Oracle Life Sciences Empirica Oracle Empirica Release Notes





Oracle Life Sciences Empirica Oracle Empirica Release Notes, Release 9.2.2.2

F91960-01

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Preface

This preface contains the following sections:

- · Documentation accessibility
- Related resources
- Access to Oracle Support
- · Additional copyright information

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.

Related resources

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

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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.

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System requirements

- Client computers
- Application server
- Database server
- · Reporting server

Client computers

Software for client computers

Software for client computers

Requirements	
Microsoft Windows 10 or later.	
Google [®] Chrome (latest public version). Microsoft [®] Edge (version 88 or later).	
Any or all of the following tools for downloadin data:	
 Adobe Acrobat Reader. Microsoft Excel, for XLS or XLSX. Microsoft Word, for DOCX files. SAS System Viewer, for XPT files. Base SAS, for SAS files. 	

Application server

- Minimum hardware for the application server
- Software for the application server

Minimum hardware for the application server

Component	Description 64-bit Intel 6-core 2.8 GHz or higher processor.	
Processor		
	Actual requirements are based on the size of the dataset and the expected number of concurrent users.	



Component	Description
Memory	16 GB RAM.
	Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Disk storage	600 GB for data.
	Actual requirements are based on the size of your dataset.
Connectivity (Internet speed for connectivity)	1 GB recommended.

Software for the application server

Component	Description	
Operating system	Oracle Linux 7.6 or later.	
Software	 Oracle Database Client that matches your database version. Select either the developer or the full installation option. The installation must include the SQL*Loader (sqlldr) utility. WebLogic 12.2.1.4 (includes ADF runtime) with Java 8 version 211 and above. 	
	 Required if you plan to use single sign-on solution IDCS: Web Tier Security Service (WTSS), Version: 21.3.3-2112151112. 	
	 Required if you plan to use single sign-on solution other than IDCS: OAM WebGate, OHS version 12.2.1.4. 	

Database server

- · Minimum hardware for the database server
- Software for the database server

Minimum hardware for the database server

Component	Description	
Processor	64-bit Intel 2-core 2.8 GHz or higher processor.	
	Actual requirements are based on the size of the dataset and the expected number of concurrent users.	
Memory	16 GB RAM.	
	Actual requirements are based on the size of the dataset and the expected number of concurrent users.	



Component	Description	
Disk storage	1.2 TB for data.	
	Actual requirements are based on the size of your dataset.	
Connectivity	1 GB recommended.	

Software for the database server

Component	Description	
Operating system	Oracle Linux 7.6 or higher	
Software	Oracle Database 19c	
	The following installation options are supported:	
	Block size: 8k	
	 Character set: AL32UTF8 	
	 NLS_LENGTH_SEMANTICS: BYTE 	
	EZ Connect	

Reporting server

· Requirements for the Oracle Analytics reporting server

Requirements for the Oracle Analytics reporting server

To use Oracle Analytics to report on Oracle Empirica Signal, your system must meet the Oracle Analytics requirements. Make sure that the Oracle Empirica Signal and Analytics run on separate servers.



Changes in the 9.2.2.2 release

The changes in the Oracle Life Sciences Empirica 9.2.2.2 release include enhancements and fixed issues. In addition, this release also includes performance improvements to the Signal Review Product-Event Combinations page and Reports.



To view release notes for versions prior to 9.2.2.1, see the Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics documentation page on the Oracle Help Center.

- Enhancements
- Issues fixed

Enhancements

- Signal management
- Performance

Signal management

Do not show alert counts in SOC carousel if there are no tracked alerts (36174776)

Do not show alert counts in SOC carousel if there are no tracked alerts (36174776)

If there are no tracked alerts for a System Organ Class then the SOC carousel will not display the 0/0 alert count.

Performance

Performance Improvements (36091155, 36091142, 36091177, 36091167)

Performance Improvements (36091155, 36091142, 36091177, 36091167)

Performance has been improved when working with the Product-Event Combinations page (36091155, 36091142), and when running reports (36091177, 36091167).

Issues fixed

- Data mining runs
- Signal management

Data mining runs

- 36174780 DM runs can fail with a SQL*Loader error
- 36174769 3D data mining runs with three variables (Drug, Event, Outcome) fail with Code 136

36174780 - DM runs can fail with a SQL*Loader error

Before

Occasionally, when an event was very rare, data mining runs that included ROR stratification would fail with a SQL*Loader error.

After

Data mining runs that include ROR stratification no longer fail when data includes rare events.

36174769 - 3D data mining runs with three variables (Drug, Event, Outcome) fail with Code 136

Before

If there were zero items for some combination of item types, such as Drug-Event-Outcome, then the 3D data mining run would fail with Code 136.

After

3D data mining runs no longer fail when there are zero items for some combination of item types.

Signal management

 36211633 - SOC Carousel is sometimes not loading when switching between Signal configurations

36211633 - SOC Carousel is sometimes not loading when switching between Signal configurations

Before

When switching from one signal configuration to another, the Product-Event Combinations page would sometimes not load. This issue occurred when the initial signal configuration's selected PEC tab was not available in the second signal configuration's PEC tabs.

After

The Product-Event Combination page displays tab selection according to Product page selection.



Changes in the 9.2.2.1 release

The changes in the Oracle Empirica 9.2.2.1 release include enhancements and fixed issues.



To view release notes for versions prior to 9.2.2.1, see the Oracle Empirica Signal and Topics Documentation page on the Oracle Help Center.

- Enhancements
- Issues fixed

Enhancements

Signal management

Signal management

• Users can control the As of Date of refresh for a timestamped interactive signal configuration (33894619)

Users can control the As of Date of refresh for a timestamped interactive signal configuration (33894619)

You can select an As Of Date when refreshing an interactive signal configuration that uses timestamped data, such as Argus Mart. Previously you were restricted to the latest As Of date in the data.

Issues fixed

- · Signal management
- Subscription data releases in Oracle Cloud

Signal management

 35523035 - Product Finder does not work when the product name contains a forward slash and authentication is SSO

35523035 - Product Finder does not work when the product name contains a forward slash and authentication is SSO

Before

If authentication was done with SSO and the product name contained forward slashes, then the Signal Review Product Finder did not find the drug. The drug could be in the drop-down list but, when selected, the table did not update with the row selected.

After

If a product with forward slashes is selected in Product Finder, the table displays the product as selected.

Subscription data releases in Oracle Cloud

 35374099 - Improved performance of data mining runs that use managed configurations and include a database restriction

35374099 - Improved performance of data mining runs that use managed configurations and include a database restriction

Before

Data mining runs that use a managed configuration and include a data base restriction could be slow.

After

The performance was improved.



Changes in the 9.2.2 release

The changes in the Oracle Empirica Signal 9.2.2 release include enhancements and fixed issues.



To view release notes for versions prior to 9.2.2, see the Oracle Empirica Signal and Topics Documentation page on the Oracle Help Center.

- Enhancements
- Issues fixed

Enhancements

- Administration
- Case series
- Data mining runs
- Drug profiles
- Signal management
- Topic management

Administration

- Support for Argus multi-enterprise signal analysis in the Oracle Cloud (16391714)
- Selection of multiple values is allowed when modifying display order (34646200)
- Additional columns available when viewing users (34724442)

Support for Argus multi-enterprise signal analysis in the Oracle Cloud (16391714)

The Oracle Empirica Signal Cloud Service now supports a configuration option for accessing multiple Argus Cloud enterprises (also known as Argus CRO mode) from a single Oracle Empirica Signal Cloud environment.

Selection of multiple values is allowed when modifying display order (34646200)

When modifying the display order, you can now select multiple values. This applies to: topic fields, topic field values, product fields, product field values, alert types, and organizing views.

Additional columns available when viewing users (34724442)

When viewing users on the Edit Users page, two additional columns are available: ID, Created.

Case series

· Case details narrative text retains line formatting (34452189)

Case details narrative text retains line formatting (34452189)

When displaying case details, the Narrative section now retains line formatting.

Data mining runs

- Support for Unicode characters in subset names (26648500)
- Support for Unicode characters in custom term names (26666598)

Support for Unicode characters in subset names (26648500)

Oracle Empirica Signal now supports using Unicode characters in subset names.

Support for Unicode characters in custom term names (26666598)

Oracle Empirica Signal now supports using Unicode characters in custom term names.

Drug profiles

Additional drug profile links (34571790)

Additional drug profile links (34571790)

In addition to the NIH DailyMed Label Information and FDA Drug Information links, the following drug profile links are now available by default:

- PubMed Literature References
- EMA Medicines Publications

Signal management

- Support the creation of a multisource signal configuration (32454984)
- Print and download product notes (33438561)
- Provide bulk removal of alerts raised by a tracked alert type (34157532)
- Default view tab on the Signal Review Add/Edit Product page (34207016)
- An increase in the number of rows displayed for the Detailed Comment field when submitting a review (34594518)
- Display customized numeric column values as integers (34594718)



- Signal configurations can be published to users with Manage Signal Configuration permission (34707429)
- New filters available when viewing similar combinations (34872062)

Support the creation of a multisource signal configuration (32454984)

Oracle Empirica Signal now supports the creation of a multisource signal configuration. A multisource signal configuration can combine the results of up to three signal configurations in a side-by-side view.

Print and download product notes (33438561)

You can now download or print the table of product notes as well as print detailed notes.

Provide bulk removal of alerts raised by a tracked alert type (34157532)

When editing alert types, you can now remove in bulk all unreviewed alerts by alert type or alert creation dates.

Default view tab on the Signal Review Add/Edit Product page (34207016)

The default signal view specified on the Add/Edit Product page or the default view selected on the Edit Signal Configuration page now appears as the left-most tab on the Signal Review Product-Event Combinations page.

An increase in the number of rows displayed for the Detailed Comment field when submitting a review (34594518)

When submitting a review, five rows of detailed comment text are displayed.

Display customized numeric column values as integers (34594718)

Previously, if a custom numeric column was added to the Signal Summary table, the values displayed with decimal values. Now, when customizing the column, if the column type is set to *N Other*, the values display as integers.

Signal configurations can be published to users with Manage Signal Configuration permission (34707429)

Previously, signal management configurations could be published only to login groups. Superusers can now publish signal management configurations to users with the Manage Signal Configuration permission. On the Manage Signal Configurations page, these users will see only the configurations published to them or their login group.

New filters available when viewing similar combinations (34872062)

When viewing similar combinations for a product-event combination, use the Show products filter to restrict the rows to the current product only, products within the same product group, or all products. Use the Show events filter to view the current event.



Topic management

• Improved display of topic table attachments (34191194)

Improved display of topic table attachments (34191194)

When viewing a topic or action attachment that was created from an Oracle Empirica Signal table, the attachment now opens in a separate window and provides information identifying the topic or action to which it is attached.

Issues fixed

- Case series
- Data mining runs
- Signal management
- Topic management

Case series

• 35058878 - Downloading case details from a product-event combinations table can take a long time or not work at all

35058878 - Downloading case details from a product-event combinations table can take a long time or not work at all

Before

Downloading case details would sometimes be extremely slow or fail with a time-out error.

After

Performance of downloading case details has been improved.

Data mining runs

 23290689 - 2D MGPS runs with RGPS enabled with interactions are listed as 3D runs in Drug Profile configurations and in Browse

23290689 - 2D MGPS runs with RGPS enabled with interactions are listed as 3D runs in Drug Profile configurations and in Browse

Before

In drug profile configurations and when browsing data mining runs, 2D MGPS runs with RGPS enabled with interactions were listed as 3D runs.

After

2D MGPS runs with RGPS enabled with interactions are listed as 2D runs.



Signal management

- 17882190 Errors on Signal Review page handled gracefully when ISM/SSM data mining runs are deleted
- 18990284 Duplicate comment type should not be allowed
- 34711853- Add Comment removed previous topic association
- 34992072 Product-Event Combinations Detail panel gives error when the event contains a slash and authentication is SSO

17882190 - Errors on Signal Review page handled gracefully when ISM/SSM data mining runs are deleted

Before

If data mining runs from a refresh were deleted, errors could be seen in the product-event combinations table and in the log file.

After

No error appears in the product-event combinations table due to the deleted data mining runs. A warning is written to the log file.

18990284 - Duplicate comment type should not be allowed

Before

If a duplicate comment type was added to a signal configuration, it resulted in duplicate rows in the Product-Event Combinations table.

After

When editing comment types, duplicates are no longer allowed.

34711853- Add Comment removed previous topic association

Before

When adding a comment to a product-event combination, if a topic association was previously added using Submit Review, the topic association was removed.

After

When adding a comment, the previous topic association is retained.

34992072 - Product-Event Combinations Detail panel gives error when the event contains a slash and authentication is SSO

Before

When selecting a product-event combination row, if the event name contained a slash (/), the Detail panel displayed a system error.

After



The Detail panel displays correctly for an event name that contains a slash.

Topic management

- 22619391 View Source Details not correct for View Similar Combos/PTs for SMQ attachments
- 34329845 Table of Contents in Topic PDF did not display Japanese characters in the note attachment name
- 34530106 -Topic General Information could be saved without completing required fields

22619391 - View Source Details not correct for View Similar Combos/PTs for SMQ attachments

Before

When you viewed source details for an attachment that you created using View Similar Combinations, if you selected PTs for SMQ for Show Events Within, Oracle Empirica Signal displayed ALL instead of PTs for SMQ.

After

View Source Details displays the correct value for Show Events Within.

34329845 - Table of Contents in Topic PDF did not display Japanese characters in the note attachment name

Before

When creating a Topic PDF, if a note attachment had Japanese characters in the attachment name, those characters did not display in the Table of Contents.

After

Japanese characters in topic attachment names display correctly.

34530106 -Topic General Information could be saved without completing required fields

Before

When editing a topic, if the topic state was changed without entering some required fields, and the user performed an action in another section, the topic could be saved without completing the required fields.

After

Saving the topic is prevented if required fields are not complete.



Change log

Date	Revised part number	Description
February 2024	F91960-01	Revised document for Oracle Empirica Signal 9.2.2.2 release.
August 2023	F82913-01	Revised document for Oracle Empirica Signal 9.2.2.1 release.
April 2023	F70450-01	Original version of this document. Created for release 9.2.2.

