

Oracle Health Sciences Empirica Signal Release Notes



Release 9.2.2
F70450-01



Oracle Health Sciences Empirica Signal Release Notes, Release 9.2.2

F70450-01

Copyright © 2019, 2023, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, and MySQL are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

Contents

Preface

Documentation accessibility	v
Related resources	v
Access to Oracle Support	v
Additional copyright information	v

1 System requirements

Client computers	1-1
Software for client computers	1-1
Application server	1-1
Minimum hardware for the application server	1-1
Software for the application server	1-2
Database server	1-2
Minimum hardware for the database server	1-2
Software for the database server	1-3
Reporting server	1-3
Requirements for the Oracle Analytics reporting server	1-3

2 Changes in the 9.2.2 release

Enhancements	2-1
Administration	2-1
Support for Argus multi-enterprise signal analysis in the Oracle Cloud (16391714)	2-1
Selection of multiple values is allowed when modifying display order (34646200)	2-1
Additional columns available when viewing users (34724442)	2-2
Case series	2-2
Case details narrative text retains line formatting (34452189)	2-2
Data mining runs	2-2
Support for Unicode characters in subset names (26648500)	2-2
Support for Unicode characters in custom term names (26666598)	2-2
Drug profiles	2-2
Additional drug profile links (34571790)	2-2

Signal management	2-2
Support the creation of a multisource signal configuration (32454984)	2-3
Print and download product notes (33438561)	2-3
Provide bulk removal of alerts raised by a tracked alert type (34157532)	2-3
Default view tab on the Signal Review Add/Edit Product page (34207016)	2-3
An increase in the number of rows displayed for the Detailed Comment field when submitting a review (34594518)	2-3
Display customized numeric column values as integers (34594718)	2-3
Signal configurations can be published to users with Manage Signal Configuration permission (34707429)	2-3
New filters available when viewing similar combinations (34872062)	2-3
Topic management	2-4
Improved display of topic table attachments (34191194)	2-4
Issues fixed	2-4
Case series	2-4
35058878 - Downloading case details from a product-event combinations table can take a long time or not work at all	2-4
Data mining runs	2-4
23290689 - 2D MGPS runs with RGPS enabled with interactions are listed as 3D runs in Drug Profile configurations and in Browse	2-4
Signal management	2-5
17882190 - Errors on Signal Review page handled gracefully when ISM/SSM data mining runs are deleted	2-5
18990284 - Duplicate comment type should not be allowed	2-5
34711853- Add Comment removed previous topic association	2-5
34992072 - Product-Event Combinations Detail panel gives error when the event contains a slash and authentication is SSO	2-5
Topic management	2-6
22619391 - View Source Details not correct for View Similar Combos/PTs for SMQ attachments	2-6
34329845 - Table of Contents in Topic PDF did not display Japanese characters in the note attachment name	2-6
34530106 -Topic General Information could be saved without completing required fields	2-6

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](#).

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 of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

1

System requirements

- [Client computers](#)
- [Application server](#)
- [Database server](#)
- [Reporting server](#)

Client computers

- [Software for client computers](#)

Software for client computers

Component	Requirements
Operating system	Microsoft Windows 10 or later.
Internet browsers	Google® Chrome (latest public version). Microsoft® Edge (version 88 or later).
Tools for downloading data	Any or all of the following tools for downloading data: <ul style="list-style-type: none">• 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.• A ZIP archive manager.

Application server

- [Minimum hardware for the application server](#)
- [Software for the application server](#)

Minimum hardware for the application server

Component	Description
Processor	64-bit Intel 6-core 2.8 GHz or higher 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	<ul style="list-style-type: none"> 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 only if you plan to use single sign-on: 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.
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: <ul style="list-style-type: none">• 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.

2

Changes in the 9.2.2 release

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



Note:

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.