Users and access**.
2. On the **Account users and access** page, search for or scroll to the user's record. In the Roles column, click edit.
3. In the **Edit user roles:** drawer, click the check box to the left of the role(s) you want to assign to the user.
4. Click **Save**.

Site level permission

Oracle Site Select users can be restricted for assignment to a subset of sites within an account. Users with the *View/manage assigned sites only* permission will be restricted to a subset of sites within their permissioned studies. To be listed as a user available to assign to a site, users must also be:

- granted at least the *Site Nomination, Evaluation and Selection* permission
- permissioned to the study
- a valid user within the account

Note

When an Oracle Site Select user loses access to a site for any reason, that user no longer receives any email notification related to the site. Examples of how users lose access include inactivation of the user account or changes to user permissions. When a user is no longer permissioned to a site, email notifications for the site are sent to the email templates default email address or to the country override email address, if specified on the email templates page.

Users granted permission to all studies and who have at least the *Site Nomination, Evaluation and Selection* permission will be available for site assignment. Additionally, a user with *View/manage assigned sites only* permission can see all sites within a study they are assigned to as a union of their other study-related permissions. Meaning, a user who has been granted only the *View/manage assigned sites only* permission will not see any sites in the site grid because that user lacks other study permissions, such as study nomination/shortlist permission.

Sites grid

The combination of an individual user's permissions, role, and team assignment affect the sites visible in the sites grid as well as the actions a user can take. Here are some examples of expected behavior:

- A user with the *View/manage assigned sites only* permission will see no sites in Step 1 for all studies if assigned in a role
- If a user is granted the *View/manage assigned sites only* permission at the team level, the user will see no sites in Step 1 for the studies defined in that team
  - If the grid is empty for either reason above, Oracle Site Select displays the following message: "No sites are available based on your current level of study and/or site permissions."
- A user granted the *Site Nomination, Evaluation and Selection* permission at the role level, but assigned the *View/manage assigned sites only* permission at the team level will have the sites in the team-assigned studies limited to only those in which they are assigned
- A user with the *Site Nomination, Evaluation and Selection* permission and the *View/manage assigned sites only* permission at the role level will see only those sites to which they are assigned for each study

Also note, bucket state counters reflect the sites visible to the user. For example: A user is permissioned to only 10 of 15 sites in the shortlist. The counter on the bucket state link for Shortlist will read Shortlist (10).

CSV/PDF downloads

An individual user's permissions also affect the content of CSV and PDF downloads. For users granted the *View/manage assigned sites only* permission, these are additional examples of expected behavior for downloads:

- All CSV downloads from Step 1 are empty because site assignment occurs on Step 2.

- CSV downloads from any bucket state in Steps 2-4 are limited to only those sites for which the user is assigned, and if no sites are assigned to a user in any bucket state of Step 2, then all downloaded CSVs will be empty
- If a user is revoked access/assignment to a site, Oracle Site Select will not retroactively reflect this change; however, future downloads of a CSV site grid will reflect the change in site permission
- A user cannot download the PDF of a site's survey results for whom the user is not permissioned to view/manage
- The download option for Site profile updates CSV includes only those sites to which the user is assigned

Revoking access and permissions

> **Note**
>
> When revoking a user's access to a study, first remove the user's site assignments from within the study's site grid.

If a user becomes ineligible to be assigned to a site for a study, the site(s) are currently not reverted to the unassigned state. For example, a user is permissioned to a study and assigned to a subset of sites within that study. The user is later removed from the study or the user has site nomination permission removed from their account. Upon revocation of the study or permission, all sites assigned to that user are not automatically reverted to the unassigned state. Existing site assignment behavior related to receiving email notifications and having the site-assigned user's email address be the reply-to email address is unchanged.

> **Note**
>
> To prevent users from receiving email alerts that are not actionable, if removing a user's site assignment, either unassign the user from the site or assign access to a different user. Users/managers can run the Site progress report in Oracle Site AnalyzeAnalyze and filter on "Assigned User" to see which sites need to be reassigned before revoking a user's access to studies.

Also note that users assigned to fewer than all sites in a study are revoked from accessing Oracle Site Analyze reports for that study.

Oracle Site Analyze reports permission

The *Analyze reports* permission provides a user with access to Oracle Site Select reports in Oracle Site Analyze based on their account and study permissions, and only permissioned users will see the Analyze reports link in the Dashboards menu. Users who have the *View Dashboards* permission, but do not also have the *Analyze reports* permission can view the Dashboards menu, but the Analyze reports link will not be listed in the menu options.

The *Analyze reports* permission also provisions and permissions the user's Oracle Analytics Cloud account in Oracle Site Analyze if he or she did not have an account before being granted *Analyze reports* permission. Users are permissioned in Oracle Site Analyze to the reports for their account(s). This means:

- A user with *Analyze reports* permission can view reports only from their Oracle Site Select account

- When a user is assigned the *Analyze reports* permission in a Team, they can only see data for the studies included in the Team(s) where they hold that permission (a.k.a. "study level filtering"). If they are assigned the *Analyze reports* permission in a Role, they will have access to all studies in Oracle Analytics Cloud, which provides broader access compared to Team-based permissions.
- If the user is assigned both a Role and a Team with *Analyze reports* permission, they will be able to see reports with all study data.

Read only permissions

Read only permissions allow a customer's auditor users to access studies in Oracle Site Select but not change data in any way. The permissions, described in detail below, align with functional areas to allow access to:

- Site grid steps and bucket states
- Notes and Reasons dialog modal
- Document management area
- Site communications area
- Setup menu and options

Because the Oracle Site Select home page displays study milestones and task actions affiliated with a user's assigned permissions, assigned read only permissions affect an audit user's home page view. An auditor user assigned one or more read only permissions will see the list of study milestones, but that user will not see any tasks listed on the home page.

Additionally, with the exception of the study setup read only permission, the other read only permissions described below can be assigned only to an individual. Assignment to teams is not supported.

Site grid view

The "Read only site grid view" permission allows auditor users to view all site grid steps and bucket states but not change any data. Auditors assigned this permission may:

- View the sites within the site grid across the Nominate, Evaluate, Select, and Finalize steps
- Filter, sort, search, and add columns to the site grid
- Paginate through a site list
- View the contributing data sources
- View the site profile
- View site invitation details

Oracle Site Select prevents an audit user who has only the Read only site grid view permission from performing any action on sites listed in the grid, including adding or viewing notes and reasons for site exclusion. Additionally, the user may not:

- Add a site to a different bucket state
- Change a site's workflow or an assigned workflow's close date
- Download a site grid CSV or survey responses
- Assign a site to an Oracle Site Select user
- See site login or invite activity

- Invite or re-invite a site
- Send finalization email or send the site to Oracle Site Activate
- Revert a site

Notes and reasons view

The "Read only notes/reasons dialog view" permission can be combined with the "Read only site grid view" permission described above to provide auditor users access to the Notes modal dialog from the site grid. The modal dialog contains study notes, site notes, and reasons for site exclusion. The user may not act on the sites in the site grid, notes, or reasons for site exclusion.

Document management view

The "Read only document management view" permission allows auditor users access to the Document submissions area. The auditor user can access all document types and countries for the study within the Document submissions area. Audit users can also view the status of each site's documents for each document type and view the document status metadata affiliated with each document.

Oracle Site Select prevents users who have only the Read only document management view permission from acting on any element of the document submissions page. The user will not have the ability to:

- Assign a user to a document
- Download a document copy from the document history popover
- Recall a CDA or generic document

Users assigned only the "Read only document management view" permission will not have the ability to see other Oracle Site Select areas, including the site grid. Additionally, the permission currently does not provide access to Generic document attestation document types on the document management page.

Site communications view

The "Read only site communications view" permission allows auditor users access to the Site communications area tool. On the Site communications page, the auditor will see all messages for the study, and the user can click a message to display its contents.

Like other read-only permissions described above, Oracle Site Select prevents the permissioned user from taking specific actions. A user who has only the "Read only site communications view" permission will not have the ability to:

- Add or reply to a message (open the message compose page)
- Affect the "read" status of the message

Additionally, users assigned only the "Read only site communications view" permission will not have the ability to see other Oracle Site Select areas, including the site grid. This is expected behavior.

Study setup view

This permission, Read only study setup view, allows an auditor user to access all study setup functional areas listed in the Oracle Site Select Setup menu.

The auditor user can navigate to each of the menu's setup pages, all of which have a disabled Done or Save button to prevent saving any change to the study settings. For each functional area, specific action restrictions apply. For instance, we disabled all controls for:

- Upload and download documents
- Upload an image to the study email template
- Add, delete, and reorder reasons
- Authenticate, create, save, and select surveys
- Remove a study level workflow definition

Users who have only the Read only study setup view permission will not see the site grid or other functional areas unrelated to study setup. However, users who have this permission can view the study home page. By design, if Read only study setup view permission is the user's only assigned permission, the home page shows the milestones for each permissioned study and no tasks for the study.

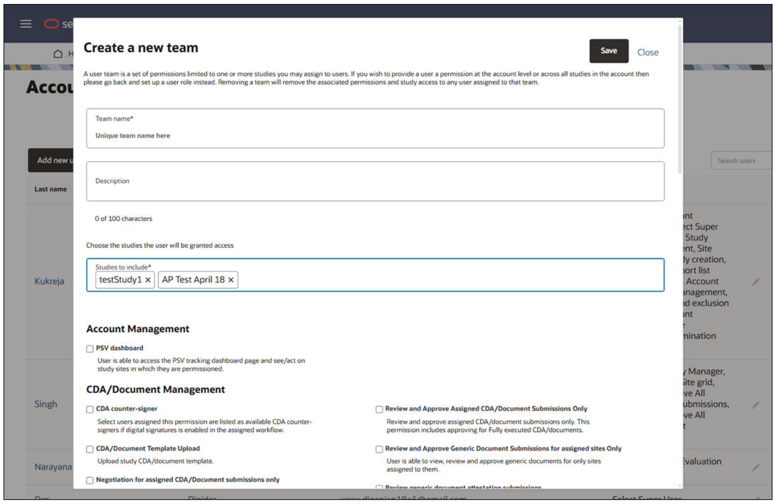
Unlike other read only permissions described above, the Read only study setup permission can be assigned to a role or team.

> **Warning**
>
> Combining a read only permission with another permission that allows the user to modify data may lead to system errors or other unexpected results. Read only permission should be added to a user account only when that user has no other conflicting permissions assigned or if other assigned permissions also grant read only access.

Study level (teams) permission

Using the team management feature, Oracle Site Select users can be permissioned by study. This feature uses the *Team management* permission, and study administrators with this permission can use the teams feature to limit the users who have visibility into a study within an account. Team managers have the ability to create, edit, and define a team using the "Configure teams" option on the Account users and access page.

Creating a team uses an interface similar to Role creation. If you have the *Team management* permission, you'll specify a unique team name and choose one or more permission(s) for the team members. In addition, the team configuration defines one or more studies within the account that the team members can access. When you create a team, you can optionally create a team description of up to 100 characters.



Once you've saved the team, you can then assign it to individual users as preferred. Note that:

- a user with any role level permission in the account has access to all studies
- a user with a team permission, but no role permission, has access to only those permissions assigned to their teams
- a user with a role permission and a team permission has all study access, but **limited to the union of their permissions**

Be aware that restrictive permissions do not necessarily override inclusive permissions. For example: If a user has *Review and Approve Assigned CDA/Document Submissions Only* permission in a team for a specific study, but has the *Review and Approve **All** CDA/Document Submissions* permission via a role, then the All CDAs permission takes precedence.

- Add, edit, or delete teams
  A user team is a set of permissions limited to one or more studies you may assign to users. When you've added or updated a team, you can assign the team to one or more users.
- Assign a team to a user
  Assigning a team to a user will grant that user access to the studies configured for that specific team. It also grants the user the permissions configured for that team in those studies.

Add, edit, or delete teams

A user team is a set of permissions limited to one or more studies you may assign to users. When you've added or updated a team, you can assign the team to one or more users.

You must have a role with *Team Management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu and click **User and access**.
2. On the **Account users and access** page, click **Configure teams**.
3. On the **Configure teams** page:

   a. to add a new team, click **Create a new team** and see step 4.

   b. to change an existing team, scroll to the existing team and click the role name and see step 4.

c. to delete an existing team, scroll to the team and click **Delete team**. Removing a team will remove the associated permissions and study access to any user assigned to that team. Read the statements in the confirmation modal, and if you want to continue with deletion, click **Proceed**.

4. At **Team name**, enter a unique name for the team or update the existing name.
5. At **Description**, enter a brief description or modify the existing description. If saved, descriptions display when you hover over more information on the Configure teams page.
6. Under **Choose the studies the user will be granted access**, type the study name(s) to search and select to assign to the team. Once selected, the studies display in the studies field. To remove a study from the list, click **X** to the right of the study name.
7. Scroll down and check the box next to each permission you want to assign to/unassign from the team.
8. At the top of the modal, click **Save**.

Assign a team to a user

Assigning a team to a user will grant that user access to the studies configured for that specific team. It also grants the user the permissions configured for that team in those studies.

You must have a role with *Team Management* permission to complete this procedure.

> **Note**
>
> To provide all studies access to a user, create a role in the Roles tab and assign the user to the role. There is no need to use the Teams feature, which restricts study access, as described below.

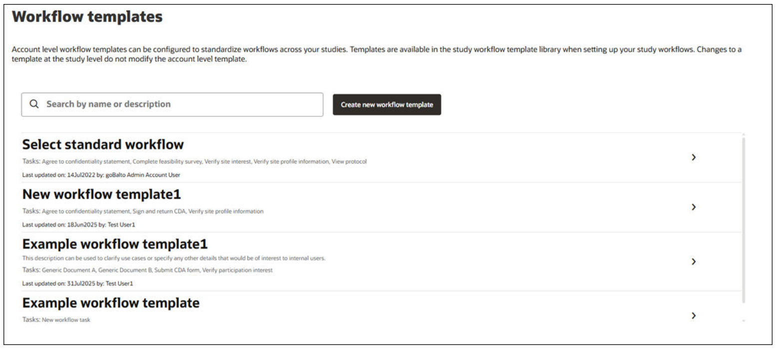
1. Click menu in the page header. Then open the **Account** menu and click **Users and access**.
2. On the **Account users and access** page, search for or scroll to the user's record. In the Teams column, click edit .
3. In the **Edit user teams:** drawer, click the check box to the left of the team(s) you want to assign to the user.
4. Click **Save**.

Workflow templates

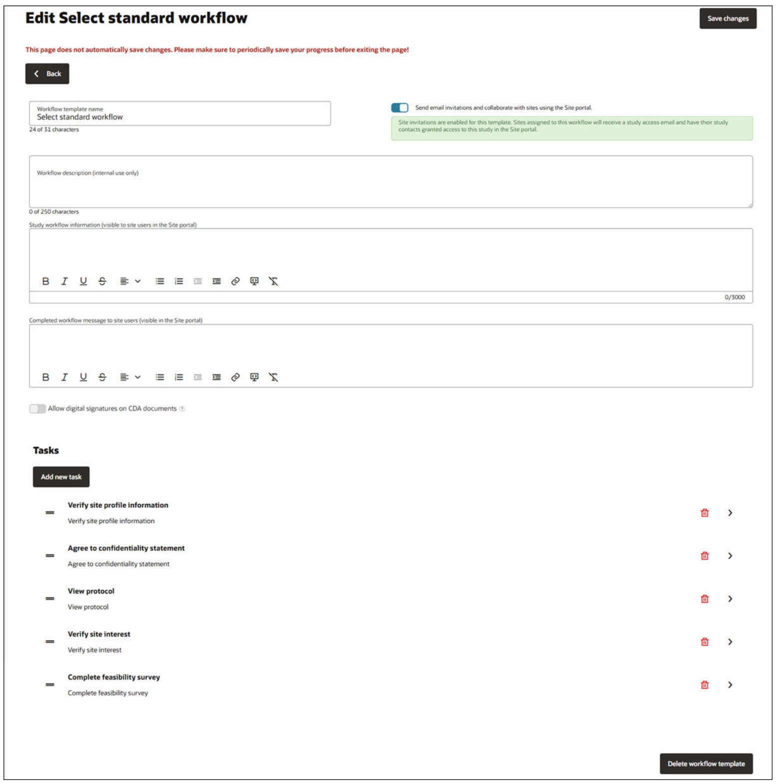
Configuring workflow templates at the account level simplifies creation of study level workflows and tasks. Templates you create are available to study administrators when they choose to add a new workflow.

Account workflows

Account level workflow configuration offers settings similar to study level workflow configuration, except for those that do not apply to templates (such as Default flag and dates). Once you save an account level workflow template, it will appear in the "Use an existing workflow template" list (also known as the "template library") when study administrators create a new study level workflow. Using an account level template helps standardize study level workflows and reduces manual setup steps.



Click the "Create new workflow template" button to start a new template from scratch, or click the arrow > next to any existing template to open its configuration page, where you can make and save updates.



On the workflow template page, you'll define:

- Workflow template name (must be unique to the account and no more than 31 characters)
- Workflow description (for internal use, up to 250 characters)
- Study workflow information (visible to sites, up to 3,000 characters)
- Completed workflow message (visible to sites, no character limit)
- Toggle to enable/disable Allow digital signatures on CDA documents

The Tasks list lets you manage the individual tasks that make up the site workflow template You can add, edit, reorder, and remove tasks as preferred. You can:

- View all existing tasks under the Workflow tasks section
- Click Create new task to add a task at the bottom of the list
- Reorder tasks by dragging them into a new position
- Click the trash can icon to delete a task
- Optionally enable Allow digital signatures on CDA documents by checking the box

Click any task to open its details drawer, where you can make edits or enter information for a new task. Task detail fields and options include:

- Task type (required): Choose from available task types. Task types already used in this workflow will not appear again, except for Generic document tasks.
  - Document task types include a document type picker
  - Survey includes a survey picker
  - Generic document task includes a task type picker
  - Agree to confidentiality task includes an option to require inputs
- Task display name (required) This name shows in Select and in the Site portal.
- Task information (optional): Add up to 2,000 characters of rich text.
- The next task becomes due after this task is completed (check box)
- When you're done working in the drawer, click Done to keep your changes, or click Cancel to discard any changes to that task.

Some tasks include unique functionality. For instance, if you choose to include "Verify site interest," "Verify site interest again," and/or "Agree to confidentiality statement" workflow tasks, and a site answers No for any of those tasks, the site will be prevented from previewing or moving to the next task unless they change their response to Yes. This is by design.

When sites answer No, the workflow task's progress icon in the Oracle Site Select site grid and in the site portal updates to a red "Discontinued" icon: When a site portal user answers "No" to a task, that action then removes them from consideration (Verify site interest, Confidentiality statement, or Verify site interest again), and the following message displays "Your response to the current task is preventing you from continuing on with this study. If you would like to resume participation, please accept the terms of the current task."

If you include the Sign and return CDA task, you can optionally enable a "Send the finalized CDA as an attachment to all study contacts" check box. When the task setting is enabled and the CDA is fully executed, Oracle Site Select sends the CDA as an attachment to the completed CDA email notification in the same document format as the finalized CDA. The document attachment will also be included in the site communication copy (archive) email if this option is enabled in the study email template settings.

When you include a Generic document task, specify one of the Action Types below. To help you choose the appropriate type, Oracle Site Select displays related subtext depending upon the value selected:

- **Download required** (default) – Use this action type to provide information to the invited site. A document template will be provided to the site. The task only requires the site user to download the file then click Done to complete the task.
- **Approval required** – Use this action type to require an uploaded document from the invited site. A document template will be provided to the site. The task requires the site user to download the file, then upload a file in response. The task will complete when a

Select document reviewer approves the uploaded file. A rejection will require the site to upload a new file.

- **Choose response** – Use this action type to require the site to review a document and choose a response. The task requires the site user to download the file and choose their affirmative or declination response. Either response will complete the task.
- **Attestation required** – Use this action type to require the site to review and attest to a document. A document template will be provided to the site along with attestation text. The task requires the site user to download the file, review the attestation text and choose their affirmative or declination response. An affirmative response is required to move on to the next task if the option "The next task becomes due after this task is completed" is selected.

The "Internal workflow task" is another with special functionality. A site assigned to a workflow with an Internal workflow task will see the task in their site portal task list, and their workflow will be paused when they reach it. The task's configured "Site display information" displays during this pause, and that message will be removed when an Oracle Site Select user completes the task.

Please note, if the site reaches their Internal workflow task but also has an ungated Generic document task pending completion, the site portal shows both task's information with the Generic document task below the Internal workflow task. The internal task will halt the workflow, but the site can still complete the Generic document task.

In Oracle Site Select, a site's details drawer shows the Workflow tasks in the configured order. When a Oracle Site Select user completes the task on behalf of the site, a modal displays the task's configured "Task information" text. That user must include an entry in the modal's Task response text field before clicking Submit to complete the internal workflow task and allow the site to resume the workflow.

At the bottom of the workflow template page, you'll see a Delete workflow template button. If you choose to delete the template, you'll confirm that action in a modal before the workflow is removed.

- Set up account-level workflow templates
  If you have the appropriate account permissions, you can create account level workflow templates to standardize workflows across your studies. Templates are available in the study workflow template library when setting up your study workflows.

Set up account-level workflow templates

If you have the appropriate account permissions, you can create account level workflow templates to standardize workflows across your studies. Templates are available in the study workflow template library when setting up your study workflows.

You must have a user role with *Account workflow template management* permission to complete this task.

1. Click menu ☰ in the page header. Then open the **Account** menu, and click **Workflow templates**.
2. ***Create new workflow instructions***: click **Create new workflow template** See below for template editing instructions.

> **Caution**
>
> The workflow page and task drawer DO NOT automatically save changes. Please make sure to periodically save your progress before exiting the page!

3. On the **Create new workflow template** page, enter a **Workflow template name**.
4. Click the on/off toggle control for **Send email invitations and collaborate with sites using the Site portal.** Warning: disabling this option means any site invited with this workflow template will not be able to upload or respond to any workflow tasks.
5. Enter an internal-only **Workflow description**.
6. Optionally complete/edit the **Study workflow information** and/or **Completed workflow message to site users** fields. These messages display in the site portal. You can format the text using the options at the bottom of the text input fields.
7. If preferred, toggle on the **Allow digital signatures on CDA documents** control.
8. Click **Add new task** to open a new task drawer. Complete or update the fields below as applicable. You may see some or all of the following options depending on the task type(s) you add to your workflow template:
   a. At **Task type**, select the task from the drop-down list.
   b. At **Task display name**, enter a different name or use the default. This name will show in Oracle Site Select and in the site portal.
   c. Optionally un-check **The next task becomes due after this task is completed** if you do NOT want the task to be gated (i.e., completing this workflow task is not required to proceed in the workflow).
   d. Optional – check **Send the finalized CDA as an attachment...** for CDA tasks.
   e. Optional – choose a **Document type** for tasks that can be completed with a Document library document (CDA, Generic, etc.).
   f. Optional – enable/disable toggles for required title, first and last name, and email address for Confidentiality statement tasks.
   g. Optional – **Choose survey** for Complete feasibility survey tasks.
   h. Optional – enable toggle for **Display study information video link...** for Generic Document tasks.
   i. For Generic document tasks, update the document name fields as desired. Select an Action type. If you selected Choose Response or Attestation required, complete the additional text fields.
   j. Click **Done** to save your settings for the task, close the drawer, and return to the workflow template page.
9. ***IMPORTANT***: Click **Save changes** on the workflow template page to save your changes.
10. Repeat the **Add new task** steps above to add all tasks required for the new workflow template. As you create the task list, you can continue to create more tasks, reorder them, and delete them as preferred. If you choose to delete a task, click to the far right of task name.
11. ***Update an existing template instructions*:**Search for or scroll to the template and click the right arrow to open the configuration page. Update as necessary and click **Save changes** to apply your updates. When you return to the Account workflow template list, the template's **Last edited on:** line will show today's date and your name.

7

Site Selection

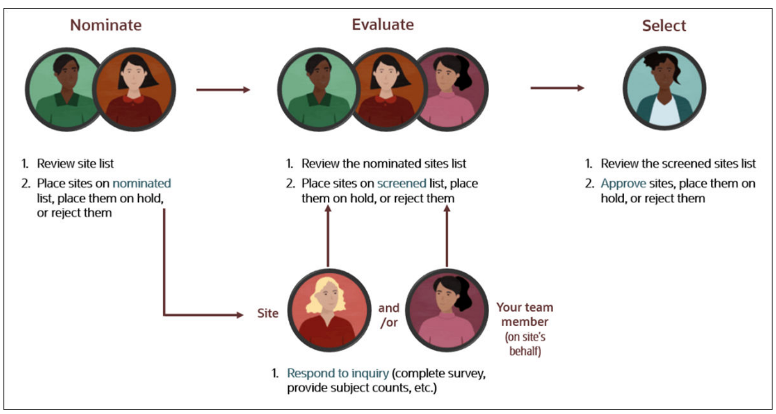
Your study team and site selection tasks

This section, intended for Oracle Site Select users who evaluate site feasibility, details the four stages (also known as "buckets" in the Oracle Site Select site selection process:

1. Nominate
2. Evaluate
3. Select
4. Finalize

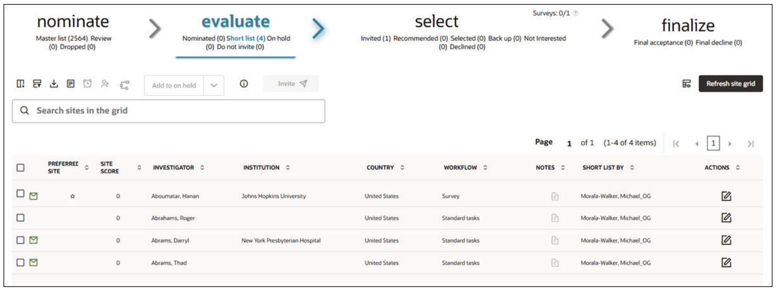
You, other members of your study team, sites, and other institution representatives may participate in the selection process in various ways as the site progresses through the selection stages. Depending upon your role, you may receive a notification to nominate, evaluate, select, and/or finalize investigators for the study.

As you complete tasks, sites also receive notifications to complete tasks in assigned workflows (such as sign the CDA or review the protocol.) If the sites choose not to use the Site portal to upload files and complete tasks, you may perform tasks and update status on their behalf, if you have the appropriate permissions.



Oracle Site Select guides you through site selection

Click a notification, a bucket (nominate, evaluate, select, or finalize) on the study home page or above any site grid, to view a master list or a list of sites that have progressed through various steps in the site selection process.



The site selection stages below describe general functionality. Your user role and permission levels may affect the actions available to you. The major bucket stages (Nominate, Evaluate, Select, and Finalize) include "bucket states" as described below:

- **Nominate** – Perform a first pass by sorting sites into review, short list, and dropped status. Bucket states are:
  - *Master list*: The default list of sites based on your study settings and data sources.
  - *Review*: A list where you can compare sites before nominating them for evaluation.
  - *Dropped*: A list of sites that do not meet your criteria.
- **Evaluate** – Collaborate to sort sites into nominated, short list, on hold, and do not invite
  - *Nominated*: A list of sites nominated by you and other team members.
  - *Short list*: A list of sites organized for invitation to participate in pre-study tasks. This is where sites can be sent an invitation letter.
  - *On hold*: A list of sites that meet most of your criteria, but may not be eligible for participation.
  - *Do not invite*: A list of sites that do not meet your criteria.
- **Select** – Progress to sorting sites into invited, recommended, selected, back up, not interested, and declined. Resend invitations, if necessary. Also view site progress through assigned workflow tasks, feasibility survey data, and site details.
  - *Invited*: A list of sites invited to complete pre-study tasks.
  - *Recommended*: A list of sites recommended for PSV and/or selection.
  - *Selected*: A list of sites organized for final selection to this study.
  - *Back up*: A list of alternate or back ups for selected sites.
  - *Not interested*: A list of sites not interested in this study.
  - *Declined*: A list of sites organized for final declination from this study
- **Finalize** – See sites in final acceptance and final decline. Send final acceptance or final decline emails to the sites.
  - *Final acceptance*: The final list of sites eligible for study participation.
  - *Final decline*: The final list of sites found ineligible for study participation.
- Site grid
  The site grid is your configurable view of sites in each site selection bucket (i.e., Nominate, Evaluate, Select, and Finalize) and bucket state (e.g., Master list, Short list, Invited, etc.). You can optionally adjust displayed columns and filter data to the view that works best for you.

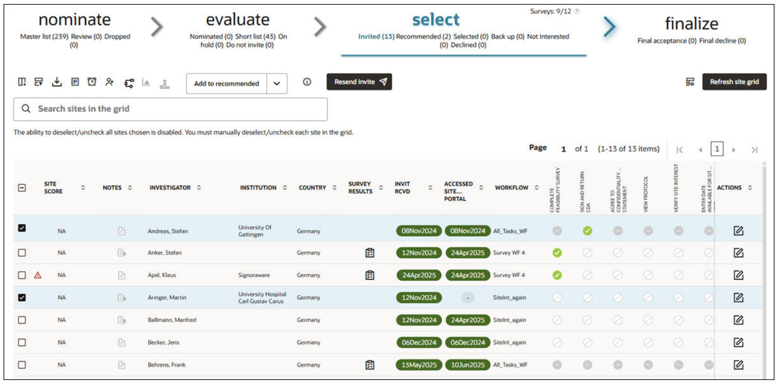
- Nominate
  View details about candidate sites, like site score or access the site profile. Refine the list by various criteria, such as study fit and experience. Select one or more sites, add them to the review or short list, or drop them if they do not meet the study criteria.
- Evaluate
  Review and act on the list of sites you or other members of your team have nominated.
- Select
  Review site workflow task progress, see survey responses as applicable, and survey analysis, and site detail views and choose the sites that will advance to the next step in the site selection process.
- Finalize
  Send acceptance emails to selected sites, view lists of sites that have accepted or declined invitation to participate in the study. If your customer account has been configured with certain integration and you have the appropriate permissions you can also migrate study sites to Oracle Site Activate and view those study sites within the Oracle Site Activate application.
- Site details drawer
  When you have permission to access the site grid, you can access a site's details drawer where you can see the site's Scorecard, Invitation and status, Workflow task progress, Site notes, and Study contacts.
- Study site history view
  When you have the appropriate permissions, you can view a study site's cross-study performance and workflow completion across all studies in the account to gain insight into a that study site's progress.
- Use notes to communicate
  Notes provide an easy way to communicate with your team members about a specific study or site.
- Retake surveys or edit survey responses
  Feasibility surveys may be reopened after they have been submitted so that responses can be changed, if necessary, and Alchemer surveys reopen the previously submitted survey with previous responses pre-populated.
- Configurable site profile
  Site profiles store extensive detail about a specific site's contact information, trial history, study contacts, and more. By customizing the sections, fields, and values, you can streamline workflows and ensure your team captures the most relevant information. For help setting this up, contact your Oracle administrator.
- Document workflow task audit
  Site grid users can download an audit file containing document workflow completion details.

Site grid

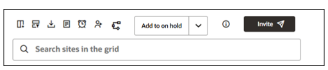
The site grid is your configurable view of sites in each site selection bucket (i.e., Nominate, Evaluate, Select, and Finalize) and bucket state (e.g., Master list, Short list, Invited, etc.). You can optionally adjust displayed columns and filter data to the view that works best for you.

Adjust site grid data and columns

Nominate, Evaluate, Select, and Finalize buckets display site lists in a grid format. You can adjust the displayed data using column and filter options (described below). You can also navigate between the buckets and bucket states by clicking the bucket/bucket state names displayed above the site grid. The Select bucket navigation also provides a "Surveys #/#" link that opens a Surveys submission overview. The overview shows the study's total submitted surveys and surveys by scoring tier, and Tier 4 includes all surveys that scored lower than Tier 3. You can access the survey submission overview link when viewing any of the selection buckets.



The site grid menu (action icons and buttons) displayed above the search field updates as necessary to show the options available to you based on your user permissions, the current bucket state, and the sites you've selected in the grid.



To adjust data displayed in any of the site grids, click the column selector icon or the filter icon in the site grid menu to choose additional columns for display or specify data filters. Note that some columns are in fixed position in the grid, and we've detailed those below. Also note, because filters typically remove data that would otherwise be displayed in the grid, Oracle Site Select outlines the filter icon if filters have been applied.

- Sort columns by clicking a column heading
- Reorder columns by selecting a column header and dragging it to a new position
- Resize columns by selecting the header, moving your cursor to the outer boundary of the column, then dragging the column boundary to the desired position.
- Display column borders by clicking the borders icon at the upper right of the grid

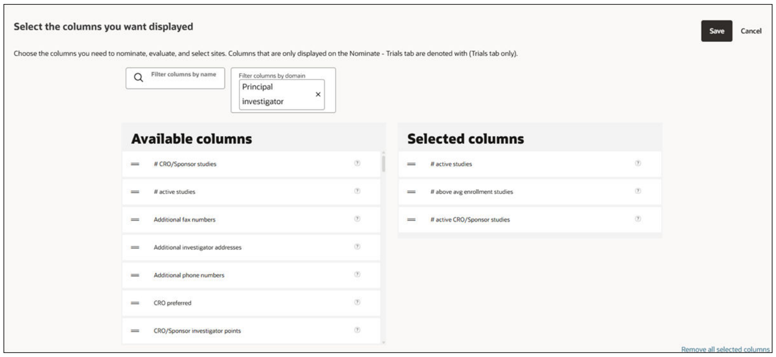
You can reorder site grid columns for your current session by clicking, dragging, and dropping column headers. Each bucket (Nominate, Evaluate, Select, and Finalize) can have its own custom column order, and your changes persist when navigating away and returning during your session.

> **Note**
>
> Column order resets when you log out or use the Column selector (described below), and the drag-and-drop order does not affect the order in site grid extracts.

Column selector

Column selections help you view data in the site grid based on your preference and applicable data for each step. Drag and drop columns you want to display in the grid ("Selected columns"), and order the columns as preferred by grabbing the handle and dragging the column to the preferred position.

Site grid column display

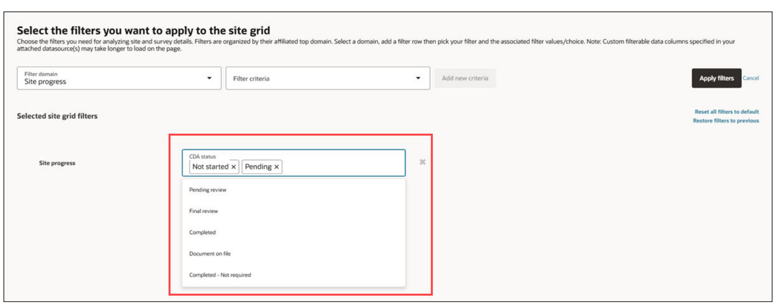


Filter selectors

You can apply unlimited filters to the site grid as available. When adding new filters, click on the "Filter criteria" selector, and you'll see all available filter options listed right away. If there are filters with the same name from different Filter domains, you'll see duplicates listed so you can pick the right one. Once you choose a filter, it shows in your filter list along with the domain it belongs to, so you'll know where it came from.

Filtering for the Site Progress CDA status column is unique in that it lets you apply multiple filters for that single column. Available filters for the CDA status column are:

- Not started
- Pending
- Pending review
- Final review
- Completed
- Document on file
- Completed – Not required



Fixed site grid columns

Some columns are "fixed" in context of the current site grid. For instance, Site score and Investigator name columns will always display in Evaluate bucket's Nominated site grid; these columns are not selectable when you choose columns in the column selector.

The table below identifies fixed site grid columns and the location where selected columns are inserted in the site grid (i.e., <selected columns>).

Where appropriate, Preferred site will be the first fixed column in the site grid if preferred sites are used in the study.

Step	Bucket state(s)	Sub-tab	Fixed columns
nominate	Master list, Review, Dropped	Sites	Preferred site, Site score, Notes, Investigator, Institution, Country, Dropped by (Dropped only) **<selected columns>**, Actions
nominate	Master list, Review, Dropped	Trials	Preferred site, Site score, Notes, Investigator, Institution, Country, Dropped by (Dropped only) **<selected columns>**, Actions
evaluate	Nominated	N/A	Preferred site, Site score, Investigator, Institution, Country, Notes, Nominated by, **<selected columns>**, Actions
evaluate	Short list	N/A	Preferred site, Site score, Investigator, Institution, Country, Workflow, Notes, Short list by, **<selected columns>**, Actions
evaluate	On hold	N/A	Preferred site, Site score, Investigator, Institution, Country, Workflow, Notes, On hold by, **<selected columns>**, Actions
evaluate	Do not invite	N/A	Preferred site, Site score, Investigator, Institution, Country, Workflow, Notes, Do not invite by, **<selected columns>**, Actions
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Site details	Preferred site, Site score, Notes, Investigator, Institution, Country, Survey results, Invite Received, Accessed Site portal, Workflow, Workflow task progress columns, Invited / Recommended / Selected by, etc. (applicable bucket state) **<selected columns>**, Actions

Step	Bucket state(s)	Sub-tab	Fixed columns
finalize	Final acceptance	Site details	Preferred site, Site score, Notes, Investigator, Institution, Country, Acceptance sent (if applicable), Finalized by, Selected by Migrated to Activate (if applicable), Survey results, Workflow, Workflow tasks progress columns, **<selected columns>**, Actions
finalize	Final decline	Site details	Preferred site, Site score, Notes, Investigator, Institution, Country, Decline sent (if applicable), Finalized by, Selected by Migrated to Activate (if applicable), Survey results, Workflow, Workflow tasks progress columns, **<selected columns>**, Actions

Export site list to CSV or Microsoft Excel

The Site grid export page makes it easy to create a CSV or Microsoft Excel report. You can even save an extract as a template for later use if you'd prefer. Just choose drag, drop, and order the data columns you want to add to the export. Oracle Site Select will include your chosen data columns in addition to the report's default, fixed columns. You will also specify the site statuses to include in the export.

When you open the download utility from a Select or Finalize bucket state, you’ll see the option to append the extract when you reach Step 3, Export/save report. Use the new option’s drop-down to specify one of the following:

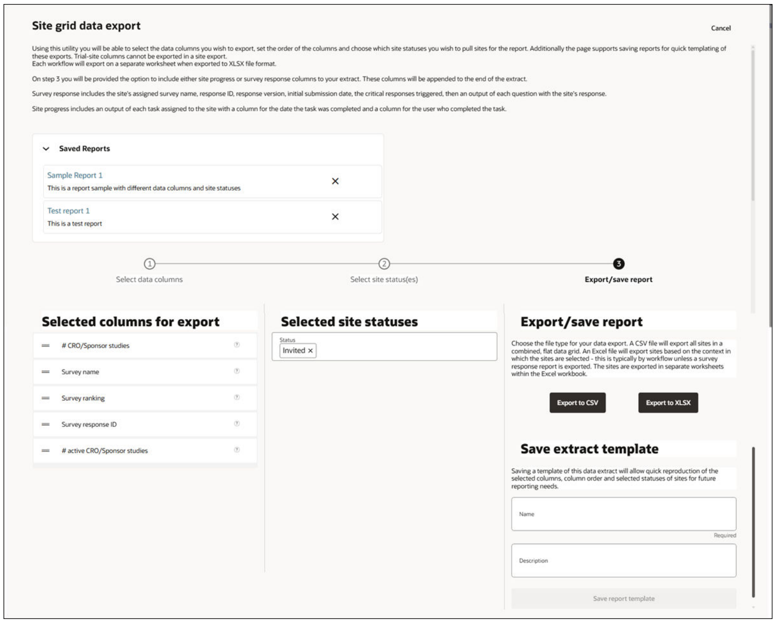
- No additional columns (default)
- Site progress task completion details
- Survey responses

If you choose to include Survey responses, you’ll have these additional extract options:

- Export only survey questions marked scored for survey responses (default selected)
- Include category % scoring

When you save the extract as a template, it displays in the "Saved Report" section at the top of the page. By default, the accordion section will be closed; you can toggle the section control to view an alphabetical list of all your saved extracts. Saved reports are specific to you and will be available across studies.

When you select an extract from the Saved Reports section, the Site grid extract page refreshes to display the report's saved and ordered columns and site statuses. You can add, remove and change the order of chosen columns without updating the saved report; however, saving updates to a previously saved report will create a new saved report. You can delete reports from your Saved Reports list as preferred at any time.



Fixed export columns

The table below identifies Oracle Site Select fixed export columns and the location where selected columns will be inserted in the export (i.e., <selected columns>).

Preferred site will be the first fixed column in a site details export if preferred sites are used in the study.

Step	Bucket state(s)	Sub-tab	Fixed columns
nominate	Master list	all	N/A - No export download option
nominate	Review	Investigator	Site score, Investigator last name, Investigator first name, **<selected columns>**
nominate	Dropped	Investigator	Site score, Investigator last name, Investigator first name, Declined by, **<selected columns>**
nominate	Review	Sites, Studies	Site score, Investigator score, Investigator last name, Investigator first name, **<selected columns>**
nominate	Dropped	Sites, Studies	Site score, Investigator score, Investigator last name, Investigator first name, Declined by, **<selected columns>**
evaluate	Nominated	N/A	Site score, Investigator last name, Investigator first name, Nominated by, **<selected columns>**

Step	Bucket state(s)	Sub-tab	Fixed columns
evaluate	Short list	N/A	Site score, Investigator last name, Investigator first name, Short listed by, **<selected columns>**
evaluate	On hold	N/A	Site score, Investigator last name, Investigator first name, Held by, **<selected columns>**
evaluate	Do not invite	N/A	Site score, Investigator last name, Investigator first name, Declined by, **<selected columns>**
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Site progress	Investigator last name, Investigator first name, Country, Site invitation email status, All site tasks completed?, Site interested?, Workflow close date, **<selected columns>**
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Survey analysis	Protocol title, Protocol number, Country, Investigator last name, Investigator first name, **<selected columns>**, Version number, Initial submission date, <1 column per question>
select	Invited	Site details	Site score, Investigator last name, Investigator first name, Invited by, Last task completed by site, **<selected columns>**
select	Recommended	Site details	Site score, Investigator last name, Investigator first name, Recommended by, Last task completed by site, **<selected columns>**
select	Back up	Site details	Site score, Investigator last name, Investigator first name, held by, Last task completed by site, **<selected columns>**
select	Not interested	Site details	Site score, Investigator last name, Investigator first name, Last task completed by site, **<selected columns>**
select	Selected	Site details	Site score, Investigator last name, Investigator first name, Selected by, Last task completed by site, **<selected columns>**

Step	Bucket state(s)	Sub-tab	Fixed columns
select	Declined	Site details	Site score, Investigator last name, Investigator first name, Declined by, Last task completed by site, Invited by, **<selected columns>**
finalize	Final acceptance	Site details	Investigator last name, Investigator first name, Institution, Site score, Selected by, Finalized by, Activate site number, **<selected columns>**
finalize	Final decline	Site details	Investigator last name, Investigator first name, Institution, Site score, Finalized by, **<selected columns>**

- Download the sites list
  Create a CSV or Microsoft Excel document with the columns and site statuses you specify. You can optionally save the report as an extract template and use it as shortcut later.

Download the sites list

Create a CSV or Microsoft Excel document with the columns and site statuses you specify. You can optionally save the report as an extract template and use it as shortcut later.

1. At the top left side of any list, click download ( ).
2. On the Site grid data export page, below **Select data columns**, drag and drop the displayed columns to your preferred order.
3. Below **Select site status(es)**, adjust the list to include the preferred site status(es) to include in the export.
4. Below **Export/save report**, click **Export to CSV** or **Export to XLSX**.
5. Optionally save the export as a template. Below **Save extract template**, enter a unique extract **Name**, add a brief **Description**, and click **Save report template**.

Nominate

View details about candidate sites, like site score or access the site profile. Refine the list by various criteria, such as study fit and experience. Select one or more sites, add them to the review or short list, or drop them if they do not meet the study criteria.

The bucket state view (i.e., Master list, Review, Dropped) will be underlined in blue. If sites have been moved to Review or Dropped, the number of sites will also display, such as "Dropped (3)."

When viewing the Master list bucket state, you'll see a timestamp at the upper left that shows the outcome from the last time the list was generated:

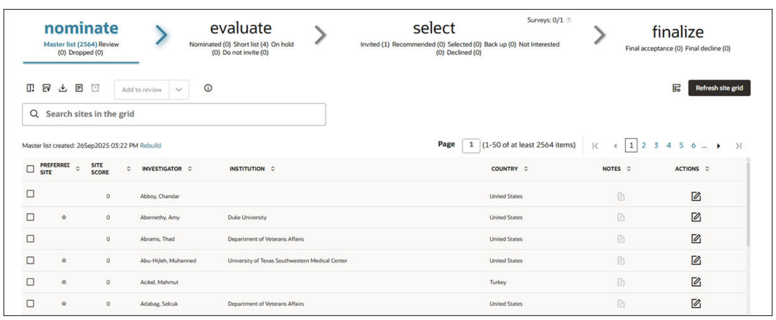
- If the master list was created successfully, you’ll see: Master list created: <date and time>
- If the master list creation failed, you’ll see a red, bold message: Master list failed creation: <date and time>

The statements above will be followed by a Rebuild link that you can optionally click to rebuild the Master list when preferred.

After selecting one or more sites in the grid, use the "Add to..." action button to move the sites to a different state. You can adjust the preferred action before or after selecting one or more rows in the grid:

- change the action, select row(s), then click the action button
- select row(s), change the action, then click the action button

> **Note**
>
> The **Deselect All** check-box does not work in tables with pagination. This is an expected, known behavior. If you click the select all checkbox, you'll see a statement above the grid advising you to manually check/uncheck sites.
>
> To manually deselect all rows in the site grid:
>
> 1. Click any row. This will deselect all other rows and select only the one you clicked. It will also open the site drawer.
> 2. Close the site drawer.
> 3. Deselect the remaining selected row.
>
> This process will leave all rows unselected.



- [Nominate sites](#)
  Advance sites through the Nominate bucket state (e.g., from Master list to Review) or move sites you've already reviewed directly to the Evaluate bucket's Short list bucket state.
- [Undo site nomination or shortlisting](#)
  If you need to reverse nomination or shortlisting, you can do so with just a few clicks.

Nominate sites

Advance sites through the Nominate bucket state (e.g., from Master list to Review) or move sites you've already reviewed directly to the Evaluate bucket's Short list bucket state.

1. When viewing any bucket state in the Nominate bucket, adjust the **Add to...** action button above the grid using the button's drop-down control and choose "Add to review," "Add to short list," "Add to Master list," or "Add to dropped."
2. In the site grid, check the box next to one or more sites.

3. Click the **Add to** action button.

Undo site nomination or shortlisting

If you need to reverse nomination or shortlisting, you can do so with just a few clicks.

1. From either the **Nominated** site list or the **Short list** site list, click the **Actions** menu next to a site or right click on a site row, then select **Move site back to Nominate-Review**.
2. Confirm the site appears in the **Review** bucket state in the **Nominate** bucket.

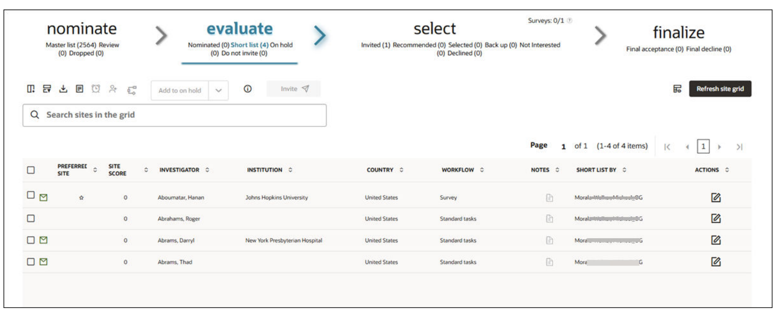
After you complete the steps above, the team member who is responsible for sending invitation emails can send invitations to sites on the **Add to nominated** list.

Evaluate

Review and act on the list of sites you or other members of your team have nominated.

In the Evaluate bucket state, you are working with your site feasibility team to further refine the site list. You can choose one or more sites and add them to the short list, place them on hold, add them to the list of sites considered for nomination, or add them to a list of sites that should not be invited.

Use the site grid menu options to download a filtered list of sites, assign workflows, assign Oracle Site Select users, etc. You can also search for specific sites in the grid, if necessary. Use the Actions menu (or right click any row) to see actions and navigation options for that site (for example, navigate to the Site profile, or view a site's details drawer).



When you have *Site nomination* permission and you're viewing sites in any of the Evaluate bucket states site grid, you can now right-click on a site’s row to see a menu option to “Move site back to Nominate – Review.” When you click this option, the site grid refreshes and the site moves back to the Review bucket state in Nominate. You will not be required to save a reason for this change.

When you have the *Revert site finalization* permission, you can right-click on any site in one of the finalization bucket states to choose a revert option:

- Final acceptance: Revert - move site to Select - Selected
- Final decline: Revert - move site to Select - Declined

If you revert a site from Final acceptance, you must confirm this action and input a reason. The reason you enter will be saved as a site note. By design, it isn't possible to revert a site that's been migrated to Oracle Site Activate, so for the Final acceptance bucket, attempting to revert a migrated site will result in an error. This is expected behavior.

When you successfully revert a finalized site, Oracle Site Select automatically adds a site note (even if no final determination email was sent).

- The note is created under your name as the user who performed the reversion.
- The note's context reflects the bucket state where the reversion occurred.
- It includes details like your name, the previous bucket state, the date, and any note content you entered.
- If a final determination email was sent, the note also includes: "A final determination email was sent by <final_email_sent_by> on <final_email_sent_at>."
- Evaluate sites
  Advance sites through the Evaluate bucket states (Nominated, Short list, On hold, and Do not invite) as appropriate. You can also optionally enter a Site note to explain your actions.

Evaluate sites

Advance sites through the Evaluate bucket states (Nominated, Short list, On hold, and Do not invite) as appropriate. You can also optionally enter a Site note to explain your actions.

1. In any Evaluate bucket state (Nominated, Short list, On hold, or Do not invite).
2. Check the box next to one or more sites in the grid.
3. Optionally add a Site note or reason that explains your actions regarding a site(s): click the notes icon to open the Site details drawer, and:

   Optionally update the **Occurred data and time**.

   Optionally select an account-level **Note label**.

   Enter the note text in the **New note** text field.

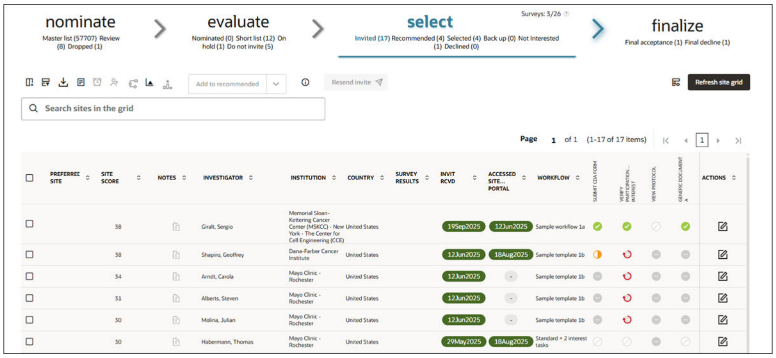
   Click **Close**.
4. Adjust the **Add to...** action button above the grid to "Add to Nominated," "Add to short list," "Add to on hold," or "Add to do not invite" as applicable to the bucket state you're in.
5. Click the action button.

Select

Review site workflow task progress, see survey responses as applicable, and survey analysis, and site detail views and choose the sites that will advance to the next step in the site selection process.

In the Select bucket state, you'll see the list of sites that you can choose to add to the study and you can evaluate their progress through assigned workflow tasks as well. In the site grid's Invit Rcvd and Accessed Site Portal columns, click the date displayed to view details about access.

You can modify the columns displayed in the Select bucket and filter the data in the site grid as preferred. The You also have an "**Add to...**" action button with options relevant to the current view (i.e., Add to invited, Add to recommended, Add to declined, etc.). If necessary, you can resend an invite after you select one or more sites in the grid.



This bucket state shows site progress through assigned workflow tasks. If necessary, you can adjust workflow settings for sites using the buttons above the site grid. Hover over the task progress icons to view progress detail.

To assist study teams in maintaining their milestones and workflow task response time targets, the Select bucket state includes indicators for overdue workflow tasks. When a site takes longer than expected to complete a task an overdue icon ( ) overlays on the task's status indicator.

The overdue indicator is "paired" with workflow task status icon. For instance, when a workflow task is in progress and the number of days the task has been available exceeds the response time target set on the study milestones page, a paired "In progress (overdue)" icon ( ) displays for that task. A workflow task that was previously overdue (i.e., "In progress (overdue)" but subsequently completed), displays the "Completed (overdue)" icon ( ) - meaning the task was completed but took longer than expected.

Overdue indications apply only to the current task - meaning a task that a site has not yet reached will not have an overdue indicator applied regardless of the response time set on the milestone page. Additionally, overdue task status is not concurrent. For example: a workflow has two tasks and each task has a response time target of one day. If the site has been working on the first task for three days then only the first task is overdue. The second task's response time indication will not start until the first task is completed.

Because generic document tasks share the same response time target input field on the milestones page, the overdue trigger functions differently from other tasks. For each generic document task that is not optional, the response time target applies to each unique instance. For example, if the response time target is five days and the site user takes three days to complete the first generic document task, then the site user has a "new" five day counter for the next generic document task.

> **Note**
>
> By design, the following tasks are never labeled as overdue:
>
> - A generic document task configured as optional
> - Not required tasks
> - Not applicable tasks
> - Discontinued tasks

When you're working in the site grid's Select or Finalize stages, click a workflow task's progress icon to view a detailed task completion modal. This modal shows task-specific information, as well as the investigator's name, specialties, institution, and any assigned users. Tasks marked as “Not required” or “Internal task pending” do not open the modal but instead display hover text that reflects their status.

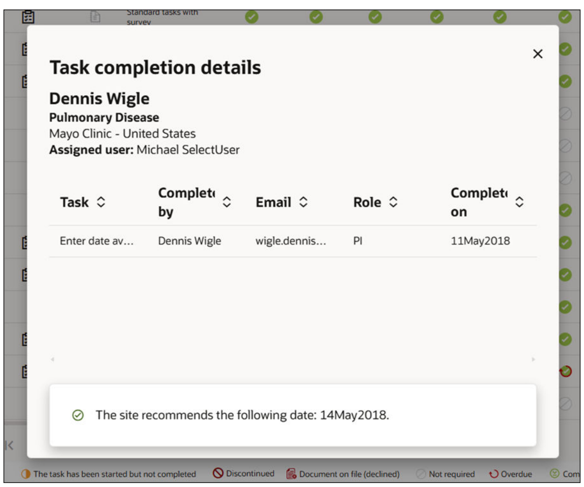
Each task's status determines what the modal or icon displays. If the task is complete, the modal includes a table listing the person who completed it, their email address, role, and the completion date. Overdue tasks append “(overdue)” to their hover text, and discontinued sites display a banner indicating the site is no longer interested in participating.

Survey tasks behave differently depending on their stage: if not yet reached, the icon doesn't open the modal; if pending or processing, the modal displays survey-specific details but no task table. Once submitted, the modal includes a success banner summarizing the survey name and score.

CDA tasks have their own progression. When downloaded, the modal shows a yellow advisory with the download date and site user. If a signed CDA is uploaded, the modal updates to show an “Uploaded” status along with a yellow advisory note, “The CDA was signed and returned by the site on <datetime>. Approval is required before the site can complete additional study tasks.” Once approved, a success banner confirms the final approval date. The modal tracks each stage of the CDA task by listing separate rows for downloaded, uploaded, and approved actions.

For document workflow tasks that are auto-completed, a banner confirms the task was completed with an existing file.

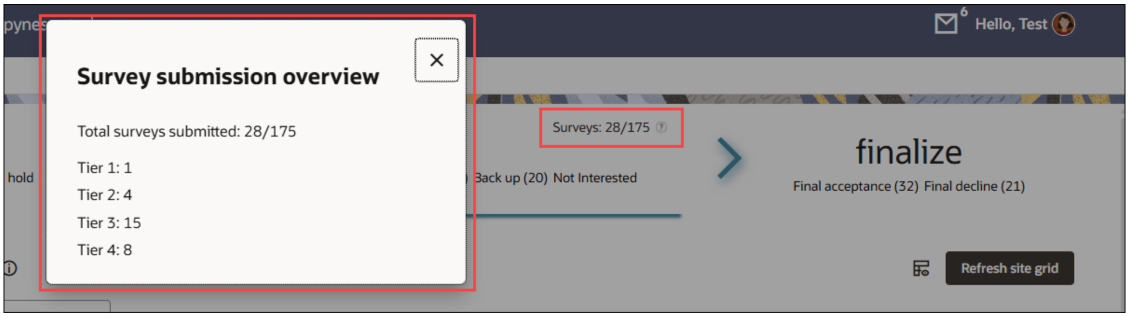
Lastly, investigator documents populated via API do not involve workflow actions. These entries are shown with the user listed as “Library import” in italics and have no associated email or role. The import date is recorded as the document's completion date, which is expected behavior.



Feasibility surveys

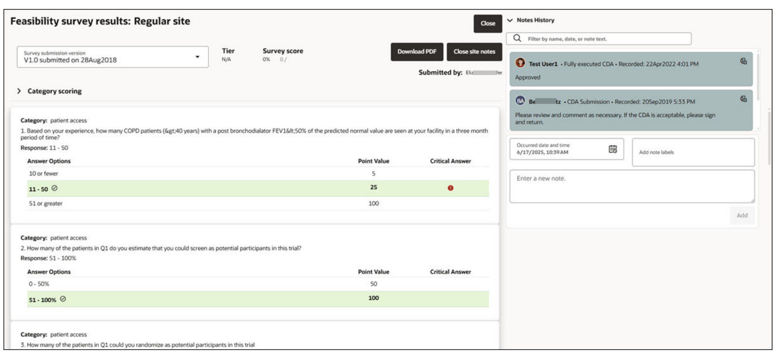
Click the "Surveys # / #" text in the Select bucket heading to view a Surveys submission overview modal. The modal shows the study's total submitted surveys and surveys by scoring tier, and Tier 4 includes all surveys that scored lower than Tier 3. Because the clickable text is in the chevron navigation panel, you can access the text link when viewing any of the selection steps. By design, clicking the link will only open the submission metric modal and will not navigate away from the current view.

You can optionally copy the modal text,if preferred. By design, you must click "X" to close the modal.



In the Select and Finalize buckets, you'll see a Survey results column. If a site has completed a survey, you'll see the survey icon in this column. Click the icon to open the survey results modal, which shows submitted survey results, grouped by survey name and version, with the most recent listed first. The results modal also includes detailed scoring, tier, raw and percentage scores, and a breakdown of each question's responses, points, and category. You can also download the selected survey as a PDF.

While viewing survey results, you can also click View Site notes to open a panel to the right of the results modal. This panel displays existing notes and allows note creation (if you have permission to create them). You can also input an occurred date, label, and note text. The survey results modal includes a Close button to exit the view and a separate Close Site notes button to hide the notes panel without closing the results modal.



Site grid CSV downloads

If preferred, you can create a CSV download for **Site portal access links** for invited sites. In the Select bucket, if you have the *Access study-specific Site portal No Login links* permission, you'll see a "Download Site portal access links" option on the site grid download button.

When you use this feature, the CSV will include a Site portal access link for each study site user listed as a Study contact who has not yet accessed the Site portal in the current bucket state. If a site has multiple users, each will appear as a separate row, and the link allows the recipient to access the Site portal for that user, with all actions audited to that user. By design, the link does not allow creating a Site portal account during that session.

The CSV includes the following columns:

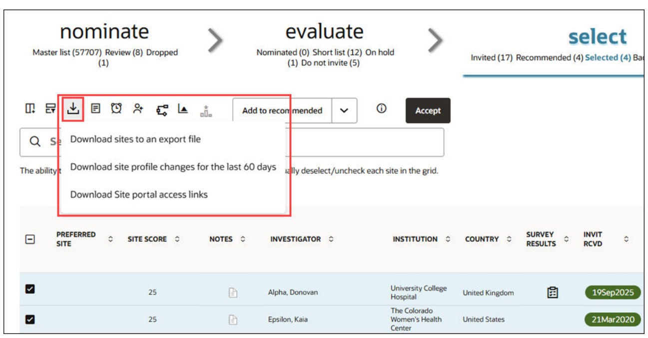
- Study name
- Study ID
- Protocol title

- Protocol number
- Investigator first name
- Investigator last name
- Institution
- Country (institution country)
- First name (Study site contact)
- Last name (Study site contact)
- Role (Study contact)
- Email (Study contact)
- Study site User link (the Site portal study-specific access link for that user)

The CSV file will be named using the format <study_name>- studysite_user_links -<date>.csv.

You can also download a CSV digest of all site profile changes made to sites in a study within the past 60 days. In the Select and Finalize buckets only, the site grid download button includes a **Download site profile changes for the last 60 days** option, which exports the site profile changes digest. By design, the download button is disabled if you have read-only site grid permissions.

When you select "Download site profile changes for the last 60 days," a CSV file is generated showing the before and after contents of any site's profile edit, provided your study uses a study-specific or account-level site profile. For studies with a study-specific site profile, the extract contains only changes to that study's profile, so changes made in other studies with an account-level site profile will not be included. For studies using an account-level site profile, you will see the before and after profile changes for the past 60 days following any edits.



- [View task status, evaluate, and select or reject sites](#)
  The Select bucket states include information about site invitations, workflow assignment and workflow task status, feasibility survey results, and more.
- [Complete tasks on behalf of sites](#)
  You may be able to complete tasks (such as the feasibility survey or interacting with a CDA) for a site that does not participate using the Site portal, or when a site completed a task externally and you need to mark it complete in Oracle Site Select. To do so, you must have the appropriate permissions for that task. If you do, you'll access the tasks in the Site details drawer Workflow tab.
- [Edit a site's profile](#)

View task status, evaluate, and select or reject sites

The Select bucket states include information about site invitations, workflow assignment and workflow task status, feasibility survey results, and more.

1. From any Select bucket state, you can optionally:

   Click the Notes icon to add a new Site note.

   Click the Survey results icon to view or download submitted survey responses.

   Click the date shown in the Invite received or Accessed site portal columns to open the Invitation and site status tab in the Site details drawer.

   Click any completed, overdue, or in progress task status to open the Task completion details modal.

   Right click any row, or click the Actions icon for any row to open multiple options appropriate to your permissions and the current bucket state (e.g., Edit site profile, View site history, Edit site data, access Study contacts, Download site documents, etc.)
2. Adjust the "**Add to...**" action button above the grid to the preferred action (e.g., Add to Back up, Add to Selected, etc. (available actions automatically adjust to the current tab view).
3. Select one or more sites in the grid, and click the action button.
4. For sites moved to the Selected bucket state:

   Accept to confirm the site for acceptance.

   Click **Finalize**, to move the site to the Finalize step.

Complete tasks on behalf of sites

You may be able to complete tasks (such as the feasibility survey or interacting with a CDA) for a site that does not participate using the Site portal, or when a site completed a task externally and you need to mark it complete in Oracle Site Select. To do so, you must have the appropriate permissions for that task. If you do, you'll access the tasks in the Site details drawer Workflow tab.

1. Access the Select or Finalize bucket state, and click the site's row in the site grid.
2. Click the **Workflow** tab and scroll to the task you want to complete.
3. For view protocol tasks only, complete the fields in the Mark task as completed externally modal and click **Save** to close the modal.
4. For other tasks, choose the option or click the link to perform the action specified in the **Action** drop-down for that task. For instance, click **Complete**, **Final Approval**, or **Completed - External**, **Completed - Not required**, etc. as applicable.
5. Repeat step 4 as necessary for all outstanding tasks that need to be marked completed on the site's behalf.
6. Scroll to the top of the Site details drawer and click **Close**.

Edit a site's profile

1. In any bucket state, right click a site's row in the grid, or click the Actions column and choose **Edit site profile**.

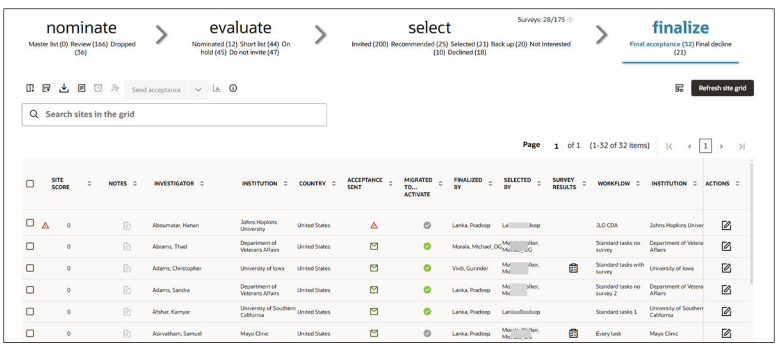
Please note: Site profiles are unique at the account level to best fit your business practices. You may or may not see Principal investigator, Institution and Site sections or you may see additional sections applicable to your organization.

2. Use the options available in the left navigation panel to choose a section to update (e.g., Principal investigator, Institution and Site). Click the field you want to change to view help text below the field input.
3. After you've completed your updates on the page, scroll to the bottom and click **Save progress** to advance to the next page or before navigating away from the Site profile.

Finalize

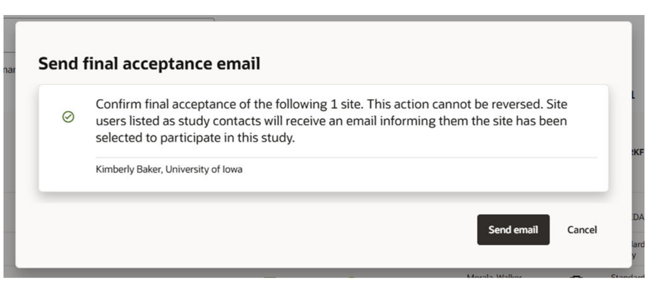
Send acceptance emails to selected sites, view lists of sites that have accepted or declined invitation to participate in the study. If your customer account has been configured with certain integration and you have the appropriate permissions you can also migrate study sites to Oracle Site Activate and view those study sites within the Oracle Site Activate application.

The finalize step shows a list of sites that accepted or declined. If you have a final site approver role (actual name varies by account) you can select one or more sites from the site grid and send them an acceptance or decline email. Use information included in the Site details, Survey analysis, and Site progress subtabs to help guide your finalization decisions (that is, to accept or decline the site).



Depending upon how Oracle Site Select is configured for your organization, you may see status columns that show if the site has already received an acceptance or decline message.

Click Send to send the site(s) an acceptance message based on your organization's Acceptance email template.



The process for declining sites is similar. When you click Send, the site(s) on the Declined list will receive a decline message based on your organizations' Decline email template.

For both acceptance and decline messages, the confirmation modal detects and displays a warning message to notify you of sites that do not have a valid email address saved in Study contacts in the site profile. This means the PI may not receive the final determination email. Study site users receiving the final determination email are not limited to those completing a workflow task.

When you close the final determination modal the site grid updates to display a gray check mark (incomplete) status icon in the "Acceptance email sent" or "Decline email sent" site grid column. On hover over, the icon displays the following tool tip text: "This site is not configured with valid study contacts. No email recipients defined." If you would like to send these sites a final determination email you must first add at least one valid study contact. This can be performed by editing the site's profile and study contact preferences.

With appropriate account configuration for Oracle Site Select-Oracle Site Activate integration, and if your user account has permission, you can open a migrated study or study site within the Oracle Site Activate application.

Similarly, a permissioned user in the Oracle Site Activate application can open a study or study site within the Oracle Site Select application. For instance, from Oracle Site Activate, users can see a study site in Oracle Site Select in the context of the study and bucket state.

Oracle Site Activate provides a "Launch site in Select" link for migrated study sites that redirects that permissioned user to the Oracle Site Select application in a new browser window. In Oracle Site Select, the user sees the site grid for the study site's current bucket state (e.g., Final acceptance site grid), filtered by the study site ID to show just that study site.

> **Note**
>
> To see the study site in Oracle Site Select, the user from Oracle Site Activate should authenticate into Oracle Site Select via Oracle's IDCS SSO (federation with the customer IDP is possible) and must be permissioned to access both the study and the site grid. Additionally, the study site must be in the user's permissioned account.

- Send acceptance or decline emails to sites (finalize step)
- Reverse site finalization
  With the appropriate user permission, you can move a site out of finalization even after the site has already received a final acceptance or declination notification.
- Export site data to Oracle Site Activate
- View migrated study or study site in Oracle Site Activate
  If Oracle Site Select to Oracle Site Activate integration exists for your account, you'll see a link to view an Oracle Site Select study in Oracle Site Activate after study or study site migration.

Send acceptance or decline emails to sites (finalize step)

You must have a role with *Site Nomination, Evaluation and Selection* permission to complete this procedure.

1. Click **finalize** in the top navigation bar.
2. Click the **Final acceptance** or **Final decline** bucket state.
3. In the site grid, check the box next to each site you want to send an acceptance or decline email.
4. Above the site grid, click **Send acceptance** or **Send decline**.

5. The list of sites that will receive and will not receive the email displays. If you chose sites that have already received the email, those are noted and they will not receive a second email.
6. Click **Send**.

   If the list of sites includes any sites that will not receive the email because the site profile does not have a valid email recipient based on study contact preferences, edit the site profile to add at least one valid study contact. Then, repeat the steps above.

Reverse site finalization

With the appropriate user permission, you can move a site out of finalization even after the site has already received a final acceptance or declination notification.

You must have *Revert site finalization* permission to complete this task.

1. On step 3 (final acceptance or final decline), check the check box for the site you want to revert.
2. In the Actions menu, click **Move to Select - Selected** (for final acceptance state), or **Move to Select - Declined** (for final decline state).
3. In the pop-in, confirm the name of the investigator and site.
4. Enter a free-text note with the reason for reversing finalization.
5. Click **Confirm**.

Export site data to Oracle Site Activate

This procedure is applicable only if your organization has licensed Oracle Site Activate and configured Oracle Site Select to migrate data. Contact your Oracle Project Manager for more information. Additionally, you must have a role with *Export Sites to Activate* permission to complete this task.

1. Click **finalize** in the top navigation bar.
2. In the Final site selection options section, check the box next to **Sites can be migrated to site activation in Activate**.

View migrated study or study site in Oracle Site Activate

If Oracle Site Select to Oracle Site Activate integration exists for your account, you'll see a link to view an Oracle Site Select study in Oracle Site Activate after study or study site migration.

An Oracle administrator must enable integration at the account level, you must have a role with *Link to Activate study* permission, and the study or study site must be migrated to Oracle Site Activate to complete this task.

- To the right of the study drop-down list, click the launch () icon. To view the study site instead, from the finalize step in the final acceptance bucket, click the green Migrated to Activate check.

  The study home page or study site page opens in Oracle Site Activate in a new browser tab.

Site details drawer

When you have permission to access the site grid, you can access a site's details drawer where you can see the site's Scorecard, Invitation and status, Workflow task progress, Site notes, and Study contacts.

Navigating to the site details drawer

When viewing the site grid, you can right-click a site row or click the Actions menu for a site to access a navigation menu. The menu will be tailored to your permission and the current bucket state, so you may see some or all of the following site detail drawer options, which we've detailed in this section:

- **Scorecard**: Opens the Scorecard tab in the site details drawer
- **Invitation and site status**: Opens the Invitation and site status tab in the site details drawer (for Invited sites only)
- **Workflow**: Opens the Workflow tab on the site details drawer
- **Site notes**: Opens the Site notes tab in the site details drawer
- **Study contacts**: Opens the Study contacts tab in the site details drawer (for Invited sites only)

Inside the drawer

Resizing: The drawer width dynamically resizes based on the tab selected and the minimum width needed to support the contents of that tab. For example, the Study contacts tab will be wider than the Workflow tab. By design, the drawer will not exceed 80% of the page width.

Saving: When you update information in a site's detail drawer from the site grid, your changes appear immediately in the drawer. However, to see those updates reflected in the grid itself the next time you open the drawer, you'll need to click the **Refresh site grid** button (upper right above the grid) after closing the drawer. This step ensures the most recent changes display in the grid.

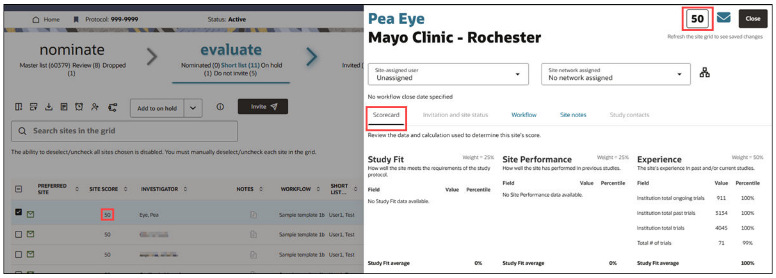
At the top of the drawer, you'll see the Investigator's first name, last name, and Institution name. Click the investigator's name to access the Site profile. You'll also see an envelope icon that links to the Communications tool. Use the drop-down selectors at the top of the drawer to update the site assignment, network, and workflow close date as necessary.

Scorecard

The site Scorecard feature is available in the site details drawer. The Scorecard tab is available to any Oracle Site Select user with site grid permissions, including those with read-only site grid or site nomination access, unless site scoring is turned off at the study level. The tab uses a three-column layout to show the scoring bucket name, assigned weight from the study setup, relevant data columns and their values, percentiles, and the approach configured for missing data (e.g., average-filling).

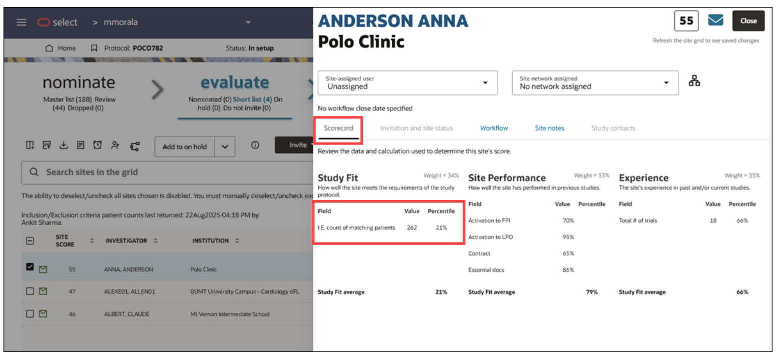
If site scores are still pending completion for a study, the Scorecard tab shows “score details pending” for each scoring bucket instead of site-specific data. While scores are pending, both the site score and the average bucket score in the drawer will display as “Pending.”

When available, site’s overall score now appears at the top of the site details drawer. The score remains visible to you across every tab within the drawer, so you can easily access key scoring information from anywhere in the drawer.



Recently we updated the "I.E. count of matching patients" site grid column to a scoreable column in the "Study fit" category. For any new study with site scoring enabled and patient counts returned (feasibility is enabled), this column will now contribute to each site's score.

Additionally, in current studies where data has been returned for this column, it will also begin contributing to site scoring, provided scoring is turned on.



Invitation and site status

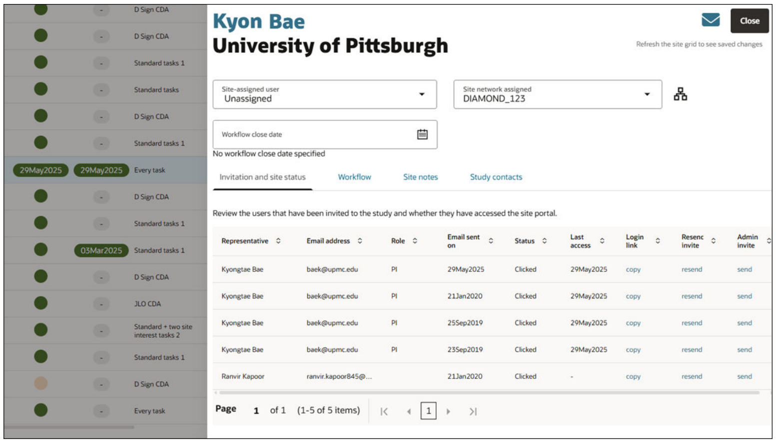
In a recent release, we streamlined site invitation details and site portal access status into one view. Instead of opening two separate modals from the site grid, you can now find this information combined in the Invitation and site status tab in the site details drawer.

In the bucket state, INVIT RCVD and ACCESSED SITE PORTAL site grid columns use status badges to reflect each site's invitation and portal activity. Badge colors indicate the most recent invitation email delivery status (red (failure), orange (in progress), green (success)) or site portal access (green with access date) or gray (no access). When you click the badge in either column, the site details drawer opens with the Invitation and site status tab selected.

The drawer’s Invitation and site status tab is available for sites in the Select and Finalize bucket states. You can review each invited user's name, email, role, invite date, email delivery status, last access date, and tools like “copy” (login link), “resend,” and “send” (admin invite), depending on your permissions. Please note that the name listed will be the user’s name as represented in the site’s profile/studysite view at the time of the invitation.

> **Note**
>
> To make sure the names appear as expected in the invitation received modal and emails, **the site profile must be set as the highest priority study data source**. If it isn’t, other sources may override the first and last name values shown to site users.

The table updates automatically as new users are invited or existing users access the site portal. You can sort both the INVIT RCVD and ACCESSED SITE PORTAL site grid columns to quickly prioritize follow-up actions.



Workflow

The Workflow tab shows each task in the site's assigned workflow and task details (like task status, related dates, etc.). As applicable, each task has a status icon (e.g., green check for completed, dash for not started, red slash for discontinued), and workflow tasks also use color background to enable quick review. Task colors are:

- Green = Completed
- Yellow = Pending
- Beige = No action (e.g., no pending document)
- Rose = Discontinued
- No color = Not started

You'll also see the Response: + the saved value for Completed tasks with an input. For instance, the Verify site interest task will display a line with Response: Yes (or No), while the Enter estimated patient count task will show a field with the site's inputted numeric value.

Complete a task on behalf of the site

You can complete the following tasks on behalf of a site from within the Workflow tab:

- View site profile
- Agree to confidentiality statement
- View protocol
- CDA document tasks
- Generic document (Download only; use Document approvals page for Approval required, Choose response, and Attestation)
- Verify site interest and Verify site interest again
- Feasibility survey
- Enter date available for site visit
- Enter estimated patient count

- Internal workflow task

Click a task's Actions button to view available completion options for that specific task (e.g., Verify Yes, Verify No, Complete - Not required, etc.); available options are dependent upon your user permissions. Some tasks may include document or template download icons (e.g., View protocol, Complete feasibility survey).

CDA workflow task

Your user role permissions affect your ability to interact with CDA document workflow tasks. See User management in these release notes for additional details.

- *Review and Approve All CDA/Document Submissions permission*: allows you to open the modal for all sites
- *Negotiation for assigned CDA/Document submissions only permission*: allows you to open the modal only if you are assigned as a CDA reviewer for the document task or you are the site-assigned user
- If you have only the *Review and Approve Assigned CDA/Document Submissions Only* permission and not the *Negotiate* or *all CDAs* permission, you cannot see the Review actions link/modal if you are not the user assigned as a CDA reviewer or the site-assigned user for the document task
- An Oracle Site Select user with the *Read only site grid view* permission will not see the Review action link
- An Oracle Site Select user with the *Read only document management* view and either the Read only site grid view or the Site nomination permission can open the review modal, but not complete the task

Additionally, please note the following related to CDA permissions:

- A user with the *Negotiation for assigned CDA/Document submissions only* permission cannot finalize/Final approve a CDA task without also having one of the “Approve” CDA permissions as well
- If an Oracle Site Select user has ‘Review and Approve Assigned CDA/Document Submissions’, then they can see the modal for all site's CDA documents.
- If an Oracle Site Select user has ‘Negotiate or all CDAs’ then they can only see the modal where the user is assigned as the CDA reviewer or the site-assigned user. The user will not be given the option to Final approve the CDA.

For an incomplete CDA document task, the modal includes an Actions section at the top where you can act on the document based on the task status:

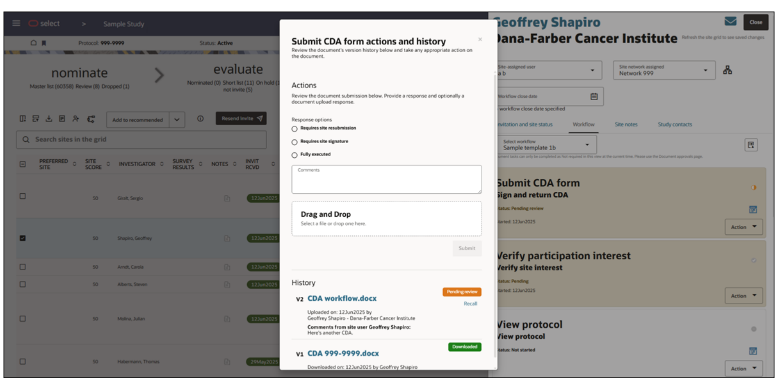
- **Not started**: Document task not started by the site. You may act on behalf of the site by uploading a document.
- **Review**: If you have the appropriate permission, you can review the document submission, provide a response, and optionally upload a document in response
- **Resubmit required**: If you have the appropriate permission, for a non-eSign document, you can complete the document task for the site by uploading a response and providing a comment. You may recall the document using the link in the modal’s History section and return the CDA task to incomplete status.
- **Final review**: If you have the appropriate permission, you can review the submission and provide a response, with an optional document upload. You may recall the document using the link in the modal’s History section and return the CDA task to incomplete status.

- **Approved**: You may recall the document using the link in the modal's history section to return the CDA task to incomplete status. You may recall the document using the link in the modal's History section and return the CDA task to incomplete status.

> **Note**
>
> When you have*Allow external completion of workflow tasks* permission, you'll see a Final approval option in the Actions menu for a CDA task. This option lets you final approve a CDA without completing the full document review cycle. You can optionally upload the finalized CDA and add a comment in a modal that displays when you click Final approval.
>
> - The Final approval option is available if no one has started the task or uploaded a file.
> - If a file has already been uploaded, you'll see a message letting you know to use Review submission instead.
> - Once final approved, the document (if uploaded) and any comments are saved to the CDA document history, the study's document submissions, and the site progress view.
> - If you don't upload a file, the original CDA template will be marked as the final version.

For each step of the document cycle, files uploaded and comments made are saved. Documents can be viewed in the study document library for the site and comments on the site's notes drawer.

The bottom of the modal is a History section where you'll see the version history for each iteration of the document's actions. A document task that has not been started will have a V1 history listing the document template for the task.



Generic Document (approval required) workflow task

For Generic document: Approval required tasks, the Actions menu includes "Review submission" as the first option. When you click Review submission, a modal opens where you can review the document's version history and take appropriate action on the document.

Your user role permissions affect your ability to interact with Generic document: Approval required workflow tasks.

- *Review and Approve All Generic Document Submissions* permission – allows you to review any site's generic documents

- *Review and Approve Generic Document Submissions for assigned sites Only* permission – allows you to review only the generic documents for sites assigned to you (link is disabled if the site is not assigned)

Oracle Site Selectusers with read only permissions will have the following experience:

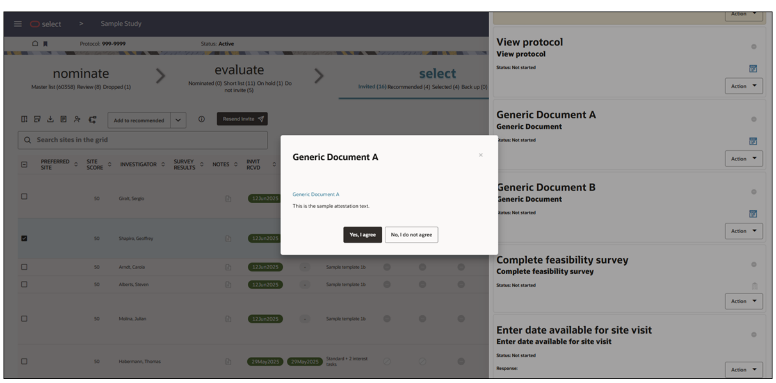
- A user with the *Read only document management* view and *Review and Approve Generic Document Submissions for assigned sites Only* can review generic documents for all sites but can only act on sites for which they are assigned
- A user with the *Read only site grid view* permission cannot click on the Review action link
- A user with the *Read only document management* view and either the Read only site grid view or the Site nomination permission can view the review modal but not complete the task

For an incomplete document task, the modal includes an Actions section at the top where you can act on the document based on the task status:

- **Not started**: Document task not started by the site. You may act on behalf of the site by uploading a document
- **Review**: Review the document submission. Provide a response and optionally upload a document in response
- **Resubmit Required**: Lists the sites that have been sent a document revision/request. The sites listed are required to upload/respond to the document request sent by the Study specialist. You can comment, upload a document, and submit.
- **Approved**: Document is complete. There is no further action available.

For each step of the document cycle, files uploaded and comments made are saved. Documents can be viewed in the study document library for the site and comments on the site's notes drawer. Completed generic document tasks display the chosen or entered Response value (e.g., Yes/No, date selected, numerical value, etc.).

The bottom of the modal is a History section where you'll see the version history for each iteration of the document's actions. A document task that has not been started will have a V1 history listing the document template for the task.



Generic Document (choose response and attestation) workflow tasks

You can also complete Generic document: Choose response and Generic document: Attestation workflow tasks from the Site details drawer > Workflow tab. If you have Site grid permission, you'll see a Complete option at the top of the task's Action menu. When clicked, a completion modal opens that shows the task name, instructions, a document download link, and the configured response or attestation options as buttons. When you choose the response or attestation, the task will be marked as completed by you and the time will also be recorded.

Completed generic document tasks display the chosen or entered Response value (e.g., Yes/No, date selected, numerical value, etc.). If necessary, you can reopen a completed task to update the response. When you save changes, your name and the updated completion time are recorded.

By design, Oracle Site Selectusers with Read only site grid view permission won’t see the a workflow task’s Complete option and can’t open the task completion modal.

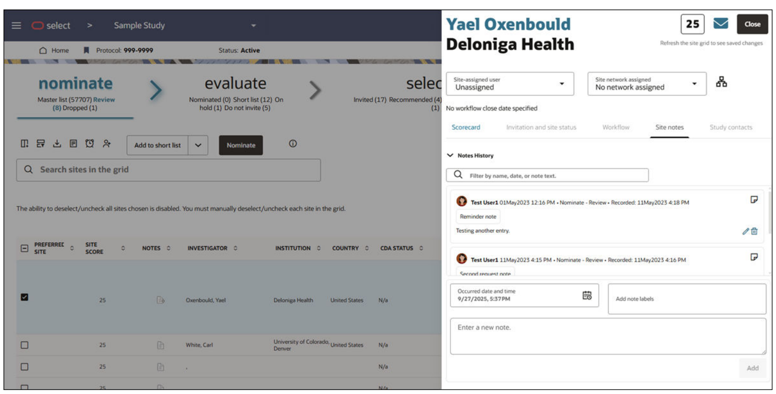
Site notes

The site grid drawer also includes a Site notes tab. If you don't already have the site grid drawer opened, you can navigate directly to the Site notes tab when you click View notes in the site grid Action menu. By design, when you click on a site's notes icon in the site grid, the Notes modal displays instead of the site grid drawer. In this scenario, the modal defaults to the Study Notes tab.

When viewing the Site notes tab in the drawer, you'll use Oracle standard components for field and text inputs. You can optionally filter the Notes history section by name, date, or note text. The Notes history section shows notes in this format:

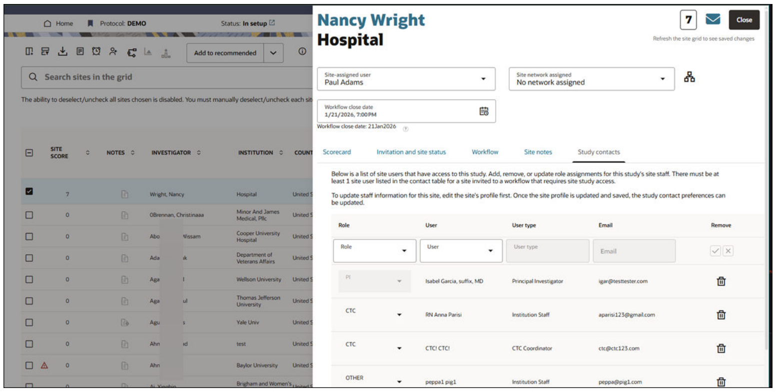
- Notes include the author's full name and listed in order of input occurred at datetime
- Format: <occurred date time> * <bucket - bucket state note was recorded> * Recorded at: <note saved date and time>

The Site notes tab also includes a note input section at the bottom where you can add a date, label and text input as preferred. If you have *Edit/delete site note* user permission, you'll see Edit and Delete icons in each saved note.



Study contacts

Study contacts is the list of site users who have access to the study. You can add, remove, or update role assignments (e.g., PI, CTC, Other, Network, IRB), but there must be at least one contact listed in the table for a site invited to a workflow that requires site study access. Additionally, to update staff information in the Study contacts list, edit the site's profile first. Once the site profile is updated and saved, the study contact preferences can be updated.



Study site history view

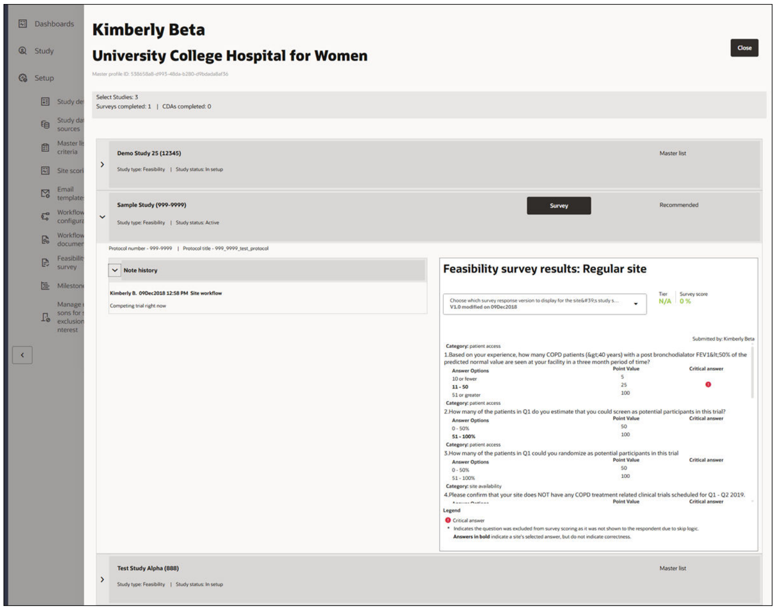
When you have the appropriate permissions, you can view a study site's cross-study performance and workflow completion across all studies in the account to gain insight into a that study site's progress.

If you are a permissioned site grid user who also has the *Cross-study study-site view* permission, you will find a View site history option in a study site's Actions menu on the site grid. The option is also available if you right-click a site row in the grid. Click View site history to open a new page with summary metrics:

- Number of Oracle Site Select studies
- Surveys completed
- CDAs completed

An accordion panel displays below the summary with identifying information for each study in the account where the study site has been used (i.e., Study number, Study type, and Study status) along with the study site's current bucket state for that study. When available, the accordion also shows CDA and Survey badges to indicate the study site completed these workflow tasks in that study.

When you click a study row, the panel expands to show the protocol number and title, and you can access Note history and Feasibility survey results, if any.



- [Access study site history view](#)
  View a study site's historical performance for studies within the account.

Access study site history view

View a study site's historical performance for studies within the account.

You will need permission to access the site grid as well as the *Cross-study study-site view* permission to complete this procedure.

1. In any site grid (meaning any selection step and bucket state), click the **Actions** option on the study site row, or right-click on the study site row. In the menu, click **View site history**.
2. In the history drawer, view the study site's summary metrics at the top of the page (total studies, surveys completed, CDAs completed.
3. Below the metrics, open and close the accordion panels using the arrows **<** and **>** at the far left of each panel. When open, you can view Survey, CDA, and Note history details as available.
4. To exit the drawer, click **Close** at the upper right.

Use notes to communicate

Notes provide an easy way to communicate with your team members about a specific study or site.

Study sites notes modal

When you access the notes modal from the site grid, you'll see subtext that clarifies how the note will be shared with your team members: "Add notes to the study to collaborate with your study team. The notes will not be affiliated with any study sites." Within the modal, you can search the Note History section for previous notes if preferred, and the Note input section at the bottom of the tab includes additional functionality (i.e., country selection and unlimited free text).

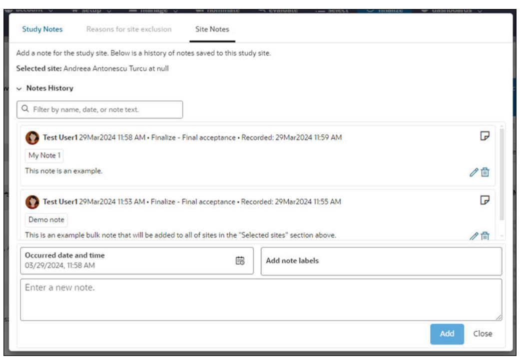
To open the modal to the Site notes tab for one site, click the site's Note column icon in the site grid. When you click on the site grid menu notes icon without selecting a site in the grid, the modal opens to display the Study notes tab by default. If you select multiple rows in the grid, and then click the site grid menu notes icon, the Notes modal displays and defaults to the Bulk site notes tab unless you choose multiple rows in a disqualifying bucket state (e.g., Dropped, Do not invite). In this case, the Notes modal displays and defaults to the Reasons for site exclusion tab, and you can navigate to the Bulk site notes tab, if preferred.

When viewing the Site Notes tab in the modal, you'll see "Selected site" at the top of the modal. You can optionally filter Notes History by name, date, or note text. The Notes History section shows notes in this format:

- Notes include the author's full name and listed in order of input occurred at datetime
- Format: <occurred date time> * <bucket - bucket state note was recorded> * Recorded at: <note saved date and time>

Note versioning

When you have the appropriate permission, each saved note in the Notes History section in the notes modal will include Edit and Delete options. These options allow you to modify any saved site note, with the exception of site notes related to a document workflow task. The original note's creation date and author name aren't changed; the edited note will have a new information section in the following format: Updated: <updated date> by: < user's full name>. Additionally, the order of the notes in the site grid is now the newest note at the bottom and the oldest note at the top for the Site Note and Site Comms and Note Digest columns.



The Data Export Utility and nightly reporting view CSV extracts will include deleted and updated notes. There will be a new column to denote the deleted note. The Oracle Site Analyze standard Notes report found in the Site progress workbook will have deleted and updated notes filtered out. Only the current note(s) will display.

If you have permission to access the Data Export Utility, site note reports will include deleted and original notes that have been updated. When you create an extract in the Notes cube, include the "is deleted" column to have visibility on which extracted notes are deleted/updated. Additionally, if a site note has been updated, then the site note exported in a site note Data Export Utility report will reflect the updated note text, label, and occurred on date.

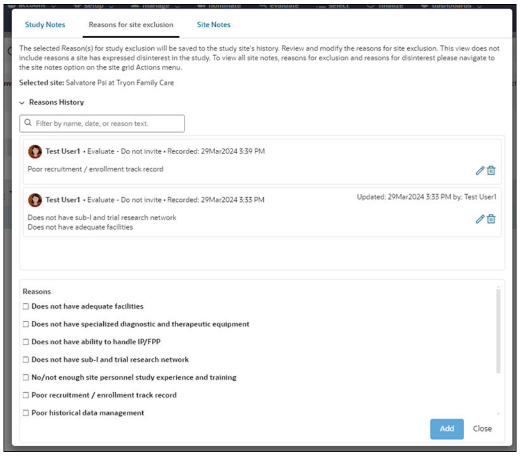
When you update or delete a site note in Oracle Site Select, it will be marked as deleted in the reporting views and nightly CSV reports. Reporting views and nightly CSV reports to include a new note_history table. The note history table outputs the history of an edit to a note.

Site exclusion notes

The note modal's Reasons for site exclusion tab is displays to the right of the Study Notes tab, when you select one or more site(s) from the site grid in any disqualifying site status bucket (i.e., Dropped, Do not invite, Declined, or Final decline). If you selected multiple sites in the grid, you can also access the modal's Bulk site notes tab. The Selected site section at the top of the modal shows the site(s) that will have a site note added with your chosen exclusion reason(s).

Choose one or more reasons for exclusion from the modal's Reasons and click Add to save. When you have the appropriate user permission, you'll also see Edit and Delete options in each saved reason for exclusion note.

If your organization has enabled the account level setting to require an exclusion reason when moving sites to a dropped bucket state (i.e., Dropped, Do not invite, or Declined.), the notes modal will display when you place one or more sites in the dropped bucket state, and you'll add the reason in the Reasons for site exclusion tab. The exclusion reason(s) will be saved for all the chosen sites even when you drop multiple sites simultaneously.

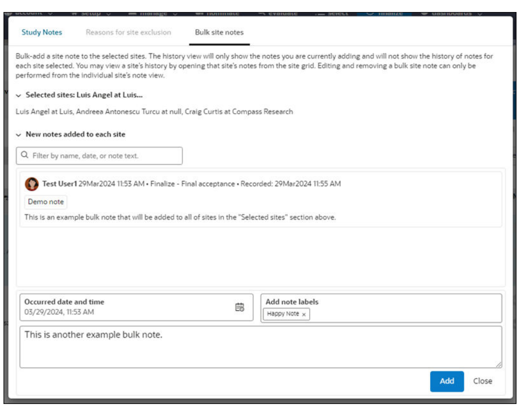


Bulk site notes

When you select multiple sites in the site grid and click the Notes icon in the site grid menu, the Study site notes modal displays and defaults to the Bulk site notes tab.

The modal's Selected sites section is an accordion that includes all the sites you selected in the grid. This accordion control is collapsed by default, but you can expand it to review the selected sites. At the bottom of the tab, you can add a site note and save it to all of the selected sites. This section includes all standard note authoring controls (i.e., Occurred date, Note label(s), and a free text note input area).

The tab's New notes added to each site section displays only the site notes you added during the current session of having the modal open. Closing the modal will clear the contents of the newly added view but will not delete any saved notes.



Note

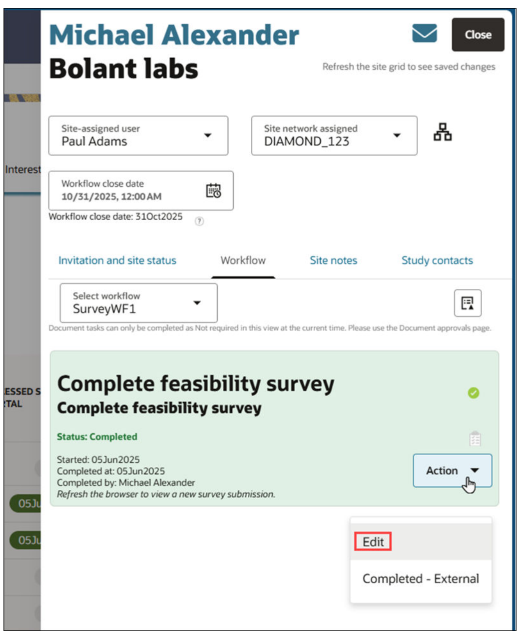
Editing and deleting a site note is not supported in the Bulk site notes tab; this functionality is available only in the individual site's note view.

Retake surveys or edit survey responses

Feasibility surveys may be reopened after they have been submitted so that responses can be changed, if necessary, and Alchemer surveys reopen the previously submitted survey with previous responses pre-populated.

Feasibility survey responses can be changed as follows:

1. The site can use the "edit" link on the Survey task within the site portal to reopen a submitted survey, or
2. The CRO user can edit the survey on behalf of the site within Oracle Site Select using the Edit link under the Actions menu in the Site details drawer, Workflow tab.



Once the survey has been resubmitted, the new responses populate into Oracle Site Select, along with the resubmission date. The original responses, scores, and date are retained in Oracle Site Select and all versions of the survey will be available to view. Please note that the CSV extract is limited to the most recent survey submission.

Configurable site profile

Site profiles store extensive detail about a specific site's contact information, trial history, study contacts, and more. By customizing the sections, fields, and values, you can streamline workflows and ensure your team captures the most relevant information. For help setting this up, contact your Oracle administrator.

Access the Site profile

There are three ways to open a site profile, and the action link you'll see, either Edit site profile or View site profile, depends on your permission level:

1. Right-click a site row in the site grid and select Edit site profile if you have edit permissions. If not, you'll see View site profile instead.
2. Use the site's Actions menu in the site grid to select Edit or View site profile, based on your access.
3. After opening the site details drawer from the site grid, click the investigator's name at the top of the drawer to open the profile.

In Oracle Site Select, the site profile page design includes section navigation links in a left side panel. The left navigation also includes links to Site network, Document library, Trial history, and Study contacts.

With configurable site profile enabled, all site profile changes are stored in an account-level data source for new studies. Site profile changes will span across all studies in the account that do not have a study-specific site profile data source.

Oracle Site Select users must have *Edit site profile permission* to modify any field in the configurable profile. The profile will be read-only for all other users. This aligns with the required permission for updates to the legacy site profile.

> **Note**
>
> As the site profile is highly configurable, the images included in this section are representative. You and others in your organization may see some or all of the sections described below, different section/field labels, etc.

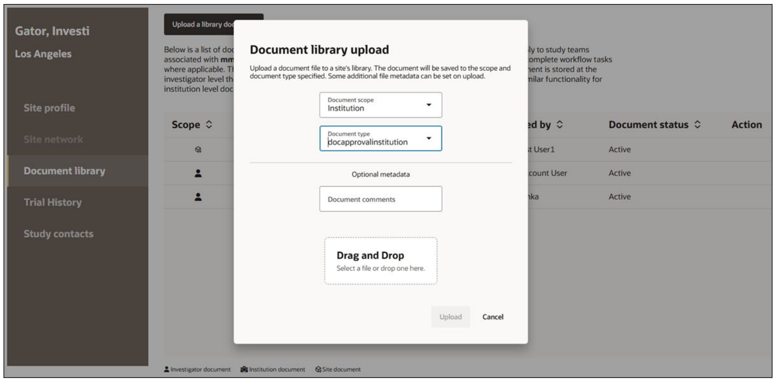
Document library

The document library section includes a list of all reusable documents for the site. When you have *Upload files to a site's document library* permission, you can upload documents directly to a site's library from the Edit site profile > Document library tab.

This makes it easy to manage files by letting you upload documents to the site, investigator, or institution libraries if the site has a matching record in the account's primary composite datasource. You'll see an Upload a library document button on the Site profile's Document library page, which is enabled only if you have permission to upload files.

Click the upload button to open a Document library upload modal and choose the Document scope (site, investigator, or institution) and Document type. The remaining fields in the modal are based on what's been set up at the account level. If the site doesn't have a related record in the primary datasource, the investigator and institution scope options will be disabled, and you'll see an error message explaining that only site-level document types are supported for that site. Helper text will guide you through the process and let you know why some options may not be available.

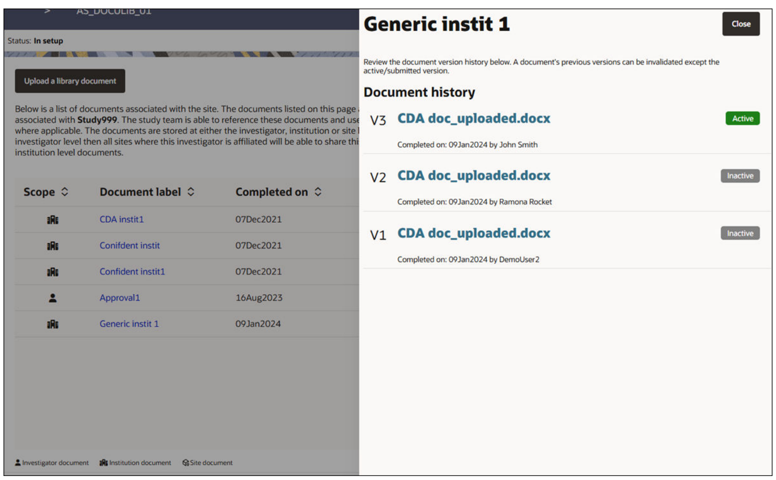
Once you select a valid document scope and type, you can add required and optional metadata and attach the file to enable the modal's Upload button. After successful upload, a confirmation message displays, and the Document library tab refreshes to include your new file.



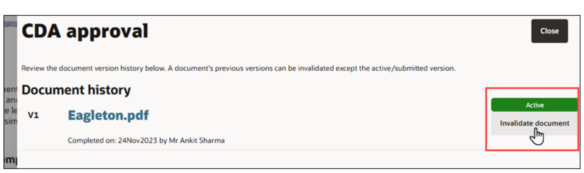
In the document grid, click a document name to open its version history drawer. The drawer shows all uploaded versions, with a green Active badge for the current version. Any older versions will show a gray Inactive badge.

Each entry includes the version number (such as V1, V2, V3), the upload date, and the user who uploaded it. Click a file name to download the document.

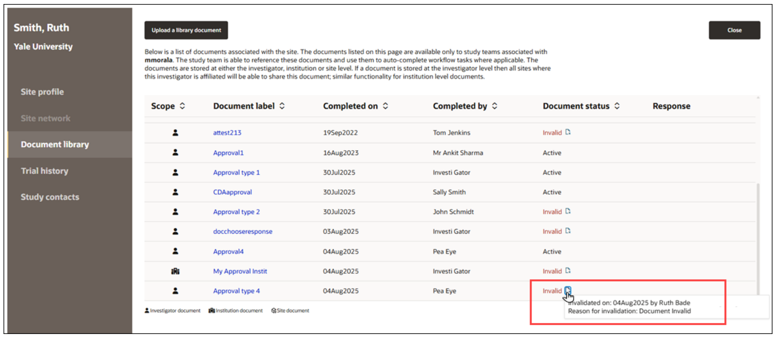
If a file was uploaded as part of a comment or submission action by a Select user, that file will also appear in the version history.



When necessary, you can invalidate the most recent version of a document in a site's Library documents tab (excluding "download only" document types). For an Active document, click the Invalidate document button, enter a required reason, and the document will be marked as invalid. Invalidation details (who performed the action, when, and why) are saved in the document history.



When viewing the Document history grid, you can hover over the invalidated document icon to see the invalidation details or click the document name to open the document drawer for full details. If a new version is later uploaded for the same document label, it becomes Active, and the invalidation details will remain visible in the document history drawer.



You also have controls to help you view and update “Choose response” type Generic documents in the site’s Document library. On the Library documents page, Oracle Site Select shows the chosen response saved in the library document metadata. If a response change reason was previously entered, a pencil icon displays and the change reason displays on hover. If the document is invalidated, no response is displayed.

In the document’s history drawer, the subtext clarifies that responses can be changed and documents can be invalidated. Invalidated documents will no longer auto-populate study tasks. You'lll see the active file listed as a download link and the response options displayed as editable radio buttons. These options reflect the original Generic document setup. If someone previously changed the response, you’ll also see the reason and details of who made the update and when. You can revise responses as needed, but each change must be confirmed with a reason.

The Document library page in the Site profile also displays responses and available actions for Generic Document Attestation types. For each relevant document stored at the investigator, institution, or site level, you see the Response option saved in the library’s metadata. If a reason for changing the response has been provided, a pencil icon with the reason appears as hover text; if the document is invalidated, no response is displayed.

In the history drawer, the active library file is available as a download link using the file’s name. Task options are offered as editable radio buttons with their text and selected states matching what is saved in the library. If a response was edited previously, you can view the previous change reason, along with who made the change and when. If you modify the response, a confirmation dialog appears requiring you to confirm and provide a reason (plain text, up to 2,000 characters, required), with options to cancel or proceed. After saving, the history drawer refreshes to show updated details.

In the Library tab, for Attestation document types, we also updated the document details drawer subtext to: "Review the library entry for this Attestation document type. The response saved to the library can be changed. The document can also be invalidated. Invalidated documents will no longer auto-populate study workflow tasks."

Trial history

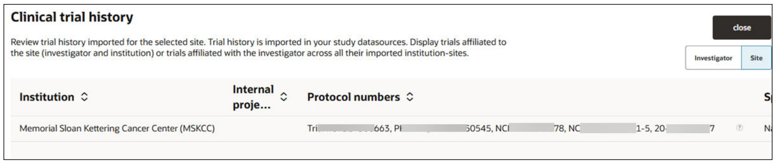
The Trial History tab in the Site profile makes it easy to review imported trial history for a selected site. The tab appears enabled in the left navigation when the study has a composite datasource attached. If no datasource is attached, the link is disabled and a hover message explains: "There are no datasources with trial history attached to this study."

On the Trial History tab, you can choose to view trials based on either:

- **Site** (default): shows trials linked to the selected site

- **Investigator**: shows trials linked to the investigator across all affiliated sites

The trial grid includes details like Institution, Protocol numbers and titles, Sponsor, start and end dates, enrollment rate, and more. You can sort any column by clicking its header. If no data is available, the page will display: ″No affiliated trials have been imported.″



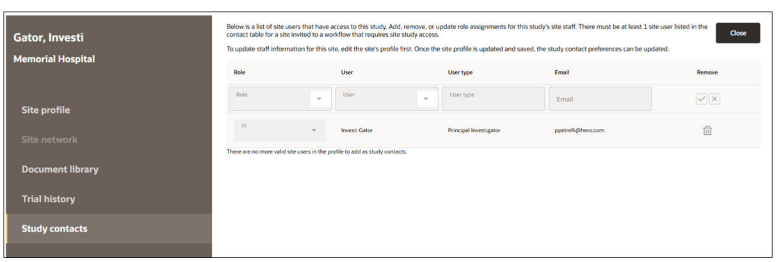
Study contacts

Study contacts display in a grid format. When you view the study contacts page from the Oracle Site Select > Edit site profile page or from the site grid > site details > Study contacts tab (but not from the Site portal > Edit site profile page), the contact display (name, user type (Investigator, Clinical Trial Coordinator (CTC), IRB contact, site staff, and network delegate), and email) for study contacts is pulled from the studysite instance instead of just the site profile. The drop-down picker to define the contact role is not affected by this change.

For example, a datasource record has “erik@example.com" for the PI email, but the site profile has “bob@sample.org.” Datasource priority determines the display. If the site profile is the lowest priority, and the site is invited, “erik@example.com" appears as the invited user’s email across all relevant pages (in Oracle Site Select and the Site portal).

If the datasource priority changes after invitation (i.e., site profile datasource placed as the study’s highest priority datasource), “erik@example.com” remains listed as the current contact, and “bob@sample.org” is now available to be added as a study contact on all relevant pages. If you remove “erik@example.com” and save, that address cannot be re-added.

The Site portal continues to show the same list of added study contacts as Oracle Site Select, regardless of datasource priority. When adding a new contact to the study contacts, Site portal users will only see site user data that originates from the site profile datasource.



Document workflow task audit

Site grid users can download an audit file containing document workflow completion details.

The Site Document Download option is in the site grid Actions and right-click menus, and you can select which document audits to download in PDF format. The most recent completed workflow document(s) audits will download, and document metadata is that of the most recent approval. This download option applies to the following completed document types:

- Agree to confidentiality statement

- View Protocol document
- CDA
- Generic document - all four types

Oracle Site Select packages multiple files into a single ZIP file if you download multiple files for a single site.