

# Oracle Life Sciences Empirica

## VAERS Signal Management Release Notes



Release 9.2.2.1  
F82917-01



F82917-01

Copyright © 2022, 2023, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, and MySQL are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

# Contents

## Preface

---

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

## 1 What's new?

---

Introduction	1-1
New in VAERS Signal Management for the Oracle Empirica Signal 9.x Release	1-2

## 2 Standard VAERS Signal Configuration

---

Standard VAERS signal configuration	2-1
-------------------------------------	-----

## 3 Standard VAERS subpopulations

---

Standard VAERS subpopulations	3-1
-------------------------------	-----

## 4 Standard data mining runs

---

Data mining runs producing disproportionality scores	4-1
VAERS All	4-2
VAERS All RGPS	4-3
VAERS US only	4-4
VAERS Elderly only	4-4
VAERS Fatal only	4-5
VAERS Female only	4-5
VAERS Male only	4-6
VAERS Pediatric only	4-6
VAERS Serious only	4-6
Data mining runs for new or changed cases	4-7
VAERS All new	4-8

VAERS New US	4-8
VAERS New Elderly	4-9
VAERS New Fatal	4-10
VAERS New Female	4-10
VAERS New Male	4-11
VAERS New Pediatric	4-11
VAERS New Serious	4-12
Data mining runs for SOC and HLT scores	4-13
VAERS All reports, SOC	4-13
VAERS All reports, HLT	4-13
VAERS US reports, SOC	4-14
VAERS US reports, HLT	4-14
Data mining run for viewing interactions	4-15
VAERS 3D, All reports	4-15

## 5 Viewing data and scores in Signal Management

---

Standard alert types	5-1
Products page	5-2
Product-Event Combinations page	5-3
Columns on the Product-Event Combinations table	5-4
Standard comments	5-4
Standard signal views	5-5
Signal sets	5-8

## 6 Change log

---

# Preface

This preface contains the following sections:

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

## Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

## Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

## Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

## Additional copyright information

This documentation may include references to materials, offerings, or products that were previously offered by Phase Forward Inc. Certain materials, offerings, services, or products may no longer be offered or provided. Oracle and its affiliates cannot be held responsible for any such references should they appear in the text provided.

# 1

## What's new?

- [Introduction](#)  
These release notes describe VAERS Interactive Signal Management for use with Oracle Empirica Signal version 9.x with VAERS data 20180430 or later.
- [New in VAERS Signal Management for the Oracle Empirica Signal 9.x Release](#)  
This topic describes what is new in VAERS Interactive Signal Management (version 3.0.0.0.100) relative to the prior scripted VAERS Signal Management (version 1.x).

## Introduction

These release notes describe VAERS Interactive Signal Management for use with Oracle Empirica Signal version 9.x with VAERS data 20180430 or later.

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

If your organization subscribes to Oracle Empirica Topics for Signal Management Cloud Service and Oracle Empirica Signal WHO UMC VAERS Extract Cloud Service, you can employ the Signal Management feature in Oracle Empirica Signal on VAERS data. If your organization has not used VAERS 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 VAERS Signal Management was originally released in 2010. In scripted VAERS Signal Management, monthly refreshes are initiated by running shell scripts on the server. Scripted VAERS Signal Management can be used with Oracle Empirica Signal versions 7.3.x and above.

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.

VAERS Interactive Signal Management requires VAERS data 20180430 or later but can be used with any 9.x release of Oracle Empirica Signal. R and RGPS package must be installed on Empirica Signal application server and RGPS must be configured in Empirica Signal.

For more information on a monthly VAERS data release, please refer to the [VAERS Data Release Notes.pdf](#) file distributed with the release. That document describes the preparation of VAERS 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 VAERS Signal Management for the Oracle Empirica Signal 9.x Release

This topic describes what is new in VAERS Interactive Signal Management (version 3.0.0.0.100) relative to the prior scripted VAERS Signal Management (version 1.x).

With VAERS Interactive Signal Management, you can:

- Manage list of products 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.
- Add columns for IME, Event Term Change Description, and Event Term Change Flag in the Product-Event views. The MedDRA version used by the underlying data configuration must support these columns.

 **Note:**

There is no mechanism provided for converting an existing scripted signal configuration to a new interactive signal configuration. To convert a scripted signal configuration to interactive, contact Oracle Support.

# 2

## Standard VAERS Signal Configuration

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

### Standard VAERS signal configuration

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

Attribute	Standard Value for VAERS Signal Management
Name	VAERS Signal Configuration
Description	VAERS Signal Management Configuration
Type	Interactive
Default signal view	Open signals with new cases 1-Month
Topic workflow configuration	N/A
Topic product field	N/A
Disable default view	No (unchecked)
Disable review period	No (unchecked)
Disable private comment	Yes (checked)
Data configuration for 2D runs	Latest VAERS (alias for most recent VAERS)
Data configuration for 3D runs	Latest VAERS (alias for most recent VAERS)
Drug variable	Vaccine type
Event variable for 2D runs	Event: PT_plus_Narrow_Alg_SMQ
Event variable for 3D runs	Event: PT
Stratification variables	Sex, AGE_GROUP_6, Report received year
Subset variable for signal history	Report received month
Subset variable for Nsince counts	Load month
Project for data mining runs	VAERS Signal Mgmt
Publish data mining runs	No (unchecked)
Allow reviewers to manage their drug's reference data	Yes (checked)



# 3

## Standard VAERS subpopulations

- [Standard VAERS subpopulations](#)  
The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the VAERS 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 VAERS subpopulations

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the VAERS 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 VAERS 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	AGE_GROUP_6 equals '18_64'
Elderly	AGE_GROUP_6 equals '65_above'
Fatal	Outcome - Died equals 'YES'
Female	Sex equals 'F'
Male	Sex equals 'M'
Pediatric	AGE_GROUP_6 equals '00_01' or '02_05' or '06_17'
Serious	Serious equals 'Y'

# 4

## Standard data mining runs

To assemble data mining counts and statistics that can be compared over time, VAERS Signal Management includes 23 data mining runs. All runs are refreshed as part of preparing a monthly Signal Management update.

All of the standard data mining runs for Signal Management are MGPS runs that are limited to the set of monitored products. These runs are assigned to the project referenced in the signal configuration. The default name of this project is *VAERS 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 product-event terms for various subpopulations.
- [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.
- [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.
- [Data mining run for viewing interactions](#)  
Oracle Empirica Signal executes a three-dimensional MGPS data mining run to investigate product-product-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 that data configuration.

### Data mining runs producing disproportionality scores

Oracle Empirica Signal performs the following data mining runs to calculate disproportionality scores for product-event terms for various subpopulations.

Data mining runs to calculate disproportionality scores for product-event terms for various subpopulations include the following:

- One run computed using all reports in VAERS.
- A second run computed on all reports in VAERS but is not subsetted and includes RGPS.
- A third run restricted to US-only reports.
- Seven additional runs corresponding to the following areas of interest: adult, elderly, fatal, female, male, pediatric, and serious

For all of the runs described in this section, the events are at the preferred term or narrow-algorithmic SMQ level of the MedDRA hierarchy.

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 20210731\_VAERS, or an alias for 20210731\_VAERS, then the All run will be named 20210731\_VAERS - All.

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

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

## VAERS All

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

Field	Description
Database restriction:	None
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ

Field	Description
Subsets:	Variable: Report received month Cumulative: Yes Order: Forward Labels: [199007]-[<6 years ago>] [199007]-[<5 years ago>] [199007]-[<4 years ago>] [199007]-[<3 years ago>] [199007]-[<2 years ago>] [199007]-[<1 year ago>] [199007]-[<9 months ago>] [199007]-[<6 months ago>] [199007]-[<3 months ago>] [199007]-[<2 months ago>] [199007]-[<1 month ago>] [199007]-[<most recent month>]
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
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

## VAERS All RGPS

Oracle Empirica Signal executes this data mining run using all reports in VAERS, including RGPS.

Field	Description
Database restriction:	None
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Include RGPS:	Yes
Calculate RGPS interactions:::	No
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes

Field	Description
Fit separate distributions:	Yes

## VAERS US only

This data mining run is restricted to US-only reports in VAERS.

Field	Description
Database restriction:	Selection logic: 1) Report source - Foreign equals 'NO'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Report received month Cumulative: Yes Order: Forward Labels: [199007]-[<6 years ago> [199007]-[<5 years ago> [199007]-[<4 years ago> [199007]-[<3 years ago> [199007]-[<2 years ago> [199007]-[<1 year ago> [199007]-[<9 months ago> [199007]-[<6 months ago> [199007]-[<3 months ago> [199007]-[<2 months ago> [199007]-[<1 month ago> [199007]-[<most recent month>]
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
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

## VAERS Elderly only

This data mining run is restricted to elderly reports in VAERS.

Field	Description
Database restriction:	AGE_GROUP_6 equals '65_above'

Field	Description
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS Fatal only

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

Field	Description
Database restriction:	Outcome - Died equals 'YES'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS Female only

This data mining run is restricted to female reports in VAERS.

Field	Description
Database restriction:	Sex equals 'F'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes

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

## VAERS Male only

This data mining run is restricted to male reports in VAERS.

Field	Description
Database restriction:	Sex equals 'M'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS Pediatric only

This data mining run is restricted to pediatric reports in VAERS.

Field	Description
Database restriction:	AGE_GROUP_6 equals '00_01' or '02_05' or '06_17'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS Serious only

This data mining run is restricted to serious reports in VAERS.

Field	Description
Database restriction:	Seriousness equals 'YES'
Item variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
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.

Data mining runs for new or changed cases consist of the following.

- One run computing new counts for all reports in VAERS.
- A second new run restricted to US-only reports.
- Six additional new runs corresponding to the following areas of interest: elderly, fatal, female, male, pediatric, and serious.

For all of the runs described in this section, the events are at the preferred term or narrow-algorithmic SMQ level of the MedDRA hierarchy.

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 VAERS signal configuration.

- [VAERS All new](#)  
This data mining run computes all new or changed counts for all reports in VAERS.
- [VAERS New US](#)  
This data mining run computes all new or changed counts for reports from the United States.
- [VAERS New Elderly](#)  
This data mining run computes all new or changed counts for elderly reports.
- [VAERS New Fatal](#)  
This data mining run computes all new or changed counts for reports with a fatal outcome.



- [VAERS New Female](#)  
This data mining run computes all new or changed counts for female reports.
- [VAERS New Male](#)  
This data mining run computes all new or changed counts for male reports.
- [VAERS New Pediatric](#)  
This data mining run computes all new or changed counts for pediatric reports from the United States.
- [VAERS New Serious](#)  
This data mining run computes all new or changed counts for serious reports.

## VAERS All new

This data mining run computes all new or changed counts for all reports in VAERS.

Field	Description
Database restriction:	None
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New US

This data mining run computes all new or changed counts for reports from the United States.

Field	Description
Database restriction:	Selection logic: 1) Report source - Foreign equals 'NO'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ

Field	Description
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Elderly

This data mining run computes all new or changed counts for elderly reports.

Field	Description
Database restriction:	AGE_GROUP_6 equals '65_above'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Fatal

This data mining run computes all new or changed counts for reports with a fatal outcome.

Field	Description
Database restriction:	Outcome - Died equals 'YES'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Female

This data mining run computes all new or changed counts for female reports.

Field	Description
Database restriction:	Sex equals 'F'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year

Field	Description
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Male

This data mining run computes all new or changed counts for male reports.

Field	Description
Database restriction:	Sex equals 'M'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Pediatric

This data mining run computes all new or changed counts for pediatric reports from the United States.

Field	Description
Database restriction:	AGE_GROUP_6 equals '00_01' or '02_05' or '06_17'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ

Field	Description
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	No
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes

## VAERS New Serious

This data mining run computes all new or changed counts for serious reports.

Field	Description
Database restriction:	Serious equals 'YES'
Item Variables:	Vaccine Type, Event: PT_plus_Narrow_Alg_SMQ
Subsets:	Variable: Load month Cumulative: Yes Order: Forward Labels: ChgsSince[<1 month ago>] ChgsSince[<3 months ago>] ChgsSince[<6 months ago>] ChgsSince[<9 months ago>] ChgsSince[<1 year ago>]
Strata Variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
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.

A pair of data mining runs computes disproportionality scores at the SOC and HLT levels of the MedDRA hierarchy using all reports in VAERS. A second pair of SOC / HLT runs is restricted to US-only reports.

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.

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

### VAERS All reports, SOC

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

Field	Description
Database restriction:	None
Item variables:	Vaccine Type, Event: SOC
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
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

### VAERS All reports, HLT

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

Field	Description
Database restriction:	None
Item variables:	Vaccine Type, Event: HLT
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
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

## VAERS US reports, SOC

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

Field	Description
Database restriction:	Selection logic: 1) Report source - Foreign equals 'NO'
Item variables:	Vaccine Type, Event: SOC
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	1
Dimensions:	2
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

## VAERS US reports, HLT

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

Field	Description
Database restriction:	Selection logic: 1) Report source - Foreign equals 'NO'
Item variables:	Vaccine Type, Event: HLT
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year

Field	Description
Minimum count:	1
Dimensions:	2
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 product-product-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 that data configuration.

- [VAERS 3D, All reports](#)  
This 3D data mining run is used to investigate product-product-event interactions.

### VAERS 3D, All reports

This 3D data mining run is used to investigate product-product-event interactions.

Field	Description
Database restriction:	None
Item variables:	Vaccine Type, Event: PT
Subsets:	None
Strata variables:	Sex, AGE_GROUP_6, Report received year
Minimum count:	5
Dimensions:	3
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single itemtypes:	Yes
Fit separate distributions:	Yes



# 5

## Viewing data and scores in Signal Management

- [Standard alert types](#)  
For each configured alert, there is one alert type, plus five 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](#)  
Use the Product-Event Combinations page to access to comprehensive product-event information and statistics.
- [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 VAERS 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 five 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, active, and scheduled by Review Period. The VAERS Signal Management-specific standard alert types include the following:

- SDR
- FATAL
- DME

- TME
- PEDIATRIC
- ELDERLY
- NEW
- SERIOUS
- FEMALE
- MALE
- INTERACTION

## 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 VAERS Signal Management-specific alert columns that you can display in the Products table in default order.

Column Name	Column Description
SDR	Number of product-event combinations meeting the SDR alert condition
Fatal	Number of product-event combinations meeting the Fatal alert condition

Column Name	Column Description
DME	Number of product-event combinations meeting the DME alert condition
TME	Number of product-event combinations meeting the TME alert condition
Pediatric	Number of product-event combinations meeting the Pediatric alert condition
Elderly	Number of product-event combinations meeting the Elderly alert condition
New	Number of product-event combinations meeting the New alert condition
Serious	Number of product-event combinations meeting the Serious alert condition
Female	Number of product-event combinations meeting the Female alert condition
Male	Number of product-event combinations meeting the Male alert condition
Interaction	Number of product-event combinations meeting the Interaction alert condition

## Product-Event Combinations page

Use the Product-Event Combinations page to access to comprehensive product-event information and statistics.

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.

- **Detail panel:** The Detail panel on the right graphically depicts Recent History, Signal Statistics, Subgroup Statistics, and Associated topics for the selected product-event combination. Topics appear only if your configuration is integrated with Oracle Empirica Topics. You can select different variables to graph, such as All EB05, Age Group, or Gender, using the drop-down lists in the Signal Statistics or Subgroup Statistics sections. To perform further actions on the data associated with a bar or donut slice, click the bar or slice to display the Action menu. You can select View Cases or other actions related to case series and reports. You can show ( ) or hide ( ) the sections in the Detail panel. If you add a comment or change the associated topic information, the panel updates.
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

Comment Text	Abbreviated Comment Text
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 VAERS 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 1-Month views as an example.

Name	Description
DME alert 1-Month	All designated medical events reported for the selected product, for which there have been one or more new reports in this review period.
Elderly alert 1-Month	All events for which [EB05(elderly) >= 2 and EB05(elderly) > EB95(adult)].
Fatal alert 1-Month	All events reported for the selected product, for which there have been one or more new fatal reports in this review period.
Female alert 1-Month	All events for which [EB05(female) >= 2 and EB05(female) > EB95(male)].
Interaction alert 1-Month	All events for which there is a product-product-event interaction signal score (INTSS) > 2.
Male alert 1-Month	All events for which [EB05(male) >= 2 and EB05(male) > EB95(female)].
Pediatric alert 1-Month	All events for which [EB05(peds) >= 2 and EB05(peds) > EB95(adult)].
SDR alert 1-Month	Statistic/Signal of Disproportionate Reporting - Events with new reports in the last review period which (1) have an EB05 score >=2 or AllRGPS_ER05 >= 1.5, (2) are not flagged as listed and (3) the comment, if present, is not one of the comments indicating signal closure/dismissal.
Serious alert 1-Month	All events reported for the selected product, for which there have been one or more new serious reports in this review period.
TME alert 1-Month	All intensively monitored (targeted medical events) product-event combinations for which there have been one or more new reports in this review period.
New alert 1-Month	All events for the selected product for which there have been one or more new reports in this review period.

The Supplemental Views include the following views for each review period. The table shows 1-Month views as an example.

Name	Description
All 1-Month	All events reported for the selected product, ordered by SOC, then by descending EB05.
All DME 1-Month	All designated medical events reported for the selected product, ordered by SOC, then by descending EB05.
All TME 1-Month	All targeted medical events reported for the selected product, ordered by SOC, then by descending EB05.

Name	Description
All signals 1-Month	All events reported for the selected product 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 product-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 1-Month	All events reported for the selected product with new reports in this review period 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 product-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 1-Month	All SMQ (Standardized MedDRA Queries) terms for the selected product, in descending order by EB05.
All trend 1-Month	All events with EB05 >= 1.5 and either Trend1=YES (EBGM increasing and non-overlapping CI relative to previous review period) or Trend2=YES (50% increase in EBGM over previous review period). The list is ordered by SOC, then by descending EB05.
All with new cases 1-Month	All events for the selected product for which there have been one or more new reports in this review period. The list is ordered by SOC, then by descending EB05.
Closed signals 1-Month	All events reported for the selected product 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 1-Month	All events reported for the selected product for which the associated comment indicates that the signal has been explicitly closed and for which there are new reports in this review period. The list is ordered by SOC, then by descending EB05.
Open signals 1-Month	All events reported for the selected product 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.

Name	Description
Open signals with new cases 1-Month	All events reported for the selected product with new reports in this review period 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.

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

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



## Signal sets

There are two signal sets for VAERS Signal Management: All reports and reports from WHO Region of the Americas only.

The signal sets for VAERS Signal Management are:

- All—All reports in the Data configuration for 2D runs specified in the signal configuration.
- US—Reports from the United States 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	<b>Yes</b>	<b>Yes</b>
Show HLT-level disproportionality scores	<b>Yes</b>	<b>Yes</b>
Show SOC-level disproportionality scores	<b>Yes</b>	<b>Yes</b>
Show MGPS statistics	<b>Yes</b>	<b>Yes</b>
Show PRR statistics	<b>No</b>	<b>No</b>
Show ROR statistics	<b>No</b>	<b>No</b>



Other actions are available by signal set as follows:

<b>Other Actions</b>	<b>All Signal Set</b>	<b>US Signal Set</b>
Show Sector Map (Products row)	<b>Yes</b>	<b>No</b>
Show Age Group / Gender Breakdown graphs (Product- Event Combinations row)	<b>Yes</b>	<b>No</b>

# 6

## Change log

<b>Date</b>	<b>Part number</b>	<b>Description</b>
August 2023	F82917-01	For the 9.2.2.1 release: <ul style="list-style-type: none"><li>• Rebranded product and book title.</li><li>• Updated the Cloud Support link in the Preface.</li><li>• Updated the Change Log.</li></ul>
November 2021	F56210-01	Original version of this document (9.2).