Oracle Life Sciences Empirica
Vigibase Signal Management Release Notes

Release 9.2.3

F87381-01

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Oracle Life Sciences Empirica Vigibase Signal Management Release Notes, Release 9.2.3

F87381-01

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Preface

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- Documentation accessibility
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WHO UMC Vigibase Signal Management Release Notes

- **Introduction**
  These release notes describe Vigibase Interactive Signal Management for use with Oracle Empirica Signal version 9.x with Vigibase data 2018Q2 or later.

- **New in Vigibase Signal Management for the Oracle Empirica Signal 9.2.3 Release**
  No new features have been added to the Vigibase Signal Management 9.2 release.

- **New in Vigibase Signal Management for the Oracle Empirica Signal 9.x Release**
  This topic describes what is new in Vigibase Interactive Signal Management (version 3.0.0.2.100) relative to the prior scripted Vigibase Signal Management (version 1.x).

- **Ability to convert a Vigibase signal configuration from scripted to interactive**
  A mechanism for converting a scripted signal configuration to a new interactive signal configuration is available.

Introduction

These release notes describe Vigibase Interactive Signal Management for use with Oracle Empirica Signal version 9.x with Vigibase data 2018Q2 or later.

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

If your organization subscribes to Oracle Empirica Topics for Signal Management Cloud Service and Oracle Empirica Signal WHO UMC Vigibase Extract Cloud Service, you can employ the Signal Management feature in Oracle Empirica Signal on Vigibase data. If your organization has not used Vigibase Signal Management before, contact Oracle Support to enable the feature in your environment. The feature facilitates ongoing monitoring of safety signals by enabling users to perform statistical analyses on successive releases of the data.

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

Vigibase Interactive Signal Management WAS was introduced in Oracle Empirica Signal 9.1.0.4. Interactive Signal Management allows configuring and refreshing Signal Management from the user interface rather than using scripts. This release also makes use of the configurable alerts feature introduced in Oracle Empirica Signal 9.0. If scripted Vigibase Signal Management was used previously, there is an optional conversion process to copy information from the old scripted Vigibase Signal Management into a newly installed Vigibase Interactive Signal Management.

Vigibase Interactive Signal Management requires Vigibase data 2018Q2 or later but can be used with any 9.x release of Oracle Empirica Signal.

For more information on a quarterly Vigibase data release, please refer to the `Vigibase Data Release Notes.pdf` file distributed with the release. That document describes the

preparation of Vigibase 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 Vigibase Signal Management for the Oracle Empirica Signal 9.2.3 Release

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

None of the fixes we have applied to the 9.2.3 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 Vigibase Signal Management for use with Oracle Empirica Signal.

New in Vigibase Signal Management for the Oracle Empirica Signal 9.x Release

This topic describes what is new in Vigibase Interactive Signal Management (version 3.0.0.2.100) relative to the prior scripted Vigibase Signal Management (version 1.x).

With Vigibase Interactive 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 alerts.

- Use review periods.

Underlying column names that were similar to AM_N_SINCE_PRIORn are now called AMNEW_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 a Vigibase signal configuration from scripted to interactive.

Ability to convert a Vigibase 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.

- Configurable Alert Type definitions.

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.

- KUR Only events.
  Vigibase Interactive 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 Vigibase Signal Management. For example, drugs to add, rename, or delete, or changes to listed (labeled), designated medical, or KUR events.

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Standard Vigibase signal configuration

- Standard Vigibase signal configuration
  This topic describes the standard attribute values for the Vigibase signal configuration.
  Your organization can modify these values as needed.

Standard Vigibase signal configuration

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

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' reference data**, will inherit the values from the scripted signal configuration.

Attribute	Standard Value for Vigibase Signal Management
Name	Vigibase Signal Configuration
Description	Vigibase 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 Vigibase (S) (alias for most recent Vigibase (S))
Data configuration for 3D runs	Latest Vigibase (S + C) (alias for most recent Vigibase (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_STRATA
Subset variable for signal history	Data Mining Quarter
Subset variable for Nsince counts	Data Load Quarter
Project for data mining runs	Vigibase Signal Mgmt
Publish data mining runs	No (unchecked)
Allow reviewers to manage their drug's reference data	Yes (checked)

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Standard Vigibase subpopulations

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  The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the Vigibase database. It also reports the results of statistical analysis performed only on reports with certain shared characteristics; for example, reports involving elderly individuals only, or reports with a fatal outcome only.

Standard Vigibase subpopulations

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the Vigibase database. It also reports the results of statistical analysis performed only on reports with certain shared characteristics; for example, reports involving elderly individuals only, or reports with a fatal outcome only.

To identify different subpopulations and types of cases in the Vigibase 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	Selection logic: 1 union 2 **1.** Seriousness equals 'Death' **2.** Reaction Outcome equals any of the following values: 'Fatal,' 'Died- reaction may be contributory,' 'Died- unrelated to reaction'
Female	Gender equals 'F'
Male	Gender equals 'M'
Pediatric	AgeGroup4 equals '00_17'
Serious	Seriousness equals 'Y'

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Standard data mining runs

To assemble data mining counts and statistics that can be compared over time, Vigibase 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 *Vigibase Signal Mgmt*.

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. Oracle Empirica 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 reports from the WHO Region of the Americas. 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 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. Oracle Empirica Signal executes these runs on the data configuration for 3D runs from the signal configuration, and names the runs in accordance with thatd ata configuration.

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. Oracle Empirica 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 2018Q2: Vigibase (S), or an alias for 2018Q2: Vigibase (S), then the All run will be named 2018Q2: Vigibase (S) - All. If the data configuration specified under **Data configuration for 2D runs** is 2018Q2: Vigibase (S+C), or an alias for 2018Q2: Vigibase (S+C), then the All run will be named 2018Q2: Vigibase (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 Vigibase signal configuration.

- **All**
  Oracle Empirica Signal executes this data mining run using all reports in Vigibase.

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

- **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.

All

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

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
PRR and ROR:	Includes non-stratified PRR and ROR; Counts are based on cases; Yates correction applied
Fill in hierarchy values:	Yes

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

AM only

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

Field	Description
Database restriction:	Region equals 'Region of the Americas'
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

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

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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:	Selection logic: 1 union 2
	1. Seriousness equals 'Death'
	2. Reaction Outcome equals any of the following values: 'Fatal,' 'Died- reaction may be contributory,' 'Died- unrelated to reaction'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
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
Fit separate distributions:	Yes

Serious only

This data mining run is restricted to serious reports only.

Field	Description
Database restriction:	Seriousness equals 'Y'
Subsets:	None
Minimum count:	1
PRR and ROR:	Not calculated
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 Vigibase signal configuration.

- All new
  This run computes new or changed counts for all reports in Vigibase.

- New AM
  This run computes new or changed counts for reports from the WHO Region of the Americas.

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

- 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.

All new

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

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
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

New AM

This run computes new or changed counts for reports from the WHO Region of the Americas.

Field	Description
Database restriction:	Region equals 'Region of the Americas'
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 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:	Selection logic: 1 union 2
	1. Seriousness equals 'Death'
	2. Reaction Outcome equals any of the following values: 'Fatal,' 'Died- reaction may be contributory,' 'Died- unrelated to reaction'
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.

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

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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 'Y'

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 reports from the WHO Region of the Americas. 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.

Oracle Empirica 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 Vigibase.

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

- AM reports, SOC
  This SOC-level run is restricted to AM reports only.

- AM reports, HLT
  This HLT-level run is restricted to AM reports only.

All reports, SOC

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

Field	Description
Item Variables:	<Drug variable>, SOC
Database restriction:	None

Field	Description
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

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

AM reports, SOC

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

Field	Description
Item Variables:	<Drug variable>, SOC
Database restriction:	Region equals 'Region of the Americas'
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

AM reports, HLT

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

Field	Description
Item Variables:	<Drug variable>, HLT
Database restriction:	Region equals 'Region of the Americas'
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. Oracle Empirica Signal executes these runs on the data configuration for 3D runs from the signal configuration, and names the runs in accordance with thatd ata configuration.

- 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 Signal Management

- **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 Vigibase Signal Management: All reports and reports from WHO Region of the Americas 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 Vigibase 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.

- 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 Oracle Empirica 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 Vigibase Signal Management-specific alert columns that you can display in the Products table in default order.

Column Name	Column Description
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.

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

   icon ( ).
   The Products page appears.

2. 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.

3. 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.

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

2. Click the product-event combination's **Row Action menu** (⋮), and then select **Submit Review**.

3. Select a comment from a predefined list of standard comments.

4. (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

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 Vigibase 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 into 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 Vigibase Signal Management: All reports and reports from WHO Region of the Americas only.

The signal sets for Vigibase Signal Management are:

- All—All reports in the Data configuration for 2D runs specified in the signal configuration.

- AM—Reports from WHO Region of the Americas 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	AM 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	AM Signal Set
Show Sector Map (Products row)	Yes	N/A
Show Age Group / Gender Breakdown graphs (Product-Event Combinations row)	Yes	N/A

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Change log

Date	Part number	Description
November 2024	F87381-01	For the 9.2.3 release: • Changed title of Chapter 1. • Added Versioned Case Series to the Standard Vigibase Signal Configuration table.
August 2023	F82919-01	For the 9.2.2.1 release: • Rebranded product and book title. • Updated the Cloud Support link in the Preface. • Updated the Change Log.
30-November-2021	F42888-03	Fixed typos and added parameters to data mining run tables in the Standard data mining runs section.
20-May-2021	F42888-02	Added setup information to Introduction topic.
20-May-2021	F42888-01	Original version of this document.