

Oracle® Life Sciences Empirica

Interactive Signal Management Setup Guide



Release 9.2.3
F94576-02
November 2024



Oracle Life Sciences Empirica Interactive Signal Management Setup Guide, Release 9.2.3

F94576-02

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Document 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 Life Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>).
- Japanese interface of Oracle Life Sciences 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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Interactive Signal Management setup overview

- [Introduction](#)
The Oracle Empirica software is a web-based analysis environment for generating statistical scores for combinations of products and events in a product safety database, and for detecting unexpected associations of products and events—known as signals.

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If your organization is licensed for Signal Management, you can use it to perform statistical analyses on successive releases of the safety databases you subscribe to.

The FDA AERS Signal Management, VAERS Signal Management, and Argus Mart Signal Management databases have been available in a scripted form for on-premise use for many years. They required installation and updating by Oracle. Beginning with Oracle Empirica 9.2.1, interactive versions of several of the databases became available allowing you to install and update the data yourself and enable configurable alerts. Oracle Empirica version 9.1 added interactive signal management for a cloud version of Vigibase Signal Management. Version 9.2.3 adds a cloud version of PMDA JADER Interactive Signal Management. AERS, VAERS, and Argus remain available from the cloud or installed on-premise.



Note:

To install a database on-premise, follow the directions in the installation and Upgrade guide associated with the product, available from the Books page on the Oracle Empirica 9.2.3 [Oracle Help Center](#) site.

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Configure an interactive signal configuration

- [Enable Signal Management in the Oracle Empirica application](#)
To turn on the Signal Management features in Oracle Empirica, enable the Signal Review site option.
- [Establish aliases for data configurations](#)
An interactive signal configuration can use aliases for data configuration for 2D runs and 3D runs. If such aliases do not already exist, you can create them.
- [Edit the interactive signal configuration](#)
The interactive signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica application.
- [Make an interactive signal configuration available for further configuration](#)
To further configure the signal configuration, a user needs to access the configuration from the Signal Review page. If you are the owner of the signal configuration, then you will have access.
- [Manage monitored products and signaling terms](#)
You can use the interactive Signal Management feature in Oracle Empirica to define the list of monitored products and signaling terms from the application user interface.
- [Validate the interactive signal configuration](#)
After you specify the list of monitored products and signaling terms for the interactive signal configuration, you must validate the configuration to ensure that your changes are valid.
- [Refresh an interactive signal configuration](#)
You refresh an interactive signal configuration to populate the data on the Signal Review page.
- [After your first refresh](#)
After you have performed your first refresh on a signal management configuration, you can start taking advantage of the features introduced in Oracle Empirica Signal 9.x.
- [Make an interactive signal configuration available to users](#)
To make an interactive signal configuration available to users, you must publish the configuration. Optionally, set the interactive signal configuration as the default for login groups.

Enable Signal Management in the Oracle Empirica application

To turn on the Signal Management features in Oracle Empirica, enable the Signal Review site option.

For more information, see the *User Guide and Online Help*.

1. Log in to the Oracle Empirica application as a superuser.
2. In the navigation pane on the left, select **Settings** .
3. In the Administer System section, select **Set Site Options**.
4. From the **Show menu items** list, select **Signal Review**.

5. Optionally, select the following Signal Management options:
 - From the **Show menu items** list, select **Allow Free Text Signal Comments**. This allows users to enter free text comments when, on the Signal Review page, they filter a product-event combination or add a comment when reviewing a signal summary. Regardless of the setting of this option, users can select from a list of predefined comments.
 - In the **Notes for Signal Management Interactions Graph** text box, enter text to display at the bottom of the Interactions page for a product-event combination on the Signal Review page.
 - In the **Product-event combination comment length** text box, enter the maximum length of detailed comments for product-event combinations on the Signals Review page.
6. Select **Save**.

You must log out and log back in for the changes to take effect.

Establish aliases for data configurations

An interactive signal configuration can use aliases for data configuration for 2D runs and 3D runs. If such aliases do not already exist, you can create them.

To add or edit aliases, you must have the Manage Aliases user permission.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Aliases**.
3. From the **Target Type** drop-down list, select **Configuration**.
4. Perform one of the following:
 - To add a new alias, select the **Add Alias** link.
 - To edit an alias, select the **Row Action menu**  for the alias, and then select **Edit**. You can edit only aliases that you have created, except that if you have the Administer Users permission, you can edit aliases created by any user in your login group.
5. In the **Alias Name** field, enter an alias name.
6. From the **Target Type** drop-down list, select **Configuration**.
7. From the **Target** drop-down list, select the target.
Select the most recent quarter for the target.

Alias Name	Target (example)
Latest VAERS	2020Q4: VAERS (S)
Latest AERS (S + C)	2017Q4: AERS (S + C)

8. Select **OK**.

Edit the interactive signal configuration

The interactive signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica application.

For example, the signal configuration specifies the data configurations and variables Oracle Empirica uses for data mining runs. For more information, see the *User Guide and Online Help*.

Review the default settings of the interactive signal configuration and change the settings as needed.

You must have the Manage Signal Configurations user permission to edit a signal configuration.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Signal Configurations**.
3. Select the interactive signal configuration's **Row Action menu** , and then select **Edit**.
4. On the Edit Signal Configurations page, edit the fields as needed.

For more information, see Edit a signal configuration in the *User Guide and Online Help*.

5. Select **Save**.

Oracle Empirica validates the signal configuration. In case of any error or warning, a message appears at the top of the page.

Make an interactive signal configuration available for further configuration

To further configure the signal configuration, a user needs to access the configuration from the Signal Review page. If you are the owner of the signal configuration, then you will have access.

Follow the steps below to publish the configuration to a user with Manage Signal Configurations permission.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Signal Configurations**.
3. Select the interactive signal configuration's **Row Action menu** , and then select **Publish**.
4. Select **Publish to Users** to publish to individual users with Manage Signal Configurations permission.

Manage monitored products and signaling terms

You can use the interactive Signal Management feature in Oracle Empirica to define the list of monitored products and signaling terms from the application user interface.

You can manage the products to monitor and the following signaling terms:

- Designated medical events
- Custom terms
- Targeted medical events
- Listed events for a monitored product

To modify the list of monitored products and signaling terms:

- The interactive signal configuration must be selected for your user.
 - You must have the Manage Signaling Terms user permission.
1. In the Oracle Empirica application, in the navigation pane on the left, select **Signal Review**

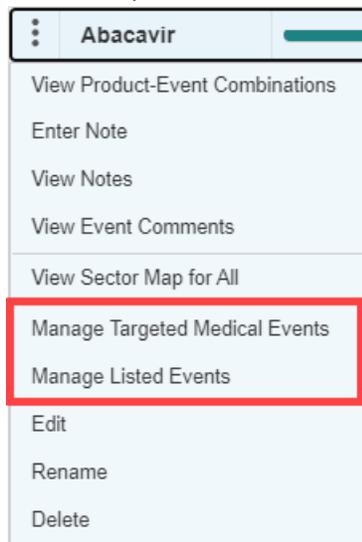


The Products page appears.

2. If the interactive signal configuration is not displayed in the **Signal Configuration** drop-down list, select it.
3. From the **Manage Reference Data** menu  in the upper right corner, select **Add Product** or **Manage Custom Terms**.
4. To add or edit products, fill in the fields according to the table in Add, edit, or change the name and term of a monitored product, or to manage signaling terms, see Add, edit, or delete a custom term in the *User Guide and Online Help*.

To manage events:

1. In the left navigation pane, select the **Signal Review** icon ().
2. If necessary, filter the Products table by selecting a product grouping from the **Products By** drop-down list, then selecting a card.
3. Select the product's **Row Action menu**  and select the appropriate command.



4. To manage designated medical events, select the **Manage Reference Data** menu  in the upper right corner, and then select **Manage Designated Medical Events**.
5. Follow the steps in Manage events and custom terms in the *User Guide and Online Help*.

Validate the interactive signal configuration

After you specify the list of monitored products and signaling terms for the interactive signal configuration, you must validate the configuration to ensure that your changes are valid.

During validation, Oracle Empirica checks the signal configuration to ensure that:

- Referenced data configurations exist.
- Referenced data configurations are valid.
- Referenced variables exist in each data configuration and are of the correct type. For example, Oracle Empirica checks whether event variables in the data configuration are of type *Event*.
- Variables referenced in custom term queries exist in each data configuration you referenced in the signal configuration.

For more information, see the *User Guide and Online Help*.

You must have the Manage Signal Configurations user permission to validate a signal configuration.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Signal Configurations**.
3. Select the signal configuration's **Row Action menu** , and then select **Validate**.
4. On the Signal Configuration Validate page, review the list of findings.
5. Select **Continue**.

Refresh an interactive signal configuration

You refresh an interactive signal configuration to populate the data on the Signal Review page.

To initiate a refresh, you must have the Manage Signal Configuration and Create Data Mining Runs user permissions. For more information, see the *User Guide and Online Help*.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Signal Configurations**.
3. Select the interactive signal configuration's **Row Action menu** , and then select **Refresh**.
4. On the Refresh Signal Management page, specify when to perform the refresh:
 - **Run as soon as possible**—The refresh is executed immediately.
 - **Do not run until**—The refresh is executed on the date and time that you specify.
5. To receive an email notification when the refresh is complete:
 - a. Select the **Email me when complete** checkbox.
 - b. Enter one or more email addresses using a comma to separate each address.

The email addresses associated with your Oracle Empirica user name appear by default. To change these email addresses, contact your site administrator.

6. Select **Submit**.
The Refresh Submitted page appears.
7. Select **Continue**.
The Signal Management Refreshes page appears. The refresh is listed in the table.
A refresh takes several hours to complete. After the status of the refresh changes to `Completed`, the contents of the Signal Review page are updated.

After your first refresh

After you have performed your first refresh on a signal management configuration, you can start taking advantage of the features introduced in Oracle Empirica Signal 9.x.

You can define product property values, edit products, and add or edit alert types for the signal configuration. However, you must have the Manage Signal Configurations, View Signal Management, and Manage Signaling Terms user permissions.

1. Define values for new product fields: **Complexity level**, **Organization**, and **Category**.
 - a. Log in to Oracle Empirica with Manage Signal Configurations permission.
 - b. In the navigation pane on the left, select **Settings** .
 - c. In the Configure System section, select **Manage Signal Configurations**.
 - d. Select the interactive signal configuration's **Row Action menu** , and then select **Edit Product Fields**.
 - e. Consult the *User Guide and Online Help* to see additional actions you can perform.
2. Assign values for product fields.
 - a. Log in to Oracle Empirica as a user with View Signal Management and Manage Signaling Terms permissions.
 - b. In the navigation pane on the left, select **Signal Review** .
 - c. Select a product's **Row Action menu** , and then select **Edit**.

 **Note:**

Complexity level, Birth date, and Review period (if enabled) are product properties that can have alert calculation impact.

- d. Consult *User Guide and Online Help* for further possible steps.
3. Add/edit/activate alert types for the next refresh:
 - a. Log in to Oracle Empirica as a user with Manage Signal Configurations and View Signal Management permissions.
 - b. In the navigation pane on the left, select **Settings** .
 - c. In the Configure System section, select **Manage Signal Configurations**.
 - d. Select an interactive signal configuration's **Row Action menu** , and then select **Edit Alert Types**.

- e. You can:
 - Add an alert type.
 - Edit an existing alert type, including designating an alert type as tracked or informational.
 - Activate or deactivate an alert type for the next refresh.
 - f. Consult *User Guide and Online Help* for further details.
4. When you are finished, refresh the Oracle Empirica configuration to reflect all the changes made.

Make an interactive signal configuration available to users

To make an interactive signal configuration available to users, you must publish the configuration. Optionally, set the interactive signal configuration as the default for login groups.

You must be a superuser to perform the following steps.

1. In the Oracle Empirica application, in the navigation pane on the left, select **Settings** .
2. In the Configure System section, select **Manage Signal Configurations**.
3. Select the interactive signal configuration's **Row Action menu** , and then select **Publish**.
4. To publish to each login group that will use Signal Management, select **Publish to Login Groups**. To publish to all login groups, select **All**.

Optionally, you can make a signal configuration the default for each login group that will use it.

Note:

Once the signal configuration is published to login groups, users are able to select it on the Signal Review page even if it is not the default for their login group.

1. From the left navigation pane, select **Settings** .
2. In the Manage Users section, select **Edit Login Groups**.
3. Perform the following for each login group to which you published the interactive signal configuration:
 - a. Select **Edit**.
 - b. Select the interactive signal configuration from the **Signal Management Configuration** drop-down list.
 - c. Select **Save**.

Note:

To access the Signal Review page and interactive signal management, users must have at least the View Signal Management permission. Users who are currently logged in to Oracle Empirica must log out and log back in.

4. Proceed to Post install.

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Change log

Date	Part number	Description
November 2024	F94576-02	Added release number to the title page.
November 2024	F94576-01	Original version of this document.
