Oracle Life Sciences Site Analyze Release Notes





Oracle Life Sciences Site Analyze Release Notes, Release 23.2

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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.



Release 23.2.0.2 (available for this release 01Mar2024)

This hotfix includes a correction for study level site submissions data included in Oracle Site Activate reports.

Stability improvement
 This section identifies an issue fixed in this release.

Stability improvement

This section identifies an issue fixed in this release.

Oracle Site Activate standard reports

Oracle Site Activate standard reports

Description	Ticket	Severity
We corrected an issue where certain metadata fields in Study Level Artifacts public view were null for sites in study level submissions. Now, for sites included in either country or study level submission, the following 11 fields are populated with the correct package and site metadata:	LSRPT-5891	2
1. country_submission_site		
2. package_id		
3. package_submission_date		
4. study_site_id		
5. site_approved		
6. site_number		
7. display_status		
8. pi_first_name		
9. pi_last_name		
10. institution		
11. irb_ec_type		

Release 23.2

See descriptions of enhancements and stability improvements published in the 23.2 GA release notes.

- What's new for Oracle Site Activate users
 Learn about new and enhanced functionality in this release.
- What's new for Oracle Site Select users
 Learn about new and enhanced functionality in this release.
- Stability improvements
 This section identifies issues fixed in this release.

What's new for Oracle Site Activate users

Learn about new and enhanced functionality in this release.

- Enhanced reports
- New fields
- Data Export Utility

Enhanced reports

Account Metrics

A new Site Used Date filter on the Account Metrics report Sites Dashboard tab allows report users to filter the report's Total Sites Used KPI and Sites Used Over Time graph to a specific date range based on when a site is marked as used. The site used date is the earliest of IP release status date, Activated status date, and In activation status + threshold days.

We also added a new Site Used filter on the Site Details worksheet. This multi-select filter defaults to All when the user navigates directly to the worksheet, and the user can check or uncheck Yes and No options as preferred. If all sites in the account are unused, the user will see All and No filter options. When both are unchecked, the report will be blank. This is expected behavior.

Note that with this release, site used criteria are updated to:

- Site has been in In activation status for longer than 30 days accumulatively
- OR site is IP released status
- OR site is in Activated status

30 days is the default value of the in activation threshold for a site to be considered used and it can be adjusted to any other numbers as needed.





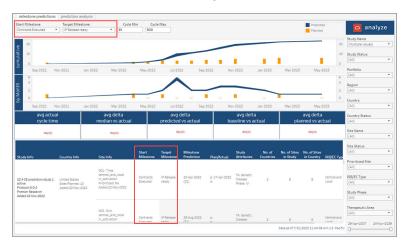
Milestone Predictions Dashboard

Report users can now select a start milestone for a cycle time and evaluate different prediction cycles against actual milestone completed dates in the report's trend graphs and tables. The Milestone Predictions worksheet includes a new Start Milestone dropdown list at the upper left. The list provides the following options:

- Contracts Executed
- Essential Documents Sent to Site
- Initial Protocol Received/Sent

The report's Target Milestone drop-down will include logical options based on the user's selection in the new Start Milestone drop-down. For instance, if the Start Milestone value is Contracts Executed, only Initial Protocol Received/Sent is available under the Target Milestone drop-down. The report's Prediction Analysis worksheet reflects the same enhancement.

Finally, the table at the bottom of the Milestone Predictions worksheet will also reflect the user's Start Milestone and Target Milestone selections.



New fields

With release 23.2, we added the following new fields:

study_level_milestones

- at_risk_at
- at_risk_user_id

study_level_milestone_history

- at risk at
- at risk reason
- at risk user id

Data Export Utility



Data Export Utility is a multi-tenant application that will be updated in Production 28 days after 23.2 General Availability (currently scheduled for 25Aug2023). This update, and the enhancements described below, will affect all Oracle Site Activate customers, regardless of their current release.

Enhanced report filter operations and saving

New filter operators

With release 23.2, Data Export Utility users can now filter data by the following operators:

- Contains (with case-sensitive text input field)
- Equals (with case-sensitive text input field)
- Not equals (with case-sensitive text input field)
- Is null
- Is not null

By design, the report's first filter, study name, use the "Equals" operator, and users may not edit this operator. For all other new filters added to the report, the default is the "Contains" operator, and users may update this to their preferred value. Users can also update operators when editing a saved report.

Save and preview improvements

With this release, we also enhanced the create and edit modal to now save all valid filter selections for the report when the user clicks the "Save and Preview". When saved, the user will see the filtered data on the preview page and in the export .csv file.

With this improvement, users no longer need to click "Save" for each filter; however, if they prefer to add additional filters, they can now click "Add" to include a new filter for the report. We also improved navigation to ensure that all filter selections remain if a user navigates between the Columns and Filters tabs before clicking "Save and Preview".

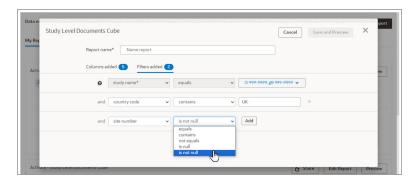
If a new filter is left as blank when a input value is required, the filter will be considered invalid and ignored upon user saving the report.

When editing existing filter, if user makes a invalid change, an error message will display when clicking "Save and Preview" and prevent user from saving the report until the filter is



fixed or removed. If user closes the modal before clicking "Save and Preview", the original filter values will remain.

We also made minor updates to combine and revise tooltip (•) text. The text is now, "Select one or more studies. For new filter, select a field from the drop-down menu, pick the appropriate operator, enter a text value to filter by if needed. To add another filter, please click on "Add" button."



New columns added to Study Milestones and Submissions cube

With release 23.2, Data Export Utility users can include the following new columns in reports created in the Study Milestone and Submissions cube:

- at risk at
- at risk by

Drag and drop column order

With release 23.2, we returned the ability for users to drag and drop selected columns to a preferred order when creating a new report or updating an existing report.

What's new for Oracle Site Select users

Learn about new and enhanced functionality in this release.

- Enhanced report
- Data Export Utility

Enhanced report

Nightly CSVs

With release 23.2 we have added new data fields to the nightly CSV dumps of reporting views. The fields will be included in the Oracle Site Select data definition library which can be requested from Oracle Services.

Survey Response Analysis

The Survey Response Analysis report now includes percent, numeric, and multiple choice question types when displaying questions and responses.

Note that response data for percentage type questions is not backfilled on survey responses prior to release 23.2. This is expected behavior. Additionally, the



percentage response provided by the site now populates the "survey question question choice answer" data field in the reporting view.

Data Export Utility

Enhanced report filter operations and saving

With release 23.2, Data Export Utility users can now filter data by the following operators:

- Contains (with case-sensitive text input field)
- Equals (with case-sensitive text input field)
- Not equals (with case-sensitive text input field)
- Is null
- Is not null

By design, the report's first filter, study name, use the "Equals" operator, and users may not edit this operator. For all other new filters added to the report, the default is the "Contains" operator, and users may update this to their preferred value. Users can also update operators when editing a saved report.

Save and preview improvements

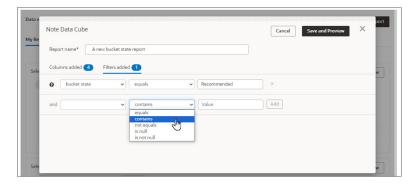
With this release, we also enhanced the create and edit modal to now save all valid filter selections for the report when the user clicks the "Save and Preview". When saved, the user will see the filtered data on the preview page and in the export .csv file.

With this improvement, users no longer need to click "Save" for each filter; however, if they prefer to add additional filters, they can now click "Add" to include a new filter for the report. We also improved navigation to ensure that all filter selections remain if a user navigates between the Columns and Filters tabs before clicking "Save and Preview".

If a new filter is left as blank when a input value is required, the filter will be considered invalid and ignored upon user saving the report.

When editing existing filter, if user makes a invalid change, an error message will display when clicking "Save and Preview" and prevent user from saving the report until the filter is fixed or removed. If user closes the modal before clicking "Save and Preview", the original filter values will remain.

We also made minor updates to combine and revise tooltip () text. The text is now, "For new filter, select a field from the drop-down menu, pick the appropriate operator, enter a text value to filter by if needed. To add another filter, please click on "Add" button."





Drag and drop column order

With release 23.2, we returned the ability for users to drag and drop selected columns to a preferred order when creating a new report or updating an existing report.

New columns added to Data Export Utility cubes

With release 23.2, Data Export Utility users can include the following new columns in reports. In alphabetical order, the new columns are:

Note data cube

- agree to confidentiality by email
- budget coord email
- budget coord first name
- · budget coord last name
- cda_downloaded_at
- cda_downloaded_by
- completed_by
- irb coord email
- irb coord first name
- irb coord last name
- legal coord email
- legal coord first name
- legal coord last name
- · regulatory coord email
- regulatory coord first name
- regulatory coord last name
- site_note_occurred_at
- trial coord email
- trial coord first name
- trial coord last name
- workflow_tasks_complete_at

Site survey responses cube

- agree_to_confidentiality_by_email
- budget coord email
- · budget coord first name
- budget coord last name
- cda_downloaded_at
- cda downloaded by
- completed_by



- irb coord email
- irb coord first name
- irb coord last name
- legal coord email
- legal coord first name
- legal coord last name
- regulatory coord email
- regulatory coord first name
- regulatory coord last name
- scorable
- · trial coord email
- trial coord first name
- trial coord last name
- workflow_tasks_complete_at

Study site data cube

- agree_to_confidentiality_by_email
- budget coord email
- budget coord first name
- budget coord last name
- cda_downloaded_at
- cda_downloaded_by
- cda_task_approved_at
- cda_task_approved_by
- cda_task_approved_by_email
- cda_task_downloaded_at
- cda_task_downloaded_by
- cda_task_downloaded_by_email
- completed_by
- completed_external_at
- completed_external_by
- completed_external_by_email
- gender_other
- gender_unknown
- irb coord email
- · irb coord first name
- irb coord last name
- legal coord email



- legal coord first name
- legal coord last name
- protocol_task_downloaded_at
- protocol_task_downloaded_by
- regulatory coord email
- regulatory coord first name
- regulatory coord last name
- · trial coord email
- trial coord first name
- trial coord last name
- workflow_tasks_complete_at

Study-site users cube

- budget coord email
- budget coord first name
- budget coord last name
- irb coord email
- irb coord first name
- irb coord last name
- legal coord email
- legal coord first name
- legal coord last name
- regulatory coord email
- regulatory coord first name
- · regulatory coord last name
- trial coord email
- · trial coord first name
- trial coord last name

Stability improvements

This section identifies issues fixed in this release.

- Data Export Utility for Oracle Site Activate
- Data Export Utility for Oracle Site Select
- Oracle Site Select standard reports



Data Export Utility for Oracle Site Activate

Description	Ticket	Severity
The Study Artifact Cube was not included in the list of selectable cubes when users generated a new report.	CHK-43394	2

Data Export Utility for Oracle Site Select

Description	Ticket	Severity	
Users could not highlight and then copy and paste the contents of individual report cells.	SEL-15677	2	

Oracle Site Select standard reports

Description	Ticket	Severity
In the Survey Responses report and nightly CSV reporting views, Tier 4 feasibility surveys were incorrectly displayed as null.	SEL-15786	2



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.	



Browser support

Use a supported or certified 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. 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 identifies the current certified or supported browsers for desktop and laptop computers:

Product	Release	Certified (Latest version as of GA)	Certified (Latest versions as of GA)
Oracle Site Analyze	23.2	None	Google Chrome, Microsoft Edge (Chromium), and Mozilla Firefox



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 release 23.2.

Date	Part number	Description
01Mar2024	F84889-03	Added hotfix 23.2.0.2 (available for this release 01Mar2024)
11Dec2023	Not applicable	Hotfix 23.2.0.1 (Internal only - no customer impact)
25Aug2023	F84889-02	General Availability Release Notes
11Aug2023	F84889-01	Pre-General Availability Release Notes

