

Oracle Life Sciences Site Select

Release Notes



Release 25.1

G24882-02

July 2025

ORACLE®

Oracle Life Sciences Site Select Release Notes, Release 25.1

G24882-02

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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://hsghbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsghbu-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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What's new

With release 25.1, Oracle Site Select introduces feature enhancements and significant user interface and navigation enhancements that improve user experience and conform to Oracle design standards. We've described the improvements in the feature area descriptions in these release notes.

- [User experience](#)
In release 25.1, we made significant user experience enhancements in Oracle Site Select and the Site portal that improve navigation, simplify tasks, and make site selection easier.
- [Account settings](#)
The account-level Email templates and settings, Users and permissions, and Workflow templates pages have been redesigned, and we made additional usability enhancements.
- [Datasources](#)
The Datasource details page has a new Definition tab where you can create, map, and publish a new datasource; the Matches table has a new Datasource column; and we made additional usability enhancements.
- [Document management](#)
This release introduces a new Document submissions page designed to make it easier to manage CDAs, Generic documents, and Feasibility survey submission PDFs in one place.
- [Email communications](#)
The Study email templates page has a new design that improves navigation and groups related settings. The invitation process is also updated to display expected recipient names.
- [Feasibility surveys](#)
Enhancements in this release improve visibility into total possible survey points, add an account-level feature to default survey questions to scored or not scored, and more.
- [Site communications](#)
A message icon in the page header lets you know when you have new messages, message creation functionality is now in a drawer, and threaded messages have usability enhancements.
- [Site details drawer](#)
You can now manage document workflow tasks in the drawer, picking a network is easier with a control at the top of the drawer, and multiple other enhancements improve usability.
- [Site grid](#)
Significant usability enhancements in this release improve navigation and visibility into site data. The site grid features new columns, simplified filtering, a new right-click menu, and multiple functional enhancements.
- [Site portal](#)
The Site portal (previously called Oracle Site Select LITE) introduces a modern, streamlined user interface and multiple functional enhancements.
- [Site profile](#)
The configurable site profile design is now standard, you can upload documents directly to a site's library, we added the Trial History tab to the site profile, and more.

- **Study setup**
Enhancements include a redesigned workflow configuration page, a simpler way to manage workflow task documents, and small updates to the milestones page.
- **User management**
Several new permissions give you more control and flexibility over managing workflow tasks, and the permissions required to update a study name have changed.

User experience

In release 25.1, we made significant user experience enhancements in Oracle Site Select and the Site portal that improve navigation, simplify tasks, and make site selection easier.

Navigation and usability

With release 25.1, Oracle Site Select introduces a redesigned user interface that reflects Oracle design standards throughout. We also updated the user experience with enhancements that improve navigation, simplify tasks, and make site selection easier. The Site portal (previously called Oracle Site Select LITE) also introduces an enhanced, modern user interface and improvements.

Accessibility improvements:

- enhanced color contrast to improve readability
- ability to keyboard tab and control every page
- consistent design principles to ensure ease of navigation and predictable layout

Common design updates you'll see in Oracle Site Select and the Site portal include:

- Oracle's standard color palette, font, icons, and input controls
- Browser tabs that show the page name
- Responsive pages that fit on phones, tablets, and desktops with no width limits



Note:


These release notes spotlight key updates (i.e., improved navigation, new features, and redesigned pages) but are not an exhaustive list of every change. Some updates in this release changed the appearance of certain features (such as colors, fonts, or icons) without affecting how they work. Those visual-only changes are not included in these release notes.

EPIC: SEL-17685

Global and persistent menus

This release includes several updates to improve navigation and give you quick access to frequently used pages.

Global Menu



We've moved the global menu (previously at the top of the page) to a new left-side drawer. Toggle the drawer open and closed by clicking menu  at the far left in the page header. The drawer organizes your available menu options into expandable sections based on your permissions:

- Dashboards
- Study
- Setup
- Account

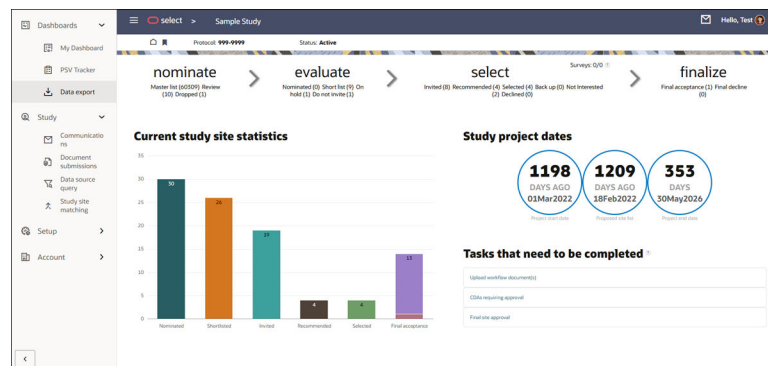
Use the expand/collapse control in the drawer's lower left corner to open or close the drawer as needed.

Page and persistent headers

We also made a few helpful updates to the page and persistent headers:

- A click on the Oracle "select" logo now takes you to the My Dashboard feature, which lists all your studies with your favorite on top with key information on CDA status and site communications.
- The study selector is now easier to find in the page header.
- A new message icon  shows the number of new messages across your studies. See the Site Communications section in these release notes for details.
- Your profile link now says "Hello, <username>." Click your avatar to access your profile, help, a link to API documentation, or log out.
- A new home icon  in the persistent header lets you return to the study home page with one click.

For the selected study, the persistent header still shows the Favorite toggle, Protocol, and Status.



EPIC: SEL-17685

Site and study loading messages

We've improved the page loading experience on the site grid, PSV tracker, and My Dashboard pages by adding clear messages for two common scenarios: when data is loading and when no results are available.

On the site grid, for example, you'll now see:

- **While data is loading:** "Please wait. The page is loading the sites."
- **When no results are available:** "There are no sites to display."

Similar messages display on the PSV tracker and My Dashboard pages to help you understand loading progress for the PSV or study grids.

EPIC: SEL-17867

Account settings

The account-level Email templates and settings, Users and permissions, and Workflow templates pages have been redesigned, and we made additional usability enhancements.


Account users and access

This release enhanced user role and team management with improved workflows and a redesigned user roles and permissions page. The page previously titled Managing user accounts is now titled Account users and access. We also retitled the link to this area in the Accounts menu. The previous users and access menu option is now titled Users and access. You'll see the Users and access menu option if you have a role with *User and Role Management* permission.

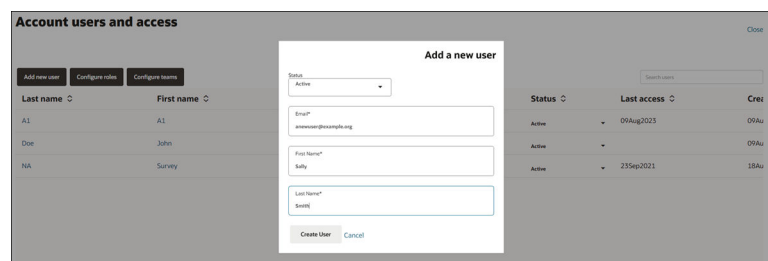
The Account users and access page includes three action buttons:

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

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

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

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



We also made usability improvements to organize user permissions in the Create/edit roles and Create/edit teams modals. When you access the roles or teams modals, you'll see related user permissions grouped under the following section headings:

- Account management

- CDA/Document Management
- Data Source Management
- Read Only Permissions
- Reporting
- Site Grid
- Site Management
- Site Selection
- Study Management
- Survey Management
- Targeted Search

Account Management

- ☐ API and Authentication Management ?
- ☐ Account disinterest and exclusion configuration ?
- ☐ Account document configuration ?
- ☐ Account email message monitoring ?
- ☐ Account email template management ?
- ☐ Account note label configuration ?
- ☐ Account study creation ?
- ☐ Account workflow template management ?
- ☐ Network profile management ?
- ☐ PSV dashboard ?
- ☐ Study administration ?
- ☐ Study details management ?
- ☐ User and Role Management ?

CDA/Document Management

- ☐ CDA counter-signer ?
- ☒ CDA/Document Template Upload ?
- ☐ Negotiation for assigned CDA/Document submissions only ?
- ☒ Review and Approve All CDA/Document Submissions ?
- ☒ Review and Approve All Generic Document Submissions ?
- ☐ Review and Approve Assigned CDA/Document Submissions Only ?
- ☐ Review and Approve Generic Document Submissions for assigned sites Only ?
- ☐ Review generic document attestation submissions ?
- ☐ Send CDAs for digital signature ?

Data Source Management

- ☐ Data Source Management ?
- ☐ Edit a datasource record ?

Read only permissions

- ☐ Read only document management view ?
- ☐ Read only site grid view ?

EPIC: SEL-18303

Account-level email templates and settings

Release 25.1 gives the Account-level email templates and configuration settings a new streamlined layout. Click Account menu > Email templates and config to open the enhanced configuration page, titled Manage account email templates. When the page opens, you'll see a horizontal tabbed menu for easy navigation. There's also a Close button in the upper right corner. Please note that Close exits the page but does not save any changes you make in the tabs, so click Save where needed.



Note:

It is important to remember to save your progress on each tab before closing the page.

Here's what you'll find in the horizontal tabs:

- **General:** Control how study digest and invitation emails appear. You can:
 - Show the study protocol title and sponsor in digest emails.
 - Set custom button labels for Login/No Login buttons in site email invites.
 - Click the Save button to apply your changes.
- **Master Email Template:** Customize the look and feel of your emails on this tab. You can:
 - Configure header and footer logos.
 - Complete rich-text enabled fields for adding:
 - * A login button introduction
 - * Login/No Login button descriptions
 - * Pre-footer text
 - Preview to confirm the email template meets your formatting and layout expectations.
 - See a list of available email placeholders you can use for dynamic content.
 - Click the Save button to apply your changes.
- **Account Email Images:** Upload and manage up to five images that can be used via placeholders in your study email templates. Images automatically save when uploaded, so there's no need to click a Save button for this tab.
- **Internal Workflow Task Notifications:** Customize internal task notification emails on this tab. You can:
 - Edit the Subject line and Email body.
 - Use placeholders in either field for dynamic content (click the Show email placeholder list link to see your options).
 - Format the Email body with rich text for a polished look.
 - Click the Save button to apply your changes.

EPIC: SEL-19020

Account workflow templates

If you have a user role with the *Account workflow template management* permission, you can access the redesigned account-level workflow templates page (Account > Workflow templates). This page lists all saved templates alphabetically and includes helpful details when available, such as workflow descriptions, tasks, last updated dates, and the names of the users who last made changes. To locate a specific template, use the search field to filter by template name or description.

To open an existing template, click the right arrow on any row. To create a new one, click the Create new workflow template button. You'll see all the familiar configuration options, including fields to define the template name, description, and messages for the study and completed workflows.

Within the template, you can scroll down to manage tasks (i.e., add, edit, delete, or reorder as needed). Click the right arrow on a task row or click the Add new task button to open the Task details drawer. This drawer lets you define the task's type, display name, and other task-specific information. The fields update automatically based on the selected task type. When you're done, click Done to apply your changes and close the drawer.

**Note:**

Clicking Done on the task details drawer does not save the task to the template. You must click the Save button on the page.

To finalize your updates, return to the main workflow template page and click Save changes at the upper right. If you no longer need the template, the Delete option is available at the bottom right, just below the task list.

EPIC: SEL-18305**Account integrations**

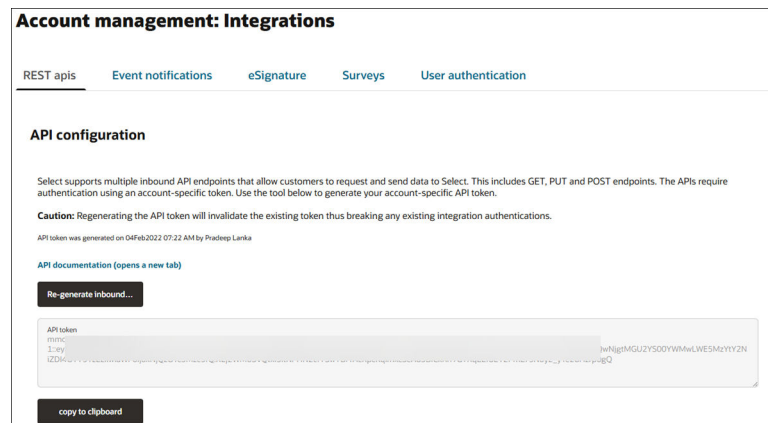
We reorganized the Account integration settings in this release to make them easier to access and manage. If you have the *API and Authentication Management* permission, you'll now see all settings under the Account > Integrations menu item.

Account pages accessible with the API and Authentication Management permission:

- General
- Event notification history and status
- Integrations

The redesigned Account management: Integrations page combines integration configuration settings into a single page with tabs for specific functionality.

- **REST APIs:** Regenerate your account's inbound API token (please use with caution as it replaces the current token, thus breaking any existing integration's authentication) and access API documentation in a new browser tab.
- **Event notifications:** Create and manage settings for site profile, site status, and Library document outbound event notification messages. Additionally, manage users that will be notified of failed event messages.
 - Email notifications for failed messages
 - * Use Add to create a new contact that will receive email notifications when an outbound event message fails
 - * Click on a contact to open a detail drawer to update the contact's notifications or to delete the contact
 - Configure outbound notification messages
 - * Use Create new message to add a new event notification configuration
 - * Click on an event message to update the configuration or delete the outbound message
- **eSignature:** Includes settings for Adobe Sign integration for CDA documents. This feature is temporarily disabled in version 25.1 and will return in a future release.
- **Surveys:** Enable or disable integration with Alchemer, select your hosting region, and reauthorize if needed.
- **User authentication:** View your Oracle IDCS configuration set by Oracle services and managed by Oracle Support. Use the "Select login test preference" section to choose between standard login or SSO for testing, and remember to click Save before leaving this tab.



EPIC: SEL-19266

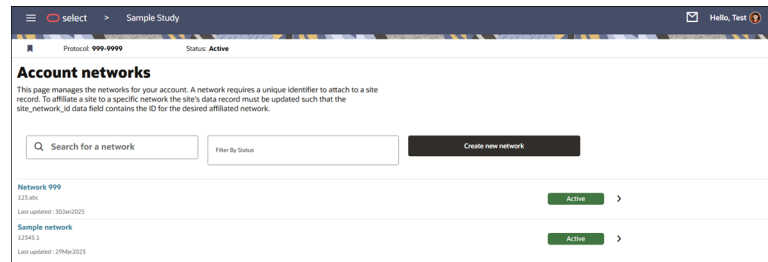
Account networks

In this release, we updated the Account networks feature to use Oracle design standards and introduced several enhancements. The redesigned Account networks page shows an alphabetical list of the account's saved networks and displays the following details for each saved network:

- Network name (required)
- Network ID (required)

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

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



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

Release 25.1 also introduces the option to delete an existing network. You'll see this option at the lower right of the Network details page, and you must confirm deletion if you click Delete network.

Account level Network deletion affects sites and site invitations as follows:

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

EPIC: SEL-19019

Account support link configuration

We made a minor text update on the Account management: General settings page to reflect an Oracle organizational name change. Under the Support link configuration section, we updated the “Direct users to Oracle Health Science support” option to read “Direct users to Oracle Life Sciences support.”

EPIC: SEL-17867

Datasources

The Datasource details page has a new Definition tab where you can create, map, and publish a new datasource; the Matches table has a new Datasource column; and we made additional usability enhancements.

Create, map, and clone datasource definition

In release 25.1, we updated the Account Data sources feature to make it easier to define and manage datasources. If you have the *Data Source Management* role permission, you can access this area from Account > Data Sources menu item.

Datasource details pages now include a "Definition" tab. Under the Manage data source definition section, for Step 1: Define datasource structure, provide a unique name, optional description, and upload a sample CSV schema. Note that for unpublished datasources, the tabs for Records, Matches, Potential matches, and Errors remain disabled until the datasource is published.

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

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

Account data source management
first-create-test

Definition Records Matches Potential matches Errors

Manage data source definition
Create the structure of your data by uploading a CSV file containing a representative sample (field names and values) of the data you will be uploading into the data source.

Step 1: Define datasource structure

Datasource name: first-create-test

Description: TEST

Upload CSV schema
Select a file or drop one here.

Changes auto-saved: 10Apr2023 03:04:09

Step 2: Map the imported columns to Select data columns
The datasource schema is the structure of the datasource - the list of data columns in the datasource. For each data column there are many attributes such as the ID name, the data type, the categorization of the columns and more. A datasource can leverage a Select standard data column or a custom data column can be created. Some Select data columns have a benefit of additional functionality such as being included in certain data exports, API outputs and usage in Analytics reports.

Tips for mapping defining a datasource

1. The CSV should contain a column of unique IDs that will be used as a unique ID (primary key).
2. The CSV must contain at least 1 row of sample data for each column. No null values allowed.
3. Use the Select column names when possible to leverage the built-in functionality of Select columns and ensure names are not duplicated with multiple custom columns.
4. When mapping a custom column ensure the data type is correct and the name is not duplicated.

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

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



Note:

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

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

Step 2: Map the imported columns to Select data columns

The datasource schema is the structure of the datasource - the list of data columns in the datasource. For each data column there are many attributes such as the UI name, the data type, the categorization of the column and more. A datasource can leverage a Select standard data column or a custom data column can be created. Some Select data columns have a benefit of additional functionality such as being included in certain data exports, API outputs and usage in Analyzer reports.

A published datasource's schema definition cannot be edited.

Define the unique ID column of the imported record

Before mapping any data columns Select requires to have a column mapped as the unique identifier for each imported row of site data. The unique ID row will allow Select to identify each row of data imported into the datasource after the datasource is defined and published.

Unique ID column from imported data
Investigator_ID

Map imported columns to Select columns

The imported columns from your CSV are listed on the left. The Select columns in your account are listed on the right. Drag and drop columns that match to map them together.

Imported columns list the column name and sample data imported with the file. When mapped to a Select column it will display the Select column's name. The unique ID column will be marked with "ID". This can be updated at any time until the datasource is published.

Select standard and custom columns created in your account are listed on the right. Each column displays the name and data type. Clicking the ? help icon will open the column's detail view which includes the description and the full attributes of the column. Each row also displays affiliation information for the column - whether it's considered in site matching, if it is a site profile column, if it is a standard Select column or a column custom to your account and whether it has been mapped to an imported column.

If there is no Select column that matches your imported column then you may create a custom data column by dragging the imported column to the "Create a custom column" area. The custom column can then be named and defined. This column will be available for all new datasources.

Step 3: Publish the datasource

Once a datasource is mapped it must be published before records are allowed to be imported. A published datasource cannot have its columns updated so please ensure the datasource is mapped correctly and completely for your study needs. After publishing the datasource can be renamed and the description updated.

Publish datasource

Clone an existing datasource

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

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

Step 3: Publish the datasource

Once a datasource is mapped it must be published before records are allowed to be imported. A published datasource cannot have its columns updated so please ensure the datasource is mapped correctly and completely for your study needs. After publishing the datasource can be renamed and the description updated.

Publish datasource

Want to clone this datasource ?

Cloning the datasource will create a copy of the datasource schema, not the data or sites. The new datasource will have the same name with _copy appended to it. This can be changed by editing the datasource name.

Clone datasource

EPIC: SEL-19208

Create a new datasource

Now, when you click "Create a new datasource" on the datasource listing page, you'll navigate to the Definition tab of a new datasource detail page, where you'll enter the datasource name and optional description. By design, the Records, Matches, Potential matches, and Errors tabs are disabled until you've successfully uploaded the schema CSV for the new datasource. Once you upload the schema CSV, the page updates to display the data source name and description in the title area, and the data source is saved as unpublished. Mapping columns also display after the schema upload is complete.

EPIC: SEL-19208

Add or update flat datasource records via CSV

With release 25.1, we added the ability to add or update records in a regular (flat) datasource via CSV upload on the Records tab, which now includes a file upload control above the site records grid. Use this control to upload a CSV file to add new site records or update existing site records.

The CSV file you upload will undergo standard processing validation (e.g., checking for valid country names, disambiguation, etc.). If errors are found, the Errors tab will show a numbered badge and a red exclamation mark to draw your attention to data issues you need to address. The tab lists each error message encountered when processing your CSV upload.

EPIC: SEL-19208

Matches table

To provide you with more information about records identified as strong matches, we added a Datasource column to the Matches table in this release. The Datasource column, positioned at the end of the table, displays the datasource for each listed record.

EPIC: SEL-19208

Loading message

When the Records, Matches, or Potential Matches tabs are loading, a context-specific message now displays until the site list finishes loading (e.g., the message on the Matches tab is “Match record loading, please wait.” If no sites are found, you’ll see the message “No records are available to display.”

EPIC: SEL-19208

Quick links

On the datasource listing page, quick links now appear only for published datasources. If a datasource is unpublished, its quick links will be hidden. This update helps clarify that you can only act on published content.

EPIC: SEL-19208

Document management

This release introduces a new Document submissions page designed to make it easier to manage CDAs, Generic documents, and Feasibility survey submission PDFs in one place.

Document submissions page

With release 25.1, Oracle Site Select introduces a new experience on the Document submissions page designed to give you better visibility and usability when managing study document submissions.

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

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

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


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

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

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

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

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

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

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

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

Happyness study document submissions

View and act on study document submissions. On this page you are able to review the actionable documents affiliated with a site's workflow. Only documents that require an action such as a submission will show. You may filter based on country or document type. Click on a document's row to open the detailed view of the document which includes the actions you may take on the document as well as the document's history.

Document date: Submitted Final review

Country:

Workflow:

Search by Institution or Investigator:

Export Document List Download selected documents

View 23 documents (10 selected)

☒ Include feasibility surveys
☐ Exclude sites discontinued in the study
☐ Show only my assigned sites

Document	Document type	Workflow	Country	Institution	Investigator	Assigned reviewer	Status	Last action date	Actions & History
<input checked="" type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	University of Wis...	Backhus, Leah	Unassigned	Final review	27Jan2020 3:44 PM	
<input checked="" type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	Bingham and W...	Bhain, Shalender	Unassigned	Final review	04Mar2020 2:58 PM	
<input type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	Duke University	Littky, Michael	Unassigned	Final review	04Mar2020 3:44 PM	
<input type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	University of Ar...	aCosta, John	Unassigned	Final review	13Nov2019 9:45 PM	
<input type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	University of Tex...	Baldogh, Irvin	Unassigned	Final review	23Jan2020 7:19 PM	
<input type="checkbox"/> Sign and return CDA	CDA	D Sign CDA	United States	University of Cal...	Barnal, Vishal	Unassigned	Final review	02Mar2020 6:10 PM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Every task	United States	University of Iowa	Baker, Kimberly	Submitted	Submitted	02Mar2020 7:57 PM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Standard tasks with survey	United States	University of Cal...	Chanzshan, Bahman	Submitted	Submitted	21Nov2019 11:53 AM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Every task	Canada	Saint Josephs H...	Cox, Gerard	Submitted	Submitted	05Dec2019 7:25 AM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Every task	United States	University of Cal...	Agrawal, Anshu	Submitted	Submitted	12Feb2019 12:29 PM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Survey only	United States	University of La...	Bickel, Scott	Submitted	Submitted	23Nov2019 12:24 PM	
<input type="checkbox"/> Complete feasibility survey	Feasibility survey	Every task	United States	University of Pitt...	Bae, Kyongdae	Submitted	Submitted	25Sep2019 5:50 PM	

If Not started: A document task that is new the current task that no submission action has been performed
 If Review: A document was submitted and requires review
 If Resubmit required: A document was submitted by Site user and has an action required by the site
 If Approved: The CDA document task is completed
 If Final review: The document is in the review or pending final signatures
 If Completed: The generic document task is completed
 If Submitted: The submitted survey when no cells have been submitted
 If Finalized: The submitted survey when no cells have been submitted

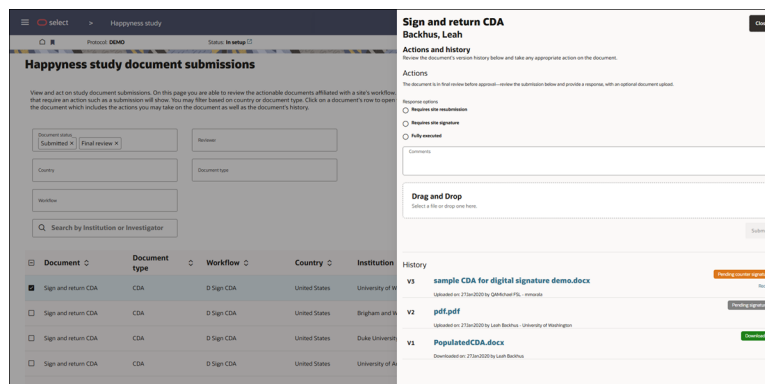
On this new Document submissions page, we've relocated the document history and actions features from the former Manage document approvals page to a history and actions drawer. Click a document's row to open the drawer from the right.

At the top of the drawer, the Actions section provides available actions based on the document type and the document workflow task status. These are:

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

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

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

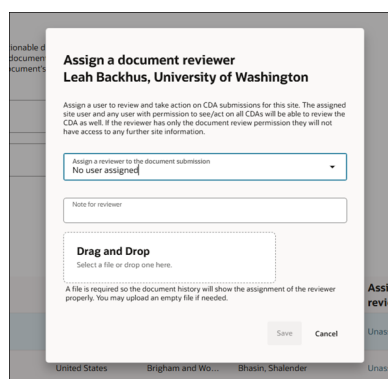


With release 25.1, we also modified requirements for assigning a CDA reviewer. This now requires a file uploaded with the reviewer assignment. Note that you should expect different behavior in the document history drawer for old studies where the review was assigned without a file. The comments to the reviewer will show on the CDA history row before the action.

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

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

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



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

Forwarded users who aren't assigned to a site can only see documents directly forwarded to them. They can view associated comments but won't see site details unless they have site grid or nomination permissions. All reassignments are recorded in the document's review history, and a new history entry is added for each reviewer update. However, the site view remains

unchanged; its status stays “Pending,” and site users don’t see reviewer changes. Once reassigned, the new reviewer will find the document added to their study homepage task list.

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

**Note:**

Adobe Sign integration for CDA document signatures is temporarily disabled in version 25.1 and will return in a future release.

EPIC: SEL-18343**Survey submission PDF history**

With this release, it’s easier to view and manage feasibility survey documents, especially when working with multiple workflows and surveys across sites. Now, you can access and download (including bulk download) survey documents from the study’s Document submissions page. To view survey submissions in the document grid, click the new “Include Feasibility survey” check box.

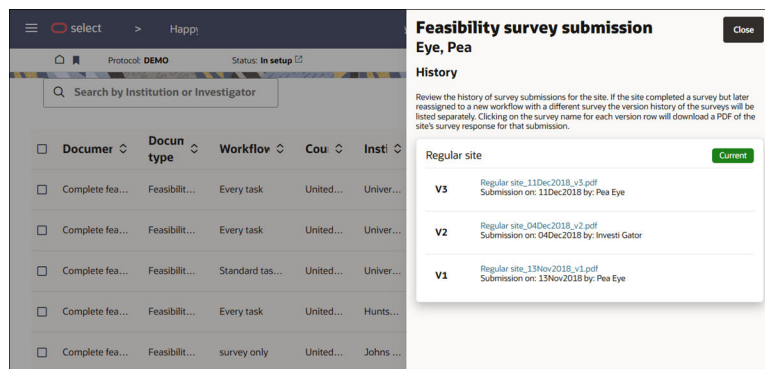
When you’ve enabled viewing feasibility surveys in the document grid, you’ll have the following survey-specific filters:

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

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

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

With this release, we also updated the *Site nomination* permission to grant access to the study’s Document submissions page. If Site nomination is your only user role permission, the document table will be empty on initial load; however, you can check the new “Include Feasibility survey” check box to view survey submission documents.



EPIC: SEL-17867

Email communications

The Study email templates page has a new design that improves navigation and groups related settings. The invitation process is also updated to display expected recipient names.

Invitation received modal

We've enhanced the study invitation process so invitations and the Invitation received modal now show the expected first and last names of the recipient. When you invite a site, Oracle Site Select uses the name from the site grid and site profile (i.e., the studysite's site instance), rather than pulling it from the site portal user's account profile, if one exists. The names will match what you see in the site grid.

Email placeholders for site user names (such as PI, CTC, IRB, and other roles) will also use the site instance data to help ensure greater consistency across the invitation experience.



WARNING:

To make sure the names appear as expected in the invitation received modal and emails, **the site profile must be set as the highest priority study data source**. If it isn't, other sources may override the first and last name values shown to site users.

EPIC: SEL-17867

Study email templates



We've redesigned the study email template configuration page to organize and make it easier to locate settings needed for study notification emails. The configuration settings function as they did before the 25.1 release. When you have *Email template management* permission, you can access the Study email templates page from the Setup menu.

When you open the page, if your study involves many countries, a message will be displayed to inform you that the page is loading. When it's finished loading, you'll find that email template settings are now organized into sections with accordion controls. Click the section's arrow ➤ to toggle any accordion open and closed.

At the top of the configuration area, use the Study-wide email template settings. The settings in this section apply across all study email templates (i.e., Default and all country-specific templates). For instance, you can upload a study image file and use the {logo_header}

population field in the body of any email template to insert that image into the email or set a default signature for unassigned sites.

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

Recipients: General (like default sender email address), Site network delegates, and Archived copies sections allow for the configuration of those respective study settings. For country templates, the Recipient section also includes the Override default settings check box. When checked and you customize the required fields for that template section, the country displays a green dot badge  in the vertical menu. If fields for that country are not completed as required, the country will display an orange attention badge .

Salutations and personalizations: Fields in this section let you configure how site users will be greeted in the study invitation and final determination emails. You can also specify the template's default signature line (Default and country-specific) in this section.

Email body templates: Choose your preferred behavior to enable no login links and the use of the Principal investigator's name in the email subject line. You'll also configure the Invitation, Final acceptance and Final decline body text in this section. Click Show email placeholder list to open the list in a drawer at the right. The drawer remains open until you click Close, allowing the list to be available to you as you compose the body text. We encourage you to Preview each of your email templates to ensure they reflect the formatting and text you intend to send. Previews populate email placeholder values with sample site data. Data is not related to an imported site.

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

Manage study email templates

[Save all changes](#) [Close](#)

Configure the email template settings for the study. When sending study invitation emails and final determination emails the settings below will allow you to customize these emails to fit your study and company brand name. There are options to configure the salutation preferences, include images in the email and even populate placeholders with study and site-specific information. Use country-level overrides to further customize your email templates. Lastly, if you wish to have templates at the workflow level you may set workflow level overrides on the study workflow configuration page.

Cross-template settings

Study-wide email template settings

The following settings are used across all study email templates. Upload a study image that you can place in any email templates.

Default signature line for unsigned sites

Study email templates allow for an assigned site owner's signature line to be populated in a study email using the [assigned_site_owner_signature] population field. If the site does not have an assigned user, the signature line below will populate the field.

```
[
B I U L T A P B C D E F G H I J K L M N O P Q R S T U V W X Y Z ]
```

Email image upload

Add a study image to your email communications. This image is limited to GIF, JPG, PNG, PNG and a maximum size of 1000kb. To place the image in the email, you must add the [page_header] population field to the body of the email template in the location you wish.

 Global Placeholder logo

Drop and Drop

Select a file or drop one here.

- Default
- Australia
- Korea, Republic of
- South Africa
- United Kingdom
- United States

- Recipients
- Salutations and personalizations
 - Dear Dr. John Smith
- Email body templates
 - ☒ Enable "No Logo" links in emails sent to sites

When invitation emails are sent to sites the default template includes a Logo button and a No Logo button. For studies in which you do not wish to provide a No Logo option at the study level click under the section "To enable" to make a country specific decision over the existing logo template override. The Logo link to studies on study design emails (not for new users) are also controlled by this option.

☐ Remove default behavior and do not populate the Participant investigator's names in the subject line of the invitation email to site recipients. By default, emails sent to recipients other than the PI will automatically include the PI's name in the subject line.

Show email placeholder list

Below are the study email templates sent to site users. Define the subject and body text for each. Add personalization and additional details using placeholder values to populate study and site information into the email.

Invitation email

Subject line

New research study opportunity

50 of 100 characters

Body content

I would like to let you know about a research study that may be of interest to your patients and ask you to consider participation.

(BRIEFLY DISCLOSE THERAPY PURPOSE OF STUDY AND WHY THEY A CHANCE FOR THIS POPULATION INCLUDING INFORMATION ON VISITS AND PARTICIPANT COMPENSATION IF APPLICABLE)

Please note that having access to this study may require that you agree to certain criteria. (IF IT IS HELPFUL TO LIST - SHARE CRITERIA IN SIMPLE LANGUAGE)

(DETAIL HERE INCLUDING MAIN EXCLUSION CRITERIA - IF IT IS HELPFUL TO LIST - SHARE CRITERIA IN SIMPLE LANGUAGE)

If you are interested in speaking with patients in your practice who may be interested in participating in this study, please feel free to contact us with the questions using the contact information provided below.

Thank you for your time and consideration.

Subject line

Appointment Letter to participate

Final acceptance email

Subject line

Appointment Letter to participate

EPIC: SEL-14685

Feasibility surveys

Enhancements in this release improve visibility into total possible survey points, add an account-level feature to default survey questions to scored or not scored, and more.

Total survey points

To improve visibility into feasibility survey scoring, we made multiple enhancements in this release to show a survey's total possible points. Using the column picker, you can optionally add a new Total Survey Points column to see the total in the context of the site grid. The column displays the total possible points a site could have received on its most recent survey submission, taking into account skip logic, branching paths, and question type (single, multiple, or grid).

The score shown in the Survey score area of the survey response modal also reflects this change. Now, you can see both the raw score and the possible score for all submitted survey versions. If a survey was submitted before this release 25.1 update, resave the scoring configuration page to view the possible points. Resaving will trigger a recalculation and population of a new scoring field for that survey.

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

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

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

- `workflow_details` - added to the `survey_response_details` object array: For each submitted survey, will populate the total possible points calculated as "`survey_total_possible_score`" and will populate the total points earned by the site for the survey as "`survey_total_points_scored`"
- `studysite_details` - this api is a dump of the `studysite` table. It outputs only the most recent survey submission version possible points as "`survey_possible_score`"

Answer Options	Point Value	Critical Answer
Kolkata	20	
Howrah	40	
Raipur	40	
Patna	80	

EPIC: SEL-17867

Alchemer login

With this release, we enhanced the Survey Definition tab to add a new "View your Alchemer account surveys" link. Click the link to open the Alchemer login page in a new browser tab.

EPIC: SEL-17867

Survey PDF downloads

The feasibility survey PDF export now includes additional footer information. With this release, we added the following details:

- Submission version: <version of the Feasibility Survey>
- Downloaded on: <download date and time ddMonyyyy hh:mm am/pm timezone>
- Page: <page number> of <total pages>

5. Are you willing to participate in this study?

Yes

Submission version: 3 Downloaded on: 02May2025 5:56 PM UTC Page: 2 of 2

EPIC: SEL-17867

Survey submission message

We enhanced Survey submission message configuration on the feasibility survey Definition tab to show this section in an accordion format and include all previously available rich text formatting functionality.

Additionally, we enhanced the Survey submission message section to include an “Update message” button at the lower right. This new functionality lets you update the message for a survey already assigned to sites.

The screenshot shows the 'Survey submission message' configuration section. It includes a title bar with a dropdown arrow and the text 'Survey submission message'. Below the title bar is a descriptive paragraph: 'Define the information displayed when this survey is submitted. The information will display on the tab opened for the survey. A different submission message is defined per study survey.' A red warning message states: 'You must save the survey definition before changes to the submission message will be reflected in your study.' The main content area contains a text editor with a placeholder message: 'Your response is being processed. The CRO/Sponsor will evaluate your survey and contact you if they have any questions.' Below the text editor is a section titled 'Logging into this study management tool provides additional functionality:' with a bulleted list: 'Communicate more quickly with your CRO/Sponsor', 'Create and manage your site profile to access more studies', and 'Access your library of signed documents'. A rich text toolbar is located below the list. At the bottom right of the configuration area is an 'Update message' button and a 'Revert' link.

EPIC: SEL-17867

Account-level default survey scoring

In this release, we added an account level feature to default survey questions to either scored or not scored. When enabled, all questions in new surveys will be unscored, and you can manually toggle individual questions to allow scoring if needed. The new option on the Account > General page will have the check box unchecked (off) by default. When the setting is off, a new survey added to the study will have the "Scored" option on each scoreable question set to "Yes" by default.

The screenshot shows the 'Account management: General settings' page. It has a 'Save' button and a 'Cancel' button in the top right corner. The page is divided into two main sections: 'Study status behavior' and 'Support link configuration'. The 'Study status behavior' section includes a checkbox for 'Hide closed studies from Select users. Site users will still see the study unless they filter closed studies.' and a section titled 'Default scoring for new surveys' with a checkbox for 'For any new survey created for a study the "Scored" setting will default to "Yes". This means every question for a new survey configured to a study will default to not being scored. Each question can be manually toggled to allow scoring.' The 'Support link configuration' section includes a radio button for 'Direct users to Oracle Life Sciences support' and a radio button for 'Configure URL for support link'. Below the radio buttons is a text input field for 'Provide a support url (i.e. https://mylife.com/help.com/)'.

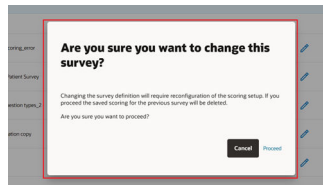
EPIC: SEL-17867

Survey scoring configuration

To prevent a scenario where an updated Alchemer survey no longer matches the configured and scored survey in Select, you must now confirm the deletion of the previously saved scoring configuration if you update the survey definition in Alchemer. A new confirmation modal lets you Cancel or Proceed. If you click:

- **Cancel:** the modal closes and restores the previously selected Alchemer survey without changing the saved scoring configuration.

- **Proceed:** the updated survey replaces the previously selected survey, the previous survey's scoring configuration will be deleted, and the green check mark on the scoring configuration tab will be removed.




EPIC: SEL-17867

Site communications

A message icon in the page header lets you know when you have new messages, message creation functionality is now in a drawer, and threaded messages have usability enhancements.

Cross-study message icon

With release 25.1, we added a new message icon  in the page header that shows you how many new messages you have across all your studies.

When you have no unread messages, or if unread messages exist only in your current study, clicking the message icon opens the Site communications page for your current study. If unread messages exist in other studies, the icon displays a badge with the total number of unread messages. Click the icon to open a drop-down list of studies that also shows the number of unread messages in each study. Studies are listed in order of oldest unread message first. Click a study name to open its Site communications page.

EPIC: SEL-18390

New message drawer

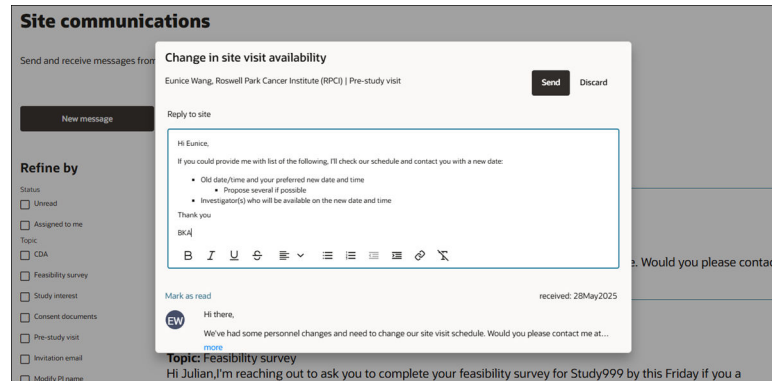
With enhancements in this release, we've moved new message functionality from a modal to a right side drawer to be consistent with other design changes in this release. When you click New message in the Site communications area, the drawer opens to provide all the previous functionality that you're used to, like single or bulk messaging, topic selection, and rich text formatting.

EPIC: SEL-18390

Threaded message with Reply

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

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



EPIC: SEL-18390

Site details drawer

You can now manage document workflow tasks in the drawer, picking a network is easier with a control at the top of the drawer, and multiple other enhancements improve usability.

General functional enhancements

We made several functional enhancements to the site details drawer in release 25.1. These are:

Resizing: The drawer width now dynamically resizes based on the tab selected and the minimum width needed to support the contents of that tab. For example, the Study contacts tab will be wider than the Workflow tab. By design, the drawer will not exceed 80% of the page width.

Saving: When you update information in a site's detail drawer from the site grid, your changes will now appear immediately in the drawer. However, to see those updates reflected in the grid itself the next time you open the drawer, you'll need to click the new Refresh site grid button (upper right above the grid) after closing the drawer. This step ensures the most recent changes are displayed.

CDA Download: You no longer need to navigate away from the site details drawer to download the pre-populated CDA template assigned to the site for the workflow. On the CDA task, click <download>. If the template contains placeholder fields, they will be populated with the assigned data in the document you downloaded.


Response value: In the site details Workflow tab, completed generic document tasks now display the chosen or entered Response value (e.g., Yes/No, date selected, numerical value, etc.).

EPIC: SEL-18373

Site assignment, Workflow close, and Network picker

In this release, we made a few updates to the top section of the site details drawer. These updates make it easier to view and manage key site information, no matter which tab you're working in.

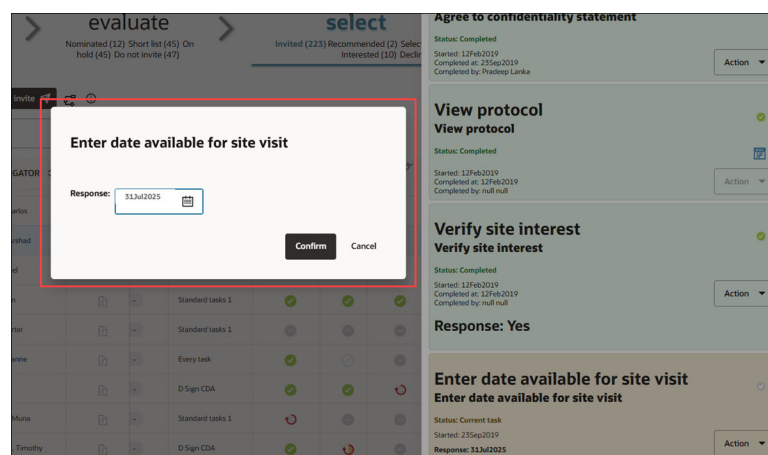
Here's what's new:

- **Simplified Site assignment:** We removed extra text from the Site assignment field to keep things clean. The field label is now "Site-assigned user." Click into the field to read: "Assign a Select user to this site. The assignment can be updated and removed."
- **Easier access to Workflow close date:** The Workflow close date picker has moved out of the Workflow tab and into the top section of the drawer, so it's always in view. The field label is "Workflow close date," and when you click into the field, you'll see: "Assign a workflow close date or update the existing workflow close date for the site."
- **New Network picker:** You'll now see a Site network assigned drop-down in the top section. This lets you assign a site to an account-level network. Only active networks are listed, and they're sorted alphabetically with the default option as "No network assigned." You can update any network assigned to the site to No network assigned as long as the site was not imported with a value for "site_network_id assigned." We've also added a network icon  next to the picker. Click it to jump straight to the Network page in the site profile.

EPIC: SEL-17685

Site visit date picker

In the Workflow drawer, the Enter date available for site visit task now includes a calendar date picker. When you click Complete in the Actions drop-down list, a new modal appears where you can select a date for the task's Response field.



EPIC: SEL-17867

Document workflow tasks

In release 25.1, we removed the Complete tasks on behalf of site page and relocated its functionality to new modals in the Site details Workflow drawer. In addition we included the document's history and the Action features to document tasks in the workflow drawer. As a

result, you can now complete or review document actions for the following document workflow tasks in the Workflow drawer:

CDA workflow task

Your user role permissions affect your ability to interact with CDA document workflow tasks. See [User management](#) in these release notes for additional details.

- *Review and Approve All CDA/Document Submissions permission*: allows you to open the modal for all sites
- *Negotiation for assigned CDA/Document submissions only permission*: allows you to open the modal only if you are assigned as a CDA reviewer for the document task or you are the site-assigned user
- If you have only the *Review and Approve Assigned CDA/Document Submissions Only* permission and not the *Negotiate* or *all CDAs* permission, you cannot see the Review actions link/modal if you are not the user assigned as a CDA reviewer or the site-assigned user for the document task
- An Oracle Site Select user with the *Read only site grid view* permission will not see the Review action link
- An Oracle Site Select user with the *Read only document management* view and either the Read only site grid view or the Site nomination permission can open the review modal, but not complete the task

Additionally, please note the following related to CDA permissions:

- A user with the *Negotiation for assigned CDA/Document submissions only* permission cannot finalize/Final approve a CDA task without also having one of the “Approve” CDA permissions as well
- If an Oracle Site Select user has ‘Review and Approve Assigned CDA/Document Submissions’, then they can see the modal for all site’s CDA documents.
- If an Oracle Site Select user has ‘Negotiate or all CDAs’ then they can only see the modal where the user is assigned as the CDA reviewer or the site-assigned user. The user will not be given the option to Final approve the CDA.

For an incomplete CDA document task, the modal includes an Actions section at the top where you can act on the document based on the task status:

- **Not started**: Document task not started by the site. You may act on behalf of the site by uploading a document.
- **Review**: If you have the appropriate permission, you can review the document submission, provide a response, and optionally upload a document in response
- **Resubmit required**: If you have the appropriate permission, for a non-eSign document, you can complete the document task for the site by uploading a response and providing a comment. You may recall the document using the link in the modal’s History section and return the CDA task to incomplete status.
- **Final review**: If you have the appropriate permission, you can review the submission and provide a response, with an optional document upload. You may recall the document using the link in the modal’s History section and return the CDA task to incomplete status.
- **Approved**: You may recall the document using the link in the modal’s history section to return the CDA task to incomplete status. You may recall the document using the link in the modal’s History section and return the CDA task to incomplete status.

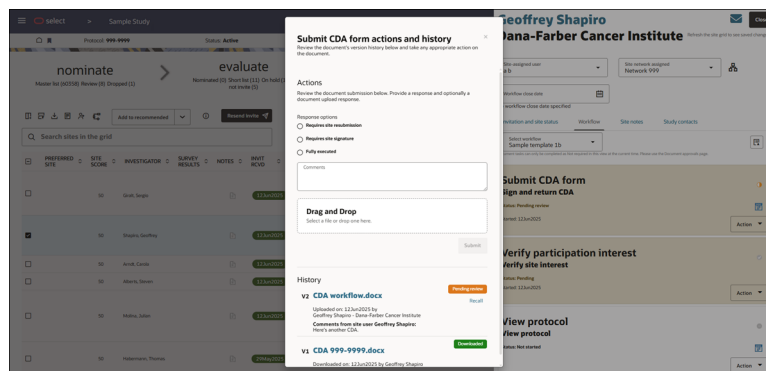
For each step of the document cycle, files uploaded and comments made are saved. Documents can be viewed in the study document library for the site and comments on the site's notes drawer.

The bottom of the modal is a History section where you'll see the version history for each iteration of the document's actions. A document task that has not been started will have a V1 history listing the document template for the task.



Note:

Adobe Sign integration for CDA document signatures is temporarily disabled in version 25.1 and will return in a future release.



Generic Document (approval required) workflow task

For Generic document: Approval required tasks, we added "Review submission" as the first option in the task's Actions menu. When you click Review submission, a modal opens where you can review the document's version history and take appropriate action on the document.

Your user role permissions affect your ability to interact with Generic document: Approval required workflow tasks. See [User management](#) in these release notes for additional details.

- *Review and Approve All Generic Document Submissions* permission – allows you to review any site's generic documents
- *Review and Approve Generic Document Submissions for assigned sites Only* permission – allows you to review only the generic documents for sites assigned to you (link is disabled if the site is not assigned)

Oracle Site Select users with read only permissions are also affected by this enhancement as follows:

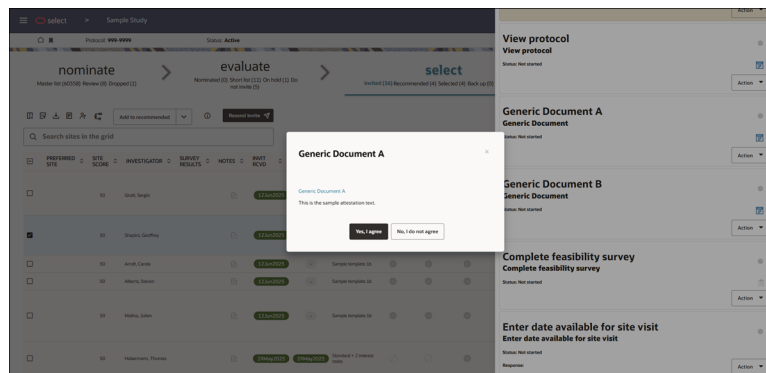
- A user with the *Read only document management* view and *Review and Approve Generic Document Submissions for assigned sites Only* can review generic documents for all sites but can only act on sites for which they are assigned
- A user with the *Read only site grid* view permission cannot click on the Review action link
- A user with the *Read only document management* view and either the *Read only site grid* view or the *Site nomination* permission can view the review modal but not complete the task

For an incomplete document task, the modal includes an Actions section at the top where you can act on the document based on the task status:

- **Not started:** Document task not started by the site. You may act on behalf of the site by uploading a document
- **Review:** Review the document submission. Provide a response and optionally upload a document in response
- **Resubmit Required:** Lists the sites that have been sent a document revision/request. The sites listed are required to upload/respond to the document request sent by the Study specialist. You can comment, upload a document, and submit.
- **Approved:** Document is complete. There is no further action available.

For each step of the document cycle, files uploaded and comments made are saved. Documents can be viewed in the study document library for the site and comments on the site's notes drawer.

The bottom of the modal is a History section where you'll see the version history for each iteration of the document's actions. A document task that has not been started will have a V1 history listing the document template for the task.



Generic Document (choose response and attestation) workflow tasks

You can also complete Generic document: Choose response and Generic document: Attestation workflow tasks from the Site details > Workflow drawer. If you have Site grid permission, you'll see a Complete option at the top of the task's Action menu. When clicked, a completion modal opens that shows the task name, instructions, a document download link, and the configured response or attestation options as buttons. When you choose the response or attestation, the task will be marked as completed by you and the time will also be recorded.

If necessary, you can reopen a completed task to update the response. When you save changes, your name and the updated completion time are recorded.

By design, Oracle Site Select users with Read only site grid view permission won't see the a workflow task's Complete option and can't open the task completion modal.

EPIC: SEL-17867

- **Nominate:** Site score → Investigator → Notes
- **Evaluate:** Site score → Investigator → Notes → Workflow
- **Select:** Site score → Investigator → Notes; “Invited by” now appears after Workflow
- **Finalize:** Site score → Investigator → Notes → Workflow

You can click any site’s workflow name in the grid to open the site details drawer. From there, use the Workflow tab to view the site’s task assignments. The Workflow tab is now enabled for all buckets except Nominate.

EPIC: SEL-18373

Task completion modal

When you’re working in the site grid’s step 3 (select) and step 4 (finalize), click a workflow task’s progress icon to view a detailed task completion modal. This modal shows task-specific information, as well as the investigator’s name, specialties, institution, and any assigned users. Tasks marked as “Not required” or “Internal task pending” do not open the modal but instead display hover text that reflects their status.

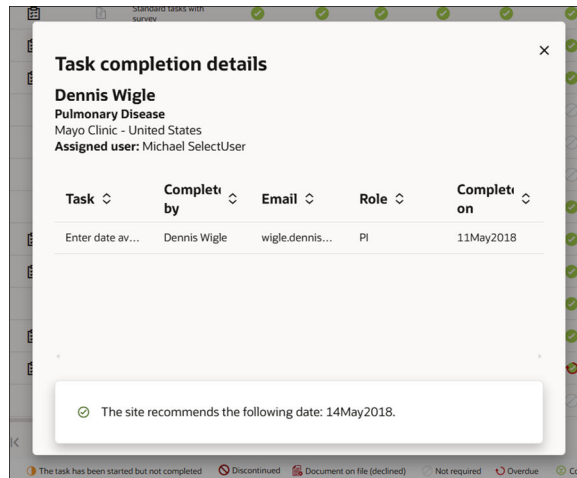
Each task’s status determines what the modal or icon displays. If the task is complete, the modal includes a table listing the person who completed it, their email address, role, and the completion date. Overdue tasks append “(overdue)” to their hover text, and discontinued sites display a banner indicating the site is no longer interested in participating.

Survey tasks behave differently depending on their stage: if not yet reached, the icon doesn’t open the modal; if pending or processing, the modal displays survey-specific details but no task table. Once submitted, the modal includes a success banner summarizing the survey name and score.

CDA tasks have their own progression. When downloaded, the modal shows a yellow advisory with the download date and site user. If a signed CDA is uploaded, the modal updates to show an “Uploaded” status along with a yellow advisory note, “The CDA was signed and returned by the site on <datetime>.” Approval is required before the site can complete additional study tasks.” Once approved, a success banner confirms the final approval date. The modal tracks each stage of the CDA task by listing separate rows for downloaded, uploaded, and approved actions.


For document workflow tasks that are auto-completed, a banner confirms the task was completed with an existing file.

Lastly, investigator documents populated via API do not involve workflow actions. These entries are shown with the user listed as “Library import” in italics and have no associated email or role. The import date is recorded as the document’s completion date, which is expected behavior.

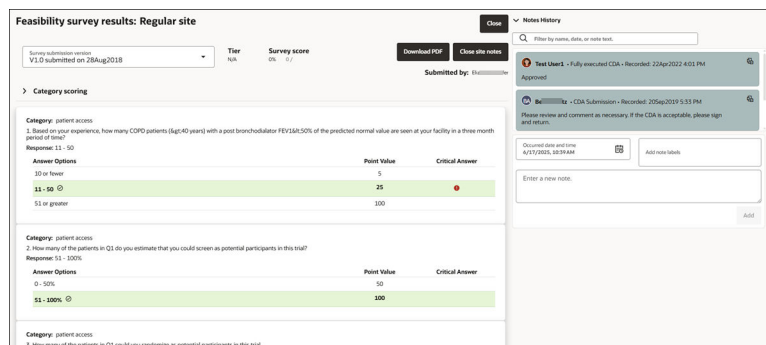


EPIC: SEL-18373

Survey results column

With the site grid redesign in this release, we removed the Site Progress, Survey Analytics, and Site History subtabs from select (step 3) and finalize (step 4). To ensure you have access to survey information, we added a new Survey results column to the select and finalize site grids. If a site has completed a survey, you'll see the survey icon  in this column. Click the icon to open the survey results modal, which shows submitted survey results, grouped by survey name and version, with the most recent listed first. The results modal also includes detailed scoring, tier, raw and percentage scores, and a breakdown of each question's responses, points, and category. You can also download the selected survey as a PDF.

While viewing survey results, you can now click View Site notes to open a panel to the right of the results modal. This panel displays existing notes and allows note creation (if you have permission to create them). You can also input an occurred date, label, and note text. The survey results modal includes a Close button to exit the view and a separate Close Site notes button to hide the notes panel without closing the results modal.



EPIC: SEL-18373

Site invitation and Site portal status

In release 25.1, we streamlined how you access key site details by combining invitation and site portal access status into one view. Instead of opening two separate modals from the site grid, you can now find this information combined in a new "Invitation and site status" tab in the

site details drawer. This enhancement makes it easier and faster to evaluate a site's invitation progress and portal access in a single location.

On Step 3 (select), we modified the behavior for the INVIT RCVD and ACCESSED SELECT LITE (now labeled “ACCESSED SITE PORTAL”) site grid columns. The columns still use status badges to reflect each site's invitation and portal activity. Badge colors indicate the most recent invitation email delivery status (red (failure), orange (in progress), green (success)) or site portal access (green with access date) or gray (no access). Now, when you click the badge in either column, the site details drawer opens with a new “Invitation and site status” tab selected.

The drawer's Invitation and site status tab is available for sites on both Step 3 (select) and Step 4 (finalize). This new tab appears first in the site details drawer's horizontal menu, and it provides a centralized view of user invitation details. Here, you can review each invited user's name, email, role, invite date, email delivery status, last access date, and tools like “copy” (login link), “resend,” and “send” (admin invite), depending on your permissions. Please note that the name listed will be the user's name as represented in the site's profile/studysite view at the time of the invitation. This is a change in invitation behavior.

The table updates automatically as new users are invited or existing users access the site portal. You can sort both the INVIT RCVD and ACCESSED SITE PORTAL columns to quickly prioritize follow-up actions.



WARNING:

To make sure the names appear as expected in the invitation received modal and emails, **the site profile must be set as the highest priority study data source**. If it isn't, other sources may override the first and last name values shown to site users.

Representative	Email address	Role	Email sent on	Status	Last access	Login link	Resend invite	Admin invite
Kyongtae Bae	baek@upmc.edu	PI	29May2025	Clicked	29May2025	copy	resend	send
Kyongtae Bae	baek@upmc.edu	PI	21Jan2020	Clicked	29May2025	copy	resend	send
Kyongtae Bae	baek@upmc.edu	PI	25Sep2019	Clicked	29May2025	copy	resend	send
Kyongtae Bae	baek@upmc.edu	PI	25Sep2019	Clicked	29May2025	copy	resend	send
Ramir Kapoor	ramir.kapoor@45@...		21Jan2020	Clicked	-	copy	resend	send

Page 1 of 1 (1-5 of 5 items)

EPIC: SEL-18373

Final approve CDA task in Workflow drawer

You now have a faster way to finalize CDA tasks when needed. When you have *Allow external completion of workflow tasks* permission, you'll see a new Final approval option in the Actions menu for a CDA task. This new option lets you final approve a CDA without completing the full document review cycle. You can optionally upload the finalized CDA and add a comment in a modal that displays when you click Final approval.

- The Final approval option is available if no one has started the task or uploaded a file.
- If a file has already been uploaded, you'll see a message letting you know to use Review submission instead.
- Once final approved, the document (if uploaded) and any comments are saved to the CDA document history, the study's document submissions, and the site progress view.
- If you don't upload a file, the original CDA template will be marked as the final version.

EPIC: SEL-18373**Site grid filter selection**

We've made it simpler to apply filters on the site grid page. Now, you don't need to pick a domain first. Instead, click on the "Filter criteria" selector, and you'll see all available filter options listed right away. If there are filters with the same name from different domains, you'll see duplicates listed so you can pick the right one. Once you choose a filter, it shows in your filter list along with the domain it belongs to, so you'll know where it came from.

EPIC: SEL-18373**Multi-select filter for Site Progress CDA Status column**

We also improved the site grid's CDA Status column so that it now supports multi-select filtering. Previously, you could only filter by one status at a time, but now you can select as many as you need. Available filter values are:

- Not started
- Pending
- Pending review
- Final review
- Completed
- Document on file
- Completed – Not required

Select the filters you want to apply to the site grid

Choose the filters you need for analyzing site and survey details. Filters are organized by their affiliated top domain. Select a domain, add a filter row then pick your filter and the associated filter values/choice. Note: Custom filterable data columns specified in your attached datasource(s) may take longer to load on this page.

Filter domain: Site progress | Filter criteria: | Add new criteria

Selected site grid filters

Site progress

CDA status: Not started x | Pending x

Pending review

Final review

Completed

Document on file

Completed - Not required

Apply filters | Reset all filters to default | Restore filters to previous

EPIC: SEL-18373**Unavailable sites message**

We've updated the message you see in the site grid when the minimum study setup tasks haven't been completed for the current bucket state. The new message is clearer and helps make it obvious that action is needed:

“Study setup is not complete. Please consult the task list on the study homepage for more information. There are no sites available to display.”

This change ensures you'll know exactly why the grid is empty and what to do next.

EPIC: SEL-18373

Revert site finalization

When you have *Site nomination* permission and you're viewing sites in any of the Evaluate bucket states site grid, you can now right-click on a site's row to see a menu option to “Move site back to Nominate – Review.” When you click this option, the site grid refreshes and the site moves back to the Review bucket state in Nominate. You will not be required to save a reason for this change.

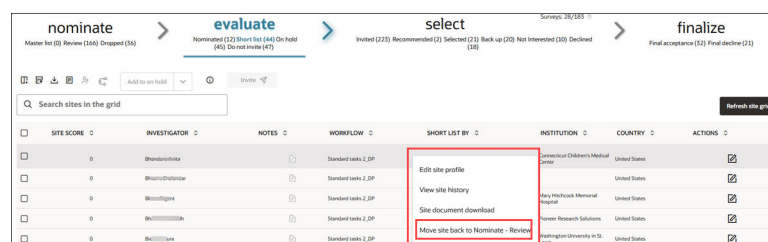
When you have the *Revert site finalization* permission, you can right-click on any site in one of the finalization bucket states to choose a revert option:

- Final acceptance: Revert - move site to Select - Selected
- Final decline: Revert - move site to Select - Declined

If you revert a site from Final acceptance, you must confirm this action and input a reason. The reason you enter will be saved as a site note. By design, it isn't possible to revert a site that's been migrated to Oracle Site Activate, so for the Final acceptance bucket, attempting to revert a migrated site will result in an error. This is expected behavior.

As before the 25.1 release, when you successfully revert a finalized site, Oracle Site Select automatically adds a site note (even if no final determination email was sent).

- The note is created under your name as the user who performed the reversion.
- The note's context reflects the bucket state where the reversion occurred.
- It includes details like your name, the previous bucket state, the date, and any note content you entered.
- If a final determination email was sent, the note also includes: “A final determination email was sent by <final_email_sent_by> on <final_email_sent_at>.”

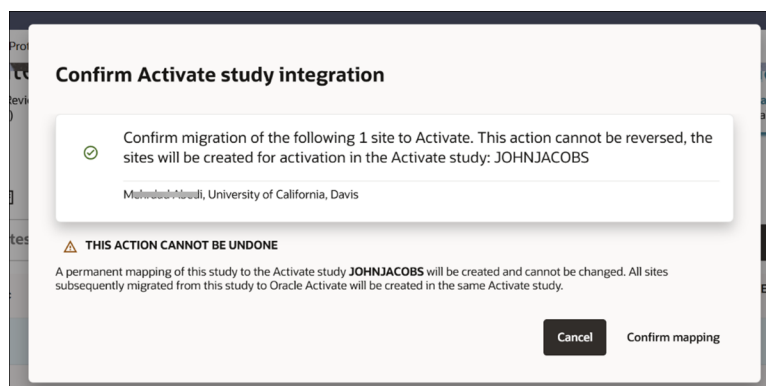


EPIC: SEL-18373

Exclude, finalize, and migrate site confirmation modals

We enhanced all modals related to confirming sites for final acceptance, final decline, and site exclusion/drop to reflect Oracle design standards. We did not make any functional changes to the modals; they work as they did before release 25.1 except for minor changes to font, icons, etc.

We also updated the modals related to migrating sites to Oracle Site Activate. Again, modals related to establishing the connection to an Oracle Site Activate study and confirming the integration function as they did previously, with minor design enhancements.




Note:

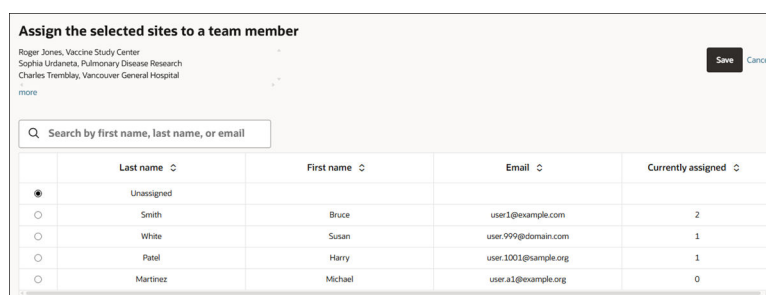
Oracle Site Activate integration is limited to the first 200 studies in Activate for an account, sorted descending.

EPIC: SEL-18373

Assign site user modal

In this release, we've improved the site grid's Assign user to sites feature. When you select one or more sites and click Add user to study sites , an updated modal opens where you can choose the Oracle Site Select user you want to assign.

The modal includes all previous functionality, but we made a usability enhancement to now list the selected sites at the top. The first three sites are always visible, and if you've selected more, you can click "more" to expand the full list.



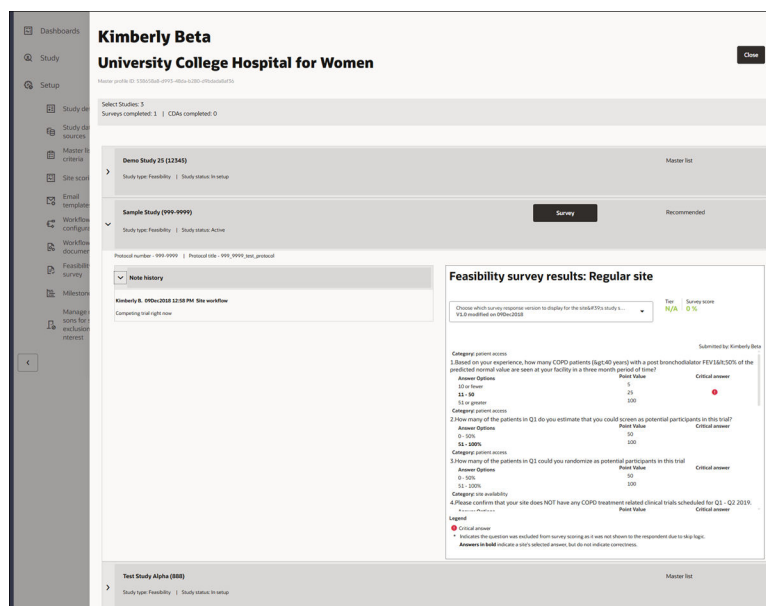
EPIC: SEL-18373

View site history

The site grid's View Site History feature functions the same as before, but with a new layout. Now, when you right-click a site's row in the grid and choose View site history from the new

context menu, the site's history details open in a drawer that opens from the right side of your screen.


The responsive drawer automatically adjusts width to accommodate the information available for that site.



EPIC: SEL-18373


Site document download

This release makes it easier to get to the Site document download feature, no matter how you prefer to navigate. Now, from any bucket state, you have a few options:

- Right-click a site's row to open the new context menu, then select Site document download
- Left-click a site's row to open the site's detail drawer. On the Workflow tab, click the new Audit icon  just above the task list
- Click the site's Action menu in the site grid and choose Site document download

EPIC: SEL-18373

CDA task status icons

We've made a small update to the CDA task status icons in the site grid to make it easier to see when the task has been started. Now, when either an Oracle Site Select user or a site user downloads the CDA document, the status icon in the site's workflow column will change to show the in progress icon  and the icon's tool tip text is "Downloaded."

EPIC: SEL-18373

Site grid CSV extract

With site grid user interface updates made in this release, we removed the site progress and survey analysis tabs in site selection Steps 3 (Select) and 4 (Finalize). To ensure you have access to the data you need, we enhanced the site grid download utility to add a new option

that lets you append survey and site progress columns to the site grid's CSV and Microsoft Excel extracts.

Now, when you open the download utility from Select or Finalize, you'll see the option to append the extract when you reach Step 3, Export/save report. Use the new option's drop-down to specify one of the following:

- No additional columns (default)
- Site progress task completion details
- Survey responses

When you choose to include Survey responses, you'll have these additional extract options:

- Export only survey questions marked scored for survey responses (default selected)
- Include category % scoring

If you choose to save the export as a report template, the survey or site progress columns you select will be saved.

Note that with this download utility enhancement, we also updated the download utility page's subtext to provide more details and guidance on expected functionality.

EPIC: SEL-18373

Site portal

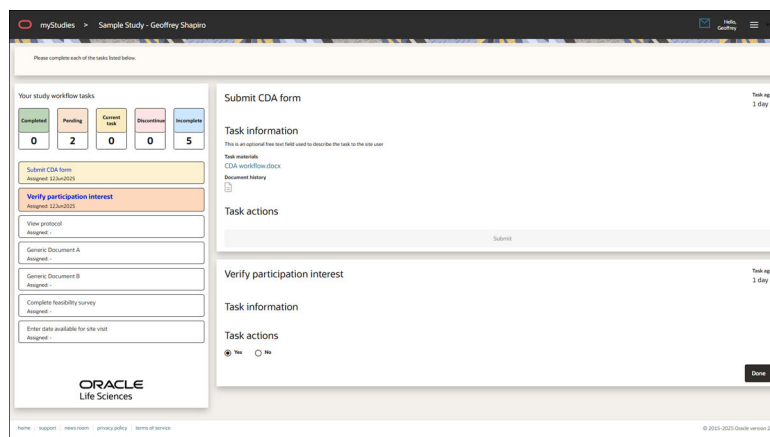
The Site portal (previously called Oracle Site Select LITE) introduces a modern, streamlined user interface and multiple functional enhancements.

Site portal user interface

Site users will see a refreshed Site portal in this release, with a new look that follows Oracle's design standards. Key improvements include:

- A modern color palette, updated fonts, redesigned icons, and streamlined input controls for a cleaner, more consistent experience
- A new navigation menu that lets site users easily switch between documents, messages, profile settings, help resources, and more

- A fully responsive layout that works smoothly across phones, tablets, and desktops, with flexible page widths for better viewing on any screen



EPIC: SEL-14865

myStudies dashboard

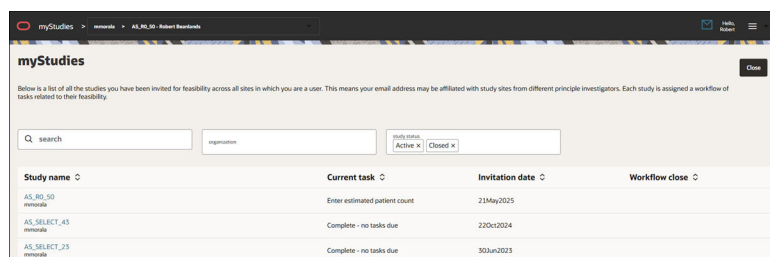
The Site portal introduces a new myStudies dashboard for logged in users in this release. The dashboard gives site users a convenient way to access all their current and past studies where they've been invited for feasibility. Sites can:

- Search by Study name, Invitation date, or Workflow close date
- Filter by Organization (customer account name) or Study status (Active or Closed)

When the page loads, the study list sorts by invitation date, with the most recent at the top. By default, Closed studies are hidden. Site users can manually adjust the filter to include Closed studies and optionally sort the table by study name, current task, invitation date, or workflow close date. Note that while Site users can still view studies that are in Closed or Cancelled status, they won't be able to edit tasks because the workflows are closed.

When a logged in user chooses a study, the Site portal's top navigation bar shows: myStudies > [Customer/Account Name] > [Study Name] (PI First and Last Name). The drop-down study selector also includes all studies across every customer account they're linked to. When the site user chooses a study, the workflow tasks for that study display on the Home page.

Site users who enter the Site portal using a No login link won't see the full dashboard. Instead, they'll see a read-only version of the navigation bar showing: myStudies > [Customer/Account Name] > [Study Name] (Site's PI First and Last Name).




EPIC: SEL-14865

Communications

With release 25.1, we enhanced the Site portal's communications feature with a cleaner layout and new functionality. Site users can now view and reply to messages directly from the portal.

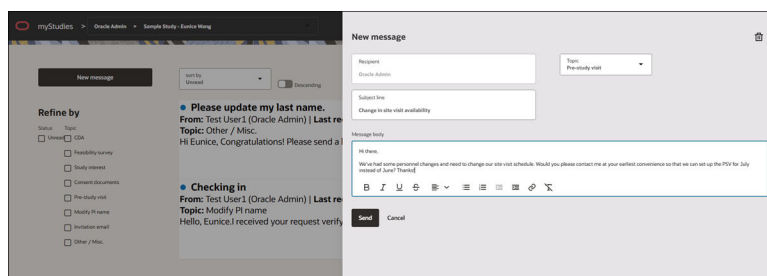
There are two easy ways for site users to access messages. They can:

- Click messaging from the navigation menu
- Click the message icon  in the page header. If there are unread messages, the icon will display a badge with the number of new messages.

The redesigned messages page shows the site user's messages in a list view, with sorting options for Unread (the default view) or Topic, along with an ascending or descending order toggle.


To read and optionally reply to a message, site users can click any message in the list to open it in a modal window.

We also improved the New message feature, which provides all previously available functionality but now launches in a drawer component that opens from the right side of the screen.



EPIC: SEL-14865

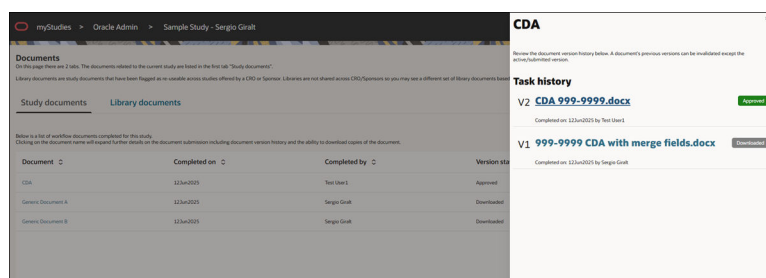
Documents

To navigate to the Documents page, site portal users will now click menu  in the page header and choose "documents" in the drop-down. The Documents page and the Study documents tab are now accessible to both logged in users and those who don't log in but access the portal via a token link instead. The Library documents tab is available only to those users who log in with a registered account.

We made the multiple helpful enhancements to the Documents page to make it easier for site portal users to view details and take action on documents related to their completed tasks:

- On both tabs, clicking a document row opens the document history drawer, where site users can view and manage documents (e.g., download, view the status badge, view user completion details, etc.).
 - The Study documents tab displays documents that have resulted from the completion of workflow tasks including the Feasibility survey template and submission versions. Users are able to view document history, recall a CDA submission and view responses to choose response/attestation tasks. If the site user updates the Response, a confirmation dialog displays, and the user must enter a reason for the change before saving.

- The Library documents tab displays documents saved to the site's library, regardless of study context. The user is able to view the document history for each document label including any changes/change reason and document upload history. If the site user updates the Response, a confirmation dialog displays, and the user must enter a reason for the change before saving.
- The Study documents tab now includes completed survey PDFs and their version history. Once the site user submits a survey, the table will include a row labeled Feasibility survey. If multiple surveys were assigned over time, each appears in the Study document list with its own history. The most recent submission is shown first. Each submission or resubmission is available in the document history drawer, where site users can download past versions (downloaded PDFs include a timestamp in the footer). Each version is labeled with the survey name.
- On the Study documents tab, in a CDA's document history drawer, site users can delete CDA documents uploaded by the site or by an Oracle Site Select user on their behalf. A trash icon appears next to files that can be deleted. If the user chooses to delete the most recent or final approved CDA document, they must confirm the deletion. Deletion applies only to CDA documents (i.e., users may not delete any file marked "Document on file" (auto-completed by the workflow) or any file from download-only tasks (e.g., Protocol or Generic document: Download)).
- On the Study documents tab, Choose response type Generic documents show the chosen option saved with the document's workflow task. On the Library documents tab, the chosen option is displayed. If the Library document also has a reason for change response stored, users can hover over the pencil icon to view the reason.



EPIC: SEL-14865

Completed workflow tasks

Site users can now view and evaluate tasks they've already completed by clicking on a previous task to open its details. By design, action buttons are disabled for all completed tasks except Feasibility surveys, which includes an "Edit survey response" link, and the Verify site interest tasks in case updates are needed.

If the workflow is still active, users can click the next available task to continue progressing through the study.

For active or closed workflows, the site user can:

- Download document templates
- View the document history, when available
- Open the site profile from the Verify site profile task
- View selected responses on Generic document tasks (Choose response or Attestation)
- See the value entered for the Enter patient count task

- View the selected date for a Site visit date task

If the workflow has been Closed and at least one task was completed, a banner with the workflow close message will display if configured, and site users can close the banner if needed. If no tasks were completed, the banner remains open, and the site user won't be able to access the workflow tasks.

EPIC: SEL-14865

Site profile

The configurable site profile design is now standard, you can upload documents directly to a site's library, we added the Trial History tab to the site profile, and more.

Configurable site profile

As of Release 25.1, Oracle Site Select now fully supports the configurable site profile. The previous site profile design has been deprecated, so all customers now interact with the updated, configurable experience.

There are three ways to open a site profile, and the action link you'll see, either Edit site profile or View site profile, depends on your permission level:

1. Right-click a site row in the site grid and select Edit site profile if you have edit permissions. If not, you'll see View site profile instead.
2. Use the site's Actions menu in the site grid to select Edit or View site profile, based on your access.
3. After opening the site details drawer from the site grid, click the investigator's name at the top of the drawer to open the profile.



Note:

The configurable site profile is a powerful tool that helps your organization tailor site data to fit your exact business needs. By customizing the sections, fields, and values, you can streamline workflows and ensure your team captures the most relevant information. For help setting this up, contact your Oracle administrator.

EPIC: SEL-20492

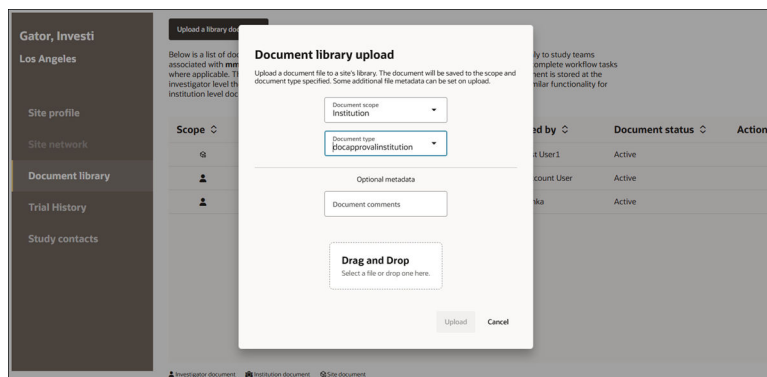
Document library

This release introduces an enhancement to Library document management. When you have a new *Upload files to a site's document library* permission, you can upload documents directly to a site's library from the Edit site profile > Document library tab.

This enhancement makes it easier to manage files by letting you upload documents to the site, investigator, or institution libraries if the site has a matching record in the account's primary composite datasource. You'll see a new Upload a library document button on the Site profile's Document library page, which is enabled only if you have permission to upload files.

Click the upload button to open a Document library upload modal and choose the Document scope (site, investigator, or institution) and Document type. The remaining fields in the modal are based on what's been set up at the account level. If the site doesn't have a related record in the primary datasource, the investigator and institution scope options will be disabled, and you'll see an error message explaining that only site-level document types are supported for that site. Helper text will guide you through the process and let you know why some options may not be available.

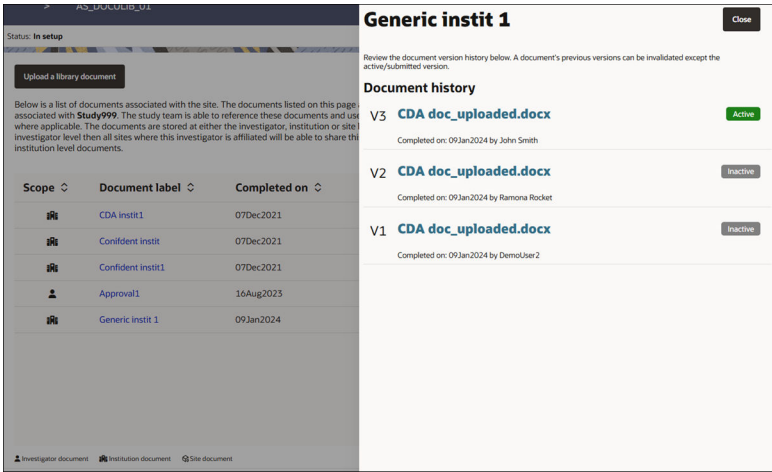
Once you select a valid document scope and type, you can add required and optional metadata and attach the file to enable the modal's Upload button. After successful upload, a confirmation message displays, and the Document library tab refreshes to include your new file.



In the document grid, click a document name to open its version history in a drawer on the right. The drawer shows all uploaded versions, with a green Active badge for the current version. Any older versions will show a gray Inactive badge.

Each entry includes the version number (such as V1, V2, V3), the upload date, and the user who uploaded it. Click a file name to download the document.

If a file was uploaded as part of a comment or submission action by an Oracle Site Select user, that file will also appear in the version history.



We also added controls to help you view and update “Choose response” type Generic documents in the site’s Document library. On the Library documents page, Oracle Site Select shows the chosen response saved in the library document metadata. If a response change reason was previously entered, a pencil icon displays and the change reason displays on hover. If the document is invalidated, no response is displayed.

In the document’s history drawer, the subtext clarifies that responses can be changed and documents can be invalidated. Invalidated documents will no longer auto-populate study tasks. You'll see the active file listed as a download link and the response options displayed as editable radio buttons. These options reflect the original Generic document setup. If someone previously changed the response, you’ll also see the reason and details of who made the update and when. You can revise responses as needed, but each change must be confirmed with a reason.

EPIC: SEL-20492

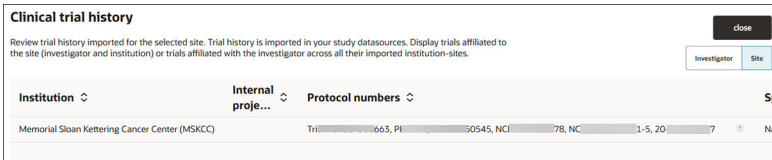
Trial history

In this release, we added a Trial History tab to the Site profile, making it easier to review imported trial history for a selected site. The tab appears enabled in the left navigation when the study has a composite datasource attached. If no datasource is attached, the link is disabled and a hover message explains: "There are no datasources with trial history attached to this study."

On the Trial History tab, you can choose to view trials based on either:

- **Site** (default): shows trials linked to the selected site
- **Investigator**: shows trials linked to the investigator across all affiliated sites

The trial grid includes details like Institution, Protocol numbers and titles, Sponsor, start and end dates, enrollment rate, and more. You can sort any column by clicking its header. If no data is available, the page will display: "No affiliated trials have been imported."



EPIC: SEL-20492

Study setup

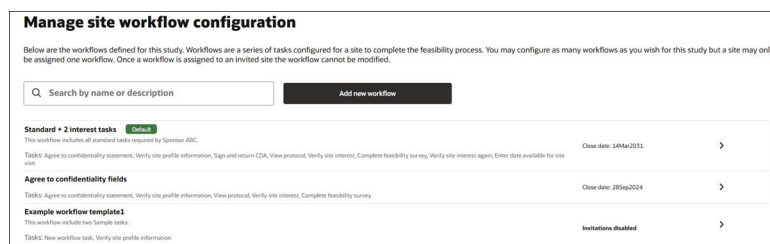
Enhancements include a redesigned workflow configuration page, a simpler way to manage workflow task documents, and small updates to the milestones page.

Study workflow configuration

In this release, you'll see significant usability enhancements to workflow configuration. When you navigate to the Manage site workflow configuration page (Setup > Workflow configuration) it now displays an alphabetical list of all saved workflows, with the default workflow pinned to the top. In addition to the workflow name, you'll see more details, if available:

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

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



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



Note:

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

On the Details tab, you'll define:

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

You'll also see a Make default button and an option to delete the workflow. The Delete workflow button is disabled if the workflow has already been assigned to an invited site. If the

button is enabled and you choose to delete, you'll confirm that action in a modal before the workflow is removed.

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

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

When tasks are enabled, you can:

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

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

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


The screenshot shows a web interface for editing a workflow. The title is 'Edit Standard + 2 Interest tasks'. There are tabs for 'Details', 'Email templates', and 'Tasks'. The 'Details' tab is active. The 'Workflow details' section includes a 'Workflow name' field with the value 'Standard + 2 interest tasks', a 'Workflow close date' field with the value '5/14/2023', and a 'Workflow description (Internal use only)' field. Below this is a 'Study workflow information' section with a rich text editor. The page has a 'Back' button, a 'Details' tab, and a 'Save' button.

EPIC: SEL-14686

Study workflow documents

In this release, Oracle Site Select introduces a new Manage workflow documents page (Setup > Workflow documents). This page replaces the existing Manage protocol documents page and the Manage CDAs, Confidentiality statements, and Generic documents page by combining the two in one convenient location.

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

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

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

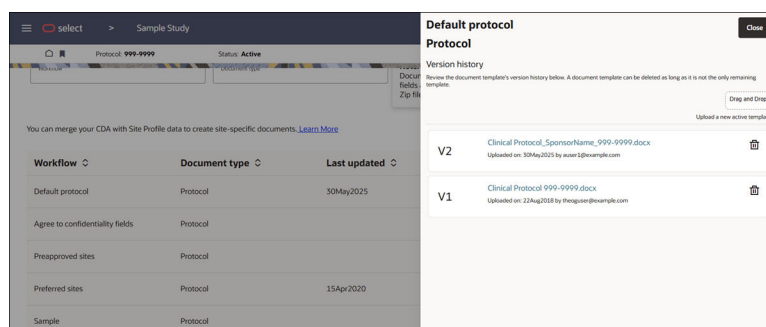


Note:

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

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

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



The screenshot displays the 'Manage workflow documents' interface. On the left, a table lists workflow documents:

Workflow	Document type	Last updated
Default protocol	Protocol	30May2025
Agree to confidentiality fields	Protocol	
Preapproved sites	Protocol	
Preferred sites	Protocol	15Apr2020
Sample	Protocol	

On the right, the 'Default protocol' version history drawer is open, showing two versions:

Version	Document Name	Uploaded on	Uploaded by
V2	Clinical Protocol_SponsorName_999-9999.docx	30May2025	user@sample.com
V1	Clinical Protocol 999-9999.docx	22Aug2018	thesuper@sample.com

EPIC: SEL-18412

Study milestones

On the milestones page country override table, we made a minor user interface update to adjust the position of the row labeled "Target number of sites final acceptance." Previously, the row displayed near the top of the table, and now it displays just above the related inputs for sites in final acceptance.

EPIC: SEL-17867

User management

Several new permissions give you more control and flexibility over managing workflow tasks, and the permissions required to update a study name have changed.

User permissions

New permissions for Confidentiality statement, CDA and Survey tasks

We added three new user permissions that separate the Confidentiality Statement, CDA and Survey tasks from the general Not Required permission.

If your Oracle Site Select role includes permission to manage other users or teams, you'll now see the new permissions under the Site management permission group, and you can add them to roles and teams as preferred:

- *Complete task as Not required: Sign and return CDA*: Allows you to mark a site's CDA task as Completed – Not required in the Site details Workflow drawer. The existing permission *Complete tasks as not required* will no longer allow you to mark a Sign and return CDA workflow task as Not required.
- *Complete task as Not required: Feasibility survey*: Allows the user to mark a site's Feasibility survey task as Completed – Not required. The existing permission *Complete tasks as not required* will no longer allow you to mark a Feasibility workflow task as Not required.
- *Complete task as Not Required: Confidentiality Statement*: Allows the user to mark a site's Confidentiality statement task as Completed – Not required. The existing permission *Complete tasks as not required* will no longer allow you to mark a Confidentiality statement workflow task as Not required.



Note:

Please use care when completing tasks as Not Required. Currently, once a task is marked as Not Required, the action cannot be undone.

New permissions for Generic Document submissions

This release introduces additional flexibility around how generic document review permissions are assigned and managed. We've separated the review permissions for generic document tasks from the broader CDA task settings.

You'll find two new permissions in the CDA/Document Management permission group. If your Oracle Site Select role allows you to manage roles or teams, you can assign these as needed:

1. *Review and Approve All Generic Document Submissions*: Allows the user to view, review, and approve all generic document submissions.

2. *Review and Approve Generic Document Submissions for assigned sites Only*: Allows the user to view, review, and approve only the generic documents for sites assigned to them.

As part of your account's upgrade to Release 25.1, users with existing CDA permissions will automatically receive one of the new generic document permissions as follows:

- Users with *Negotiation for assigned CDA/Document submissions only* or *Review and Approve All CDA/Document Submissions* will now have *Review and Approve All Generic Document Submissions* permission
- Users with *Review and Approve Assigned CDA/Document Submissions Only* will now have *Review and Approve Generic Document Submissions for Assigned Sites Only* permission

Please note that CDA and generic document permissions are not linked by default. When assigning roles or creating teams, selecting a CDA permission will not automatically assign a corresponding generic document permission. Be sure to manually add the appropriate generic document permission when needed.

EPIC: SEL-17867

Study names

In this release, we modified the permissions required to edit a study name. Previously, you needed *Study details management* and *Study administration* permissions. With this enhancement, you'll need *Study details management* and *Account study creation* permissions to edit the study name.

EPIC: SEL-17867

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Impact analysis

Review a summary of the business and functional impact for enhancements in the 25.1 release.

Enhancement	Enablement setting	Impact
User experience Navigation and usability	None	Provides improved navigation for a more streamlined user experience
User experience Global and persistent menus	None	Faster access to key features improves productivity
User experience Site and study loading messages	None	Displays informative messages during loading or when no data is found, improving transparency for users
Account settings Account users and access	Yes - <i>User and Role Management</i> permission	Easier to manage users, roles, and teams with a clearer and organized layout
Account settings Account level email templates and settings	None	Organizes email configuration into tabs for easier editing, previewing and branding across studies
Account settings Account workflow templates	Yes - <i>Account workflow template management</i> permission	Makes it easier to create, edit and manage reusable task templates with a cleaner interface
Account settings Account integrations	Yes - <i>API and Authentication Management</i> permission	Centralizes API, event notifications, and authentication settings into a single streamlined interface for easier configuration and troubleshooting
Account settings Account networks	None	Provides a cleaner layout and easier management of networks with improved visibility, search, and delete options
Account settings Account support link configuration	None	Updates a support link text to reflect Oracle Life Sciences branding for consistent user experience
Datasources Create, map, and clone datasource definition	Yes - <i>Data Source Management</i> role permission	Enhances usability with a new definition tab and guided steps to define, map and publish data sources more efficiently. Allows users to reuse existing datasources, reducing setup time and minimizing errors.
Datasources Create a new datasource	Yes - <i>Data Source Management</i> role permission	Provides more intuitive starting point with autosave and immediate access to mapping tools once a schema is uploaded

Enhancement	Enablement setting	Impact
Datasources Add or update flat datasource records via CSV	Yes - <i>Data Source Management</i> role permission	Enables bulk record management through CSV uploads, simplifying updates and saving time
Datasources Matches table	Yes - <i>Data Source Management</i> role permission	New datasource column added to the Matches table, improving visibility into the source of each matched record
Datasources Loading message	Yes - <i>Data Source Management</i> role permission	Displays context-specific messages during loadings, helping users understand system status
Datasources Quick links	Yes - <i>Data Source Management</i> role permission	Clarifies which datasources are actionable by hiding quick links for unpublished datasources
Document management Document submissions page	Yes - When you have any of the following permissions, you can access the new page from the Study > Document submissions menu item: <ul style="list-style-type: none"> • <i>Negotiation for assigned CDA/Document submissions only</i> • <i>Review and Approve All CDA/Document Submissions</i> • <i>Review and Approve Assigned CDA/Document Submissions Only</i> • <i>Read only document management view</i> 	Simplifies document tracking and review with filters, exports, and version history
Document management Survey submission PDF history	Yes - <i>Site nomination</i> permission to grant access to the study's Document submissions page	Enables viewing, filtering, and bulk downloading of survey submission PDFs, improving document management and auditability
Email communications Invitation received modal	None	Improves the invitation experience by displaying recipient names consistently sourced from the site grid and site profile, improving clarity in site communications
Email communications Study email templates	Yes - <i>Email template management</i> permission	Simplifies email template management and accordion controls, making it easier to configure and customize study notification emails
Feasibility surveys Total survey points	None	Displays total possible survey points in the site grid and survey response modal for better scoring visibility
Feasibility surveys Alchemer login	None	Adds direct link to Alchemer login for easy survey access

Enhancement	Enablement setting	Impact
Feasibility surveys Survey PDF downloads	None	Improves survey PDF exports with detailed footer info including submission version and timestamps
Feasibility surveys Survey submission message	None	Enables rich text formatting and updates to survey submission message for clearer communication
Feasibility surveys Account-level default survey scoring	Yes - <i>user must have permissions to Account management page to enable scoring settings</i>	Adds account-level default scoring settings to control how survey questions are scored
Feasibility surveys Survey scoring configuration	None	Requires confirmation when updating Alchemer surveys to prevent scoring configuration mismatches
Site communications Cross-study message icon New message drawer Threaded message with Reply	None	Enhances collaboration with a new cross-study message icon, centralized message drawer, and threaded replies for better tracking and streamlined communication across studies
Site details drawer General functional enhancements	None	Enhances usability with cleaner layout, improved visibility of key site info, and faster access to study actions
Site details drawer Site assignment, Workflow close, and Network picker	None	Streamlines site management by allowing direct site assignment, easier workflow closure and intuitive network selection from the site details drawer
Site details drawer Site visit date picker	None	New date picker control added to capture planned site visit dates, making it easier to track and update visit scheduling information

Enhancement	Enablement setting	Impact
Site details drawer Document workflow tasks	<p>Yes -</p> <ul style="list-style-type: none"> <i>Review and Approve All CDA/Document Submissions permission</i>: allows you to open the modal for all sites <i>Negotiation for assigned CDA/Document submissions only permission</i>: allows you to open the modal only if you are assigned as a CDA reviewer for the document task or you are the site-assigned user If you have only the <i>Review and Approve Assigned CDA/Document Submissions Only</i> permission and not the <i>Negotiate or all CDAs</i> permission, you cannot see the Review actions link/modal if you are not the user assigned as a CDA reviewer or the site-assigned user for the document task An Oracle Site Select user with the <i>Read only site grid view</i> permission will not see the Review action link An Oracle Site Select user with the <i>Read only document management view</i> and either the <i>Read only site grid view</i> or the <i>Site nomination</i> permission can open the review modal, but not complete the task <p>Additionally, please note the following related to CDA permissions:</p> <ul style="list-style-type: none"> A user with the <i>Negotiation for assigned CDA/Document submissions only</i> permission cannot finalize/Final approve a CDA task without also having one of the “<i>Approve</i>” CDA permissions as well If an Oracle Site Select user has ‘<i>Review and Approve Assigned CDA/Document Submissions</i>’, then they can see the modal for all site’s CDA documents. If an Oracle Site Select user has ‘<i>Negotiate or all CDAs</i>’ then they can only see the modal where the user is assigned as the CDA reviewer or the site-assigned 	Introduces a new actions and history drawer that centralizes task actions and version history improving reviewer efficiency and visibility into document activity

Enhancement	Enablement setting	Impact
	user. The user will not be given the option to Final approve the CDA.	
Site grid Site grid design Workflow column and details drawer access Task completion modal Survey results column Site invitation and Site portal status Final approve CDA task in Workflow drawer	Yes - <i>Allow external completion of workflow tasks</i> permission	Improves overall site list usability with better filters, sorting and layout updates that make it easier for users to find and manage site data across studies
Site grid Site grid filter selection Multi-select filter for Site Progress CDA Status column	None	Adds new filtering options and improves filter layout, enabling users to narrow results more precisely and manage sites more efficiently
Site grid Unavailable sites message	None	Displays a clear message when no sites meet the current setup criteria, helping users quickly understand why the site list appears empty
Site grid Revert site finalization Exclude, finalize, and migrate site confirmation modals	Yes - <i>Site nomination</i> permission, <i>Revert site finalization</i> permission	Allows users to revert final acceptance/final decline decisions, offering greater flexibility in managing site selection workflows and correcting errors if needed
Site grid Assign site user modal	None	Introduces a streamlined modal for assigning Oracle Site Select users to study sites, improving efficiency and consistency in managing sites
Site grid View site history	None	Provides users with a centralized view of site history, improving visibility of site history information
Site grid Site document download	None	Enables users to download the latest version of the submitted site documents from any bucket state
Site grid CDA task status icons	None	Visual status indicators on CDA tasks, allowing users to quickly assess progress
Site grid Site grid CSV extract	None	Allows users to export the site grid view to a CSV file, making it easier to share, analyze or archive site data outside the application

Enhancement	Enablement setting	Impact
Site portal Site portal user interface myStudies dashboard Communications Documents Completed workflow tasks	None	Delivers a modernized and more intuitive experience for site users with a redesigned interface and streamlined access to key study information, including dashboards, messages, documents, and completed tasks—enhancing usability and site engagement
Site profile Configurable site profile	None	Enables customization of the site profile layout and fields, allowing customers to tailor data views to their workflows and capture site-specific information more effectively
Site profile Document library	Yes - <i>Upload files to a site's document library</i> permission	Centralizes access to important study documents, improving visibility and making it easier for users to find and reference shared content.
Site profile Trial history	None	Provides a detailed view of a site's past participation in trials, helping users evaluate site experience and inform site selection decisions
Study setup Study workflow configuration	None	Allows users to define and tailor study-specific workflows, improving alignment with organizational processes and enhancing operational efficiency
Study setup Study workflow documents	Yes - <i>CDA/Document Template Upload</i> permission, <i>Study Setup Management</i> permission. If you have both, or the <i>Read-only Study Setup</i> permission, you'll see everything.	Enables management of workflow-associated documents within the study, supporting better organization, version control, and traceability across goals
Study setup Study milestones	None	Improves usability by repositioning the row to its related input fields for better context and clarity

Enhancement	Enablement setting	Impact
User management User permissions	<p>Yes - Three new user permissions that separate the Confidentiality Statement, CDA and Survey tasks from the general Not Required permission.</p> <p><i>Complete task as Not required: Sign and return CDA, Complete task as Not required: Feasibility survey, Complete task as Not Required: Confidentiality Statement</i></p> <p>Two new permissions in the CDA/ Document Management permission group.</p> <p><i>Review and Approve All Generic Document Submissions, Review and Approve Generic Document Submissions for assigned sites Only</i></p> <p>Existing CDA permissions will automatically receive one of the new generic document permissions as follows:</p> <ul style="list-style-type: none"> • Users with <i>Negotiation for assigned CDA/Document submissions only</i> or <i>Review and Approve All CDA/ Document Submissions</i> will now have <i>Review and Approve All Generic Document Submissions</i> permission • Users with <i>Review and Approve Assigned CDA/ Document Submissions Only</i> will now have <i>Review and Approve Generic Document Submissions for Assigned Sites Only</i> permission 	Introduces new permissions allowing users more control and flexibility managing workflow tasks, generic document review roles
User management Study names	<p>Yes - <i>Study details management</i> and <i>Account study creation</i> permissions</p>	Updates permissions required to edit study names, improving control and security over study information

3

New known issues

These are the unresolved issues found during the development of this release.

- [Communications](#)
- [Data sources](#)
- [Document library](#)
- [Feasibility surveys](#)
- [Site grid](#)
- [Site portal](#)
- [Site profile](#)
- [User management](#)

Communications

Description	Ticket	Severity
Accept and decline email template hover text does not display as configured in the study level email template settings.	SEL-20383	4
When the message list has been filtered using one of the "Refine by" options, the filter is incorrectly removed if a user expands a message using the "more" link and then closes that message.	SEL-20986	4

Data sources

Description	Ticket	Severity
A timeout error may occur when replacing the CSV schema for an unpublished Oracle datasource. This can happen with larger datasources or more complex schema updates. Workaround: If the timeout error occurs, create a new datasource using the updated CSV schema.	SEL-19634	3

Document library

Description	Ticket	Severity
When navigating the section menu on the Edit Site Profile or View Site Profile page using the arrow up/down keys, users are unable to shift focus to the Document Library menu item. This issue prevents access to the Document Library keyboard-only navigation.	SEL-20169	4

Feasibility surveys

Description	Ticket	Severity
A Microsoft Excel error occurs when opening the survey scoring configuration's Enhanced questions and criteria report. Workaround: Open the report using an alternate spreadsheet software like LibreOffice Calc, or allow Excel to repair the error if available.	SEL-19465	3
Points from a skipped dependent question are incorrectly included in survey and category score calculations even when the question is not shown to the user, due to skip logic.	SEL-20101	2

Site grid

Description	Ticket	Severity
Dates in the Invitation received (Invit Rcvd) column do not sort in ascending or descending order as designed.	SEL-21037	3

Site portal

Description	Ticket	Severity
Inconsistent display behaviors when the study close message is shown.	SEL-21041	3

Site profile

Description	Ticket	Severity
The Role column in the Study contacts table does not include the IRB role as designed.	SEL-20619	3

User management

Description	Ticket	Severity
When viewing the Oracle Site Select User profile, the page footer (i.e., Oracle corporate links, copyright, and release version) incorrectly displays in a separate frame at the bottom of the screen.	SEL-20453	4

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Previously reported known issues

See the unresolved issues reported prior to this current release.

- [Data integration APIs](#)
- [Datasources](#)
- [Integration](#)
- [Study management](#)

Data integration APIs

Description	Ticket	Severity
API GET for a studysite's profile returns an error if the site profile is not found instead of returning an empty object as designed.	SEL-16321	3

Datasources

Description	Ticket	Severity
Users who have the appropriate permission to delete a datasource are unable to do so in the Oracle Site Select user interface.	SEL-15673	3

Integration

Description	Ticket	Severity
When the maximum number of sites (400) are migrated in bulk to a new or existing study in Oracle Site Activate, the status icons for each site do not reflect a successful migration until the page is refreshed.	SEL-3630 SEL-3631	3

Study management

Description	Ticket	Severity
When a user adds a new study to a myDashboard view with over 300 studies, the Study Name field in the "Add a new study to the account" modal does not immediately display entered characters, and users may experience a delay of several seconds.	SEL-14970	3

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Deprecated known issues

These issues are no longer applicable (e.g., does not occur, will not be prioritized for a fix, working as designed, or does not affect current functionality). We removed the items from the known issues list.

- [Document management](#)
- [Feasibility surveys](#)
- [Workflows](#)

Document management

Description	Ticket	Severity
If a CDA or generic document has not been downloaded or submitted for a study, the target graphs on the Document approvals page do not display.	SEL-5395	4

Feasibility surveys

Description	Ticket	Severity
In survey configuration, Survey tiering is required but this is not indicated in the user interface. Currently, new surveys can be incorrectly configured without tiering and the Alchemer survey response is not received.	SEL-18527	2

Workflows

Description	Ticket	Severity
If the site profile includes duplicate email addresses (e.g., CTC and additional staff is the same and with the same Email address) an error will occur when the Oracle Site Select user attempts to change the site's workflow assignment.	SEL-20673	3

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Severity definitions

Learn more about how we describe the four issue severity levels.

Severity	Description
1	Your production use of the supported programs is stopped or so severely impacted that you cannot reasonably continue work. You experience a complete loss of service. The operation is mission critical to the business and the situation is an emergency.
2	You experience a severe loss of service. Important features are unavailable with no acceptable workaround; however, operations can continue in a restricted fashion.
3	You experience a minor loss of service. The impact is an inconvenience, which may require a workaround to restore functionality.
4	You request information, an enhancement, or documentation clarification regarding your software but there is no impact on the operation of the software. You experience no loss of service. The result does not impede the operation of a system.

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Browser support

Use a certified or supported web browser to ensure expected functionality and technical support.

Our goal is to provide customers with the best experience and advanced capabilities while maintaining maximum security. As products are enhanced, older browsers may no longer provide the capabilities required to support these key objectives. Therefore, we test the current release as follows to certify and/or support browsers:

- Certified browsers undergo full testing for new features and regressions. Browser-related issues found after release are prioritized for fixes in future patches or releases.
- Supported browsers undergo focused testing on commonly-used pages. We also address all browser-related critical and blocker issues that originate in our applications.

The following table specifies the certified and supported browsers for desktop and laptop computers:

Product	Release	Certified (Latest versions as of GA)	Supported (Latest version as of GA)
Oracle Site Select application	25.1	Google Chrome and Microsoft Edge (Chromium)	None
Oracle Site Select site portal	25.1	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

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Revision history

This book's revision date history and part number list will develop over time as we make major, minor, and hotfix releases available for this release.

Date	Part number	Description
17Jul2025	G24882-02	General Availability Release Notes
04Jul2025	G24882-01	Pre-General Availability Release Notes