Oracle Life Sciences Site Select

Release Notes

Release 24.1
F95248-06
July 2024

Oracle Life Sciences Site Select Release Notes, Release 24.1

F95248-06

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Preface

This preface contains the following sections:

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

Documentation accessibility

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

Diversity and Inclusion

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

Related resources

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

Access to Oracle Support

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

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

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

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

1
Release 24.1.2

Review the enhancements and corrections made in the 24.1.2 minor release.

- What's new
  Learn about new and enhanced functionality in this minor release.
- Stability improvements
  These are the issues we fixed in this minor release.

What's new

Learn about new and enhanced functionality in this minor release.

- Learning Health Network integration
  Enhanced Learning Health Network integration allows for patient count display in the site grid and includes related data export updates.

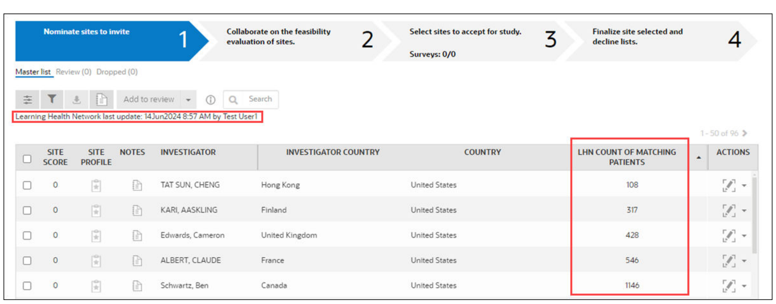
Learning Health Network integration

Enhanced Learning Health Network integration allows for patient count display in the site grid and includes related data export updates.

Patient counts in site grid

When a study has defined Learning Health Network (LHN) patient inclusion and exclusion criteria, and patient counts have been received from the LHN database, you can view the counts on the site grid when you add a new "LHN count of matching patients" data column. The LHN reports patient counts by institution so the count received for an LHN institution will reflect for all study sites affiliated with that institution in your site grid.

If an Oracle Site Select study manager updates the study's Learning Health Network patient inclusion and exclusion criteria the affiliated patient counts will null, and the site grid column will update to reflect the new count. Above the site grid, a new indicator shows you when the last patient count update happened and who made the change. The indicator has the label: Learning Health Network last update: <date and time> by <user's first and last name>, and it displays only when the study has Learning Health Network criteria saved.



Data exports

In this release, we enhanced data exports and reporting views as follows to reflect the Learning Health Network patient count enhancements described above:

- You can include the new “LHN count of matching patients” data column when you create CSV or Microsoft Excel exports using the site grid export utility.
- Nightly CSV studies and study_sites views include the last datetime the Learning Health Network service requested and received patient counts for the study. The study_sites view also includes the Learning Health Network patient count data for sites whose institutions matched incoming Learning Health Network patient count data for that study.
- For sites past the nominations bucket state (i.e., not including the Master list, Review, or Dropped buckets), the study_sites reporting view includes the Learning Health Network patient count data for sites whose institutions matched incoming Learning Health Network patient count data for that study.

> **Note:**
>
> To use the enhancements described above, your organization's account must be configured with the Learning Health Network feature. Please contact your Oracle services representative to discuss the requirements for enabling this functionality for your account.

Stability improvements

These are the issues we fixed in this minor release.

- Feasibility surveys
- Site grid
- Site workflow

Feasibility surveys

Description	Ticket	Severity
On the Site progress tab in Step 3 the Completed on date shown for the Feasibility survey task was incorrectly reporting the completion of the task. Note: The Site progress survey completion popover shows the details of the task completion, which is when Oracle Site Select processes the workflow task completion. This is different than when the survey is submitted in Alchemer, which is reported on the Survey analysis tab's Survey status column.	SEL-18052	2

Site grid

Description	Ticket	Severity
In the site grid drawer's Workflow tab, the "Complete" Action option for a workflow's Enter estimated patient count task was incorrectly disabled, so the user could not complete the task in the workflow drawer.	SEL-17737	3

Site workflow

Description	Ticket	Severity
When completing a workflow in Oracle Site Select LITE where the Agree to confidentiality task requires a user to input the title, email, and/or name of the user completing the task, the Oracle Site Select LITE user interface allowed completion of the task without showing the inputs for the required fields. The workflow must have more than one task.	SEL-17848	3

2

Release 24.1.1.1 (available for this release 07Jun2024)

Describes a correction included in the 24.1.1.1 hotfix release.

- Stability improvement
  We corrected a feasibility survey issue in this hotfix.

Stability improvement

We corrected a feasibility survey issue in this hotfix.

- Feasibility surveys

Feasibility surveys

Description	Ticket	Severity
An error occurred when saving a large feasibility survey scoring configuration.	SEL-17927	2

3

Release 24.1.1

Review the enhancements and corrections made in the 24.1.1 minor release.

- What's new
  Learn about new and enhanced functionality in this minor release.
- Stability improvements
  These are the issues we fixed in this minor release.
- Service notice
  We've made a change to Business partner collaboration functionality.

What's new

Learn about new and enhanced functionality in this minor release.

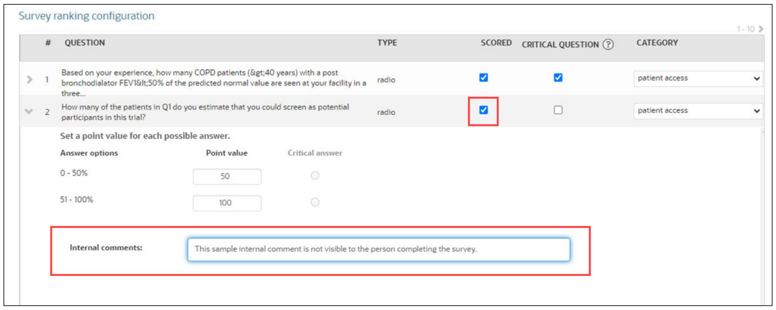
- Feasibility surveys
  Now you can add internal comments to feasibility survey questions.
- Reporting
  Two Data Export Utility cubes now include a new invited_at data column.
- Site profile
  Configurable site profile enhancements include a change to the way field labels display and a new configuration option to order data columns.
- Study setup
  Search for and select diagnosis, medication, and lab codes when specifying inclusion and exclusion criteria on the Learning Health Network patients tab.
- Workflow tasks
  Now you can complete an Agree to confidentiality statement workflow task on behalf of a site from within the site grid drawer, capture the attestor's information using new fields, and add new related columns to the site grid if preferred.

Feasibility surveys

Now you can add internal comments to feasibility survey questions.

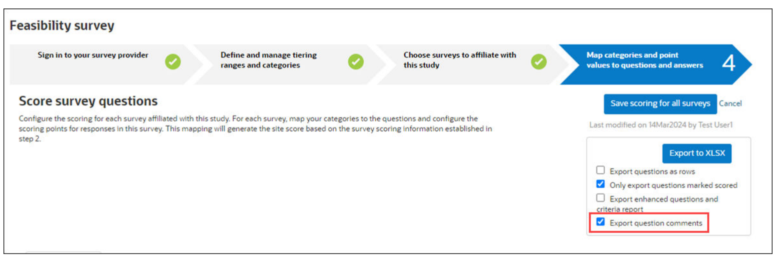
Internal comments

With release 24.1.1, we enhanced feasibility survey questions to support internal comments. Survey questions marked as Scored now provide an Internal comments text input field where you can add a comment or other internal information about the survey question.



You can optionally include internal comments in a survey configuration export. Check the new “Export question comments” option on the survey configuration export page to include a Comments column in the Oracle Site Select exports. If you also enable the “Only export questions marked as scored” option, the export will include internal comments for just those scored questions; otherwise, the exports will include comments for all questions.

> **Note:**
>
> If an internal comment is added to a survey question and the question is later unmarked for scoring, the comment will remain and will be included in exports. Additionally, internal comments are not included in the site grid survey responses export. This is expected behavior.



Reporting

Two Data Export Utility cubes now include a new invited_at data column.

Data Export Utility

With this release, we made a minor reporting enhancement to add an invited_at data column to the Data Export Utility. This column indicates when a site was moved to the invited bucket state, including sites that were invited without an invitation email. You'll find the invited_at column in the Study sites data cube and the Site survey responses cube.

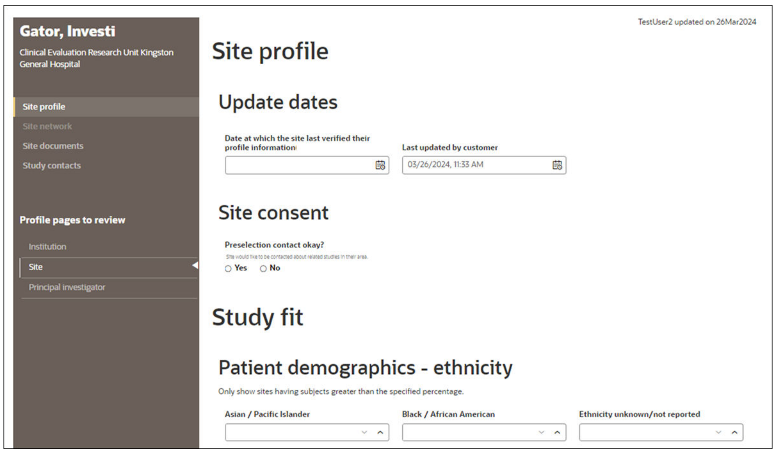
Site profile

Configurable site profile enhancements include a change to the way field labels display and a new configuration option to order data columns.

Configurable site profile

Field labels

If your organization uses the configurable site profile feature, you'll notice a user interface change to field labeling when in Edit mode. To ensure lengthy field labels always display in full, they now display above the field instead of within the field. This change affects all field inputs within the configurable site profile regardless of type (i.e. Boolean, string, etc.).



Data field ordering

With this release, we enhanced configurable site profile setup options to allow an Oracle Administrator to order individual data columns within a categorization section. When ordered, data columns within a category or subcategory will display based on the order number then alphabetically.

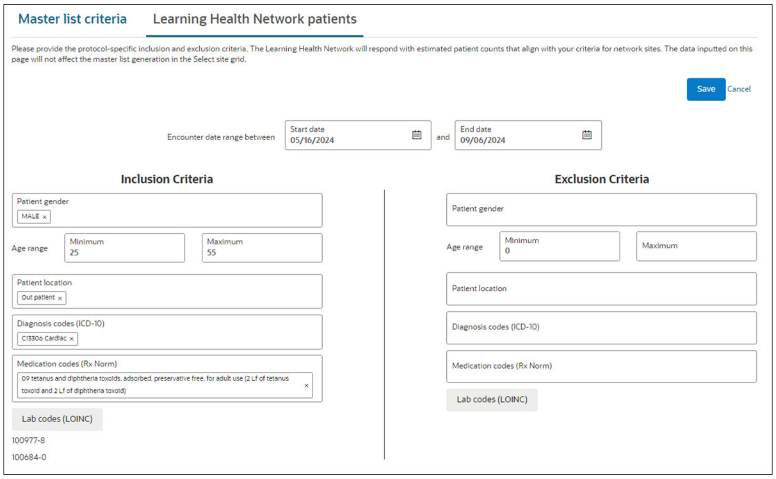
> **Note:**
>
> Please contact your Oracle services representative to discuss the requirements for setting up this enhanced functionality.

Study setup

Search for and select diagnosis, medication, and lab codes when specifying inclusion and exclusion criteria on the Learning Health Network patients tab.

Learning Health Network patient criteria

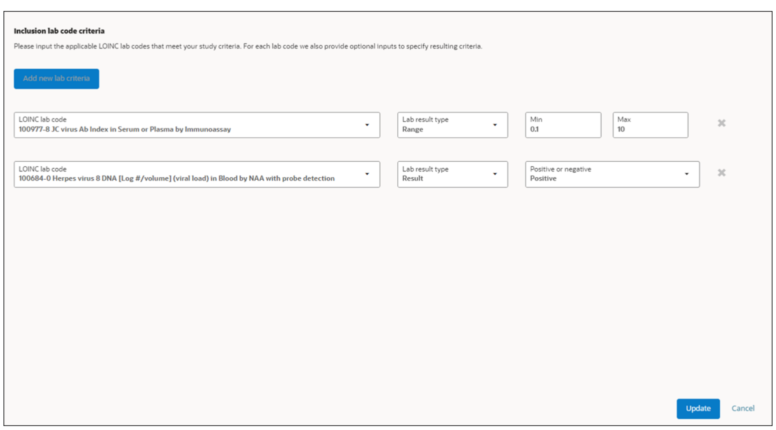
When specifying inclusion and exclusion criteria on the Learning Health Network patients tab, you can now search for and select diagnosis (ICD-10), medication (Rx Norm), and lab (LOINC) codes. For each of the criteria, you can search for a value by code number or the code's description text.



The multi-select diagnosis code and medication code fields, now labeled “Diagnosis codes (ICD-10)" and "Medication codes (Rx Norm),” respectively, allow you to search based on the code or display name. Click in the desired field and start typing the first few characters of the code or name to see a filtered list of available values. For both of the fields, you can also optionally remove any selected codes by clicking the X inside the code field.

For Lab codes, click the “Lab codes (LOINC)” button to open a new modal that will show previously selected lab codes, if any. In the modal, you can add or delete LOINC codes that reflect your study criteria. When you choose a code to add, you’ll also see inputs to specify Range (minimum and maximum units) or Result (positive or negative) as applicable.

To close the modal, you can click Update, which will update the selected lab values and return to the Learning Health Network patients tab. Alternatively, you can click Cancel, which will discard any changes you made in the modal and return to the Learning Health Network patients tab.



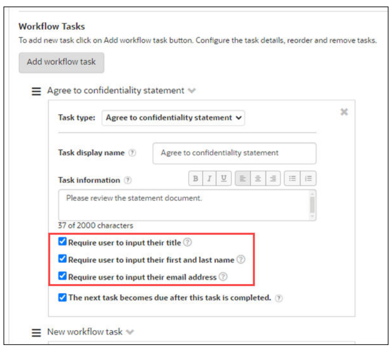
Workflow tasks

Now you can complete an Agree to confidentiality statement workflow task on behalf of a site from within the site grid drawer, capture the attestor's information using new fields, and add new related columns to the site grid if preferred.

Agree to confidentiality statement workflow task

New fields

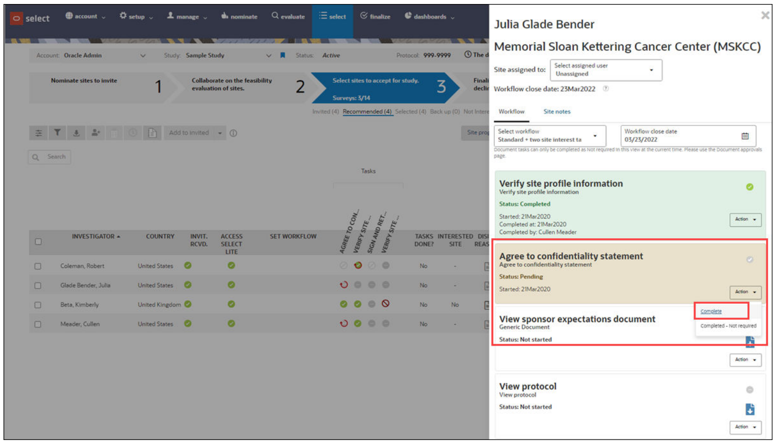
In this release, we enhanced the configuration for the Agree to Confidentiality statement workflow task to add new data fields for the document attestor’s information. The study workflow configuration page and account workflow template configuration page now include the options to require the input of title, name, and email address. You can optionally enable any or all of the new fields. When the site or an Oracle Site Select user acting on behalf of the site responds Yes to the task, they must input data for the enabled field(s) to complete it. By design, if you attempt to edit a study workflow with a site invited, the new field options will be disabled.



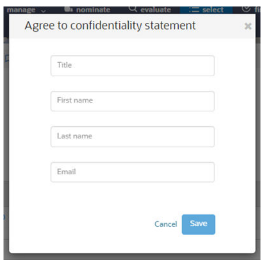
Agree to confidentiality statement task completion

We enhanced the site grid drawer’s Workflow tab, the Complete tasks on behalf of a site page, and Oracle Site Select LITE to display the new data fields described above when configured as required.

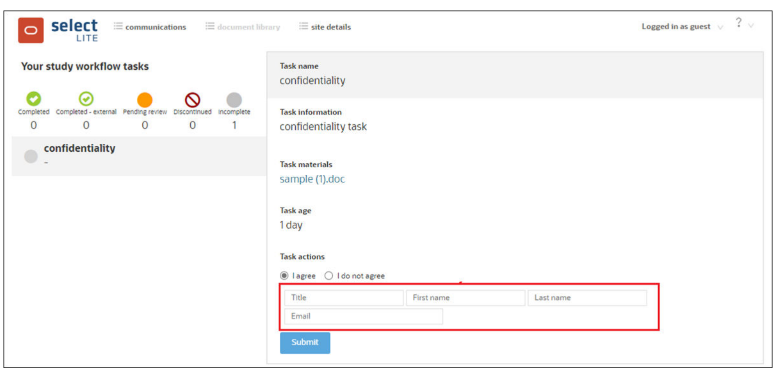
Site grid drawer Workflow tab: With release 24.1.1, you can now complete an Agree to confidentiality statement task from within the site grid drawer’s Workflow tab. The task’s Action drop-down now provides a “Complete” option. When you select Complete and click I agree, a modal displays where you must input and submit any required attestor data (title, name, and email address). You can re-complete the task if necessary, and the data saved to the attestor fields will update to reflect the updated information. For example, if the original response was Yes and the required fields were populated, and you later resubmitted with No, then the choice is updated, and the required fields will be null.



Complete tasks for this site page: After agreeing to the task, a modal displays where you will input data to the title, first name, last name, and email address fields (as configured) to save the information and complete the task. Like the Workflow tab described above, you can re-complete the task if necessary.



Oracle Site Select LITE: When a site user agrees to the Agree to confidentiality statement task (i.e. clicks Yes) and it has one or more required attestor data fields, the task will display the required field(s) in the Task actions area. The site must complete the required field(s) to enable the Submit button. Note that there is no change in behavior if the site does not agree (i.e. chooses No).



New Site progress columns

The Agree to confidentiality statement enhancements described above also introduce new Site progress data columns that you can add to the site grid if preferred:

- **Agree to confidentiality user title -** The user's inputted title when completing the site's Agree to confidentiality workflow task

- **Agree to confidentiality user first name -** The user's inputted first name when completing the site's Agree to confidentiality workflow task
- **Agree to confidentiality user last name -** The user's inputted last name when completing the site's Agree to confidentiality workflow task
- **Agree to confidentiality user email -** The user's inputted email address when completing the site's Agree to confidentiality workflow task

When you add any of the above columns to the site grid, you can sort the grid by clicking the column name; however, the new columns are not filterable within the grid. Using the Site grid export tool, you can add the data columns above to a CSV for Microsoft Excel format export.

Stability improvements

These are the issues we fixed in this minor release.

- Communications
- Feasibility surveys
- Site grid

Communications

Description	Ticket	Severity
When a site existed in multiple studies, Study digest emails were incorrectly sent to the site from a closed study.	SEL-17389	3

Feasibility surveys

Description	Ticket	Severity
Survey response PDF downloads did not include greater than or equal to and less than or equal to symbols as expected.	SEL-17605	3

Site grid

Description	Ticket	Severity
The "Completed - Not required" icon did not display as expected for sites with a CDA in pending status.	SEL-17598	3
When the View protocol task was completed in succession for two sites, the site grid drawer Workflow tab for the second of the two sites did not correctly reflect the completed task and instead showed the task as not started.	SEL-17746	3

Service notice

We've made a change to Business partner collaboration functionality.

Business partner collaboration

With release 24.1.1, we removed the Business partner collaboration feature from Oracle Site Select. This removal will have no impact on Oracle Site Select customers.

4
Release 24.1

See descriptions of new features, enhancements, and stability improvements, as well as issue lists published in the 24.1 GA release notes.

- What's new
  Learn about new features and enhanced functionality with this release.
- Impact analysis
  Review a summary of the business and functional impact for enhancements in the 24.1 release.
- Stability improvements
  These are the issues we fixed in this release.
- New known issue
  We identified an unresolved issue during the development of this release.
- Previously reported known issues
  See the unresolved issues reported prior to this current release.
- Deprecated known issues
  This issue is 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 item from the known issues list.

What's new

Learn about new features and enhanced functionality with this release.

- Communications
  Now you can send archived copies of emails to an unlimited number of email addresses.
- Datasources
  Improved messaging informs you of a nominated site's bucket state, and user interface improvements ensure a consistent display of input controls.
- Feasibility surveys
  A new survey ranking feature groups sites based on survey performance, report updates include category and ranking data, and surveys can be scored 0 when a site provides a critical response.
- Investigator repository
  We improved datasource viewing to include all imported records in a paginated view, and if you have the appropriate permission, you can edit and delete a datasource record.
- Site grid
  Oracle Site Select introduces a new site grid drawer component with workflow tasks and site notes, you can now download docs from Step 4, and Reasons are now included in exports containing Site notes and Site comms and notes columns.
- Site notes
  We made significant enhancements to Study notes, Site notes, Bulk site notes, and Reason for exclusion notes to improve your user experience and add new functionality. We also redesigned the Account note label configuration page.

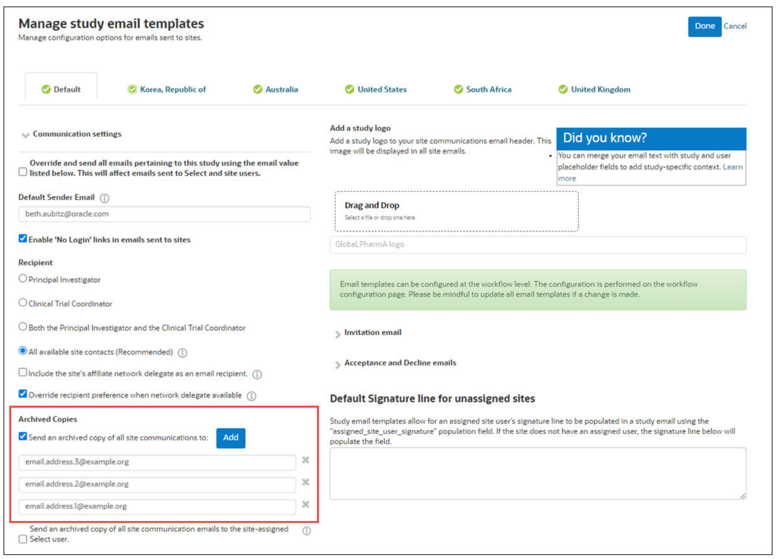
- Site workflow
  You can now complete a workflow task using a unique Completed – Not required status, and we added an account level setting to limit the number of reasons a site user may choose when giving a reason for declining the study.

Communications

Now you can send archived copies of emails to an unlimited number of email addresses.

Archived study emails

In this release, we enhanced study email templates to accept multiple email addresses for archived copies of study emails. The “Send an archived copy of all site communications to:” input is now a control that allows you to add or remove any number of email addresses. Please note that the control does not allow duplicate addresses, and the email template page will not save if you leave a blank field or input an invalid address.



Epic: SEL-16363

Datasources

Improved messaging informs you of a nominated site's bucket state, and user interface improvements ensure a consistent display of input controls.

Datasource query page

We improved error messaging on the Datasource query page Investigator and Trials tabs to let you know when a site already exists in a specific bucket state. In this scenario, the error message now identifies the bucket state, and it provides basic profile information. The message includes the PI name and institution name as the values displayed in the site grid under current data merging rules.

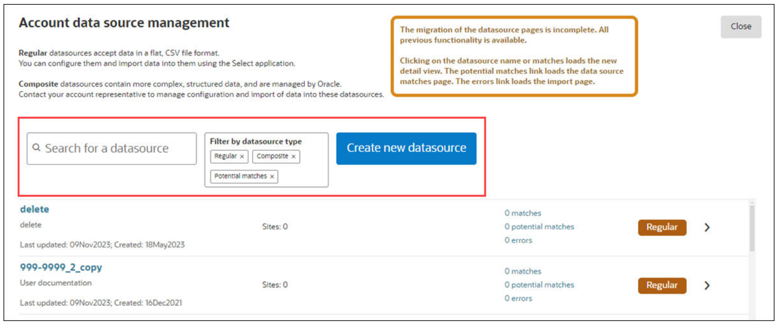
The enhanced message format is: “This site has already been nominated and is currently in the <bucket> - <bucket state> status. The site is listed as: <pi first name> <pi last name>, <institution>

Study site ID: <study_site_id>”.

Epic: SEL-16363

Account data source management page

The Account data source management page has minor user interface updates to ensure inputs display at the same height as buttons. The datasource type multi-select picker expands to a greater height only when you select enough values to require additional display space.

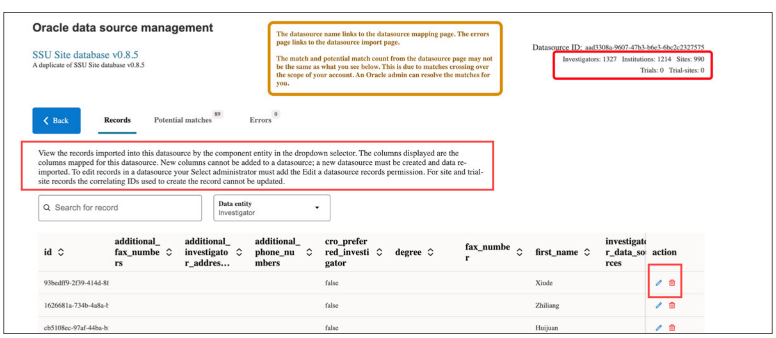


Epic: SEL-16396

Datasource details page

With release 24.1, we made several enhancements to the datasource details page to improve your user experience. These changes are:

- New descriptions for imported records on the Records and Matches tabs display above the records table.
- Record counts for regular (flat) and composite datasources display at the upper right of the page:
  - Regular – the number of sites in the datasource
  - Composite – the number of each component record in the datasource (i.e., Investigators, Institutions, Sites, etc.)
- Minor user interface updates to icon colors and search field height



> **Note:**
>
> We made several additional functionality updates to datasources in this release. See the Investigator Repository chapter in these release notes for details.

Epic: SEL-16396

Feasibility surveys

A new survey ranking feature groups sites based on survey performance, report updates include category and ranking data, and surveys can be scored 0 when a site provides a critical response.

Survey ranking

With this release, Oracle Site Select introduces a new feasibility survey ranking feature. You can access this feature by clicking a new “Survey ranking configuration” link on the survey configuration page (step 4). The link opens a page where you will configure survey ranking for the selected survey.

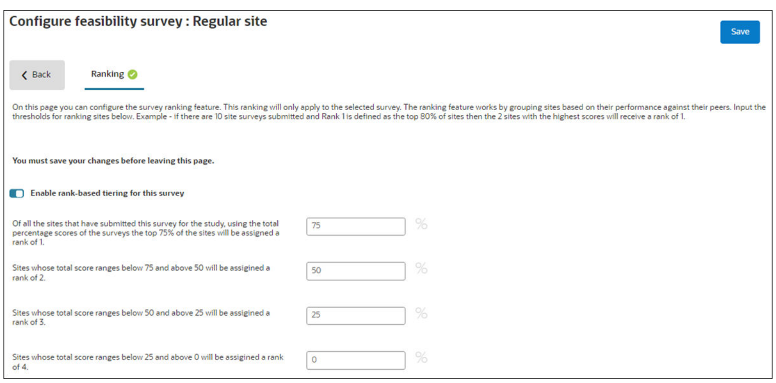
Ranking setup

The ranking feature works by grouping sites based on their performance against their peers. For example, when 10 site surveys are submitted, and Rank 1 is defined as the top 80% of sites, the 2 sites with the highest scores will receive a rank of 1. Click the control labeled "Enable rank-based tiering for this survey" to enable the tier fields. By default, the rank thresholds are:

- Rank 1: 70
- Rank 2: 50
- Rank 3: 25
- Rank 4: 0

If you prefer values other than the defaults, enter descending integers between 0 and 100 (inclusive). Each rank you enter must be less than the rank above it (i.e., when Rank 1 is 80, Rank 2 must be 79 or below). Note that the field’s narrative description updates to reflect your entry as you enter rank values. Additionally, if you input a rank of 0 in the Rank 1, 2, or 3 fields, the field(s) below that 0 entry will be disabled.

Please save your changes before leaving the configuration page.



> **Note:**
>
> When two surveys have the same score, but the ranking configuration makes it so that there can only be one site in the rank that the score lies in, Oracle Site Select will arbitrarily put one of those sites into the next ranking. Additionally, if the criterion is set high (e.g., 99%), the system will still put one site into Rank 1, regardless of the number of sites (at minimum, each rank allows one site to be placed into it).

Site grid and calculations

If you have permission to use the site grid, you can add a new Survey ranking column. The column shows the survey ranking assigned to the site based on the survey assigned and the most recent calculation.

You'll also see a new ranking icon () on the Survey analysis tab on Step 3 and Step 4. By design, the new icon is disabled if the study has no surveys configured for ranking or no sites are invited. When you click the enabled icon, Oracle Site Select recalculates the rankings of sites shown in the grid based on their survey scores for sites assigned to a survey with ranking enabled. If no surveys are submitted for a survey with a calculated ranking, Oracle Site Select assigns all sites for that survey to a rank of 0. The Survey ranking column updates with the newly calculated rankings for each site, and you'll see the following confirmation text above the table after you click the recalculation button for the first time: “Survey rankings updated: <date and time in DDMMMYYYY HH:MM timezone>”.

For sites that submitted a survey (Survey1) but were then reassigned to a new workflow and then submitted a different survey (Survey2), these sites will only have their active survey submissions considered for ranking. For example, 10 sites take Survey1. The top 9 sites are reassigned to Survey2 and submit that survey. Survey1 will still be ranked based on the only site left that submitted the survey. The 9 sites that took Survey2 will be ranked against the ranking criteria for Survey2 only. Additionally, Survey ranking will consider sites across all post-invitation bucket states (e.g., Recommended, Not interested, and Final acceptance). The same rankings apply to the sites regardless of which bucket state they are found.

Updates made to the site's survey ranking data column are reflected in:

- The site grid Survey ranking column itself
- The Survey ranking column extracted from the site grid to CSV or Microsoft Excel
- The Survey ranking column when added to the following Oracle Site Select APIs:
  - workflow_details - in the survey_response_details for each survey object as "survey_ranking"
  - studysite_details - as "feasibility_survey_ranking"
- The column(s) available in the Study site reporting views
- The columns available in the Data Export Utility Site survey responses cube and Study site data cube (column is "survey ranking")

Epic: SEL-16950

Survey reporting

Scoring exports
We enhanced the survey scoring exports to include category scoring information and survey ranking configuration, if applicable.

Export enhanced questions and criteria report

The Survey question categories worksheet now includes an output table with these columns:

- Categories – Each category applied to a question for scoring (existing behavior)
- Minimum score achievable – Total minimum points for all scored questions in the category
- Maximum score achievable – Total maximum points for all scored questions in the category

By design, if a survey category is defined but not selected for a question, it won't be listed in the above category scoring table.

For each survey worksheet, we added a Question category column just after the Question column. Question category shows the selected category for that question, and is empty when no category has been selected.

We also enhanced the scoring configuration tab for each survey to include the survey ranking configuration in table format. Tabs for surveys with no survey ranking enabled will not include the table. When included, the table displays to the right of the scoring table and shows the survey's ranks and configured values for the percentage of sites responding.

Normal Export to XLSX report

The Survey question categories worksheet now includes an output table with these columns:

- Categories – Each category applied to a question for scoring (existing behavior)
- Minimum score achievable – Total minimum points for all scored questions in the category
- Maximum score achievable – Total maximum points for all scored questions in the category

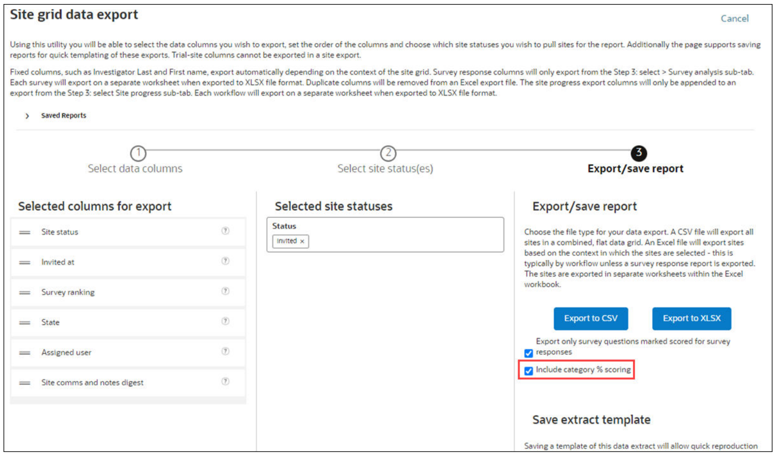
If a survey category is defined but not selected for a question, it won't be listed in the above category scoring table.

The survey score sheet now includes a table with configured ranking for each survey with Survey ranking enabled. Surveys without ranking enabled do not include the new table. When included, the table shows the survey site's ranks and configured values for the percentage of sites responding.

Site grid export utility
On the Survey Analysis tab (Step 3 or 4), you can now create a site grid extract that includes site survey ranking and category scores along with the survey response data.

You can optionally include the "Survey ranking" column in the extract, and when a survey has survey rank scoring enabled, the column will show the site ranking for all sites assigned to a survey that has ranking enabled. The column displays just after any columns you may have selected in the site grid for inclusion in the export and just to the left of the Survey version number column.

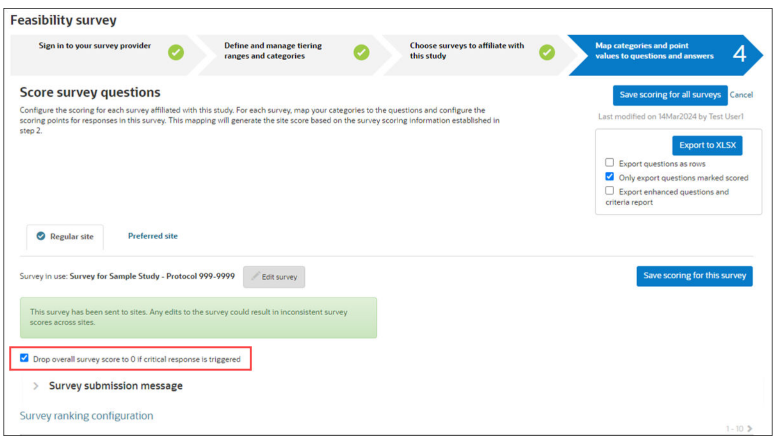
We also updated the Site grid data export with a new "Include category % scoring" check box. This new option is turned off by default; check the box to include the scores of each category in your export. The export will have one column for each category, with the category name as the column header and the category score shown as a percentage. You'll find the column to the left of the Survey ranking column, if applicable, and just after any columns you selected in the site grid for export.



Epic: SEL-16950

Survey scoring

If you are responsible for configuring study surveys, you can now turn on a new option to score the survey as zero if a site provides a critical answer. On the study survey configuration page, Step 4, you'll find a new "Drop overall survey score to 0 if critical response is triggered" check box. The check box is unchecked by default. If you check the box to enable the option, the survey score will be 0 when a site responds critically, regardless of the category scores and scores from other questions.



Epic: SEL-16363

Investigator repository

We improved datasource viewing to include all imported records in a paginated view, and if you have the appropriate permission, you can edit and delete a datasource record.

Datasource view and edit

In release 24.1, Oracle Site Select introduces the ability to view all records in regular (flat) and composite datasources, as well as permission-based record editing and deletion.

Viewing datasource content

For both regular and composite datasources, you'll see a new "Records" menu item on the datasource details page above the records table. We also enhanced this view to replace the previous 50-record preview with a paginated view with 25 records per page. If applicable to the datasource, you can select a page or advance through the available pages using the pagination control at the lower left of the records table.

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

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

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

Composite datasource searches the following columns by entity:

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

Viewing datasource records

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

Editing or deleting datasource records

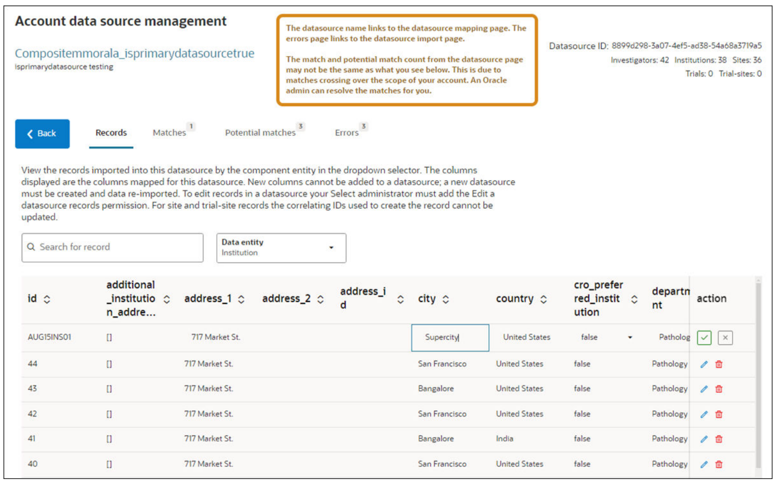
When you have a new *Edit a datasource record* permission, you'll see a fixed Action column with Edit () and Delete () action icons at the far right of the records table. Note that this new permission is a user role permission that doesn't apply to Teams. The permission allows you to edit regular and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

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

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

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

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



Epic: SEL-16629

Site grid

Oracle Site Select introduces a new site grid drawer component with workflow tasks and site notes, you can now download docs from Step 4, and Reasons are now included in exports containing Site notes and Site comms and notes columns.

Workflow tasks in site grid drawer

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

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

Assigned workflow and close date

When the site's assigned workflow has a defined close date, you'll see the date just below the site assignment control. Hover over the more information icon ( ) to see a countdown with the number of days remaining before the workflow closes. If you prefer, you can remove the workflow close date.

You can reassign a site to a different workflow if you have the required Site nominate permission. Click the "Select workflow" drop-down to see an alphabetical list of available workflows, and choose the workflow to assign. Oracle Site Select will display the following text in a confirmation window so that you're aware of the impact of the reassignment:

“Please confirm that you wish to reassign the site to the <WorkflowName>workflow.

Any tasks that have been completed in a site's current workflow will need to be completed again in the new workflow.

If there is an assigned survey change, the site's survey status will be reset and scoring will be determined by the site's responses to the new survey if applicable.

Last completed workflow task:<LastCompletedTaskName>"

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

Workflow tasks

The Workflow tab shows each task in the site’s assigned workflow and task details (like task status, related dates, etc.). As applicable, each task has a status icon (e.g., green check for completed, dash for not started, red slash for discontinued), and workflow tasks also use color background to enable quick review. Task colors are:

- Green = Completed
- Yellow = Pending
- Beige = No action (e.g., no pending document)
- Rose = Discontinued
- No color = Not started

You’ll also see the Response: + the saved value for Completed tasks with an input. For instance, the Verify site interest task will display a line with Response: Yes (or No), while the Enter estimated patient count task will show a field with the site’s inputted numeric value.

Complete a task on behalf of the site

Release 24.1 includes enhancements that allow you to complete the following tasks on behalf of a site from within the Workflow tab:

- View site profile
- View protocol
- Generic document (Download only; use Document approvals page for Approval required, Choose response, and Attestation)
- Verify site interest and Verify site interest again
- Feasibility survey
- Enter date available for site visit
- Enter estimated patient count
- Internal workflow task

Click a task's Actions button to view available completion options for that specific task. For example, an enabled Actions button for the Verify site interest task includes options to Verify

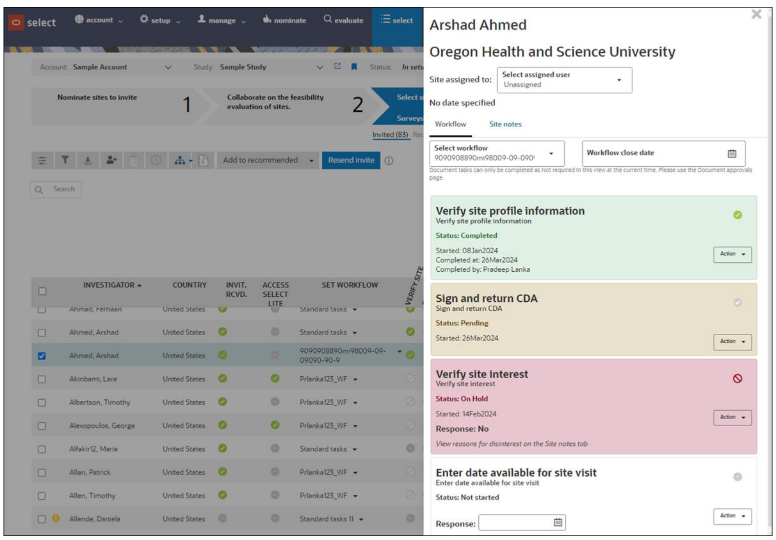
Yes, Verify No, and Complete – Not required. Some tasks will include document or template download icons (e.g., View protocol, Complete feasibility survey) as appropriate.

With release 24.1, you can only complete the document tasks listed below as “Completed - Not required” in the workflow drawer view. To manage the following Document tasks, please use the Document approvals page:

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

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

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



> **Tip:**
>
> We plan to continue enhancements to the site grid drawer's Workflow tab in future releases.

Epic: SEL-16396

Site notes tab in site grid drawer

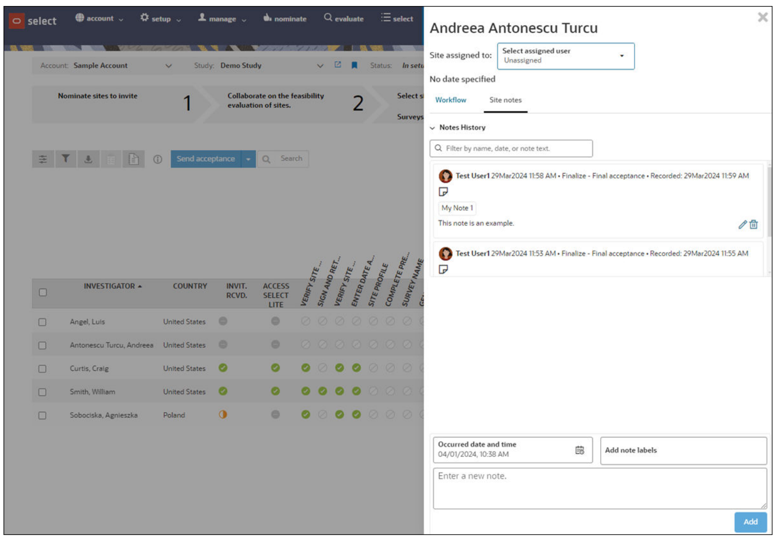
The site grid drawer, described above, also includes a Site notes tab. If you don't already have the site grid drawer opened, you can navigate directly to the Site notes tab when you click View notes in the site grid Action menu. By design, when you click on a site's notes icon in the site grid, the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

When viewing the Site notes tab in the drawer, you'll use Oracle standard components for field and text inputs. You can optionally filter the Notes history section by name, date, or note text. The Notes history section shows notes in the previously defined format, meaning:

- Notes include the author's full name and listed in order of input occurred at datetime
- Format: <occurred date time> * <bucket - bucket state note was recorded> * Recorded at: <note saved date and time>

The Site notes tab also includes a note input section at the bottom, which provides all previously available site note functionality for date, label, and text inputs.

> **Note:**
>
> This release also includes other significant Notes enhancements (such as note versioning). See the Site notes chapter in these release notes to learn more about new features and functionality for Site notes and Reasons for site exclusion notes.



Epic: SEL-16396

Site document download

You can now download site documents from Step 4 Final acceptance and Final decline buckets. We added this option to the Actions drop-down list, and the feature works as it does under Step 3.

Epic: SEL-16363

Site note extract column

On the Site note and the Site comms and notes digest columns, each line that exports a site's disinterest or exclusion reason now includes the selected reasons and any inputted "other" reason text. When multiple reasons exist for that line, they are separated with a semicolon.

Epic: SEL-16363

Agree to confidentiality response column

With release 24.1, we added a new Agree to confidentiality response column that shows the saved response for the Agree to confidentiality workflow task. You can add the new column to the site grid using the site grid column picker, and you can filter the response (Yes or No) if preferred. You can also export the column to CSV and Microsoft Excel via the site grid extract utility.

Please note that when a site is reassigned from a workflow with a completed Agree to confidentiality task to a new workflow with the same Agree to confidentiality workflow task, the task's status will be incomplete in the reassigned workflow, but the previous response will be saved. After you (or another Oracle Site Select user) complete the new workflow's task, the Agree to confidentiality task column data will update to reflect the new response value.

Epic: SEL-16363

Site notes

We made significant enhancements to Study notes, Site notes, Bulk site notes, and Reason for exclusion notes to improve your user experience and add new functionality. We also redesigned the Account note label configuration page.

Study sites notes modal

With release 24.1, we enhanced the site grid's notes modal to use Oracle standard components for field and text inputs on all tabs (i.e., Study Notes, Reasons for site exclusion, Site Notes, and Bulk site notes). We also enhanced note functionality as appropriate.

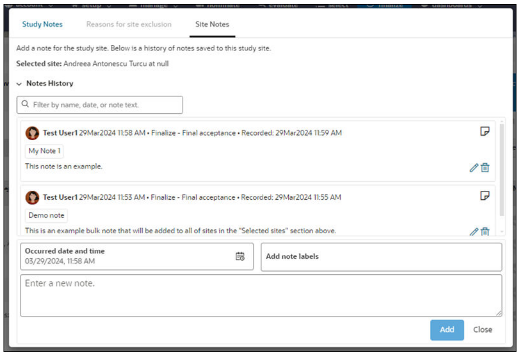
When you access the Study notes tab in the modal, you'll see new subtext that clarifies how the note will be shared with your team members: "Add notes to the study to collaborate with your study team. The notes will not be affiliated with any study sites." You can search the Note History section for previous notes if preferred, and the Note input section at the bottom of the tab includes all previously available functionality (i.e., country selection and unlimited free text).

To open the modal to the Site notes tab for one site, click the site's Note column icon () in the site grid. You can also manage notes for a single site on the new site grid drawer's Site notes tab. Learn about that enhancement in the Site grid section of these release notes.

When you click on the site grid menu notes icon without selecting a site in the grid, the modal opens to display the Study notes tab by default. If you select multiple rows in the grid, and then click the site grid menu notes icon, the Notes modal displays and defaults to the Bulk site notes tab unless you choose multiple rows in a disqualifying bucket state (e.g., Dropped, Do not invite). In this case, the Notes modal displays and defaults to the Reasons for site exclusion tab, and you can navigate to the Bulk site notes tab, if preferred.

When viewing the Site Notes tab in the updated modal, you'll see "Selected site" at the top of the modal. This area was previously labeled "Note for." You can optionally filter Notes History by name, date, or note text. The Notes History section shows notes in the previously defined format, meaning:

- Notes include the author's full name and listed in order of input occurred at datetime
- Format: <occurred date time> * <bucket - bucket state note was recorded> * Recorded at: <note saved date and time>



Epic: SEL-16396

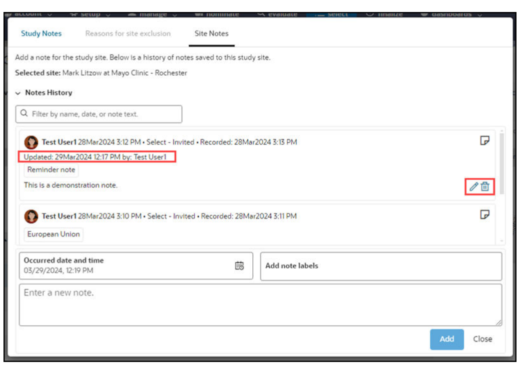
Site note versioning

When you have a new *Edit/delete site note* user permission, you'll see new Edit ( ) and Delete ( ) icons in each saved note in the Notes History section in the notes modal and in the site grid drawer's Site notes tab. These options allow you to modify any saved site note, with the exception of site notes related to a document workflow task.

When you click Edit while viewing a note in the Site note modal or Site grid drawer, the original note's text copies into the note text entry box at the bottom of the modal or drawer. The copied note also includes the selected note labels and the saved Occurred at date and time. You can edit the note as you prefer, click Update, and then confirm to save your changes.

The original note's creation date and author name aren't changed; the edited note will have a new information section in the following format: Updated: <updated date> by: < user's full name>. Additionally, the order of the notes in the site grid is now the newest note at the bottom and the oldest note at the top for the Site Note and Site Comms and Note Digest columns.

The Data Export Utility and nightly reporting view CSV extracts will include deleted and updated notes. There will be a new column to denote the deleted note. The Oracle Site Analyze standard Notes report found in the Site progress workbook will have deleted and updated notes filtered out. Only the current note(s) will display.



If you have permission to access the Data Export Utility, site note reports will include deleted and original notes that have been updated. When you create an extract in the Notes cube, include the "is deleted" column to have visibility on which extracted notes are deleted/updated. Additionally, if a site note has been updated, then the site note exported in a site note Data Export Utility report will reflect the updated note text, label, and occurred on date.

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

Epic: SEL-16363

Site exclusion notes

We also enhanced the site notes modal to replace the previous Reasons tab with a Reasons for site exclusion tab that uses Oracle standard inputs and controls.

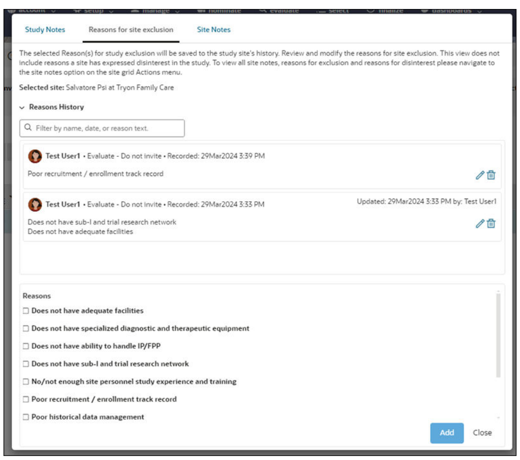
The Reasons for site exclusion tab will be enabled and displayed by default, to the right of the Study Notes tab, when you select one or more site(s) from the site grid in any disqualifying site status bucket (i.e., Dropped, Do not invite, Declined, or Final decline). If you selected multiple sites in the grid, you can also access the modal's Bulk site notes tab. Additionally, when you open the site grid drawer for any site in a disqualifying bucket state (e.g., Do not invite, etc.), the drawer's Site notes tab will have an Add reasons for site exclusion link that opens the Reasons for site exclusion tab in the modal.

The Selected site section at the top of the modal shows the site(s) that will have a site note added with your chosen exclusion reason(s). Choose one or more reasons for exclusion from the modal's Reasons and click Add to save.

New reasons added on the Reasons for site exclusion tab are visible in the site notes view immediately. So, after you Add a reason in the notes modal, you can see it in the site grid drawer on the Site notes tab without refreshing the page.

When you have the new Edit/delete site note user permission, you'll also see new Edit ( ) and Delete ( ) icons in each saved reason for exclusion note. Click Edit and the Reasons section updates to display the reason(s) from the note. Adjust the reasons as preferred (e.g., Select an additional reason, uncheck a reason, etc.), and click Update. In the confirmation pop-up, click Confirm to save your edits. The screen will refresh to show the revised note text and a new Updated information section with the date, time, and user name. To delete a site exclusion reason note completely, click the note's Delete icon and click Confirm in the confirmation pop-up.

If your organization has enabled the account level setting to require an exclusion reason when moving sites to a dropped bucket state (i.e., Dropped, Do not invite, or Declined.), the notes modal will display when you place one or more sites in the dropped bucket state, and you'll add the reason in the Reasons for site exclusion tab. The exclusion reason(s) will be saved for all the chosen sites even when you drop multiple sites simultaneously.



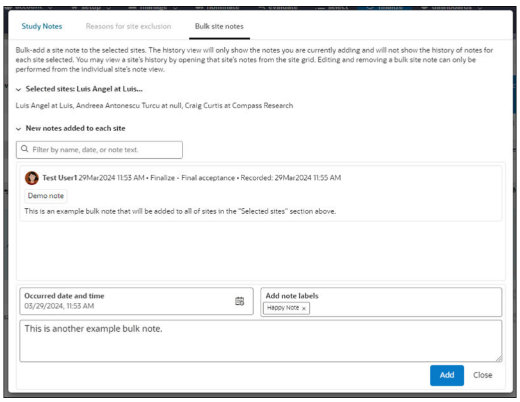
Epic: SEL-16396

Bulk site notes

When you select multiple sites in the site grid and click the Notes icon ( ) in the site grid menu, the updated Study site notes modal displays and defaults to the Bulk site notes tab.

The modal’s Selected sites section is an accordion that includes all the sites you selected in the grid. This accordion control is collapsed by default, but you can expand it to review the selected sites. At the bottom of the tab, you can add a site note and save it to all of the selected sites. This section includes all standard note authoring controls (i.e., Occurred date, Note label(s), and a free text note input area).

The tab’s New notes added to each site section displays only the site notes you added during the current session of having the modal open. Closing the modal will clear the contents of the newly added view but will not delete any saved notes. Also, note that editing and deleting a site note is not supported in the Bulk site notes tab; this functionality is available only in the individual site’s note view.



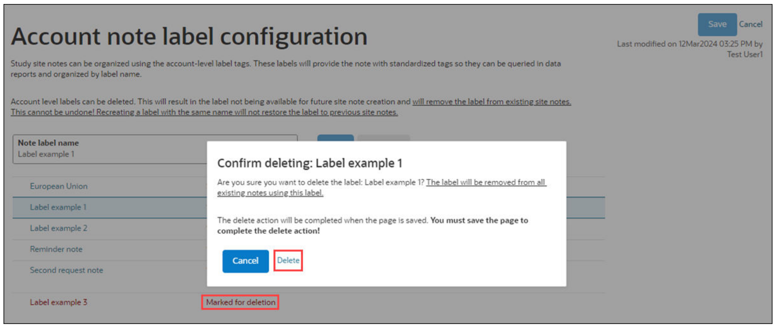
Epic: SEL-16396

Site note labels

With this release, we redesigned the Account note label configuration page to use Oracle standard design components. If you have permission to access this page, you can add and now remove labels at the account level.

If you remove a label, you must confirm this action to tag that label as “Marked for deletion.” When you save the page, any label with the deletion tag will be removed from the label list. Not saving the page will result in the label not being deleted. Please note that label removal is a permanent action. To ensure you understand the impact of removal, we added the following warning text above the label list: “Account level labels can be deleted. This will result in the label not being available for future site note creation and will remove the label from existing site notes. This cannot be undone! Recreating a label with the same name will not restore the label to previous site notes.”

The page’s Add and Save buttons are enabled when the Note label name field is not blank. If you’ve Marked a label for deletion, the Save button will be active even if the Note label name field is blank, and you’ll need to Save the page to complete the delete action.



Epic: SEL-16396

Site workflow

You can now complete a workflow task using a unique Completed – Not required status, and we added an account level setting to limit the number of reasons a site user may choose when giving a reason for declining the study.

Workflow task not required

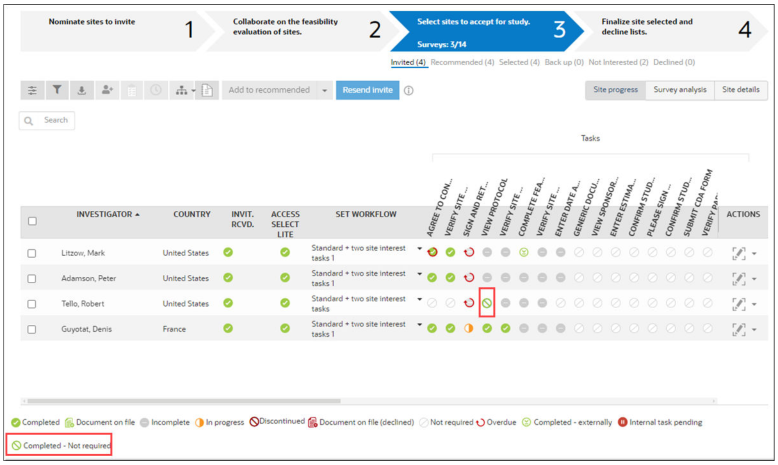
With release 24.1, we added the ability to complete a workflow task as “Not required.” This enhancement allows you to close a task as complete using the unique “Completed – Not required” status to ensure accurate reporting and site workflow task management. An example use of this option is if a site has a master CDA on file and you wish to differentiate between completing the task and marking it completed not required.

You must have the new “Complete tasks as Not required” permission to use the new functionality. Oracle Site Select users with the appropriate business role to manage permissions can add the new Complete tasks as Not required permission to a new or existing user role definition. The new permission is also available to teams, including business partner collaboration teams.

When you have the required permission, you can complete as not required any workflow task displayed in the new site grid drawer's Workflow tab, and you will be listed as the Completed by user. Also note:

- A workflow task completed as not required will be reflected in Oracle Site Select LITE as completed, and the site user will not need to complete the task.
- A document task completed as not required will have the template document saved as the final document of the task.
- The workflow task completion status for a task marked not required will have “Completed - Not required” status ( ) on the Site progress tab and in the new Workflow drawer.
- All study_site view reporting (e.g., Site grid, daily CSV extracts, and Data Export Utility) will reflect the new Completed - Not required status as appropriate.
- This option is not available on the site grid action menu > Complete tasks for this site page.

We also updated site grid filters for workflow task status to include “Completed - Not required” and “Completed – External” values. In a previous release, we enhanced Oracle Site Select with external workflow task completion functionality; the “Completed – External” filter was inadvertently omitted from the task filters with that enhancement. The affected domains and filters for the new filters in this release are Site progress > CDA status and Survey analysis > Survey status.

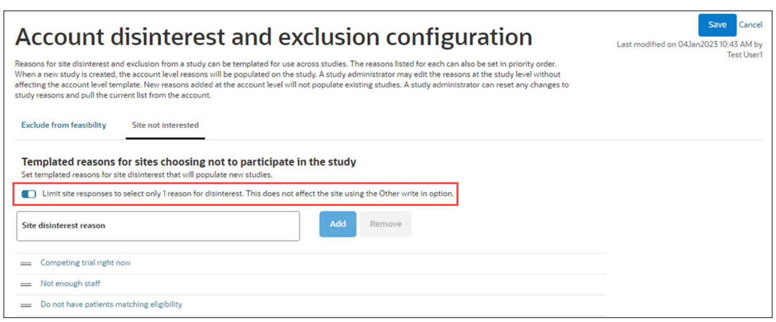


Epic: SEL-16363

Account level site workflow configuration

At the account level, we added a new check box option to limit the number of reasons a site user may choose when giving a reason for declining the study. The check box option for this limiter is on the Account disinterest and exclusion configuration page, Site not interested tab.

The new “Limit site responses…” check box will be unchecked by default. When checked, a site user may choose just one reason for disinterest after declining study participation. The one reason limit will also affect you if you decline participation on a site’s behalf. However, you and the site user can always input any reason as an Additional reason Note in the “Why don’t you want to participate?” dialog.



Epic: SEL-16363

Impact analysis

Review a summary of the business and functional impact for enhancements in the 24.1 release.

Enhancement	Enablement setting	Impact
Communications Archived study emails	None	Allows user to send archived copy of study emails to multiple email addresses

Enhancement	Enablement setting	Impact
Datasources Datasource query page	None	Enhanced error messaging on the data source query page now provides bucket state and basic profile information.
Datasources Account datasource management page	None	Enhanced user interface display
Datasources Datasource details page	None	Improved user experience with new descriptions for imported records, provides record counts on top right side of page.
Feasibility surveys Survey ranking	None	User with permission to access site grid can trigger recalculation of site ranking per survey responses.
Feasibility surveys Survey reporting	None	Export survey scoring now includes min/max achievable score for each category and % of sites responding per each rank
Feasibility surveys Survey scoring	None	Ability to now select the option to score the survey as zero if a site provides a critical answer
Investigator repository Datasource view and edit	New permission must be enabled: Edit a datasource record	Allows permissioned users to edit and delete datasource records from the data source details page.
Site grid Workflow tasks in site grid drawer	None	Users with permission to complete tasks on behalf of sites will now also have the ability to access Workflow drawer. This new drawer provides details of the assigned workflow and close date, enables user for quick review with color coded background display and allows permissioned user to complete task on behalf of site and view site notes in the grid drawer
Site grid Site notes tab in site grid drawer	None	Allows user working in the workflow drawer to also view and filter site notes directly from the site notes tab within the new drawer
Site grid Site document download	None	Allows user to now download site documents from step 4
Site grid Site note extract column	None	Site note and Site comms and notes digest columns now includes selected reasons and any inputted "other" reason text
Site grid Agree to confidentiality response column	None	New column "Agree to confidentiality response" available to be added to the site grid, that shows the saved response for the Agree to confidentiality workflow task.

Enhancement	Enablement setting	Impact
Site notes Study sites notes modal	None	Study Sites notes modal and notes functionality has been enhanced to provide subtext for better clarity and ease of use.
Site notes Site note versioning	New permission must be enabled: Edit/delete site note	Provides permissioned user with the options to Edit and Delete each saved note in the Notes History section and in the site grid drawer's Site Notes tab. When notes are edited, the original note's and the edited note's versioning is maintained.
Site notes Site exclusion notes	None	Site notes modal has now been enhanced to replace Reasons tab with "Reasons for site exclusion" tab and uses Oracle standard inputs and controls.
Site notes Bulk site notes	None	When permissioned user selects multiple sites in the site grid and clicks on Notes icon, the study site notes modal defaults to the Bulk site notes tab.
Site notes Site note labels	None	Account note label configuration page now allows user to add and remove labels at the account level.
Site workflow Workflow task not required	New permission must be enabled: Complete tasks as Not required	Allows for permissioned users to complete task that is not required to be completed in the workflow
Site workflow Account level site workflow configuration	None	"Limit site responses..." check box available under site workflow configuration at the account level limits the number of disinterest reasons that site user may choose while declining the study.

Stability improvements

These are the issues we fixed in this release.

- Digital signature
- Site workflow

Digital signature

Description	Ticket	Severity
An Adobe sign authentication error displayed when a user attempted to open the Workflow configuration page in an account where digital signature integration wasn't configured.	SEL-16952	3

Site workflow

Description	Ticket	Severity
The Workflow name field on the Workflow configuration page incorrectly displayed more than the maximum 31 characters.	SEL-17120	3

New known issue

We identified an unresolved issue during the development of this release.

- Site grid

Site grid

Description	Ticket	Severity
The "Completed - Not required" icon does not display as expected for sites with a CDA in pending status.	CHK-17598	3

Previously reported known issues

See the unresolved issues reported prior to this current release.

- Data integration APIs
- Datasources
- Document management
- 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

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

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

Deprecated known issues

This issue is 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 item from the known issues list.

- Milestones

Milestones

Description	Ticket	Severity
It is not possible for users to delete response time values on the Manage Milestones page.	SEL-2474	3

5 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.

6 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	24.1	Google Chrome and Microsoft Edge (Chromium)	None
Oracle Site Select LITE	24.1	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox

7 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
09Jul2024	F95248-06	Corrected 24.1.2 release date from 08Jul2024 to 09Jul2024
08Jul2024	F95248-05	Added 24.1.2 patch release
07Jun2024	F95248-04	Added 24.1.1.1 hotfix (available for this release 07Jun2024)
20May2024	F95248-03	Added 24.1.1 patch release
26Apr2024	F95248-02	General Availability Release Notes
11Apr2024	F95248-01	Pre-General Availability Release Notes