Oracle Life Sciences Site Select Release Notes



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ORACLE

Oracle Life Sciences Site Select Release Notes, Release 23.3

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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/lifesciences/support/ or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.



1 Release 23.3.2

Read about the enhancements and corrections made in the 23.3.2 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 release.

What's new

Learn about new and enhanced functionality in this minor release.

Site profile

Configurable site profile left navigation allows for ordered domains, and new functionality allows your organization to define user-friendly text prompts for configurable site profile fields.

Site profile

Configurable site profile left navigation allows for ordered domains, and new functionality allows your organization to define user-friendly text prompts for configurable site profile fields.

Configurable site profile

Oracle Site Select introduces the following configurable site profile enhancements with release 23.3.2:

Left navigation

We enhanced the profile's left navigation settings to display domains in order when defined for the data columns. Domains without a specified order will be organized alphabetically and displayed after those with a specified order.

Profile display name

A new "profile_display_name" datasource definition attribute will allow your organization to define user-friendly field text (e.g., a question for a site user). An Oracle administrator can edit the new column attribute for all standard and custom site profile data columns.

Note:

Please contact your Oracle project manager to discuss the preferred domain order for left navigation as well as the values preferred for field-level question text.



Stability improvements

These are the issues we fixed in this release.

- Feasibility surveys
- Reporting

Feasibility surveys

Description	Ticket	Severity
When a site had multiple surveys after being assigned	SEL-17105	3
to multiple workflows, Oracle		
Site Select users were unable		
to download prior survey		
responses as the PDF		
download had only the latest		
completed survey version. We corrected this issue so that the		
site grid's Site document		
download option now provides		
a drop-down list with the		
survey name and correctly		
downloads a PDF of each		
assigned survey's submitted responses. We also updated		
the Survey analysis > Survey		
response modal to ensure the		
Download PDF link downloads		
a PDF of each assigned		
survey's submitted responses.		

Reporting

Description	Ticket	Severity
Data Export Utility reports did not reflect the most recent data for the Agree to confidentiality statement workflow task as expected. The Study site users, Study Sites, Notes, and Site Survey Responses cubes now correctly reflect the most recent Agree or Disagree action datetime, response, and user name and email.		SEL-17123



Description	Ticket	Severity	
When a feasibility survey title was changed after the survey was sent to a site and the site resubmitted the survey, duplicate data was created in the notes view that prevented appropriate data refresh. We corrected this issue to ensure proper update of the survey title after each survey response.	2	SEL-17158	



2 Release 23.3.1

Review the enhancements and corrections made in the 23.3.1 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 release.
- New known issue This section identifies an unresolved issue found during the development of this release.

What's new

Learn about new and enhanced functionality in this minor release.

- Feasibility surveys
 We made minor text updates to authentication error messages.
- Site grid A new Site progress data column shows when a site was added to the Invited bucket state.
- Site profile

We added the option to update Oracle Site Select site profile standard data column attributes and made additional enhancements to improve configurable site profile usability.

User profile access for Oracle administrators
 Oracle administrators can access user profiles via email address.

Feasibility surveys

We made minor text updates to authentication error messages.

Authentication error messages

We removed obsolete vendor references from authentication error and warning messages. These updates are:

- All error messages referring to Survey Monkey have been updated to refer to Survey provider
- All error and warning messages referring to SurveyGizmo have been updated to refer to Alchemer



Site grid

A new Site progress data column shows when a site was added to the Invited bucket state.

Invited at column

With release 23.3.1, we added a new "Invited at" data column to record the datetime the site was moved to the Invited bucket state. Please note that the existing column "Invitation sent at" is unchanged and will continue to reflect when a site was first sent an invitation email.

While Invited at shows when a site moved to the Invited bucket state, it does not update if a user moves the site out of and back to the invited bucket state. Similarly, the column does not update if the site is reassigned a workflow or when a reinvitation email is sent to a site user. These are expected behaviors.

Oracle Site Select site grid users can optionally add the Invited at column to the grid. The column supports filtering by single date or date range, and users can include it if preferred when creating site grid extracts in CSV or Microsoft Excel format.

The daily report view CSV also includes the Invited at column. We added it to the study sites, study_activities, and study_milestone_activities reporting views.

Site profile

We added the option to update Oracle Site Select site profile standard data column attributes and made additional enhancements to improve configurable site profile usability.

Configurable site profile

With release 23.3.1, we made the following enhancements to the configurable site profile:

Modify standard data column attributes

We enhanced configurable site profile mapping functionality to allow for modifications to Oracle Site Select standard data column attributes (e.g., column display name, hide column, etc.). When an Oracle administrator makes these updates on the customer's behalf, they will save at the account level and will reflect on the account's configurable site profile pages.

Site grid users will see an updated column Display name on the site grid column selector and filter pages. Site grid data extracts will also reflect the changes made to standard and custom site profile columns. For instance, a site grid CSV extract will reflect a column's modified Display name. Site Analyze and Data Export Utility extracts will not reflect column name modifications. It is expected behavior that these extracts will continue to use the existing database column names.

When populating email template placeholders, a placeholder related to a site profile column will not be affected by any changes to a column's attributes. For example, if the Oracle administrator changes the display name for the "first_name" column, then the placeholder for an investigator's first name will work as expected.

The CSV datasource creation and mapping page will also reflect any changes made to a standard or custom site profile column's attributes. Datasource managers will see



updated column Display names when mapping fields and defining data field properties.

Data validation

We added validation for minimum and maximum values for numeric fields. When a user enters values outside of the field's configured integer value range, an error message will display below the field to guide the user in entering an acceptable value. The top of the page will display the error and error field. The site profile also displays a red exclamation mark ($^{(0)}$) in the left navigation to make the user aware of the error.

Please note the digest of validation warnings will include the line, "Entering messages region. Press F6 to navigate back to prior focused element." This is expected behavior.

Account: Demo Study: Sample	Status: In setup	Protocol: UJHNKL	
Gator, Investi Laval University	There are fields with incorrect input format Please fill out in the correct format: Gender - unknon Messages region has new messages. Press F6 to nar		Test User1 updated on 16Jan202-
Site profile	General info		
Site documents		Has precision medicine exp	NORD affiliation?
Study contacts	EMA OMS Location ID	We there this site has experience with precision medicine.	Whether this site is affiliated with the National Organisation for Pare Diseases (NORD).
Profile pages to review	Site address 1	Site address 2	Site city 👻
Institution			
Principal investigator	Site country -	Site department	Site department type •
Site 1	Site discontinued Indicator that this site record has been marked for discontinue from future studies. Reference the discontinue, reason field for further detail.	Site discontinued reason	Site fax

Complete tasks on behalf of site

Oracle Site Select users will now see the Oracle Site Select LITE version of the configurable site profile when completing a "Verify site profile" workflow task on a site's behalf.

User profile access for Oracle administrators

Oracle administrators can access user profiles via email address.

When a legacy Oracle Site Select user account does not include a first or last name, the Manage users and roles page does not include a hyperlink to access that user's profile to make any necessary change. An enhancement in this release allows Oracle administrators to access the user's profile via the email address field when there is no first or last name link available.

Stability improvements

These are the issues we fixed in this release.

- Data integration APIs
- Site grid
- Site profile
- Site workflow



Data integration APIs

Description	Ticket	Severity	
The Authentication and API configuration page Done button was incorrectly disabled if Adobe Sign digital signature functionality wasn't turned on. We corrected this issue so that users can update settings (e.g., Login button text, Support link, etc.) without enabling Adobe Sign, if preferred. Additionally, we made a minor user interface update to change the Done button label to Save and close.	SEL-16892	2	

Site grid

Description	Ticket	Severity
When creating site grid exports from the Invited bucket state, the reports did not include sites from all selected site statuses.	SEL-16913	3
The Site grid data export utility did not open as expected when users clicked the Download sites to export file button in the Review or Dropped bucket states.	SEL-16926	2

Site profile

Description	Ticket	Severity	
Configurable site profile pages became unresponsive when users attempted to update a free text string array field, such as pi_emails.	SEL-16908	3	
A configurable site profile did not display error text (e.g., missing field entry) at the top of the profile page as designed.	SEL-16949	3	



Site workflow

Description	Ticket	Severity	
On the workflow configuration page, when email template override was enabled, email template inputs did not display as expected after navigating away from the workflow and back.	SEL-16842	3	
The workflow level email template didn't override the study level workflow email template when the setting to override was enabled.	SEL-16887	2	

New known issue

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

• Digital signature

Digital signature

Description	Ticket	Severity
An Adobe Sign authentication error displays when a user attempts to open the Workflow configuration page in account where digital signature integration is not configured.	SEL-16952	3



3 Release 23.3

See descriptions of new features, enhancements, and stability improvements, as well as issue lists published in the 23.3 GA release notes.

What's new

In release 23.3, Oracle Site Select Select introduces configurable site profile functionality that allows you to define site profile sections, fields, and field values to reflect your unique business needs. Site Select also introduces the study criteria necessary to query Learning Health Network patient counts and many other enhancements.

- Impact analysis Review a summary of the business and functional impact for enhancements in the 23.3 release.
- Stability improvements These are the issues we fixed in this release.
- New known issue This section identifies an unresolved issue found during the development of this release.
- Previously reported known issues See the unresolved issues reported prior to this current release.
- 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 items from the known issues list.

What's new

In release 23.3, Oracle Site Select Select introduces configurable site profile functionality that allows you to define site profile sections, fields, and field values to reflect your unique business needs. Site Select also introduces the study criteria necessary to query Learning Health Network patient counts and many other enhancements.

• Data integration APIs

Studysite Get APIs have new data columns, Profile Details GET API documentation includes new details, and Account administrators can now configure email notifications for failed Event messages.

Data exports

Name field validation ensures feasibility survey names and workflow task names meet Microsoft Excel file name requirements.

- Datasources The Account data source management and match details pages have a new design.
- Digital signature Customers can now configure Adobe Sign to use their Adobe Sign account by default.
- Feasibility surveys

A new enhanced scoring export includes scoring setup criteria, scored questions no longer require category, and reporting views include Percentage question type data.



Integration

The Identity Cloud Service user creation API has additional user data requirements, and customers can now update a SAML message Entity ID field when necessary.

• Site grid

The site grid now has improved column selector page usability, new Learning Health Network and completed tasks columns, and enhanced feasibility survey and Site progress exports.

• Site profile

Oracle Site Select introduces configurable site profile functionality and new demographic data validation error text.

• Study management

The study milestones page has a new design that improves usability, the Master list criteria page is enhanced with a new Learning Health Network patients tab, and more.

Workflow tasks

Now you can optionally allow site users to complete certain workflow tasks at any point in the workflow.

Data integration APIs

Studysite Get APIs have new data columns, Profile Details GET API documentation includes new details, and Account administrators can now configure email notifications for failed Event messages.

Studysite GET APIs

With release 23.3, we enhanced the Workflow Details GET and Studysite Details GET APIs to include the following study data columns:

- cda_approved_at: (CDA approved) The datetime the site's CDA was final approved
- **close_date:** (Workflow close date) The closing date assigned to a site's workflow
- current_workflow_task: (Current task to complete) The workflow task the site is currently assigned to complete
- final_acceptance_at: (Final accept email sent) When the site's final acceptance email
- **final_decline_at**: (Final decline email sent) When the site's final declination email was sent
- first_select_lite_access_at: (First accessed SL) The datetime the site first accessed Select LITE
- **last_invitation_sent_at:** (Most recent invitation sent at) The most recent datetime a site was sent an invitation email
- last_select_lite_access_at: (Last accessed SL) The most recent datetime a site user accessed Select LITE
- last_workflow_task_completed: (Last task completed) The most recent workflow task completed by the site
- not_interested_at: (Not interested on) When the site was placed in the not interested bucket state



- second_invitation_email_sent_at: (2nd invitation) The datetime a second invitation was sent (resend invitation) to a site
- selected_at: (Selected on) When the site was placed in the selected bucket state
- study_site_contacts: (Recipient emails) The list of email addresses invited with current access to the study
- survey_start_at: (Feasibility survey started on) When the first user clicked on the site's survey task
- survey_start_by: (Feasibility survey started by) The first user who clicked on the site's survey task
- third_invitation_email_sent_at: (3rd invitation) The datetime a third invitation was sent (resend invitation) to a site

We also updated the Profile Details GET API documentation. The Summary section now describes why some responses will return empty strings as expected behavior. Summary text is now:

"Fetches the site profile record for a study site in a specified study.

This route is useful for obtaining the site profile record of a particular study site from a study. If the route is successful, the return will display the full contents of the site profile data source of the study site.

The site profile includes some fields that are editable by the site and others that are only editable by an Oracle Site Select user, such as a CRO or Sponsor. It does not include all fields that may have been imported via the data source. There is no way to update a site profile other than some user action via the UI. Site profile changes should be compared against the data source or source of truth for the data to evaluate the change and then make a corresponding update in the data source if necessary.

NOTE: If a site does not have a site profile record written to the study's accessible site profile datasource then this API will return an empty object."

Epic: SEL-16124

Event message retry failure notification

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

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



me	ly@gobalto.com via sendgrid.net	
	illowing event notification message failed to send to your programmed endpoint. Please log i ect and check the account > history and status page for details on these failures.	n
FA	S	
Nha	is Select?	
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	spect and protect your privacy. Please see the <u>Oracle Privacy Policy</u> and <u>Terms of Service</u> for information	r

Epic: SEL-16124

Data exports

Name field validation ensures feasibility survey names and workflow task names meet Microsoft Excel file name requirements.

Feasibility survey and workflow name validation

We added input validation to feasibility survey name and workflow name validation to ensure Microsoft Excel extracts open as expected. This enhancement applies to the following areas:

- Setup > Workflow configuration page, Workflow name field
- Account > Workflow template page, Workflow name field
- Setup > Feasibility survey > Step 3 (choose survey) page, Survey name field

Helper text and field validation messages now state: "Workflow names cannot exceed 31 characters, be called "History", begin or end with an apostrophe or contain the following special characters: / \? * : []".

Epic: SEL-16124

Datasources

The Account data source management and match details pages have a new design.

Account datasources

Account data source management page

Oracle Site Select introduces the first phase of a redesigned Account data source management page in this release. The new design improves usability and makes viewing details for each datasource easier. Bold advisory text at the top of the page helps users understand the page's development status and functionality available to them: "The migration of the datasource pages is incomplete. All previous functionality is available. Clicking on the datasource name or matches loads the new detail view. The potential matches link loads the data source matches page. The errors link loads the import page."

The redesigned page includes search and filtering options above the datasource list. Users can search by datasource name and description and filter the list by datasource



type (Regular, Composite, Unpublished, Errors, and Potential matches). The blue Create new datasource button above the list opens the Manage data source creation page.

The datasource list initially loads up to 25 rows and will load all available datasources as the user scrolls down. The list displays datasource information in a four-column layout:

- 1. Datasource name, description, and updated date(s)
- 2. Number of successful record imports
- 3. Counts for disambiguation matches, potential matches, and error data with links to open the associated pages for record matching or error resolution
- Datasource type (Primary, Composite, or Regular) Primary datasource (if applicable to the account) will always display at the top of the list

Account data source manager Regular datasources accept data in a flat. (5% life for foru can configure them and import data into them composite datasource contain more complex, stru- contact your account representative to manage con	ormat. using the Select application. citured data, and are managed by Oracle. figuration and import of data into these datasources.	The migration of the datasource pages is incomplete. All previous functionality is available. Clicking on the datasource mane or matches loads the area detail view. The potential matches link loads the data source matches page. The errors link loads the import page.				
Sample Primary Datasource Primary Datasource Primary datasource for OCITest Last updated: 22Jun2023, Created: 09Mar2021	Investigators: 47 Institutions: 46 S Trials: 6 Trial-sites: 5		0 matches 1 potential matches 0 errors	Primary	>	
Sample datasource Attached to a study Last updated: 25Sep2023; Created: 25Sep2023	Investigators: 1 Institutions: 1 Siter Trials: 1 Trial-sites: 1	٤1	0 matches 0 potential matches 0 errors	Composite	>	
Test datasource 3 Last updated: 20Sep2023; Created: 20Sep2023	Sites: 10		0 matches 0 potential matches 0 errors	Regular unpublished	>	
Test datasource 2 Last updated: 19Sep2023; Created: 19Sep2023	Sites: 150		0 matches 0 potential matches 0 errors	Regular	>	
Test Datasource 1	Sites: 75		0 matches 0 potential matches 0 errors	Regular	>	

Match detail page

This release also introduces a new match detail page, which uses Oracle standard design and navigation elements. The page has a tabbed layout (Matches, Potential matches, and Errors) with counts for each record type. This page also includes bold advisory text at the top that helps guide users (see image below).

The "Matches" tab is a new functionality that shows users the record(s) matched on import with existing records in the account. Please note: match and potential match count from the datasource page may not be the same as what you see in the displayed table. This is due to matches crossing over the scope of the account which cannot be displayed to customers due to privacy reasons. An Oracle administrator can resolve the matches for you.

ccount data s ample Datasour	source manage		The datasource name lin errors page links to the The match and potentia may not be the same as matches crossing over th admin can resolve the m	datasource import I match count from what you see below he scope of your as	page. In the datasource page w. This is due to		Import ID: 27100705-#90e-4950-9ee5-450485e1821			
K Back	atches Potent	ial matches Er	rors 51							
Q Search for record	First name 😂	PI emails \$	Institution 🗘	Account City ≎	matches [®] 1 State ≎	Cross-accor	unt matches ⑦ 1709 Address 1 ≎	Address	0 1	
Last name 💠	First name 🗘			•					0 1	
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Last name dransfield dransfield	mark	Pl emails ≎ mdrans99@uab.edu	Institution 🗘 university of alaba university of alaba	City 🗢	State 🗢		Address 1 0		0	
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Epic: SEL-16123



Digital signature

Customers can now configure Adobe Sign to use their Adobe Sign account by default.

Adobe Sign

With release 23.3, we enhanced Adobe Sign configuration components to remove the option to use the Oracle-provided account and allow customers to use any Adobe Sign account they wish by default. Oracle administrators can configure the inputs to point to the Oracle-provided account if preferred.

To ensure users understand the effect of changing the configuration, we updated the Digital signature configuration section helper text. The text is now:

"NOTE: Changing the account source may cause issues with pending document signature transactions.

Customers are able to leverage their contracted Adobe sign account or their own Adobe sign account for use in Oracle Site Select. Signature transactions will be created in the customer's account. User and permission management is the responsibility of the customer. Site users will be created in the Oracle Adobe sign account.

To complete the configuration, please provide your organization's Adobe sign account integration information below or ask your Oracle administrator to configure your contracted account."

A user with permission to access the Authentication and API configuration page will configure Digital signature by enabling integration with Adobe Sign and saving the following proprietary credentials:

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

When configured and authenticated successfully, the current authentication status displays just below the save button.

Di	gital signature configuration
	and the second sec
sur	stomers can enable their document signature workflow to allow digital signatures by themicating their account credentials below. Select currently supports an integration with Adobe on for the CDA workflow only.
~	Enable integration with Adobe Sign to allow digital signing of documents.
	NOTE: Changing the account source may cause issues with pending document signature transactions.
	Customers are able to leverage their contracted Adobe sign account or their own Adobe sign account for use in Select. Signature transactions will be created in the customer's account. User and permission management is the responsibility of the customer. Site users will be created in the Oracle Adobe sign account.
	To complete the configuration, please provide your organization's Adobe sign account Integration information below or ask your Oracle administrator to configure your contracted account.
	Customer Adobe sign account URL
	https://example.echosign.com
	Application client ID
	CB1
	Application client secret
	OK7
	Save credentials
	Select is currently authenticated with Adobe Sign and digital signatures are enabled. User: demoselect123+stest@gmail.com Group: Default Group
	Re-authorize with Adobe Sign

Epic: SEL-16124



Feasibility surveys

A new enhanced scoring export includes scoring setup criteria, scored questions no longer require category, and reporting views include Percentage question type data.

Enhanced scoring export

Release 23.3 introduces a new "Export enhanced questions and criteria report" option that will include the scoring setup criteria for feasibility survey questions in the export. With this option, a user can export the scoring configuration with all survey questions or only those questions marked as Scored. By design, the new enhanced export option does not support formatting with questions as rows. The Export questions as rows formatting option is disabled automatically when the user chooses the enhanced export option.

0	select	🌐 account 🗸	Ø setup	, 1	nanage 🧹	📥 nominate	Q	evaluate	∷≣ select	𝔅 finalize	C das	hboards .		Test User1	0	, ? .
	Account	Sample Account	it v	Study	Sample Stu	ıdy	~ 1	Status	Active		Protocolt	999-9999			-	9 196
	Feasibi	ility surve	У													
	Sig	n in to your surve	ey provider	• >		nd manage tierir nd categories	æ	0	Choose this ste	e surveys to affili udy	iate with	0	Map categori values to que	es and point stions and answers	Ø	
	Score	e survey qu	uestions										Save s	coring for all surve	S Cance	
	scoring p step 2.	e the scoring for e points for response Regular site	each survey affilia	ted with thi	s study. For ea	ich survey, map y	our cate ased on	gories to th the survey	e questions ani	d configure the stion established i	In		Export	on OlNov2023 by Tr Export to questions as rows port questions mark enhanced questions art	XLSX ed scored]
	Survey in	use: Survey for S	Sample Study - F	rotocol 99	9-9999	Edit survey								Save scoring for thi	is survey	

Epic: SEL-16124

Save scoring configuration with uncategorized scored questions

An enhancement to the feasibility survey scoring configuration allows survey managers to save their progress when configuring feasibility scoring by now allowing survey scoring configurations to be saved without specifying a category for scored questions.

Epic: SEL-16124

Percentage question type data in reporting views

Recent enhancements to include feasibility survey questions and responses for Alchemer percentage type questions did not include migration for data saved before the 23.1.1 release. With this 23.3 release, applicable reporting views now have data for percentage type questions for feasibility surveys completed before April 2023.

Epic: SEL-16124

Integration

The Identity Cloud Service user creation API has additional user data requirements, and customers can now update a SAML message Entity ID field when necessary.

Oracle Identity Cloud Service integration

The Identity Cloud Service user creation API now requires the user's first name, last name, and email address. This enhancement ensures that API user creation rules follow the same requirements as creating a user within the Oracle Site Select user interface.



Epic: SEL-16124

SAML message Entity ID field

This release added a new field to Single Sign On (SSO) and Oracle Identity Cloud Service (IDCS) integration settings. An Oracle Site Select user who has permission to access integration configuration settings can now use the optional Issuer field to update the SAML message Entity ID field. The new field has the following default values:

- SSO: passport-saml
- IDCS: the value inputted into the "URL for IdP to redirect SSO user" field

Epic: SEL-16124

Site grid

The site grid now has improved column selector page usability, new Learning Health Network and completed tasks columns, and enhanced feasibility survey and Site progress exports.

Site grid column selector

In release 23.3, we redesigned the column selector page so that it's easier to select columns displayed when nominating, evaluating, and selecting sites. Users can search for, select, drag and drop, and reorder the data columns as preferred. The page also includes a "Remove all selected columns" link that will reset the user's selected columns and restore them to the "Available" columns area.

Select the columns you want displayed Select sites. Columns that are only displayed on the Nominate - Trials tab are denoted with (Trials tab only).								
	Q. Filter columns by name Filter columns by domain Institution x							
	Available columns		Selected columns					
	Additional addresses	۲	I Site status	T				
	= Address 1	۲	= Institution	O				
	Address 2	۲	= Country	T				
	CRO preferred institution	۲	State	T				
	= City	۲	 Assigned user 	T				
	= Department	۲	— Site comms and notes digest	T				
	EMA OMS Organisation ID	۲						
	= Fax numbers	۲						
	= IR8/EC type	0		Remove all selected columns				



Data columns

Learning Health Network columns

To support integration with Oracle Learning Health Network (LHN), we added a new Oracle Site Select standard data column, "LHN num of matching patients." This institution domain column reflects the number of patients for the institution that match the study inclusion and exclusion criteria. We also added an "LHN institution ID" column, which identifies the unique LHN institution ID.

Related enhancement: Master list criteria page includes Learning Health Network criteria



All tasks completed on column

We also added a new "All tasks completed on" site progress domain column, which reflects the datetime that all tasks were completed for a site's assigned workflow. Note that this includes Internal workflow tasks; when a site is assigned to a different workflow, the column nulls. This is expected behavior.

Users can optionally select the All tasks completed on column for display in the site grid and filter the column by a single date or date range, as preferred. The column is also available to export to CSV and Microsoft Excel via the site grid extract utility and will be available in the nightly CSV reporting view download.

Epic: SEL-16124

Site grid survey response export

We enhanced site grid exports to allow users to export only scored questions when exporting feasibility survey responses from the Survey analysis tab. The new option, "Export only survey questions marked scored for survey responses," displays only when the export originates from the Survey analysis tab. By default, the new export option is checked.

> Saved Reports			
Select data columns		② Select site status(es)	S Export/save report
Selected columns for export		Selected site statuses	Export/save report
— Site status	۲	Status	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
= Institution	Ð		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
= Country	٢		workbook.
= State	٢		Export to CSV Export to XLSX
 Assigned user 	۲		Export only survey questions marked scored for survey responses

Epic: SEL-16124

Site progress export

When site grid users create CSV and Microsoft Excel exports from the Site progress subtab of Step 3 or Step 4, exports list workflow tasks as follows:

- CSV: lists all workflow task columns in the same order as found on the Oracle Site Select Site progress page
- Microsoft Excel: Sites separated by workflow via worksheets. The extract lists all workflow task columns in the workflow's configured order.

Epic: SEL-16124

Site profile

Oracle Site Select introduces configurable site profile functionality and new demographic data validation error text.

Configurable site profile

In release 23.3, Oracle Site Select introduces configurable site profile functionality that allows customers to define site profile sections, fields, and field values as required for their unique business needs. Please contact your Oracle administrator for more details on how to map and implement this functionality.

When an Oracle administrator enables configurable site profile functionality for the account, the enhanced design replaces the legacy site profile design. All links and navigation that



previously allowed users to access the legacy site profile will access the configurable site profile instead. For example, an Oracle Site Select user completing the site profile task will access the configurable site profile.

In Oracle Site Select, the configurable site profile page design includes section navigation links in a left side panel and uses Oracle standard elements for fields, buttons, and icons. The left navigation also includes links to Site networks, Documents, and Study contacts. A triangle identifies the current page, an exclamation mark indicates a required question on the page is not answered, and a check mark indicates all data fields on that page are not null.

In edit mode, users will find Cancel and Save progress buttons on each page except the last, which provides a Save and complete button instead. Each page will also include a validation banner that displays when required fields require input.

Gator, Investi			Test User1 updated on 22May2023 Site reviewed on 15Aug2023
Department of Veterans Affairs	Institution inform	nation	
Site profile Site network Site documents Study contacts	EMA OMS Organisation ID IRB/EC type	Institution Department of Veterans Affairs	Institution type
Profile pages to review Institution	Location Geographic location information for institution. Additional addresses Alternate addresses for the institution.		+ Add
	Address 1 1201 Broad Rock Blvd Department	Address 2 Mcguire Vamc 111-P	City Richmond
	Fax numbers Fax numbers for institution		🕂 Add
	Phone numbers Phone numbers for institution		+ Add
	Postal code	State Virginia	Country United States
	Integration		
	Institution primary fax	Institution primary phone	
			e Profile. Clicking Done saves changes across all tabs. will set it to false and remove any required field error.
Please review each page above before closing			Cancel Save progress

With configurable site profile enabled, all site profile changes are stored in an accountlevel data source for new studies. Site profile changes will span across all studies in the account that do not currently have a study-specific site profile data source.

Oracle Site Select users must have *Edit site profile* permission to modify any field in the configurable profile. The profile will be read-only for all other Oracle Site Select users. This aligns with the required permission for updates to the legacy site profile.

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



Select LITE ≡ communications	≅ document library	Logged in as guest $ _{\nabla} = \stackrel{?}{?} _{\nabla}$
Study: 18.1.1_3066 — Investi Gator	~	
Gator, Investi		mmorala updated on 275ep2022 Site reviewed on 09Jun2020
arnegie mellon	Institution information	
Site profile Study contacts	EMA OMS Organisation ID	Institution type
	Carnegie mellon	
Profile pages to review	IRB/EC type Local	
Institution	Location	
	Geographic location information for institution.	
	Additional addresses Alternate addresses for the institution.	+ Add
	Address 1 1265 Pineview Dr Address 2	City Morgantown
	Department	
	Fax numbers Fax numbers for institution	+ Add
	Phone numbers Phone numbers for institution	+ Add

Epic: SEL-16193

Validation error text

We enhanced the standard site profile demographic pages to include new validation messaging. When the total for a demographic group section exceeds 100%, error messaging displays below the page's Done button. Oracle Site Select will display a separate Error for each demographic group (i.e., Gender, Age, Race, and Ethnicity).

Eye, Pea Ohio State U					
					Test User1 updated on 07Jul2020
Contacts	Study contacts	Documents	Patient demographics	Facility information	Done Cancel
					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.
					Error: Gender cannot exceed 100%. Please adjust the inputted value(s).
					Error: Age cannot exceed 100%. Please adjust the inputted value(s).
Please prov	vide detail on the com	position of the	patient populations most co	mmonly treated by your site.	
Enter a per	centage amount for e	ach option belo	w. The total percentage for e	each section must add up to 100%.	
Gender				Total: 140	
				e sum of this section nnot exceed 100%	
Female		Male			
55	%	85	%		



Study management

The study milestones page has a new design that improves usability, the Master list criteria page is enhanced with a new Learning Health Network patients tab, and more.

Study milestones page

We redesigned the study milestones page to make setting study milestones, tasks, and country-level overrides easier. The page is now organized under a horizontal menu to reduce scrolling and improve usability. It also uses Oracle standard design elements for fields and navigation.



	Manage milestones and task planning Mestones are used to identify critical stages along a project simeline. The efficiency of your study is improved by entering the values below.						
Study Stud	dy-site status Workflow tasks Country						
	Project start date Jul 24, 2023	Proposed site list finalized Feb 18, 2022					
	Project end date	Target number of subjects 140					

Milestone and task sections function as they did previously (e.g., validated entry for number and date values, reporting output remains the same, etc.). However, we added new Country start and Country end fields at the top of the country level milestone overrides page. The new date fields default to the Project start date and Project end date defined on the Study tab and can be updated as necessary.

Study Study-site status Wo	rkflow tasks Country				
he default values of the country level mile		level milestone values. These	values can be modified when	necessary.	Target sites: 14 Target subjects: 140
	Australia	South Africa	United Kingdom	United States	Korea, Republic of
Country start	Jul 22, 2023	Jul 22, 2023	Jul 22, 2023	Jul 22, 2023	Jul 22, 2023 🛗
Country end	Nov 23, 2023	Nov 23, 2023	Nov 23, 2023	Nov 23, 2023	Nov 23, 2023
Target number of sites final acceptance	24 ~ ^	3 ~ ^	3 ~ ^	~ ^	3 ~ ^
Target number of subjects	50 ~ ^	30 ~ ^	30 ~ ^	~ ^	30 ~ ^
Target number of sites recommended	~ ^	~ ^	~ ^	~ ^	× •
25% of sites in recommended	Ē	Ē	Ē	Ē	

Epic: SEL-16123

Learning Health Network patient query

In release 23.3, Oracle Site Select introduces the study criteria necessary to query Oracle Cerner's Learning Health Network patient counts. When Learning Health Network integration is enabled at the account level, the Master list criteria page includes a new "Learning Health Network patients" tab. Using this tab, users can specify protocol inclusion/exclusion criteria, including an encounter date range and protocol-specific inclusion and exclusion criteria (e.g., patient gender, age range, diagnosis and lab codes, etc.). The Learning Health Network will respond with estimated patient counts that align with the study's criteria for network sites.

PLEASE NOTE: Data inputted on the Learning Health Network patients tab does not affect the master list generation in the site grid.

Master list criteria	Learning Health Netwo	rk patients			
Please provide the protocol-specific in page will not affect the master list gen	iclusion and exclusion criteria. The Learnin; ieration in the Select site grid.	g Health Network will respond with e	stimated patient coun	ts that align with your criteria for netw	ork sites. The data inputted on this
					Save Cancel
	Encounter date range between	Start date	and End date	•	
Inclu	usion Criteria			Exclusion Crit	eria
Patient gender			Patient gene	ler	
Age range O O	Maximum age for incl	lusion	Age range	Minimum age for exclusion 0	Maximum age for exclusion
Patient location			Patient loca	tion	
Diagnosis codes			Diagnosis co	ides	
Lab codes			Lab codes		
Medication codes			Medication	codes	

Related enhancement: New Learning Health Network columns

Please contact your Oracle representative to discuss enabling this new feature for your organization's account.



Epic: SEL-16273

Study status view filter

We made a minor text change to the user profile Filter study list section to add a second sentence to the helper text. The text now reads: "The study dropdown list and myDashboard page will be filtered to show only the selected study statuses selected. A refresh of your browser is required after saving the change."

Epic: SEL-16124

PSV tracker values

With this release, we enhanced the PSV tracker page to allow users to remove saved values when necessary. Users can clear and save new values for the Assigned user, PSV scheduled (date), and PSV status fields.

Epic: SEL-16124

Workflow tasks

Now you can optionally allow site users to complete certain workflow tasks at any point in the workflow.

Workflow task completion order

A new workflow task configuration option will allow site users to complete certain tasks at any point in their assigned workflow. All site and internal workflow tasks now include this option: "The task becomes due after this task is completed." The new option is enabled (checked) by default, and we've updated the default behavior for the Generic document task to be enabled by default as well.

Expected behavior for the task is:

- **New option enabled (default)**: no behavior change for the task. The next task in the workflow will show only when the site completes the current task.
- **New option disabled**: The task will show in Oracle Site Select LITE along with the next workflow task. Completing this workflow task is not required to proceed in the workflow.

To help users understand the impact of using this option, we added the following helper text: "By default the workflow task is gated. When this option is not enabled, site users will see this task in parallel with other workflow tasks until complete. There is no completion order enforced when this option is unchecked."

This workflo invited site.	w's activities can be edited until ar	n invited sit	e has bee	n assign	ed. The	workflo	w will loo	:k once	assigned to an
	Default task name			Task n	ame sh	own to	sites * (50 char	acters maximum)
Veri	fy site profile information	Verify s	ite profile	informat	ion				ж
1 Task information 7			B.	Ι <u>Ψ</u>	E	-	=	:=	IE
P	Please review all sect	tions in the	e profile ar	nd updat	e as neo	essary.			
	66 of 2000 characters								

Epic: SEL-16124



Impact analysis

Review a summary of the business and functional impact for enhancements in the 23.3 release.

Enhancement	Enablement setting	Impact
Data integration APIs Studysite GET APIs	None	Makes further datapoints available in GET calls
Data integration APIs Event message retry failure notification	None	Increases awareness of event failure
Data exports Feasibility survey and workflow name validation	None	Users are informed of compatible naming conventions
Datasources Account datasources	None	The new page redesign enhances user experience and facilitates a seamless view of detailed information associated with each data source.
Digital signature Adobe Sign	None	Allows customers to use any Adobe Sign account they wish by default.
Feasibility surveys Enhanced scoring report	None	Enables users to export the scoring configuration, encompassing either all survey questions or exclusively those questions designated as Scored.
Feasibility surveys Save scoring configuration with uncategorized scored questions	None	Convenience of saving when incomplete
Feasibility surveys Percentage question type data in reporting views	None	Data for percentage type questions for feasibility surveys completed before April 2023 now reported.
Integration Oracle Identity Cloud Service integration	None	Ensures that API user creation rules follow the same requirements as creating a user within the Oracle Site Select user interface
Integration SAML message Entity ID field	None	Option to update the Entity ID field
Site grid Site grid column selector	None	Enhanced ease in selecting columns displayed
Site grid Data columns	The Learning Health Network (LHN) column is available in the site grid but the LHN option must be enabled in order to receive data for the study.	Leverages the LHN to identify matching patients

Enhancement	Enablement setting	Impact
Site grid Site grid survey response export	None	Convenience of only exporting scored survey responses
Site grid Site progress export	None	Workflow tasks listed in order
Site profile Configurable site profile	An Oracle administrator must toggle the account to use the configurable site profile. The services team will be engaged to work with the customer to define new columns if needed and updates to existing columns as requested.	Removes the need for a separate 'View' site profile page and allows for customer specific site profile configuration.
Site profile Validation error text	None	Users are informed of new validation messaging display
Study management Study milestones page	None	Improves usability and page navigation
Study management Learning Health Network patient query	Oracle administrator must enable integration to the Learning Health Network (LHN) for the account	Set parameters for how to leverage LHN to identify patients required by study
Study management Study status view filter	None	Users are informed of refreshing the page.
Study management PSV tracker values	None	Ease of correction of PSV data
Workflow tasks Workflow task completion order	None	Allows site users to complete certain tasks at any point in their assigned workflow

Stability improvements

These are the issues we fixed in this release.

- Datasources
- Site grid
- Site workflow

Datasources

Description	Ticket	Severity	
The account level data source matches page did not allow users to view or choose the primary composite datasource.	SEL-16652	3	



Site grid

Description	Ticket	Severity	
Study trial-site views (i.e., Nominate site grid Trial subtab and View site profile Trial history tab) did not correctly restrict a site's affiliated trials to only records found in study- attached datasources.	SEL-16119	2	

Site workflow

Description	Ticket	Severity	
The site feasibility survey task	SEL-16705	2	
remained on the previous			
workflow if the site submitted a			
survey at the same time as			
they were reassigned to a new			
workflow with a different			
survey. We corrected this			
issue so that if this occurs, the			
survey task shows as			
incomplete in the site grid			
(because the second survey			
has not yet been submitted).			
Oracle Site Select will also			
display the following error			
message to help guide users:			
"The assigned survey for this			
site has changed. The site has recently submitted a survey			
that does not match the			
currently-assigned survey.			
This submission has been			
ignored. Please advise the site			
to use the new survey link.			
Contact Oracle support to			
remove this error message."			

New known issue

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

• Site workflow



Site workflow

Description	Ticket	Severity	
On the workflow configuration page, when email template override has been enabled, email template inputs do not display as expected after navigating away from the workflow and back.	SEL-16842	3	
Workaround: After the page autosaves, refresh the page using the browser refresh option. The changes are saved, but they do not load in the user interface without a refresh.			

Previously reported known issues

See the unresolved issues reported prior to this current release.

- Data integration APIs
- Datasources
- Document management
- Integration
- Milestones
- 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	

Milestones

Description	Ticket	Severity
It is not possible for users to delete response time values on the Manage Milestones page.	SEL-2474	3
Workaround : To change a text value, select the value in the field and overwrite it with a new value.		

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

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 items from the known issues list.

- Browser compatibility
- Feasibility surveys

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

Feasibility surveys

Description	Ticket	Severity
Due to an issue with the third- party Alchemer API, continuous sum (percentage) type survey questions are not 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.	SEL-15646	3
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.	SEL-15656	3



4 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.

5 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	23.3	Google Chrome and Microsoft Edge (Chromium)	None
Oracle Site Select LITE	23.3	Google Chrome and Microsoft Edge (Chromium)	Mozilla Firefox



6 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
20FEB2024	F89196-04	Added minor release 23.3.2
16Jan2024	F89196-03	Added minor release 23.3.1
13Dec2023	F89196-02	General Availability Release Notes
21Nov2023	F89196-01	Pre-General Availability Release Notes

