

Oracle Health Sciences Empirica Signal Release Notes



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F55801-01



Oracle Health Sciences Empirica Signal Release Notes, Release 9.2.1

F55801-01

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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](#).

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.

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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
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	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: <ul style="list-style-type: none"> 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.

Component	Description
Connectivity	1 GB recommended.

Software for the database server

Component	Description
Operating system	Oracle Linux 7.6 or higher.
Software	Oracle Database 19c These databases are supported with the following installation options: <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 and Oracle Database instance requirements.

Component	Description
Software	<ul style="list-style-type: none">• Oracle Fusion Middleware 12.2.1.4.• Oracle Analytics Server version 6.4 with Java 8 and unlimited encryption extensions (JCE).• Linux server name hosting Oracle Analytics.• Linux non-privileged username used for the Oracle Analytics installation.• Oracle Empirica Signal release 9.2.1 or later, installed and configured.

2

Changes in the 9.2.1 release



Note:

To view release notes for versions prior to 9.2.1, see the Empirica Signal product page on Oracle Help Center.

- [Enhancements](#)
- [Issues fixed](#)

Enhancements

- [Administration](#)
- [Signal management](#)
- [Subscription data releases in the Oracle Cloud](#)
- [Topic management](#)

Administration

- [Audit records are no longer truncated \(31632607\)](#)
- [Audit records identify the user submitting an import for Report Outputs and their Aliases \(31649015\)](#)
- [Objects created by a data release import have Created By set to the user who submitted the data import \(31649054\)](#)
- [Support IDCS \(33806921\)](#)

Audit records are no longer truncated (31632607)

Previously, for larger audit records, the User Activity Audit Trail would truncate the text displayed in the Additional Information column. Now these audit records display in their entirety with the Additional Information text spanned across multiple rows.

Audit records identify the user submitting an import for Report Outputs and their Aliases (31649015)

When viewing records created via data release import in the User Activity Audit Trail, the Username column will identify the user who submitted the import. These records include Report Outputs and corresponding Report Output Aliases (newly created or modified). Audit records that existed prior to updating to 9.2.1 will not be modified.

Objects created by a data release import have Created By set to the user who submitted the data import (31649054)

Objects created by a data release import have Created By set to the user who submitted the data import. The objects include Runs, Report Outputs and Aliases.

Support IDCS (33806921)

Empirica Signal now supports Identity Cloud Service for user management on Oracle Cloud Infrastructure.

Signal management

- [New VAERS Interactive Signal Management \(31740938\)](#)
- [Product properties added to Product Details panel \(32103286\)](#)
- [Implement EMA IME list in the Product-Event Combinations table \(33074167\)](#)
- [New Products finder on the Products table \(33879786\)](#)
- [Product-event combinations with any history are retained \(33994430\)](#)

New VAERS Interactive Signal Management (31740938)

You can now employ interactive signal management for VAERS data. VAERS Interactive Signal Management enables you to configure datasets for data mining runs, create tracked alert types and refresh the configuration from the application user interface.

VAERS interactive signal management requires VAERS data 20180430 or later. The R and RGPS packages must be installed on the application server and RGPS must be configured in Oracle Empirica Signal.

Product properties added to Product Details panel (32103286)

When viewing details for a specific product on the Products page an additional accordion is provided in the Product Details panel. When a product row is selected, the Product Details accordion displays properties such as Display name, Category, and Organization.

Implement EMA IME list in the Product-Event Combinations table (33074167)

On the Product-Event Combinations table three new columns are now available: IME, Event Term Change Flag, and Event Term Change Description. If the source data for the configuration uses MedDRA 24.1 or later, these columns are populated during refresh of the configuration.

New Products finder on the Products table (33879786)

You can now quickly find a product in the Products table on the Signal Review Product page. A new Find product tool is provided on the Products table. With this tool you can

select or enter a product name to more easily locate the matching product's row in the table.

Product-event combinations with any history are retained (33994430)

Product-event combinations (PECs) with any prior history, including comments, alerts, or topic associations, are now retained, even if they do not show up in current run results. This ensures you do not lose visibility in situations such as when preferred terms (PTs) are demoted or renamed in a new MedDRA release. Counts and scores might be blank for these retained PECs, but change-tracking information will be included along with the applicable comment, alert, or topic columns. The MedDRA path is included until the next MedDRA dictionary release. These rows are included in alerting, enabling you to, for example, define an alert to show all demoted PTs.

Subscription data releases in the Oracle Cloud

- [Identify suspended data offerings \(33872147\)](#)

Identify suspended data offerings (33872147)

If the subscription to a data offering has expired for any reason, the status of previously Available and new data releases will show as Suspended on the Manage Subscription Data Releases page. You cannot access new data releases for a suspended data source; only release notes for those data periods will be accessible.

Topic management

- [Improve editing and saving for topics and actions \(32688784\)](#)
- [Include TWC information in topic PDF \(33358146\)](#)

Improve editing and saving for topics and actions (32688784)

The following improvements were made to the Topic Editor:

- To prevent unnecessary saves, the Save button available on the Topic or Action General Information section is disabled until you change any field value.
- To indicate that a change has been made to the Topic or Action General Information section a yellow circle icon appears in the navigation menu and in the header bar of the Topic Editor.
- To prevent loss of data, if you attempt to exit the Topic Editor without saving, or return to the topic without saving the action, a message appears enabling you to confirm or cancel your choice.

Include TWC information in topic PDF (33358146)

The topic PDF now displays the topic workflow configuration name and topic workflow configuration ID.

Issues fixed

- [Administration](#)
- [Case series](#)

- [Installation and configuration](#)
- [Signal management](#)
- [Topic management](#)
- [User interface](#)

Administration

- [33388894 - Ownership of a Saved List does not transfer after deleting a user](#)

33388894 - Ownership of a Saved List does not transfer after deleting a user

Before

After a user was deleted, the Created By field of the Saved List still displayed the details of the deleted user.

After

Ownership of a saved list is transferred to the user who performs the user deletion.

Case series

- [33947213 - Creating Case Series from drilldown after using View Signal History returns an error message](#)

33947213 - Creating Case Series from drilldown after using View Signal History returns an error message

Before

After navigating from View Signal History in the Product-Event Combinations table, when the user chose Create Case Series, Transfer to Case Series, or Reports then an error message was displayed.

After

When selecting the Create Case Series, Transfer to Case Series or Reports options after viewing Signal History, you no longer receive an error message.

Installation and configuration

- [33585994 - Release notes are missing from About page](#)

33585994 - Release notes are missing from About page

Before

In previous versions, you could access archived release notes for Signal, Topics, and Signal Management from a link on the About page.

After

Now, the About page link directs you to the Oracle Help Center, ensuring you always have access to the latest release notes.

Signal management

- [33408150](#) - Signal review products table sometimes displays an empty table
- [34152434](#) - Breakdown graphs do not appear when accessed from the Similar Combinations window
- [34234296](#) - Performance problem with View Similar Combinations

33408150 - Signal review products table sometimes displays an empty table

Before

In Signal Review, the Products table was not refreshed if you tried to sort any column, navigate to another page, and then enter a note.

After

The Products table is refreshed after you sort a column, navigate to another page, then enter a note.

34152434 - Breakdown graphs do not appear when accessed from the Similar Combinations window

Before

In the Similar Combinations window, if you selected View Age Group Breakdown or View Gender Breakdown from the row action menu in the table, a blank window would appear instead of the graph.

After

The View Age Group Breakdown and View Gender Breakdown graphs are displayed as expected when accessed from the Similar Combinations window.

34234296 - Performance problem with View Similar Combinations

Before

In the Similar Combinations window, you may have experienced poor performance when sorting or filtering the table.

After

Sorting and filtering the Similar Combinations table works as expected, with no performance issues.

Topic management

- [33408772](#) - Sorting is case sensitive in Topic Management and Signal Review tables

33408772 - Sorting is case sensitive in Topic Management and Signal Review tables

Before

In Signal Review carousels and tables and in Topics and Actions graphs, tables, and filters, the text sorting was case-sensitive.

After

Capitalization no longer has any effect on sort order.

User interface

- [29998596 - User profile tooltip does not show full username](#)

29998596 - User profile tooltip does not show full username

Before

When hovering the mouse over the user profile menu in the upper right corner of the application, the tooltip may not have shown the full username.

After

When you hover over the user profile menu, the complete username is now displayed.