Oracle Health Sciences Empirica Signal

AERS Signal Management for Use with Oracle Empirica Signal Installation and Upgrade Instructions

Release 9.2

F34878-01

Oracle Health Sciences Empirica Signal AERS Signal Management for Use with Oracle Empirica Signal Installation and Upgrade Instructions, Release 9.2

F34878-01

Copyright © 2002, 2021, 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 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" or "commercial computer software documentation" 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 Interactive AERS Signal Management installation overview

Introduction 1-1
About the installation process 1-2
Before you begin 1-2

2 Install and configure an interactive AERS signal configuration

Install an interactive AERS signal configuration 2-1
Make the Release Notes accessible to users from the Oracle Empirica Signal application 2-3
Enable Signal Management in the Oracle Empirica Signal application 2-4
Establish aliases for AERS data configurations 2-4
Edit the interactive AERS signal configuration 2-5
Make an interactive AERS signal configuration available for further configuration 2-5
Manage monitored drugs and signaling terms 2-6
Validate the interactive AERS signal configuration 2-7
Refresh an interactive AERS signal configuration 2-8
Make an interactive AERS signal configuration available to users 2-8

3 Upgrading AERS signal configuration

Upgrading AERS signal configuration from 8.1.1.1 to 9.0 3-1
Upgrading AERS signal configuration from 9.0 to 9.x 3-2

4 Post install/upgrade (recommended)

Post install/upgrade (recommended) 4-1

5 Change log

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

Interactive AERS Signal Management installation overview

- Introduction
  The Oracle Empirica Signal software is a web-based analysis environment for generating statistical scores for combinations of drugs and events in a drug safety database, and for detecting unexpected associations of drugs and events (signals).
- About the installation process
  The installation process for AERS interactive Signal Management includes installing the AERS Signal configuration on the Oracle Empirica Signal application server and enabling the Signal Management features.
- Before you begin
  To perform the installation you need access to the Oracle Empirica Signal 9.x distribution media and required user names and passwords.

Introduction

The Oracle Empirica Signal software is a web-based analysis environment for generating statistical scores for combinations of drugs and events in a drug safety database, and for detecting unexpected associations of drugs and events (signals).

The Oracle Empirica Signal application supports data from the FOI (Freedom of Information) FDA spontaneous adverse event reports database distributed by NTIS (National Technical Information Service) and prepared by Oracle for use with Oracle Empirica Signal. Users access the data in Oracle Empirica Signal by using the AERS data configurations.

If your organization is licensed for Signal Management, users can employ the Signal Management feature in Oracle Empirica Signal on AERS data. The feature facilitates ongoing monitoring of safety signals by enabling users to perform statistical analyses on successive releases of the data.

A scripted form of AERS Signal Management was originally released in 2005. In scripted AERS Signal Management, quarterly refreshes are initiated by running shell scripts on the server. Scripted AERS Signal Management can be used with Oracle Empirica Signal versions 7.3.x and above.

Oracle Empirica Signal 8.1.1 introduced a new AERS Signal Management that is interactive rather than scripted and Oracle Empirica Signal 9.0 enhanced interactive signal management introducing configurable alerts. Interactive AERS Signal Management can be installed with Oracle Empirica Signal 8.1.1 and above and requires AERS data 2017Q3 or later. If scripted AERS Signal Management was used previously, there is an optional conversion process to copy information from the old scripted AERS Signal Management into the new interactive AERS Signal Management.

About the installation process

The installation process for AERS interactive Signal Management includes installing the AERS Signal configuration on the Oracle Empirica Signal application server and enabling the Signal Management features.

You must perform these installation tasks:

- Install the interactive AERS Signal configuration on the Oracle Empirica Signal application server.
- For users of scripted AERS Signal Management, convert the scripted AERS Signal Management to the new interactive AERS Signal Management.
- Configure the Oracle Empirica Signal application to enable the Signal Management features.

Follow the instructions in Install and configure an interactive AERS signal configuration and Post install/upgrade (recommended) to install.

If you are already using AERS interactive Signal Management with Oracle Empirica Signal 8.1.1, the upgrade process for Oracle Empirica Signal 9.x includes:

- Upgrading your AERS interactive Signal configuration on the Oracle Empirica Signal application server.
- Configuring the Oracle Empirica Signal application to enable new Signal Management features.

Follow the instructions in Upgrade AERS signal configuration and Post install/upgrade (recommended) to upgrade.

Before you begin

To perform the installation you need access to the Oracle Empirica Signal 9.x distribution media and required user names and passwords.

To perform the installation, you need:

- Access to the Oracle Empirica Signal 9.x distribution media, which contains:
  - `AERS_Prep_3_0_0_1_xxx.zip`—A Zip archive file for interactive AERS Signal Management.
  - `AERS_Signal_Management_for_Use_with_Empirica_Signal_9.1_Installation_and_Upgrade_Instructions.pdf`
  - `AERS_Signal_Management_for_Use_with_Empirica_Signal_9.1_Release_Notes.pdf`
- The user name, password, and TNS name of the Oracle Empirica Signal database user account.
- The user name and password associated with a non-privileged user account on the Oracle Empirica Signal application server.
- The user name and password associated with an administrator account on the Oracle WebLogic Server Administration console.

- To convert an existing scripted AERS Signal Management to an interactive AERS Signal Management:
  - The password for the AERS_SIGNAL_PREP database account used by the scripted AERS Signal Management.
  - The ID of the scripted AERS signal configuration you are converting from. To find this ID, in Oracle Empirica Signal, in the left navigation pane click **Settings**, then, in the Configure System section, select **Manage Signal Configurations**.
  - The ID of the interactive AERS signal configuration you are converting to. This ID appears at the end of the interactive AERS signal configuration installation. To find this ID, in the Oracle Empirica Signal application, after the installation of an interactive AERS signal configuration, in the left navigation pane click **Settings**, then, in the Configure System section, select **Manage Signal Configurations**.

2

Install and configure an interactive AERS signal configuration

- Install an interactive AERS signal configuration
  Perform these steps using the non-privileged user account on the application server.
- Make the Release Notes accessible to users from the Oracle Empirica Signal application
  Make sure that users have access to the Release Notes.
- Enable Signal Management in the Oracle Empirica Signal application
  You enable the **Signal Review** site option to turn on the Signal Management features in Oracle Empirica Signal.
- Establish aliases for AERS data configurations
  An interactive AERS signal configuration can use aliases for Data configuration for 2D runs and Data configuration for 3D runs. If such aliases do not already exist, you can create them.
- Edit the interactive AERS signal configuration
  The interactive AERS signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica Signal application.
- Make an interactive AERS signal configuration available for further configuration
  To make an interactive AERS signal configuration available to you for further configuration, you must publish to your login group.
- Manage monitored drugs and signaling terms
  You can use the interactive Signal Management feature in Oracle Empirica Signal to define the list of monitored products and signaling terms from the application user interface.
- Validate the interactive AERS signal configuration
  After you specify the list of monitored products and signaling terms for the interactive AERS signal configuration, you must validate the configuration to ensure that your changes are valid.
- Refresh an interactive AERS signal configuration
  You refresh an interactive AERS signal configuration to populate the data on the Signal Review page.
- Make an interactive AERS signal configuration available to users
  To make an interactive AERS signal configuration available to users, you must publish and set the interactive AERS signal configuration as default for login groups.

Install an interactive AERS signal configuration

Perform these steps using the non-privileged user account on the application server.

1. If it does not already exist on the Oracle Empirica Signal application server, create the following directory:

   ```
   /u01/stage/projects
   ```

2. Copy the `AERS_Prep_3_0_0_1_xxx.zip` file from the distribution media to:

   `/u01/stage/projects`

3. Change your current directory to `/u01/stage/projects` as follows:

   ```
   cd /u01/stage/projects/
   ```

4. Unpack the `AERS_Prep_3_0_0_1_xxx.zip` file into a temporary directory, for example:

   ```
   $ unzip AERS_Prep_3_0_0_1_xxx.zip -d /u01/stage/projects/
   ```
   The `aers_ism_prep` subdirectory is created.

5. Navigate to the `aers_ism_prep` subdirectory, for example:

   ```
   $ cd /u01/stage/projects/aers_ism_prep
   ```

6. Execute the following command to give execute permissions to all .sh files:

   ```
   $ chmod u+x common/*.sh sigdet/*.sh site/*.sh
   ```

7. Navigate to `aers_ism_prep/sigdet`, for example:

   ```
   $ cd /u01/stage/projects/aers_ism_prep/sigdet
   ```

8. Execute the following command to give write permissions to the database directory:

   ```
   $ chmod u+w db
   ```

9. Execute the `main_install_sigmgt.sh` script to initiate the installation:

   ```
   $ ./main_install_sigmgt.sh <signal database account name>@<TNS_name>
   ```
   where `<signal database account name>` is the Oracle Empirica Signal database user account name, for example, **webvdme**, and `<TNS_name>` is the TNS name that the application server uses to access the database server.

   A password prompt appears.

10. Enter **<password>**, where **<password>** is the Oracle Empirica Signal database user account password.

    A second password prompt appears.

11. Reenter **<password>**.

    The database tables for the interactive AERS signal configuration are populated. The `install_sigmgmt.log` file is created in the `sigdet/sigmgt/install/log` subdirectory.

> **Note:**
>
> If you enter the password incorrectly, an error such as this appears in the `install_sigmgmt.log` file: `Error returned from execution of "sqlplus /NOLOG @db/connect webvdme @db/fetch_next_config_id".`

If the `AERS SM` project already exists, error messages may appear, including the following:

```
ERROR at line 1:ORA-xxxxx: unique constraint (WEBVDME.UC_PROJECTS1)
violated
```

```
ERROR at line 1:ORA-xxxxx: table or view does not exist
ERROR at line 1:ORA-xxxxx: sequence does not exist
```

You can disregard these errors.

Make the Release Notes accessible to users from the Oracle Empirica Signal application

Make sure that users have access to the Release Notes.

1. Obtain the most recent version of the `AERS Signal Management for Use with Oracle Empirica Signal Release Notes.pdf` file.
   a. Go to the Oracle Help Center.
   b. Select the latest release version of Oracle Empirica Signal and Topics.
   c. On the Books page under Release Notes, select *AERS Signal Management for Use with Oracle Empirica Signal Release Notes*.

      The file downloads.
2. As a non-privileged user on the application server, copy the .pdf file to the `<INSTALL_DIR>/relnotes` directory, for example:

   `/u01/stage/Signal_Install/Signal/relnotes`
3. Redeploy the Oracle Empirica Signal WebLogic Server instance:
   a. In an Internet browser, navigate to the Oracle WebLogic Server Administration Console:

      `https://<servername>:<port>`
   b. Log in using the administrator credentials provided to you by the system administrator.
   c. In the Domain Structure pane, click **Deployments**.
   d. In the Change Center pane, click **Lock & Edit**.
   e. In the Deployments table, select **Signal**.
   f. Click **Update**.
   g. Click **Next**, then click **Finish**.
   h. In the Change Center pane, click **Activate Changes**.

      The deployment is updated.

> **Note:**
>
> After logging in to Oracle Empirica Signal, users can access the *AERS Signal Management for Use with Oracle Empirica Signal Release Notes* by selecting **Settings** from the left navigation pane and then **About**. On the About page, click the **here** link.

Enable Signal Management in the Oracle Empirica Signal application

You enable the **Signal Review** site option to turn on the Signal Management features in Oracle Empirica Signal.

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

1. Log in to the Oracle Empirica Signal application as a superuser.
2. In the navigation pane on the left, click the **Settings** icon ( ).
3. In the Administer System section, click **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. Click **Save**.

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

Establish aliases for AERS data configurations

An interactive AERS signal configuration can use aliases for Data configuration for 2D runs and Data configuration for 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 Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
2. In the Configure System section, click **Manage Aliases**.
3. From the **Target Type** drop-down list, select **Configuration**.
4. Perform one of the following:
   - To add a new alias, click the **Add Alias** link.
   - To edit an alias, click the **Row Action menu** (⋮) for the alias, and then click **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 Target.

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

8. Click **OK**.

Edit the interactive AERS signal configuration

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

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

Review the default settings of the interactive AERS 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 Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
2. In the Configure System section, click **Manage Signal Configurations**.
3. Click the interactive AERS signal configuration's **Row Action menu** ( ), and then click **Edit**.
4. On the Edit Signal Configurations page, edit the fields as needed.

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

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

Make an interactive AERS signal configuration available for further configuration

To make an interactive AERS signal configuration available to you for further configuration, you must publish to your login group.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
2. In the Configure System section, click **Manage Signal Configurations**.
3. Click the interactive AERS signal configuration's **Row Action menu** ( ), and then click **Publish**.
4. Publish to your login group.

Manage monitored drugs and signaling terms

You can use the interactive Signal Management feature in Oracle Empirica Signal 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

For more information about monitoring products and maintaining signaling terms, see Add, edit, or change the name of a monitored product and Manage events and custom terms in the *User Guide and Online Help*.

To modify the list of monitored products and signaling terms:

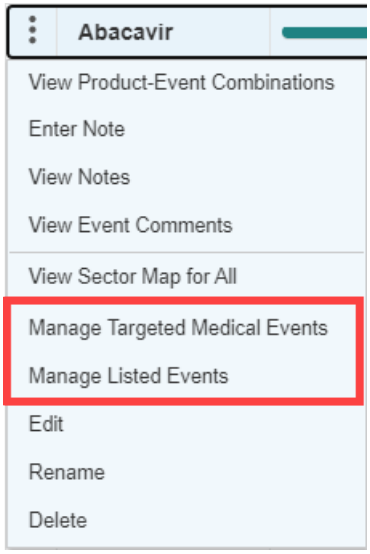
- The interactive Oracle Argus Mart signal configuration must be selected for your user.
- You must have the Manage Signaling Terms user permission.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ( ).

   The Products page appears.
2. If the interactive Oracle Argus Mart 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 of a monitored product in the *User Guide and Online Help*. 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, click the **Signal Review** icon ( ).
2. To manage listed events or targeted medical events, click the product's **Row Action menu** ( ) and select the appropriate command.



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

Validate the interactive AERS signal configuration

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

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

Refresh an interactive AERS signal configuration

You refresh an interactive AERS 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 Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
2. In the Configure System section, click **Manage Signal Configurations**.
3. Click the interactive AERS signal configuration's **Row Action menu** (), and then click **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** check box.
   b. Enter one or more email addresses using a comma to separate each address.

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

   The Refresh Submitted page appears.
7. Click **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.

Make an interactive AERS signal configuration available to users

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

You must be a superuser to perform the following steps.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the interactive AERS signal configuration's **Row Action menu** ( ), and then click **Publish**.
4. Publish to each login group that will use AERS Signal Management (or to **All**).

Optionally, you can make an AERS signal configuration the default for each login group that will use it. Note that once the signal configuration is published to login groups, users will be 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, click **Settings**.
2. In the Manage Users section, click **Edit Login Groups**.
3. Perform the following for each login group to which you published the interactive AERS signal configuration:
   a. Click **Edit.**
   b. Select the interactive AERS signal configuration in the **Signal Management Configuration** drop-down list.
   c. Click **Save**.

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

4. Proceed to Post install/upgrade.

3

Upgrading AERS signal configuration

- Upgrading AERS signal configuration from 8.1.1.1 to 9.0
  You can upgrade an AERS interactive signal configuration from 8.1.1.1 to 9.0.
- Upgrading AERS signal configuration from 9.0 to 9.x
  The required upgrade for AERS signal management is done as part of the Oracle Empirica Signal 9.0 to 9.x upgrade.

Upgrading AERS signal configuration from 8.1.1.1 to 9.0

You can upgrade an AERS interactive signal configuration from 8.1.1.1 to 9.0.

1. Rename your `/u01/stage/projects/aers_ism_prep` directory to `aers_ism_prep_2_0` for safe keeping.
2. Copy the `AERS_Prep_3_0_0_1_xxx.zip` file from the distribution media to:

   `/u01/stage/projects`
3. Change your current directory to `/u01/stage/projects` as follows:

   ```
   cd /u01/stage/projects/
   ```
4. Unpack the `AERS_Prep_3_0_0_1_xxx.zip` file into a temporary directory, for example:

   ```
   $ unzip AERS_Prep_3_0_0_1_xxx.zip -d
   /u01/stage/projects/
   ```
   The `aers_ism_prep` subdirectory is created.
5. Navigate to the `aers_ism_prep/sigdet/db` directory, for example:

   ```
   $ cd /u01/stage/projects/aers_ism_prep/sigdet/db
   ```
6. Run `update_AERS_ISM_8_1_1_1_to_9_0.sql` script in SQL*PLUS providing AERS Signal Management configuration Id as parameter:

   ```
   $ sqlplus <signal database account name>@<TNS_name>
   @update_AERS_ISM_8_1_1_1_to_9_0 <SMC_Id>
   ```
   where:

   - `<signal database account name>` is the Oracle Empirica Signal database user account name, for example, webvdme.
   - `<TNS_name>` is the TNS name that the application server uses to access the database server.
   - `<SMC_Id>` is the ID of the Signal configuration to update.

   You will be prompted to enter the Oracle Empirica Signal account password.
7. Inspect `update_AERS_ISM_8_1_1_1_to_9_0.log` log file for possible errors.

> **Note:**
>
> If application is not re-started after upgrade, the first refresh may fail. To avoid that, restart the Oracle Empirica Signal application after the upgrade.

Upgrading AERS signal configuration from 9.0 to 9.x

The required upgrade for AERS signal management is done as part of the Oracle Empirica Signal 9.0 to 9.x upgrade.

4

Post install/upgrade (recommended)

- Post install/upgrade (recommended)
  If you're upgrading from Oracle Empirica Signal 8.1.1.1, or you have never taken advantage of Signal Management features in Oracle Empirica Signal 9.x, we recommend that you perform the post install/upgrade steps in this section.

Post install/upgrade (recommended)

If you're upgrading from Oracle Empirica Signal 8.1.1.1, or you have never taken advantage of Signal Management features in Oracle Empirica Signal 9.x, we recommend that you perform the post install/upgrade steps in this section.

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.

To define product property values, edit products, and add or edit alert types, 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 the Oracle Empirica Signal application with Manage Signal Configurations permission.
   b. In the navigation pane on the left, click the **Settings** icon ( ).
   c. In the Configure System section, click **Manage Signal Configurations**.
   d. Click the interactive AERS signal configuration's **Row Action menu** ( ), and then click **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 the Oracle Empirica Signal application as a user with View Signal Management and Manage Signaling Terms permissions.
   b. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ( ).
   c. Click a product's **Row Action menu** ( ), and then click **Edit**.

   > **Note:**
   > Complexity level, Birthdate, 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 the Oracle Empirica Signal application as a user with Manage Signal Configurations and View Signal Management permissions.
   b. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).
   c. In the Configure System section, click **Manage Signal Configurations**.
   d. Click an interactive AERS signal configuration's **Row Action menu** ( ), and then click **Edit Alert Types**.
   e. You can:
      i. Add an alert type.
      ii. Edit an existing alert type, including designating an alert type as tracked or informational.
      iii. Activate or deactivate an alert type for the next refresh.
   f. Consult *User Guide and Online Help* for further details.
4. You must refresh the Oracle Empirica Signal configuration to reflect all the changes made.

5 Change log

Date	Part number	Description
30-Nov-2021	F34878-01	Changed 9.1 release references to 9.x.
20-May-2021	F31978-01	Revised document for Oracle Empirica Signal 9.1 release.
4-Sept-2019	F17115-01	Revised document for Oracle Empirica Signal 9.0 release.
27-Jul-2018	E93842-01	Original version of this document.