Oracle Life Sciences Site Select

Information for CRO and Sponsor Users

Release 24.2
G15013-02
September 2024

Oracle Life Sciences Site Select Information for CRO and Sponsor Users, Release 24.2

G15013-02

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Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

Product documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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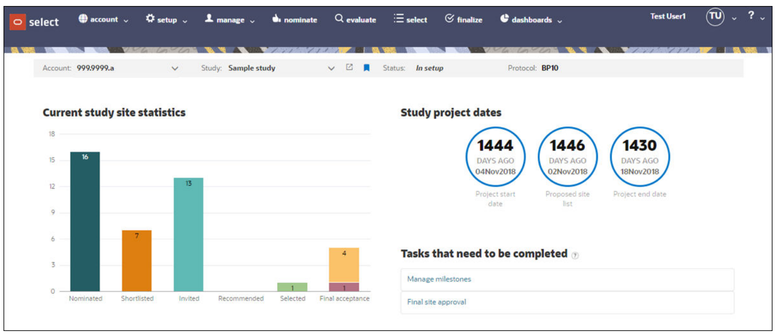
About Oracle Site Select

If you're new to Oracle Site Select, use this guide to learn 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.

Predefined tasks drive the work

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

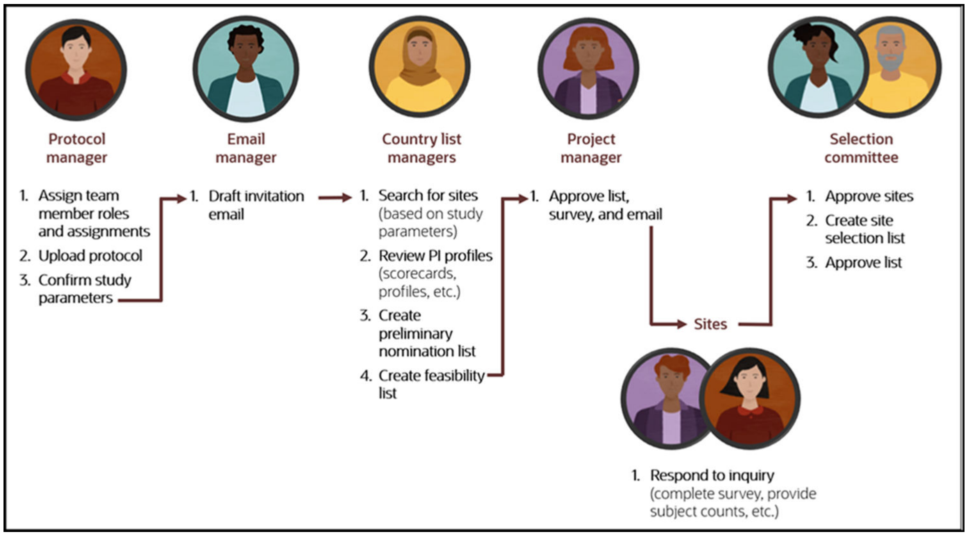


Intelligent, centralized site recommendations

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 Oracle Site Select LITE, sites 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.

- Navigating in Oracle Site Select
  The application provides global menus, links, and dashboards that allow you to transition between views and pages.
- Managing your profile to customize your experience
  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.

Navigating in Oracle Site Select

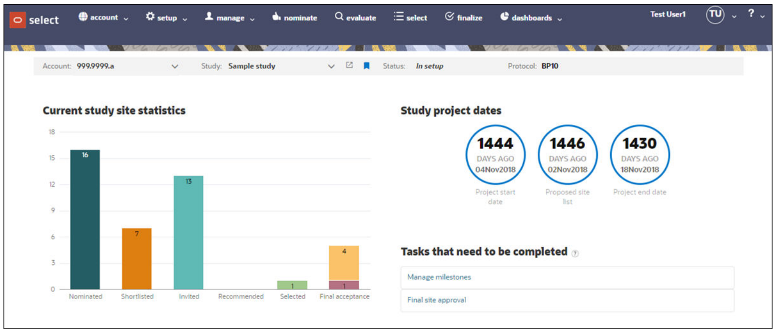
The application provides global menus, links, and dashboards that allow you to transition between views and pages.

A persistent global navigation menu displays at the top of every page. Site selection mode and menu options available to you (e.g., setup, manage, nominate, etc.) depend upon your role and the permissions granted for your user account. Oracle Site Select controls which options display within the global navigation drop-down menus based on permissions granted for your user account. This means that you might have access to the "setup" drop-down menu, but the menu will include only those actions you have permission to access.

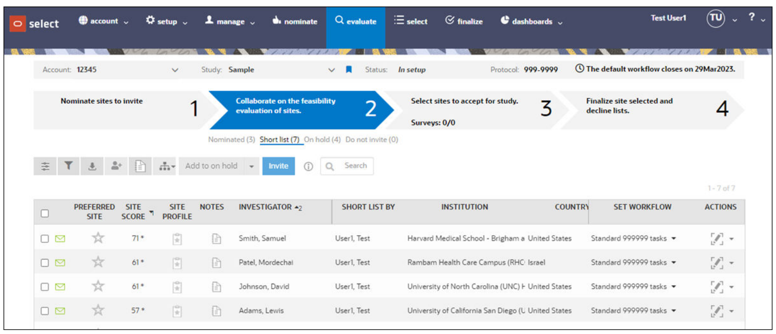
At the far right of the global navigation menu, click the drop-down menu to the right of the circular profile icon to access your user profile settings. To access product or API documentation or the Oracle support home page, click the down arrow to the right of the question mark.

You'll see another persistent menu below the global navigation menu where you can navigate between accounts and studies depending on your assigned permissions and studies. If you've been assigned to multiple studies, you can optionally favorite your frequently accessed studies by clicking the bookmark ( ) to the right of the study name. Your favorite studies automatically sort to the top of the Studies drop-down list. Just click the bookmark again to unfavorite any study. If you have user permission to view other studies, use the Study drop-down to choose a different study. The Study drop-down supports type-ahead search logic.

The study home page includes bar charts, milestone visualizations, 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.



If you perform site selection tasks, you can quickly switch between nominate, evaluate, select, and finalize modes by clicking the chevron arrows above the site grid. Blue indicates the current mode (for example, in the image below, the current mode is Evaluate). You can also see the highlighted "evaluate" option in the global navigation at the top of the page. You can change modes using the options in the global navigation rather than clicking the chevron arrows if you prefer.



The global navigation Dashboards menu provides access to site status dashboards, reporting options, and the myDashboard study-level dashboard feature. Access to each dashboard menu item is permission-based, so you may see some or all options.

The myDashboard feature (accessed from the Dashboards menu) provides a study grid that provides 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 the myDashboard 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.

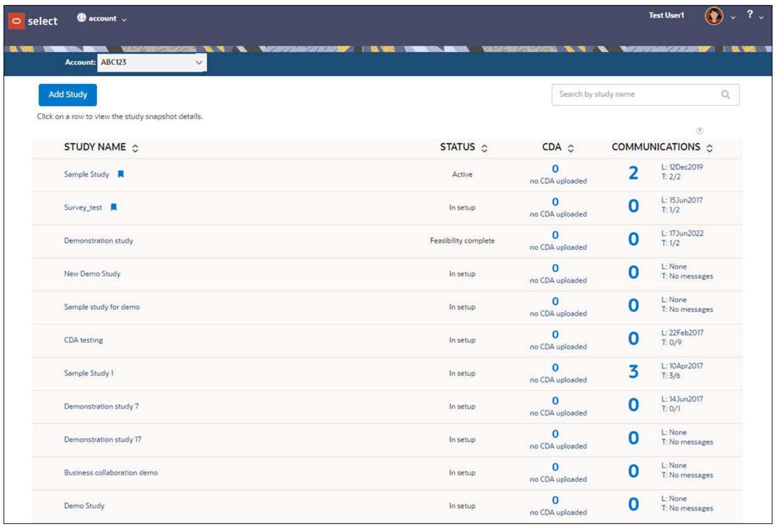
When viewing the myDashboard study grid, if you click the "select" logo at the top left, the grid automatically displays the previous study's home page if in session. If no study is in session and you click the logo, the most recent study visited displays.

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. When the CDA count is "1" or above, you can click the count and navigate to the country page for the most recently received CDA.

The Communications column to see if unread messages might need to be addressed. This column reflects multiple totals; the number shown to the left of the communication totals is the total unread communications from sites assigned to you for the study. The stacked numbers on the right are:

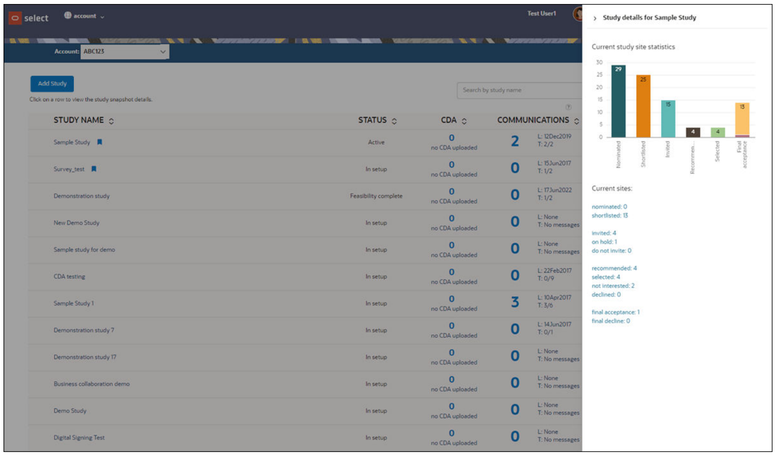
L = Date last message received from a site in the study

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



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



Managing your profile to customize your experience

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.

In the global navigation bar at the top of any Oracle Site Select page, click the down arrow to the right of the circular initials icon. Once you access the 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.

Periodically, you'll need to change your application password. At the lower left of the Profile page, you'll see how many days remain before automatic password expiration. However, you can change your password at any time using the "Manage your password" fields on the Profile page.

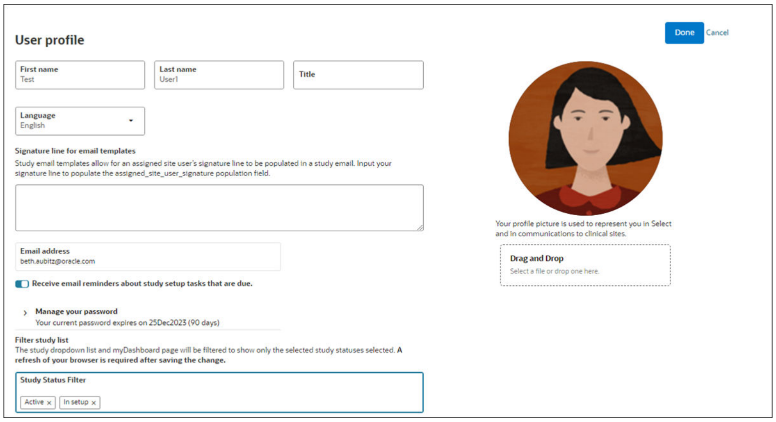
> **Note:**
>
> If your organization has configured single-sign on (SSO) integration with Oracle Site Select, you won't need to manage your password on the user Profile page shown below. Instead, your user ID and password will be managed by your organization's identity provider application (e.g., an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

You can optionally specify the study status(es) you prefer to view in the study drop-down list and on your myDashboard 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 your profile page's Filter study list control.

On the right side of the Profile page, you can optionally upload your photo. If you choose to do so, the photo replaces the circular initial icon in the global navigation bar. 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 photo will also be attached to emails that are sent to sites to help personalize site communications.



- 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 accont 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 goBalto.com, and follow the password reset instructions included in the email.

Related Topics

- 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.

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 upper right of any page, click the down arrow next to your profile name or picture, then select **manage profile**.
2. Click **Manage your password** to expand the panel.
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 of 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 **Save password**.

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

3
Study Setup

This section, intended for study administrators and protocol managers, describes how to set up and manage studies in Oracle Site Select.

- Setting up studies
  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.
- Defining study workflows
  Defining a study's workflows involves detailed planning around the order in which sites complete individual workflow tasks and identifying required documentation and communication.
- Defining study disinterest and exclusion reasons
  When sites indicate they are disinterested in study participation, they must provide one or more reasons. Administrators can specify a list of reasons displayed to sites in Oracle Site Select LITE or when Oracle Site Select users complete tasks on behalf of a site.
- Defining study milestones
  To ensure your team stays on track with key study accomplishments like site enrollment targets, define study milestones when you set up your study.
- Defining site scoring parameters (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.

Setting up studies

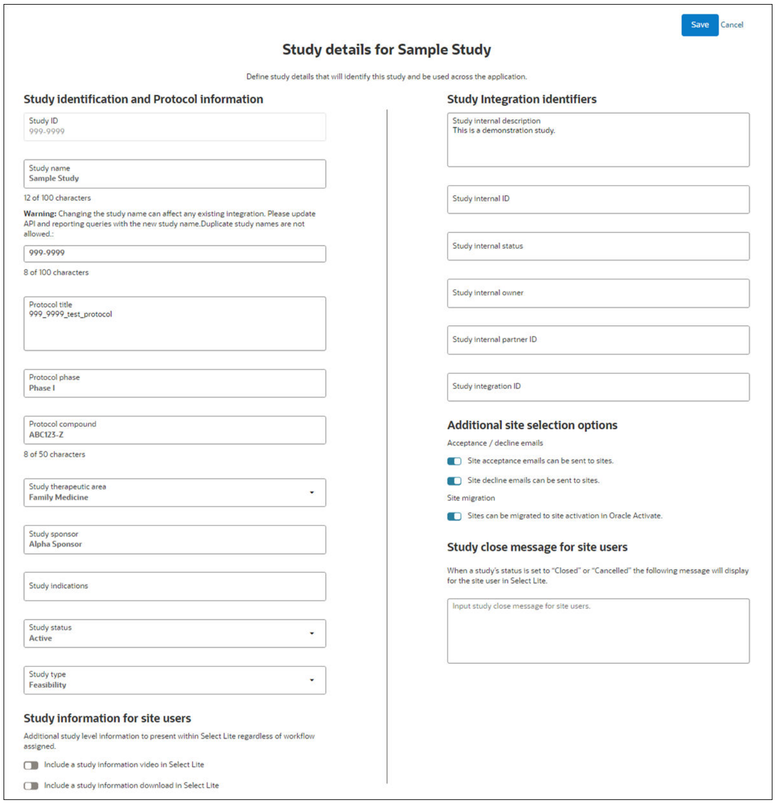
Permissioned users can set up studies in Oracle Site Select with attributes that help you and your team members track those studies based on various parameters. Parameters include protocol number and title, protocol phase and compound, study status and type, and more.

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 navigation "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 drop-down list in the persistent header.



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 drop-down list in both Oracle Site Select and Oracle Site Select LITE. 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:

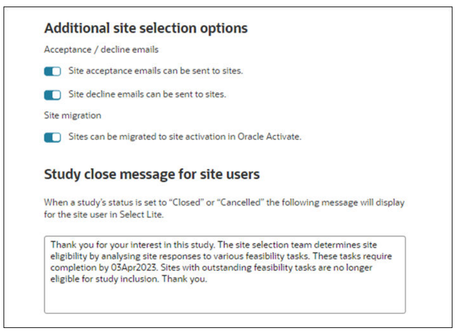
- Feasibility (default)
- Internal insights
- Investigator outreach
- Pre-award

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 Oracle Site Select LITE. 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 Oracle Site Select LITE home page in the study information panel. Importantly, access to the document in Oracle Site Select LITE 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 users in Oracle Site Select LITE 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.



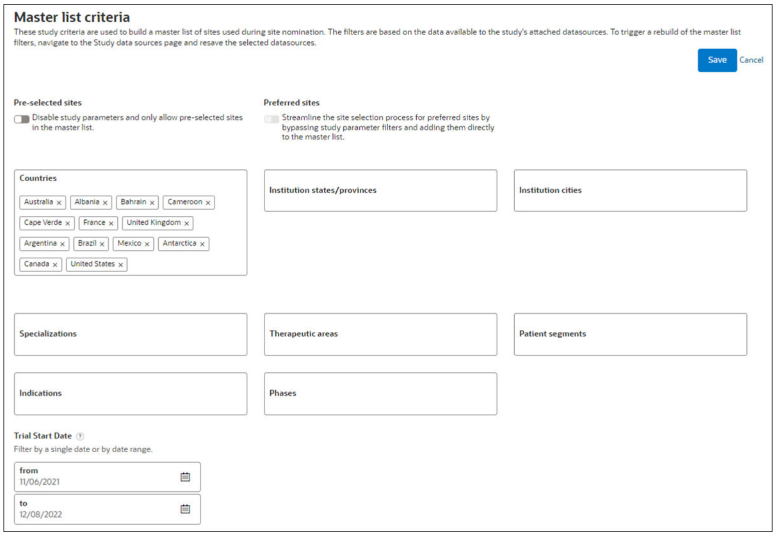
Master list criteria page

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 navigation "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.

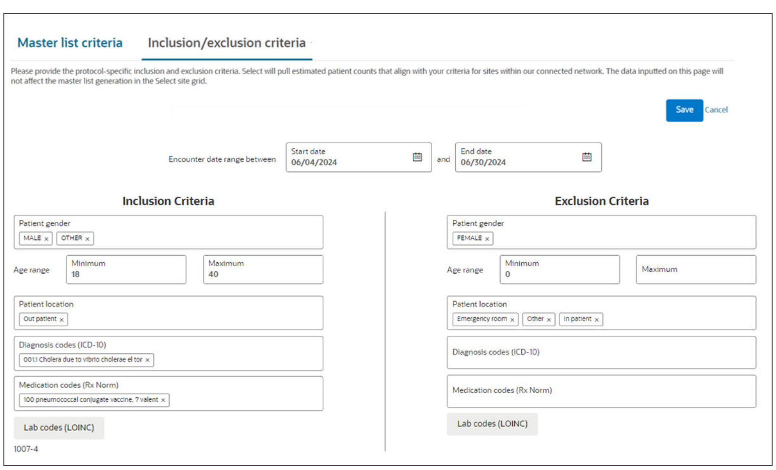


When your organization has enabled Oracle Learning Health Network integration, the Master list criteria page will be split into two tabs, Master list criteria and Inclusion/exclusion criteria.

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.



- Define 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 can provide estimated patient counts that align with the study criteria.

Define 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.

> **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.
2. In the top navigation, hover over **setup** and click **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 Select Lite**: By design, this control is not actionable. Contact your Oracle administrator to enable the video option. When enabled, the control displays as toggled on on the Study details page so you can validate the video link.
   - **Include a study information download in Select Lite**: 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 Oracle Site Select LITE 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 Oracle Site Select LITE 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.
2. In the top navigation bar, hover over **setup** and click **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 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 the **Study** drop-down list.

2. In the top navigation bar, hover over **setup** and click **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**.

Defining study workflows

Defining a study's workflows involves detailed planning around the order in which sites complete individual workflow tasks and identifying required documentation and communication.

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 site. If you have the appropriate permissions, you'll define the workflows using the **Manage site workflow configuration** page options. Note that some organizations define workflows using account-level templates.

Step 1, **Add the workflows required for this study**, allows you to move a workflow to Step 2 by clicking the plus sign. In Step 2, you'll add a close date for the workflow(s) and set a default workflow. Workflows available to you in Step 1 may be the default system workflows or preconfigured, account-level workflows that include specific tasks. If using an account-level workflow, you can modify it as necessary for the study, but your changes will not affect the account-level workflow template.

You'll specify a unique workflow name (40 characters max) in Step 3. You'll also optionally enable other workflow details (e.g., digital signature and site collaboration, workflow description, and more). If preferred, you can also apply Rich Text Formatting to text that displays to site users in Oracle Site Select LITE. (i.e., the workflow description and closing message).

Next, you'll see the option to Override the default and country-specific email templates for studysites assigned the workflow. If you enable this optional setting, the form expands to include new fields where you will create workflow-specific email templates for the invitation, final acceptance, and final decline emails. For each template, options match those available on the Study email template settings page, including the ability to use placeholder values in the text area and preview the template. When studysites are assigned to a workflow with the Workflow-specific email templates option selected, the following email sending behaviors apply:

- For that workflow, Oracle Site Select will use the configured templates at the workflow level for the invitation, re-invitation, final acceptance, and final decline emails
- A site reassigned to the workflow will not receive a new invitation email with the workflow-specific email template. However, if the site is later re-invited to the study, then they will receive the workflow-specific email invitation
- Email templates will not include a No login link if the Manage study email templates page has that option configured at the level in which the site would receive an email template (default vs. country override)
- Email template salutation and personalization preferences will follow the configured study email template preferences based on the applicable default or country override

The lower section of the Manage site workflow configuration page includes workflow tasks. In the Site task library, at the left, click a plus sign to add that task into the workflow list on the right side. Once all the tasks are in the panel at the right, you can reorder them as necessary by using the up and down arrows to relocate tasks into the preferred position. You can also optionally change a task name that is displayed to sites and format task information as preferred.

A checkbox configuration option will allow site users to complete certain tasks at any point in their assigned workflow. All site and internal workflow tasks include this option: “The task becomes due after this task is completed.” The option is enabled (checked) by default, which means the next task in the workflow will show only when the site completes the current task (a.k.a the task is "gated"). You can uncheck the box if preferred so that completing that workflow task is not required to proceed in the workflow.

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 icon status of the workflow task on the Oracle Site Select site progress tab and in Oracle Site Select LITE displays a red "Discontinued" icon: When an Oracle Site Select LITE 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 for the site user:

“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 Oracle Site Select LITE 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, Oracle Site Select LITE will show 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, the Complete tasks on behalf of site page lists the Internal workflow task in the configured workflow order. When the user clicks the Complete button, 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.

- Configure 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.
- Configure account-level workflow templates
  If you have account setup permissions, 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.

Configure 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. In the top navigation bar, hover over **setup** and select **site workflow configuration**.
2. In Section 1, click (+) to select a workflow to use for the study.
3. In Section 2, enter a **Close Date** for the workflow. If the study has multiple workflows, click the radio button for the workflow you prefer as the default.
4. In Section 3:
   a. Check the box to allow digital signatures on CDA documents.

   b. Check the box to allow sending email invitations to sites.
   c. Enter a new workflow name, if necessary.
   d. Optional – enter an internal-only workflow description.
   e. Optional – enter a workflow description that will display in Oracle Site Select LITE. Format the text as preferred.
   f. Optional – enter a completed workflow message that will display in Oracle Site Select LITE. Format the text as preferred.
   g. From the **Site task Library** on the left, click (+) to the right of any task that you want to add to the **Workflow tasks** list in Section 3.
   h. In the **Workflow tasks** list, reorder tasks using the (⌃) and (⌄) buttons.
   i. Optionally change any **Task names** displayed to sites (50 character maximum; supported special characters are: `1234567890-=~!@#$%^&*()_+[]\;',./{}|:"<>?).
   j. For each task, add **Task information** text that will display for the task in Oracle Site Select LITE. Format the text as preferred. ***Exception***: For "Internal workflow tasks" only, Task information displays to a Oracle Site Select user on the "Complete tasks on behalf of site" page, and Oracle Site Select LITE will display the text you enter into the "Site display information" field instead.
   k. 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).
   l. For CDA tasks, indicate a default countersigner (if any) and indicate the document type. If preferred, enable the option to Send the finalized CDA via email attachment.
   m. 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.
   n. If necessary, you can remove any tasks by clicking **X** next to the task name.
5. Click **Done**.

Configure account-level workflow templates

If you have account setup permissions, 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. In the top navigation bar, hover over **account** and select **workflow configuration**.
2. In the left panel, click plus (+) to add a new template.
3. Enter a unique **Workflow template name** (required).
4. Enter an internal-only **Workflow description**.
5. If preferred, check the box to allow digital signatures on CDA documents.
6. Enter **Study workflow information** text that will display in Oracle Site Select LITE. Format the text as preferred.
7. Enter a **Completed workflow message** that will display in Oracle Site Select LITE. Format the text as preferred.

8. In the Workflow Tasks section, click **Add workflow task** to display a "New workflow task" form.
9. In the task form, select the **Task type**. The form updates as necessary to display any unique options and fields for the task. Complete fields as necessary and repeat to create all tasks desired for the workflow template.
10. Click and hold order (☰) to drag and drop tasks into the preferred order.
11. Scroll to the top of the page and click **Save**.

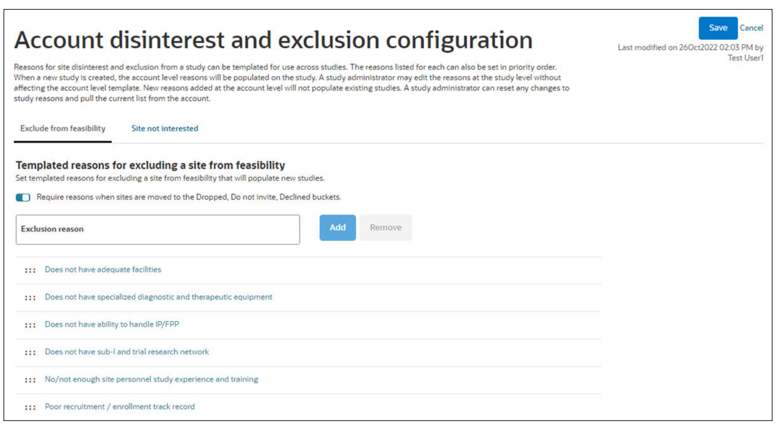
Defining study disinterest and exclusion reasons

When sites indicate they are disinterested in study participation, they must provide one or more reasons. Administrators can specify a list of reasons displayed to sites in Oracle Site Select LITE 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 your organization's account level. Reason configuration at the account level allows you to add and remove free text reasons, optionally switch on a setting to require reasons, and adjust default reasons to your preferred order.

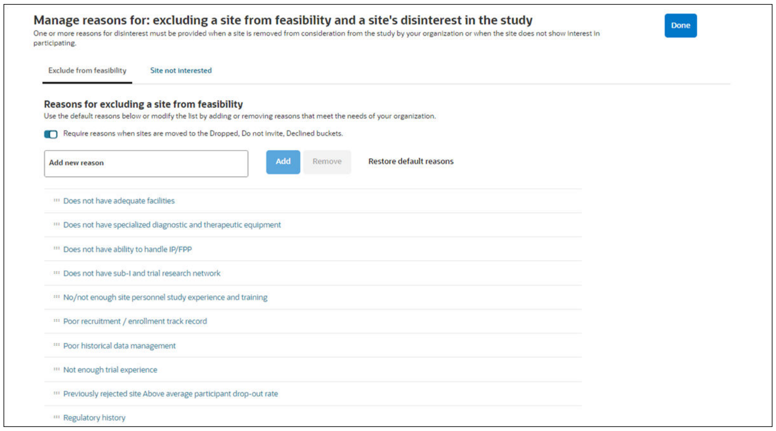
Configured account level reasons automatically populate for new studies in the order you define in the template. Study administrators can modify pre-populated reasons when setting up a new study without affecting the saved account template. Account level reasons can also be added or removed from the templates at any time without affecting the reasons populated on existing studies. The updated set of reasons will populate a new study created after changes are saved at the account level.

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

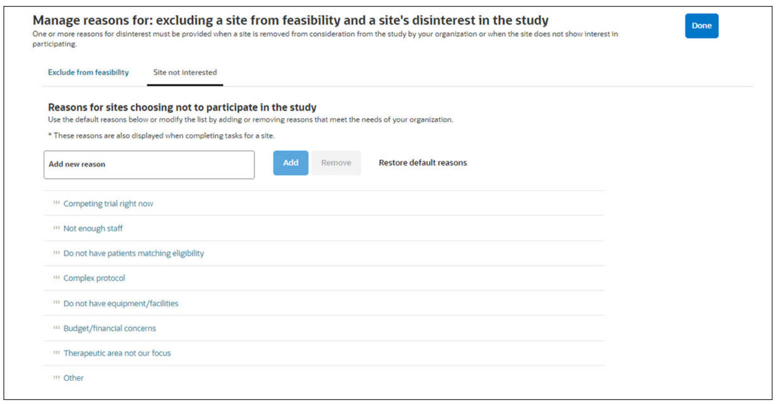


Defining the site decline list is easy: add new reasons (100 characters max.), drag-and-drop reasons to a new display order, and remove reasons as preferred by selecting and clicking "Remove." Administrators can also optionally require the Oracle Site Select user to specify a reason when excluding a 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.



On the study level page below, 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



- Configure account level study disinterest and exclusion reasons
  You can template reasons for site disinterest and exclusion at the account level. Configured account level reasons automatically populate for new studies in the order defined in the template. Study administrators can modify prepopulated reasons when setting up a new study without affecting the saved account template.
- Configure site decline reasons
  Provide one or more reasons for disinterest when a site is removed from consideration from the study by your organization.
- Configure study disinterest reasons
  Manage the list of available site study disinterest reasons. Depending on the needs of your organization, you can use default reasons, add new reasons, and delete reasons that don't apply.

Configure account level study disinterest and exclusion reasons

You can template reasons for site disinterest and exclusion at the account level. Configured account level reasons automatically populate for new studies in the order defined in the template. Study administrators can modify prepopulated reasons when setting up a new study without affecting the saved account template.

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

1. In the top navigation bar, hover over **account** and choose **Disinterest and exclusion**.

2. Click the **Exclude from feasibility** or **Site not interested** tab.
3. If you clicked Exclude from feasibility, optionally toggle the **Require reasons...** switch ( ) to the on (right side) position. This switch does not apply to the Site not interested tab. If you clicked Site not interested, optionally toggle the **Limit site responses**... switch to the on (right side) position. This switch does not apply to the Exclude from feasibility tab.
4. To add a custom reason, type the reason in the **Exclusion reason** or **Site disinterest reason** field. Click **Add**.
5. 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**.
6. 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.
7. At the upper right, click **Save**.

Configure site decline reasons

Provide one or more reasons for disinterest when a site is removed from consideration from the study by your organization.

1. In the top navigation bar, hover over **setup** and choose **manage reasons for study exclusion/disinterest**.
2. On the **Manage reasons for: excluding a site from feasibility and a site's disinterest in the study** page, click the **Exclude from feasibility** tab.
3. Optional: If you want to make specifying a site decline reason mandatory for users, click the **Require reasons when sites are moved to the Dropped, Do not invite, and Final decline buckets** switch control to enable.
4. Review the default list of site exclusion reasons, 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 reasons, use the handle to the left of the reason text to drag and drop to the preferred position.
   d. To discard all changes, click **Restore default reasons**.
5. Click **Done**.

Configure study disinterest reasons

Manage the list of available site study disinterest reasons. Depending on the needs of your organization, you can use default reasons, add new reasons, and delete reasons that don't apply.

1. In the top navigation bar, hover over **setup** and choose **manage reasons for study exclusion/disinterest**.
2. On the **Manage reasons for: excluding a site from feasibility and a site's disinterest in the study** page, click the **Site not interested** tab.
3. Review the default list of reasons a site might choose not to participate in the study, then:
   a. To add a new reason, enter the reason text in the **Add new reason** field (100 character max) and click **Add**.

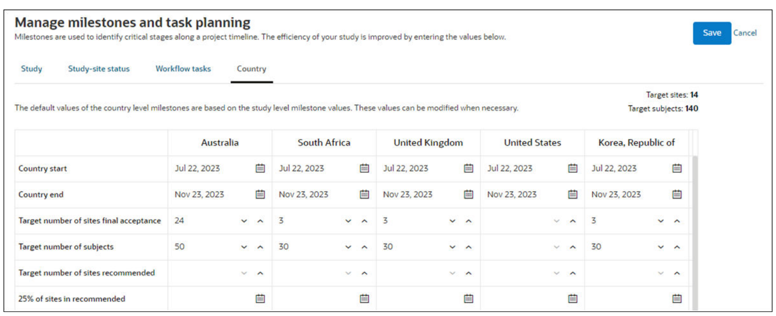
   b. To delete any default reason, select any reason from the list to populate the reason field. Click **Remove**.
   c. To reorder reasons, use the handle to the left of the reason text to drag and drop to the preferred position.
   d. To discard all changes, click **Restore default reasons**.
4. Click **Done**.

Defining study milestones

To ensure your team stays on track with key study accomplishments like site enrollment targets, define study milestones when you set up your study.

These 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 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 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. In the top navigation bar, hover over **setup** and click **milestones**.
2. On the **Study** tab, complete the **Project start date**, and **Project end date**, **Proposed site list finalized**, and **Target number of subjects** fields.
3. 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.

4. 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.
5. Click **Save**.

Defining site scoring parameters (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.

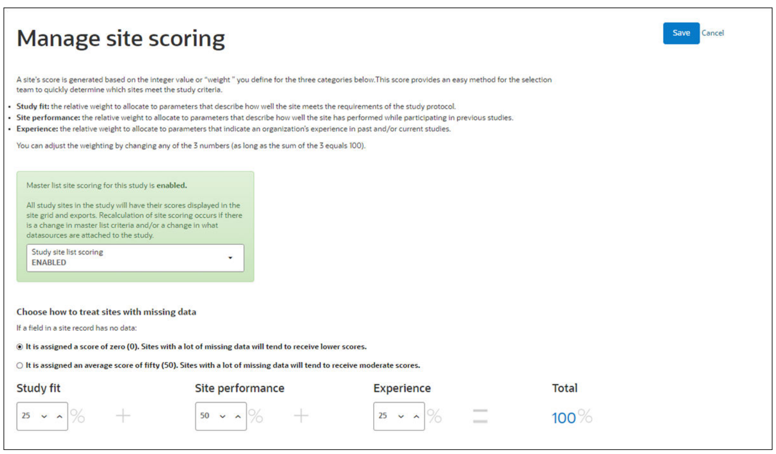
If your organization doesn't use site scoring for your existing studies, you can turn it off for your existing studies to improve site grid loading time. New studies will have site scoring turned off by default, and you can turn it on if preferred. The master list scoring control has a yellow highlight 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" text note at the upper left of the grid to see the last time the master list was built.



- Set site scoring parameters (weighting)
  The integer 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 site scoring parameters (weighting)

The integer 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.

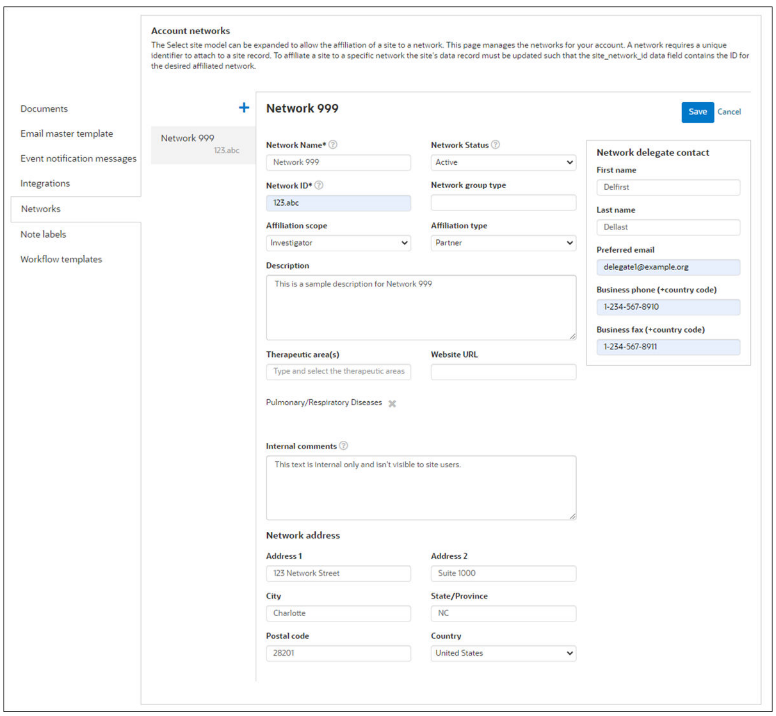
1. In the top navigation bar, hover over **setup** and click **site scoring**.
2. Confirm study site scoring is **Enabled**, or change control from **Disabled** to **Enabled**.
3. For empty data fields in site records, using the radio button, assign a score of 0 or 50.
4. At **Study fit**, **Site performance**, and **Experience**, indicate the relative importance of each criteria. The sum of the weighting you assign to all three categories must equal 100%.
5. Click **Save**.

4 Network management

Networks 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.).



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.

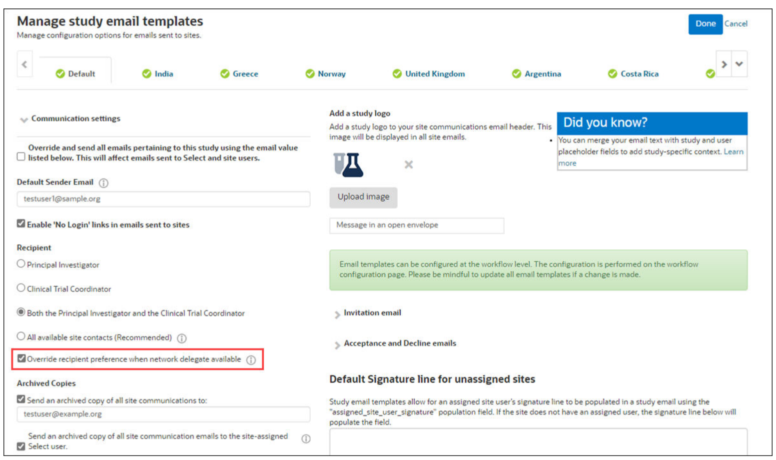
Site profile Network tab

When an account has at least one saved network profile, the Site profile and Site scorecard pages in Oracle Site Select and the Edit site profile page in Oracle Site Select LITE 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 Oracle Site Select LITE, as these fields are not intended for site users.

Networks and study invitations

When an account has at least one saved network profile, the Manage study email templates page Default template tab includes an "Override recipient preference when network delegate available" check box. The check box is enabled by default for new studies in accounts that have at least one configured network profile.

When the check box is enabled, and the site record is affiliated with a network, the network delegate contact is the only email recipient (listed as the only Study contact) to receive study invitation and correspondence emails. After invitation, the network delegate will be listed on the "Invitation email status" pop-over, and the delegate will be able to access Oracle Site Select LITE for the site's feasibility workflow. Study contacts may be updated after invitation to include additional site profile contacts with study access in Oracle Site Select LITE.



- Add a site network profile
  Add site network profiles at the account level by creating unique network records with a name, identifier, and other metadata.

Add a site network profile

Add site network profiles at the account level by creating unique network records with a name, identifier, and other metadata.

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

1. In the top navigation bar **account** menu, click **networks**.
2. Click the plus button to add a new site network.
3. Enter a **Network Name** (required).
4. Enter a **Network ID** (required).

5. Complete, as applicable, all remaining fields. Note that the **Network delegate contact** section affects study invitations sent to sites associated with the network.
6. Click **Save**.

5 Authentication and Data Integration

Oracle Site Select provides optional integration solutions at access (user authentication), data (API), and application levels.

User Authentication

Oracle Site Select and Oracle Site Select LITE support two methods for user authentication:

1. Log in with username and password
2. Single Sign On (SSO)

Username and password

Manual login with username and password is the default user authentication method. This option allows for periodic password changes. Users can also manually change their passwords at any time using a reset option in their user profiles.

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 the customer’s trusted Identity Provider (IDP) system (e.g., an employee portal). An Oracle Site Select user who has a role with API and Authentication Management permission will manage the account’s Oracle Site Select IDP configuration.

SSO integration affects all users in the customer’s Oracle Site Select account. Once enabled, SSO authentication overrides the default username and password authentication, and all users in the account must access Oracle Site Select via SSO.

Login 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 logout, 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) - Oracle Site Select LITE users

SSO authentication allows sites to access their studies via integration between Oracle Site Select and an identity provider (IDP) application (e.g., a customer-managed portal). When the "Enable Select Lite" option has been enabled on the Study Details page, users who have permission to access the Authentication and API configuration page can configure SSO for sites in the "Authentication options" section of the page.

When a site accesses Oracle Site Select LITE 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 logout, Oracle Site Select LITE users who logged in:

- **With SSO** are redirected to their IDP
- **With user name and password** are redirected to the Oracle Site Select LITE login page

Single Sign On (SSO) - via integration with Oracle Identity Cloud Service

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.

An Oracle Site Select user with "API and Authentication Management" permission can configure this authentication on the “IDCS auth” account integrations subpage. Settings allow the user to specify:

- Enable/disable authentication - Disabled by default. When enabled, the user must complete the following required fields:
  - Entry point – The IDP URL
  - IDP public certificate – Security certificate file upload
  - Default role - Single selection drop-down list populated by the account's existing user roles

When the configuration user disables 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 a 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.

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

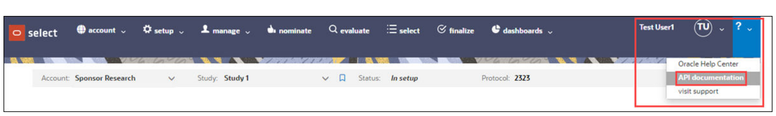
Data Integration APIs

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 above from a link in the Oracle Site Select application. Click the drop-down menu at the far right of the global navigation menu and choose **API documentation** to display the documentation in a new browser tab.



PUSH Service

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 endpointd(s) when an Oracle Site Select or Oracle Site Select LITE 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

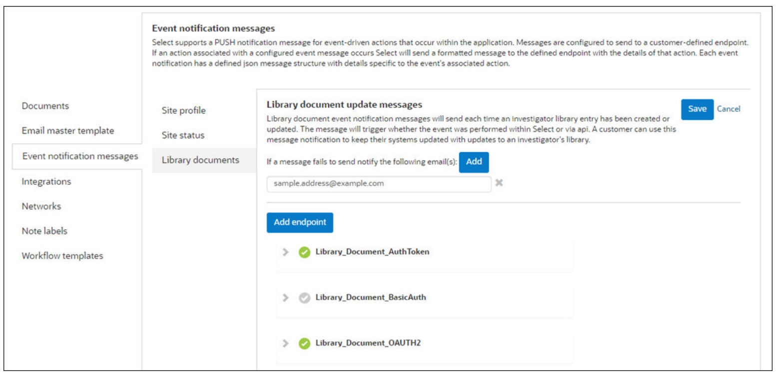
When an account has a primary composite datasource created, the account administrator can configure event notification messages that send each time an investigator library entry has been created or updated within Oracle Site Select, Oracle Site Select LITE, or via API. The PUSH service sends a message 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

Oracle Site Select administrative users who have permission to manage event notification messages access the configuration page from the “event notification” option in the Accounts menu. The page allows users to define message options for the Site status, Site profile, and Library document update event message types, as appropriate to the account.

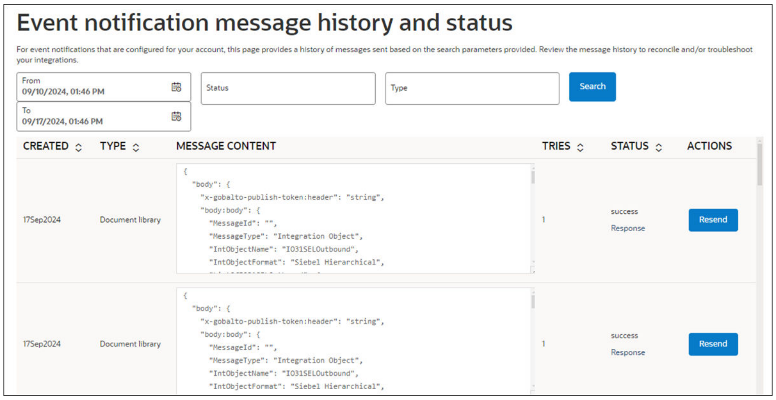


Event notification message history

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 displays when you select the "history and status" option from the account menu. Here you'll find a list of matching event messages sent outbound based on a specified date range, status, and type search criteria.

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.

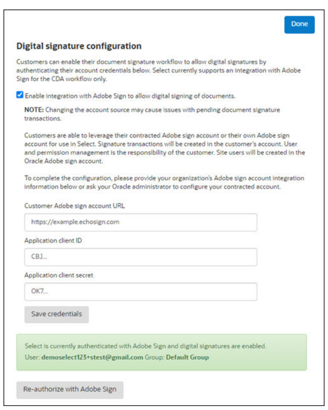


Digital signature configuration

An Oracle Site Select user who has a role with API and Authentication Management permission will configure authentication on the account's Authentication and API configuration page. Customers can use any contracted Adobe Sign account they wish by default, and user and permission management is the responsibility of the customer. Site users will be created in the Oracle Adobe Sign account.

To configure, the account administrator provides the customer'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 the customer's account credentials, Adobe Sign creates signature transactions in the customer's account. For example, in an Oracle Site Select environment configured with customer-provided account credentials, the customer 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 customer's EU Adobe Sign account.

In the customer-provided account credential model, customers have 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

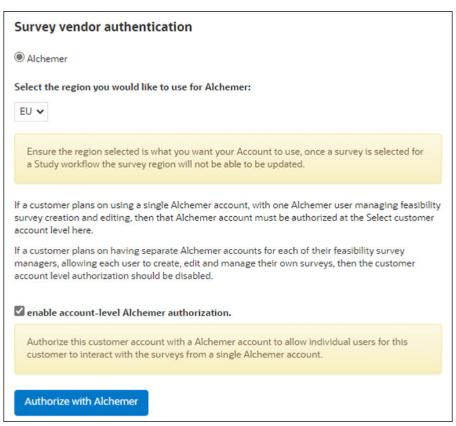
Oracle Site Select users who have permission to access the Authentication and API configuration page can configure Alchemer as the account's survey vendor.

The user can enable account-level authorization for Alchemer, if preferred. This configuration provides flexibility for authorization of a single or multiple survey vendor accounts as follows:

- **Enabled** – If the customer plans to use a single survey vendor account, with one Alchemer user managing feasibility survey creation and editing.
- **Disabled** – If the customer plans to use separate survey vendor accounts per study for each feasibility survey manager, allowing each user to create, edit and manage their own surveys.

Oracle Site Select customers outside of the United States can authenticate with the Alchemer EU server if appropriate. The “Survey vendor selection and authentication” section of the Authentication and API configuration page displays the region selector when Alchemer is the selected survey vendor.

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 the account survey vendor but account-level Alchemer authorization is not enabled. For example, 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.



- Enable Single Sign On (SSO) authentication
  Once enabled for your organization's account, SSO authentication overrides default username and password authentication, and all users in the account can then access Oracle Site Select via SSO.

- Enable Single Sign On (SSO) authentication for site users
  When enabled, this authentication method allows sites to access their studies via integration between Oracle Site Select and an identity provider (IDP) application (e.g., a customer-managed portal).
- Enable Single Sign On (SSO) authentication via Oracle Identity Cloud Service Integration
  When enabled and configured for the account, users can access Oracle Site Select and other licensed Oracle Identity Cloud Service applications using a single login portal.
- Enable User name and password authentication
  User name and Password authentication is the default authentication method. It is not necessary to complete this task unless you are reverting a Single Sign On (SSO) authentication setup for your organization.
- 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.
- 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 outbound PUSH messages
  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
  Customers 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.

Enable Single Sign On (SSO) authentication

Once enabled for your organization's account, SSO authentication overrides default username and password authentication, and all users in the account can then access Oracle Site Select via SSO.

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

1. From the **account** menu, click **integrations**.
2. In the **Local/SSO auth** section, click the **Single Sign On (SSO)** radio button.
3. At **Entry Point**, enter the identity provider entry point URL.
4. At **IDP public certificate**, click **Attach**. Browse to the location where you've stored the certificate and click the file to upload.

5. 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.
6. 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.
7. Optional: Check the **Enable SSO for invited sites** check box.
8. Optional: At **Select Lite Entry Point**, enter the identity provider entry point URL.
9. Optional: At **Select Lite IDP public certificate**, click **Attach**. Browse to the location where you’ve stored the certificate and click the file to upload.
10. Click **Save**.

Enable Single Sign On (SSO) authentication for site users

When enabled, this authentication method allows sites to access their studies via integration between Oracle Site Select and an identity provider (IDP) application (e.g., a customer-managed portal).

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

1. From the **account** menu, select **integrations**.
2. Below the **Integrations** heading, click **Local/SSO auth**.
3. Under **Choose an authentication method**, click **Single Sign On (SSO)**.
4. Check the box for **Enable SSO for invited sites**.
5. Under **Select Lite Entry Point**, enter the identity provider URL.
6. Click **Save**.

Enable Single Sign On (SSO) authentication via Oracle Identity Cloud Service Integration

When enabled and configured for the account, users can access Oracle Site Select and other licensed Oracle Identity Cloud Service applications using a single login portal.

You must have a role with *Authentication and API configuration* 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. From the **account** menu, click **integrations**.
2. In the **IDCS auth** section, check the **Enable Oracle IDCS authentication** check box.
3. At **Entry Point**, enter the entry point URL.
4. At **IDP public certificate**, click **Attach**. Browse to the location where you’ve stored the certificate and click the file to upload.
5. 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.
6. Click **Save**.

Enable User name and password authentication

User name and Password authentication is the default authentication method. It is not necessary to complete this task unless you are reverting a Single Sign On (SSO) authentication setup for your organization.

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

1. From the **account** menu, click **integrations**.
2. In the **Local/SSO auth** section, click the **User name and password (standard)** radio button.
3. Click **Save**.

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 global navigation menu, click the down arrow.
2. Click **API documentation**.

The API documentation site opens in a new browser tab.

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.

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

1. From the **account** menu, click **Authentication and API configuration**.
2. At the right, in the API configuration section, click **Generate token**.

The token displays in the API token field.

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. From the **account** menu, click **Authentication and API configuration**.
2. At the right, in the API configuration section, click **Regenerate token**.

The updated token displays in the API token field.

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. From the **account** menu, click **Authentication and API configuration**.
2. At the right, in the API configuration section, click the **API token** field to highlight the token.
3. Copy the token using Ctrl + C or Command + C on your keyboard

Enable outbound PUSH messages

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. From the **account** menu, click **event notification**.
2. On the left side of the Event notification messages page, select **Site profile**, **Site status**, or **Library documents**.
3. Expand the configuration panel, and click the radio button to enable the message type (enabled state is blue).
4. Enter the preferred **End point name**.
5. At **Endpoint URL**, enter the customer-managed integration endpoint URL.
6. Optionally check Wrap message tag for **Siebel OpenAPI Integration**. If enabled, complete the **OpenAPI object name** and **OpenAPI root** fields.
7. At **Authentication Type**, choose either **Authentication token** or **Basic authentication**, or **OAuth 2.0**.
8. 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**, **Scope**, **Grant type**, and **Client authentication** method
9. At the upper right of the page, click **Save**.

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. In the top navigation bar, hover over **account** and select **history and status**.
2. Use the date, status, and type filters to refine the event messages list.

3. Click a message to view sending details.
4. You can optionally copy a message's response object details when necessary. In the **Status** column, click the **Response** link to view the object details in a modal window.
5. 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

Customers 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. From the **account** menu, click **Authentication and API configuration**.
2. In the **Digital signature configuration** section, click the “**Enable integration with Adobe Sign**…” check box.
3. Enter the **Customer Adobe sign account URL**, **Application client ID**, and **Application client secret**, then click **Save credentials** and **Authorize with Adobe Sign**.
4. At the upper right, click **Done**.

6 Account management

Configure account specific settings as preferred for your organization.

- General account settings
  Specify preferred labels for Oracle Site Select LITE account login/no login buttons, optionally specify an alternate support link, and configure display behavior for closed studies.

General account settings

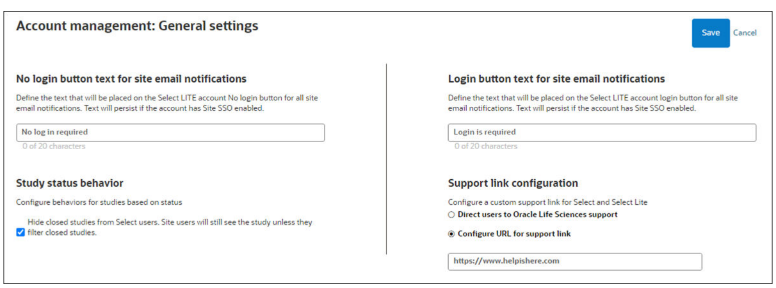
Specify preferred labels for Oracle Site Select LITE account login/no login buttons, optionally specify an alternate support link, and configure display behavior for closed studies.

No login and Login button text configuration

On the Account management: General settings page, you have the option to define the text label that displays on the Oracle Site Select LITE account "No login" and "Login" buttons for site-facing communications. Specify up to 20 alphanumeric characters, for the button labels. Special characters are allowed; however, rich text formatting is not supported. Note that the text persists if you organization's account has site single sign on (SSO) enabled.

All site-facing email notifications that include an Oracle Site Select LITE login (or no login) option will use the button text you specify. These emails include, but are not limited to:

- Site welcome invitation
- New site user email digest
- CDA requires resubmission
- CDA final approval



Hide studies from view

When you have permission to access the Account management: General settings page, you can optionally turn on a setting to hide studies that are in Closed or Canceled status. When turned on, Closed and Cancelled 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 myDashboard page.

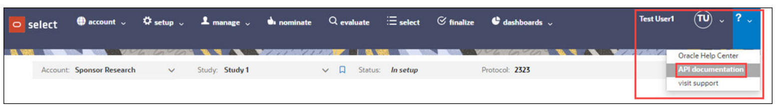
The Study details page includes an optional "Study close message for site users" section where study managers can create a message to display in Oracle Site Select LITE. A message saved in that section displays in Select LITE when the study's status is Closed or Cancelled and the account level setting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

Support link configuration

If your organization prefers provide its own support for your Oracle Site Select and Oracle Site Select LITE users, you can configure a custom support URL to display in the global navigation drop-down menu. 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 Oracle Site Select LITE global navigation automatically redirect to the configured URL.

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

- In Oracle Site Select and Oracle Site Select LITE, 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 custom button text for site email notifications
  You can optionally specify text to replace the default "No login" and "Log in required" button text in email notifications sent to sites.
- 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 application header in Oracle Site Select and in Oracle Site Select LITE.

Configure custom button text for site email notifications

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

You must have a role with *API and Authentication 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. From the **account** menu, select **general**.
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 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 application header in Oracle Site Select and in Oracle Site Select LITE.

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

1. From the **account** menu, click **general**.
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**.

7

Import and Manage Data

This section, which is intended for users who have the datasource manager role, describes Oracle Site Select supported datasources and describes how to map and import regular datasources.

- Understanding composite and regular datasources
  Oracle Site Select supports use of composite (complex and structured) and regular (flat) datasources.
- Managing multiple datasources
  Data merges can be completed by different methods when a study has multiple attached datasources. Standard Oracle Site Select columns have predefined data merging while customer datasource managers define data merging for custom columns. Additionally, when a study has multiple datasources, datasource managers can define datasource priority.
- Citeline datasource
  When subscribed and configured, one or more studies in an account can include the curated Citeline datasource.
- Mapping and importing regular datasources
  Oracle Site Select users who have permission to access the Data source management page have the ability to create, import, and publish one or more study data sets.
- Disambiguating data
  The Oracle Site Select data disambiguation match resolution feature surfaces possible matching records that require human review and intervention to resolve.
- Performing targeted investigator and trial searches
  With the appropriate user permissions, you can find and add investigators and trials directly to the Nominate bucket.

Understanding composite and regular datasources

Oracle Site Select supports use of composite (complex and structured) and regular (flat) datasources.

Composite

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

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.

Viewing datasource content

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 also search the record grid. Enter a value in the search field, and 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

Viewing records

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).

Editing or deleting records

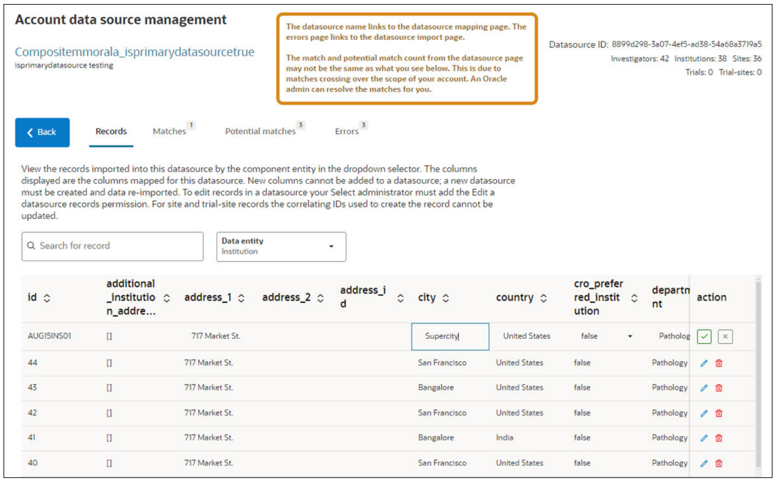
When you have *Edit a datasource record* permission, you'll see a fixed Action column with Edit and Delete action icons at the far right of the records table. Note that this permission is a user role permission that doesn't apply to Teams. The permission allows you to edit regular and composite datasource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

You can also delete a record from a datasource, and you'll need to confirm this action. For regular datasources, deleting a record removes the record from the datasource. For composite datasources, please plan carefully for the following outcomes:

- Deleting a composite investigator or institution record that has a site correlation will cascade delete the site and any affiliated trial-site record(s)
- Deleting a composite trial record that has a trial-site correlation will cascade delete the affiliated trial-site record(s)



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 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.

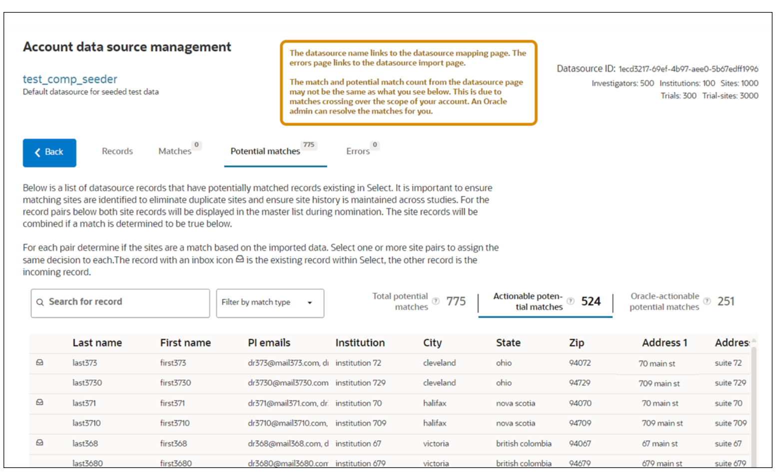
Only an Oracle administrator can see and act on potential matches or duplicates in a site profile datasource.

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 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 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.

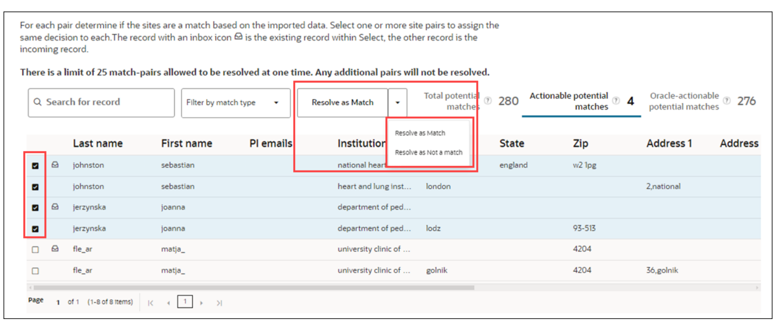
If you choose **Resolve as Match**, Select updates the records as it did previously, meaning:

- 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**, 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.



Managing multiple datasources

Data merges can be completed by different methods when a study has multiple attached datasources. Standard Oracle Site Select columns have predefined data merging while customer datasource managers define data merging for custom columns. Additionally, when a study has multiple datasources, datasource managers can define datasource priority.

Merging data

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.

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.”

Datasource priority

Datasource managers can adjust the priority of the study's site profile datasource. The datasource itself corresponds to the account or study level site profile datasource attached to the study.

On the **Choose data sources for <study name>** page, a Datasource manager 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").

After the Datasource manager saves the updated priority order, the site grid updates immediately to show the appropriate data. Site grid exports and Oracle Site Select reporting views also reflect the data displayed in the site grid after the priority order update.

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.

- Define regular datasources for a study

- 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.

Define regular datasources for a study

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. From the home page under **setup**, click **study data sources**.
2. 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.
3. To modify datasource ranking in right side list, drag and drop datasources to the preferred order.
4. 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.

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. On the **account** drop-down menu, click **account data sources**.
2. On the row for the datasource you want to clone, click the datasource name.
3. At the upper left, click the datasource name a second time.
4. At the far right, click **Clone datasource**.

Citeline datasource

When subscribed and configured, one or more studies in an account can include the curated Citeline datasource.

Oracle Site Select offers a study datasource with the full Citeline subscription. Oracle Site Select customers who have this subscription level can request that an Oracle administrator add this datasource to their studies. Please contact your Oracle project manager for subscription details.

Mapping and importing regular datasources

Oracle Site Select users who have permission to access the Data source management page have the ability to create, import, and publish one or more study data sets.

If you have the data source manager role in Oracle Site Select, you will have access to the Data source management page.

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 an existing datasource definition

On the Manage data source definition page, the Clone datasource option copies an existing datasource schema and reloads the page to display the copy with "_copy" appended to the name. On the copy, change the name and description as preferred.

The copying process does not replicate the data or sites in the original datasource; however, for flat/regular datasources, the datasource copy includes the data structure CSV file from the original datasource. You can overwrite the file with a new CSV and modify fields and field mappings in the copy as preferred.

Publish a regular datasource

Once data definition is complete, you can publish the datasource to your account in Oracle Site Select. The datasource will be private to your account.

Import to a regular datasource

For any published datasource in your account, you can import data in CSV format.

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.

Institution country name validation

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.

- Create a new regular datasource
- Import data for an unpublished regular datasource
- Map regular datasource fields to standard data fields
- Create custom data fields
- Publish a regular datasource

Create a new regular 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. On the home page, under **account**, click **account data sources**.
2. On the Account data source management page, click **Create new data source**.
3. On the Manage data source creation page, in section 1, enter the **Data source name** and **Description**.
4. Click **Import CSV** button.
5. Browse to the location where you've saved the CSV with all the fields in your datasource, and click **OK**.

Import data for an unpublished regular 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. On the global navigation bar under **account**, click **account data sources**. On the Account data source management page, you will see a list of all the datasources for your account. You can import data for Regular datasources marked "unpublished."
2. Click a datasource name. Below the **Account data source management** page heading, click the datasource name again.
3. On the **Manage datasource definition** page, click **Import CSV**.
4. The data fields in your data import CSV must match those of the data fields you mapped while creating the datasource.

Once you complete the procedure above, you will see a message that data is being imported and you will see a progress indicator under the Date column. Once the data import is complete, the imported date appears under Date column.

The imported data records are displayed in the Data tab in the Imported data preview table. If there are any errors in the source file, the error messages are displayed in the Error tab.

Map regular datasource fields to standard data fields

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. In section 2, **Map your data source fields**, in the **Your source data fields** subsection, the fields from your CSV display. Search for any field using the free text search box or by using the filters.
2. Find the unique identifier field and click the radio button to the right of the field.

   (Optional) Hover over the information icon ( ) to view a description of the Oracle Site Select field.

   (Optional) You can find matchable fields by viewing the matchlogic icon ( ). Oracle Site Select uses matching fields to identify matching sites in other data sources.
3. To map a field to a Oracle Site Select standard field, first find your field in left column ("Your source data fields").
4. Next, find the associated Standard field in the middle column ("Select data fields").
5. Now, drag the source data field onto the corresponding Oracle Site Select data field.

When you've completed the procedure above, you'll see that under the field name, the name of the field it was mapped to displays. You can remove the mapping by clicking delete ( ).

Create custom data fields

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.

If you can't find an appropriate Oracle Site Select standard field to map your source data field to, you can create a custom data field.

1. To create a custom field, first find your source data field in the left column of Step 2.
2. Click + drag your source data field onto the **Create a custom data field** section in the Step 2 middle column.
3. In the right column, Step 3, the name of the newly created custom field displays. You can change the column's **Display name** and enter a short **Description**.
4. By default, Oracle Site Select will pick a data type based on the sample value included in your CSV. Change the **Data type**, if necessary, by picking a different one from the drop-down menu.
5. Next, pick a **Category** and **sub-category** for the field. The categories determine if the field is just for searching or used for both searching and scoring. Click the **computer monitors** ( ) to view category and sub-category descriptions.
6. Pick a **section** for your field. If none of the sections in the drop-down apply to your field you can create a new section by typing the section name in the free text field.

7. If you want to use your field for filtering, click the check box. This field will become visible in the search criteria.
8. If you want to use your field for investigator scoring, click the checkbox, and choose a scoring methodology. This field will affect the search criteria.

All changes are automatically saved. Click the **computer monitor** ( ) at any time to view a setting's description.

Publish a regular 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. On the top right of the Manage data source definition page, click the **Publish** button.
2. You will see a pop-up asking you to confirm your action. Click **Publish** again to publish the datasource to your account.

Disambiguating data

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.

- Disambiguate data

Disambiguate data

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. On the home page, under **account**, click **data source matches**.
2. On the **Resolve data source matches** page, use the **Data Source** drop-down list to search for and select the datasource if necessary.
3. A list displays potential matching records in pairs. Bold fields indicate a match. Review the data for each pair of potential matching records.

4. If the records match, click **Yes** to resolve the potential match and display the merged record in the master list.
5. 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.

Performing targeted investigator and trial searches

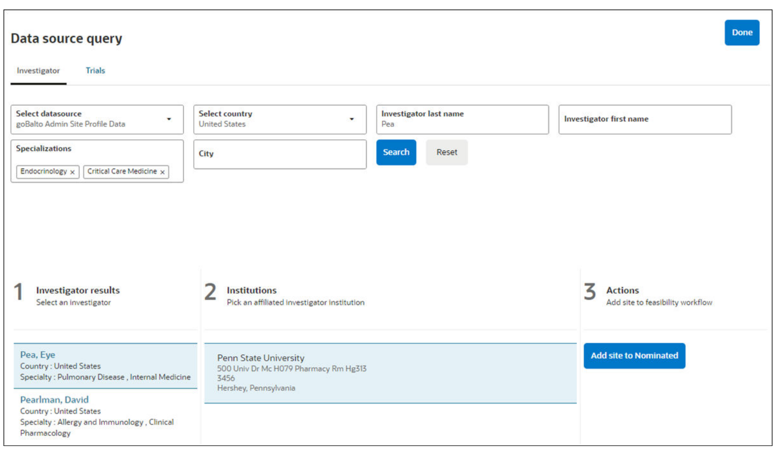
With the appropriate user permissions, you can find and add investigators and trials directly to the Nominate bucket.

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. This option is available under the global navigation bar's "manage" menu, with "data source query."

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
- Perform a targeted trial search

Perform a targeted investigator search

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

1. On the home page, under **manage**, click **data source query**.
2. 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.
3. Click **Search**.
4. In the lower portion of the page, at **1 Investigator results**, select an investigator from the results list.
5. At **2 Institutions**, choose the investigator's affiliated institution.
6. 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.
7. Click **Done**.

Perform a targeted trial search

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

1. From the home page, on the **manage** menu, click **data source query**.
2. 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.
3. Click **Search**.
4. In the lower portion of the page, at **1 Trials**, select a trial from the results list.
5. At **2 Sites**, pick the site(s) you want to import into the study workflow.
6. 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.
7. Click **Done**.

8 User Accounts and Roles

This section, which is intended for users in a study administrator or study manager role, describes how to manage user accounts, roles, and permissions in Oracle Site Select.

- Performing super user tasks
  A member of your organization is the Oracle Site Select super user. This individual can add users and assign roles that determine the tasks members of your study team can complete.
- Managing user accounts
  If you have the appropriate permission, you can manage role and permission settings for individual Oracle Site Select users and user teams.
- Creating new roles and adding permissions
  When you have the appropriate permission, you can create new roles and specify individual permissions associated with the new roles.
- Managing roles
  With the appropriate permission, you can add and edit user roles either individually or in bulk.

Performing super user tasks

A member of your organization is the Oracle Site Select super user. This individual can add users and assign roles that determine the tasks members of your study team can complete.

If you are the super user, you will receive an email notification with information about logging into Oracle Site Select. Your first task is to add user accounts for other study team members. Each team member you add receives an email notification with a link to access Oracle Site Select. For security reasons, the email notification link is valid for a limited time.

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 assign team members to one or more roles for various studies.

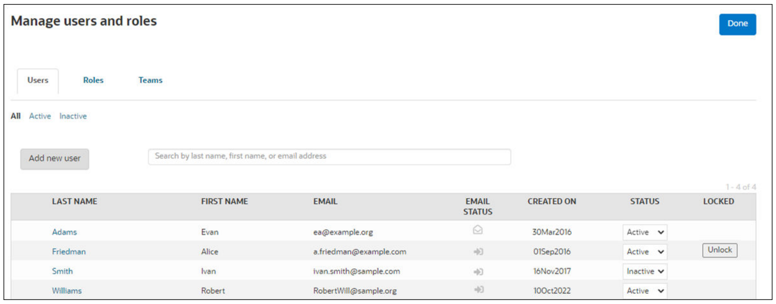
Managing user accounts

If you have the appropriate permission, you can manage role and permission settings for individual Oracle Site Select users and user teams.

On the Manage users and roles page, you can access settings for individual users, roles, or teams using the tabs above the grid. You'll also find options to filter the lists. For instance, you can filter the list to All, Active, or Inactive user accounts on the Users tab.

If you want to know the status of a user's activation and unlock emails, hover over the status icons in the Email Status column. Tool tip text shows the user's most recent action for the email if any.

If you want to prevent a user from accessing Oracle Site Select, you can change that user's Status from Active to Inactive using the Status controls on the Users tab.



- Add new team members
- Add or change a team member's name and status

Add new team members

1. In the top navigation bar, hover over **account** and select **users and roles**.
2. Click **Add new user**.
3. To make the new team member inactive when their account is created, at **Status**, select **Inactive**.
4. Enter the team member’s first and last name.
5. Enter the team member’s email address.
6. Click **Create user**.

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

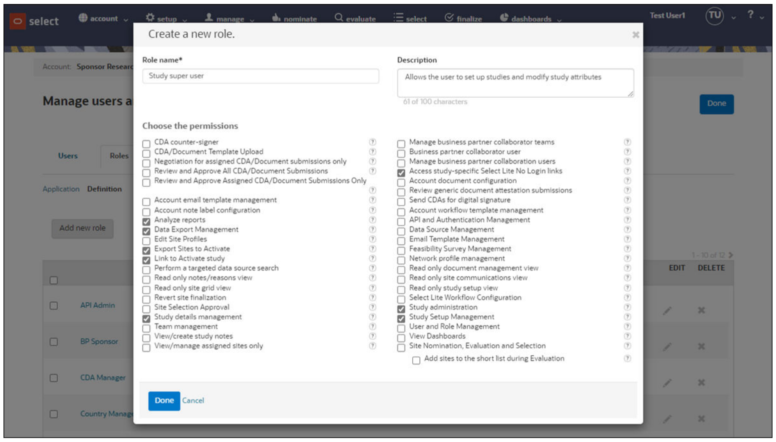
Add or change a team member's name and status

1. In the top navigation bar, hover over **account** and select **users and roles**.
2. Click the user’s last name.
3. Change the user’s first name, last name, or status.
4. Click **Update user**.

Creating new roles and adding permissions

When you have the appropriate permission, you can create new roles and specify individual permissions associated with the new roles.

To create a new role, enter the Role name and optional description. Check the box next to each permission you want to include in the role. Permission descriptions display when you hover over the question mark to the right of each permission name.



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 Oracle Site Select LITE 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 myDashboard.
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.
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).

Permission	Description
Data Source Management	Create and manage private datasources.
Edit Datasource Record	Edit and delete data source records from the data source details page.
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.
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 approvals area from the global "manage" menu.
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 approvals page.
Review and Approve Assigned CDA/ Document Submissions only	Approve fully executed CDAs or Documents.
Review generic document attestation submissions	Output details for a generic document attestation submission to a file in PDF format.
Select Lite Workflow Configuration	Configure Oracle Site Select LITE 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.

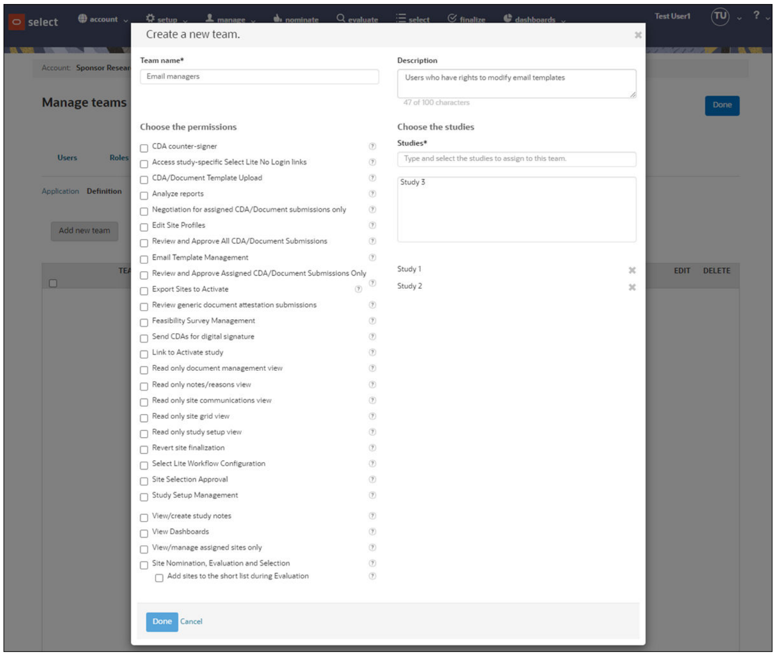
Permission	Description
Site Selection Approval	Approve sites for invitation to participate and for activation.
Send CDAs for digital signature	Assign CDA signers and send a CDA for digital signature.
Study administration	Set and modify a study's Status and Type values in the study setup process.
Study 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 myDashboard 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

- Study level permission
- Site level permission
- Oracle Site Analyze reports permission
- Read only permissions

Study level 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 "teams" option under the global account menu.

Through an interface similar to Role creation, study administrators will specify a unique team name and choose one or more permission(s) for the team members. In addition, the team defines one or more studies within the account that the team members can access. Administrators can optionally create a team description of up to 100 characters.



When the team has been created, administrators can then assign the team to one or more individual users. 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**

Administrators should 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.

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 dashboard menu, but the Analyze reports link will not be listed in the drop-down menu.

The *Analyze reports* permission also automatically provisions and permissions the user's Tableau 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
- If the user is assigned to specific studies, the user can see only the reports data for assigned studies
- Create or update a team
- Restrict study level access

- Restrict site level access

Create or update a team

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

1. In the top navigation bar, hover over **account** and select **teams**.
2. On the **teams** tab, click **Definition**.
3. To add a new role, click **Add new team**, or to change an existing team, click the pencil (edit) icon.
4. At **Team name**, add or enter a unique name for the team.
5. (Optional) At **Description**, enter a brief description.
6. Under **Choose the permissions**, check the box next to each permission you want to assign to the team. Hover your mouse over the question mark(s) to see a brief description of permission attributes.
7. Under **Choose the studies**, type the study name(s) and select to assign to the team. Once selected, the studies display below the "Studies" field. To remove a study from the list, click the "**X**" icon to the right of the study name.
8. Click **Done**.

Restrict study level access

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 as described below.

1. Create a team.
2. On the **Teams** tab, search for a user. In the results list, click **Change team** to the right of the user name.
3. Check the box to the left of the team(s) you want to apply for the user.
4. Click **Done**.

Restrict site level access

You must have a role with *Team Management* permission to complete this task. Additionally, you must have a team available to complete this procedure. See the "Create or edit a Team" procedure, if necessary.

1. Create a team.
2. On the **Teams** tab, search for a user. In the results list, click **Change team** to the right of the user name.
3. Check the box to the left of the team(s) you want to apply for the user.
4. Click **Done**.
5. On the site grid, assign the team member to sites.

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 on the Select and Finalize Site progress subtabs

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 the Login link, Resend invite, and Admin invite columns in the INVIT RCVD site grid modal (Select and Finalize steps)
- 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 approvals area from the global manage menu. The auditor user can access all document types and countries for the study within the Document approvals 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 approvals page. The user will not have the ability to:

- Click on any icon/action in the Actions column
- 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 from the "manage" menu. 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 a message (open the message compose page)
- Toggle the "star" column on or off
- 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.

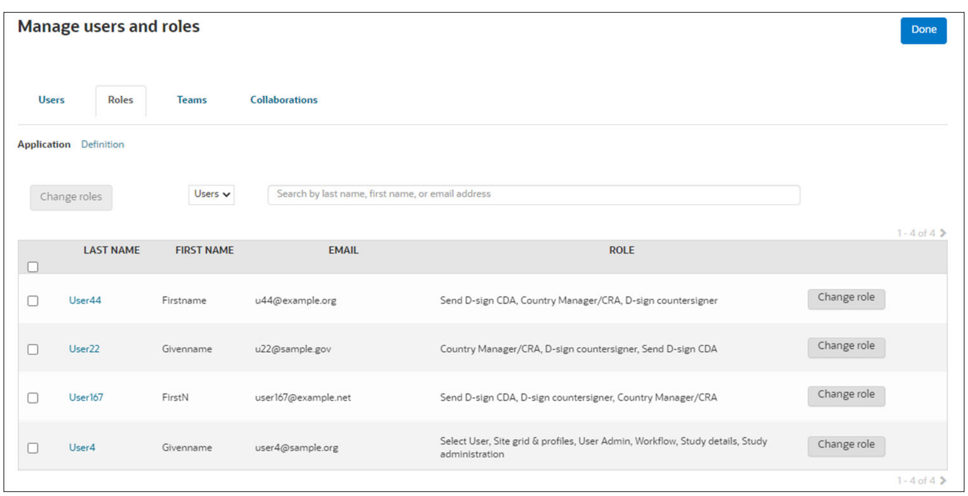
Unlike other read only permissions described above, the Read only study setup permission can be assigned to a role or team.

> **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.

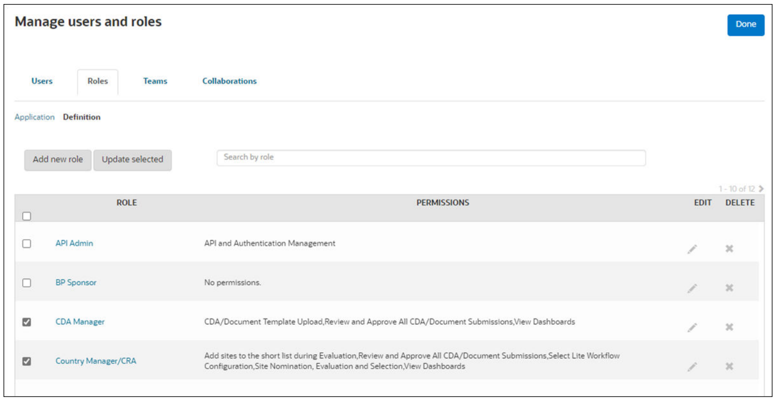
Managing roles

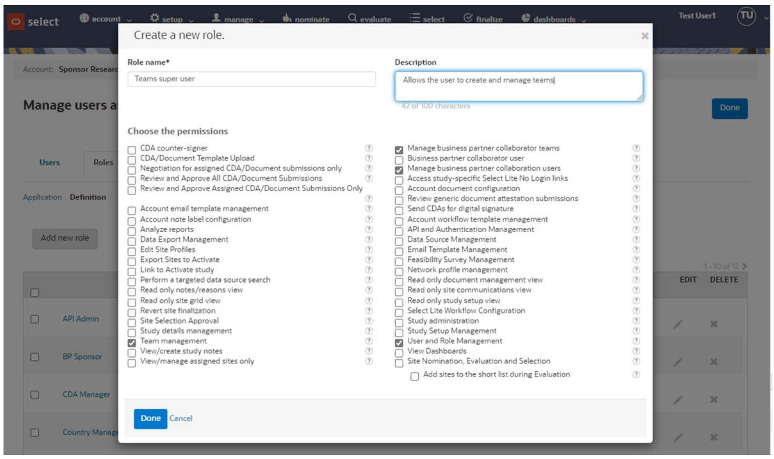
With the appropriate permission, you can add and edit user roles either individually or in bulk.

On the Roles tab, use the Application area to add or edit a role for individual users. You can also make changes in bulk by clicking the check box to the left of multiple user last names and clicking the Change roles button.



On the Roles tab, use the Definition area to define a new role, edit an existing role's permissions, or delete an unnecessary role.





- [Add or update roles](#)
- [Assign team members to a role](#)

Add or update roles

1. In the top navigation bar, hover over **account** and select **users and roles**.
2. Click **Roles**.
3. Click **Definition**.
4. To add a new role, click **Add new role**, or to change an existing role, click **Update selected**.
5. At **Role name**, enter a unique name for the role.
6. At **Description**, enter a brief description.
7. Check the box next to each permission you want to assign to the role. Hover your mouse over the question mark(s) to see a brief description of permission attributes.
8. Click **Done**.

Assign team members to a role

1. In the top navigation bar, hover over **account** and select **users and roles**.
2. Click **Roles**.
   a. To assign a role for a single team member, click the checkbox to the left of the last name then click **Change role** to the far right and select the role you want to assign.

b. To assign a role to multiple team members, check the box next to each name, then click **Change roles** (above the user list) and select the role you want to assign.

9
Site Selection

This section, intended for country list managers and project managers, details the four steps in the Oracle Site Select site selection process:

1. nominate
2. evaluate
3. select
4. finalize

- Site selection progress
  You, other members of your study team, sites, and other institution representatives may participate in the site selection process in various ways as the site progresses through the four selection steps.
- Oracle Site Select guides you through the four site selection steps
  Click a notification, a tab at the top of any Oracle Site Select page, or one of the progress chevrons to view a master list or a list of sites that have progressed through various steps in the site selection process.
- Working with the site grid
  The site grid is your configurable view of sites in each site selection bucket state. With just a few clicks, you can optionally adjust displayed columns and filter data to the view that works best for you.
- 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.
- Using notes to communicate
  Using notes is an easy way to communicate with your team members about a specific study or site.
- Site profile shows performance and history
  Site profiles store extensive detail about a specific site's contact information, trial history, related facilities, and more.
- Step 1: 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.
- Step 2: Evaluate
  Review and act on the list of sites you or other members of your team have nominated.
- Step 3: Select
  Review site information in site progress, survey analysis, and site detail views and choose the sites that will advance to the next step in the site selection process.
- Step 4: 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

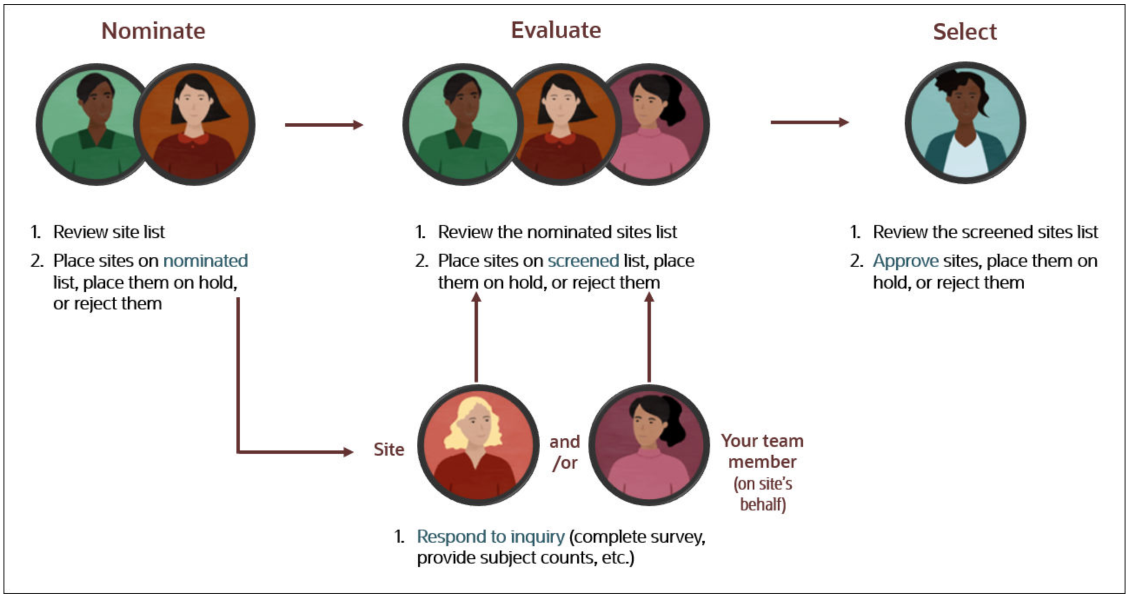
sites to Oracle Site Activate and view those study sites within the Oracle Site Activate application.

Site selection progress

You, other members of your study team, sites, and other institution representatives may participate in the site selection process in various ways as the site progresses through the four selection steps.

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 (such as sign the CDA or review the protocol.) If your sites choose not to use Oracle Site Select LITE to upload files and complete tasks, you may perform tasks and update status on their behalf.



Oracle Site Select guides you through the four site selection steps

Click a notification, a tab at the top of any Oracle Site Select page, or one of the progress chevrons to view a master list or a list of sites that have progressed through various steps in the site selection process.

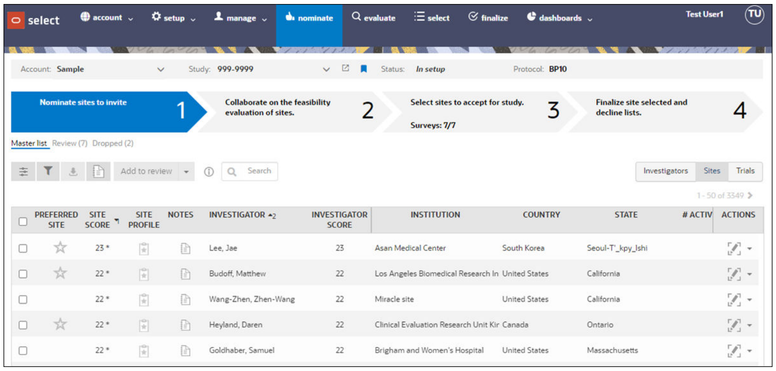
The site selection steps below describe general functionality. Your user role and permission levels may affect the actions available to you.

Nominate – Perform a first pass by sorting sites into review, short list, and dropped status

Evaluate – Collaborate to sort sites into nominated, short list, on hold, and do not invite

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 tasks, feasibility survey data, and site details.

Finalize – See sites in final acceptance and final decline. Send final acceptance or final decline emails to the sites.



Working with the site grid

The site grid is your configurable view of sites in each site selection bucket state. With just a few clicks, you can optionally adjust displayed columns and filter data to the view that works best for you.

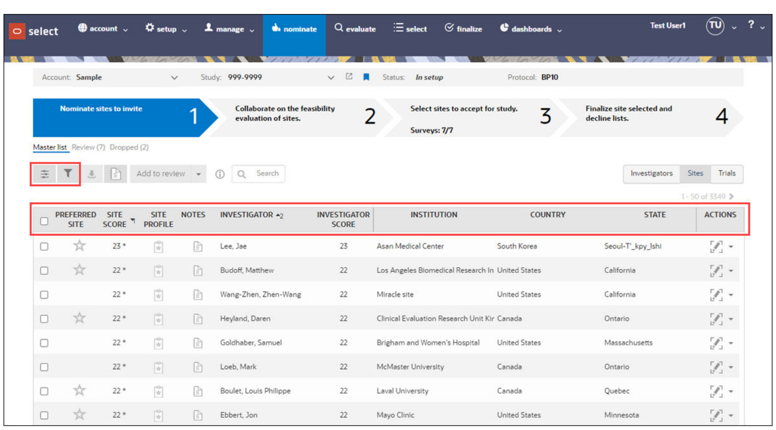
All four of the site selection steps display site lists in a grid format. You can adjust the displayed data using column and filter options (described below). You can also navigate between the four selection steps by clicking the chevron graphics above the site grid. The step 3 chevron is unique in that it includes clickable "Surveys #/#" text 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 4 selection steps.

To adjust data displayed in any of the site grids, click the column selector icon to choose additional columns for display.

- Sort columns by clicking a column heading
- Sort multiple columns by pressing the Shift key and then clicking column titles
- 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.

If you choose sort the site list by multiple columns (by holding down Shift and clicking multiple column headers), Oracle Site Select indicates the sort order next to the column header.

Click the filter selector icon to choose criteria and values to include. 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.



Site score: To see how the score was calculated, choose **View site profile** from the **Actions** menu, or click the site profile icon.

Site profile: Click the profile icon to view the scorecard, contact information, patient demographics, trial history, trial performance, and facility information.

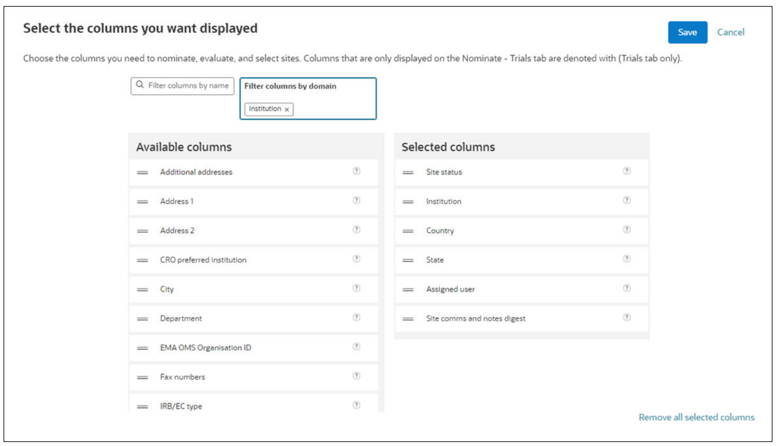
Notes: Click the note icon to add notes, see the notes history, and reason(s) for changes to site status. A plus sign on the note icon indicates a note was entered.

Actions: Depending on the selection step, click the Actions icon to see a list of operations you can perform for that step, such as view/edit profile and complete tasks for the site.

Column selector

Column selections help you view data in the site grid based on your preference and applicable data for each step. Specify the columns you want to display in the grid, and order the columns as preferred.

Site grid column display



Oracle Site Select retains your column settings from session to session. You can adjust the displayed columns at any time by clicking the column selector ( ) to return to the selection page.

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 the step 2 (evaluate), Nominated site grid; these fixed 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	Investigator	Investigator score, Notes, Investigator, **<selected columns>**, Actions

Step	Bucket state(s)	Sub-tab	Fixed columns
nominate	Master list, Review, Dropped	Sites	Site score, Investigator score, Site profile, Notes, Investigator, **<selected columns>**, Actions
nominate	Master list, Review, Dropped	Studies	Site score, Investigator score, Site profile, Notes, Investigator, **<selected columns>**, Actions
evaluate	Nominated	N/A	Site score, Site profile, Notes, Investigator, Nominated by, **<selected columns>**, Actions
evaluate	Short list	N/A	Site score, Site profile, Notes, Investigator, Short list by, **<selected columns>**, Set workflow, Actions
evaluate	On hold	N/A	Site score, Site profile, Notes, Investigator, On hold by, **<selected columns>**, Actions
evaluate	Do not invite	N/A	Site score, Site profile, Notes, Investigator, Do not invite by, **<selected columns>**, Actions
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Site progress	N/A – column selector disabled
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Survey analysis	N/A – column selector disabled
select	Invited, Recommended, Selected, Back up, Not interested, Declined	Site details	Site score, Site profile, Notes, Investigator, Invited/Recommended/ Selected by, Last completed task, **<selected columns>**, Set workflow, Actions
finalize	Final acceptance	Site details	Investigator, Site profile, Notes, Site score, Selected by, Finalized by, **<selected columns>**, Acceptance email sent, Actions
finalize	Final decline	Site details	Investigator, Site profile, Notes, Site score, Finalized by, **<selected columns>**, Decline email sent, Actions
finalize	Final acceptance, Final decline	Survey analysis	N/A – column selector disabled

Site grid drawer

Workflow tab

When you have permission to complete tasks on behalf of sites, you'll see a Workflow option in the site grid Actions menu that opens the site grid drawer component from the right side of your screen. The drawer defaults to the Workflow tab and includes a Site notes tab, which you do not need explicit permission to access. At the top of the drawer, you'll see the Investigator's first name, last name, and Institution name as well as the site's assigned Oracle Site Select user. You can update the site assignment, if necessary, using the "Site assigned to" control.

Oracle Site Select users with the read-only site grid permission can view the site's Workflow tab, but actions are disabled because these users do not have the appropriate permission to make an update to the site.

Assigned workflow and close date

When the site's assigned workflow has a defined close date, you'll see the date just below the site assignment control. If you prefer, you can remove the workflow close date.

You can reassign a site to a different workflow if you have the required *Site nominate* permission; the Select workflow field provides an alphabetical list of available workflows. Oracle Site Select will display a confirmation window so that you're aware of the impact of the reassignment.

For a site that has been assigned a workflow but has not yet been invited, the task list will only contain the helper text "The workflow tasks for the site will be created when the site is invited to the study."

Workflow tasks

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
- 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

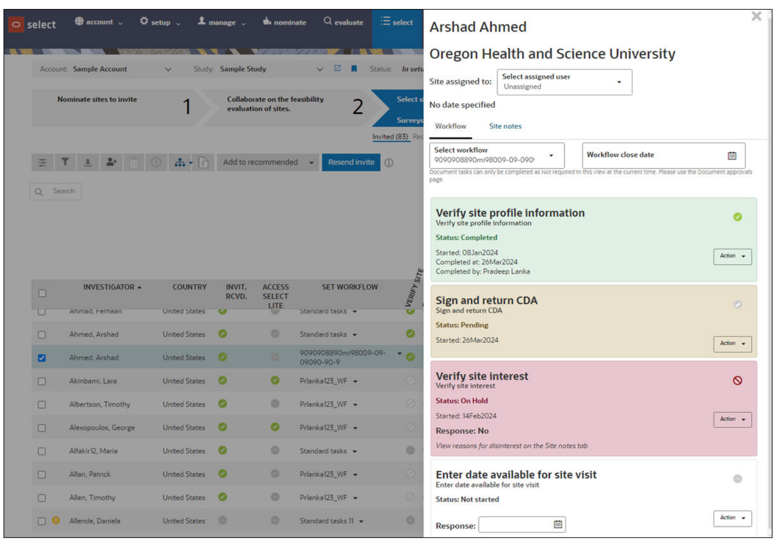
Click a task's Actions button to view available completion options for that specific task (e.g., Verify Yes, Verify No, Complete - Not required, etc.); available options are dependent upon your user permissions. Some tasks may include document or template download icons (e.g., View protocol, Complete feasibility survey).

Currently, you can only complete the document tasks listed below as “Completed - Not required” in the workflow drawer view. To manage the following Document tasks, please use the Document approvals page:

- CDA document
- Generic document (Approval required, Choose response, and Attestation)

Note that if you re-complete or re-submit a completed workflow task within the workflow tab, you’ll replace the existing submission and be marked as the submitting user. Please confirm this action in the confirmation modal.

Currently, a document task completed as Not required will not have the site listed on the Document management page, Approved tab. This is intentional since the document was not "Approved" but rather bypassed.



Site notes tab

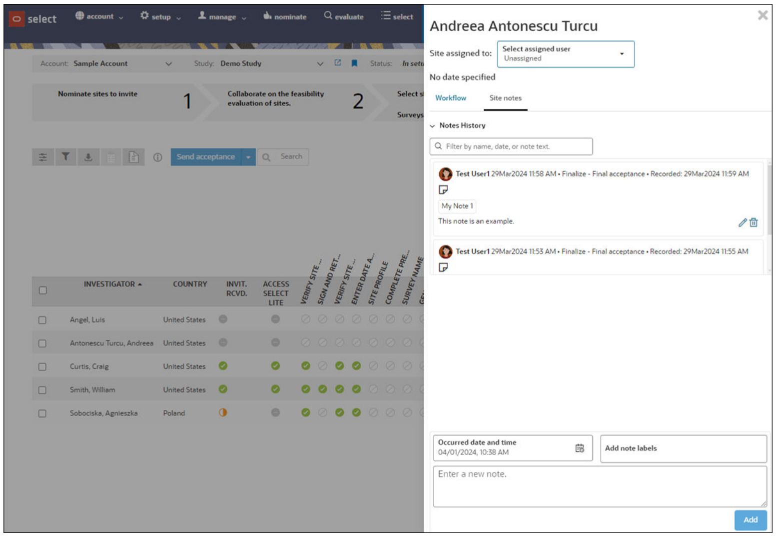
The site grid drawer also includes a Site notes tab. If you don't already have the site grid drawer opened, you can navigate directly to the Site notes tab when you click View notes in the site grid Action menu. By design, when you click on a site's notes icon in the site grid, the Notes modal displays 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

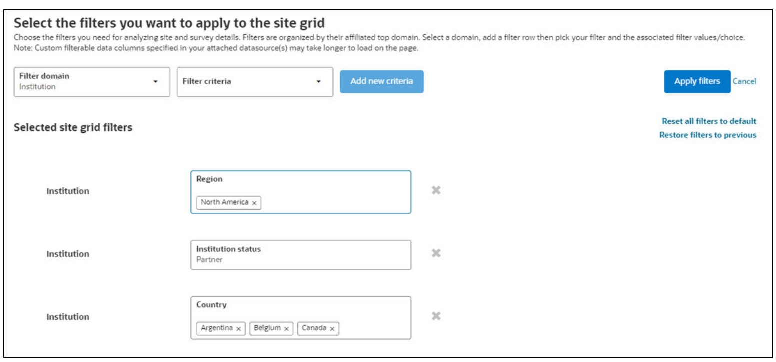
- Format: <occurred date time> * <bucket - bucket state note was recorded> * Recorded at: <note saved date and time>

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.



Filter selectors

Site grid users can apply filters to the site grid as preferred. When adding new site grid filters, you'll first choose a top domain (e.g., Site, Principal Investigator, Institution, etc.) and then choose Filter criteria from the drop-down lists at the top of the page. Add new criteria to add a filter row in the "Selected site grid filters" section. You can add an unlimited number of filter rows, and you'll select the preferred filter and the associated filter values/choice for each filter row.



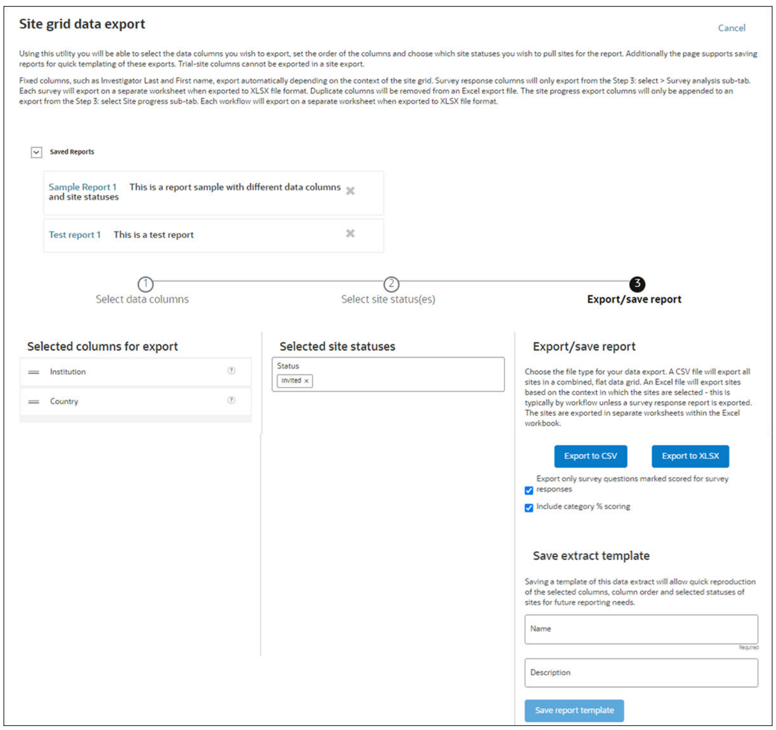
Export site list to CSV or Microsoft Excel

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.

If you create the export from the Survey analysis tab, step 3 (Export/save report) gives you the option to "Export only survey questions marked scored for survey responses. This option will be checked by default, so uncheck it if this is not your preferred setting.

If 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	Investigator score, Investigator last name, Investigator first name, **<selected columns>**

Step	Bucket state(s)	Sub-tab	Fixed columns
nominate	Dropped	Investigator	Investigator 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>**
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>**

Step	Bucket state(s)	Sub-tab	Fixed 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>**
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 acceptance	Survey analysis	Protocol title, Protocol number, Country, Investigator last name, Investigator first name, Activate site number, **<selected columns>**, Version number, Initial submission date, <1 column per survey question>
finalize	Final decline	Site details	Investigator last name, Investigator first name, Institution, Site score, Finalized by, **<selected columns>**

Step	Bucket state(s)	Sub-tab	Fixed columns
finalize	Final decline	Survey analysis	Protocol title, Protocol number, Country, Investigator last name, Investigator first name, **<selected columns>**, Version number, Initial submission date, <1 column per survey question>

- Download the sites list

Download the sites list

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**.

Study site history view

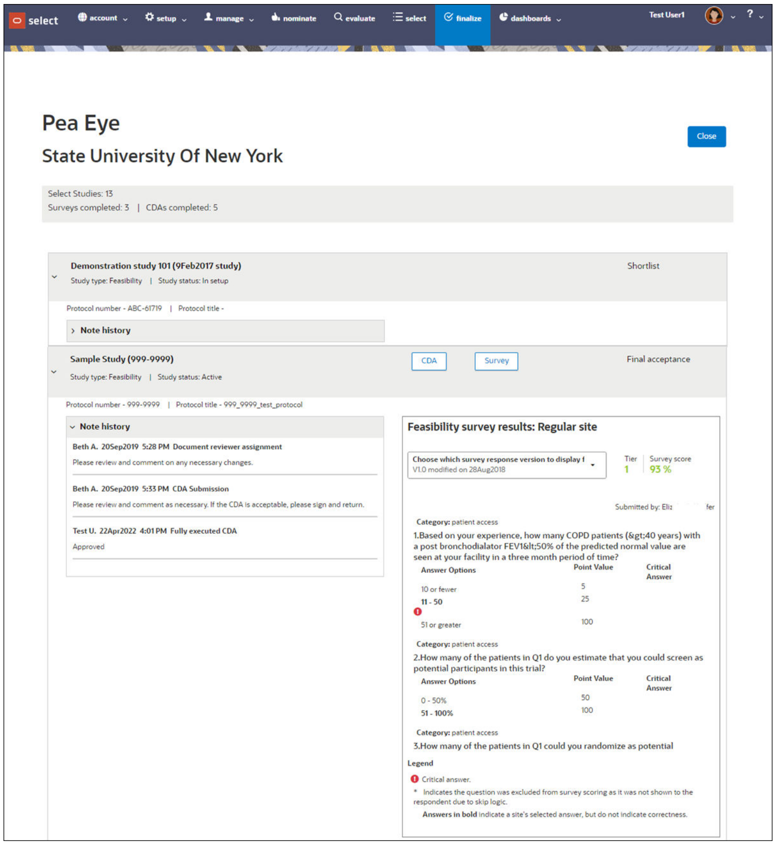
When you have the appropriate permissions, you can view a study site's cross-study performance and workflow completion across all studies in the account to gain insight into a that study site's progress.

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. Click the option 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. In the Actions drop-down menu, click **View site history**.
2. 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 **<** 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 page, click **Close** at the upper right.

Using notes to communicate

Using notes is 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).

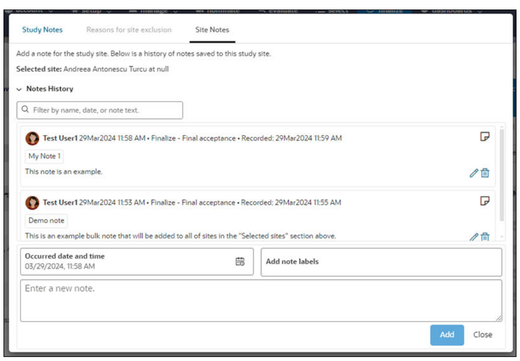
To open the modal to the Site notes tab for one site, click the site's Note column icon in the site grid. When you click on the site grid menu notes icon without selecting a site in the grid, the modal opens to display the Study notes tab by default. If you select multiple rows in the grid, and then 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.

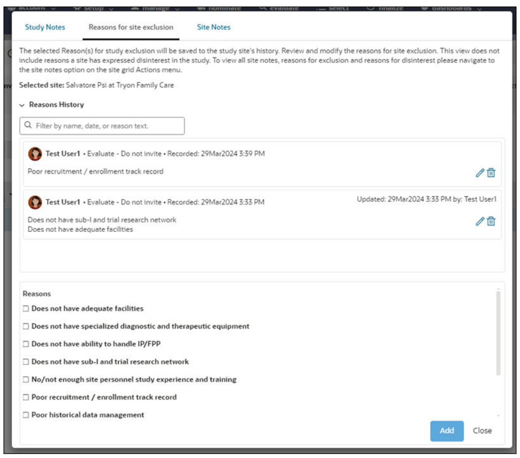
When you update or delete a site note in Oracle Site Select, it will be marked as deleted in the reporting views and nightly CSV reports. Reporting views and nightly CSV reports to include a new note_history table. The note history table outputs the history of an edit to a note.

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.

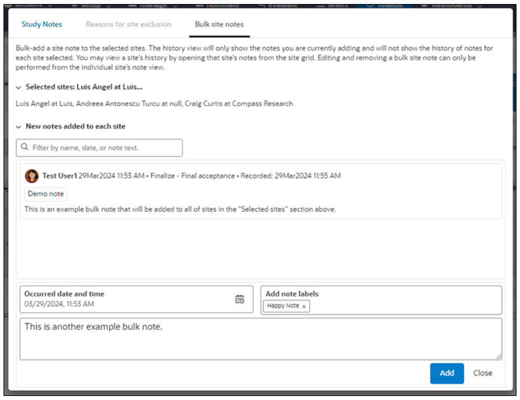


Bulk site notes

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.

- 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. Account level labels can also be deleted.

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. Account level labels can also be deleted.

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

1. From the **account** menu, choose **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.

Site profile shows performance and history

Site profiles store extensive detail about a specific site's contact information, trial history, related facilities, and more.

> **Note:**
>
> Oracle Site Select supports alternate site profiles that can be enabled for your organization upon request. Please contact your Oracle services representative to discuss the site profile that best fits your unique organizational needs.

Legacy (default) site profile

On the Oracle Site Select nominate, evaluate, select or finalize tabs, you can click the site's profile icon to display a scorecard that shows how the site scored on the study's key criteria. The scorecard shows the site's overall score, which is a weighted average of the site's study fit, performance, and experience.

Oracle Site Select calculates the score using the following formula:

Study fit	Site performance	Experience	
(percentile x weight)	+(percentile x weight)	+(percentile x weight)	= Site score
(0 x 0.33)	+(0 x 0.33)	+(65 x 0.34)	= 22

You'll also see the number of site publications and IND filings during the last five years, the value of grants, patient availability, and GCP training. Additionally, you can view the site's historical score, the scoring algorithm used to calculate the site's score, and underlying data associated with each site's score; this provides transparency into the raw data used to generate the score.

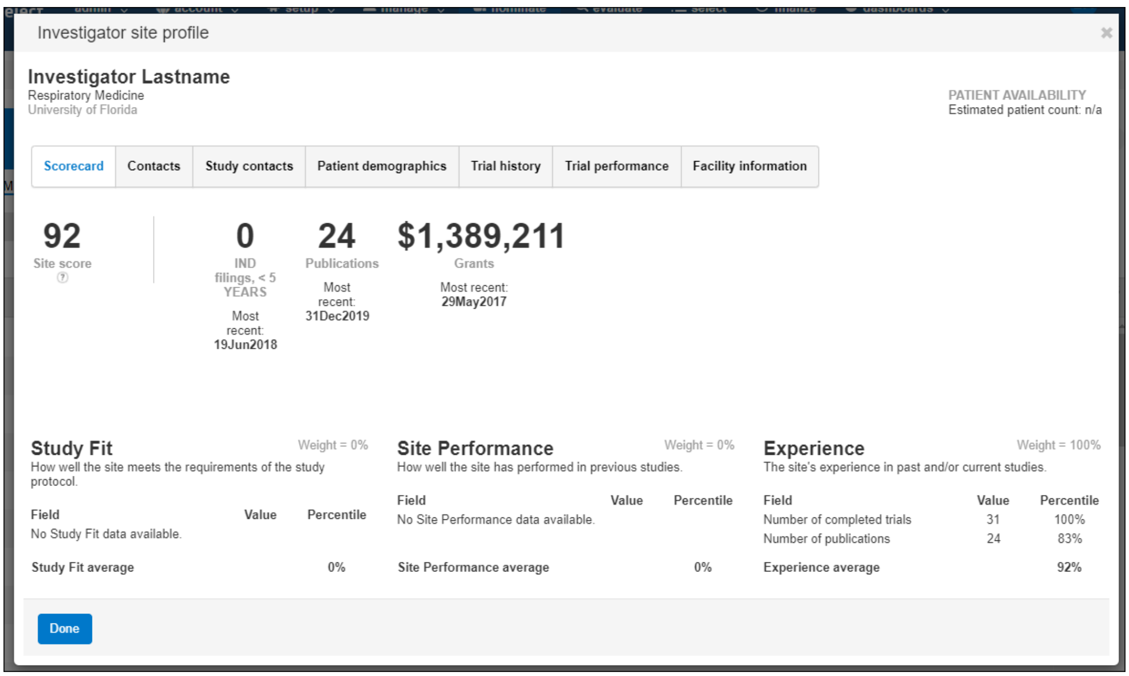
Oracle Site Select uses a standard algorithm for all sites to ensure that your site selection process is objective and unbiased. You can export a CSV file of scoring data fields, raw percentile scores, and final weighted score for one or more sites.

Note:

Customers can choose to show or hide various tabs in the site profile; therefore, the images in this section are representative. At the account level, an Oracle administrator can enable/disable display for the following standard site profile tabs:

- Contacts (including the Investigator, Institution, and Site subtabs)
- Contacts > Site (hides only the Site subtab under Contacts)
- Facility information
- Patient demographics

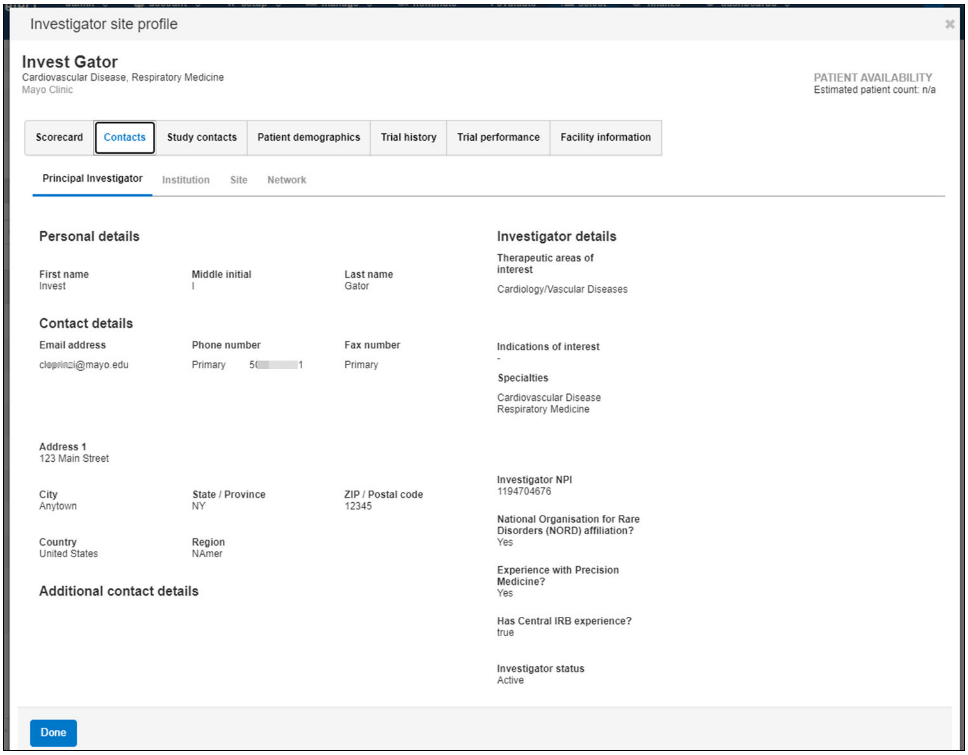
The above site profile tabs display by default, and customers may choose to hide any or all of these tabs as preferred. When hidden, a tab is not visible to site users in Oracle Site Select LITE or to Oracle Site Select users viewing the site scorecard and the Edit site profile page.

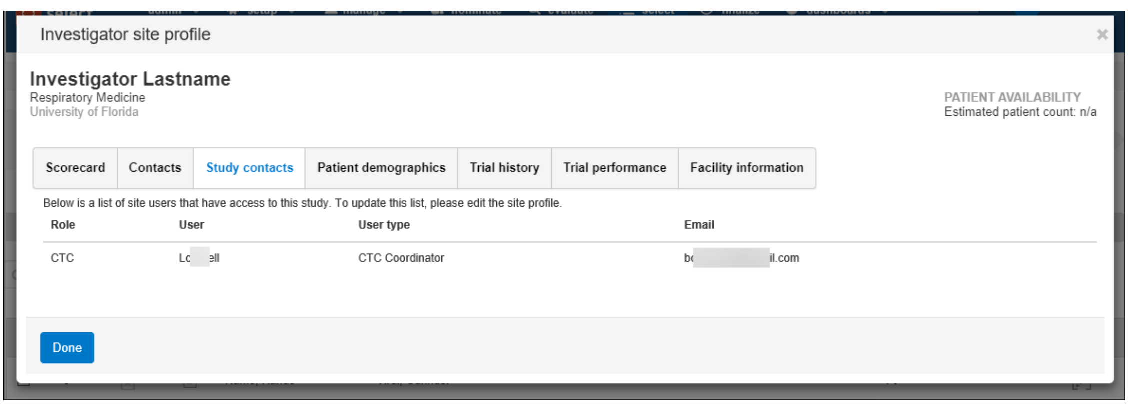


Other tabs in the profile show:

- Contact information for the principal investigator, trial coordinator, IRB coordinator, and other institution staff
- Study contacts (populated with a list of invited site users with listed site users dependent upon email template preferences)
- Regulatory actions (this tab displays only if there is regulatory action data available)
- Patient demographics
- Trial history (the number and a list of active and completed trials)
- Trial performance:
  - Recruitment – the site's enrollment history for the study's therapeutic area over time including the average planned subjects per trial, average randomized subject count, actual subject counts, and a list of studies included in the counts

- Cycle times – the site's SSU average cycle times for contracts and essential document collection, submissions, IP release, time from prestudy visit (PSV) to site initiation visit (SIV), time from activation to first patient in (FPI), and time from activation to last patient out (LPO)
- Facility information – type, diagnostic capabilities, facility information, on site lab certifications, facility training, and affiliates





Oracle Site Select and Oracle Site Select LITE users can use the Study contacts tab to identify site contacts and specify, at the study level, which site contacts should have study access and receive notifications. The Study contacts tab displays a grid of invited site users. Oracle Site Select users who have *Edit site profiles* permission and Oracle Site Select LITE users can add additional contacts, edit assigned roles (CTC or Other), and remove contacts as necessary for any individual.

Study site users listed in the study contacts grid have an assigned role and will receive all future email notifications for the study, as appropriate to the role and study email template settings. Study email template settings affect which users are available to be listed in the study contacts grid and the functionality available for the grid. Below are a few examples of this tab's behavior.

Example 1 - A study has email template preference set to email all site users, so the study contacts grid lists all invited site users.

- The PI automatically has the “PI” role.
- The default Clinical Trial Coordinator, defined on the profile’s “Contacts” tab, automatically has the “CTC” role.
- The institution staff users' roles, including an IRB Coordinator defined on the profile’s “Contacts” tab, are listed as “Other.”
  - An institution staff user can have their changed from Other to CTC, and the default CTC can have their role changed to Other.
- The “Add” button on the Study contacts tab is disabled because all available users have been invited.
  - If the user chooses to Remove a CTC or Other user from the grid, the Add button will be enabled.
  - If the user chooses to Add a user to the grid, the only available user will be the user just removed from the grid.

Example 2 – A study has email templates preference set to email only the PI, so the study contacts grid lists only the PI. This is not an editable row.

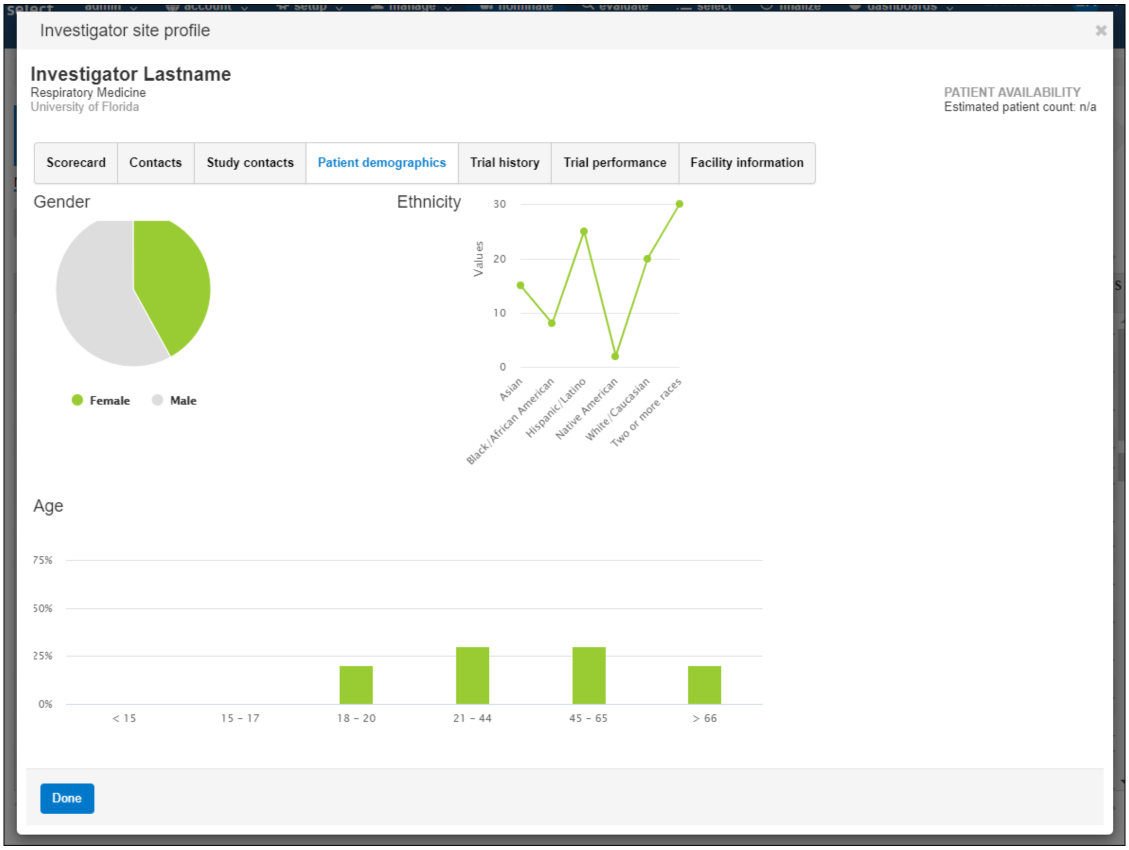
- The PI automatically has the “PI” role.
- “Add” and “Remove” controls on the Study contacts tab are disabled because the read-only PI row is the only role in scope for display on the tab.

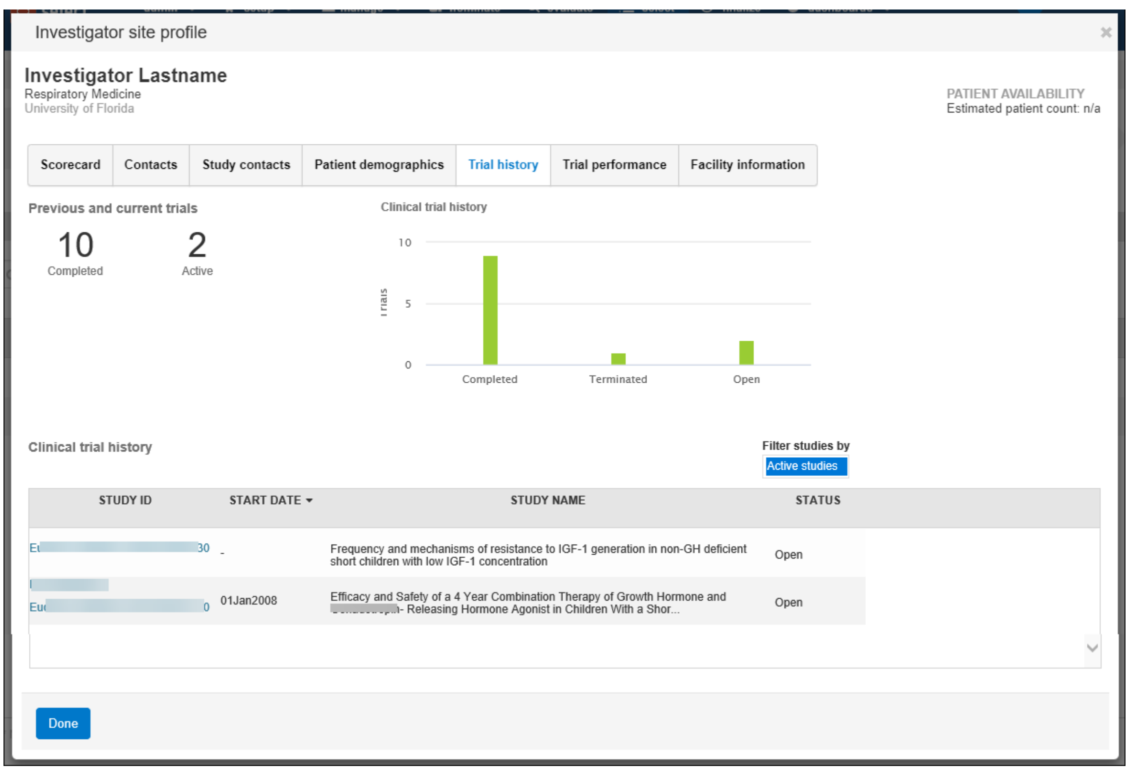
Example 3 – A study has email templates preference set to PI and CTC only. Upon site invitation, the grid lists the PI and the default CTC.

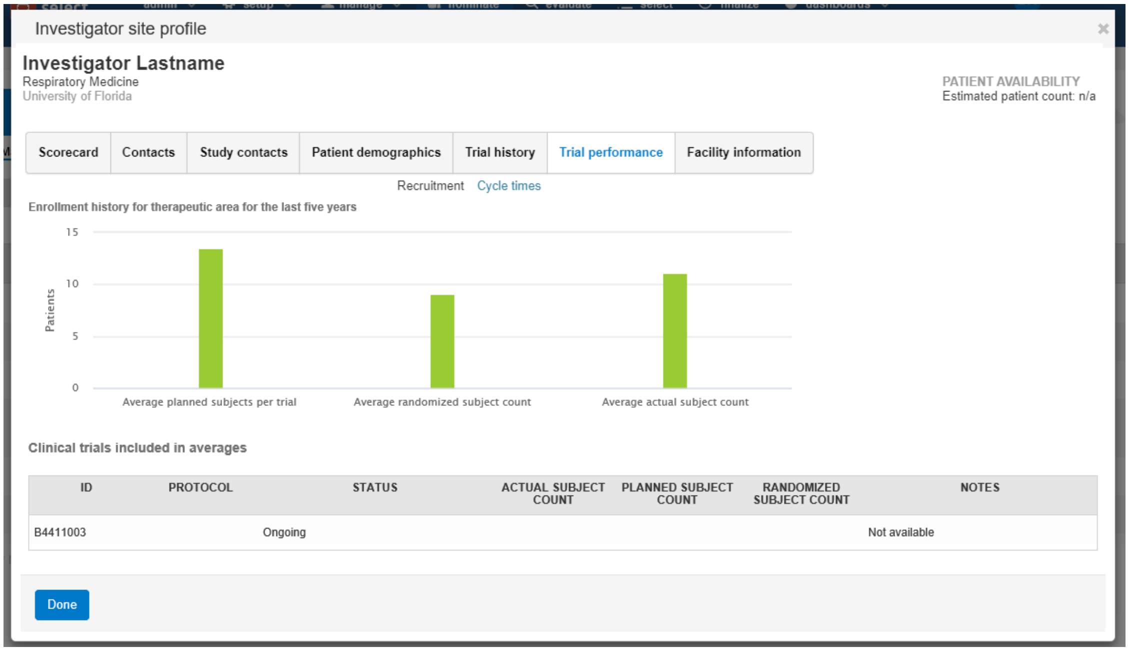
- The PI automatically has the “PI” role.
- The default Clinical Trial Coordinator, defined on the profile’s “Contacts” tab, automatically has the “CTC” role.
  - The user may not change the default CTC's role, because CTC is the only available option; however, the user can remove the default CTC.
  - The user can Add another user (institution staff or default IRB Coordinator) and that staff member will default to the role of CTC, again because CTC is the only available option. This logic allows the study to have multiple CTCs for a study site, if preferred.
  - A study invitation email will be sent to any user added to the study preferences as a CTC.

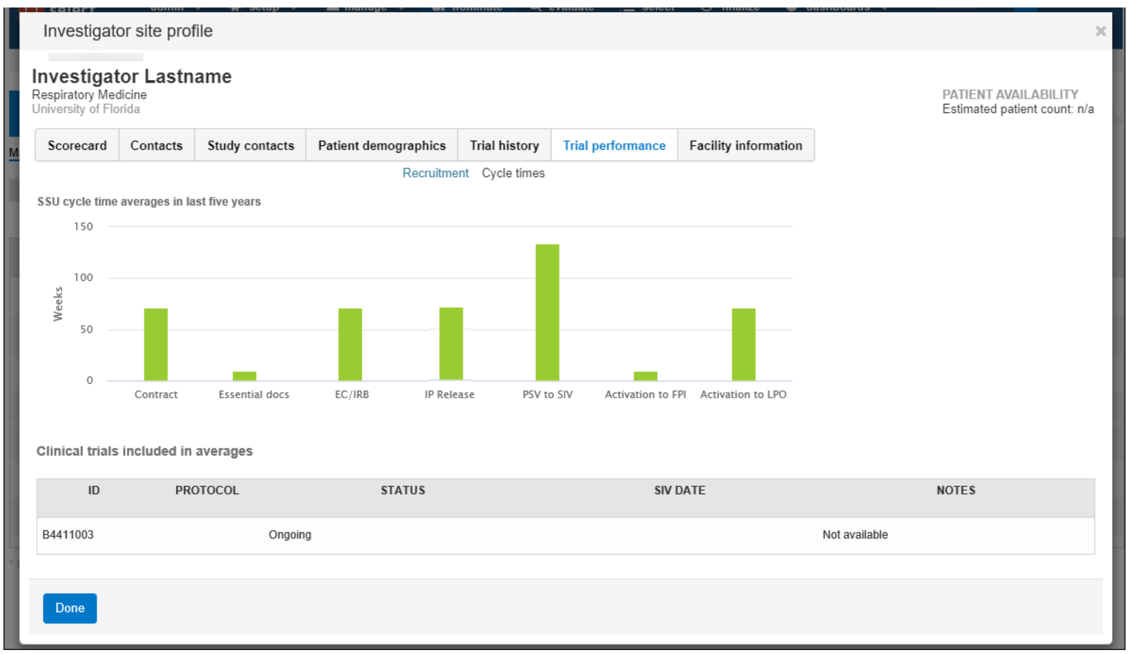
Example 4 – A user deleted from the site profile will be removed from the study contacts grid and have their study access and email notifications revoked.

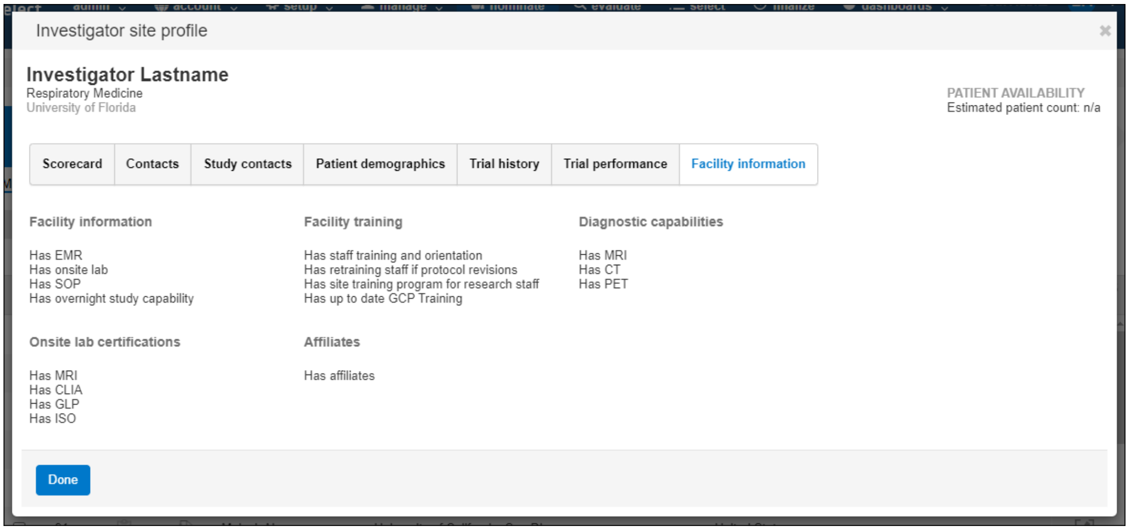
> **Note:**
>
> A contact’s data (title, name, suffix, and degree) displayed in the Study contacts grid reflects the site profile data rather than the data saved in the Oracle Site Select LITE user profile. If a site user changes the Oracle Site Select LITE user profile name, the updates save successfully but do not impact the data displayed on the Study contacts grid. However, when an Oracle Site Select user or a site user updates a study contact site user's name within in the site's profile, the Study contacts grid reflects the updated information.


Investigator site profile
Investigator Lastname
Respiratory Medicine
University of Florida
PATIENT AVAILABILITY
Estimated patient count: n/a
Scorecard
Contacts
Study contacts
Patient demographics
Trial history
Trial performance
Facility information
Gender
Female
Male
Ethnicity
Values
Asian
Black/African American
Hispanic/Latino
Native American
White/Caucasian
Two or more races
Age
75%
50%
25%
0%
< 15
15 - 17
18 - 20
21 - 44
45 - 65
> 66
Done


Investigator site profile
Investigator Lastname
Respiratory Medicine
University of Florida
PATIENT AVAILABILITY
Estimated patient count: n/a
Scorecard
Contacts
Study contacts
Patient demographics
Trial history
Trial performance
Facility information
Previous and current trials
10
Completed
2
Active
Clinical trial history
Completed
Terminated
Open
Clinical trial history
Filter studies by
Active studies
STUDY ID
START DATE
STUDY NAME
STATUS
Frequency and mechanisms of resistance to IGF-1 generation in non-GH deficient short children with low IGF-1 concentration
Open
01Jan2008
Efficacy and Safety of a 4 Year Combination Therapy of Growth Hormone and
- Releasing Hormone Agonist in Children With a Shor...
Open
Done


Investigator site profile
Investigator Lastname
Respiratory Medicine
University of Florida
PATIENT AVAILABILITY
Estimated patient count: n/a
Scorecard
Contacts
Study contacts
Patient demographics
Trial history
Trial performance
Facility information
Recruitment
Cycle times
Enrollment history for therapeutic area for the last five years
15
10
5
0
Patients
Average planned subjects per trial
Average randomized subject count
Average actual subject count
Clinical trials included in averages
ID
PROTOCOL
STATUS
ACTUAL SUBJECT COUNT
PLANNED SUBJECT COUNT
RANDOMIZED SUBJECT COUNT
NOTES
B4411003
Ongoing
Not available
Done


Investigator site profile
Investigator Lastname
Respiratory Medicine
University of Florida
PATIENT AVAILABILITY
Estimated patient count: n/a
Scorecard
Contacts
Study contacts
Patient demographics
Trial history
Trial performance
Facility information
Recruitment
Cycle times
SSU cycle time averages in last five years
150
100
50
0
Weeks
Contract
Essential docs
EC/IRB
IP Release
PSV to SIV
Activation to FPI
Activation to LPO
Clinical trials included in averages
ID
PROTOCOL
STATUS
SIV DATE
NOTES
B4411003
Ongoing
Not available
Done



Study-specific site profiles

Oracle Site Select offers a study-specific site profile feature. When enabled for the account by an Oracle administrator, this feature allows site profile updates made within a study to be stored in a data source specific only to that study. This feature is an alternate implementation to the account level site profile (described above). Your organization's Oracle Site Select account will be configured with either account level site profile (default setting) or study-specific site profile.

In Oracle Site Select and Oracle Site Select LITE, profile page titles include the text "for this study only" so users who are viewing or editing the profile quickly see that the profile applies to the current study.

Configurable site profile

Configurable site profile functionality that allows customers to define site profile sections, fields, and field values as required for their unique business needs. Please contact your Oracle administrator for more details on how to map and implement this alternate site profile functionality.

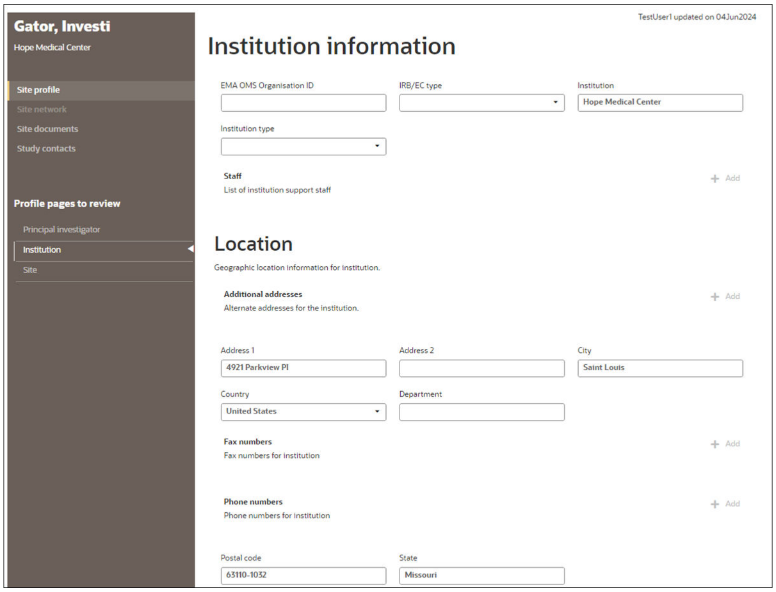
When an Oracle administrator enables configurable site profile functionality for the account, an enhanced design replaces the legacy site profile design (described above). All links and navigation that previously allowed users to access the legacy site profile will access the configurable site profile instead. For example, an Oracle Site Select user completing the site profile task will access the configurable site profile.

In Oracle Site Select, the configurable site profile page design includes section navigation links in a left side panel and uses Oracle standard elements for fields, buttons, and icons. The left navigation also includes links to Site networks, Documents, 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 currently 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.

Oracle Site Select LITE will also use the enhanced page design for accounts with configurable site profile enabled.



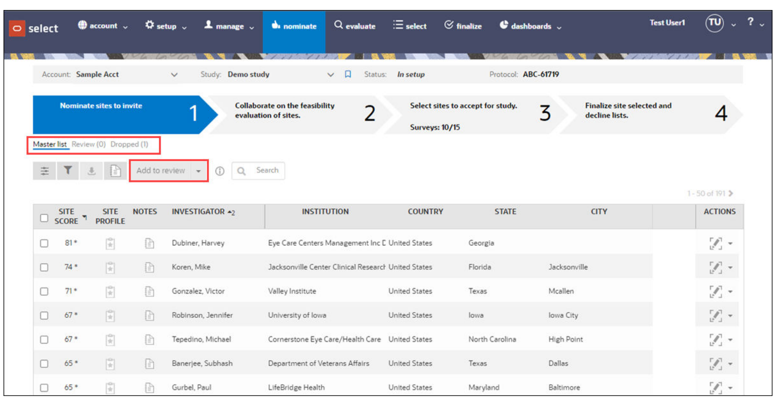
Step 1: Nominate

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 current list 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)."

Use the "Add to..." action button to move 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



- Nominate sites
- Undo site nomination or shortlisting

Nominate sites

1. Click **nominate** in the top navigation bar.

2. Click the filter button to apply filters to the refine the site grid using filter criteria.
3. Expand the Site, Institution, Principal investigator, Site progress, and/or Survey analysis sections and click the checkboxes or add other required values to the filter options you want to use.
4. Click **Done**.
5. Adjust column display in the site grid by clicking the column button.
6. Use the type-ahead search to identify columns you would like to include, and click > to move the columns into the selected list. Use the up and down buttons to define the display order.
7. Click **Done**.
8. To view a site's scorecard, click the icon in the **Site profile** column.
9. To leave a note or reason that explains your actions regarding a site, click the icon in the **Notes** column, and enter a note on the **Notes** tab, click the **Reasons** tab and select one or more reasons.
10. Click **Done**.
11. Review the site attributes displayed in the site grid (values displayed depend on columns and filters chosen above).
12. Adjust the "Add to..." action button to "Add to review," "Add to short list," or "Add to dropped"
13. Check the box next to one or more sites and click the Step 8 action button.

After you complete the procedure above, your team members who are assigned to perform site screening receive an email notification to evaluate the nominated sites.

Undo site nomination or shortlisting

1. From either the **Nominated** tab or the **Short list** tab, click the **Actions** menu next to a site, then select **Move to Nominate-Review**.
2. Confirm the site appears in the **Review** bucket in the **Nominate** step.

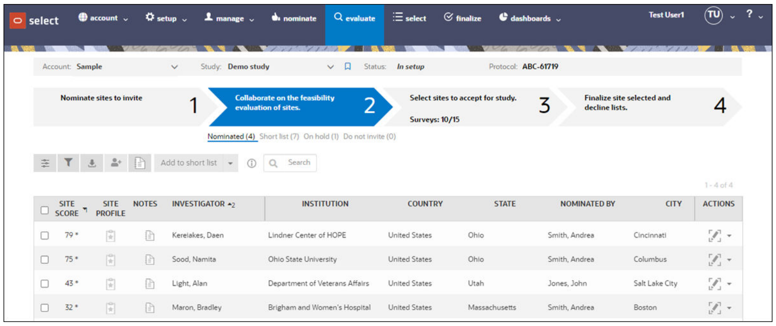
After you complete the steps above, the team member who is responsible for sending invitation emails can send invitations to sites on the **Add to nominated** list.

Step 2: Evaluate

Review and act on the list of sites you or other members of your team have nominated.

On the Nominated list, you can choose one or more sites, 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.

You can export a list of sites with your preferred data columns for review. Use the search field to locate a specific site.



- Evaluate sites

Evaluate sites

1. Click **evaluate** in the top navigation bar.
2. To view the site's score card, click the icon in the **Site profile** column.
3. To leave a note or reason that explains your actions regarding a site, click the notes icon, and:

   Enter a note on the **Notes** tab.

   Click the **Reasons** tab and select one or more reasons.

   Click **Done**.
4. Adjust the "Add to..." action button to "Add to short list," "Add to on hold," or "Add to do not invite".
5. Check the box next to one or more sites and click the Step 4 action button.

Step 3: Select

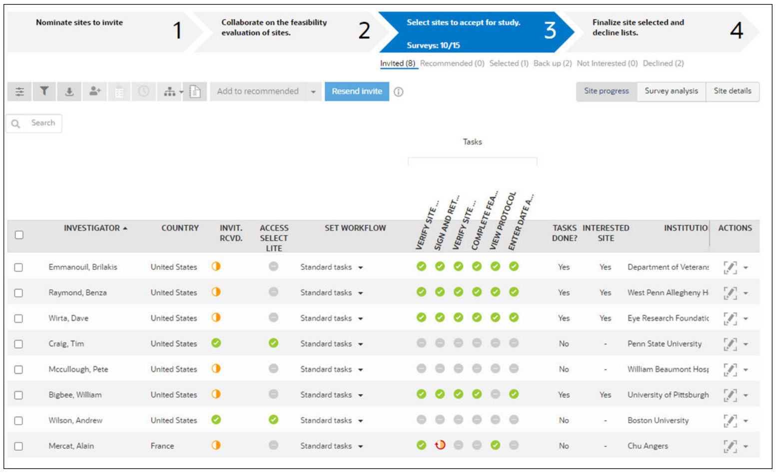
Review site information in site progress, survey analysis, and site detail views and choose the sites that will advance to the next step in the site selection process.

In the select step, you'll see the list of sites that you can choose to add to the study. Note that the sites will not receive confirmation that they are added to the study until the finalize step (step 4).

The select step gives you three views of site data for each of the select step bucket states (Invited, Recommended, Selected, Back up, Not interested, and Declined). The three tabbed views are: Site progress, Survey analysis, and Site details. You can modify the columns displayed or filter the data in the site grid for any of these views. 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.).

Site progress view

This tab 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.



Note:

If an investigator's INVIT RCVD column displays an Incomplete ( ) or In progress ( ) icon, the invitation email transmission progress is not yet complete. If necessary, refresh the page to update the status.

To assist study teams in maintaining their milestones and workflow task response time targets, the Site progress subtab 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.

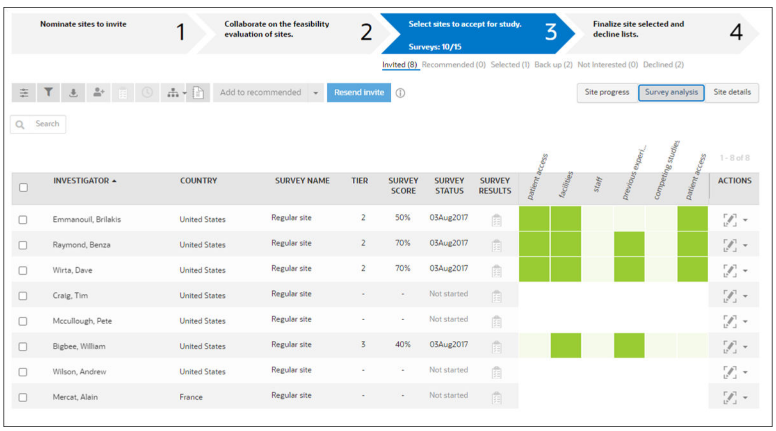
Because generic document tasks share the same response time target input field on the milestones page, the overdue trigger functions differently from other tasks. For each generic document task that is not optional, the response time target applies to each unique instance. For example, if the response 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

Survey analysis view

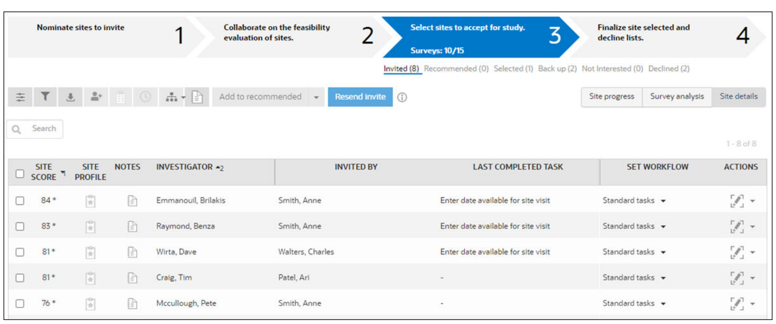
The Survey analysis view gives you access to feasibility survey details. Survey category scores display as color valued cells, with higher scores represented as a darker green value. Questions whose responses have triggered a critical response are indicated with a red mark in the cell. Hover over an individual cell to display the category point score or click the cell to access question, answer, and point value details.

If preferred, you can download a PDF or CSV format export containing survey responses. You'll find these options among the buttons above the site grid.

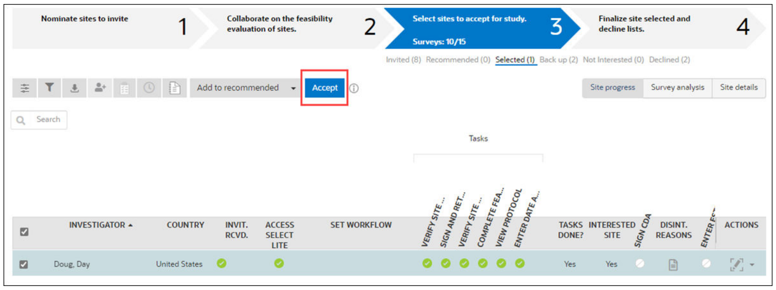


Site details

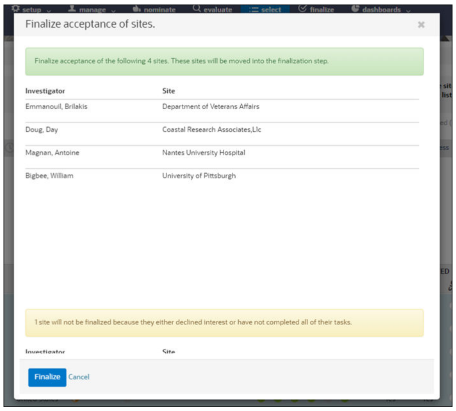
In the Site details view, you'll find site score, profile link, and notes along with additional high-level details about tasks and more.



When all of a site's tasks are completed, check the site row in the grid and click the blue Accept button.



Sites listed in will be moved into the finalize step. Sites must express interest in the study and/or complete all of their tasks to move to finalization. If Oracle Site Select detects that either of these are not true, the sites will not be moved to finalization and an informational message displays.



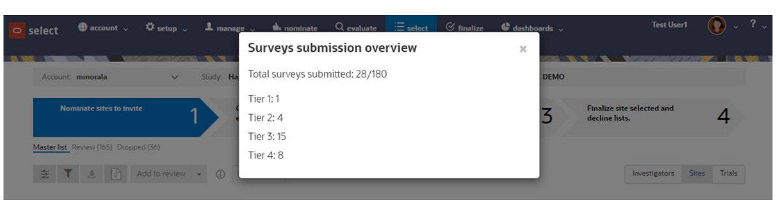
If you have *Revert site finalization* permission you can reverse final acceptance and final decline of sites. Reversing finalization allows you to move a site from final acceptance to (step 3) Selected, or from Final decline to (step 3) Declined using an option under the Actions menu. You will not have the ability to move sites directly from final accept to final decline (or final decline to final accept).

When reversing site finalization, you can also enter a note about moving the site. Notes are saved in the site notes field and tagged with the user taking the action and a time stamp. Notes are also tagged with the originating state a ">", then the ending state (e.g., Final decline > Declined).

Survey submission metrics

Click the "Surveys # / #" text in the Step 3 (select) chevron 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.



- View status, evaluate, and select or reject sites

- Run site workflows from the select step
- Complete tasks on behalf of sites
- Change a site's profile

View status, evaluate, and select or reject sites

1. Click **select** in the top navigation bar.
2. Click the **Site progress** tab at the upper right to view a site's progress through assigned workflow tasks.
3. Click the **Survey analysis** tab at the upper right, to evaluate category scoring.

   Category scores display as color valued cells, with higher scores represented as a darker green value. Questions whose responses triggered a critical response are indicated with a red mark in the cell.

   Hover over an individual cell to display the category point score or click the cell to access question, answer, and point value details.
4. Click the **Site details** tab at the upper right to view the site score, profile link, notes, and other details.
5. Adjust the "Add to..." action button to the preferred action (e.g., Add to back up, Add to selected, etc. (available actions automatically adjust to the current tab view)
6. For sites moved to the Selected list:

   Accept to confirm the site for acceptance.

   Click **Finalize**, to move the site to the Finalize step.

Run site workflows from the select step

1. Click **select** in the top navigation bar.
2. Check the box next to one or more sites.
3. From the workflow icon select a workflow.
4. Click **Apply**.

Complete tasks on behalf of sites

Use this procedure to complete tasks (such as the feasibility survey or uploading a CDA) for a site that does not participate using Oracle Site Select LITE, or when a site completed a task externally and you need to mark it complete in Oracle Site Select.

1. Click **select** or **finalize** in the top navigation bar.
2. In the site grid **Actions** menu next to the site's name, select **Complete tasks for this site**.
3. The task to perform displays in the **Task** column. Choose the option or click the link to perform the action specified in the **Action** column. For view protocol tasks only, complete the fields in the Mark task as completed externally modal and click **Done** to close the modal.
4. Click **Done**, **Final Approval**, or **External** as applicable to the task.
5. Repeat step 3 for all outstanding tasks that need to be marked completed on the site's behalf.

Change a site's profile

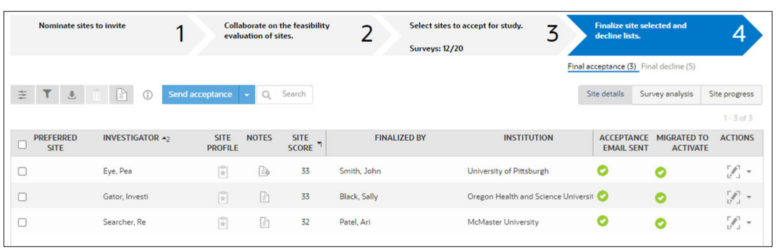
> **Note:**
>
> If you change a site's profile, the site will see your changes on their Site details tab the next time they log into Oracle Site Select LITE (the fields you change appear with a bell next to them).

1. Click **select** in the top navigation bar.
2. At **Study**, select the desired study.
3. Next to the investigator's name, click the **Actions** menu and select **Edit site profile**.
4. Add or change the investigator's contact information, patient demographics, and facility information as desired.
5. Click **Done**.

Step 4: Finalize

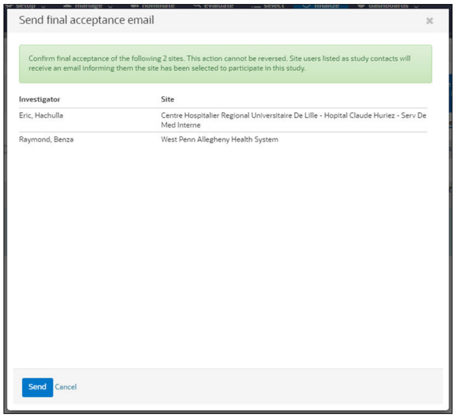
Send acceptance emails to selected sites, view lists of sites that have accepted or declined invitation to participate in the study. If your customer account has been configured with certain integration and you have the appropriate permissions you can also migrate study sites to Oracle Site Activate 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.

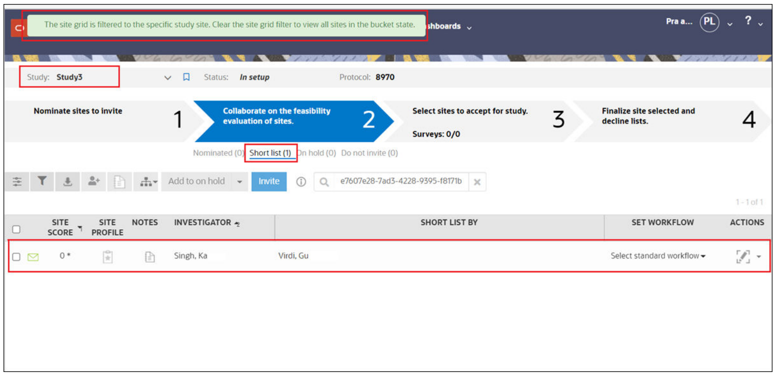
When you close the final determination modal the site grid updates to display a gray check mark (incomplete) status icon in the "Acceptance email sent" or "Decline email sent" site grid column. On hover over, the icon displays the following tool tip text: "This site is not configured with valid study 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.

10 Site Status

This section, intended for country list managers and project managers, describes how to view site status, the Pre-Study Visit tracking dashboard, and email invitations in Oracle Site Select.

- Monitoring overall site status
  See the status of site enrollment for a study's invited and selected sites, check cycle time averages across that study, and use the Pre-Study Visit dashboard to track site visits prior to finalization.
- Monitoring site email invitations
  Review the status and outcome of a study's invitations in graphical and tabular formats.

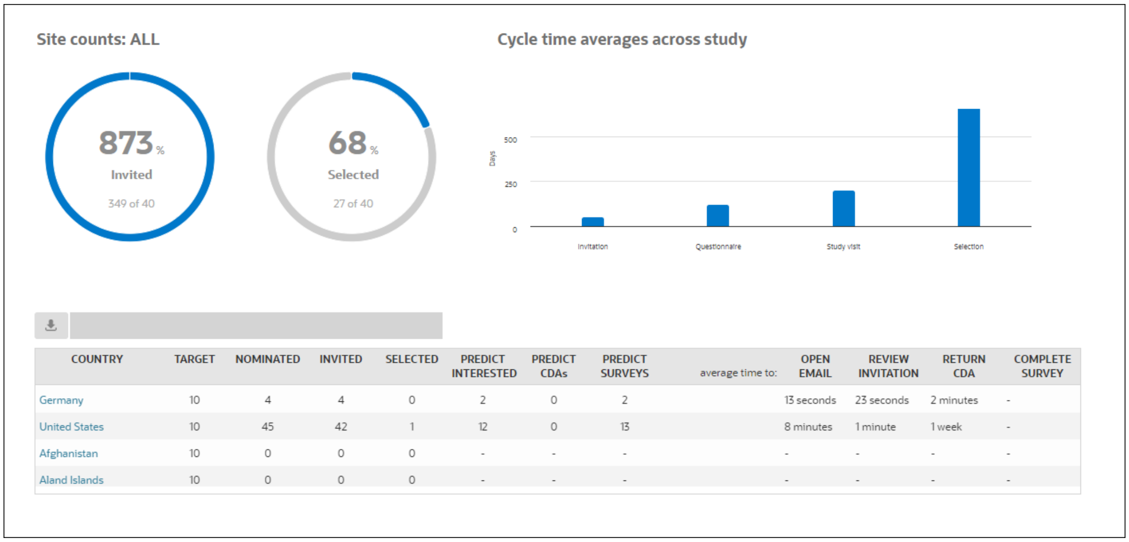
Monitoring overall site status

See the status of site enrollment for a study's invited and selected sites, check cycle time averages across that study, and use the Pre-Study Visit dashboard to track site visits prior to finalization.

When you have a role with *View Dashboards* permission, you can see the real-time status of site enrollment and site counts as study team members and sites complete tasks, compare progress across countries, and manage email invitations. On the site counts dashboard, you'll find the:

- 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

On the "Site counts: ALL" view, you'll find the study countries listed below circular and bar graphs. Click a country name to view a country-level dashboard.

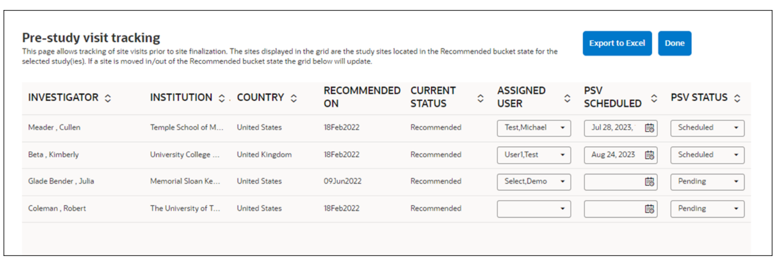


Click a country name on the Site counts dashboard to drill down to the country-level dashboard where you can view site status and drill to site details like the site's study fit, performance, experience, and more.

If you have *PSV dashboard* permission, you can also use the Pre-Study Visit dashboard to track site visits. The dashboard includes a study picker that lists only those studies you have permission to access. Sites included in the grid 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



- View site counts

View site counts

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

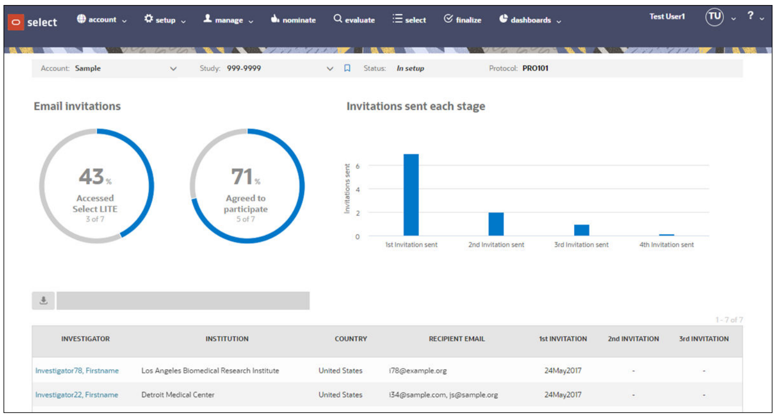
1. In the top navigation bar, click **dashboards** then click **site counts**.
2. (Optional) To see a list of details by country, click the country name to view:
   - List of sites in the country
   - Number of subjects for each site
   - Current site status

- Site score cards, surveys, and screening summaries (click the corresponding icon to see details)
- Notes and reasons associated with each site

Monitoring site email invitations

Review the status and outcome of a study's invitations in graphical and tabular formats.

On the email invitations dashboard, you'll see 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 can resend the invitation if a site hasn't responded.



- View a site's invitation status
- Resend a site's study invitation
- Resend invitations to individual site users

View a site's invitation status

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

- In the top navigation bar, click **dashboards** then 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 dash for no response)

Resend a site's study invitation

1. In the top navigation bar, click **select**.
2. Check the box next to each site that you want to receive another invitation, then click **Resend Invitation**.
3. Click **Done**.

Resend invitations to individual site users

1. On the step 3 (select) Site progress tab, click the green check mark in the **INVIT. RCVD.** column for the investigator.
2. In the modal, locate the row for the individual. At the far right, click **resend**.

11 Document Management

Study administrators, protocol and CDA managers, and email managers can use this section to learn how to manage documents in Oracle Site Select so study sites can view, download, and complete document related workflow tasks.

- Managing CDAs and confidentiality statements
  Some study workflows require supporting documents, like a CDA or confidentiality statement. You can upload CDAs and confidentiality statement documents into Oracle Site Select and share them with sites at the appropriate time (as specified in your workflows).
- Managing CDA submissions and approvals
  If you have the appropriate document review privileges, you can view every round of a CDA's review cycle on the manage menu's Document Approvals page.
- Signing CDAs digitally with Adobe Sign integration
  Oracle Site Select offers CFR Part 11-compliant digital signature for the CDA workflow through optional subscription to Adobe Sign. Your Oracle Project Manager will provide subscription details.
- Recalling a CDA
  When appropriate, you can recall a CDA document that was sent to a study site within the CDA workflow and recall a CDA submitted by a study site user or by an Oracle Site Select user on the study site's behalf.
- Managing protocols
  You'll need to specify key protocol information in Oracle Site Select, such as the study name and study number, IRB/EC type, countries, and therapeutic area. Then upload the protocol in Microsoft Word or Adobe Acrobat (PDF) format and run a workflow to drive the process required to deliver the document to sites.
- Managing generic documents
  Generic Document is a specific workflow task available in the Task Library when you create or modify a workflow under Site workflow configuration.
- Document Library
  The Document Library feature allows for document reuse and automates the completion of workflow tasks using stored library documents associated to study site, investigator, or institution.
- Document workflow task audit
  Site grid users can download an audit file containing document workflow completion details.

Managing CDAs and confidentiality statements

Some study workflows require supporting documents, like a CDA or confidentiality statement. You can upload CDAs and confidentiality statement documents into Oracle Site Select and share them with sites at the appropriate time (as specified in your workflows).

With Oracle Site Select CDA management functionality, you can

- upload CDA documents individually or as multiple documents zipped into a single file

- manage as many confidentiality documents as needed to address the specific requirements of various sites and sponsors
- create as many workflows as needed and attach a different CDA and/or confidentiality document to each one

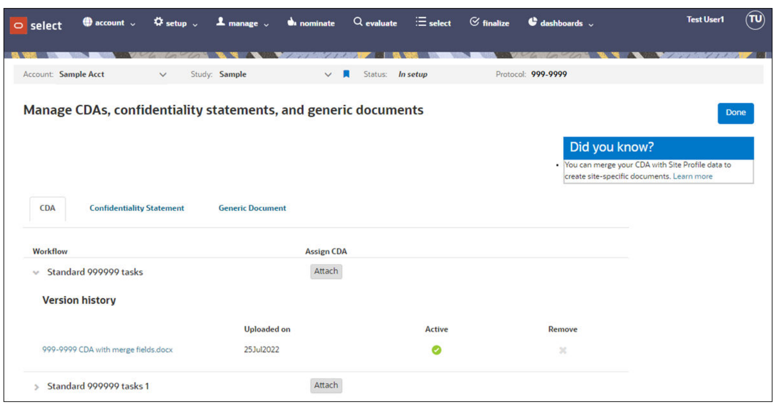
If necessary, you can replace a confidentiality document with a newer version at any time – when you do so, sites that have not uploaded a signed confidentiality document will receive the most recent version.

For workflows that have documents attached, you'll see the version and date uploaded, and you can add or remove the document version from the workflow (the last added document becomes the default). So, each site in a study can perform workflow steps appropriate for the site; create a workflow type that addresses the needs of various sites in the study and then assign a workflow type to each site.

On the setup tab's CDAs, confidentiality statements, and generic documents page (below), you'll see the list of workflows that require a document attachment. Choose the appropriate tab, then click Attach to upload the document(s) for the workflow.

In study workflow setup, you can also specify a Generic Document task. If you do so, Oracle Site Select includes the tab here, and if you give a specific name to the generic document, for example "Sponsor Expectations Document," the tab on the page below reflects the unique name you specify.

Expand a section to view and manage previous document versions. If you are replacing a previously uploaded document, attach the new document first, then Remove ( ) to remove the old version.



- Upload a confidentiality document to a workflow
- Upload a CDA on a site's behalf
- Remove a CDA template
- Pre-populating documents with site-specific values

Upload a confidentiality document to a workflow

Before you begin: this procedure shows you how to attach a confidentiality document to an existing workflow. If you need to define a new workflow, see "Configure workflows for sites" in this document. You can upload files in Microsoft Word, Adobe Acrobat (PDF), or ZIP file format.

1. In the top navigation bar, hover over **setup** and click **CDAs, confidentiality statements, and generic documents**.

2. Next to the desired workflow, click **Attach** and upload a CDA or confidentiality statement.
3. Click **Done**.

Upload a CDA on a site's behalf

1. In the top navigation bar, click **select**.
2. From the site's **Actions** menu, click **Complete tasks for this site**.
3. In the **Action** column, complete the activity, then click **Done**.

Remove a CDA template

1. In the top navigation bar, hover over **setup** and select **CDAs, confidentiality statements, and generic documents**.
2. Click the down arrow to expand the details section of the workflow associated with the document.
3. Click the **X** next to the document. If the document was shared with one or more sites, click:
   a. **Preserve workflow**, to share the new document only with sites that have not received the document, or
   b. **Restart workflow**, to have existing sites redo activities defined in the workflow using the new document.

Pre-populating documents with site-specific values

Oracle Site Select allows for merging of current Site Profile and study setup data to create site-specific CSV and generic documents. This functionality is available for Microsoft Word .docx files.

Oracle Site Select recognizes special placeholders that it replaces with values specific to the site that is downloading the CSV or generic document. Placeholders you add to the .docx file must be enclosed between curly braces {field_name}. Please note that spaces are not allowed within the curly braces.

Valid placeholders are:

{assign_user_email}	{pi_full_name}
{assign_user_name}	{pi_last_name}
{compound}	{pi_middle_name}
{inst_address1}	{pi_npi}
{inst_address2}	{pi_state}
{inst_city}	{pi_suffix}
{inst_country}	{pi_title}
{inst_department}	{pi_zip}
{inst_full_address}	{study_id}
{inst_name}	{protocol_number}

{inst_state}	{protocol_title}
{inst_zip}	{study_indications}
{pi_address1}	{study_sponsor}
{pi_address2}	{today_date}
{pi_city}	{today_date_eu}
{pi_country}	{today_date_us_mon}
{pi_degree}	{today_date_us_long}
{pi_department}	{today_date_us_verbose}
{pi_first name}	{trial_phase}
{pi_full address}	N/A

Managing CDA submissions and approvals

If you have the appropriate document review privileges, you can view every round of a CDA's review cycle on the manage menu's Document Approvals page.

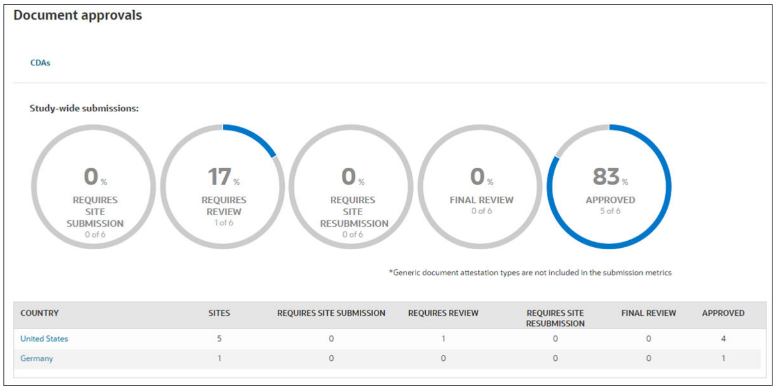
On the Document Approvals page, you can see:

- name of the user/site user who submitted the document
- name of the user who approved/rejected the document
- comment(s) left by the user who reviewed the document
- date and time of document submission, review, or status update
- document version
- color-coded document status (e.g., green = Approved, orange = Pending review, red = Rejected)

Oracle Site Select also emails CDA managers when a new CDA document has been submitted for review. The email includes Study ID, protocol number, protocol title, and any associated reasons or comments.

Users who have one or more CDAs assigned to them also see a new task, “CDAs requiring approval” on the home page when they log into a study. This task displays only if the CDA is assigned to the logged in user or if the user is the assigned site user. CDA managers, who see all CDAs in a study, will not view the task if no CDAs are assigned to them.

The Document Approvals page below includes a graph of submission statuses at the country level. Click the tabs above the graph to view details and action options for each status. Click a country name to view details about submitted documents and status.



Oracle Site Select represents CDA actions and statuses as follows:

Action	Performed by site or CRO/Sponsor	Document Approvals tab status	Site grid CDA status	Document Approval page status (Document History)
CDA task reached, no download performed	Site Oracle Site Select LITE user or Oracle Site Select user acting on behalf of a site	Requires site submission	Incomplete	<none>
Downloaded the CDA template	Site Oracle Site Select LITE user or Oracle Site Select user acting on behalf of a site	Requires site submission	Pending	Downloaded
Uploaded a document with comments	Site Oracle Site Select LITE user or Oracle Site Select user acting on behalf of a site	Requires review	Pending review	Pending review
Selected the "Requires resubmission" option and uploaded a document	CRO/Sponsor	Requires site resubmission	Pending	Requires resubmission
Updated and uploaded a document	Site Oracle Site Select LITE user or Oracle Site Select user acting on behalf of a site	Requires review	Pending review	Pending review
Selected the "Requires site signature" or "Send for digital signatures" option and uploaded a document	CRO/Sponsor	Requires site resubmission	Pending	Pending signature

Action	Performed by site or CRO/Sponsor	Document Approvals tab status	Site grid CDA status	Document Approval page status (Document History)
Signed and sent back	Site Oracle Site Select LITE user or Oracle Site Select user acting on behalf of a site	Final review	Final review	Pending counter signatures
Uploads the fully executed CDA and task approved. Note: For digital signature CDA, once the CRO/ Sponsor user counter signs the CDA in Adobe, the CDA is approved.	CRO/Sponsor	Approved	Completed	Approved

Site grid CDA status legend

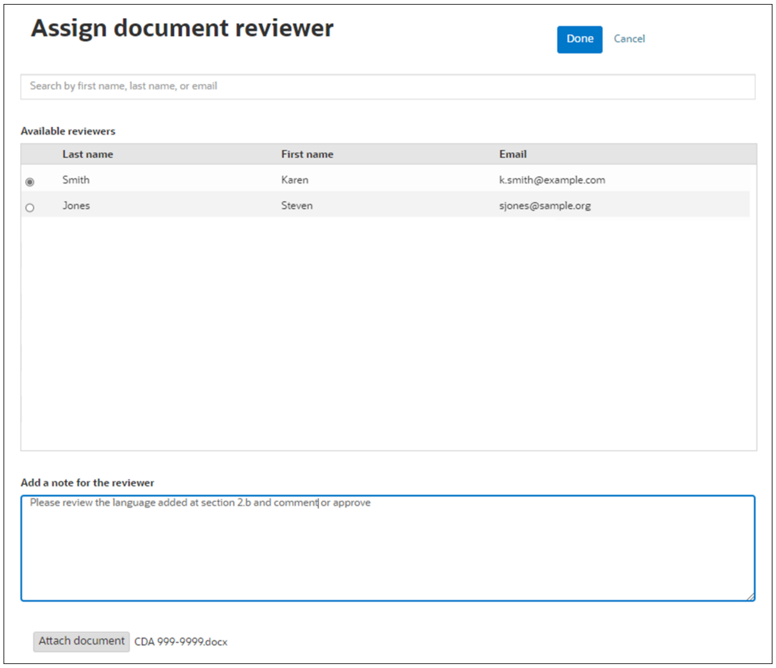
- Pending – Document is pending an action by the site
- Pending review – Document is pending review by the CRO/Sponsor
- Final review – Document is pending counter signature by the CRO/Sponsor
- Completed – Document is fully executed approved by CRO/Sponsor
- N/A – No CDA task is available for this workflow and site
- Not started – Site has taken no action on the document or the task yet

Document Approval page document status legend

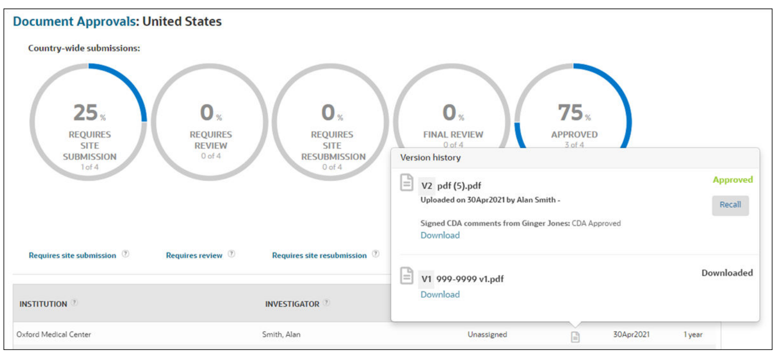
- Downloaded – The CDA template was downloaded by the site and no other action has been taken
- Pending review – Document is pending review by the CRO/Sponsor
- Requires site resubmission – Document requires resubmission by the site
- Pending signature – Document is pending a signature by the site
- Pending counter signature – Document is pending counter signature by the CRO/Sponsor
- Approved – Document is fully executed approved by CRO/Sponsor

You can also reassign CDAs to other Oracle Site Select users and optionally upload new/annotated files within the reassignment workflow. When viewing the list of submitted documents on the Document Approvals page, you can click the hyperlinked “Assigned Reviewer” to view a list of users who have CDA review permission for the study. Reassignment activity, including any related comments, will not be visible to site users.

When you assign a reviewer, that user will receive an email notifying them of the assignment and the email includes the Study ID, protocol number, protocol title, and any associated reasons regarding the reassignment.

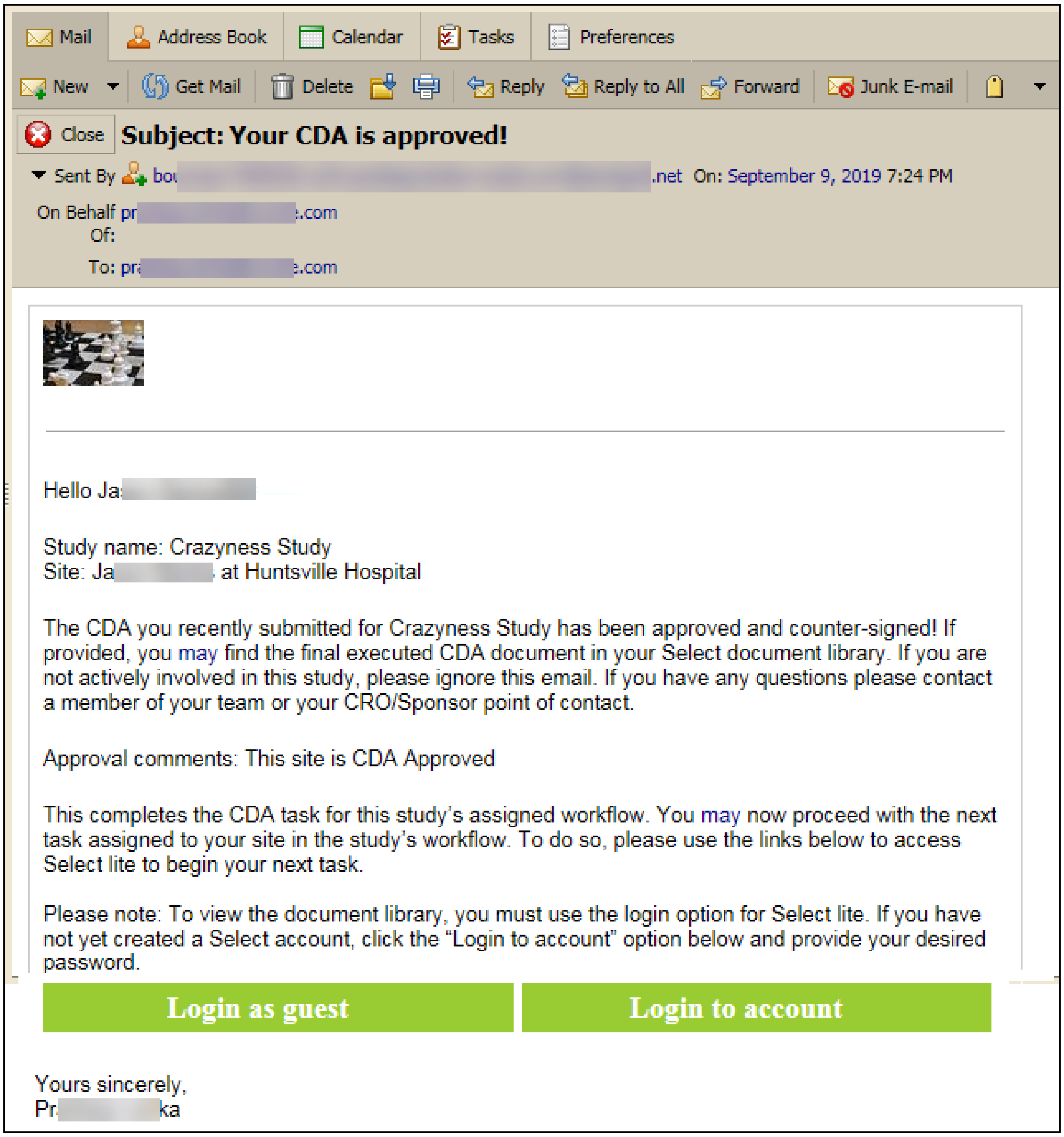


Click Document History ( ) to see the full document history (download, submission(s), approvals) and comments, if any. If it's necessary to recall a CDA, you'll find that option in the Document History pop-in as well.



When a CDA has been approved, Oracle Site Select sends a final approval notification by email. This email specifies the study name, and site as well as

- Confirmation that the CDA task has been completed
- If provided, where the recipient can access the executed CDA in Oracle Site Select LITE
- Call to action to proceed with the next assigned task in the workflow



Additionally, the CDA approval notification email will include the finalized CDA as a document attachment if this setting is enabled at the CDA workflow task level. When the task setting is enabled, and the CDA is fully executed, Oracle Site Select sends the CDA as an attachment 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.

- View CDA status
- Assign/reassign a CDA reviewer

View CDA status

1. In the top navigation bar, hover over **manage** and click **document approvals**.
2. To see the status of sites within a country, click the country name.
3. Click a tab under Document Approvals: [Country Name]

- **Requires site submission** – lists sites that have not yet uploaded a CDA, as well as the date and elapsed time since the request
- **Requires review** – lists all open requests for CDA review/approval
- **Requires site resubmission** – lists all open requests for resubmission along with the assigned reviewer, the full document history to date, and the date and elapsed time since the request
- **Final review** – lists documents that are pending digital counter signature
- **Approved** – lists all CDAs that have completed the approval process. You can also review the complete document history here.

Assign/reassign a CDA reviewer

1. In the top navigation bar, hover over **manage** and select **document approvals**.
2. To see the status of sites within a country, click the **country name**.
3. On the **Requires approval** or **Requires site resubmission** tab, in the **Assigned reviewer** column, click the name of the currently assigned reviewer or click the **Unassigned** link.
4. On the **Available reviewers** list, choose the preferred reviewer.
5. Optionally add a free-text note for the reviewer.
6. Optionally attach a document.
7. Click **Done**.

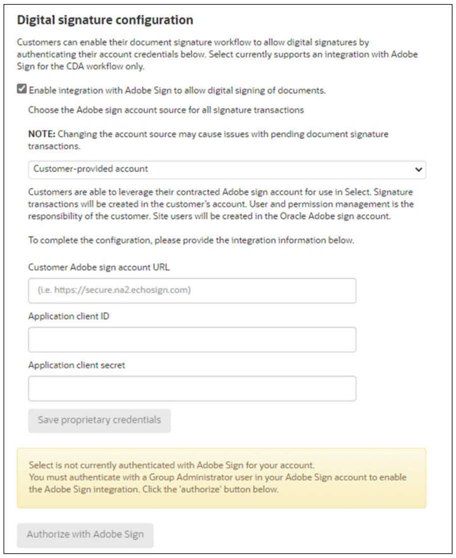
The assigned reviewer will receive an email notification about the assignment.

Signing CDAs digitally with Adobe Sign integration

Oracle Site Select offers CFR Part 11-compliant digital signature for the CDA workflow through optional subscription to Adobe Sign. Your Oracle Project Manager will provide subscription details.

Configuring the Adobe Sign integration

If your organization has an active Adobe Sign subscription, and if you have permission to access the Authentication and API configuration page, you can enable Adobe Sign integration. You must authenticate with an Adobe Sign Group Administrator user ID to enable the Adobe Sign integration. Once successful authentication occurs, a green text box indicates the current authentication state as well as the authenticated user ID and Adobe Sign Group.

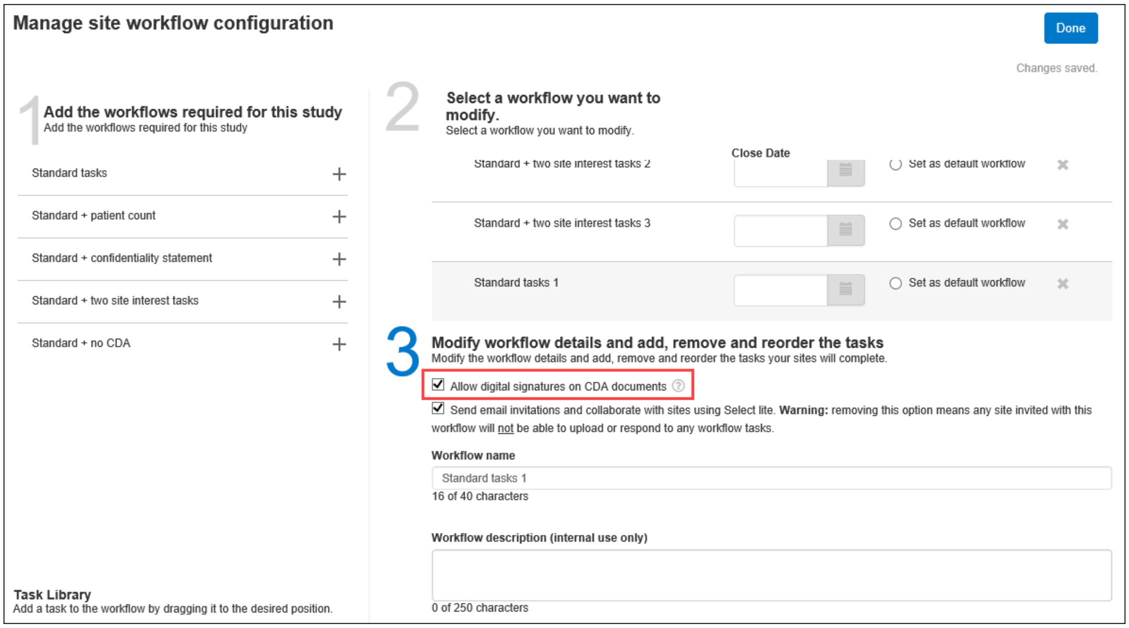


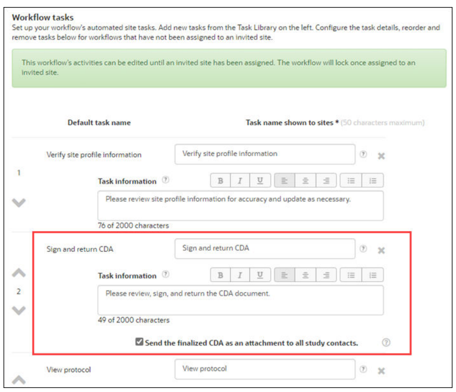
> **Note:**
>
> Digital signature authentication requirements ensure the user sending digital signature documents cannot maliciously or accidentally log in with an Adobe Sign account outside the customer's domain (group). The CDA sender's group ID must match the account group ID when authenticating an Oracle Site Select user for the first time with Adobe Sign, or the user will not be permitted to create digital signature transactions. When the group IDs do not match, Oracle Site Select displays the error, "Digital signature authorization failed: The user being authorized is in the Adobe Sign group <groupName1>, but your account requires a user from the <groupName2> group. Reauthorize with a user from the correct group."

Configuring workflow tasks for digital signature

Once enabled for the account, Oracle Site Select users who have permission to configure site workflows will have the option to enable digital signatures on CDA workflow tasks. The option allows the CDA to have a site user and/or Oracle Site Select counter signer assigned to the CDA for digital signatures. By default, the digital signature workflow option is enabled for authorized accounts and new/editable workflows.

> **Note:**
>
> Note: Oracle Site Select supports only Microsoft Word (DOCX) and PDF format documents for digital signature in the CDA workflow.





CDA workflow task configuration to provides a "Default countersigner" field where an Oracle Site Select user can optionally specify an individual as the default assigned CDA counter signer. When populated, the individual’s name automatically populates in the Document action modal’s Counter Signer field with an asterisk preceding the name. The user can still include an optional, free-text comment for the assigned counter signer, if preferred.

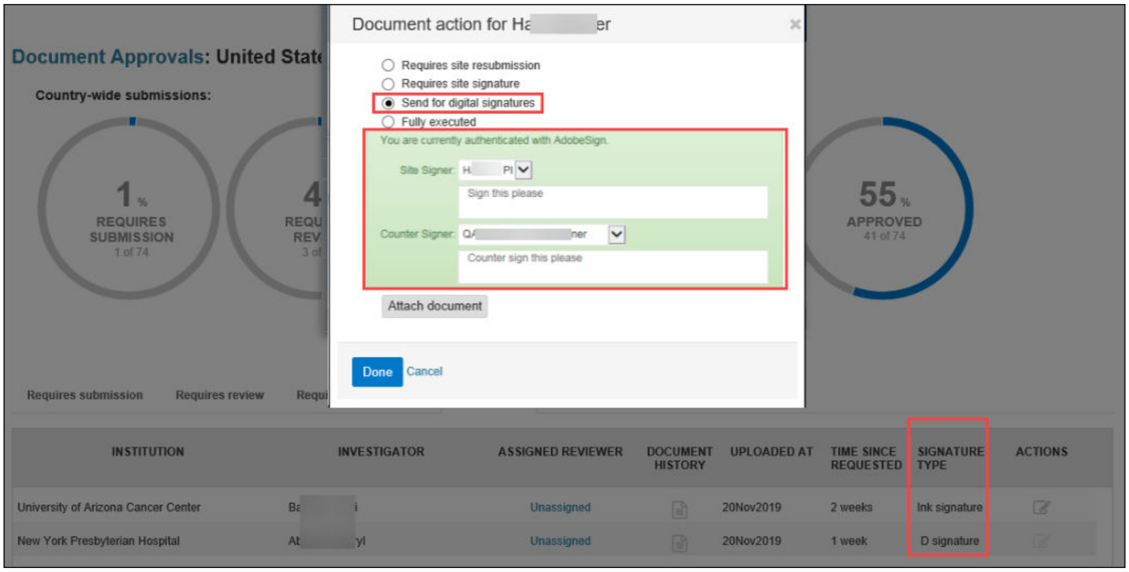
If the configured default counter signer is ineligible for counter signature for some reason (e.g., user account lock, insufficient permissions, etc.), the Document action modal displays an error and the user can choose another valid counter signer, if preferred.

Specify signer(s)

Users who have a role with *Send CDAs for digital signature* permission can assign CDA signers and send a CDA for digital signature. These assigners must be created in the Oracle Adobe Sign account. Users who have a role with *CDA counter signer* permission are listed as available CDA counter signers if digital signature is enabled in the assigned workflow. As described above, a workflow can also be configured to include a default counter signer, which automatically populates the Document action modal's "Counter Signer" field. For counter signer users, please note that individuals with an existing Adobe Sign account that was not originally created by Oracle may not be assigned as a counter signer to a CDA in Oracle Site Select.

Oracle Site Select supports assigning one digital signer for the site and one digital counter signer. Site users will complete the signature process before counter signers begin the process. Under the Document Approvals page Final Review tab, for documents of Signature

Type "D signature," the Action option “Send for digital signatures” expands a Document action modal where the Oracle Site Select user can specify a site signer and optionally specify an Oracle Site Select user as counter signer prior to attaching a document. The Document action modal also includes a free text area where the assigner can include an optional private message for signers. The private message text is displayed only in Adobe Sign and is not visible in Oracle Site Select LITE or Oracle Site Select.



When the workflow allows the CDA to be digitally signed, a site user must be specified to sign the document. Otherwise, the CDA will follow the previously available wet ink signature workflow and will not be forwarded to Adobe Sign.

The available lists of Site and Counter Signers follow specific guidelines:

Site Signer

- Based on the email recipient preferences for that study site and limited to those who received the study site invitation. The site digital signature CDA email notification will be sent to the assigned site signer regardless of which site user last uploaded the CDA.

Counter Signer

- Account users assigned the *CDA counter-signer* permission:
  - AND the user must have either or both of the following permissions assigned to them for this study:
    - *Review and Approve All CDA/Document Submissions*
    - *Review and Approve Assigned CDA/Document Submissions Only*
  - AND the user must be permissioned to the study and the site

A customer's Adobe Sign group user can log into Adobe Sign to locate the document transaction, if necessary. Transactions stored in Adobe Sign will use the following naming convention:

study name> ":" <PI last name> "," <PI first name> "at" <Institution name> "CDA"

The digital signature feature is reflected in the Document Approvals interface. For instance, a country-specific “Final review” donut chart and a "Final review" tab allows Oracle Site Select users to view documents that are pending counter signatures. If necessary, users can also Recall the document from within the Document History view.

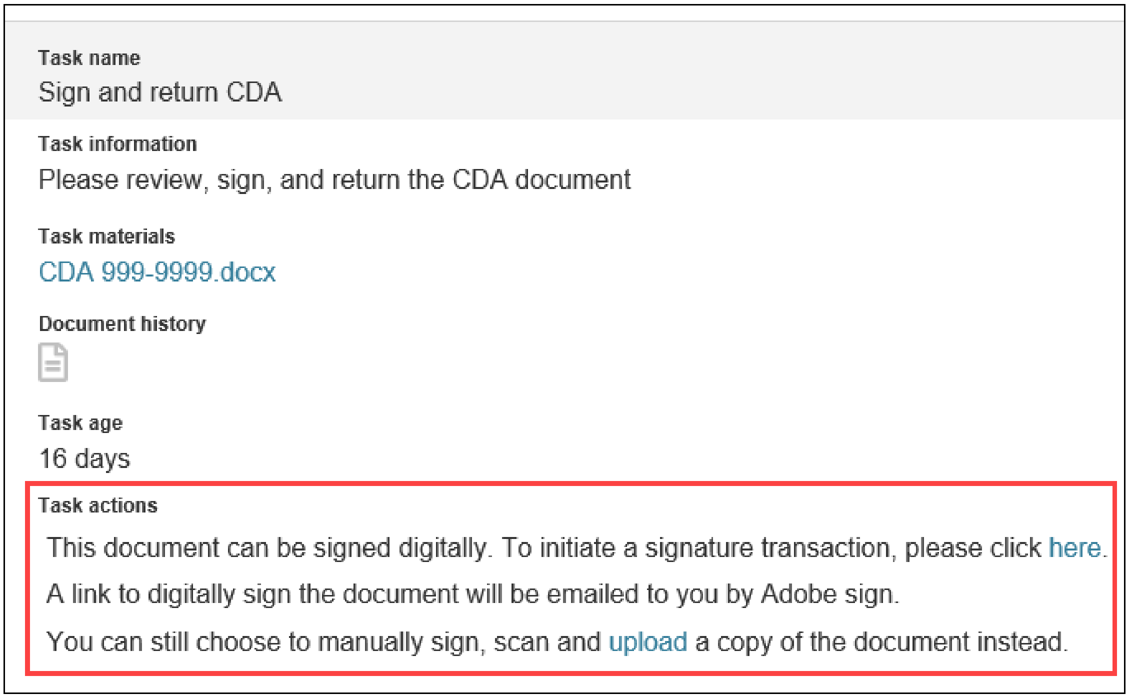
Note:

If a CDA in a digital signature transaction is recalled, the entire CDA digital transaction will be cancelled in Adobe Sign. The CDA will then return to the "Pending review" status. This is expected behavior.

Oracle Site Select LITE digital signature messaging

When a CDA has been sent to a site for digital signature (i.e., the Adobe Sign transaction is pending), the CDA's task panel in Oracle Site Select LITE displays two different text messages depending upon whether or not the user is the assigned site signer.

Text displayed to user assigned to digitally sign the CDA	**Text displayed to site user who is not the assigned site signer**
"You have been assigned as the digital signer for this document. *Please check your email for a document link from Adobe sign. You will be required to log in with your Adobe Sign credentials to complete the signature process.* *If you are new to Adobe sign, an account has been created for you. Please check your email to activate your account before proceeding with the signature process.* *If this is in error, please contact your study administrator.* *You can still choose to manually sign, scan and upload a copy of the document instead."* The "upload" text noted in the last line of the message above is a hyperlink that opens the CDA upload modal in Oracle Site Select LITE. If the assigned digital signature signer chooses to manually upload a signed CDA, the user does not have to download the most recent CDA before uploading a wet ink signed CDA.	*"This document has been assigned to <Assigned User> at <Assigned User Email> for digital signature. If this is in error, please contact your study administrator.* *You can still choose to manually sign, scan and upload a copy of the document instead."* The "upload" link noted in the last line of the text above opens the CDA upload modal in Oracle Site Select LITE if the site user chooses to manually upload a signed CDA instead of following the digital signature process. For this unassigned site user, the CDA upload does not require a CDA download when the CDA is pending a digital signature, and the site user can download the most recent CDA template and comment/upload a "wet ink" CDA – even if the user is not the digital signature assigned signer.



Site initiated digital signature transaction

Site users have the ability to initiate a CDA digital signature transaction when:

1. The CDA workflow task is enabled for digital signature
2. The CDA does not have an assigned site signer
3. The CDA is not currently in a “Pending review” or “Pending final review” status and
4. No other active digital signature transaction exists for the study-site

When all four of the above conditions are true, Oracle Site Select LITE will display messaging that the user will receive a link via Adobe Sign email to digitally sign the document. The message also notes the user has the option to manually upload a signed CDA, if preferred. If the site user chooses to initiate the transaction, default private message text will be included in the Adobe Sign transaction as follows below:

- **Site signer**: You initiated this digital signature for study: <study name> on: <digital signature transaction creation date>
- **Counter signer**: The site user <site user who created the transaction> created this digital signature transaction on <digital signature transaction creation date> for the study: <study name>.

When a workflow task does not specify a default counter signer, Adobe Sign creates the transaction with only the site user who initiates the transaction. If a CDA workflow task does specify a default counter signer, the Adobe Sign transaction includes the site signer as the initiating Oracle Site Select LITE user and then the workflow-defined counter signer, in that order.

> **Note:**
>
> A site user may not initiate a digital signature transaction on a CDA returned via the action "Site resubmission required." This is by design, as the Oracle Site Select user choosing that action is assumed to require the site to provide edits before allowing site signature.

- Enable Adobe Sign Integration
  Customers 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.
- Assign CDA digital signers

Enable Adobe Sign Integration

Customers 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. From the **account** menu, click **Authentication and API configuration**.
2. In the **Digital signature configuration** section, click the "**Enable integration with Adobe Sign**…" check box.
3. Enter the **Customer Adobe sign account URL**, **Application client ID**, and **Application client secret**, then click **Save credentials** and **Authorize with Adobe Sign**.
4. At the upper right, click **Done**.

Assign CDA digital signers

> **Note:**
>
> If your organization has subscribed to and enabled Adobe Sign integration for CDAs, Oracle Site Select supports assigning one digital signer for the site and one digital counter signer. Site users will complete the signature process before counter signers begin the process.

1. From the **manage** menu, click **document approvals**.
2. On the Document Approvals page, select a country from the grid.
3. On the **Final Review** tab, click **Actions** ( ) for the document that requires digital signature. The document must have a "Signature type" of "D signature."
4. In the **Document action** modal, click the **Send for digital signatures** radio button.
5. In the green panel, use the **Site Signer** drop-down menu to select the site signer who will digitally sign the document in Adobe Sign.

6. You may optionally add a private note to the Site signer, which will display only in Adobe Sign.
7. You may optionally use the **Counter Signer** drop-down menu to identify an Oracle Site Select user who will be assigned to counter sign the document in Adobe Sign.
8. You may optionally add a private note to the Counter Signer, which will display only in Adobe Sign.
9. Click **Attach document** to upload a document for signature.
10. Click **Done**.

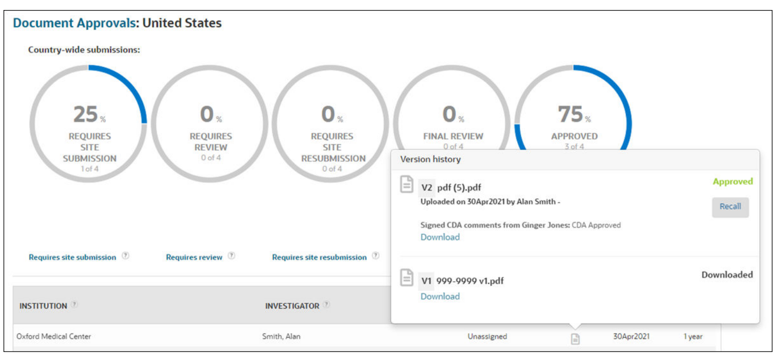
Recalling a CDA

When appropriate, you can recall a CDA document that was sent to a study site within the CDA workflow and recall a CDA submitted by a study site user or by an Oracle Site Select user on the study site's behalf.

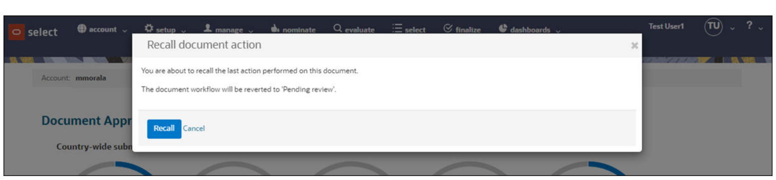
Permissions on which CDA documents, if any, you can recall follow your CDA-assigned permission(s); no additional permission is required to recall a CDA. For example, if you have the *Negotiation for assigned CDA/Document submissions only* permission, you can recall only those CDAs that are in the scope of that permission.

Site users who have authenticated into Oracle Site Select LITE via a username/password can delete their last uploaded CDA by navigating to the Document library tab in Oracle Site Select LITE. This includes CDAs they uploaded as well as those uploaded on their behalf.

When you view the Document approvals area on either the Requires site resubmission or Approved tab, you'll see a Recall action button in the Document History modal. The Recall button is available only for the most recent document. By design, the Recall button is not available on a Final Approved document that was auto-completed by a document found in a site's document library.



If you click Recall, a confirmation modal displays that shows the outcome of the Recall action (e.g., "The document workflow will be reverted to Pending review"). If appropriate for the document, additional warning text may display. For example, "You are about to recall the document submitted to the site for review. This will remove the document from the site's document library and active document task. It will also revert the document workflow back to Requires approval. If the site has already downloaded the document, this feature will not remove that download from their system."



If you recall the document:

- The document link is removed from the Oracle Site Select LITE document library and the Oracle Site Select LITE action task bar
- The CDA workflow is reverted back to the Oracle Site Select user (e.g., the document submission is "undone")
- Comments associated with the document are removed
- No email notification is sent to the Oracle Site Select user or site users

If you request a resubmission from a site, but do not upload a document, and you then want to recall that "submission," the recall action will revert the action of requesting a resubmission, but it will not impact a document submission.

- There is no document link to remove from the Oracle Site Select LITE document library nor the Oracle Site Select LITE action task bar
- The CDA workflow is reverted back to the Oracle Site Select user
- The audit log is updated to reflect the recall
- No email notification is sent to any Oracle Site Select or Oracle Site Select LITE user
- The comments associated with the submission are removed

- Recall a CDA

Recall a CDA

1. In the top navigation bar, hover over **manage** and select **document approvals**.
2. On the CDA tab, select a country.
3. Click either the **Requires site resubmission** or **Approved** tab.
4. Locate the investigator's row, and click the **Document History** icon.
5. Click **Recall**.
6. In the confirmation modal, click **Recall**.

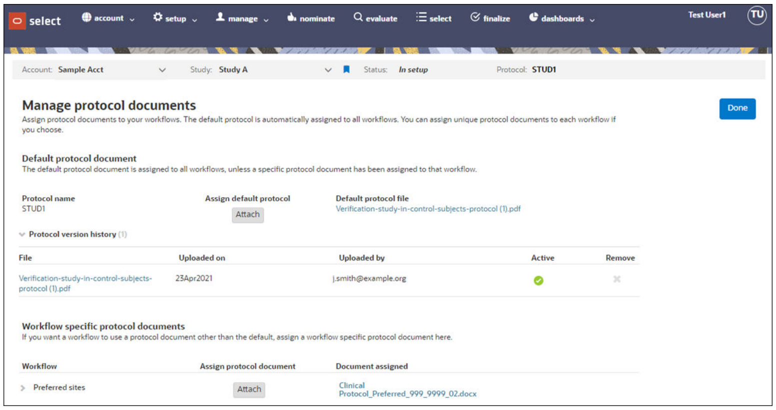
Managing protocols

You'll need to specify key protocol information in Oracle Site Select, such as the study name and study number, IRB/EC type, countries, and therapeutic area. Then upload the protocol in Microsoft Word or Adobe Acrobat (PDF) format and run a workflow to drive the process required to deliver the document to sites.

Just like confidentiality documents, you can:

- Define multiple workflows so that different protocol documents, such as the full protocol or a synopsis, can be delivered to various sites
- Designate a default protocol document to automatically assign to all workflows
- Manage multiple versions of protocols so that sites receive the latest protocol version

If a protocol changes, you can upload a new version. On the "Manage protocol documents" page, click the "Protocol version history" section to expand the section and view previous protocol versions. You can view or download the protocol file or click "X" to remove the file.



If you choose to remove a protocol document, Oracle Site Select will detect if the document is in use by sites, and you'll have the choice to preserve or restart the workflow.

- Upload a study protocol to a workflow

Upload a study protocol to a workflow

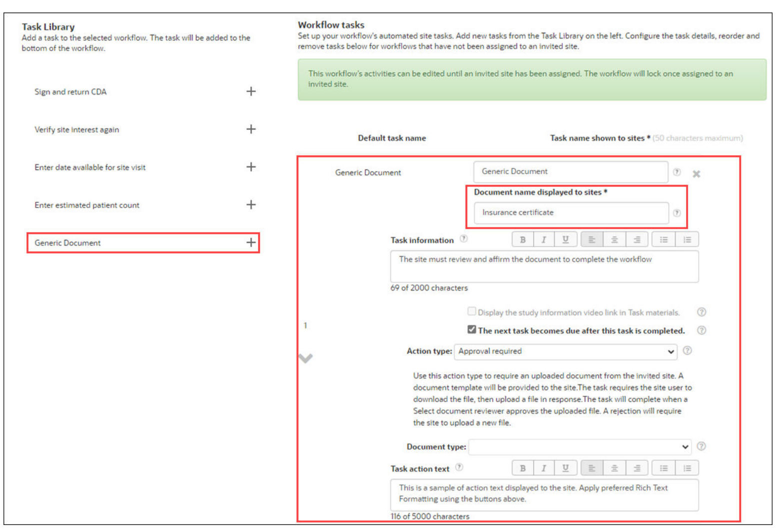
You must have a role with *Study Setup Management* permission to complete this task.

1. In the top navigation bar, hover over **setup** and click **manage protocol documents**.
2. To add a default protocol, in the **Default protocol** document section, click **Attach** and upload the protocol.
3. To add a protocol document that is specific to a workflow (for example, a PSP for sites who do not need the full protocol), in the **Workflow specific protocol document** section, next to the desired workflow, click **Attach** and upload the protocol document.

Managing generic documents

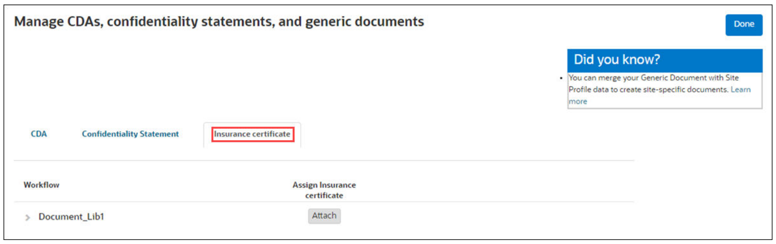
Generic Document is a specific workflow task available in the Task Library when you create or modify a workflow under Site workflow configuration.

When you select the Generic Document task, you will upload the document you want to manage, and you'll specify the document name you want to display to sites.



A generic document task will require a specific action taken by the site to complete the task. Action types available when configuring a generic document workflow task include Approval, Attestation, Choose response, and Download. A site's assigned workflow may include multiple generic document tasks, which are differentiated by the task display names and the action types.

Once defined in the Workflow Task list, the Generic Document displays as a separate tab under the Setup menu's "CDAs, confidentiality statements, and generic documents" option. The display name specified for the document in the workflow task is displayed as the tab's name. Click Attach to navigate to your hard drive and upload the document. You can upload a document of any type (e.g., DOCX, PDF, PPT, XLS, ZIP, etc.).



- Upload a generic document
- Download generic document attestation details
  Output details for a generic document attestation submission to a PDF file.

Upload a generic document

1. In the top navigation bar, hover over **setup** and click **Site workflow configuration**.
2. At the upper left, choose the workflow to which you will add the Generic Document task. Rename the workflow to a unique name and optionally add a description.
3. In the Task Library, drag and drop the Generic Document task to the task list. Reorder tasks as necessary (drag and drop).
4. Click the Generic Document task to expand. Enter the document name that sites will see, and click the document option checkboxes as applicable.
5. Click **Done**.
6. In the top navigation bar, hover over **setup** and click **Manage CDAs, confidentiality statements, and generic documents**.
7. Click the tab for the document name you specified in step 4.
8. Click **Attach** to browse to your hard drive and upload the document.
9. Click **Done**.

Download generic document attestation details

Output details for a generic document attestation submission to a PDF file.

You must have a role with CDA document review permission as well as a the *Review generic document attestation submissions* permission to complete this task.

1. In the global navigation bar, hover over **manage** and click **document approvals**.
2. Click the generic document's tab.
3. In the country grid, click the country name link.
4. Click the **Completed** tab and scroll to the right to view the **Actions** column.
5. Click download ( ) to export the attestation detail to a PDF document.

The document downloads and has the following file name format:
<studyID> _ <Country name > _ <PI last name> - <pi first name> - <institution name> - <generic document task internal name> - <datetime workflow task completed>.PDF

Document Library

The Document Library feature allows for document reuse and automates the completion of workflow tasks using stored library documents associated to study site, investigator, or institution.

Document labels

The Account document label configuration page allows your account's permissioned administrator to identify a Document Library document by label designation. 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 and spaces, emojis, and special characters (~!@#$ %^&*()_+-= []:'';'<>,./?).

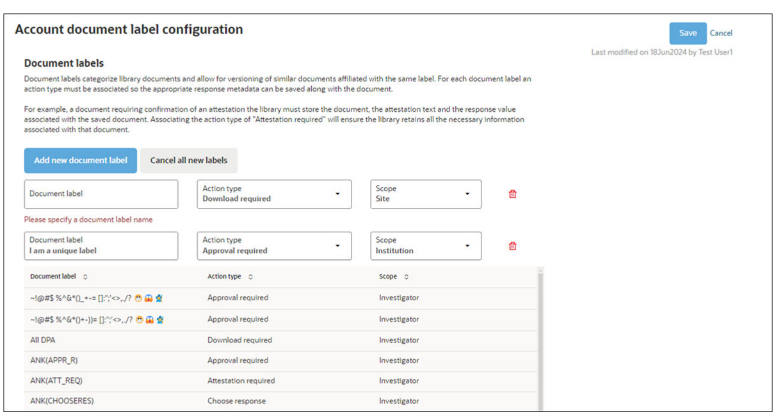
On the Account document label configuration page, the study administrator must also specify one of the following Action Types when adding a new document label:

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

Finally, the study administrator must 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 the study administrator saves the new document label to the list, you may not change the entry; however, the administrator can create a new document label if necessary.



Document labels in workflow tasks

Document-related workflow tasks use your account's defined document labels. If you have permission to configure site workflows, you can specify a Document label for document related tasks. This configuration provides the required association between the workflow task and document label. When an invited investigator is assigned to the workflow, the document label/ workflow task association allows for automated completion/approval of the task if the related site, investigator, or institution scoped document exists in the library.

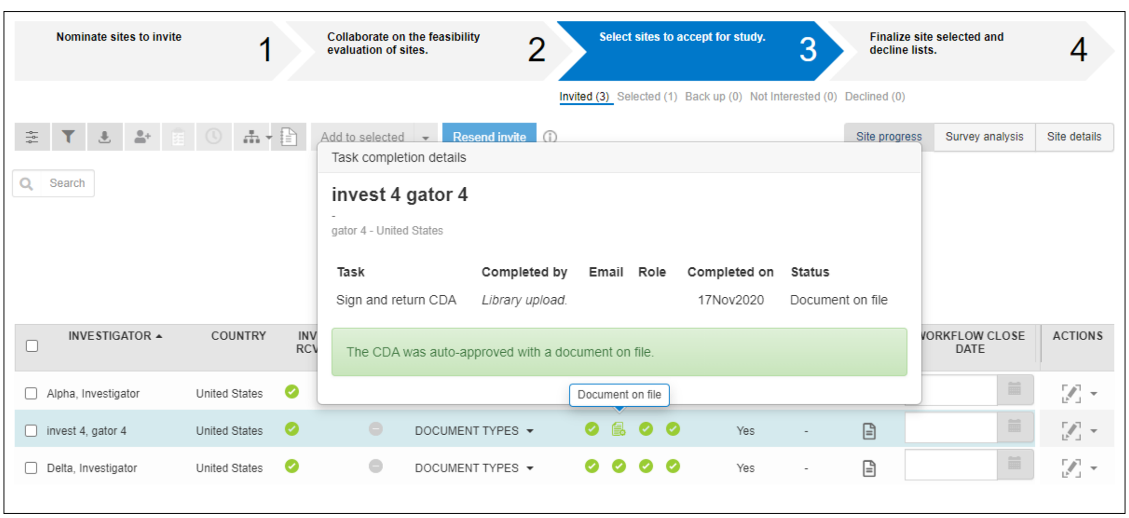
Tasks manually completed

When a document workflow task has been tagged with a document label, but no document with that label is available for that investigator in the Document Library, Oracle Site Select saves the document to the library when the workflow task is manually completed/approved by the site user in Oracle Site Select LITE or by the Oracle Site Select user on behalf of the site. The document is then available in the investigator's library for future task autocompletion. The document's “Completed by” value is saved, and displayed in future studies, as the user who clicked Done on the initial workflow task, or for CDAs, the Oracle Site Select user who performed the initial final approval.

> **Note:**
>
> If a site user selects “No” for an agree to confidentiality statement task that has been tagged with a document label, the document is not saved to the Document Library for that investigator. This is by design as this logic allows the investigator to review and respond “Yes” to the confidentiality statement in a future study.

Task completed with document on file

Oracle Site Select and Oracle Site Select LITE differentiate auto-completed tasks from manually completed tasks using “Document on file” text and/or icon ( ), as appropriate to the page or page element. For instance, on the Oracle Site Select Site Progress tab, the document on file icon displays in the site grid for workflow tasks that were completed with a library file. When appropriate, manually completed workflow tasks display Completed ( ).



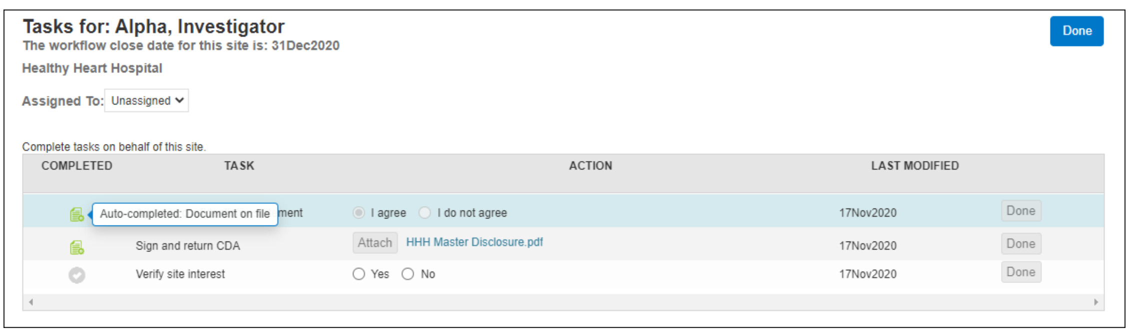
On the Manage document approvals page, if a generic document or CDA workflow task auto-completes using a document in the Document Library, the page reflects that completion and indicates the task/document completed from a library document (i.e., Status is "Document on file"). For a document task associated with a document label that is "manually" completed, the behavior of the Document approvals page is as follows:

- An Agree to confidentiality statement workflow task that has a configured Document label is not displayed/referenced on the document approvals page
- A Generic document workflow task is not displayed/referenced on the Document Approvals page if the task has a configured Document label but does not require a signature
- When a document workflow task auto-approves using a library document that was imported via API, the date of the approval is the date of the API import and the Completed By user is listed as "Library import"

Additionally, the following are expected behaviors for the Document Approvals area CDA Recall functionality:

- The “Recall” button is not available for documents with the status of "Document on file"
- When a CDA workflow task has a configured Document label, and the task/document is manually approved for study1 on day1, the document is saved to the Document Library. If on day2 the site is invited to study2, the site’s assigned CDA workflow task is auto-completed with the CDA in the Document Library (status of "Document on file"). If the site decides on day3 to recall the CDA from study1, the auto-completed CDA on study2 will not recall.
- An approved CDA associated with a Document label (but not in a status of "Document on file") from its originating study will be allowed to be recalled and the associated library document will be invalidated with the reason "Approved original document recalled"

Oracle Site Select also indicates auto-completed document workflow tasks when a user completes a task on behalf of a site. The "Tasks for" page displays document on file ( ) when appropriate in the Completed column.



When a workflow task has a document label association and the investigator for the site has a document associated with that document label, the workflow task auto-populates with that document to auto-complete/approve itself.

The following scenarios describe the expected behavior:

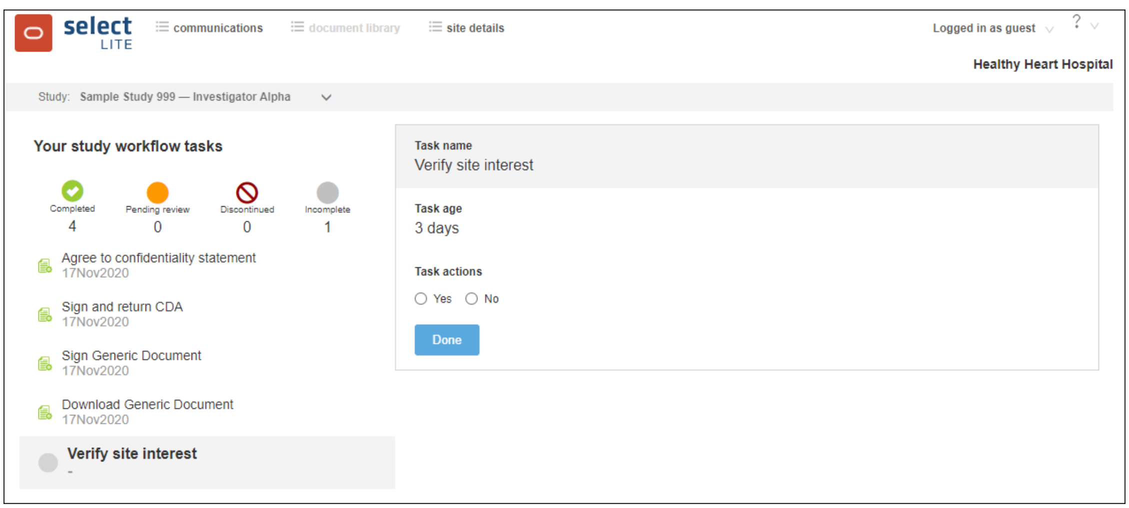
1. A site is invited to a workflow with the Generic document workflow tasks below. On study invitation, the tasks auto-complete as Oracle Site Selectpulls the matching document(s) from the investigator’s document library (not the template uploaded to the workflow's configuration). The site is marked as having completed the workflow tasks as follows:
   a. Task 1: A Generic document task with “Download required” Action Type
   b. Task 2: A Generic document task with “Approval” Action Type
   c. Task 3: A Generic document task with “Attestation” Action Type. For this type, Oracle Site Selectalso stores the response affirmation, declination, chosen response, and attestation text

d. Task 4: A Generic document task with “Choose response” Action Type. For this type, Oracle Site Selectalso stores the response affirmation, declination, chosen response, and attestation task action text

2. A Generic document task with “Attestation” Action Type that is auto-completed by an Document Library document where the attestation response is “declined” now displays a document on file declined ( ) task indicator icon. The site progress popover displays information on the original user who completed the task.
3. A studysite cube Data Export Utility report includes the workflow completion "by" and "on" as the document library completed_by and completed_on values stored for auto-completed/approved workflow tasks.
4. An account has a primary datasource with SiteA (investigatorA + institutionA). This investigator has a document associated with docLabelA. For study1, a CSV is imported as a new flat datasource and attached to the study with SiteB that disambiguates as an exact match to SiteA in the primary datasource. The primary datasource is NOT attached to Study1. When SiteB is invited to a workflow that leverages docLabelA, the workflow task will auto-complete with the investigator's library document.

In Oracle Site Select LITE, site users also see an indication of auto-completed document workflow tasks. The home page displays document on file ( ), under the "Your study workflow tasks" list, when applicable, and to ensure the task status count above the list displays the correct number of Completed tasks.

> **Note:**
>
> The date displayed below a task's label is the original completion/approval date stored in the Document Library for the populated document.



The Oracle Site Select LITE site document library also indicates auto-completed documents by displaying Document Version Status as "Document on file," when appropriate. Site users do not have the ability to Delete a document on file. In this case, no action displays in the library "Action" column.

Note:

Oracle Site Select does not support saving institution-scoped library documents via the completion of a site workflow task. A workflow task affiliated with an institution-scoped document label does not save to the document library if completed by a site user (i.e., document on file) or by an Oracle Site Select user acting on behalf of the site (i.e., not auto-completed). To save an institution-scoped document to the library, send the document using the Library POST or PUT APIs.

Populate library using the Library POST API

Your organization can optionally upload known documents to the Document Library using the Library POST or PUT API. Each POST or PUT request must include

- Unique investigator ID – from the primary datasource
- Scope – Investigator or Institution
- Document label – created by the account administrator on the “Account document label configuration” page in the Oracle Site Select application. If an entry of the specified document label already exists for the investigator, the new entry becomes the latest version.

The API also accepts an optional_metadata (string) property that provides your organization with a method to manage invalid documents, when necessary. The optional property accepts is_invalid (Boolean) and invalid_reason (string) attributes. If the POST message includes the optional_metadata property, but no attributes are specified, is_invalid defaults to false. An example of the property is: {"is_invalid":true,"invalid_reason":"Expired"}.

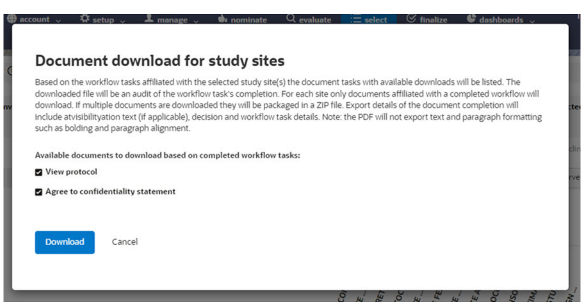
Document workflow task audit

Site grid users can download an audit file containing document workflow completion details.

The Site Document Download option is in the site grid Actions menu, 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.



12
Email and Site communications

Learn how email managers can set up and modify account-level and study-level email templates in Oracle Site Select. The section also describes a feature that allows permissioned users to resend or retry email communications, and it describes the Site communications area that is available to all users.

- Manage 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.
- Manage study level email templates
  Study 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.
- 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.
- Manage Site communications area
  Send and receive site messages within the Oracle Site Select application.

Manage 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.

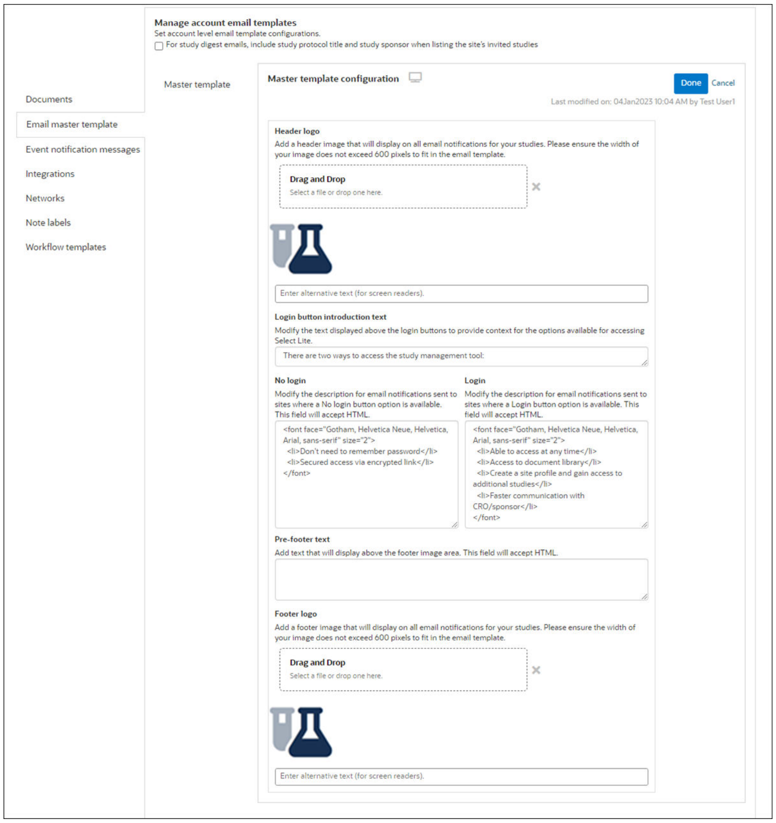
Oracle Site Select users with *Account email template management* role permission access the Manage account email templates page to optionally configure the following placeholders:

- Header logo image (600 px width max, any resolution, 5MB max, and JPEG, GIF, or PNG file type)
- Login button introduction text
- Text describing the “No login” link
- Text describing the “Login” link
- Pre-footer text that displays directly above the footer image
- Footer logo image (600 px width max, any resolution, 5MB max)

All text input fields accept HTML; however, Javascript (i.e., "<script>” or “</script>” HTML tag) is not supported in any field.

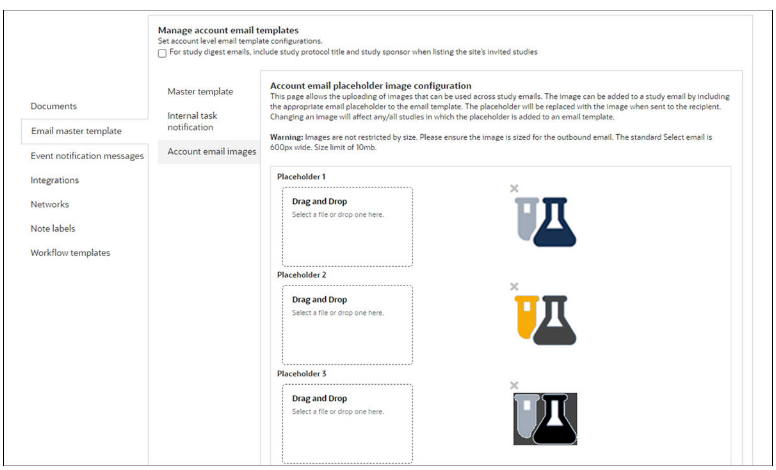
The account email template configuration page also includes preview functionality to help you validate configured images and text display as intended before saving the changes.

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.

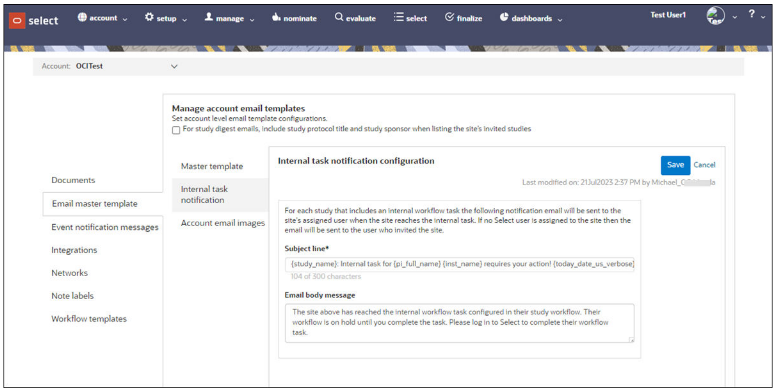


You can also configure account level email image placeholders. This option allows you to upload images that can be used across study emails when the study email template has the corresponding account-level image placeholder (i.e., account_image_<number>).

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).



If your organization uses Internal workflow tasks, you can create email notifications specific to those tasks. On the Manage account email templates page, Internal task notification section, configure the template to include the preferred subject line and message body. Both areas support email placeholder values. 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 account email templates
  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 templates

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.

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

1. In the global navigation menu, click **account** and click **email template configuration**.
2. If appropriate, optionally check the box labeled **For study digest emails, include study protocol title and study sponsor when listing the site's invited studies**.
3. 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.
4. Below the logo image, enter alternative text for the Header logo. This text can be read by screen reader applications.
5. At **Login button introduction text**, optionally modify the text that will display above login buttons. If not modified, the text will be "There are two ways to access the study management tool."
6. Under the **No login** section, modify the default description text that displays in email notifications when the no login button is available. The field accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
7. Under the **Login** section, modify the default description text that displays in email notifications when login button is available. The field accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
8. Under the **Pre-footer text** section, enter text to display above the footer image area. The field accepts non-Javascript formatted HTML (i.e., no "<script>" tag allowed).
9. Under the **Footer logo** section, click **Upload image** and browse to locate a logo image that does not exceed the maximum of 600 pixels.

10. In the text field below **Upload image**, enter alternative text for the Footer logo. This text can be read by screen reader applications.
11. At the top of the page, preview ( ) the configured template.
12. Click **Done**.

Manage study level email templates

Study 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

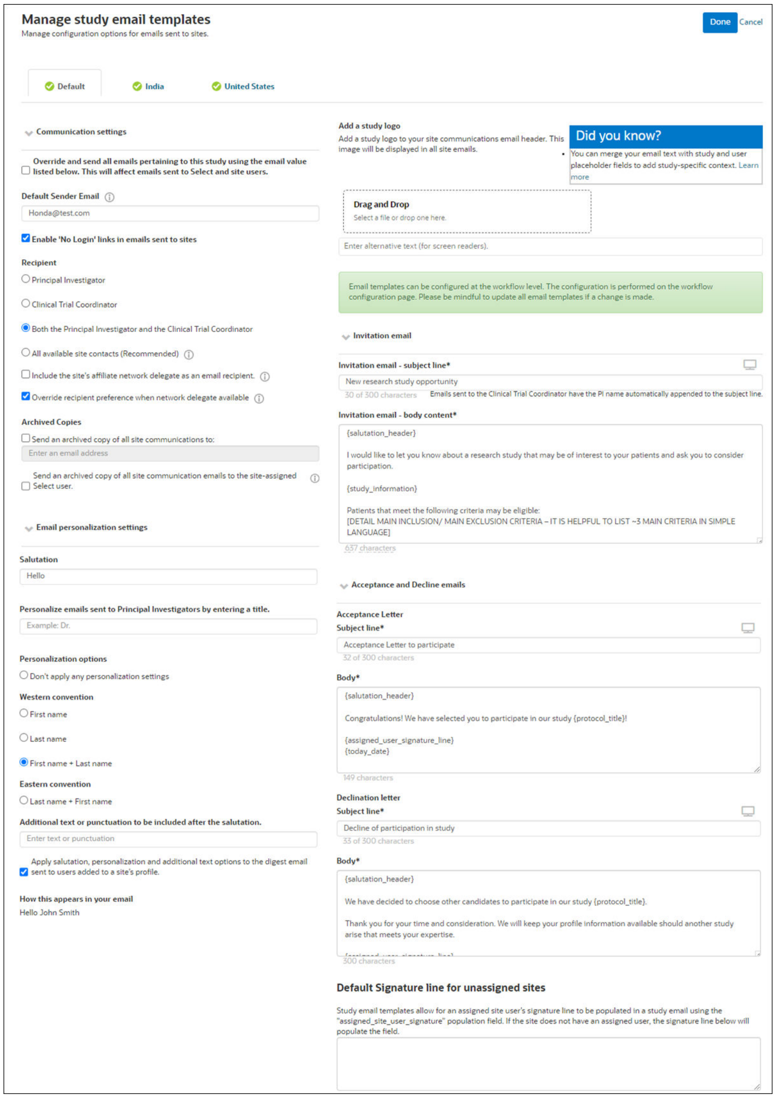
Oracle Site Select users with *Email Template Management* role permission can configure site email notifications and attributes on the Manage study email templates page.

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

Click a country tab and enable "Override default settings" to customize templates by country.

> **Note:**
>
> You must define a study logo and email salutation settings for all new studies. These attributes are not defaulted.



Email template attributes

The left side of the page provides multiple template settings to configure preferred sender, recipient, and salutation.

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 Oracle Site Select LITE 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 Oracle Site Select LITE 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, Oracle Site Select LITE 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 Oracle Site Select LITE 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.

Study logo

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 top of the tab's right side column. 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)

Email message text

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.
{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
{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

Placeholder	Description
{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 ( ) templates to validate that placeholders in the template heading and body display as expected and ensure that curly braces are not displayed by mistake.

Assigned user signature

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

- Configure study level email templates
- Resend study invitation to sites
- Add custom logo to study level email templates
- Send copy of email to a specific CRO/Sponsor address
- Disable No login links in emails

Configure study level email templates

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 the Manage study email templates page, see the **Did you know?** box to access the full list of placeholders and formatting requirements.

1. In the top navigation bar, hover over **setup** and click **email templates**.
2. Click the tab for the template you want to change (default or specific country).
3. (Default tab only) Optionally check the **Override and send all emails...** check box, and **Default Sender Email**, enter the email address of the person who will be sending the email.
4. (Optional) Check the **Enable 'No Login' links in emails sent to sites** check box if you intend to allow sites to access Oracle Site Select LITE without creating an account.
5. At **Recipient**, select the role you want to receive the message (PI, coordinator, both, or All available site contacts).
6. (Optional) If configured for your account, check **Include the site's affiliate network delegate as an email recipient**.
7. (Optional) If configured for your account, check **Override recipient preference when network delegate available**.
8. (Optional) At **Archived Copies**, check the **Send a copy of all site communications to:** check box and specify a single email address as the receiving address. 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) Check **Send an archived copy of all site communication emails to the site-assigned Select user**.
10. (Optional) If you want to personalize emails with country-specific salutations:
    a. Under **Personalization options**, 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.
    b. To add a custom salutation, at **Salutation** enter a message (see how your message appears in **How this appears in your email** at the bottom of the section).
    c. To add a title to the salutation, enter a title, such as “Dr.," in the **Personalize emails sent to Principal Investigators** by entering a title field.
    d. (Optional) add custom text or punctuation after the salutation in the **Enter text or punctuation** field.
11. (Optional) Check **Apply salutation, personalization and additional text options to the digest email sent to users added to a site's profile**.

12. At **Add a study logo**, click in the **Drag and Drop** field to browse to and upload a logo or drag and drop the image directly into the field. Use a JPEG, GIF, or PNG file type up to 1000KB max file size.
13. In the text field below the **Drag and Drop** field, enter alternate text for the image. This this text can be read by screen reader software.
14. In the **Invitation email** and **Acceptance and Decline emails** sections:
    a. At **subject line** enter the subject you want sites to see when viewing the email in their inboxes.
    b. At **body content**, enter the message.
15. Preview ( ) the configured template to confirm the content and appropriate use of placeholders, if any.
16. Click **Done**.

Resend study invitation to sites

1. In the top navigation bar, click **select**.
2. In the site grid, check the box next to each site that you want to receive an invitation, then click **Resend invite**.
3. A modal displays. For each listed user, choose an **Action** (Keep, Remove, or Add) from the drop-down list.
4. Click **Send to unresponsive sites** or **Send to all sites**.

Add custom logo to study level email templates

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

1. In the top navigation bar, hover over **setup** and select **email templates**.
2. On the default tab, in the **Add a study logo** section, click **Upload image**.
3. Choose an image of your company logo from your hard drive or other storage location. The image must be 100KB or less and must be a .png, .jpg, .jpeg, or .gif format.
4. You can optionally add alternative text to display for screen readers.
5. Click **Done** to save the changes to your 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.

Disable No login links in emails

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.

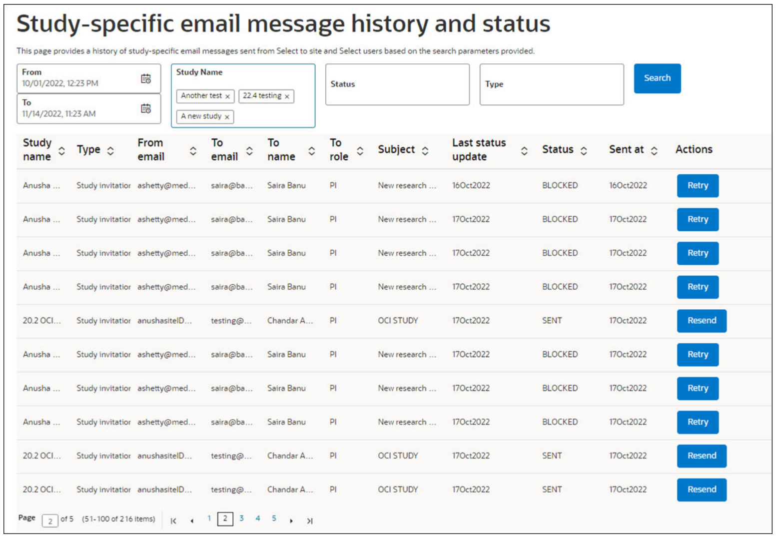
1. In the top navigation bar, hover over **setup** and select **email templates**.
2. On the default tab, in the **Communication settings** section, check the box for **Enable "No login" links in emails sent to sites**.
3. An informational message displays.
4. Click **Done**.

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. 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 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 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. In the global navigation menu, click **account** 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. In 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.

Manage Site communications area

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.

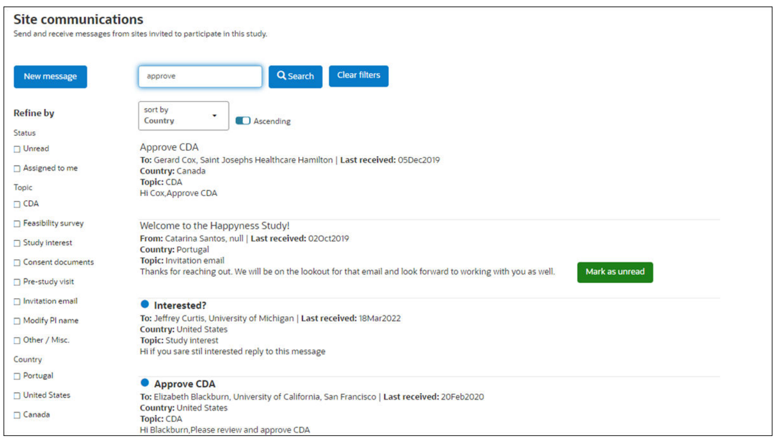
When you have the existing *Site nomination, Evaluation and Selection* user role permission, you'll access the Site communication tool by clicking the Message site option in the site grid Actions menu. You can also access the tool via the site communication option in the global Manage menu. The enhanced message modal loads with the site pre-populated as the recipient. In the Site communications tool, you can:

- 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
- see unread messages (toggle the read status of the message to Read)
- toggle a message to Unread without the message being opened

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)



You can also access the Site communication tool from the site grid 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.

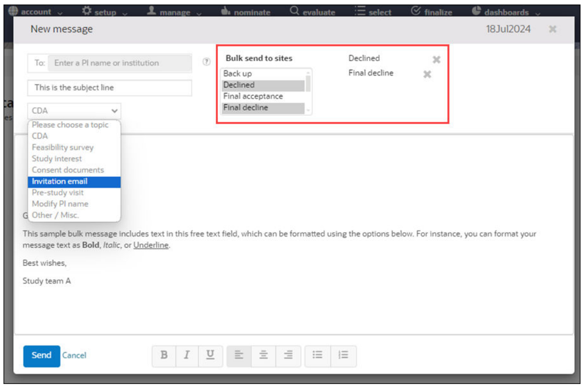
Site communications supports sending bulk messages to all sites in a specific bucket as well. Open a New message, and select the preferred bucket from the Bulk send to sites list. You can send the message to sites that are in any of the post-invitation bucket states:

- 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.



13 Feasibility Surveys

This section describes how survey managers create, choose, and score feasibility surveys using the Alchemer tool and Oracle Site Select.

- Using the online survey tool
  If you have the survey manager role associated to your user account, you can use Alchemer online survey tools to create and manage feasibility surveys in Oracle Site Select.
- Alchemer supported survey question types
  Alchemer offers many question types that allow CROs and sponsors to create highly customized feasibility surveys.
- Configure surveys and settings
  Configure feasibility surveys, scoring, and ranking for your study.
- Retaking surveys or editing 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.
- Creating survey response reports
  In the select or finalize steps, you can optionally create feasibility survey response reports in either CSV or PDF format. If you choose CSV, the extract includes a row for all sites in the site grid. PDF format will allow you to create a report for one or more selected (checked) sites in the site grid.

Using the online survey tool

If you have the survey manager role associated to your user account, you can use Alchemer online survey tools to create and manage feasibility surveys in Oracle Site Select.

Surveys you create using Alchemer are communicated to sites via Oracle Site Select Survey results. Site tiering and scoring are all viewed from within Oracle Site Select, and you can save and reuse survey responses for future studies.

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

- Configure survey vendor integration
  Specify the survey vendor region and authorization method for the account.

Configure survey vendor integration

Specify the survey vendor region and authorization method for the account.

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

1. From the **account** menu, click **Authentication and API configuration**.
2. At **Survey vendor authentication**, confirm **Alchemer** selection.
3. Use the **Select the region you would like to use for Alchemer** drop-down to authenticate with servers in either the **NA** or **EU** region.
4. To set account-level authorization, check the **Enable account-level authorization** check box.
5. At the top of the page, click **Done**.

Alchemer supported survey question types

Alchemer offers many question types that allow CROs and sponsors to create highly customized feasibility surveys.

The following tables detail question types that are 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

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
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
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

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
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
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
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

Question Type	Export from Select via PDF	Export from Select via CSV	Export from Analyze via CSV
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.
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.

Configure surveys and settings

Configure feasibility surveys, scoring, and ranking for your study.

Configure study feasibility surveys

When you have the *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>

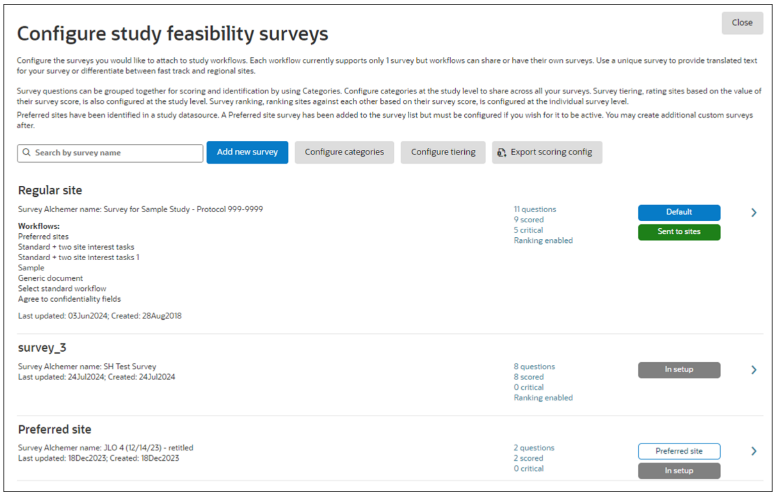
The list also shows question count details for each listed survey. Question counts are clickable links to the settings area for that detail line (e.g., the questions/scored/critical preview numbers on the survey list link to the scoring detail subtab for that survey). The links are:

- # 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 blue 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.

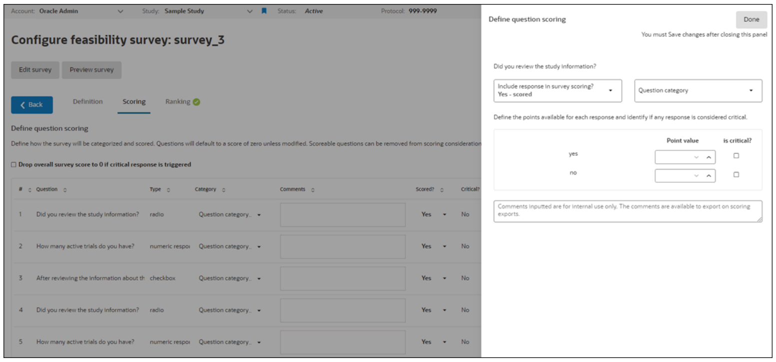
On the Preferred site survey's Definition tab, below the Study survey short name field (which is not editable), you'll see a check box option with the following label and helper text: "Disable this survey option so preferred sites receive the survey they are assigned in their workflow. Note: If this 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. 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.

- Choose surveys to affiliate with a study
  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.
- Edit existing surveys
- Preview a survey
- Configure rank-based survey tiering
  The survey ranking feature works by grouping sites based on their performance against their peers. Use these instructions to input the thresholds for ranking sites.
- Create survey submission message
  Define the information displayed when a survey is submitted. You can create a unique message for each survey affiliated with the study.
- Map categories and points to survey questions
  Configure the scoring for each survey affiliated with your study. For each survey, map categories to the questions and configure the scoring points for survey responses.
- 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.

Choose surveys to affiliate with a study

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.

> **Tip:**
>
> To simplify finding surveys in Oracle Site Select, add a study ID to your survey titles.

1. In the top navigation bar, hover over **setup** and choose **feasibility survey**.
2. Click **Add new survey**.
3. Enter a **Survey short name**, which will display as the tab name, in reports, and in the site progress view.
4. If preferred, click **Make default survey**.
5. Select a survey from the list.
6. (Optional) Repeat steps 3-6 to associate additional surveys for this study.
7. Click **Save**.

Edit existing surveys

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 **Edit survey** at the top of the page or, in the list of available surveys, click in the Edit column.

The Alchemer tool will open, and 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.

Preview a survey

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 **Preview survey** at the top of the page or, in the list of available surveys, click

   in the Preview column to view the survey in a new browser tab.

Configure rank-based survey tiering

The survey ranking feature works by grouping sites based on their performance against their peers. Use these instructions to input the thresholds for ranking sites.

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. In the survey list, click at the far right of the row for the survey you want to configure.
3. Click the **Ranking** tab.
4. Above the question grid, click **Survey ranking configuration**.
5. Turn on the **Enable rank-based tiering for this survey** switch.
6. 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.
7. Click **Save**.

   When you save ranking, a green check mark displays next to the Ranking tab.

Create survey submission message

Define the information displayed when a survey is submitted. You can create a unique message for each survey affiliated with the study.

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. Locate the survey that you want to add the message to in the survey list, and click › at the far right of the row.
3. On the **Definition** tab, just above the survey grid, click the **Survey submission message** button to open the message modal.
4. Click in the text field to enable editing. You can optionally format the message using the emphasis, alignment, bullets, and numbering options displayed at the upper right of the text field.
5. Click **Save**.
6. Optional: If the study has multiple associated surveys, repeat the above steps for each survey you want to have a submission message

Map categories and points to survey questions

Configure the scoring for each survey affiliated with your study. For each survey, map categories to the questions and configure the scoring points for survey responses.

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. In the survey list, click › at the far right of the row for the survey you want to configure.
3. Click the **Scoring** tab.
4. If applicable to this survey, check the **Drop overall survey score to 0 if critical response is triggered** checkbox (above the survey question list).
5. 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. Open the scoring drawer by clicking in the **Edit** column. If you use the scoring drawer method, remember to click **Done** to close the drawer, or your changes will be lost.
6. Repeat step 5 for all questions.
7. Click **Save** or **Save all changes**.

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**.

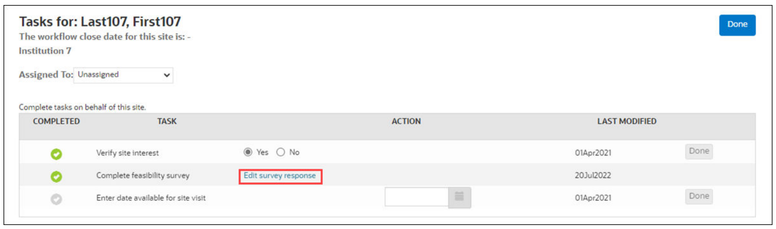
   Oracle Site Select creates an export file with the following naming convention: <studyName>-surveyScoringConfig-<ddMONyyyy>.xlsx.

Retaking surveys or editing 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 Oracle Site Select LITE 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 survey response” link under the Actions tab on the Survey Analysis sub-tab

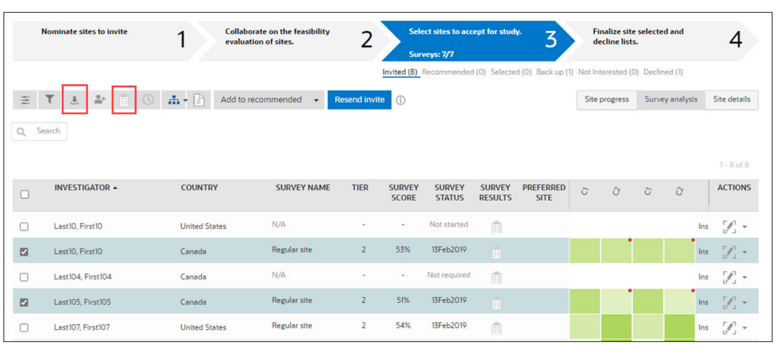


Once the survey has been resubmitted, the new responses populate into Oracle Site Select, along with the resubmission date. The original responses, scores, and date are retained in Oracle Site Select and all versions of the survey will be available to view. Please note that the CSV extract is limited to the most recent survey submission.

Creating survey response reports

In the select or finalize steps, you can optionally create feasibility survey response reports in either CSV or PDF format. If you choose CSV, the extract includes a row for all sites in the site grid. PDF format will allow you to create a report for one or more selected (checked) sites in the site grid.

The feasibility survey analysis CSV export and PDF download identify questions that were not answered due to survey design (i.e., skip logic). Skipped questions are indicated with “N/A” in the CSV and PDF.



The CSV format extract includes the following content:

- First name (Investigator)
- Last name (Investigator)
- Institution type
- Institution name
- Institution address 1

- Institution address 2
- Institution city
- Institution state
- Institution Zip code
- Investigator phone
- Investigator fax
- Investigator email
- Protocol title (current study)
- Protocol number (current study)
- Initial submission date
- Survey submission date (most recent submission)
- Survey submission version
- Survey total score
- Survey tier
- Question response chosen (question number and text as the column header)

The PDF format report identifies the date the survey was submitted, study name, investigator name, and country as well as each question and the investigators response (in bold).

Sample PDF

Sample

Do[illegible]ha
University College Hospital
United Kingdom

Completed: 13Apr2019

Legend

Answers in bold indicate a site's selected answer.

1. Based on your experience, how many COPD patients (>40 years) with a post bronchodialator FEV1<50% of the predicted normal value are seen at your facility in a three month period of time?

   - 10 or fewer
   - 11 - 50
   - ☑ **51 or greater**

2. How many of the patients in Q1 do you estimate that you could screen as potential participants in this trial?

   - 0 - 50%
   - ☑ **51 - 100%**

3. How many of the patients in Q1 could you randomize as potential participants in this trial

   - ☑ **0 - 50%**
   - 51 - 100%

- Export survey responses to PDF

Export survey responses to PDF

1. In the top navigation bar, click **select**.
2. In the **Invited** list, select one or multiple sites that have completed the feasibility survey.
3. Click the **Download a PDF of survey responses for selected sites** button.

> **Note:**
>
> If you selected multiple sites on the Invited list, Oracle Site Select will generate a .zip file for download.