Oracle Life Sciences Empirica

PMDA JADER Signal Management Release Notes

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Oracle Life Sciences Empirica PMDA JADER Signal Management Release Notes, Release 9.2.3

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PMDA JADER Signal Management Release Notes

Introduction

These release notes describe PMDA JADER Interactive Signal Management for use with Oracle Empirica version 9.2.3 with JADER data 202409 or later.

The Oracle Empirica software is a web-based analysis environment for generating statistical scores or 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 the Empirica Signal PMDA JADER Database, you can use the Signal Management feature in Oracle Empirica Signal on JADER data. If your organization has not used *JADER Signal Management* before, contact Life Sciences Support to enable the feature in your environment. The feature facilitates ongoing monitoring of safety signals by allowing users to perform statistical analysis on successive releases of the data.

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 9.0.

JADER Interactive Signal Management requires JADER data 202409 or later but can be used with any 9.x release of Oracle Empirica. R and RGPS packages must be installed on the Empirica Signal application server and RGPS must be configured in Oracle Empirica Signal.

For more information on a monthly JADER data release, please refer to the *JADER Database Release Notes*.pdf file distributed with the release. That document describes the preparation of JADER 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.

PMDA JADER for Signal Management is new for Oracle Empirica 9.2.3

This topic describes the PMDA JADER for Signal Management that is new for Oracle Empirica 9.2.3.

PMDA JADER (Japanese Adverse Drug Event Report) for Signal Management is now available for subscribers in Oracle Cloud.

With *JADER Signal Management*, you can:

- Monitor a drugs and signaling terms from within Oracle Empirica.
- Initiate a refresh from within Oracle Empirica.
- Add alerts.
- Define review periods.
- Configure JADER in English or Japanese.
- Update the JADER data on a quarterly basis covering three months of update data.

Also, starting from this release, defining a **Serious** alert will be unavailable. In JADER, the **Seriousness** field does not exist.

None of the .features or fixes we have applied the 9.2.3 release affect the user workflow or the application's functionality.

This database includes all data from 2004 through January 2023, as released by the Japanese authority PMDA (Pharmaceutical and Medical Devices Agency). Oracle refers to this data set as JADER 3.0.0.1.100. The purpose of these release notes is to describe the procedures taken by Oracle to prepare the JADER data for use with Empirica Signal version 9.2.3 and above. The standard configurations delivered with the data and the recommended parameters for periodic data mining runs are also described.

The use of the JADER adverse event data is subject to the PMDA terms of use, as well as the Oracle Empirica Signal Cloud Service Description available at www.oracle.com/contracts. The PMDA web site can be viewed at www.pmda.go.jp (limited information available in English).

About PMDA JADER for Signal Management

A new version of the JADER (Japanese Adverse Drug Event Report) database is now available for subscribers in Oracle Cloud.

This database includes all data from 2004 through January 2023, as released by the Japanese authority PMDA (Pharmaceutical and Medical Devices Agency). Oracle refers to this data set as JADER 3.0.0.1.100. The purpose of these release notes is to describe the procedures taken by Oracle to prepare the JADER data for use with Oracle Empirica Signal version 9.2.3 and above. The standard configurations delivered with the data and the recommended parameters for periodic data mining runs are also described.

Usage of the JADER adverse event data is subject to the PMDA terms of use, as well as the Oracle Empirica Signal Cloud Service Description available at www.oracle.com/contracts. The PMDA web site can be viewed at www.pmda.go.jp (limited information available in English).

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 *JADER Signal Management* for use with Oracle Empirica Signal.

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Standard JADER signal configurations

Rename to: Standard JADER signal configurations

- JADER Signal Configuration Defaults
  The *JADER Signal Management* defaults can be modified by your organization.

JADER Signal Configuration Defaults

The *JADER Signal Management* defaults can be modified by your organization.

After installation the *JADER Signal Management* Configuration attributes will be as follows:

Attribute	JADER Signal Management English	JADER Signal Management Japanese
Name	JADER Signal Configuration EN	JADER Signal Configuration JP
Description	JADER Signal Configuration English	JADER Signal Configuration Japanese
Type	Interactive	Interactive
Default signal view	Open signals with new cases 3-Months	Open signals with new cases 3-Months
Topic workflow configuration	-1 (not associated)	-1 (not associated)
Topic product field	-1	-1
Disable default view	No	No
Disable review period	No or Yes	Yes
Disable private comment	Yes	Yes
Data configuration for 2D runs	Latest JADER EN (S)	Latest JADER JP (S)
Data configuration for 3D runs	Latest JADER EN (S+C)	Latest JADER JP (S+C)
Drug variable	Generic Name (EN)	Generic Name (JP)
Event variable for 2D runs	PT_plus_Narrow_Alg_SMQ (EN)	PT_plus_Narrow_Alg_SMQ (JP)
Event variable for 3D runs	PT (EN)	PT (JP)
Stratification variables	STANDARD_STRATA	STANDARD_STRATA
Subset variable for signal history	Data Mining Quarter	Data Mining Quarter
Subset variable for Nsince counts	Data Load Quarter	Data Load Quarter
Project name for data mining runs	JADER Signal Mgmt EN	JADER Signal Mgmt JP
Publish data mining runs	No	No
Allow reviewers to manage their drugs' reference data	Yes	Yes
Supported data source(s)	PMDA	PMDA
Language (Internal only)	EN	JP

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Standard JADER subpopulations

Standard JADER subpopulations

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all records in the *JADER Signal Management* 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 *JADER Signal Management* 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 '20_69'
Elderly	AgeGroup4 equals '70_Above'
Fatal	Reaction Outcome Death = 'YES'
Female	Gender equals 'F'
Male	Gender equals 'M'
Pediatric	AgeGroup4 equals '00_19'

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Standard data mining runs

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

The JADER signal management implementation uses the following types of data mining runs:

- Data mining runs to produce disproportionality scores and report counts for the JADER data set that are incorporated into the signal summary table.
- Data mining runs to determine new or significantly changed cases relative to prior time periods.
- Data mining runs to produce disproportionality scores for the HLT and SOC levels of the MedDRA hierarchy.
- A 3D data mining run that is used to identify Drug-Drug-Event interactions that may merit further investigation.

> **Note:**
>
> Run descriptions in this document use the JADER Signal Management Configuration Attributes as installed. If attribute values, such as Strata Variables, are modified then the runs for the next refresh will be impacted accordingly.

- Data mining runs produce disproportionality scores
  JADER signal management information is based on nine data mining runs monthly refreshed to produce the disproportionality scores for drug-event terms.
- Disproportionality Analysis Time Periods
  To track changes to disproportionality scores over time, the signal summary table maintains disproportionality scores for five quarterly time periods.
- Data mining runs for new or changed cases
  Seven cumulative subset data mining runs are performed to determine 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 that is used to identify Drug-Drug-Event interactions that may merit further investigation.

Data mining runs produce disproportionality scores

JADER signal management information is based on nine data mining runs monthly refreshed to produce the disproportionality scores for drug-event terms.

What you need to know about JADER signal management data mining runs

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

JADER signal management information refreshes quarterly the drug-event terms calculated in the disproportionality scores and include the following runs:

- One run computed using all reports in JADER.
- A second run computed on all reports in JADER but is not subsetted and includes RGPS.
- A third run restricted to Spontaneous-only reports. Additionally, there are six data mining runs that correspond to the following areas of interest: adult, elderly, fatal, female, male, and pediatric.
- Six additional runs corresponding to the following areas of interest: adult, elderly, fatal, female, male, and pediatric.

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.

- JADER All
  Oracle Empirica Signal executes this data mining run using all reports in JADER.
- JADER Spontaneous only
  This data mining run is restricted to spontaneous-only reports in JADER.
- JADER Adult only
  This data mining run is restricted to **adult reports** only.
- JADER Elderly only
  This data mining run is restricted to elderly reports in JADER.
- JADER Fatal only
  This data mining run is restricted to reports with a fatal outcome in JADER.
- JADER Female only
  This data mining run is restricted to female reports in JADER.
- JADER Male only
  This data mining run is restricted to male reports in JADER.
- JADER Pediatric only
  This data mining run is restricted to pediatric reports in JADER.

JADER All

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

Field	Description
Database restriction:	None
Item variables:	Generic Name (<JP), (EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets:	Variable: Data Mining Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata variables:	STANDARD_STRATA
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
Limit Results To:	Set of products that are being monitored for signal management

JADER Spontaneous only

This data mining run is restricted to spontaneous-only reports in JADER.

Field	Description
Database restriction:	None
Item variables:	Generic Name (<JP), (EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets:	Variable: Data Mining Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarters>]
Strata variables:	STANDARD_STRATA
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
Limit Results To:	Set of products that are being monitored for signal management

JADER Adult only

This data mining run is restricted to **adult reports** only.

Field	Description
Database restriction:	AgeGroup4 equals '20_69'
Subsets:	None
Strata Variables:	STANDARD_STRATA
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single item types:	Yes
Fit separate distributions:	Yes
Limit Results To	Set of products that are being monitored for signal management

JADER Elderly only

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

Field	Description
Database restriction:	AgeGroup4 equals '70_above'
Item variables:	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets:	None
Strata variables:	STANDARD_STRATA
Minimum count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in hierarchy values:	Yes
Exclude single item types:	Yes
Fit separate distributions:	Yes
Limit Results To	Set of products that are being monitored for signal management

JADER Fatal only

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

Field	Description
Database restriction:	Reaction Outcome Death equals 'YES'
Item variables:	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets:	None
Strata variables:	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER Female only

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

Field	Description
Database restriction:	Gender (EN) equals 'F'
Item variables:	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets:	None
Strata variables:	STANDARD_STRATA
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
Limit results to:	Set of products that are being monitored for signal management

JADER Male only

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

Field	Description
Database restriction:	Gender (EN) equals 'M'
Item variables:	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets:	None
Strata variables:	STANDARD_STRATA
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
Limit results to	Set of products that are being monitored for signal management

JADER Pediatric only

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

Field	Description
Database restriction:	AgeGroup4 equals '00_19'
Item variables:	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets:	None

Field	Description
Strata variables:	STANDARD_STRATA
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
Limit results to	Set of products that are being monitored for signal management

Disproportionality Analysis Time Periods

To track changes to disproportionality scores over time, the signal summary table maintains disproportionality scores for five quarterly time periods.

The time periods in chronological order (most recent time period first) are:

- Most recent quarter
- One quarter ago
- Two quarters ago
- Three quarters ago
- Four quarters ago

In addition, the signal summary and drug overview tables maintain information for each product's alerts that are appropriate to the review period assigned to the product at the time of refresh. When review periods are not enabled, it is assumed that the single supported review period is 3-Months. The review periods are:

- 3-Months
- 6-Months
- 9-Months
- 12-Months

Signal history also contains the following periods:

- One year ago (replacing Four quarters ago)
- Two years ago
- Three years ago
- Four years ago
- Five years ago
- Six years ago

Data mining runs for new or changed cases

Seven cumulative subset data mining runs are performed to determine 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 JADER.
- A second new run restricted to Spontaneous-only reports.
- Five additional new runs corresponding to the following areas of interest: elderly, fatal, female, male, and pediatric.

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.

- JADER All new
  This data mining run computes all new or changed counts for all reports in *JADER Signal Management*.
- JADER New Spontaneous
  This data mining run computes all new or changed counts for reports from the Spontaneous.
- JADER New Elderly
  This data mining run computes all new or changed counts for elderly reports.
- JADER New Fatal
  This data mining run computes all new or changed counts for reports with a fatal outcome.
- JADER New Female
  This data mining run computes all new or changed counts for female reports.
- JADER New Male
  This data mining run computes all new or changed counts for male reports.
- JADER New Pediatric
  This data mining run computes all new or changed counts for pediatric reports..

JADER All new

This data mining run computes all new or changed counts for all reports in *JADER Signal Management*.

Field	Description
Database restriction	None
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 year ago>] [2004Q1]-[<3 year ago>] [2004Q1]-[<2 year ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Spontaneous

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

Field	Description
Database restriction	Report Type (EN) equals 'Spontaneous'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Elderly

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

Field	Description
Database restriction	AgeGroup4 equals '70_above'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Fatal

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

Field	Description
Database restriction	Reaction Outcome Death equals 'YES'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Female

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

Field	Description
Database restriction	Gender (EN) equals 'F'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Male

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

Field	Description
Database restriction	Gender (EN) equals 'M'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER New Pediatric

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

Field	Description
Database restriction	AgeGroup4 equals '00_19'
Item Variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)

Field	Description
Subsets	Variable: Data Load Quarter Cumulative: Yes Order: Forward Labels: [2004Q1]-[<6 years ago>] [2004Q1]-[<5 years ago>] [2004Q1]-[<4 years ago>] [2004Q1]-[<3 years ago>] [2004Q1]-[<2 years ago>] [2004Q1]-[<1 year ago>] [2004Q1]-[<3 quarters ago>] [2004Q1]-[<2 quarters ago>] [2004Q1]-[<1 quarter ago>] [2004Q1]-[<most recent quarter>]
Strata Variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

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 is performed to compute disproportionality scores at the SOC and HLT levels of the MedDRA hierarchy using all reports in JADER Signal Management.

A second pair of SOC and HLT runs is performed that is restricted to Spontaneous-only reports.

- JADER All reports, SOC
  This data mining run computes disproportionality scores at the SOC level of the MedDRA hierarchy using all reports in *JADER Signal Management*.
- JADER All reports, HLT
  This data mining run computes disproportionality scores at the HLT level of the MedDRA hierarchy using all reports in *JADER Signal Management*.
- JADER Spontaneous reports, SOC
  This SOC-level data mining run is restricted to spontaneous reports only in *JADER Signal Management*.
- JADER Spontaneous reports, HLT
  This HLT-level data mining run is restricted to spontaneous reports only in *JADER Signal Management*.

JADER All reports, SOC

This data mining run computes disproportionality scores at the SOC level of the MedDRA hierarchy using all reports in *JADER Signal Management*.

Field	Description
Database restriction	None
Item variables	Generic Name (<JP, EN>), SOC (<JP, EN>)
Subsets	None
Strata variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER All reports, HLT

This data mining run computes disproportionality scores at the HLT level of the MedDRA hierarchy using all reports in *JADER Signal Management*.

Field	Description
Database restriction	None
Item variables	Generic Name (<JP, EN>), HLT (<JP, EN>)
Subsets	None
Strata variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER Spontaneous reports, SOC

This SOC-level data mining run is restricted to spontaneous reports only in *JADER Signal Management*.

Field	Description
Database restriction	Report Type (EN) equals 'Spontaneous'
Item variables	Generic Name (<JP, EN>), PT_plus_Narrow_Alg_SMQ (<JP, EN>)
Subsets	None
Strata variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

JADER Spontaneous reports, HLT

This HLT-level data mining run is restricted to spontaneous reports only in *JADER Signal Management*.

Field	Description
Database restriction	Report Type (EN) equals 'Spontaneous'
Item variables	Generic Name (<JP, EN>), HLT (<JP, EN>)
Subsets	None
Strata variables	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

Data mining run for viewing interactions

Oracle Empirica Signal executes a three-dimensional MGPS data mining run that is used to identify Drug-Drug-Event interactions that may merit further investigation.

- JADER 3D, All reports
  This 3D data mining run is used to investigate product-product-event interactions.

JADER 3D, All reports

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

Field	Description
Database restriction:	None
Item variables:	Generic Name (<JP, EN>), PT (<JP, EN>)
Subsets:	None
Strata variables:	STANDARD_STRATA
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
Limit Results To	Set of products that are being monitored for signal management

5

View data and scores in Signal Management

The Signal Management feature of Oracle Empirica Signal allows you to view standard alert types, comments, signal views, and signal sets.

- Standard alert types automatically installed
  The standard alert types are a predefined set of columns that you can apply to the Product-Event Combinations table.
- Start your work on the Products page
  Open the Products page to access alert information and track review of alerts for products.
- View and filter product-event details
  View and filter comprehensive product-event information and statistics for relevant products.

Standard alert types automatically installed

The standard alert types are a predefined set of columns that you can apply to the Product-Event Combinations table.

They can help you identify and prioritize potential safety issues with pharmaceutical products.

For each configured alert, there is one alert type. Each alert type has a Label, Column Name, Description, and alert type rules based on either the product's Review Period or Complexity level/Periodicity. 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.

Each installed alert type has four alert rules based on the review periods. The Condition and Selected columns are dependent on the review period. For example, there are the following *Fatal* alert conditions:

- Condition for Fatal alert 1-quarter: FATALNEW_N_PRIOR1 > 0
- Condition for Fatal alert 2-quarter: FATALNEW_N_PRIOR2 > 0
- Condition for Fatal alert 3-quarter: FATALNEW_N_PRIOR3 > 0
- Condition for Fatal alert 4-quarter: FATALNEW_N_PRIOR4 > 0

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

- SDR
- Fatal
- DME
- TME
- Pediatric

- Elderly
- New
- Female
- Male
- Interaction

Start your work on the Products page

Open the Products page to access alert information and track review of alerts for products.

The Products page shows a summary of all or one monitored products and alerts that you configured.

To access the Products page you must make sure that you are provisioned with the appropriate permissions.

> **Note:**
>
> Depending on your role and permissions, some of these options may or may not be available to you. If you can't see what you are looking for, reach out to your Oracle project manager to revise your permissions.

1. On the Home page, select the Signal Review icon, to the left the navigation pane (

Figure 5-1 Signal Review icon

)
The Products page opens with the following drop-downs available:

- **Data Configurations**: Choose **JADER Signal configuration** for English or Japanese languages to indicate the source data used to display the information in the application. When you choose a data configuration, it remains selected until you select a different one.
- **Products By**: Group and filter products you track by **Category**, **Complexity**, **Organization**, **Product group**, or assigned **Reviewer**. The corresponding products appear in the Products table. Move back and forth through the cards with the dots below them or the right arrow at the right. Every time you select a card, the graphic details panel and filters the Products table update.
- **Products** table: Search the find icon

Figure 5-2 Find icon

for the a product name, for example, Abacavir.

- **Product Event-Combination**: Click the options icon from product name in the Products table and select **View Product-Event Combinations**,

Figure 5-3 Options icon

to investigate current refresh runs, previous refresh rows with unreviewed alerts or comments.

- **Graphic details panel** - Read the summary panel of either the selected Products By card or the Product to the right.

2. Select the options from the list of data configurations you can access.

- Manage the Products table
  You access all functions to perform on an individual product from the Products page.

Related Topics

- #unique_54

Manage the Products table

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

1. On the Signal Review page, view the **Products** table details.
2. Select a drug row, for example Abacavir.
3. Click on a product group card to focus on one product from that group.
4. View specific alert columns display in the **Products** table in the following default order with the **JADER Signal Management** configuration:

Column Name	Column Description	Column Condition (N-month)	Column Selected columns (N-month)	Column Sort by
SDR - Statistic/ Signal of Disproportionate Reporting	Number of product-event combinations meeting the SDR alert condition.	Indicates a product-event combination for which at least one new report was received during the current period, where the EB05 score is at least 2 or ER05 is at least 1.5, the event is not a listed event, and the current comment on the event is not one of Labeled, Indication Related,Uninformative, Prior Review.	• DRUG_NAME • PT • STATUS • ALERTS • ALLNEW_N_PRIORN • ALL_N • ALLRGPS_ER05 • ALL_EB05 • ALL_EB05_PRIORN • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • ALL_EB05 desc

Column Name	Column Description	Column Condition (N-month)	Column Selected columns (N-month)	Column Sort by
Fatal	Number of product-event combinations meeting the Fatal alert condition.	Indicates a product-event combination for which at least one new report with a fatal outcome was received during the current period.	• DRUG_NAME • PT • STATUS • ALERTS • FATALNEW_N_PRIORN • FATAL_N • FATAL_EB05 • ALL_N • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • FATAL_EB05 desc
DME - Designated medical events	Number of product-event combinations meeting the designated medical events alert condition.	Indicates a product-event combination that involves a designated medical events and that includes at least one new report during the current period.	• DRUG_NAME • PT • STATUS • ALERTS • ALLNEW_N_PRIORN • ALL_N • ALL_EB05 • ALL_EB05_PRIORN • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • ALL_EB05 desc
TME - Targeted medical event	Number of product-event combinations meeting the targeted medical event alert condition.	Indicates a product-event combination that is a targeted medical event combination and that includes at least one new report during the current period.	• DRUG_NAME • PT • STATUS • ALERTS • ALLNEW_N_PRIORN • ALL_N • ALL_EB05 • ALL_EB05_PRIORN • NOTE • NOTE_DATE	• DRUG NAME • STATUS • ALL_EB05 desc
Pediatric	Number of product-event combinations meeting the pediatric alert condition.	Indicates a product-event combination where the EB05 score for the pediatric subpopulation is at least 2 and the lower bound of the 90% EBGM confidence interval for the pediatric subpopulation is greater than the upper bound of the 90% EBGM confidence interval for the adult subpopulation.	• DRUG_NAME • PT • STATUS • ALERTS • PEDIATRICNEW_N_PRIORN • PEDIATRIC_N • PEDIATRIC_EB05, • ADULT_EB95 • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • PEDIATRIC_EB05 desc

Column Name	Column Description	Column Condition (N-month)	Column Selected columns (N-month)	Column Sort by
Elderly	Number of product-event combinations meeting the Elderly alert condition.	Indicates a product-event combination where the EB05 score for the elderly subpopulation is at least 2 and the lower bound of the 90% EBGM confidence interval for the elderly subpopulation is greater than the upper bound of the 90% EBGM confidence interval for the adult subpopulation.	• DRUG_NAME • PT • STATUS • ALERTS • ELDERLYNEW_N_PRIORN • ELDERLY_N • ELDERLY_EB05 • ADULT_EB95 • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • ELDERLY_EB05 desc
New alert type	Number of product-event combinations meeting the New alert condition.	Indicates a product-event combination for which at least one new report was received during the current period.	• DRUG_NAME • PT • STATUS • ALERTS • ALLNEW_N_PRIORN • ALL_N • ALL_EBGM • ALL_EB05 • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • ALL_EB05 desc
Female	Number of product-event combinations meeting the Female alert condition.	Indicates a product-event combination where the EB05 score for the female subpopulation is at least 2 and the lower bound of the 90% EBGM confidence interval for the female subpopulation is greater than the upper bound of the 90% EBGM confidence interval for the male subpopulation.	• DRUG_NAME • PT • STATUS • ALERTS • FEMALENEW_N_PRIORN • FEMALE_N • FEMALE_EB05 • MALE_EB95 • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • FEMALE_EB05 desc

Column Name	Column Description	Column Condition (N-month)	Column Selected columns (N-month)	Column Sort by
Male	Number of product-event combinations meeting the Male alert condition.	Indicates a product-event combination where the EB05 score for the male subpopulation is at least 2 and the lower bound of the 90% EBGM confidence interval for the male subpopulation is greater than the upper bound of the 90% EBGM confidence interval for the female subpopulation.	• DRUG_NAME • PT • STATUS • ALERTS • MALENEW_N_PRIORN • MALE_N • MALE_EB05 • FEMALE_EB95 • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • MALE_EB05 desc
Interaction	Number of product-event combinations meeting the Interaction alert condition.	Indicates a product-event combination for which there is a product-product-event interaction signal score lower than two (INTSS) > 2.	• DRUG_NAME • PT • STATUS • ALERTS • MAX_INTSS • ALLNEW_N_PRIORN • ALL_N • ALL_EB05 • ALL_EB05_PRIORN • NOTE • NOTE_DATE	• DRUG_NAME • STATUS • ALL_EB05 desc

View and filter product-event details

View and filter comprehensive product-event information and statistics for relevant products.

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 donuts 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.

- Add standard comments
  You can add a comment to a combination on the Product-Event Combinations page.
- Customize the 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.
- Customize signal sets for JADER Signal Management
  There are two signal sets for *JADER Signal Management*:

Add 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 **View Product-Event Combinations** in the action menu ( ), and then select **Submit Review** from the next action menu.
3. Select a comment from a predefined list of standard comments.
4. Select the check-box **Suppress product-event combination** if
5. (Optional) If signal management is integrated with topics, you can associate a topic with a product-event combination.
6. (Optional) If your system supports free text comments, enter an additional Detailed comment, under the comment drop-down selection.

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

Customize the 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 *JADER 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

These views are automatically created and published to all available login groups as part of installing JADER Signal Management.

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

Name	Description
DME alert 3-Months	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 3-Months	All events for which [EB05(elderly) >= 2 and EB05(elderly) > EB95(adult)].
Fatal alert 3-Months	All events reported for the selected product, for which there have been one or more new fatal reports in this review period.
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 product-product-event interaction signal score (INTSS) > 2.
New alert 3-Months	All events for the selected product for which there have been one or more new reports in this review period.
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)].
SDR alert 3-Months	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.
TME alert 3-Months	All intensively monitored (targeted medical events) product-event combinations 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 3-Month views as an example.

Name	Description
All 3-Months	All events reported for the selected product, ordered by SOC, then by descending EB05.
All DME 3-Months	All designated medical events reported for the selected product, ordered by SOC, then by descending EB05.
All TME 3-Months	All targeted medical events reported for the selected product, ordered by SOC, then by descending EB05.

Name	Description
All signals 3-Months	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 3-Months	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 3-Months	All SMQ (Standardized MedDRA Queries) terms for the selected product, in descending order by EB05.
All trend 3-Months	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 3-Months	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 3-Months	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 3-Months	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 3-Months	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.
Open signals with new cases 3-Months	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.

Customize signal sets for JADER Signal Management

There are two signal sets for *JADER Signal Management*:

- **All** —All signal sets that signal set corresponds to all reports in the JADER.
- **Spontaneous** —Signal set that corresponds to JADER Standard runs.

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

1. Click the **Signal Review**, in the Oracle Empirica Signal application, in the navigation pane on the left, 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 Set Configuration	All	Spontaneous
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	Spontaneous Signal Set
Show Sector Map (Products row)	**No**	**Yes**
Show Age Group / Gender Breakdown graphs (Product-Event Combinations row)	**Yes**	**No**

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Change log

Change log

Date	Part number	Description
July 2025	G31194-02	Updated some back-end structural elements that don't impact the information in this publication.
November 2024	F94461-02	Added release number to the title page.
November 2024	F94461-01	Original version of this document.