Oracle Health Sciences Empirica Signal

Oracle Argus Mart Data and Signal Management for Use with Oracle Empirica Signal Installation and Upgrade Instructions

Release 9.2

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ORACLE®

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

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Contents

4   Upgrading Argus Mart signal configuration

5   Post install/upgrade (recommended)

Preface

This preface contains the following sections:

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

Documentation accessibility

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Related resources

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- 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

Oracle Argus Mart data and Argus signal management installation overview

- [About the installation and upgrade process](#)
  The Oracle Empirica Signal application supports data from the Oracle Argus Mart application. Users access the data in Oracle Empirica Signal by using the Oracle Argus Mart data configurations. For example, users can reference the Oracle Argus Mart data configurations when creating data mining runs, queries, case series, and reports for ad hoc analyses.

- [Before you begin](#)
  You need access to the Oracle Empirica Signal distribution media and required user names and passwords.

About the installation and upgrade process

The Oracle Empirica Signal application supports data from the Oracle Argus Mart application. Users access the data in Oracle Empirica Signal by using the Oracle Argus Mart data configurations. For example, users can reference the Oracle Argus Mart data configurations when creating data mining runs, queries, case series, and reports for ad hoc analyses.

If your organization is licensed for Signal Management, users can employ the signal management feature in Oracle Empirica Signal on the data. The feature facilitates the ongoing monitoring of safety signals by enabling users to perform statistical analysis on successive updates of safety data. Users employ the feature by using the Argus Mart signal configuration to populate the Signal Review page. For more information, see the *User Guide and Online Help*.

The installation process for the Oracle Argus Mart data configurations includes:

- Updating Oracle Argus Mart 8.0 (and later) for use with Oracle Empirica Signal 9.x.
- Setting up the Argus data configurations on the Oracle Empirica Signal application server.

The installation process for the Oracle Argus Mart signal configurations includes:

- Installing the Oracle Argus Mart signal configuration on the Oracle Empirica Signal application server.
- Configuring the PL/SQL custom procedure to run from the Argus ETL hook.
- Configuring the Oracle Empirica Signal application to enable the signal management feature.

The upgrade process for Oracle Argus Mart signal configuration is covered in [Upgrading Argus Mart signal configuration](#).

Before you begin

You need access to the Oracle Empirica Signal distribution media and required user names and passwords.

To install the Argus Mart data configuration, you need:

- An Oracle Argus Mart in which ETL has been run.
- Access to the Oracle Argus Mart 8.0 update for Oracle Empirica Signal 9.2 distribution media, which contains:
    - `Update_AM_for_Signal_9_2_0_0_xxx.zip`
    - `Empirica_Signal_Argus_Installation.pdf`
    - `Oracle Argus Mart Release Notes 9.2.pdf.`
    - `Argus_Prep_3_0_0_1_xxx.zip` —A Zip archive file. Optional for Argus Signal Management.
- The user name, password, and TNS name of the system, AM_MART_USER, and webvdme database user accounts.
- The user name and password associated with a non-privileged user account on the Oracle Empirica Signal application server.
- The MedDRA version used for each time period in the data.
- The user name and password associated with an administrator account on the Oracle WebLogic Server Administration console.

2

Set up the Oracle Argus Mart data configurations in Oracle Empirica Signal

- **About the Oracle Argus Mart data configurations**
  The data configurations provide access to the cases in the database tables that you can analyze using Oracle Empirica Signal. For example, the Argus Spontaneous (S+C) data configuration includes only spontaneous reports from Oracle Argus Mart, but both suspect and concomitant drug records for those cases.

- **Make the Release Notes accessible to users from the Oracle Empirica Signal application**
  You must make the Release Notes accessible for users to install Argus Mart data and Argus Signal Management.

- **Install MedDRA accounts on the Oracle Empirica Signal database**
  Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for each version of MedDRA used to code the data.

- **Set up Oracle Argus Mart 8.2 for use with Oracle Empirica Signal**
  To set up Oracle Argus Mart 8.2 and later for use with Oracle Empirica Signal, follow the appropriate procedure based on your existing installation.

- **Load the Oracle Argus Mart data configurations into the Oracle Empirica Signal application**
  You load the data configurations into Oracle Empirica Signal to enable users to work with data from the Oracle Argus Mart application.

- **Specify the MedDRA version for each time period in an Oracle Argus Mart data configuration**
  You must specify the MedDRA version used for each time period in the data. A time period is a range of dates during which only one MedDRA version was used to code the data.

- **Validate the Oracle Argus Mart data configurations**
  Validate the Oracle Argus Mart data configurations before you attempt to publish the configurations. For more information about the validation process, see the *User Guide and Online Help*.

- **Publish the Oracle Argus Mart data configurations**
  Publish the Oracle Argus Mart data configurations to the login groups and users that require access to the configurations.

- **Attach the PL/SQL custom procedure to the Argus ETL hook**
  Oracle Argus Mart provides ETL Hooks for custom procedures that can be used to extend the existing behavior of the Argus Mart ETL.

About the Oracle Argus Mart data configurations

The data configurations provide access to the cases in the database tables that you can analyze using Oracle Empirica Signal. For example, the Argus Spontaneous (S+C) data configuration includes only spontaneous reports from Oracle Argus Mart, but both suspect and concomitant drug records for those cases.

You set up the following Oracle Argus Mart data configurations:

- ARGUS (S)
- ARGUS (S+C)
- Argus Spontaneous (S)
- Argus Spontaneous (S+C)

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

You must make the Release Notes accessible for users to install Argus Mart data and Argus Signal Management.

1. Obtain the most recent version of the `Oracle Argus Mart Data and Argus 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 *Oracle Argus Mart Data and Argus 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 a Web browser, navigate to the Oracle WebLogic Server Administration Console:

   `https://<servername>:<port>/console`

   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.

   After logging in to Oracle Empirica Signal, users can access the *Oracle Argus 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.

Install MedDRA accounts on the Oracle Empirica Signal database

Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for each version of MedDRA used to code the data.

You create the user accounts using the `MedDRAxxx.zip` files provided by Oracle. **xxx** indicates the version of MedDRA. For example, a `MedDRA191.zip` file is for MedDRA version 19.1.

If a user account already exists on the database server for a given version of MedDRA, do not recreate the account.

The application server is assumed to be Linux. If installing from a Windows server, please contact Oracle support.

For each MedDRA account that you need to create, perform these steps using the non-privileged user account on the application server.

- For MedDRA 19.0 and prior
  Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for MedDRA 19.0 and prior to code the data.

- For MedDRA 19.1 and later
  Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for MedDRA 19.1 and later to code the data.

For MedDRA 19.0 and prior

Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for MedDRA 19.0 and prior to code the data.

1. Copy the `MedDRAxxx.zip` file from the distribution media to a temporary directory on the server.

2. Unpack the `MedDRAxxx.zip` file into a temporary directory, for example:

   `$ unzip MedDRAxxx.zip -d /u01/stage/`
   The `MedDRAxxx` subdirectory is created.

3. Navigate to the `/MedDRAxxx` directory, for example:

   `$ cd /u01/stage/MedDRAxxx`

4. Using a text editor, open the `Create_MedDRA.sql` file.

   a. Locate the `DEFINE ORACLE_DBF_FILE` statement.

   b. Edit the path portion in the `DEFINE ORACLE_DBF_FILE` statement to point to the desired location for the Oracle tablespace data files.

      Keep the single quotes and use `&SCHEMA.a.dbf` as the last part of the string.

      The path can point to any existing location on the database server. However, the Oracle tablespace data files are usually located in the `oradata` subdirectory of the Oracle Database installation directory.

   c. Optionally, change the default password. Be sure to abide by your site's password policies.

The default password has the same value as the username.

Locate the `DEFINE PASSWORD='&SCHEMA'` line near the top, and replace `&SCHEMA` with the desired password.

   d. Save and close the file.

5. Execute the `Create_MedDRA.sql` script as the **system** user to create the `MEDDRAxxx` tablespace and user account, for example:

```
$ sqlplus system@<TNS_name> @Create_MedDRA.sql
```
A password prompt appears.

6. Enter the **system** database account password, and press **Enter**.

7. Execute the **imp** command to populate the MedDRA tablespace you created in a previous step, for example:

```
$ imp userid=MEDDRAxxx@<TNS_name> file=MEDDRAxxx.dmp full=Y
Log=Imp_MEDDRAxxx.log
```

A password prompt appears.

8. Enter a password for the **MEDDRAxxx** database account, and press **Enter**.

Installation produces log files in the `MedDRAxxx` directory, including counts of imported records for each table:

```
imp_MEDDRAxxx.log
```

```
Create_MedDRA.log
```

9. To verify that the import has completed successfully, compare the record counts in `imp_MEDDRAxxx.log` to the counts of exported records in `exp_MEDDRAxxx.log`.

For MedDRA 19.1 and later

Data from the Oracle Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for MedDRA 19.1 and later to code the data.

1. Copy the `MedDRAxxx.zip` file from the distribution media to a temporary directory on the server.

2. Unpack the `MedDRAxxx.zip` file into a temporary directory, for example:

```
$ unzip MedDRAxxx.zip -d /u01/stage/
```
The `MedDRAxxx` subdirectory is created.

3. Navigate to the `MedDRAxxx/Linux` directory, for example:

```
$ cd /u01/stage/MedDRAxxx/Linux
```

4. Give execute permissions on the shell script files:

```
$ chmod +x *.sh
```

5. Execute the installer:

```
$ ./install.sh
```

6. Follow the on-screen prompts to install `MedDRA xx.x`.

The following is a sample transcript of the prompts and information that the installer generates.

Pre-installation checks

The installer performs a series of checks to ensure that the required software components are available.

```
Empirica Signal Data Release Installation Program Version <version>
Pre-installation checks:
  sqlplus ................................................ INSTALLED
  imp ................................................... INSTALLED
  tnsping ............................................... INSTALLED
  builtin echo .......................................... AVAIL.
  builtin printf ........................................ AVAIL.
```

Oracle TNS name

The installer prompts for the target TNS name, which will be used in the rest of the steps.

Enter the TNS name and press **Enter**.

```
Please enter your database's TNS name:
```
The installer attempts to verify the TNS name provided. After three failed attempts, the installer will terminate with an error. If verified, the installer indicates success.

```
TNS name <TNS NAME> verified successfully.
```
Password for privileged Oracle user

Creating and dropping schemas requires elevated privileges. The installer prompts for a privileged Oracle user account name. The default privileged Oracle user account name is **SYSTEM**.

```
Please enter Privileged user's Oracle user name [SYSTEM]:
```

Enter the password for this account and then press **Enter**.

Your response will not be echoed to the screen but will be masked by a series of asterisks.

```
Please enter SYSTEM's password:
```

The installer attempts to verify the password provided. After three failed attempts, the installer will terminate with an error. If verified, the installer indicates success.

```
SYSTEM password verified successfully.
```
Oracle Empirica Signal or Oracle Empirica Study application user name (not applicable for MedDRA 19.1)

If Oracle Empirica Signal or Oracle Empirica Study is installed, press **Enter**.

```
Is an Empirica application installed in the target database <TNS NAME> [Y|N]?
```
Enter the Oracle user name (for example, **WEBVDME** or **STUDY**) and password for the application when prompted.

```
Please enter Empirica application's Oracle user name [WEBVDME]:
Please enter WEBVDME's password:
```

If verified, the installer indicates success.

```
WEBVDME password verified successfully.
```

Installation

The installer presents the option to install the `MedDRA xx.x` data account. If the data account already exists, drop and re-install the account. Press **Enter** or enter **Y** to install `MedDRA xx.x`, or enter **N** to skip.

```
Install MEDDRA xxx [Y|N]?
```
Enter a secure password for the **MEDDRAxxx** Oracle user, subject to any site-specific policies or restrictions.

> **Note:**
>
> Your site's database may have specific password policies or restrictions. For example, your database may not allow the password to be the same as the account name. Take this into account when choosing the password for this account.

Your response will not be echoed to screen but will be masked by a series of asterisks.

```
Please enter a new password for MEDDRAxxx:
```
Enter the same password for verification. Your response will once again be masked by a series of asterisks. After three failed attempts, the installer will terminate with an error. If verified, the installer continues.

```
Please re-enter the same password for verification:
```
Enter the full directory path for datafiles on your database server or press **Enter** to accept the default.

> **Note:**
>
> The installer does not have the ability to verify remote system paths. Please make sure that the path you are entering is correct. Linux file and directory paths are case sensitive and use forward slashes to separate path components.

```
Please enter the absolute datafiles directory path [/u01/app/oradata/
ORCL]:
```
Data review

The installer presents all of the information it has collected. Passwords are masked by a series asterisks. Inspect the list carefully before proceeding. If necessary, press **Ctrl+C** to abort the installation and retry with the corrected information. If the information is correct, press any key to proceed with the installation.

```
Please review your selections and press any key to continue or Ctrl+C
to abort:
 TNS name ......................................... ORCL
 Privileged user .................................. SYSTEM
 SYSTEM password .................................. ********
 Signal or Study user ............... .............. WEBVDME
 WEBVDME password ................................. ********
 Install MEDDRA xxx ............................... Y
 Drop MEDDRAxxx ................................... N
```

```
 Create MEDDRAxxx ................................... Y
 Password .......................................... ********
 Datafiles Dir. .................................... /u01/app/oradata/ORCL
 Postinstall initialization ........................ None
Please press any key to continue or Ctrl+C to abort:
```

Installation progress and summary

Updates are printed to the screen as installation progresses. Any errors encountered also display. For an error-free installation, the installer will report success before exiting.

```
Installing MEDDRA xxx ...
Creating user MEDDRAxxx ...
Schema MEDDRAxxx created successfully.
Importing data into MEDDRAxxx ...
Data imported successfully.
Computing statistics for MEDDRAxxx ...
Statistics for MEDDRAxxx computed successfully.
MEDDRA xxx installed successfully.
All data components installed successfully.
```

Installation produces log files in the `MedDRAxxx` directory, including counts of imported records for each table:

```
Create_MedDRA.log
imp_MEDDRAxxx.log
```

To verify that the import has completed successfully, compare the record counts in `imp_MEDDRAxxx.log` to the counts of exported records in `exp_MEDDRAxxx.log`.

Set up Oracle Argus Mart 8.2 for use with Oracle Empirica Signal

To set up Oracle Argus Mart 8.2 and later for use with Oracle Empirica Signal, follow the appropriate procedure based on your existing installation.

The procedure you follow to set up Oracle Argus Mart 8.2 or later for use with Oracle Empirica Signal depends on whether you are performing a new installation or if you already have an existing integration of Oracle Argus Mart with Oracle Empirica Signal. Select the appropriate link below based on your situation.

- Set up a new Oracle Argus Mart 8.2 Integration for use with Oracle Empirica Signal
  If you are integrating Oracle Argus Mart 8.2 or later for use with Oracle Empirica Signal for the first time (no existing integration), perform these steps using the non-privileged user account on the application server.

- Update an Existing Oracle Argus Mart 8.x Integration
  If Oracle Argus Mart 8.x or later is already integrated with Oracle Empirica Signal and you are upgrading the integration to Oracle Argus Mart 8.2 or later, perform these steps using the non-privileged user account on the application server.

Set up a new Oracle Argus Mart 8.2 Integration for use with Oracle Empirica Signal

If you are integrating Oracle Argus Mart 8.2 or later for use with Oracle Empirica Signal for the first time (no existing integration), perform these steps using the non-privileged user account on the application server.

Note: If a previous version of Oracle Argus Mart is already integrated with Oracle Empirica Signal, follow the procedure found at Update an Existing Oracle Argus Mart 8.x Integration .

1. Copy the `Update_AM_for_Signal_9_2_0_0_xxx.zip` file from the distribution media to a temporary directory on the server.

2. Unpack the `Update_AM_for_Signal_9_2_0_0_xxx.zip` file into a temporary directory, for example:

    ```
    $ unzip Update_AM_for_Signal_9_2_0_0_xxx.zip -d /u01/stage/
    ```

    The `/UPDATE_AM_FOR_SIGNAL` subdirectory is created.

3. Navigate to the `/UPDATE_AM_FOR_SIGNAL` directory, for example:

    ```
    $ cd /u01/stage/UPDATE_AM_FOR_SIGNAL
    ```

4. Using a text editor, open the `create_argus_spontaneous_configurations.sql` file.

5. Locate the following `WHERE` clause:

    ```
    WHERE UPPER (report_type_ve) IN (''SPONTANEOUS'',''LITERATURE'')
    ```

    The WHERE clause describes the spontaneous reports from the Oracle Argus Mart database user account.

6. Modify the WHERE clause as needed.

7. Save and close the file.

8. Execute the `UPDATE_AM_8_0_FOR_SIGNAL_8_1.sql` script as the **am_mart_user**, for example:

    ```
    $ sqlplus am_mart_user@<TNS_name> @UPDATE_AM_8_0_FOR_SIGNAL_8_1.sql
    ```
    A password prompt appears.

9. Enter the **am_mart_user** database account password, and then press **Enter**.

Update an Existing Oracle Argus Mart 8.x Integration

If Oracle Argus Mart 8.x or later is already integrated with Oracle Empirica Signal and you are upgrading the integration to Oracle Argus Mart 8.2 or later, perform these steps using the non-privileged user account on the application server.

Note: If you are performing a new installation, see Set up a new Oracle Argus Mart 8.2 Integration for use with Oracle Empirica Signal .

1. Copy the `Update_AM_for_Signal_9_2_0_0_xxx.zip` file from the distribution media to a temporary directory on the server.

2. Unpack the `Update_AM_for_Signal_9_2_0_0_xxx.zip` file into a temporary directory, for example:

```
$ unzip Update_AM_for_Signal_9_2_0_0_xxx.zip -d /u01/stage/
```

The `/UPDATE_AM_FOR_SIGNAL` subdirectory is created.

3. Navigate to the `/UPDATE_AM_FOR_SIGNAL` directory, for example:

```
$ cd /u01/stage/UPDATE_AM_FOR_SIGNAL
```

4. Execute the `Update_Argus_Mart_to_8.2.sql` script as the **am_mart_user**. For example:

```
$ sqlplus am_mart_user@<TNS_name> @Update_Argus_Mart_to_8.2.sql
```

A password prompt appears.

5. Enter the **am_mart_user** database account password, and then press **Enter**.

Load the Oracle Argus Mart data configurations into the Oracle Empirica Signal application

You load the data configurations into Oracle Empirica Signal to enable users to work with data from the Oracle Argus Mart application.

- ARGUS (S)
- ARGUS (S+C)
- Argus Spontaneous (S)
- Argus Spontaneous (S+C)

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

1. Navigate to the `/u01/stage/UPDATE_AM_FOR_SIGNAL` directory, for example:

```
$ cd /u01/stage/UPDATE_AM_FOR_SIGNAL
```

2. Execute the `@init_configuration_account.sql` script as the **system** user and provide the Oracle Empirica Signal and Oracle Argus Mart database user accounts on the command line:

```
$ sqlplus system@<TNS_name> @init_configuration_account.sql webvdme
AM_MART_USER
```

The script enables Oracle Empirica Signal to import the Oracle Argus Mart data configurations from the **am_mart_user** database user account without requiring Oracle Empirica Signal users to enter the database user account password.

A password prompt appears.

3. Enter the **system** account password, and then press **Enter**.

4. Log in to the Oracle Empirica Signal application as a user with the Manage Configurations user permission.

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

6. In the Configure System section, click **Manage Configurations**.

7. Click **Import Configurations**.

8. Below the list of database user accounts, click **Import Configurations from a Different Account**.

9. In the **Oracle account** field, enter **AM_MART_USER**.

10. From the **Add to existing database group** drop-down list, select a database group. For example, AM Mart.

11. Click **OK**.

12. Verify that the four Oracle Argus Mart data configurations are listed on the Manage Configurations page.

Specify the MedDRA version for each time period in an Oracle Argus Mart data configuration

You must specify the MedDRA version used for each time period in the data. A time period is a range of dates during which only one MedDRA version was used to code the data.

For example, suppose that the Oracle Argus Mart data includes the following rows:

Case ID	Start	Stop
100	01-01-2004	06-01-2004
200	06-01-2004	01-01-2005
300	01-01-2005	-

Additionally, suppose that different versions of MedDRA were used to code the Oracle Argus Mart data:

*   MedDRA version 6.1 was used until June 1, 2004.

*   MedDRA version 7.0 was used between June 1, 2004 and January 1, 2005.

*   MedDRA version 7.1 was used starting January 1, 2005.

You would specify the version of MedDRA used for each time period as described in this procedure.

1. In a Web browser, navigate to the Oracle Empirica Signal login page.

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

3. From the Configure System section, click **Manage Configurations**.

4. Click the Oracle Argus Mart data configuration's **Row Action menu** ( ), and then click **Edit**.

    The Modify Configuration page appears.

5. On the top table, click **Edit** in the far right column for the data configuration.

6. On the Edit Configuration Details page, from the **Event Hierarchy Version Table** field, click **Select/Edit Table**.

    The Event Hierarchy Accounts for Configuration window appears.

7. To specify only one MedDRA version for all of the Oracle Argus Mart data, enter the Oracle Empirica Signal database account name for the MedDRA version in the first row of the Hierarchy Account column, for example:

8. To specify a different MedDRA version for each time period in the Oracle Argus Mart data:

   a. In the first row of the **Date** column, enter the last date of the earliest time period.

      The date must be in *mm / dd / yyyy* format.

      > **Note:**
      >
      > Each date includes a time stamp of 12:00:00 a.m. unless you specify a time stamp. For example, if you specify that MedDRA version 6.1 was used until (<=) 06/01/2004 and MedDRA version 7.0 was used thereafter, then MedDRA 7.0 is applied to source data coded at 12:00:01 a.m. on June 1, 2004.

   b. In the first row of the **Hierarchy Account** column, enter the MedDRA account name.

   c. Fill in one row for each time period in the Oracle Argus Mart data, for example:

      If you need additional rows, you can select **Add additional empty rows upon saving**, and click **Save**.

      For the last time period, enter only the Oracle database account name for the MedDRA version.

9. Click **Save**.

Validate the Oracle Argus Mart data configurations

Validate the Oracle Argus Mart data configurations before you attempt to publish the configurations. For more information about the validation process, see the *User Guide and Online Help*.

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

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click

   the **Settings** icon (⚙).

2. Click **Manage Configurations**.

3. Click **Validate Configurations**.

4. Select the Oracle Argus Mart data configurations:

   • ARGUS (S)

   • ARGUS (S+C)

   • Argus Spontaneous (S)

   • Argus Spontaneous (S+C)

5. Click **Validate**.

   After a few moments, a confirmation message appears.

6. Click **Continue**.

Publish the Oracle Argus Mart data configurations

Publish the Oracle Argus Mart data configurations to the login groups and users that require access to the configurations.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click

   the **Settings** icon (⚙).

2. Click **Manage Configurations**.

3. Click **Select Rows**.

4. Select the Oracle Argus Mart data configurations:

   • ARGUS (S)

   • ARGUS (S+C)

   • Argus Spontaneous (S)

   • Argus Spontaneous (S+C)

5. Click **Publish**.

6. Set the group and individual permissions for the configuration.

7. Click **Save**.

   A confirmation message appears.

8. Click **Continue**.

Attach the PL/SQL custom procedure to the Argus ETL hook

Oracle Argus Mart provides ETL Hooks for custom procedures that can be used to extend the existing behavior of the Argus Mart ETL.

Follow the steps below to configure the CUSTOM ROUTINE AFTER ETL hook.

1. Log in to the Oracle Argus Safety application.

2. From the menu bar, click **Argus Console**.

   The menu bar updates for Argus Console.

3. From the new menu bar, click **System Configuration**.

4. Click **System Management** (Common Profile Switches).

   On the left side of the screen, a list of all system-managed common profile switches appears.

5. Expand the Common Profile folder, and click **Argus Mart**.

   The Modify Argus Mart page appears.

6. Navigate to the CUSTOM ROUTINE AFTER ETL hook, and enter:

   ```
   Empirica_Utils.Populate_smqmap_casescore
   ```

For additional information about custom procedures with Oracle Argus Mart, see the *Argus Mart Extensibility Guide*.

3

Install and configure an Oracle Argus Mart signal configuration

- **About the Oracle Argus Mart signal configuration**
  The Oracle Argus Mart signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica Signal application.

- **Install the Oracle Argus Mart signal configuration**
  You must install the Oracle Argus Mart signal configuration.

- **Enable signal management in the Oracle Empirica Signal application**
  Enable the **Show menu items: Signal Review** site option to turn on the signal management features in Oracle Empirica Signal.

- **Edit the Oracle Argus Mart signal configuration**
  Review the default settings of the Oracle Argus Mart signal configuration and change the settings as needed.

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

- **Refresh the Oracle Argus Mart signal configuration**
  You refresh an Oracle Argus Mart signal configuration to update the data on the Oracle Empirica Signal Signal Review page.

- **Make the Oracle Argus Mart signal configuration available to users**
  To make an Oracle Argus Mart signal configuration available to users, you must publish and set the Oracle Argus Mart signal configuration as default for login groups.

About the Oracle Argus Mart signal configuration

The Oracle Argus Mart 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 variables the application uses for data mining runs. For more information, see the *User Guide and Online Help*.

When you install the Oracle Argus Mart signal configuration, queries are created in the **Argus Signal Mgmt** project. Each query is a specification for retrieving a subset of cases from a data configuration in data mining runs.

Install the Oracle Argus Mart signal configuration

You must install the Oracle Argus Mart 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 `Argus_Prep_3_0_0_1_xxx.zip` file from the distribution media to:

   `/u01/stage/projects`

3. Unpack the `Argus_Prep_3_0_0_1_xxx.zip` file into a temporary directory, for example:

   `$ unzip Argus_Prep_3_0_0_1_xxx.zip -d /u01/stage/projects/`
   The `/argus_prep` subdirectory is created.

4. Navigate to the `/argus_prep` directory, for example:

   `$ cd /u01/stage/projects/argus_prep`

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

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

6. Navigate to the `/argus_prep/sigdet` directory, for example:

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

7. Execute the following command to give write permissions to the db directory:

   `$ chmod u+w db`

8. 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`. `<TNS_name>` is the TNS name that the application server uses to access the database server.

   A password prompt appears.

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

   A second password prompt appears.

10. Reenter **<password>**.

    The database tables for the Oracle Argus Mart 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 `Argus Signal Mgmt` 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.

Enable signal management in the Oracle Empirica Signal application

Enable the **Show menu items: Signal Review** site option to turn on the signal management features in Oracle Empirica Signal.

1. Log in to the Oracle Empirica Signal application as a superuser.

2. In the Oracle Empirica Signal application, 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.

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

6. Click **Save**.

Edit the Oracle Argus Mart signal configuration

Review the default settings of the Oracle Argus Mart 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. On the Manage Signal Configurations page, click the Oracle Argus Mart signal configuration's **Row Action menu** ( ), and then click **Edit**.

4. On the Edit signal Configuration page, edit the fields as needed.

   For more information, see the *User Guide and Online Help* by clicking the Help link on the page.

5. Click **Save**.

   Oracle Empirica Signal validates the signal configuration. Warnings and errors appear at the top of the page.

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*.

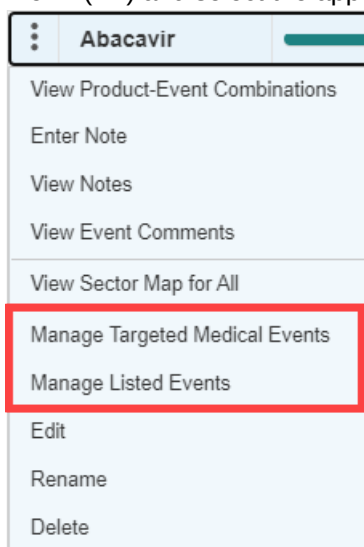**To modify the list of monitored products and signaling terms:**

- 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 Oracle Argus Mart signal configuration

After you specify the list of monitored products and signaling terms for the Oracle Argus Mart 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 Oracle Argus Mart signal configuration's **Row Action menu** ( ), and then click **Validate**.

    The Signal Configuration Validation page appears.

4. Review the list of findings.

5. Click **Continue**.

Refresh the Oracle Argus Mart signal configuration

You refresh an Oracle Argus Mart signal configuration to update the data on the Oracle Empirica Signal Signal Review page.

To initiate a refresh, you must have the Manage Signal Configurations 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 Oracle Argus Mart signal configuration's **Row Action menu** ( ), and then click **Refresh**.

    The Refresh Signal Management page appears.

4. 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.

The time for the refresh to complete varies based on the size of your Oracle Argus Mart data. After the status of the refresh changes to Completed, the contents of the Signal Review page are updated.

Make the Oracle Argus Mart signal configuration available to users

To make an Oracle Argus Mart signal configuration available to users, you must publish and set the Oracle Argus Mart 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 Oracle Argus Mart signal configuration's **Row Action menu** ( ), and then click **Publish**.

4. Publish to each login group that will use Argus signal management (or to **All**).

5. In the navigation pane on the left, click the **Settings** icon ( ).

6. In the Manage Users section, click **Edit Login Groups**.

7. Perform the following for each login group to which you published the Oracle Argus Mart signal configuration:

    a. Click **Edit.**

    b. From the **Signal Management Configuration** drop-down list, select the Oracle Argus Mart signal configuration.

    c. Click **Save**.

> **Note:**
>
> To access the Signal Review page and Oracle Argus Mart signal management, users who are currently using Oracle Empirica Signal and who have at least the View Signal Management permission must log out and log back in.

4
Upgrading Argus Mart signal configuration

- Upgrading Oracle Argus Mart signal configuration from 8.1.x to 9.0
  To upgrade an Oracle Argus Mart signal configuration from 8.1.x to 9.0 perform these steps.

- Upgrading Oracle Argus Mart signal configuration from 9.0 to 9.x
  The required upgrade for Oracle Argus Mart signal management is done as a part of the Oracle Empirica Signal 9.0 to 9.x upgrade.

Upgrading Oracle Argus Mart signal configuration from 8.1.x to 9.0

To upgrade an Oracle Argus Mart signal configuration from 8.1.x to 9.0 perform these steps.

1. Make sure that the Oracle Argus Mart Signal Management configuration is updated to 8.1.

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

   `/u01/stage/projects`

3. Copy the `Argus_Prep_3_0_0_1_xxx.zip` file from the distribution media to:

   `/u01/stage/projects`

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

   `cd /u01/stage/projects/`

5. Unpack the `Argus_Prep_3_0_0_1_xxx.zip` file into a temporary directory, for example:

   `$ unzip Argus_Prep_3_0_0_1_xxx.zip -d /u01/stage/projects/`
   The `/argus_prep` subdirectory is created.

6. Navigate to the `argus_prep/sigdet/db` directory, for example:

   `$ cd /u01/stage/projects/argus_prep/sigdet/db`

7. Run `update_Argus_ISM_8_1_1_to_9_0.sql` script in SQL*PLUS providing Argus Signal Management configuration Id as parameter, for example

   `$ sqlplus <signal database account name>@<TNS_name>`
   `@update_Argus_ISM_8_1_1_to_9_0 <SMC_Id>`
   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.

8. Inspect `update_Argus_ISM_8_1_1_to_9_0.log` log file for possible errors.

> **Note:**
>
> If the 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 Oracle Argus Mart signal configuration from 9.0 to 9.x

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

5
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 9.0, we recommend that you follow these post install/upgrade instructions 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 9.0, we recommend that you follow these post install/upgrade instructions in this section.

After you have performed your first refresh on a signal management configuration, you can do the following to start taking advantage of the features introduced in Oracle Empirica Signal 9.0.

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 Argus signal configuration's **Row Action menu** ( ), and then click **Edit Product Fields**.

   e. Consult the 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 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 Argus 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 Online Help for further details.

4. You must refresh the signal configuration to reflect all the changes made.