

Oracle Life Sciences Site Select

Release Notes



Release 23.2
F84372-03
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Oracle Life Sciences Site Select Release Notes, Release 23.2

F84372-03

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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 23.2.0.1 (available for this release 26Oct2023)

This hotfix includes a feasibility survey enhancement and a site grid export correction.

- [What's new](#)
Learn about the feature enhancement included in this release.
- [Stability improvement](#)
Describes a site grid export issue we corrected in this release.

What's new

Learn about the feature enhancement included in this release.

- [Feasibility surveys](#)
New validation logic prevents download failures caused by non-ASCII characters.

Feasibility surveys

New validation logic prevents download failures caused by non-ASCII characters.

Survey results download

When building a PDF download of feasibility survey results, new character validation removes non-ASCII characters (e.g., Japanese characters) from Alchemer survey questions and responses. This enhancement prevents instability and ensures PDF files download as expected. Additionally, this enhancement affects only the survey PDF download.

Stability improvement

Describes a site grid export issue we corrected in this release.

- [Site grid](#)

Site grid

Description	Ticket	Severity
The Site progress site grid export did not report workflow task completion details for all currently assigned tasks as expected. This issue occurred when a site was reassigned to a workflow with tasks that had the same type and name as those in a previously assigned workflow.	SEL-16674	2

2

What's new

This section details new and enhanced functionality with this release.

- [Data integration APIs](#)
A new API clones existing datasources and account administrators can now optionally add multiple PUSH notification endpoints
- [Document management](#)
We enhanced document library functionality, added helper text on the Document management page, and more
- [Feasibility surveys](#)
Multiple feasibility survey enhancements include improved question scoring, submission response download, and more
- [Notes](#)
Site notes now include selected disinterest and exclusion values and additional details
- [Site grid](#)
The Site grid export page has a new design, the Site communications and digest data column has multiple data and format improvements, and more
- [Study site management](#)
Permissioned users can now track assignments, scheduling, and status for pre-study visits; site profile enhancements introduce new and relabeled fields, and more
- [Study management](#)
The site counts dashboard now includes study prediction data, multiple enhancements make it easier to control which studies are viewable, and more
- [Workflow](#)
Oracle Site Select introduces internal workflow task functionality

Data integration APIs

A new API clones existing datasources and account administrators can now optionally add multiple PUSH notification endpoints

Datasource clones

A new Datasource Clone API will clone an existing composite or flat datasource within a customer's account and keep the existing data column mapping of the cloned datasource. The API requires an existing datasource ID. The datasource ID provided isn't required to be a published datasource. Oracle datasources may not be cloned.

The API accepts the following optional Datasource name and Datasource description body attributes:

- **Datasource name** – If provided, the name must be unique to the account. If not provided, the cloned datasource will have "_copy" appended to the end of the name.
- **Datasource description** – If not provided, the description is "A duplicate of <original datasource name>".

We updated API documentation to include the Datasource Clone API described above. Users can access detailed API information using the "API documentation" link in the Oracle Site Select global navigation help (?) menu.

EPIC: SEL-15402

Event message endpoints

In this release, we enhanced API configuration to allow Oracle Site Select administrators to configure multiple PUSH notification endpoints as necessary to support their business needs. Oracle Site Select will send a message for each PUSH notification message type as per the configuration for that specific endpoint.

The API configuration area for PUSH notifications now includes an "Add endpoint" button. When clicked, an accordion-style panel opens where the administrator will complete the necessary fields to define the new endpoint. If a PUSH notification endpoint already exists for the account, the new accordion opens above the existing endpoint to provide the necessary endpoint configuration inputs.

EPIC: SEL-15402

Document management

We enhanced document library functionality, added helper text on the Document management page, and more

Document library

Task completion modal

For auto-completed document tasks, the Task completion details modal Completed By and Email columns now display "Library upload" instead of the user name and email of the user who uploaded the document. Similarly, the Data Export Utility "Agree to Confidentiality" column now displays "Library upload" for auto-completed document tasks.

Document library saving

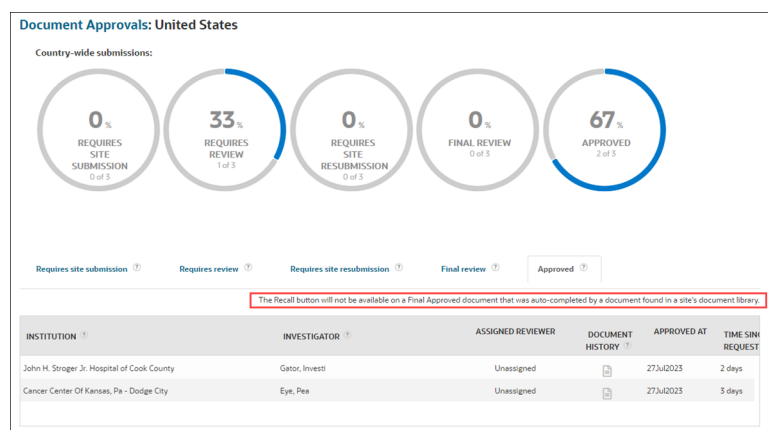
With release 23.2, we enhanced document library saving to include institution and site scoped documents from workflow task completion. When an invited site does not have the document available in their library, the submitted document will be saved to the site's library at the defined scope upon task completion. The document library previously accepted only investigator scoped documents when completing a document task affiliated with a library document type and the document previously didn't exist in the site's library; this enhancement adds institution and site scoped documents.

Metadata associated with the saved document will be associated with the file added to the document library and will be based on the document type. The document's "completed on" value will be the datetime value of the document approval or task completion.

EPIC: SEL-12753

Document management page

We added helper text to the Approved tab on the Document management page to clarify why a CDA document doesn't have a Recall button. The new helper text is: "The Recall button will not be available on a Final Approved document that was auto-completed by a document found in a site's document library."



EPIC: SEL-12753

Study site document download

Workflow task completion download

Oracle Site Select users with site grid permission can now download the workflow task completion audit record for a site's completed feasibility survey submission. The downloaded PDF format file includes metadata for the most recent submission.

The PDF export file name uses the following naming convention: <studyID> _ <Country name> _ <PI last name> - <pi first name> - <institution name> - <workflow task UI name> - <datetime workflow task completed>.PDF.

Note that this functionality is not available for feasibility surveys completed externally.

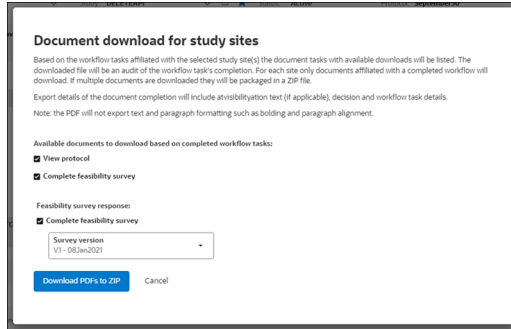
Site document download modal

We enhanced the Site document download modal to improve document ordering. Now, the modal lists downloadable documents in the workflow configuration order from the site's workflow.

The Site document download modal also has a new "Feasibility survey response" download section that displays when the site has at least one survey submission. Users can check the

download option in this section and choose the preferred feasibility survey version to include in the PDF download. The selection list defaults to the most recent version.

We also made a minor user interface improvement to relabel the Site document download modal's "Download" button. When users choose one file to download, the label is "Download to PDF." If the user selects multiple files for download, the label is "Download PDFs to ZIP."



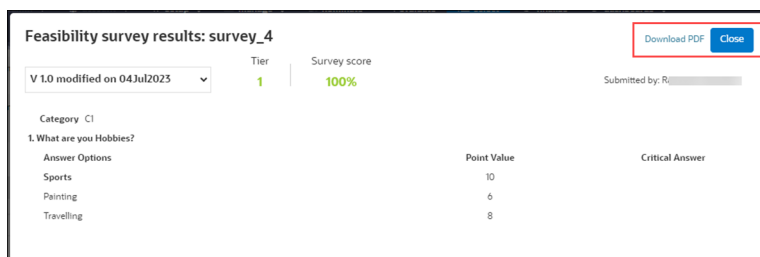
EPIC: SEL-15561

Feasibility surveys

Multiple feasibility survey enhancements include improved question scoring, submission response download, and more

Submission response download

Using a new Download PDF link in the survey response modal, Oracle Site Select users can now download survey submission questions and responses to PDF for any selected survey version. We also made a minor labeling update in the survey response modal to change the "Done" button to "Close."



EPIC: SEL-15561

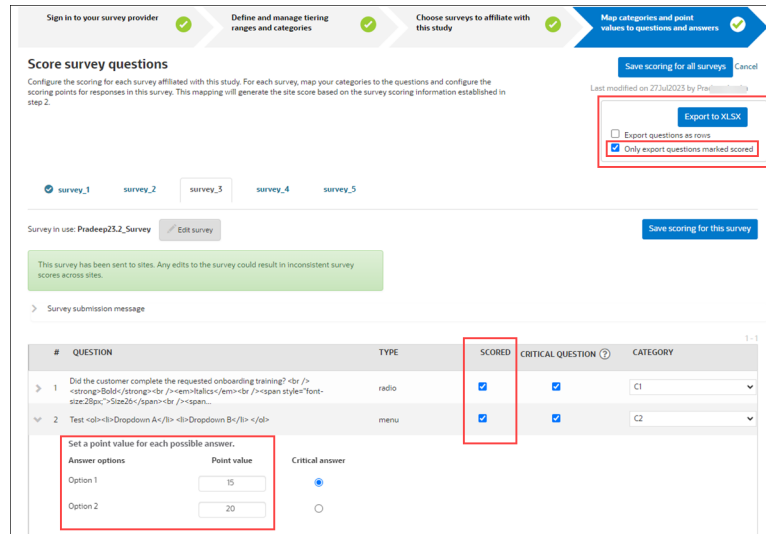
Question scoring

With this release, Oracle Site Select users can now mark specific scorable feasibility survey questions as scored. On the Score survey questions page, a new Scored check-box defaults to enabled and checked for all scorable questions. Users can uncheck the box as preferred. If unchecked, Oracle Site Select displays the following helper text: "This scoreable question is marked as not scored. To make it scoreable enable to "scored" option."

We also removed the requirement that users specify a Category before saving changes to the Score survey questions page.

Users can now optionally export only those questions marked as scored. Users will see a new "Only export questions marked scored" check box at the upper right on the

Score survey questions page. This new option is checked by default; users can uncheck it as preferred. If unchecked and a user runs an export, then questions that are Not scoreable and questions that have the “scored” check box unchecked will be exported to the Microsoft Excel file and the output will be “Not scored” for those questions. The "scored" questions will output as expected.



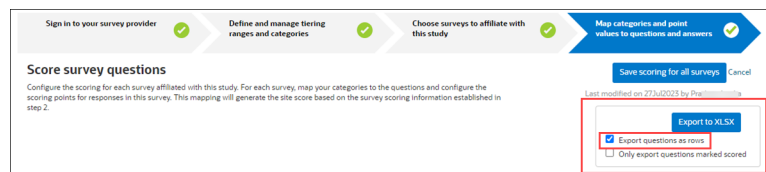
EPIC: SEL-14956

Configuration export output

With release 23.2, we made the following usability improvements to the feasibility survey configuration export:

- The "Is critical" column is relabeled to "Critical response."
- When a feasibility survey question is critical, the export now populates the corresponding question response cell with the response instead of "critical."

The Export to XLSX feature is also enhanced to include a new "Export questions as rows" check box option. When checked, Oracle Site Select generates the report in a transposed format, with questions as rows and "Survey scoring," "Critical response," and "Category" as columns in the exported file.



EPIC: SEL-14956

Feasibility survey results export

We enhanced the feasibility survey results extract, accessed from the Step 3 or 4 site grid, Survey analysis subtab, to make it easier for users to see critical survey responses. Extracts now include a fixed column called "Critical responses" that outputs the responses answered critically for both CSV and Microsoft Excel exports. Critically answered questions not marked as "scored" in the survey scoring configuration will not be included in Critical responses. In Excel exports, the cell corresponding to the critical response(s) now has a red background.

EPIC: SEL-14956

HTML character removal

With release 23.2, we removed special characters (HTML) from the feasibility survey scoring configuration and feasibility survey response exports to make the exports easier to read. For both exports, column headers no longer include HTML characters for font decoration, formatting, or paragraph alignment. We also removed HTML characters from question response rows for the feasibility survey response export.

Column headers and response rows will support basic styling as follows:

- paragraph and line breaks
- numbered lists display but are not indented/formatted exactly the same as in the survey
- bulleted lists display but are not indented/formatted exactly the same as in the survey. Bullets display as an asterisk



Note:

Microsoft Excel renders some special characters incorrectly in UTF-8 compliant CSV files that contain non-English characters. This issue is specific to Microsoft Excel issue; the file content displays correctly in LibreOffice Calc (Ubuntu). The workaround for this issue is as follows:

1. Open the CSV file using **Notepad**.
2. Click **File -->Save As**.
3. In the dialog window that appears, select **ANSI** from the **Encoding** field. Click **Save**.
4. Open this new CSV file using Microsoft Excel. Non-English characters display correctly.

EPIC: SEL-14956

Feasibility survey submission message

In this release, we added a new "Survey submission message" text input section to the feasibility survey configuration page. The new section includes the following default submission message text:

"Feasibility survey successfully completed.

Your response is being processed. The CRO/sponsor will evaluate your survey and contact you if they have any questions.

Logging into this study management tool provides additional functionality:

- Faster communication with your CRO / Sponsor
- Create a site profile and gain access to additional studies
- Access your library of signed documents"

Survey managers can optionally customize the submission message as preferred so the message displayed to site users is unique to the survey. The new text input section

supports standard text formatting options (e.g., emphasis, alignment, bullets, and numbering).

EPIC: SEL-15402

Percentage type survey questions

In release 23.1.1 we enhanced reporting views to include feasibility survey questions and responses for Alchemer percentage type questions. Please note that Percentage type question response data has not been backfilled on survey responses prior to the 23.1.1 release. Additionally, the percentage response provided by the site will now populate the "survey_question_question_choice_answer" data field in the reporting view.

EPIC: Not applicable - Clarification note

Notes

Site notes now include selected disinterest and exclusion values and additional details

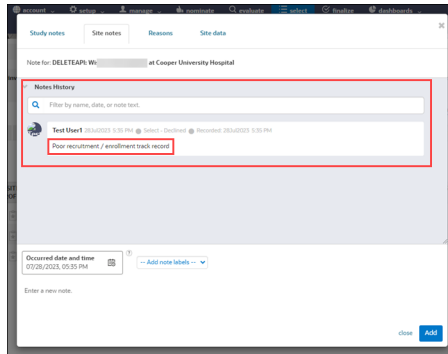
Site notes

Previously, exclusion and disinterest reasons appeared in Site notes only when the user added a comment to the reason chosen from the list of values. This release enhanced the Notes functionality to display the selected reason and additional detail.

When an Oracle Site Select user or site chooses only a list of values reason for site exclusion or disinterest and does not include a comment, the Site notes tab displays the following detail:

- The name of the user who selected the reason
- The bucket state where the reason was recorded (e.g., if the site was being placed into Decline when the user selected the reason, then "Select - Declined" is the value)
- Date and time when the reason was recorded

Example: Ari Patel * Select - Declined * Recorded: 28Jun2023 9:11 PM



EPIC: SEL-15402

Site grid

The Site grid export page has a new design, the Site communications and digest data column has multiple data and format improvements, and more

Site grid export

We redesigned the site grid export page to make creating reports easier and include the option to save an extract as a template for later use. Users can now choose drag, drop, and order the data columns they want to add to the export. Oracle Site Select will include the user's chosen data columns in addition to the report's default, fixed columns. Users will also specify the site statuses to include in the export.

Because site grid context affects the report content, we added helper text above the selection area to help users understand column availability and report structure. The helper text is: "Fixed columns, such as Investigator Last and First name, export automatically depending on the context of the site grid. Survey response columns will only export from the Step 3: select > Survey analysis sub-tab. Each survey will export on a separate worksheet when exported to XLSX file format. Duplicate columns will be removed from an Excel export file. The site progress export columns will only be appended to an export from the Step 3: select Site progress sub-tab. Each workflow will export on a separate worksheet when exported to XLSX file format."

If the user chooses to save the extract as a template, it displays in the "Saved Report" section at the top of the page. By default, the accordion section will be closed, and a user can toggle the section control to view an alphabetical list of all their saved extracts. Saved reports are specific to the user and will be available across studies.

When the user selects an extract from the Saved Reports section, the Site grid extract page refreshes to display the report's saved and ordered columns and site statuses. A user can add, remove and change the order of chosen columns without updating the saved report; however, saving updates to a previously saved report will create a new saved report. Users can delete reports from their Saved Reports list as preferred at any time.

Site grid data export Cancel

Using this utility you will be able to select the data columns you wish to export, set the order of the columns and choose which site statuses you wish to pull sites for the report. Additionally the page supports saving reports for quick templating of these exports. Trial-site columns cannot be exported in a site export.

Fixed columns, such as Investigator Last and First name, export automatically depending on the context of the site grid. Survey response columns will only export from the Step 3: select > Survey analysis sub-tab. Each survey will export on a separate worksheet when exported to XLSX file format. Duplicate columns will be removed from an Excel export file. The site progress export columns will only be appended to an export from the Step 3: select Site progress sub-tab. Each workflow will export on a separate worksheet when exported to XLSX file format.

▼ Saved Reports

Sample Report 1 This is a report sample with different data columns and site statuses ✕

Test report 1 This is a test report ✕

① Select data columns ② Select site status(es) ③ Export/save report

Selected columns for export

- Site status
- Institution
- Country
- State
- Assigned user
- Site comms and notes digest

Selected site statuses

Status

Short list x

Export/save report

Choose the file type for your data export. A CSV file will export all sites in a combined, flat data grid. An Excel file will export sites based on the context in which the sites are selected - this is typically by workflow unless a survey response report is exported. The sites are exported in separate worksheets within the Excel workbook.

Export to CSV
Export to XLSX

Save extract template

Saving a template of this data extract will allow quick reproduction of the selected columns, column order and selected statuses of sites for future reporting needs.

Name Required

Description

Save report template

EPIC: SEL-14513

Site comms and digest data column

Changes to formatting and data in the Site comms and digest column make the information easier to read. First, the column sorts each line by date and time, listed at the front of the line, with the most recent at the top. Additional changes in this release are:

Sent invitation emails:

- Message subject and body removed from the digest
- Invitation emails are combined into a single digest line when multiple emails are sent together (e.g., site invitation plus three study contact members). Please note that because the line combines all recipients of a type of email sent on a particular day, the row can have only the date and does not include the time. This is expected behavior.
- Re-sent invitations listed on separate lines
- **Example** with all study contact recipients listed in the same line: 03Jul2023; INVITATION TO PARTICIPATE; Sender: testuser@example.com; Recipient: johndoe@site.com; sitecoordinator@site.com; additionalcontact@site.com

Site notes added in the user interface:

- For the digest column only (not the "Site notes" column), format updated to: <date inputted/reported in the note>; Inputted: <date note saved>; Note subject: <labels added to note>; Logged by: <user full name who added the note>; <note content>
- If the user did not select a note date, the digest line starts with the date the note was saved if the user did not select a date.
- The "Inputted:" section displays only if the note has a label.
- Example line: 05Dec2022 7:13 PM; Note Subject: "Outgoing Phone Call", "Survey"; Logged by Joan Smith: <Content of the Note> Called Ben at the site and reminded him to do the survey.

Site communication messages:

- Digest line format updated to: 08Dec2022 5:37 PM; Communication Subject: CDA; Outbound E-mail; Recipient: John Smith; <Communication content>

CDA comments and actions:

- Digest line format updated to: 08May2023 2:21 PM; CDA Submission to/from Site; Submitted by: <User/Site User full name>; <Content of the Comments>

EPIC: SEL-15402

Site progress data columns

Site grid users can now display and export multiple new Site progress columns. In alphabetical order, the columns are:

- **CDA approved by** – The name (last name, first name) of the user who most recently approved the site's CDA task
- **CDA approved by email** – The email of the user who most recently approved the site's CDA task
- **CDA downloaded at** – The datetime the first user clicked to download the CDA document from the workflow task
- **CDA downloaded by** – The name (last name, first name) of the first user who clicked on the site's CDA task
- **CDA downloaded by email** – The email of the user who first clicked on the site's CDA task
- **Protocol downloaded at** – The datetime the first user clicked to download the protocol document from the workflow task
- **Protocol downloaded by** – The name (last name, first name) of the first user who clicked on the site's protocol task

The columns above that define a value that is the "first user" or "first time" will not be updated regardless of any repeat actions on the task. However, the CDA approved columns will update their values if the CDA is recalled and re-approved.

EPIC: SEL-15402

Single Sign On route to view site

In release 23.2, customer accounts configured to utilize SSO for user authentication (not related to Oracle Identity Cloud Service) now have a route available that will allow users to directly view a specific site in the Oracle Site Select site grid within a specific study once their login is authenticated. This route only requires the studysite's ID as a parameter. Helper text on the Site grid page directs the user to clear the site grid filter to view all sites in the bucket state if preferred.

The site displays only when the site exists in the user's permissioned account, and the user is:

- Authenticated into Oracle Site Select via SSO
- Permissioned to the study
- Permissioned to the site grid

This feature does not apply to customers that log in directly from the Oracle Site Select login page.

EPIC: SEL-15402

Study site management

Permissioned users can now track assignments, scheduling, and status for pre-study visits; site profile enhancements introduce new and relabeled fields, and more

Pre-Study Visit dashboard

In release 23.2, Oracle Site Select introduces Pre-study visit tracking. A new “PSV dashboard” permission grants users view and edit access for a new PSV tracker via a new Dashboards menu item. An Oracle Site Select user who manages user roles and permissions can add the PSV dashboard permission to a new or existing role definition and add the permission when defining a team or business collaboration team.

The Pre-study visit tracking page includes a study picker that lists only those studies the logged-in user has permission to access. Sites included in the grid have progressed to at least the Recommended bucket state, and by design, the grid displays sites even when they have moved out of Recommended. The Current Status column indicates the site’s current bucket state.

Editable columns in the grid allow PSV dashboard users to update values for:

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

Pre-study visit tracking
This page allows tracking of site visits prior to site finalization. The sites displayed in the grid are the study sites located in the Recommended bucket state for the selected study(ies). If a site is moved in/out of the Recommended bucket state the grid below will update.

[Export to Excel](#) [Done](#)

INVESTIGATOR	INSTITUTION	COUNTRY	RECOMMENDED ON	CURRENT STATUS	ASSIGNED USER	PSV SCHEDULED	PSV STATUS
Meader, Cullen	Temple School of M...	United States	18Feb2022	Recommended	Test,Michael	Jul 28, 2023, 10:00	Scheduled
Beta, Kimberly	University College ...	United Kingdom	18Feb2022	Recommended	User1,Test	Aug 24, 2023, 10:00	Scheduled
Glade Bender, Julia	Memorial Sloan Ke...	United States	09Jun2022	Recommended	Select,Demo		Pending
Coleman, Robert	The University of T...	United States	18Feb2022	Recommended			Pending

PSV dashboard users can also export the dashboard to Microsoft Excel. The export, with the default file name format “Select - PSVtracking - <ddMONyyyy>.xlsx.,” will be formatted as follows:

- The study name is the title of each Excel worksheet
- Each worksheet includes the sites from each study selected in the study picker
- The PSV tracker columns are the columns in each worksheet
- The site rows in the PSV tracker export to each worksheet with the data displayed in the grid

Study site ID	Investigator first name	Investigator last name	Institution	Country	Selection step	Selection sub-step	Recommended on	PSV assigned user	PSV status	PSV scheduled date
2026291-4170-42	Cullen	Meader	Temple School of United States	United States	selection	recommended	2/18/2022	Test, Michael	Scheduled	7/28/2023
5204240-1114-40	Kimberly	Beta	University College United Kingdom	United Kingdom	selection	recommended	2/18/2022	User1, Test	Scheduled	8/24/2023
44019240-7140-43	Robert	Coleman	The university of United States	United States	selection	recommended	6/9/2022	Select, Demo	Pending	
14814140-2140-42	Julia	Glade Bender	Memorial Sloan Ke United States	United States	selection	recommended	6/9/2022	Select, Demo	Pending	

When the PSV dashboard user clicks Done, they will navigate to the homepage for the last study they visited. If no study is in session, the user’s myDashboard page displays instead.

EPIC: SEL-11118

Site profile

Patient demographics

With release 23.2, we made three enhancements to the Site profile's Patient Demographics tab:

1. New input validation ensures totals for the Gender, Age, Race, and Ethnicity sections equal 100%. Validation also includes text and green, orange, and red font color feedback in the user interface (e.g., total in green when 100). Additionally, the page's "Done" button will be enabled only when all section totals are 100%.
2. The Gender section now includes Other and Unknown gender fields. We also added these fields to the Oracle Site Select Standard site profile columns. Like Male and Female gender fields, these new Other and Unknown fields can be imported via datasource imported and mapped, displayed in and exported from the site grid, viewed in the site scorecard, etc.
3. In the Race section, we relabeled "Native American" to "Indigenous / Native American." We also updated the description to: "A person belonging to a group that is native to a particular place with strong ties to surrounding natural resources and historical continuity with pre-colonial and/or pre-settler societies (e.g., Native Americans, First Peoples, Aboriginal people, etc)." Additionally, in the Site scorecard, the label "Native American" is now "Indigenous."

The screenshot displays the 'Patient demographics' tab of a site profile. It features several sections with input fields and percentage indicators:

- Gender:** Fields for Female (25%), Male (25%), Other (19%), and Unknown (40%). A red box highlights a 'Total: 109' error, stating 'The sum of this section cannot exceed 100%'.
- Age:** Fields for age groups: < 15 yrs, 15 - 17 yrs, 18 - 20 yrs, 21 - 44 yrs, 45 - 65 yrs, and > 66 yrs. A red box highlights a 'Total: 0' error, stating 'The sum of this section is currently below 100%'.
- Race:** Fields for Asian, Black / African American, Hawaiian / Pacific Islander, Indigenous / Native American, and White / Caucasian. A red box highlights a 'Total: 0' error, stating 'The sum of this section is currently below 100%'.

At the top right, there is a 'Done' button and a 'Cancel' button. A message above the 'Done' button reads: 'Please review/update all tabs of the Profile. Clicking Done saves changes across all tabs. Double clicking a checkbox will set it to false and remove any required field error.'

Activation contacts

The Site profile's Site Contacts subtab now includes a new "Activation contacts" section to optionally record contact details for the site's Budget, Legal, and Regulatory coordinators. By design, users can enter partial data for each contact (e.g., only last name); all fields are optional. Oracle Site Select will forward Activation contact data for use in the site activation phase.

An Activation contact's data can be imported via a datasource import and will save to the Site profile when the site profile record is saved for a site. Additionally, an update to an Activation contact's saved data will update that contact's record in the Site profile datasource.

Oracle Site Select site grid users can add Budget, Legal, and Regulatory coordinator contact detail columns to the grid and export the data if preferred. However, Oracle Site Select will not send study-related emails to Activation contacts, and users may not add Activation contacts to Study contacts in the Site profile. This is expected behavior and is by design.

EPIC: SEL-15402

Site history

With release 23.2, we added the "master profile ID" to the Site history page. The ID displays just below the study site's institution name and can be helpful if troubleshooting site matching issues. This ID is an internal ID used mainly by Oracle Support and Services.

EPIC: SEL-15402

Study management

The site counts dashboard now includes study prediction data, multiple enhancements make it easier to control which studies are viewable, and more

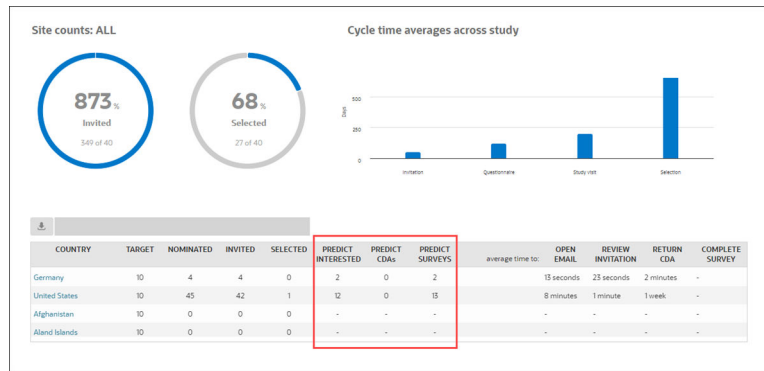
Study predictions

With release 23.2, Oracle Site Select introduces predictive data to the Site counts dashboard. The prediction model uses study metadata and current operational data to predict by country the number of sites expected to be interested in the study, complete their CDA, and complete their survey. Predictions will update as the number of sites invited to the study increases and the user refreshes the site counts dashboard page.

Predictions display in three new columns on the site counts dashboard:

1. Predict interested
2. Predict CDAs
3. Predict surveys

The site counts dashboard CSV download will also include the prediction data when available.



EPIC: SEL-15120

Study status view filter

Oracle Site Select users can now specify the study status(es) they prefer to view in the study drop-down list and on their myDashboard page. Users will find the new control on their User profile page. For example, if a user only wants to see studies in Active status they can filter for only Active studies in the Filter study list. The myDashboard page and the study drop-down menu will only list Active studies in which the user is permissioned.

Upon upgrade to release 23.2, the Study status filter picker will be blank for all users, and studies of every status will show on the study drop-down and myDashboard page. Study view will be restricted only after the user updates and saves the new Study status filter with at least one study status.

By design, if a user types in the name of a study filtered out by status, they will not be able to find or pull the study in the study drop-down. Study status restriction will also prevent them from viewing studies filtered out if a site grid page is inspected or the "View source" is shown on the browser.

User profile Done Cancel

First name: Test, Last name: User1, Title: []

Signature line for email templates: []

Email address: test.user@example.com

Receive email reminders about study setup tasks that are due.

[Manage your password](#) Your current password expires on 05Sep2023 (57 days)

Filter study list
The study dropdown list and myDashboard page will be filtered to show only the selected study statuses selected.

Study Status Filter

Feasibility complete
On hold
Closed
Cancelled

EPIC: SEL-15402

Hide studies

Oracle Site Select users with permission to access the Authentication and API configuration page can now optionally turn on a setting to hide studies in Closed or Cancelled status. When turned on, Closed and Cancelled studies will hide from Oracle Site Select users so they do not need to take any action to remove them from their study list and myDashboard page.

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

Additional site selection options

Acceptance / decline emails

Site acceptance emails can be sent to sites.

Site decline emails can be sent to sites.

Site migration

Sites can be migrated to site activation in Oracle Activate.

Study close message for site users

When a study's status is set to "Closed" or "Cancelled" the following message will display for the site user in Select Lite.

Thank you for your interest in this study. The site selection team determines site eligibility by analysing site responses to various feasibility tasks. These tasks require completion by 03Apr2023. Sites with outstanding feasibility tasks are no longer eligible for study inclusion. Thank you.

When the message defined in study details displays in Oracle Site Select LITE, the site user cannot complete any pending workflow tasks, including the Verify site profile information task. However, the site user can edit the profile, send communications, and see the document library (if logged in). Additionally, Closed and Cancelled studies display at the bottom of the site user's study list if the user has logged in.

The screenshot shows the Oracle Site Select LITE interface for a study named "OClim - James Busse". The top navigation bar includes "select LITE", "communications", "document library", and "site details". The user is logged in as a guest. The study status is "OClim - James Busse" and a warning indicates "Feasibility tasks must be completed by 03Apr2023".

The "Your study workflow tasks" section shows a progress bar with four categories: Completed (4), Completed - external (0), Pending review (0), and Discarded (0). Below the progress bar, several tasks are listed with their due dates:

- Sign and return CDA (06Dec2021)
- Verify site profile information (21Mar2023)
- View protocol (21Mar2023)
- Verify site interest (21Mar2023)
- Complete feasibility survey (-)
- Enter date available for site visit (-)

A yellow message box is overlaid on the "Verify site profile information" task, containing the text: "Thank you for your interest in this study. The site selection team determines site eligibility by analysing site responses to various feasibility tasks. These tasks require completion by 03Apr2023. Sites with outstanding feasibility tasks are no longer eligible for study inclusion. Thank you."

EPIC: SEL-15402

Study email templates

Reasons exclude placeholder

Users who configure email templates can now include a new {reasons_exclude} placeholder in the invitation, final accept, and final decline email templates. When added to the outbound email message template, the placeholder lists all the selected reasons for exclusion assigned to a site. If a site has no reasons for exclusion, the outbound message includes an empty string with no spaces or special characters.

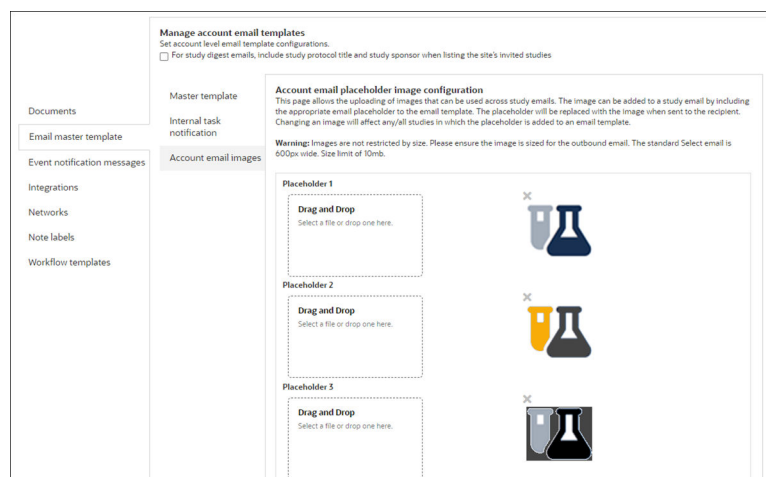
With this enhancement, we included list item delimiter logic to ensure the exclusion reasons display appropriately based on the number of reasons (i.e., commas and "and" placed between the reasons if there are more than two). We also updated the {reasons_decline} placeholder to ensure this existing placeholder uses the same delimiter logic.

Account level image placeholder

Account administrators can now configure account level email image placeholders. The administrator can upload images that can be used across study emails when the corresponding account-level image placeholder has been added to the study email template.

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

We added the five account level image placeholders to the email template placeholder list (i.e., "account_image_<number>"). When a user includes an account image placeholder in a study email template, the outbound email message will include the image saved for the account image placeholder, if any.



EPIC: SEL-15402

Study milestones

We enhanced the Country milestones table on the Study milestones page to have a fixed leftmost column when the study includes enough countries to require that users scroll horizontally to input country level values.

EPIC: SEL-15402

Workflow

Oracle Site Select introduces internal workflow task functionality

Internal workflow tasks

In this release, we enhanced Oracle Site Select to add Internal workflow task functionality. By design, only an Oracle Site Select user can view and complete the Internal workflow task, and a site's workflow will be paused when they reach an Internal workflow task. After the Oracle Site Select user completes the internal task, the site is unblocked, and they can resume progress through their remaining workflow tasks.

Task configuration

We enhanced the Site workflow configuration page to adjust labeling and add a new section. The Task Library section is now "Site task library," and the section's helper text is "Add a site level task to the selected workflow. The site task will be added to the bottom of the workflow."

A new "Internal task library" section displays below the Site task library and has the helper text "Add an internal task to the selected workflow. Internal tasks are only visible to Select users. The internal task will be added to the bottom of the workflow." A study administrator can configure an Internal workflow task on the account level template if preferred; however, users can add only one instance of an Internal workflow task for any given workflow.

When selected for inclusion in a workflow, the internal task fields and configuration options are:

- **Task user interface display name:** Shown on the Site Progress tab but does not display in Oracle Site Select LITE
- **Task information:** Optional field that describes the internal task to as Oracle Site Select user
- **Site display information:** Message displayed to the site in Oracle Site Select LITE when the internal workflow task is reached. The text in this field overlays the site's current workflow tasks until an Oracle Site Select user completes the internal task.

We also enhanced the study milestones page to add a response time target field for the Internal workflow task. The Study milestones page saves any added value and only displays the field on page refresh if a study workflow includes the Internal workflow task.

Task behavior

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

Please note, if the site reaches their Internal workflow task but also has a pending ungated Generic document task pending completion, Oracle Site Select LITE will show both task's information with the Generic document task below the Internal workflow task. The internal task will halt the workflow, but the site can still complete the Generic document task.

In Oracle Site Select, the Complete tasks on behalf of site page lists the Internal workflow task in the configured workflow order. When the user clicks the Complete button, a modal displays the task's configured "Task information" text. The user must include an entry in the modal's Task response text field before clicking Submit to complete the internal workflow task. The Task response text entry is the "internal

workflow text task" and users can view and export this data from the site grid. We added the following columns, which users can add to the Site grid as preferred:

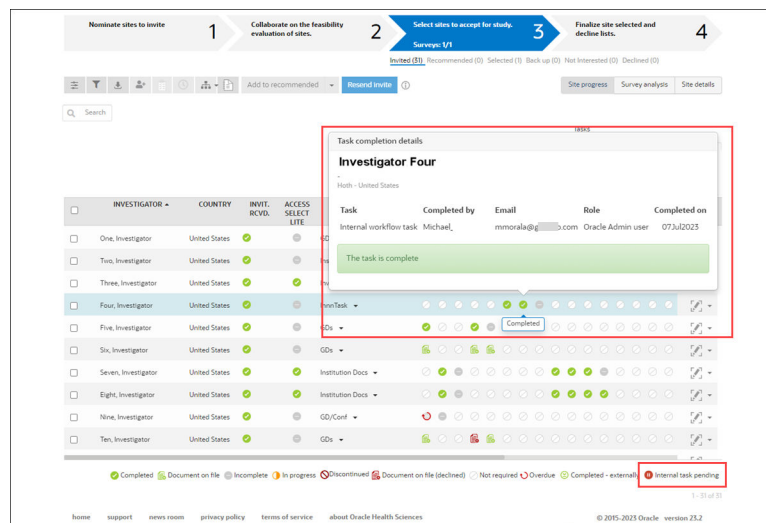
- **Internal text task completed at:** The datetime the Oracle Site Select user completed the site's internal workflow text task
- **Internal text task completed by:** The Oracle Site Select user's full name who completed the site's internal workflow text task
- **Internal text task response:** The Oracle Site Select user's response when completing the site's internal workflow text task



The Site progress tab displays the configured Internal workflow task name defined in the configuration and the task's status icon (e.g., Complete, Not required). A new Internal task pending status icon (🔴) helps Oracle Site Select users understand when an internal workflow task has paused a site's progress. The icon displays when:

- the site reaches the Internal workflow task
- a site has an optional Generic document task and they reach the Internal workflow task as the current workflow task.

The Site Progress tab will also include a status modal to show the Internal workflow task's completion details (i.e., status, who completed the task, and when) as appropriate. Additionally, the task status modal shows the Task response text saved when the Oracle Site Select user completed the task on behalf of the site.

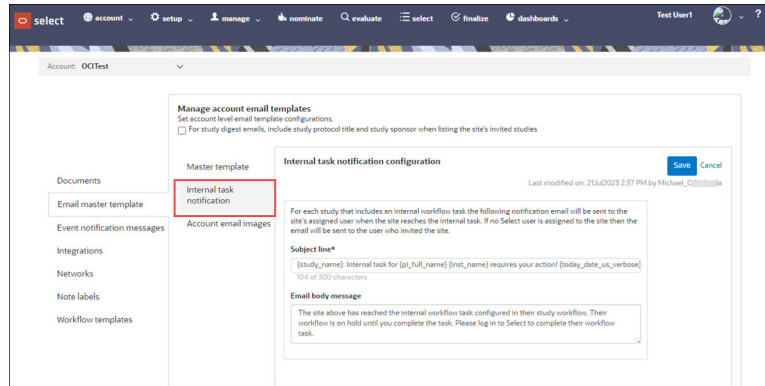


Internal task pending email notification

We updated the Account email master template page to add a new "Internal task notification" template item. Oracle Site Select users with Account email template management role permission will configure the template to include the preferred subject line and message body. Both areas support email placeholder values. For each study that includes an internal workflow task, the configured notification email will be sent to the site's assigned Oracle Site

Select user when the site reaches the internal task. If the site does not have an assigned user, the email will be sent to the user who invited the site.

In this release, we also made a minor user interface update to relabel the Done button on the Email template configuration page. The button is now labeled "Save."



EPIC: SEL-14794

3

Impact analysis

Review a summary of the business and functional impact for enhancements in the 23.2 release.

Enhancement	Enablement setting	Impact
Data integration APIs Datasource clones	None	None
Data integration APIs Event message endpoints	None	None. No changes to existing integrations on upgrade.
Document management Document library	None	None
Document management Document management page	None	None
Document management Study site document download	Optional: No New permission required: No Dependent feature: No	Users now have another site document download from the site grid.
Feasibility surveys Submission response download	Optional: No New permission required: No Dependent feature: No	Allows users to download survey submission questions and responses to PDF for any selected survey version.
Feasibility surveys Question scoring	None	Default behavior on upgrade. Users should be trained on the new option.
Feasibility surveys Configuration export output	None	None
Feasibility surveys Feasibility survey results export	None	None
Feasibility surveys HTML character removal	None	Customers will no longer need to remove HTML encoding on exports. They may need to update their post-export processing.
Feasibility surveys Feasibility survey submission message	Optional: No New permission required: No Dependent feature: No	Allows survey managers to optionally customize the submission message.
Feasibility surveys Percentage type survey questions	None	Oracle Site Analyze reports and nightly CSV reporting downloads will now contain data for percentage type survey questions. Customers should update their processing of survey data.
Notes Site notes	None	None

Enhancement	Enablement setting	Impact
Site grid Site grid export	Optional: No New permission required: No Dependent feature: No	Users can now save report template for later use.
Site grid Site comms and digest data column	None	There are format and content changes to the exporting data for this data column.
Site grid Site progress data columns	None	Customer has new data columns for export.
Site grid Single Sign On route to view site	None	None
Study site management Pre-Study Visit dashboard	Optional: No New permission required: Y (PSV dashboard) Dependent feature: No	Pre-study visit tracking
Study site management Site profile	Optional: No New permission required: No Dependent feature: No	New input validation, new relabeled fields, and Site Contacts has a new Activation contact section.
Study site management Site history	None	None
Study management Study predictions	Optional: No New permission required: No Dependent feature: No	Identification of favorable sites
Study management Study status view filter	Optional: No New permission required: No Dependent feature: No	Users can now specify the status(es) they prefer to view.
Study management Hide studies	Optional: Yes New permission required: No Dependent feature: No	Allows for studies in Closed or Cancelled status to be hidden from the study drop-down list and myDashboard page.
Study management Study email templates	Optional: No New permission required: No Dependent feature: Y (permission 'Account email template management')	Design email templates
Study management Study milestones	None	None
Workflow tasks Internal workflow tasks	Optional: Yes New permission required: No Dependent feature: No	Allows Oracle Site Select user to insert an internal task.

4

Stability improvements

These are the issues we fixed in this release.

- [Document management](#)
- [Feasibility surveys](#)
- [Notes](#)
- [Single Sign On](#)
- [Study site workflows](#)

Document management

Description	Ticket	Severity
Users encountered an error when attempting to download a CDA document.	SEL-15865	1

Feasibility surveys

Description	Ticket	Severity
When downloading a survey response PDF for a survey that has a special character like "&" in the question text or response, the special character was incorrectly replaced with an HTML encoding (e.g., &).	SEL-15856	3

Notes

Description	Ticket	Severity
Selected site disinterest reasons did not display as expected in the site notes user interface.	SEL-16121	2

Single Sign On

Description	Ticket	Severity
Users in accounts configured with Single Sign On integration could manually reset their Oracle Site Select passwords.	SEL-16333	2

Study site workflows

Description	Ticket	Severity
In a study with multiple feasibility surveys, if one of the surveys did not have a completed setup, all study workflows with affiliated surveys would show as disabled in the site grid workflow assignment drop-down. After this fix, Oracle Site Select applies per-survey workflow validation, so if other workflows in the study have an affiliated survey with a completed setup, the workflows will be selectable from the drop-down.	SEL-15964	3

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New known issues

This section identifies unresolved issues found during the development of this release.

- [Data integration APIs](#)
- [Data exports](#)

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

Data exports

Description	Ticket	Severity
<p>Survey configuration extracts and survey response extracts may error when attempting to open the file in Microsoft Excel. This issue is related to worksheet names, which are based on the survey or workflow name.</p> <p>Workarounds:</p> <ul style="list-style-type: none">• Avoid Duplicate Names: Please refrain from using the same names for both surveys and workflows.• Non-Blank Names: Ensure that survey and workflow names are not left blank; provide meaningful names for each.• Name Length Limit: Keep names within 31 characters to avoid any issues.• Unsupported Special Characters: Avoid using special characters such as <code>/ \ ? * : []</code> in the name as they are not supported.• Avoid Apostrophe at the Beginning or End: Do not start or end the name with an apostrophe (<code>'</code>). However, you may use apostrophes between text or numbers in a name.• Avoid "History" Alone: The name "History" is reserved in Microsoft Excel. While you may use the word "history" in combination with other words or characters, avoid using it as the sole name.	SEL-16310	2

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Previously reported known issues

See the unresolved issues reported prior to this current release.

- [Browser compatibility](#)
- [Datasources](#)
- [Document management](#)
- [Feasibility surveys](#)
- [Integration](#)
- [Milestones](#)
- [Study management](#)

Browser compatibility

Description	Ticket	Severity
If an Oracle Site Select LITE user copies and pastes the “No login” link from an invitation email into a Chrome browser incognito window, the user cannot upload a signed CDA from Oracle Site Select LITE.	SEL-4737	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

Feasibility surveys

Description	Ticket	Severity
<p>Due to an issue with the third-party Alchemer API, continuous sum (percentage) type survey questions are not currently included in survey results accessed from the Oracle Site Select user interface or survey export. This is not an issue in Oracle Site Select but affects survey responses for Oracle Site Select.</p> <p>Workaround: When creating a survey in Alchemer do not change a question's type. Remove the question and add a new question of the new type. Example: A survey has not been sent to sites yet. A question was originally built as a textbox list input, but you'd like to change it to continuous sum. Remove the textbox list question, add a new question to the survey, and select the type as continuous sum.</p>	SEL-15646	3
<p>A survey with a radio button grid question may not download the responses for the question due to an error with the third-party Alchemer API.</p> <p>Workaround: Resubmit the survey and download the responses.</p> <p>Preventive measure:</p> <p>When creating a survey in Alchemer do not change a question's type. Remove the question and add a new question of the new type. Example: A survey has not been sent to sites yet. A question was originally built as a textbox list input but you'd like to change it to continuous sum. Remove the textbox list question then add a new question to the survey and select the type as continuous sum.</p>	SEL-15656	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

Milestones

Description	Ticket	Severity
It is not possible for users to delete response time values on the Manage Milestones page. Workaround: To change a text value, select the value in the field and overwrite it with a new value.	SEL-2474	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

Issues listed here 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 item from the known issues list.

- [Study setup](#)

Study setup

Description	Ticket	Severity
When a user searches for and selects a Country, Therapeutic area, or Specialization on the Master list criteria page, the search bar closes and the user needs to click the field again to search for and select an additional value.	SEL-14520	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.

9

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	23.2	Google Chrome and Microsoft Edge (Chromium)	None
Oracle Site Select LITE	23.2	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, or hotfix releases available for this release.

Date	Part number	Description
26Oct2023	F84372-03	Added hotfix 23.2.0.1 (available for this release 26Oct2023)
24Aug2023	F84372-02	General Availability Release Notes
10Aug2023	F84372-01	Pre-General Availability Release Notes