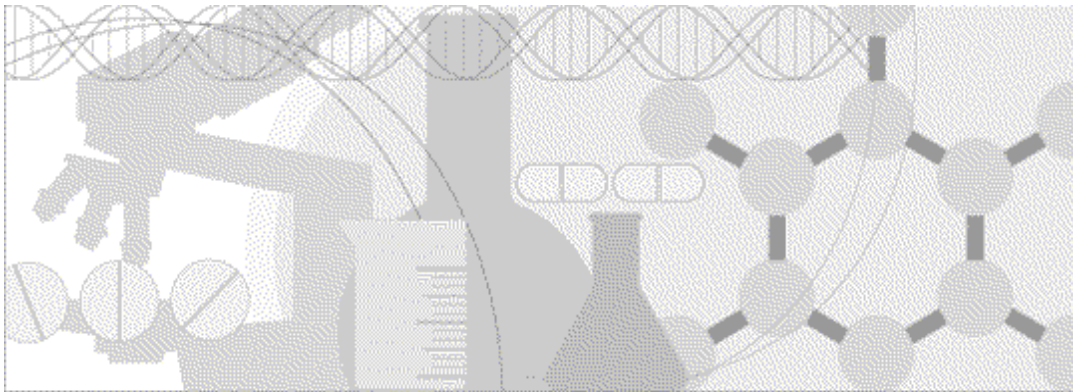


Installation Instructions

Oracle[®] Health Sciences Argus Mart Data and Argus Signal Management for Use with Empirica Signal 8.1.0.2



ORACLE

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CHAPTER 1

Product overview

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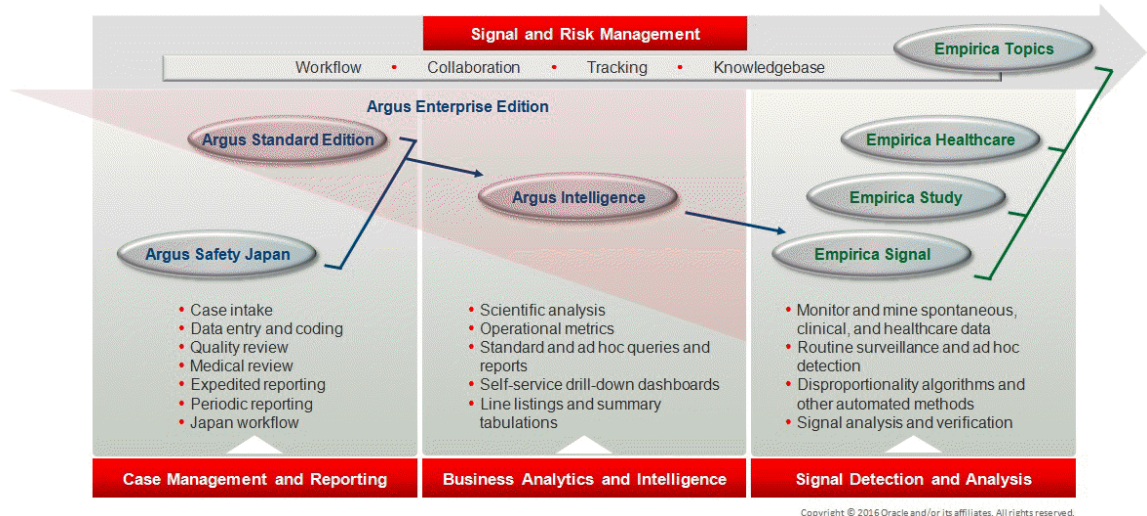
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The Oracle® Health Sciences Safety Suite

This product is part of the Oracle® Health Sciences Safety Suite, an integrated solution for end-to-end pharmacovigilance from adverse event management to signal management, through the entire lifecycle of a medicinal product from clinical trials to post-marketing surveillance.

Oracle Health Sciences Safety Suite

Integrated Solution for End-to-End Vigilance Through the Entire Product Lifecycle



The Oracle® Health Sciences Safety Suite consists of the following components:

- Oracle Argus Standard Edition:** Manage and report adverse events through a workflow including case intake, data entry, coding, quality review, medical review, expedited reporting, and periodic reporting. Modules include Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, and Oracle Argus Unblinding.
- Oracle Argus Enterprise Edition:** In addition to managing the adverse event workflow and reporting, employ a powerful and flexible business analytics and intelligence platform for both scientific analysis and operational metrics. Modules include Oracle Argus Analytics, Oracle Argus Insight, Oracle Argus Mart, Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle® Health Sciences Adverse Event Integration Pack for Oracle® Health Sciences InForm and Oracle Argus.
- Oracle Argus Safety Japan:** Manage and report adverse events in Japan, and connect the global and local workflows using a single database.
- Oracle® Health Sciences Empirica Topics:** Manage and document safety signals through a workflow including validation, prioritization, assessment, confirmation/refutation, and resulting actions.
- Oracle® Health Sciences Empirica Study:** Detect and analyze safety signals in clinical trial data including adverse events, clinically significant labs, electrocardiograms, vital signs, and shifts from baseline.
- Oracle® Health Sciences Empirica Signal:** Detect and analyze safety signals in post-marketing spontaneous adverse reaction data including public health authority databases and/or private in-house databases such as Oracle Argus.

- **Oracle® Health Sciences Empirica Healthcare Analysis:** Evaluate safety signals in healthcare data including electronic medical records and administrative claims, and support pharmacoepidemiology, comparative effectiveness analysis, and health economics and outcomes research.

For more information on Argus Safety, visit the Oracle® Health Sciences Safety Suite page at:

<http://www.oracle.com/goto/pharmacovigilance/index.html>

Introduction to the Empirica Signal software

The 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).

CHAPTER 2

Argus Mart data and Argus signal management installation overview

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About the installation process

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

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

The installation process for the Argus Mart data configurations includes:

- Updating Argus Mart 8.0 (or higher) for use with Empirica Signal 8.1.0.2.
- Setting up the Argus data configurations on the Empirica Signal application server.

The installation process for the Argus Mart signal management configuration includes:

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

Before you begin

You need:

- An Argus Mart in which ETL has been run.
- Access to the Argus Mart 8.0 update for Empirica Signal 8.1 distribution media, which contains:
 - **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip**—A Zip archive file.
 - **Empirica_Signal_Argus_Installation.pdf**—This document in PDF format.
 - **Oracle Argus Mart Release Notes 8.0.pdf**.
 - **Argus_Prep_2_0_0_0_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 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.

CHAPTER 3

Setting up the Argus Mart data configurations in Empirica Signal

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About the Argus Mart data configurations

You set up the following Argus Mart data configurations:

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

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

Copying release notes to the /relnotes directory

Make the Argus Mart Data Release Notes available from the Contents tab in the *User Guide and Online Help*.

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

- 1 On the distribution media, locate the latest version of the **Oracle Argus Mart Release Notes.pdf** file.
- 2 Copy the file to the `<INSTALL_DIR>/relnotes` directory on the Empirica Signal application server, for example:

```
$ cp 'Oracle Argus Mart Release Notes 8.0.pdf'  
/u01/stage/Signal_Install/Signal/relnotes
```

If the file already exists in the directory, replace the file.

- 3 Redeploy the Empirica Signal WebLogic Server instance:
 - a In an Internet browser, navigate to the Oracle WebLogic Server Administration Console, for example:
`https://<servername>:7002/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 **Finish**.
 - h In the Change Center pane, click **Activate Change**.
The deployment is updated.

Installing MedDRA accounts on the Empirica Signal database

Data from the 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.

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

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

For MedDRA versions starting 19.1 and after:

- 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.

For MedDRA 19.0 and prior

- 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 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 Type 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 Type 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

- 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.
```

Empirica application user name (not applicable for MedDRA 19.1)

If there is an Empirica application installed, such as Signal or Study, press **Enter**.

```
Is an Empirica application installed in the target database <TNS NAME>
[Y|N]?
```

If there is an Empirica application installed, 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 of 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**.

Updating Argus Mart 8.0 for use with Empirica Signal

8.1.0.2

For Argus Mart 8.0 and higher, perform these steps using the non-privileged user account on the application server.

- 1 Copy the **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip** file from the distribution media to a temporary directory on the server.
- 2 Unpack the **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip** file into a temporary directory, for example:

```
$ unzip Update_AM_8_0_for_SIGNAL_8_1_0_0_xxx.zip -d /u01/stage/
```

The **/UPDATE_AM_8_0_FOR_SIGNAL_8_1** subdirectory is created.

- 3 Navigate to the **/UPDATE_AM_8_0_FOR_SIGNAL_8_1** directory, for example:

```
$ cd /u01/stage/UPDATE_AM_8_0_FOR_SIGNAL_8_1
```

- 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 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 Type the **am_mart_user** database account password, and press **Enter**.

Loading the Argus Mart data configurations into the Empirica Signal application

You load the following data configurations into Empirica Signal to enable users to work with data from the 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_8_0_FOR_SIGNAL_8_1` directory, for example:

```
$ cd /u01/stage/UPDATE_AM_8_0_FOR_SIGNAL_8_1
```

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

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

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

A password prompt appears.

- 3 Type the **system** account password, and press **Enter**.
- 4 Log in to the Empirica Signal application as a user with the Manage Configurations user permission.
- 5 Click **Settings**.
- 6 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, type **AM_MART_USER**.
- 10 Specify a database group. For example, AM Mart.
- 11 Click **OK**.
- 12 Verify that the four Argus Mart data configurations are listed on the Manage Configurations page.

Specifying the version of MedDRA used for each time period in the Argus Mart data

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 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 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 an Internet browser, navigate to the Empirica Signal login page.
- 2 Log in to the Empirica Signal application as a user with the Manage Configurations user permission.
- 3 Click **Settings**.
- 4 Click **Manage Configurations**.
- 5 Click the row menu for one of the Argus Mart data configurations, and select **Edit**.
The Modify Configuration page appears.
- 6 In the top table, click **Edit** in the far right column for the data configuration.
The Edit Configuration Details page appears.
- 7 In the **Event Hierarchy Version Table** field, click **Select/Edit Table**.
The Event Hierarchy Accounts for Configuration window appears.
- 8 To specify only one MedDRA version for all of the Argus Mart data, type the Empirica Signal database account name for the MedDRA version in the first row of the Hierarchy Account column, for example:

	Date	Hierarchy Account
ALL DATES	<input type="text"/>	MEDDRA61
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>

- 9 To specify a different MedDRA version for each time period in the Argus Mart data:
 - a In the first row of the **Date** column, type 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, type the MedDRA account name.
- c Fill in one row for each time period in the Argus Mart data, for example:

Define Effective Dates for the Event Hierarchy Accounts

	Date	Hierarchy Account
	DATE <= 06/01/2004	MEDDRA61
06/01/2004	< DATE <= 01/01/2005	MEDDRA70
01/01/2005	< DATE	MEDDRA71

Add additional empty rows upon saving

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

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

- 10 Click **Save**.

Validating the Argus Mart data configurations

Validate the 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 Empirica Signal application, click **Settings**.
- 2 Click **Manage Configurations**.
- 3 Click **Validate Configurations**.
- 4 Select the 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**.

Publishing the Argus Mart data configurations

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

- 1 Click **Settings**.
- 2 Click **Manage Configurations**.
- 3 Click **Select Rows**.
- 4 Select the 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**.

Attaching PL/SQL Custom Procedure to Argus ETL Hook

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 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 Argus Mart, see the *Argus Mart Extensibility Guide*.

CHAPTER 4

Installing and configuring the Argus Mart signal management configuration

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About the Argus Mart signal management configuration

The Argus Mart signal management configuration defines the behavior and content of the Signals tab in the Empirica Signal application. For example, the signal management 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 Argus Mart signal management 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.

Installing the Argus Mart signal management configuration

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

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

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

- 2 Copy the **Argus_Prep_2_0_0_0_xxx.zip** file from the distribution media to:

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

- 3 Unpack the **Argus_Prep_2_0_0_0_xxx.zip** file into a temporary directory, for example:

```
$ unzip Argus_Prep_2_0_0_0_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**, 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_sigmgmt.sh** script to initiate the installation:

```
$ ./main_install_sigmgmt.sh <signal database account name>@<TNS_name>
```

where *<signal database account name>* is the Empirica Signal database user account name, for example, **webvdme**, and *<TNS_name>* is the TNS name that the application server uses to access the **<db>** server.

A password prompt appears.

- 9 Type **<password>**, where **<password>** is the Empirica Signal database user account password.

A second password prompt appears.

- 10 Retype **<password>**.

The database tables for the Argus Mart signal management configuration are populated. The **install_sigmgmt.log** file is created in the **sigdet/sigmgmt/install/log** subdirectory.

Note: If you type 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 following error message appears, the **Argus Signal Mgmt** project already exists:

```
ERROR at line 1:
ORA-00001: unique constraint (WEBVDME.UC_PROJECTS1) violated
```

You can disregard the error.

Note: To create more than one Argus Signal Management configuration for Argus Mart, repeat step 5.

Enabling signal management in the Empirica Signal application

Enable the **Show "Signals" tab** site option to turn on the signal management features in Empirica Signal.

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

- 1 Log in to the Empirica Signal application as a superuser.
- 2 Click **Settings**.
- 3 Click **Set Site Options**.
- 4 Select **Show "Signals" tab**.
- 5 Optionally, set the following signal management options:
 - Allow Free Text Signal Comments
 - Notes for Signal Management Interactions Graph
 - Drug-event combination comment length
- 6 Click **Save**.

Editing the Argus Mart signal management configuration

Review the default settings of the Argus Mart signal management configuration and change the settings as needed.

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

- 1 In the Empirica Signal application, click **Settings**.

- 2 Click **Manage Signal Configurations**.

The Manage Signal Configurations page appears.

- 3 Click the row menu for the Argus Mart signal management configuration you created in the previous procedure, and then click **Edit**.

The Edit Signal Configuration page appears.

- 4 Fill in the fields.

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

- 5 Click **Save**.

Empirica Signal validates the signal configuration. Warnings and errors are displayed at the top of the page.

Managing monitored drugs and signaling terms

The interactive signal management features in Empirica Signal enable you to define aspects of the Argus Mart signal management configuration such as:

- The drugs to monitor.
- Custom terms and designated medical events for the signal configuration.
- Targeted medical events and listed events for a monitored drug.

You must have the Manage Signaling Terms user permission to modify the list of monitored drugs and signaling terms.

- 1 In the Empirica Signal application, click **Signals**.

The Drug-Event Combinations page appears.

- 2 Click **Drug Overviews**.

The Drug Overviews page appears.

- 3 Edit the list of monitored drugs and signaling terms as needed.

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

Validating the Argus Mart signal management configuration

After you specify the list of monitored drugs and signaling terms for the Argus Mart signal management configuration, you validate the configuration to ensure that your changes are valid.

During validation, Empirica Signal checks the signal management 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, 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 management configuration.

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

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

- 1 In the Empirica Signal application, click **Settings**.
- 2 In the Configure System section, click **Manage Signal Configurations**.
- 3 Click the row menu for the signal configuration, and then click **Validate**.

The Signal Configuration Validation page appears.

- 4 Review the list of findings.
- 5 Click **Continue**.

Refreshing the Argus Mart signal management configuration

Refresh the Argus Mart signal management configuration to update the data in the Empirica Signal Signals tab.

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

You must have the Manage Signal Configuration and Create Data Mining Runs user permissions to initiate a refresh.

- 1 In the Empirica Signal application, click **Settings**.
- 2 Click **Manage Signal Configurations**.
- 3 Click the row menu for the Argus Mart signal management configuration, 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 Type one or more email addresses using a comma to separate each address.
The email addresses associated with your 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 Argus Mart data. After the status of the refresh changes to Completed, the contents of the Signals tab is updated.

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- **My Oracle Support** (<https://support.oracle.com>)—*Release Notes* and *Known Issues*.
- **Oracle Help Center** (<http://docs.oracle.com/en/industries/health-sciences/empirica-signal-topics/index.html>)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

If the software is available for download, the complete documentation set is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>).

All documents may not be updated for every Empirica Signal release. Therefore, the version numbers for the documents in a release may differ.

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>.

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support.

For phone support visit: <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html>.

To send an email use one of the following addresses:

For Japanese support: saasclinicalsupportjp_ww@oracle.com

For all other countries: saasclinicalsupport_ww@oracle.com

Documentation

Item	Description	Part number	Last updated
<i>Release Notes</i>	The <i>Release Notes</i> document provides descriptions of new features, enhancements, and bug fixes as well as system requirements.	E-84224-01	8.1.0.2
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in the release, along with workarounds, if available.	E70268-02	8.1
<i>User Guide and Online Help</i>	The <i>User Guide and Online Help</i> provides step-by-step instructions on how to use the Empirica Signal and Empirica Topics applications to perform statistical analyses of safety data.	E70269-01	8.1
<i>Installation and Upgrade Instructions</i>	The <i>Installation and Upgrade Instructions</i> document provides instructions on how to install and configure the environment for the Empirica Signal software.	E-84237-01	8.1.0.2
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides guidance and recommendations on securely installing, configuring, and managing the Empirica Signal software and its system components.	E60408-01	8.1
<i>Topics API Guide</i>	The <i>Topics API Guide</i> describes how to integrate a proprietary application with Empirica Topics.	E77813-01	8.1
<i>Topics Reporting and Oracle Business Intelligence Configuration Guide</i>	The <i>Topics Reporting and Oracle Business Intelligence Configuration Guide</i> provides system requirements and configuration instructions for integrating OBIEE with the Empirica Signal application.	E60409-01	8.1
<i>Argus Mart Data and Argus Signal Management Installation Instructions</i>	The <i>Argus Mart Data and Argus Signal Management Installation Instructions</i> describe how to import proprietary data maintained in Argus Mart to Empirica Signal and how to install and configure Argus signal management.	E87283-01	8.1.0.2
<i>Argus Mart Data and Argus Signal Management Release Notes</i>	The <i>Argus Mart Data and Argus Signal Management Release Notes</i> describe new features, enhancements, and bug fixes to the Argus Mart data configurations for Empirica Signal. They also document the Argus Mart data tables available to Empirica Signal and the default signal management configuration.	E76553-01	8.1

Item	Description	Part number	Last updated
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes licenses and notices for third party technology that may be included or distributed with the Empirica Signal software.	E78170-01	8.1
