

# Oracle Life Sciences Empirica

## FDA AERS Signal Management Release

### Notes



Release 9.2.3  
F87387-01

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# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

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# 1

## FDA AERS Signal Management Release Notes

- [Introduction](#)  
These release notes describe interactive FDA AERS Signal Management for use with Oracle Empirica Signal version 9.2.x.x with FDA AERS data 2017Q3 or later.
- [New in AERS Signal Management for the Oracle Empirica Signal 9.2.3 Release](#)  
No new features have been added to the AERS Signal Management 9.2.3 release.
- [New in FDA AERS Signal Management for the Oracle Empirica Signal 9.2.2.1 Release](#)  
The default Subset variable for FDA AERS signal history has been changed from `FDA_Quarter` to `FDA_Quarter_Init`.
- [New in AERS Signal Management for the Oracle Empirica Signal 9.2 Release](#)  
No new features have been added to the AERS Signal Management 9.2 release.
- [New in AERS Signal Management for the Oracle Empirica Signal 9.1 Release](#)  
After upgrading AERS Signal Management 9.0 for use with Oracle Empirica Signal 9.1, signal configurations will support a Detailed Comment column in Product-Event Combinations tables.
- [New in AERS Signal Management for the Oracle Empirica Signal 9.0 Release](#)  
After upgrading AERS Signal Management 8.x for use with Oracle Empirica Signal 9.0, signal configurations will support configurable alert types.
- [New in AERS Signal Management for the Oracle Empirica Signal 8.1.1 Release](#)  
This section describes what is new in interactive AERS Signal Management (version 2.x) relative to the prior scripted AERS Signal Management (version 1.x).

### Introduction

These release notes describe interactive FDA AERS Signal Management for use with Oracle Empirica Signal version 9.2.x.x with FDA AERS data 2017Q3 or later.

Interactive FDA AERS Signal Management is the Signal Management feature of Oracle Empirica Signal as used with the FOI (Freedom of Information) FDA spontaneous adverse event reports (FAERS) database. Oracle refers to this data as AERS. The AERS database includes all SRS (pre-1997) and AERS data for all medical products licensed for marketing in the US and is updated and released quarterly by the FDA.

Oracle prepares quarterly AERS data for use with Oracle Empirica Signal. Each quarter, your system administrator installs the new AERS data and runs a set of MGPS data mining runs to refresh the statistics reported by Signal Management, including report counts (N) and EB05, EBGM, and EB95 scores. These release notes describe the database restrictions that identify subpopulations or types of cases within the AERS database, the data mining runs that are used to produce scores reported by Signal Management, and the options you have for displaying the AERS data and generated statistics in Signal Management.

For more information on a quarterly AERS data release, please refer to the `FDA AERS Data Release Notes.pdf` file distributed with the release. That document describes the preparation of AERS data for use with Oracle Empirica Signal, including Oracle tables and

table views, record counts, duplicate removal, standard data configurations, and a complete data mining table schema.

## New in AERS Signal Management for the Oracle Empirica Signal 9.2.3 Release

No new features have been added to the AERS Signal Management 9.2.3 release.

Upgrade of AERS signal management configurations is done via the upgrade to Signal 9.2.3.

## New in FDA AERS Signal Management for the Oracle Empirica Signal 9.2.2.1 Release

The default Subset variable for FDA AERS signal history has been changed from `FDA_Quarter` to `FDA_Quarter_Init`.

Prior to the change, the default subset variable was `FDA_QUARTER`. `FDA_Quarter` represents the quarter year corresponding to the FDA receipt date. This value changes with a case follow-up. This change could make it difficult to locate a case from one refresh to the next, since the case's subset value may have changed.

For new FDA AERS signal configuration installations, the default subset variable is now `FDA_Quarter_Init`. `FDA_Quarter_Init` represents the quarter year corresponding to initial FDA receipt date. This value does not change. Therefore, a case remains in the same subset with each refresh.

For existing FDA AERS signal configuration installations, the subset variable for signal history can be modified by editing the signal configuration.

## New in AERS Signal Management for the Oracle Empirica Signal 9.2 Release

No new features have been added to the AERS Signal Management 9.2 release.

None of the fixes we have applied to the 9.2 release affect the user workflow or the application's functionality. No new features have been added and the upgrade does not affect users working with AERS Signal Management for use with Oracle Empirica Signal.

## New in AERS Signal Management for the Oracle Empirica Signal 9.1 Release

After upgrading AERS Signal Management 9.0 for use with Oracle Empirica Signal 9.1, signal configurations will support a Detailed Comment column in Product-Event Combinations tables.

### **Detail Comment column added to Product-Event Combinations table**

The Detailed Comment column contains details of the most recent comment entered for the product-event combination.

You must enable the **Allow Free Text Signal Comments** site option, you can include a **Detailed Comment** column on the Product-Event Combinations table. The detailed comment also appears on the View Event Comments page selected from a product's **Row Action Menu**.

Depending on your **Allow Free Text Signal Comments** site option setting, the comment may be truncated in the Product-Event Combinations table. However, the entire content of the Detailed Comment downloads.

For more information, see Set site options in the *User Guide and Online Help*.

## New in AERS Signal Management for the Oracle Empirica Signal 9.0 Release

After upgrading AERS Signal Management 8.x for use with Oracle Empirica Signal 9.0, signal configurations will support configurable alert types.

Configurable alert types are based on Review period or Complexity level/ periodicity. This allows for the scheduling of an alert based on the product properties of review period, complexity level, and birthdate.

Alert types can be informational or tracked. The Signal Review page measures the user's tracked alert review progress with review/total counts and graphical displays. When the user completes Submit Review on a product-event combination for which there is at least one un-reviewed alert, the tracked alert reviewed counts and alert graphs update to reflect that the tracked alert(s) have been reviewed. Informational alerts counts are static and do not contribute to the product's alerts reviewed progress. By default, all standard alerts are review-period-based and informational. The standard set of configurable alerts types can be modified and permissioned users can configure new alert types.

New standard product properties are available: Display name, Category, Complexity level, Birthdate, and Organization. Complexity level and Birthdate contribute to Complexity level-based alert types. Signal administrators define acceptable values for: Category, Complexity level, and Organization.

After upgrading AERS Signal Management 8.x for use with Oracle Empirica Signal 9.0, the view category, Drug Overview Alerts, will be referred to as Product Alerts.

- [20002214 - Open views reference Pending Case Review](#)  
Previously, the "Open signals" and "Open signals - new cases" views referenced an obsolete comment type, "Pending Case Review," in the SQL WHERE clause.
- [28931081 - Only first review period views are populated](#)  
Previously, views were only populated for the signal configuration's first review period. This made it difficult to enable and use the Review Periods feature.
- [29319493 - Distinguish between Comments & Private Comment Column Types](#)  
Previously, in the AERS signal configuration, the Drug-Event Columns table referenced column type Note for both Comments and Private Comments and column type Note Date for both Comment Dates and Private Comment Dates.

### 20002214 - Open views reference Pending Case Review

Previously, the "Open signals" and "Open signals - new cases" views referenced an obsolete comment type, "Pending Case Review," in the SQL WHERE clause.

This issue has been fixed. The "Open signals" and "Open signals - new cases" views now reference the comment type, "Bring to Meeting," in the SQL WHERE clause.



## 28931081 - Only first review period views are populated

Previously, views were only populated for the signal configuration's first review period. This made it difficult to enable and use the Review Periods feature.

This issue has been fixed. Alert views are now populated for all of the signal configuration's review periods.

## 29319493 - Distinguish between Comments & Private Comment Column Types

Previously, in the AERS signal configuration, the Drug-Event Columns table referenced column type Note for both Comments and Private Comments and column type Note Date for both Comment Dates and Private Comment Dates.

This issue has been fixed. The Product-Event Columns table now uses column types Note, Note Date, Private Note, and Private Note Date for the columns Comment, Comment Date, Private Comment, and Private Comment Date, respectively.

# New in AERS Signal Management for the Oracle Empirica Signal 8.1.1 Release

This section describes what is new in interactive AERS Signal Management (version 2.x) relative to the prior scripted AERS Signal Management (version 1.x).

With interactive AERS Signal Management, you can:

- Manage list of drugs to monitor and signaling terms from within the application rather than externally.
- Initiate a refresh from within the application rather than externally.
- Use newly added Female and Male subpopulations and alerts.
- Use review periods.

Underlying column names that were similar to US\_N\_SINCE\_PRIORn are now called USNEW\_N\_PRIORn, and Keep Under Review (KUR) events have been renamed as Targeted Medical Events (TMEs).

Additionally, a mechanism for converting an existing scripted signal configuration to a new interactive signal configuration is available. For more information, see:

- [Ability to convert an AERS signal configuration from scripted to interactive](#)  
A mechanism for converting a scripted signal configuration to a new interactive signal configuration is available.

## Ability to convert an AERS signal configuration from scripted to interactive

A mechanism for converting a scripted signal configuration to a new interactive signal configuration is available.

The conversion will preserve:

- Monitored drug list.

- Keep under review (KUR) events, which are referred to as **Targeted Medical Events (TMEs)** in interactive Signal Management.
- Listed (labeled) events.
- Designated medical events.
- Custom drug and event terms.
- Reviewer assignments for drugs and drug-event combinations.
- Custom comment types.
- Comment history (both public and private) for drug-event combinations.
- Associated topics for drug-event combinations.
- Drug notes.
- Custom views for the Drug-Event Combinations page including publication status.
- Signal configuration properties including name, description, integrated topic workflow configuration and topic product field, default view, and properties for runs including the drug variable, event variables for 2D and 3D runs, stratification and subset variables, and the project for runs.

The conversion will not preserve:

- Customizations to Drug Overviews column labels, tooltips, or to associated views.
- Customizations to Drug-Event Combinations column labels or tooltips.
- Information that distinguishes "Ongoing" from "\*\*\*NEW\*\*" alerts. Following the first refresh after conversion, all alerts appear as "\*\*\*NEW\*\*". The Oracle Empirica Signal application makes the distinction between "Ongoing" and "\*\*\*NEW\*\*" for subsequent refreshes.
- KUR Only events. Interactive AERS Signal Management cannot limit the events monitored for a drug to only those that are in the Keep Under Review list. All events will be monitored.
- Any changes not yet processed in a refresh of your scripted AERS Signal Management. For example, drugs to add, rename, or delete, or changes to listed (labeled), designated medical, or KUR events.

For more information, see *AERS Signal Management for User with Empirica Signal 9.0 Installation Instructions* .

# 2

## Standard AERS Signal Configuration

- [Standard AERS Signal Configuration](#)  
This section describes the standard attribute values for the AERS signal configuration. Your organization can modify these values as needed.

### Standard AERS Signal Configuration

This section describes the standard attribute values for the AERS signal configuration. Your organization can modify these values as needed.

The AERS signal configuration is compatible with data sources identified as NTIS Public Release (the value for SOURCE in the SOURCE\_INFO table in the AERS data account).

If you convert your scripted signal configuration to an interactive signal configuration, all defaults other than **Type**, **Publish data mining runs**, and **Allow reviewers to manage their drugs's reference data**, will inherit the values from the scripted signal configuration.

Attribute	Standard Value for AERS Signal Management
Name	AERS Signal Configuration
Description	AERS Signal Management Configuration
Type	Interactive
Default signal view	Open signals with new cases 3-Months
Topic workflow configuration	N/A
Topic product field	N/A
Versioned case series	N/A
Disable default view	No (unchecked)
Disable review period	Yes (checked)
Disable private comment	Yes (checked)
Data configuration for 2D runs	Latest AERS+SRS (S) (alias for most recent AERS+SRS (S))
Data configuration for 3D runs	Latest AERS+SRS (S + C) (alias for most recent AERS+SRS (S + C))
Drug variable	Generic_Name
Event variable for 2D runs	PT_plus_Narrow_Alg_SMQ
Event variable for 3D runs	PT
Stratification variables	STANDARD_STRAT
Subset variable for signal history	FDA_Quarter
Subset variable for Nsince counts	Data Load
Project for data mining runs	AERS Signal Mgmt
Publish data mining runs	No (unchecked)

Attribute	Standard Value for AERS Signal Management
Allow reviewers to manage their drug's reference data	Yes (checked)

# 3

## Standard AERS Subpopulations

- [Standard AERS Subpopulations](#)

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the AERS database. For comparison, it also reports the results of statistical analysis performed only on reports with certain shared characteristics within the database: for example, reports involving elderly individuals only, or reports with a fatal outcome only.

### Standard AERS Subpopulations

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the AERS database. For comparison, it also reports the results of statistical analysis performed only on reports with certain shared characteristics within the database: for example, reports involving elderly individuals only, or reports with a fatal outcome only.

To identify different subpopulations and types of cases in the AERS database, a set of standard queries is supplied and then used as database restrictions in data mining runs.

The standard subpopulations or types of cases used for Signal Management are:

Population	Default Query
Adult	AgeGroup4 equals '18_64'
Elderly	AgeGroup4 equals '65_above'
Fatal	Outcome Died equals 'YES'
Female	Gender equals 'F'
Male	Gender equals 'M'
Pediatric	AgeGroup4 equals '00_17'
Serious	Seriousness equals 'YES'

# 4

## Standard Data Mining Runs

To assemble data mining counts and statistics that can be compared over time, AERS Signal Management includes 22 data mining runs. All runs are refreshed as part of preparing a quarterly Signal Management update.

All of the standard data mining runs for Signal Management are MGPS runs that are limited to the set of monitored drugs. These runs are assigned to the project referenced in the signal configuration. The default name of this project is `AERS Signal Mgmt.`

If your user role includes access to the Data Mining Results tab in Oracle Empirica Signal, you can view complete run details for any run. Click the Data Mining Results tab, select the data mining run from the drop-down list, and then click **View Run Details**.

The following types of runs are included:

- [Data Mining Runs Producing Disproportionality Scores](#)  
Oracle Empirica Signal performs the following data mining runs to calculate disproportionality scores for drug-event terms for various subpopulations. Signal executes these runs on the data configuration specified for **Data configuration for 2D runs** in the signal configuration, and names the runs in accordance with that data configuration.
- [Data Mining Runs for New or Changed Cases](#)  
The cumulative subset data mining runs identify new and significantly changed reports relative to prior time periods. Oracle Empirica Signal executes these runs on the Data configuration for 2D runs from the signal configuration, and names the runs in accordance with that Data configuration.
- [Data Mining Runs for SOC and HLT Scores](#)  
Oracle Empirica Signal performs the following data mining runs to compute disproportionality scores at the SOC and HLT levels of the MedDRA event hierarchy for All reports and for US reports. Signal executes these runs on the Data configuration for 2D runs from the signal configuration, and names them in accordance with that Data configuration.
- [Data Mining Run for Viewing Interactions](#)  
Oracle Empirica Signal executes a three-dimensional MGPS data mining run to investigate Drug-Drug-Event interactions between reports that may merit further investigation.

### Data Mining Runs Producing Disproportionality Scores

Oracle Empirica Signal performs the following data mining runs to calculate disproportionality scores for drug-event terms for various subpopulations. Signal executes these runs on the data configuration specified for **Data configuration for 2D runs** in the signal configuration, and names the runs in accordance with that data configuration.

For example, if the data configuration specified under **Data configuration for 2D runs** is `2017Q3: AERS+SRS (S)`, or an alias for `2017Q3: AERS+SRS (S)`, then the All run will be named `2017Q3: AERS+SRS (S) - All`. If the data configuration specified under **Data configuration for 2D runs** is `2017Q3: AERS (S+C)`, or an alias for `2017Q3: AERS (S+C)`, then the All run will be named `2017Q3: AERS (S+C) - All`.

The runs use the Drug and Event variables for the 2D runs from the signal configuration as item variables.

The runs are stratified using the Stratification variables from the signal configuration.

In the descriptions that follow, the values shown in angle brackets (<>) represent values from the AERS signal configuration.

- [All](#)  
Oracle Empirica Signal executes this data mining run using all reports in AERS.
- [Adult only](#)  
This data mining run is restricted to adult reports only.
- [Elderly only](#)  
This data mining run is restricted to elderly reports only.
- [Fatal only](#)  
This data mining run is restricted to reports with a fatal outcome only.
- [Female only](#)  
This data mining run is restricted to female reports only.
- [Male only](#)  
This data mining run is restricted to male reports only.
- [Pediatric only](#)  
This data mining run is restricted to pediatric reports only.
- [Serious only](#)  
This data mining run is restricted to serious reports only.
- [US only](#)  
This data mining run is restricted to reports from US only.

## All

Oracle Empirica Signal executes this data mining run using all reports in AERS.

Field	Description
Database restriction:	None
Subsets:	Variable: <subset variable for signal history> Cumulative: Yes Order: Forward Labels: [1968Q1]-[<6 years ago>] [1968Q1]-[<5 years ago>] [1968Q1]-[<4 years ago>] [1968Q1]-[<3 years ago>] [1968Q1]-[<2 years ago>] [1968Q1]-[<1 year ago>] [1968Q1]-[<3 quarters ago>] [1968Q1]-[<2 quarters ago>] [1968Q1]-[<1 quarter ago>] [1968Q1]-[<most recent quarter>]
Minimum count:	1

Field	Description
PRR and ROR:	Includes non-stratified PRR and ROR; Counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Adult only

This data mining run is restricted to adult reports only.

Field	Description
Database restriction:	AgeGroup4 equals '18_64'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Elderly only

This data mining run is restricted to elderly reports only.

Field	Description
Database restriction:	AgeGroup4 equals '65_above'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Fatal only

This data mining run is restricted to reports with a fatal outcome only.

Field	Description
Database restriction:	Outcome Died equals 'YES'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated



Field	Description
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Female only

This data mining run is restricted to female reports only.

Field	Description
Database restriction:	Gender equals 'F'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Male only

This data mining run is restricted to male reports only.

Field	Description
Database restriction:	Gender equals 'M'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Pediatric only

This data mining run is restricted to pediatric reports only.

Field	Description
Database restriction:	AgeGroup4 equals '00_17'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes

Field	Description
Fit separate distributions:	Yes

## Serious only

This data mining run is restricted to serious reports only.

Field	Description
Database restriction:	Seriousness equals 'YES'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## US only

This data mining run is restricted to reports from US only.

Field	Description
Database restriction:	US Report equals 'YES'
Subsets:	Variable: <Subset variable for signal history> Cumulative: Yes Order: Forward Labels: [1968Q1]-[<6 years ago>] [1968Q1]-[<5 years ago>] [1968Q1]-[<4 years ago>] [1968Q1]-[<3 years ago>] [1968Q1]-[<2 years ago>] [1968Q1]-[<1 year ago>] [1968Q1]-[<3 quarters ago>] [1968Q1]-[<2 quarters ago>] [1968Q1]-[<1 quarter ago>] [1968Q1]-[<most recent quarter>]
Minimum count:	1
PRR and ROR:	Includes non-stratified PRR and ROR; counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Data Mining Runs for New or Changed Cases

The cumulative subset data mining runs identify new and significantly changed reports relative to prior time periods. Oracle Empirica Signal executes these runs on the Data configuration for 2D runs from the signal configuration, and names the runs in accordance with that Data configuration.

The runs use the Drug and Event variables for the 2D runs from the signal configuration as item variables.

The runs are stratified using the Stratification variables from the signal configuration.

In the descriptions that follow, the values shown in angle brackets (<>) represent values from the AERS signal configuration.

- [All New](#)  
This run computes new or changed counts for all reports in AERS.
- [New Elderly](#)  
This run computes new or changed counts for elderly reports only.
- [New Fatal](#)  
This run computes new or changed counts for reports with a fatal outcome only.
- [New Female](#)  
This run computes new or changed counts for female reports only.
- [New Male](#)
- [New Pediatric](#)  
This run computes new or changed counts for pediatric reports only.
- [New Serious](#)  
This run computes new or changed counts for serious reports only.
- [New US](#)  
This run computes new or changed counts for reports from US sources only.

### All New

This run computes new or changed counts for all reports in AERS.

Field	Description
Database restriction:	None
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No

Field	Description
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Elderly

This run computes new or changed counts for elderly reports only.

Field	Description
Database restriction:	AgeGroup4 equals '65_above'
Subsets:	Variable: <Subset variable for Nsince counts>Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Fatal

This run computes new or changed counts for reports with a fatal outcome only.

Field	Description
Database restriction:	Outcome Died equals 'YES'
Subsets:	Variable: <Subset variable for Nsince counts>Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Female

This run computes new or changed counts for female reports only.

Field	Description
Database restriction:	Gender equals 'F'
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Male

This run computes new or changed counts for male reports only.

Field	Description
Database restriction:	Gender equals 'M'
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Pediatric

This run computes new or changed counts for pediatric reports only.

Field	Description
Database restriction:	AgeGroup4 equals '00_17'
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New Serious

This run computes new or changed counts for serious reports only.

Field	Description
Database restriction:	Seriousness equals 'YES'
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## New US

This run computes new or changed counts for reports from US sources only.

Field	Description
Database restriction:	US Report equals 'YES'

Field	Description
Subsets:	Variable: <Subset variable for Nsince counts> Cumulative: Yes Order: Forward Labels: ChgsSince[<1 quarter ago>] ChgsSince[<2 quarters ago>] ChgsSince[<3 quarters ago>] ChgsSince[<1 year ago>]
Minimum count:	1
PRR and ROR:	Not calculated
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Data Mining Runs for SOC and HLT Scores

Oracle Empirica Signal performs the following data mining runs to compute disproportionality scores at the SOC and HLT levels of the MedDRA event hierarchy for All reports and for US reports. Signal executes these runs on the Data configuration for 2D runs from the signal configuration, and names them in accordance with that Data configuration.

The runs use the Drug variable from the signal configuration as one of the item variables. Also, the runs are stratified using the Stratification variables from the signal configuration.

- [All reports, SOC](#)  
This data mining run computes disproportionality scores at the SOC level of the MedDRA hierarchy using all reports in AERS.
- [All reports, HLT](#)  
This data mining run computes disproportionality scores at the HLT level of the MedDRA hierarchy using all reports in Vigibase.
- [US reports, SOC](#)  
This SOC-level run is restricted to US reports only.
- [US reports, HLT](#)  
This HLT-level run is restricted to US reports only.

### All reports, SOC

This data mining run computes disproportionality scores at the SOC level of the MedDRA hierarchy using all reports in AERS.

Field	Description
Item Variables:	<Drug variable>, SOC
Database restriction:	None
Subsets:	None
Minimum Count:	1

Field	Description
PRR and ROR:	Includes non-stratified PRR and ROR; counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## All reports, HLT

This data mining run computes disproportionality scores at the HLT level of the MedDRA hierarchy using all reports in Vigibase.

Field	Description
Item Variables:	<Drug variable>, HLT
Database restriction:	None
Subsets:	None
Minimum Count:	1
PRR and ROR:	Includes non-stratified PRR and ROR; counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## US reports, SOC

This SOC-level run is restricted to US reports only.

Field	Description
Item Variables:	<Drug variable>, SOC
Database restriction:	US Report equals 'YES'
Subsets:	None
Minimum Count:	1
PRR and ROR:	Includes non-stratified PRR and ROR; counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## US reports, HLT

This HLT-level run is restricted to US reports only.



Field	Description
Item Variables:	<Drug variable>, HLT
Database restriction:	US Report equals 'YES'
Subsets:	None
Minimum Count:	1
PRR and ROR:	Includes non-stratified PRR and ROR; counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## Data Mining Run for Viewing Interactions

Oracle Empirica Signal executes a three-dimensional MGPS data mining run to investigate Drug-Drug-Event interactions between reports that may merit further investigation.

- [3D, All reports](#)

### 3D, All reports

Field	Description
Configuration:	<Data configuration for 3D runs>
Item Variables:	<Drug variable>, <Event variable for 3D runs>
Database restriction:	None
Subsets:	None
Strata Variables:	<Stratification variables>
Minimum count:	5
PRR and ROR:	Not calculated
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

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## Viewing Data and Scores in Oracle Empirica Signal

- [Standard Alert Types](#)  
For each configured alert, there is one alert type, plus four predefined rules (one for each review period).
- [Products Page](#)  
You access all the functions you can perform on an individual product from the Products page.
- [Product-Event Combinations Page](#)  
The Product-Event Combinations page is organized into panels that provide easy access to a variety of functions and comprehensive product-event information and statistics. You don't have to drill down through menus and pages to get to the function you want to perform.
- [Columns on the Product-Event Combinations table](#)  
In Signal Review in Oracle Empirica Signal, the Product-Event Combinations page displays a table with rows for product-event combinations and columns for data and statistics.
- [Standard Comments](#)  
You can add a comment to a combination on the Product-Event Combinations page.
- [Standard Signal Views](#)  
A signal view is a predefined set of columns and sorting preferences that you can apply to the Product-Event Combinations table. In addition, a signal view may contain a SQL expression to limit the rows that display in the table to product-event combinations that meet certain criteria.
- [Signal Sets](#)  
There are two signal sets for AERS Signal Management: All reports and reports from US sources only.

### Standard Alert Types

For each configured alert, there is one alert type, plus four predefined rules (one for each review period).

The condition for each standard alert type rule matches the Where Clause in its corresponding user-accessible view.

The view for each alert type rule is a hidden view with columns and sort the same as its corresponding user-accessible view and Where Clause of the form <alert type name>\_ALERT is not null.

By default, the standard alert types are informational, and scheduled by Review Period. The AERS Signal Management-specific standard alert types include the following:

- SDR
- FATAL

- DME
- TME
- PEDIATRIC
- ELDERLY
- NEW
- SERIOUS
- FEMALE
- MALE
- INTERACT

## Products Page

You access all the functions you can perform on an individual product from the Products page.

1. In Oracle Empirica Signal, from the navigation pane on the left, click the **Signal Review**

icon ()

The Products page appears and contains:

- **Products By drop-down and cards:** Using the Products By drop-down list, you can group the products you are tracking by product group, category, complexity, organization, or assigned reviewer. The grouping is reflected in the cards displayed below the Products By drop-down. For each grouping, there is a card that includes all products as well as the individual elements of the grouping. You can move back and forth through the cards with the dots below them or the right-arrow at the right. Selecting a card updates the graphic details panel and filters the Products table.
- **Products table:** Below the cards is a table containing the individual products that match the Products By filter. If you select the All card, all monitored products appear. If you select a product group card, only the products in that group appear. The graphic details on the right update to match the selection.
- **Graphic details panel:** To the right of the Products By panel and the Products table is a summary panel of either the selected Products By card or the selected Product. The panel contains sections that can be expanded or collapsed. The sections available depend on the selected item and the signal configuration. The Tracked Alerts and Informational Alerts sections are always available. The Open Topics section is available if your signal configuration is integrated with Topics. The Notes section is available when you select a Product. You can show or hide the sections in the graphic details panel.


The following table lists the AERS Signal Management-specific alert columns that you can display in the Products table in default order.

Column Name	Column Description
Drug	Drug term
SDR	Number of unlisted events with new reports and EB05 >= 2
FATAL	Number of events with new fatal reports since the prior period
DME	Number of designated medical events with new reports since the prior period

Column Name	Column Description
TME	Number of intensively monitored events (targeted medical events) with new reports since the prior period
PEDIATRIC	Number of events newly exceeding threshold [EB05(peds)>=2 and EB05(peds)>EB95(adult)] since the prior period (where peds = ages 0 through 17, and adult = ages 18 through 64)
ELDERLY	Number of events newly exceeding threshold [EB05(elderly)>=2 and EB05(elderly)>EB95(adult)] since the prior period (where adult = ages 18 through 64, and elderly = ages 65 and above)
NEW	Number of events with new reports since the prior period
SERIOUS	Number of events with new serious reports since the prior period
FEMALE	Number of events newly exceeding threshold [EB05(female)>=2 and EB05(female)>EB95(male)] since the prior period
MALE	Number of events newly exceeding threshold [EB05(male)>=2 and EB05(male)>EB95(female)] since the prior period
INTERACT	Number of events newly exceeding threshold [INTSS>2] since the prior period

## Product-Event Combinations Page

The Product-Event Combinations page is organized into panels that provide easy access to a variety of functions and comprehensive product-event information and statistics. You don't have to drill down through menus and pages to get to the function you want to perform.

- In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon (). The Products page appears.
- Click a product name or an alert count. The Product-Event Combinations page appears. This page contains:
  - Product Summary information (across the top and always on display):** Product statistics appear here and include the product name, product group, percentage reviewed gauge, reviewed tracked alerts/total tracked alerts, and the number of pending alerts, open topics (only available if the selected signal configuration is integrated with Topics), and comments. Under the product name is the selected Products By card.
  - System Organ Class (SOC) cards:** The cards represent the alerts grouped by MedDRA system organ class. The counts represent tracked alerts Reviewed/Total. Selection of a card filters the Product-Event Combinations table.
  - Product-Event Combinations table:** Lists the product-event details for the selected product. The number of product-event combinations appear in a row above the table and includes the total number of product-event combinations, the sort order, and the number of rows per page and the page number.

By default, each tab represents an alert. The rows and columns displayed in the tab's table are defined by the alert's view and further filtered by the card selection. You can add tabs and customize the columns.

- To select the columns to display, click the **Header Action menu** (⋮), and then click **Columns**.  
For information on each column that you can select, rest the cursor on a column heading to display a description.

## Columns on the Product-Event Combinations table


In Signal Review in Oracle Empirica Signal, the Product-Event Combinations page displays a table with rows for product-event combinations and columns for data and statistics.

To select columns to display in this table, click **Columns** (or **Columns and Rows**) and enter your selection criteria in the window that appears.

If you hover the cursor over a column heading on the Product-Event Combinations table, a tooltip shows the column description followed by the corresponding database column name in square brackets. You can use these database column names to write SQL Where clauses that restrict the rows on the Product-Event Combinations table.

## Standard Comments

You can add a comment to a combination on the Product-Event Combinations page.

- In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ()
- Click the product-event combination's **Row Action menu** (⋮), and then select **Submit Review**.
- Select a comment from a predefined list of standard comments.
- (Optional) If your system supports free text comments, enter additional detailed comments.

The following table lists the standard comments that you can select, along with the abbreviated version that displays in the Comment column on the Product-Event Combinations page. Your organization may have modified these.


Comment Text	Abbreviated Comment Text
Closed Labeled	Labeled
Closed Indication Related	Indication Related
Closed Uninformative	Uninformative
Closed Prior Review	Prior Review
Closed Team Meeting	Team Meeting
Open Bring to Meeting	Bring to Meeting
Open Pending Further Information	Pending Further Info
Open Of Note	Of Note
Open Topic	Topic

## Standard Signal Views

A signal view is a predefined set of columns and sorting preferences that you can apply to the Product-Event Combinations table. In addition, a signal view may contain a SQL expression to limit the rows that display in the table to product-event combinations that meet certain criteria.

The following table lists the set of standard, predefined signal views that are available for AERS Signal Management. You can also create your own. To see a list of available views, click the **Add Tab** button.

### Tip:

If you have set the user preference for allowing SQL Where Clause for viewing signals, you can review the SQL statement used to select the rows for an added tab by selecting **Columns** from the Product-Event Combinations **Header Action menu** ().

### Note:

By default, the standard signal views do not take the Filter flag into consideration. If you want to exclude suppressed combinations from a particular view, put parentheses around the existing SQL Where Clause and add the following:

and (FILTER is NULL or FILTER='NO')

For example, if you want the DME Alert view to exclude suppressed combinations, change its SQL Where Clause from

DME\_ALERT is not NULL

to

(DME\_ALERT is not NULL) and (FILTER is NULL or FILTER='NO').

The standard signal views are grouped in two categories:

- Product Alerts
- Supplemental Views

The Product Alerts category includes the following views for each review period. The table shows 3-Months views as an example.

Name	Description
DME alert 3-Months	All designated medical events reported for the selected drug, for which there have been one or more new reports in the last 3-Months.
Elderly alert 3-Months	All events for which [EB05(elderly) >= 2 and EB05(elderly) > EB95(adult)].
Fatal alert 3-Months	All events reported for the selected drug, for which there have been one or more new fatal reports in the last 3-Months.

Name	Description
Female alert 3-Months	All events for which [EB05(female) >= 2 and EB05(female) > EB95(male)].
Interaction alert 3-Months	All events for which there is a drug-drug-event interaction signal score (INTSS) > 2.
Male alert 3-Months	All events for which [EB05(male) >= 2 and EB05(male) > EB95(female)].
Pediatric alert 3-Months	All events for which [EB05(peds) >= 2 and EB05(peds) > EB95(adult)].
Serious alert 3-Months	All events reported for the selected drug, for which there have been one or more new serious reports in the last 3-Months.
TME alert 3-Months	All "targeted medical event" combinations for which there have been one or more new reports in the last 3-Months.

The Supplemental Views include the following views for each review period. The table shows 3-Months views as an example.

Name	Description
All 3-Months	All events reported for the selected drug, ordered by SOC, then by descending EB05.
All DME 3-Months	All designated medical events reported for the selected drug, ordered by SOC, then by descending EB05.
All signals 3-Months	All events reported for the selected drug for which either EB05 >=2 or there is a non-null comment. (A non-null comment is taken to indicate that, even if the current EB05 is < 2, the drug-event combination was considered to be a signal sometime in the past or that a reviewer has marked it as a signal during the current review period.) The list is ordered by SOC, then by descending EB05.
All signals with new cases 3-Months	All events reported for the selected drug with new reports in the last 3-Months for which either EB05 >=2 or there is a non-null comment. (A non-null comment is taken to indicate that, even if the current EB05 is < 2, the drug-event combination was considered to be a signal sometime in the past or that a reviewer has marked it as a signal during the current review period.) The list is ordered by SOC, then by descending EB05.
All SMQ 3-Months	All SMQ (Standardized MedDRA Queries) terms for the selected drug, in descending order by EB05.
All TME 3-Months	All targeted medical events reported for the selected drug, ordered by SOC, then by descending EB05.
All trend 3-Months	All events with EB05 >= 1.5 and either Trend1=YES (EBGM increasing and non-overlapping CI relative to 3-Months ago) or Trend2=YES (50% increase in EBGM over 3-Months ago). The list is ordered by SOC, then by descending EB05.

Name	Description
All with new cases 3-Months	All events for the selected drug for which there have been one or more new reports in the last 3-Months. The list is ordered by SOC, then by descending EB05.
Closed signals 3-Months	All events reported for the selected drug for which the associated comment indicates that the signal has been explicitly closed. The list is ordered by SOC, then by descending EB05.
Closed signals with new cases 3-Months	All events reported for the selected drug for which the associated comment indicates that the signal has been explicitly closed and for which there are new reports in the last 3-Months. The list is ordered by SOC, then by descending EB05.
Open signals 3-Months	All events reported for the selected drug for which one of the following is true: 1) there is a comment which is not one of the comments indicating signal closure; or 2) EB05 >=2 and the comment, if present, is not one of the comments indicating signal closure. The list is ordered by SOC, then by descending EB05.
Open signals with new cases 3-Months	All events reported for the selected drug with new reports in the last 3-Months for which one of the following is true: 1) there is a comment which is not one of the comments indicating signal closure; or 2) EB05 >=2 and the comment, if present, is not one of the comments indicating signal closure. The list is ordered by SOC, then by descending EB05.
New alert 3-Months	All events for the selected drug for which there have been one or more new reports in the last 3-Months.
SDR alert 3-Months	Statistic/Signal of Disproportionate Reporting - Events with new reports in the last 3-Months which (1) have an EB05 score >=2, (2) are not flagged as listed and (3) the comment, if present, is not one of the comments indicating signal closure/dismissal.

Additionally, Supplemental Views includes one view that is not review-period specific.

Name	Description
Filtered	Rows limited to drug-event combinations with Filter = Yes.

## Signal Sets



There are two signal sets for AERS Signal Management: All reports and reports from US sources only.

The signal sets for AERS Signal Management are:

- All—All reports in the Data configuration for 2D runs specified in the signal configuration.
- US—Reports from US sources only.



To view a confidence interval trend graph and other information about a combination on the Product-Event Combinations page:

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ().
2. In the Products table, click the product name.
3. On the Product-Event Combinations page, from product-event combination's **Row Action** menu () , click **View Signal History**.

Information for the two signal sets displays in Signal History as follows:

Signal History	All Signal Set	US Signal Set
Show Confidence Interval Trend graph	Yes	Yes
Show HLT-level disproportionality scores	Yes	Yes
Show SOC-level disproportionality scores	Yes	Yes
Show MGPS statistics	Yes	Yes
Show PRR statistics	N/A	N/A
Show ROR statistics	N/A	N/A

Other actions are available by signal set as follows:

Other Actions	All Signal Set	US Signal Set
Show Sector Map (Drug Overviews row)	Yes	N/A
Show Age Group / Gender Breakdown graphs (Drug-Event Combinations row)	Yes	N/A

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## Change log

Date	Revised part number	Description
22-Nov-2024	F87387-01	For the 9.2.3 release: <ul style="list-style-type: none"><li>• Changed the title of Chapter 1.</li><li>• Added Versioned Case Series to the Standard AERS Signal Configuration table.</li></ul>
16-Aug-23	F82913-01	Added release note for Oracle Empirica Signal 9.2.2.1 release. Moved bug fixes for 9.0 release to Release Notes chapter.
30-Nov-21	F34875-01	Updated document for Oracle Empirica Signal 9.2 release. Added parameters to data mining run tables in the Standard Data Mining Runs section.
31-Aug-20	F31974-01	Revised document for Oracle Empirica Signal 9.1 release.
1-Nov-19	F17116-02	Removed incorrectly included and duplicated What's New items.
5-Sept-19	F17116-01	Revised document for Oracle Empirica Signal 9.0 release.
31-July-18	E93841-01	Original version of this document.