Oracle Health Sciences Empirica Signal

Oracle Argus Mart Data and Signal Management for Use with Oracle Empirica Signal Release Notes

Release 9.1

F31976-01

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Oracle Health Sciences Empirica Signal Oracle Argus Mart Data and Signal Management for Use with Oracle Empirica Signal Release Notes, Release 9.1

F31976-01

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Preface

This preface contains the following sections:

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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

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- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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Introduction

- **Introduction**
  These *Release Notes* describe the Oracle Argus Mart data for use with Oracle Empirica Signal release 9.1.

- **New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 9.1 Release**
  After upgrading Oracle Argus Mart Signal Management 9.0 for use with Oracle Empirica Signal 9.1, signal configurations will support a Detailed Comment column in Product-Event Combinations tables.

- **New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 9.0 Release**
  After upgrading Oracle Argus Mart 8.x for use with Oracle Empirica Signal 9.0, signal configurations will support configurable alert types.

- **New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 8.1 Release**
  After upgrading Oracle Argus Mart 8.x for use with Oracle Empirica Signal 8.1, new data configurations become available. These configurations include reports that have REPORT_TYPE_VE as default criteria in `Spontaneous', `Literature'.

Introduction

These *Release Notes* describe the Oracle Argus Mart data for use with Oracle Empirica Signal release 9.1.

They also describe Argus Signal Management for use with Oracle Empirica Signal.

New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 9.1 Release

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

Detail Comment column added to Product-Event Combinations table

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

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

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

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

New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 9.0 Release

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

Oracle Empirica Signal 9.0 configurable alert types are based on Review period or Complexity level/ periodicity. This allows for the scheduling of an alert based on the product properties of review period, complexity level, and birthdate.

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

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

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

New in Oracle Argus Mart Signal Management for the Oracle Empirica Signal 8.1 Release

After upgrading Oracle Argus Mart 8.x for use with Oracle Empirica Signal 8.1, new data configurations become available. These configurations include reports that have REPORT_TYPE_VE as default criteria in `Spontaneous', `Literature'.

The spontaneous reports are as follows:

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

The drilldown maps for all configurations now include more variables, including those referenced in the default case scoring algorithm. This allows users of Argus Signal Management to see the values that contribute to the report's case score when viewing Case Details.

After upgrading Oracle Argus Mart for use with Oracle Empirica Signal 9.0, the DOSE_UNIT and DAILY_DOSE_UNIT columns are added to the SM_DOSE table. If a user wants to use these variables in Oracle Empirica Signal, a user with Manage Configurations permission can add them to the data configurations.

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MedDRA Standardized MedDRA Query (SMQ) Support

- **MedDRA Standardized MedDRA Query (SMQ) Support**
  The Oracle Argus Mart data includes the assignment of SMQs based on criteria defined in the *Introductory Guide for Standardised MedDRA Queries (SMQs) Version x.y*, published by the International Federation of Pharmaceutical Manufacturers and Associations.

MedDRA Standardized MedDRA Query (SMQ) Support

The Oracle Argus Mart data includes the assignment of SMQs based on criteria defined in the *Introductory Guide for Standardised MedDRA Queries (SMQs) Version x.y*, published by the International Federation of Pharmaceutical Manufacturers and Associations.

The SMQ support is as follows:

- Narrow and broad definitions of SMQs are implemented.
- Select Algorithmic SMQs are implemented.
- The *(Event/SMQ) PT_plus_SMQ* event variable includes values for all PTs and SMQs associated with each report, where the SMQ records have been inserted into the data as part of the Argus Mart ETL data preparation. The *(Event/Narrow SMQ) PT_plus_ Narrow_SMQ* event variable provides only PTs and Narrow SMQ data for data mining, querying, and reporting.

> 💡 **Tip:**
>
> There are no hierarchy values for SMQs in data mining results. Also, the prepared source data does not have hierarchy values for SMQs; thus, hierarchy values for SMQs do not appear in second-level drilldown (the Case Details page). Also note that SMQs do not appear in the MedDRA Hierarchy Browser.

- Calculations made by MGPS data mining runs are not affected by the addition of SMQ values in the Argus Mart data.

When you access the **Release Notes and Other Documents** topic under **Getting Started** in the *Empirica Signal and Topics Online Help* Table of Contents, the following documents are available:

- *Introductory Guide for Standardised MedDRA Queries (SMQs) Version x.y*
- *Introductory Guide MedDRA Version x.y*

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Oracle Argus Mart Data Tables and Views

- **Oracle Argus Mart Data Tables**
  The primary tables in the Oracle Argus Mart Data account are listed here.

- **Oracle Argus Mart Additional Views**
  SM_PRODUCT table has a view that excludes records for concomitant drugs.

Oracle Argus Mart Data Tables

The primary tables in the Oracle Argus Mart Data account are listed here.

Table	Type of Data
SM_CASE	Demographic
SM_CAUSE_OF_DEATH	Cause of death
SM_DOSE	Dosing
SM_EVENT_PLUS_SMQ	PT plus all SMQs
SM_EVENT_PRODUCT	Event-Product
SM_INDICATIONS	Indications
SM_INGREDIENTS	Ingredients
SM_LAB	Lab
SM_NARRATIVE	Narratives
SM_NEONATES	Neonate
SM_PARENT_INFO	Parent information
SM_PAT_HIST	Patient History
SM_PREGNANCY	Pregnancy
SM_PRODUCT	Product
SM_REPORTERS	Reporter

Oracle Argus Mart Additional Views

SM_PRODUCT table has a view that excludes records for concomitant drugs.

Table or View Name	Suspect?	Concomitant?
SM_PRODUCT table	Y	Y
SM_PRODUCT_S view	Y	-

SM_EVENT_PLUS_SMQ table views exclude or include different SMQs:

Table or View Name	PTs	Narrow SMQs?	Broad SMQs?	Alg. SMQs?
SM_EVENT_PLUS_SMQ table	Y	Y	Y	Y
SM_EVENT_PLUS_SMQ_NARROW view	Y	Y	-	-
SM_EVENT view	Y	-	-	-

Every table and view has a _SPONT view (for example, SM_CASE has SM_CASE_SPONT) which restricts the data to just the records in cases that qualify as spontaneous. The criteria for spontaneous cases is established when signal management is installed and the default is REPORT_TYPE_VE in ('SPONTANEOUS , 'LITERATURE').

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Argus Mart Data Configurations

- Data Configurations

  The Oracle Argus Mart data release includes four standard configurations.

Data Configurations

The Oracle Argus Mart data release includes four standard configurations.

Standard Configuration	Description
RGUS (S)	All ARGUS datamart cases. Suspect products only.
ARGUS (S+C)	All ARGUS datamart cases. Suspect and concomitant products only.
ARGUS SPONTANEOUS (S)	Spontaneous Argus datamart cases. Suspect products only.
ARGUS SPONTANEOUS (S+C)	Spontaneous Argus datamart cases. Suspect and concomitant products only.

> **Tip:**
>
> **(S)** or **(S+C)** abbreviation in the configuration name indicates whether that configuration includes only records for drugs that are identified as Suspect (S) in the report, or records for both the Suspect drugs and Concomitant drugs (S+C).

For a complete list of the variables that are included in configurations, see Data Mining Table Schema.

For a complete list of the variables available for inclusion in configurations, see *Oracle Argus Mart ETL Mapping Document*.

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Data Mining Table Schema

- **About the Data Mining Table Schema**
  Use the data mining table schema for data mining.

- **SM_CASE Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_CASE table.

- **SM_CAUSE_OF_DEATH Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_CAUSE_ OF_DEATH table.

- **SM_DOSE Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_DOSE table.

- **SM_EVENT View**
  The SM_EVENT view on the SM_EVENT_PLUS_SMQ table is created using a SQL WHERE clause.

- **SM_EVENT_PLUS_SMQ Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_EVENT_ PLUS_SMQ table.

- **SM_EVENT_PLUS_SMQ_NARROW View**
  The SM_EVENT_PLUS_SMQ_NARROW view on the SM_EVENT_PLUS_SMQ table is created using a SQL WHERE clause.

- **SM_EVENT_PRODUCT Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_EVENT_ PRODUCT table.

- **SM_INDICATIONS Table**
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- **SM_INGREDIENTS Table**
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  Information about the Oracle Empirica Signal configuration variables from the SM_LAB table.

- **SM_NARRATIVE Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_ NARRATIVE table.

- **SM_NEONATES Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_ NEONATES table.

- **SM_PARENT_INFO Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_PARENT_ INFO table follows.

- **SM_PAT_HIST Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_PAT_HIST table.

- **SM_PREGNANCY Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_PREGNANCY table.

- **SM_PRODUCT Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_PRODUCT table.

- **SM_REPORTERS Table**
  Information about the Oracle Empirica Signal configuration variables from the SM_REPORTERS table.

About the Data Mining Table Schema

Use the data mining table schema for data mining.

The following tables and views:

- Are the basis for the previously described standard Oracle Empirica Signal data configurations.

- Have been prepared for use with data mining.

SM_CASE Table

Information about the Oracle Empirica Signal configuration variables from the SM_CASE table.

Configuration Variable	Column	Description
(Case) Blinding Status	UNBLINDING_STATUS_VE	Study blinding status
(Case) Case Number	CASE_NUM	Case number
(Case) Conmed List	CONMED_LIST_DV	Concomitant medication list
(Case) Country of Incidence	COUNTRY_VE	Country in which the case occurred
(Case) Device Case YN	DEVICE_CASE_YN	Y/N: Case has at least one suspect device
(Case) Drug Case YN	DRUG_CASE_YN	Y/N: Case has at least one suspect drug
(Case) Followup Date	FOLLOWUP_DATE	Date of follow-up
(Case) Followup Number	REV	Case follow-up number
(Case) Initial Report Date	INIT_REPT_DATE	Date first reported
(Case) Listedness	LISTEDNESS_VE	Case listedness
(Case) Outcome	EVT_OUTCOME_VE	Case outcome
(Case) Patient Ethnicity	ETHNICITY_VE	Patient Ethnicity
(Case) Patient Height cm	PAT_HEIGHT_CM	Patient height in centimeters
(Case) Patient Weight Kg	PAT_WEIGHT_KG	Patient weight in kilograms

Configuration Variable	Column	Description
(Case) Pregnancy	PREGNANCY_VE	Pregnancy case (Yes/No/UNK/NA)
(Case) Protocol Number	PROTOCOL_NUM	Case protocol number
(Case) Report Type	REPORT_TYPE_VE	Type of report (spontaneous, clinical trial, etc.)
(Case) Seriousness Text	SERIOUSNESS_TEXT_DV	Seriousness text
(Case) Study Description	STUDY_DESC	Case study description
(Case) Study Name	BLIND_NAME	Study name
(Case) Study Number	STUDY_NUM	Case study number
(Case) Study Phase	DEV_PHASE_VE	Case study phase
(Case) Study Type	STUDY_TYPE_VE	Case study type
(Case) SUSAR Case YN	SUSAR_YN_VE	Y/N: SUSAR case
(Case) Vaccine Case YN	VACCINE_CASE_YN	Y/N: Case has at least one suspect vaccine
(Case) ValidEnd	VALIDEND	Valid end date
(Case) ValidStart	VALIDSTART	Valid start date
(Case/derived) AgeGroup3	AGE_GROUP_3_DV	Age group in years: 00_64, 65_ above, UNK
(Case/derived) AgeGroup4	AGE_GROUP_4_DV	Age group in years: 00_17, 18_64, 65_above, UNK
(Case/derived) AgeGroup9	AGE_GROUP_9_DV	Age group in years: 00_01, 02_04, 05_12, 13_17, 18_45, 46_64, 65_74, 75_above, UNK
(Case/derived) Event List	EVENT_LIST_DV	List of preferred terms. (S) indicates serious; (U) indicates unlisted for primary suspect drug. Listedness is determined by CDS listedness for trial reports, other- wise CORE listedness.
(Case/derived) Fatal YN	FATAL_YN_DV	Y/N: Case is fatal
(Case/derived) HCP YNU	HCP_YNU_DV	Y/N/U: Indicates if case has at least one reporter who is a Health Professional
(Case/derived) Last Significant Update	LAST_SIGNIF_UPDATE_DV	Date associated with the last significant follow-up for the case
(Case/derived) Last Significant Update Month	LAST_SIGNIF_UPDATE_ MONTH_DV	Subset month associated with the last significant follow-up for the case
(Case/derived) Last Significant Update Quarter	LAST_SIGNIF_UPDATE_ QUARTER_DV	Subset quarter associated with the last significant follow-up for the case. These quarters follow Schedule A.

Configuration Variable	Column	Description
(Case/derived) Last Significant Update Week	LAST_SIGNIF_UPDATE_WEEK_ DV	Subset ISO week associated with the last significant follow-up for the case
(Case/derived) Patient Age Years	AGE_YEARS_DV	Age converted to years
(Case/derived) Patient BMI	BMI_DV	Patient body mass index
(Case/derived) Patient Gender	GENDER_CLEAN_VE	Patient's sex (F/M/U) , with NULL converted to U
(Case/derived) Received Half Year	RECEIVED_HALFYEAR_DV	Half-year of initial date of report (e.g., 200306, 200312, etc.)
(Case/derived) Received Month	RECEIVED_MONTH_DV	Month of initial date of report (e.g., 200304)
(Case/derived) Received Quarter	RECEIVED_QUARTER_DV	Quarter-year of initial date of report (e.g., 200303, 200306, etc.)
(Case/derived) Received Year	RECEIVED_YEAR_DV	Year of initial date of report
(Case/derived) Seriousness YN	SERIOUSNESS_VE	Y/N: Case is serious
(Case/derived) STANDARD_ STRATA	STANDARD_STRATA_AG9_DV	Gender + agegroup9 + received year
(Case/derived) STANDARD_ STRATA_AG4	STANDARD_STRATA_AG4_DV	Gender + agegroup4 + received year
(Case/derived) STANDARD_ STRATA_ARGUS	STANDARD_STRATA_DV	Gender + ARGUS agegroup + received
(Case/derived) Subset_3Year_ Group	SUBSET_3YEAR_GROUP_DV	Data up to 2000 lumped together in a single group. Post 2000 categorizes reports into three year groups (as in [2001-2003]) based on the initial date
(Case/derived) Subset_Month	SUBSET_MONTH_DV	Month of initial date of report. Dates prior to 2000 grouped together into larger sets
(Case/derived) Subset_Quarter	SUBSET_QUARTER_DV	Quarter of initial date of report, following Schedule A. Dates prior to 2000 are grouped together into larger sets
(Case/derived) Subset_Week	SUBSET_WEEK_DV	I SO week of initial date of report. Dates prior to 2000 are grouped together into larger sets
(Case/derived) Subset_Year	SUBSET_YEAR_DV	Year of initial date of report. Dates prior to 2000 are grouped together into larger sets

Configuration Variable	Column	Description
(Case/derived) Suspect Drug List	SUSPDRUG_LIST_DV	List of suspect products. (P) indicates primary suspect product. * indicates company product
(Case/derived) Treatment List	TREATMENT_LIST_DV	List of treatment products

SM_CAUSE_OF_DEATH Table

Information about the Oracle Empirica Signal configuration variables from the SM_CAUSE_ OF_DEATH table.

Configuration Variable	Column	Description
(Cause of Death) Autopsy Results	RESULTS_VE	Status of autopsy results
(Cause of Death) Case Number	CASE_NUM	Case number
(Cause of Death) Cause of Death Autopsy	CAUSE_AUTOPSY	Autopsy cause of death
(Cause of Death) Cause of Death Reported	CAUSE_REPTD	Death cause as reported
(Cause of Death) Cause Type	CAUSE_TYPE_VE	Cause of death / autopsy result
(Cause of Death) Date of Death	DEATH_DATE	Date of death
(Cause of Death) Detailed Cause of Death	DETAILED_CAUSE	Detailed cause of death
(Cause of Death) HLGT	CAUSE_HLGT	Death cause HLGT
(Cause of Death) HLT	CAUSE_HLT	Death cause HLT
(Cause of Death) SOC	CAUSE_SOC	Death cause SOC
(Cause of Death) Sort ID	CAUSE_SORT_ID	Cause of death sort order
(Cause of Death) Term Type	TERM_TYPE_VE	Term type
(Cause of Death) ValidEnd	VALIDEND	Valid end date
(Cause of Death) ValidStart	VALIDSTART	Valid start date

SM_DOSE Table

Information about the Oracle Empirica Signal configuration variables from the SM_DOSE table.

Configuration Variable	Column	Description
(Dose) Case Number	CASE_NUM	Case number
(Dose/derived) Product Exposure Family Name	PROD_EXPOS_FAMILY_NAME_ DV	Product family name, with expo- sure name for known study products

Configuration Variable	Column	Description
(Dose/derived) Product Exposure Generic Name	PROD_EXPOS_GENERIC_NAME_DV	Product generic name, with expo- sure name for known study products
(Dose/derived) Product Exposure Name	PROD_EXPOS_PRODUCT_NAME_DV	Product name, with exposure name for known study products
(Dose) Total Regimen Dosage	TOTAL_REG_DOSE	Total dosage regimen as reported
(Dose) ValidEnd	VALIDEND	Valid end date
(Dose) ValidStart	VALIDSTART	Valid start date

SM_EVENT View

The SM_EVENT view on the SM_EVENT_PLUS_SMQ table is created using a SQL WHERE clause.

The SM_EVENT view on the SM_EVENT_PLUS_SMQ table is created using this SQL WHERE clause:

```
WHERE EVENT_TYPE = 'PT' AND INCLUDE_YN = 'Y'
```

Information about the Oracle Empirica Signal configuration variables from the SM_EVENT view on the SM_EVENT_PLUS_SMQ table follows.

Configuration Variable	Column	Description
(Event) Associated with Rechallenge YN	RECHALL_RELATED_YN_VE	Y/N: Associated with rechallenge
(Event) Case Number	CASE_NUM	Case number
(Event) Congenital Anomaly YN	SERIOUS_CONGEN_ANOM_VE	Y/N: Event congenital anomaly seriousness criteria
(Event) Death YN	SERIOUS_DEATH_VE	Y/N: Event death seriousness criteria
(Event) Detail	DETAILS_LT	Event detail
(Event) Disability YN	SERIOUS_DISABLE_VE	Y/N: Event disability seriousness criteria
(Event) Event Diagnosis YN	EVENT_DIAGNOSIS_VE	Y/N: Event diagnosis
(Event) Event Outcome	EVENT_OUTCOME_VE	Event outcome
(Event) Frequency	EVT_FREQ_VE	Event frequency
(Event) HLGT	EVENT_HLGT	Event High Level Group Term
(Event) HLT	EVENT_HLT	Event High Level Term
(Event) Hospitalized YN	SERIOUS_HOSP_VE	Y/N: Event hospitalized seriousness criteria
(Event) Intensity	EVENT_INTENSITY_VE	Event intensity
(Event) Lack of Efficacy YN	EFFICACY_YN_VE	Y/N: Lack of efficacy
(Event) Life-threatening YN	SERIOUS_LIFE_THREAT_VE	Y/N: Event life-threatening seriousness criteria
(Event) LLT	EVENT_LLT	Event Lower Level Term

Configuration Variable	Column	Description
(Event) Medically Serious YN	MED_SERIOUS_VE	Y/N: Medically serious event
(Event) Onset Date	ONSET_DATE	Onset date of event
(Event) Other Details	SC_OTHER_TEXT	Details of other seriousness criteria
(Event) Other YN	SERIOUS_OTHER_VE	Y/N: Event other seriousness criteria
(Event) Patient Prior History YNU	PAST_HIST_VE	Y/N/U: Patient has prior history?
(Event) PT	EVENT_PT	Event Preferred term
(Event) Req Intervention YN	SERIOUS_INTERVENTION_VE	Y/N: Event intervention seriousness criteria
(Event) Sequence Number	EVENT_SEQ_NUM	Event sequence number
(Event) Serious YN	EVENT_SERIOUSNESS_VE	Y/N: Event seriousness
(Event) SOC	SOC	Event System Organ Class
(Event) SOC Abbrev	EVENT_SOC	Event System Organ Class abbreviation
(Event) Sort ID	EVENT_SORT_ID	Event sort order
(Event) Treatment Received YNU	TREATED_YNU_VE	Y/N/U: Treatment received
(Event) ValidEnd	VALIDEND	Valid end date
(Event) ValidStart	VALIDSTART	Valid start date
(Event/derived) Duration Text	EVENT_DURATION_TEXT_DV	Text describing duration of event. Calculated by Argus from onset date to event stop date
(Event/derived) Onset Delay	ONSET_DELAY_TEXT_DV	Text describing onset delay from last dosage
(Event/derived) Onset Latency	ONSET_LATENCY_TEXT_DV	Text describing onset latency from first dosage
(Event/derived) Seriousness Criteria	EVENT_SERIOUSNESS_TEXT_ DV	Summary of event seriousness criteria. Combination of the letters FLMDCIHO, for fatal, life threat, med significant, disability, congen anom, intervention, hosp, other

SM_EVENT_PLUS_SMQ Table

Information about the Oracle Empirica Signal configuration variables from the SM_EVENT_ PLUS_SMQ table.

Configuration Variable	Column	Description
(Event/SMQ) Case Number	CASE_NUM	Case number

Configuration Variable	Column	Description
(Event/SMQ) PT_plus_SMQ	EVENT_PT	PT or SMQ Name; includes narrow, broad, and 5 algorithmic SMQs
(Event/SMQ) Term Type	EVENT_TYPE	Type of term: PT/SMQ
(Event/SMQ) ValidEnd	VALIDEND	Valid end date
(Event/SMQ) ValidStart	VALIDSTART	Valid start date

SM_EVENT_PLUS_SMQ_NARROW View

The SM_EVENT_PLUS_SMQ_NARROW view on the SM_EVENT_PLUS_SMQ table is created using a SQL WHERE clause.

The SM_EVENT_PLUS_SMQ_NARROW view on the SM_EVENT_PLUS_SMQ table is created using the following SQL WHERE clause:

```
WHERE INCLUDE_YN = 'Y' AND (EVENT_TYPE = 'PT' OR (EVENT_TYPE = 'SMQ' AND
IS_NARROW = 'Y')
```

As a result, the PT_plus_Narrow_SMQ variable offered by this view includes MedDRA preferred terms and narrow standardized MedDRA queries for data mining. Information about the Oracle Empirica Signal configuration variables from the SM_EVENT_ PLUS_SMQ_NARROW view follows.

Configuration Variable	Column	Description
(Event/Narrow SMQ) Case Number	CASE_NUM	Case number
(Event/Narrow SMQ) PT_plus_ Narrow_SMQ	EVENT_PT	PT or Narrow SMQ Name
(Event/Narrow SMQ) Term Type	EVENT_TYPE	Type of term: PT/SMQ
(Event/Narrow SMQ) ValidEnd	VALIDEND	Valid end date
(Event/Narrow SMQ) ValidStart	VALIDSTART	Valid start date

SM_EVENT_PRODUCT Table

Information about the Oracle Empirica Signal configuration variables from the SM_EVENT_ PRODUCT table.

Configuration Variable	Column	Description
(Event Drug) As Determined Causality	DET_CAUSALITY_VE	As determined causality
(Event Drug) As Reported Causality	RPT_CAUSALITY_VE	As reported causality
(Event Drug) Case Number	CASE_NUM	Case number
(Event Drug) Dechallenge	DECHALLENGE_VE	Dechallenge

Configuration Variable	Column	Description
(Event Drug) Description Reported	DESC_REPTD	Description reported
(Event Drug) Event Sequence Number	EVENT_SEQ_NUM	Event sequence number
(Event Drug) Listedness Company Data Sheet	LISTEDNESS_CDS_VE	Event/product listedness from company datasheet
(Event Drug) Listedness Core Data Sheet	LISTEDNESS_CORE_VE	Event/product listedness from core data sheet
(Event Drug) Maximum Stop Dose Date	MAX_STOP_DATETIME_DV	Latest stop dose date
(Event Drug) Minimum Start Dose Date	MIN_START_DATETIME_DV	Earliest start dose date
(Event Drug) Onset Date	ONSET_DATE	Onset date of event
(Event Drug) Onset Delay	ONSET_DELAY	Onset delay from last dosage
(Event Drug) Onset Latency	OFFSET_LATENCY_TEXT_DV	Onset latency from first dosage
(Event Drug) Onset Latency Text	ONSET_LATENCY_TEXT_DV	Onset latency text
(Event Drug) Product Sequence Number	PROD_SEQ_NUM	Product sequence number
(Event Drug) PT	PT	Event Preferred Term
(Event Drug) Rechallenge YNU	RECHALLENGE_VE	Y/N/U: Rechallenge
(Event Drug) ValidEnd	VALIDEND	Valid end date
(Event Drug) ValidStart	VALIDSTART	Valid start date
(Event Drug/derived) Family Name	PROD_EXPOS_FAMILY_NAME_ DV	Product family name, with exposure name for known study products
(Event Drug/derived) Generic Name	PROD_EXPOS_GENERIC_ NAME_DV	Product generic name, with exposure name for known study products
(Event Drug/derived) Product Name	PROD_EXPOS_PRODUCT_ NAME_DV	Product name, with exposure name for known study products

SM_INDICATIONS Table

Information about the Oracle Empirica Signal configuration variables from the SM_ INDICATIONS table.

Configuration Variable	Column	Description
(Indication) Case Number	CASE_NUM	Case number
(Indication) HLGT	IND_HLGT	Indication High Level Group Term
(Indication) HLT	IND_HLT	Indication High Level Term

Configuration Variable	Column	Description
(Indication) LLT	IND_LLT	Indication Low Level Term
(Indication) PT	IND_PREF_TERM_DV	Indication Preferred Term
(Indication) SOC	IND_SOC	Indication System Organ Class
(Indication) ValidEnd	VALIDEND	Valid end date
(Indication) ValidStart	VALIDSTART	Valid start date
(Indication/derived) Family Name	PROD_EXPOS_FAMILY_NAME_ DV	Product family name, with exposure name for known study products
(Indication/derived) Generic Name	PROD_EXPOS_GENERIC_ NAME_DV	Product generic name, with exposure name for known study products
(Indication/derived) Product Name	PROD_EXPOS_PRODUCT_ NAME_DV	Product name, with exposure name for known study products

SM_INGREDIENTS Table

Information about the Oracle Empirica Signal configuration variables from the SM_ INGREDIENTS table.

Configuration Variable	Column	Description
(Ingredient) Case Number	CASE_NUM	Case number
(Ingredient) Concentration	CONCENTRATION	Concentration
(Ingredient) Concentration Unit	CONCENTRATION_UNITS_V E	Concentration unit
(Ingredient) Ingredient	INGREDIENT_VE	Ingredient
(Ingredient) Ingredient Sequence Number	ITEM	Ingredient sequence number
(Ingredient) Product Sequence Number	SEQ_NUM	Product sequence number
(Ingredient) ValidEnd	VALIDEND	Valid end date
(Ingredient) ValidStart	VALIDSTART	Valid start date

SM_LAB Table

Information about the Oracle Empirica Signal configuration variables from the SM_LAB table.

Configuration Variable	Column	Description
(Lab) Case Number	CASE_NUM	Case Number
(Lab) Lab Results	LAB_RESULTS	Lab Results
(Lab) Test Name	LAB_TEST_NAME	Test Name
(Lab) Valid End	VALIDEND	Valid end date

Configuration Variable	Column	Description
(Lab) Valid Start	VALIDSTART	Valid start date

SM_NARRATIVE Table

Information about the Oracle Empirica Signal configuration variables from the SM_NARRATIVE table.

Configuration Variable	Column	Description
(Narrative) Case Number	CASE_NUM	Case number
(Narrative) Narrative	NARRATIVE_DV	Narrative
(Narrative) Type	NARRATIVE_TYPE_DV	Narrative type
(Narrative) ValidEnd	VALIDEND	Valid end date
(Narrative) ValidStart	VALIDSTART	Valid start date

SM_NEONATES Table

Information about the Oracle Empirica Signal configuration variables from the SM_NEONATES table.

Configuration Variable	Column	Description
(Neonates) APGAR Score #1	APGAR1	APGAR score #1
(Neonates) APGAR Score #2	APGAR2	APGAR score #2
(Neonates) APGAR Score #3	APGAR3	APGAR score #3
(Neonates) Birth Type	BIRTH_TYPE_VE	Birth type
(Neonates) Case Number	CASE_NUM	Case number
(Neonates) Delivery Notes	NOTES	Delivery notes
(Neonates) Delivery Type	DELIVERY_TYPE_VE	Delivery type
(Neonates) Fetal Outcome	FETAL_OUTCOME_VE	Fetal outcome
(Neonates) Sort ID	SORT_ID	Neonates sort order
(Neonates) ValidEnd	VALIDEND	Valid end date
(Neonates) ValidStart	VALIDSTART	Valid start date
(Neonates) Weight in Grams	WEIGHT_GRAMS	Weight in grams

SM_PARENT_INFO Table

Information about the Oracle Empirica Signal configuration variables from the SM_PARENT_ INFO table follows.

Configuration Variable	Column	Description
(Parent Info) Case Number	CASE_NUM	Case number
(Parent Info) Parent Age	AGE	Parent age

Configuration Variable	Column	Description
(Parent Info) Parent Age Unit	AGE_UNIT_VE	Parent age unit
(Parent Info) Parent Breastfeeding YN	BREASTFEEDING_VE	Y/N: Parent breastfeeding
(Parent Info) Parent Date of Birth	DOB	Parent date of birth
(Parent Info) Parent Date of LMP	DATE_OF_LMP	Parent date of LMP
(Parent Info) Parent Gender	GENDER_VE	Parent's sex
(Parent Info) Parent Medical History Text	MED_HIST_TEXT	Parent's medical history text
(Parent Info) ValidEnd	VALIDEND	Valid end date
(Parent Info) ValidStart	VALIDSTART	Valid start date

SM_PAT_HIST Table

Information about the Oracle Empirica Signal configuration variables from the SM_PAT_HIST table.

Configuration Variable	Column	Description
(Patient History) Case Number	CASE_NUM	Case number
(Patient History) Condition	CONDITION	Patient history condition
(Patient History) Condition Continuing YN	CONDITION_CONTINUING_VE	Y/N: Is patient history condition ongoing
(Patient History) Condition Indication	CONDITION_INDICATION	Patient history indication
(Patient History) Condition Note	CONDITION_NOTE	Patient history note
(Patient History) Condition Parent YN	CONDITION_PARENT_YN_VE	Y/N: Patient history condition is for parent
(Patient History) Condition Reaction	CONDITION_REACTION	Patient history condition reaction
(Patient History) Condition Sort ID	CONDITION_SORT_ID	Patient history condition sort order
(Patient History) Condition Type	CONDITION_TYPE_VE	Condition type
(Patient History) ValidEnd	VALIDEND	Valid end date
(Patient History) ValidStart	VALIDSTART	Valid start date

SM_PREGNANCY Table

Information about the Oracle Empirica Signal configuration variables from the SM_PREGNANCY table.

Configuration Variable	Column	Description
(Pregnancy) Breastfeeding YN	BREASTFEEDING_YN_VE	Y/N: Breastfeeding
(Pregnancy) Case Number	CASE_NUM	Case number
(Pregnancy) Date of LMP	DATE_OF_LMP	Date of LMP
(Pregnancy) Gestation Exposure Period	GESTATION_EXPOSURE_ PERIOD	Weeks from LMP to drug exposure
(Pregnancy) Number of Fetus	NUMBER_OF_FETUS	Number of fetus
(Pregnancy) Parent	PARENT_VE	Parent flag
(Pregnancy) Prospective	PROSPECTIVE_VE	Prospective
(Pregnancy) Trimester of Exposure	EXP_TRIMESTER_VE	Trimester of exposure
(Pregnancy) ValidEnd	VALIDEND	Valid end date
(Pregnancy) ValidStart	VALIDSTART	Valid start date
(Pregnancy) Weeks at Onset	WEEKS	Weeks at onset
(Pregnancy) Breastfeeding YN	BREASTFEEDING_YN_VE	Y/N: Breastfeeding

SM_PRODUCT Table

Information about the Oracle Empirica Signal configuration variables from the SM_ PRODUCT table.

Configuration Variable	Column	Description
(Drug) Abuse YN	ABUSE_YN_VE	Y/N: Abuse
(Drug) Case Number	CASE_NUM	Case number
(Drug) Case Number	CASE_NUM	Case number
(Drug) Company Drug Code	CO_DRUG_CODE	Company drug code
(Drug) Dechallenge Date	DECHALL_DATE	Dechallenge date
(Drug) Dechallenge YNU	DECHALLENGE_VE	Y/N/U: Dechallenge flag
(Drug) Device YN	DEVICE_YN_VE	Y/N: Device
(Drug) Drug Sort ID	DRUG_SORT_ID	Drug sort order
(Drug) Drug YN	DRUG_YN_VE	Y/N: Product is a drug
(Drug) Duration	DRUG_DURATION_SECOND S	Duration text
(Drug) Formulation	FORMULATION_VE	Formulation
(Drug) Indication List	INDICATION_LIST_DV	List of indications for product
(Drug) Interaction YNU	INTERACTION_YNU_VE	Y/N/U: Drug interaction
(Drug) Onset Latency	LATENCY_TEXT_DV	Text describing onset latency from first dosage
(Drug) Overdose YN	OVERDOSE_YN_VE	Y/N: Overdose
(Drug) Product Exposure Product Name	EXPOS_PRODUCT_NAME_V E	Product name for exposure product
(Drug) Product Family Name	PROD_FAMILY_NAME_VE	Product family name

Configuration Variable	Column	Description
(Drug) Product Generic Name	PROD_GENERIC_NAME_VE	Product generic name
(Drug) Product Name	PROD_PRODUCT_NAME_VE	Product name
(Drug) Product Sequence Number	PROD_SEQ_NUM	Product sequence number
(Drug) Product Type	DRUG_TYPE_VE	Product type (suspect, concomitant, treatment)
(Drug) Rechallenge YNU	RECHALLENGE_VE	Y/N/U: Rechallenge performed
(Drug) Route (Patient)	ROUTE_VE	Route of administration (patient)
(Drug) Total Dosage	TOTAL_DOSE	Auto-calculated by Argus, based on daily dose, duration, frequency
(Drug) Total Dosage Units	TOTAL_DOSE_UNIT_VE	Value for the total dosage units
(Drug) Vaccine YN	VACCINE_YN_VE	Y/N: Product is a vaccine
(Drug) ValidEnd	VALIDEND	Valid end date
(Drug) ValidEnd	VALIDEND	Valid end date
(Drug) ValidStart	VALIDSTART	Valid start date
(Drug) ValidStart	VALIDSTART	Valid start date
(Drug) WHO Drug Code	WHO_DRUG_CODE	WHO drug code
(Drug/derived) Drug Duration Text	DRUG_DURATION_TEXT_DV	Drug duration converted to text
(Drug/derived) Family Name	FAMILY_NAME_VE	Product family name
(Drug/derived) Preferred Product Name	PREFERRED_PRODUCT_NAME_DV	Drug name variable designed for data mining. Product family name, when available, else the product generic name, else product name. Exposure names are used for known study products.
(Drug/derived) Preferred PSUR Product Name	PREF_PSUR_PRODUCT_NAME	PSUR Group Name (if defined), otherwise Preferred Product Name
(Drug/derived) Product Exposure Family Name	PROD_EXPOS_FAMILY_NAME_ DV	Product family name, with expo- sure name for known study products
(Drug/derived) Product Exposure Generic Name	PROD_EXPOS_GENERIC_NAME_DV	Product generic name, with exposure name for known study products
(Drug/derived) Product Exposure Name	PROD_EXPOS_PRODUCT_NAME_DV	Product name, with exposure name for known study products

SM_REPORTERS Table

Information about the Oracle Empirica Signal configuration variables from the SM_ REPORTERS table.

Configuration Variable	Column	Description
(Report Source) Case Number	CASE_NUM	Case number
(Report Source) HCP Flag YNU	HCP_YNU_VE	Y/N/U: Reporter is health care professional
(Report Source) Report Type	REPORTER_TYPE_VE	Report type
(Report Source) Sort ID	REPORT_SOURCE_SORT_I D	Report source sort order
(Report Source) ValidEnd	VALIDEND	Valid end date
(Report Source) ValidStart	VALIDSTART	Valid start date

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Argus Signal Management

- **About Argus Signal Management**
  Argus Signal Management is the Signal Management feature of Oracle Empirica Signal, as used with your Oracle Argus Mart database.

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

- **Standard Argus Subpopulations**
  The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all spontaneous records in the Argus database.

- **Case Scoring**
  Argus Signal Management supports Case Scoring.

- **Standard Data Mining Runs**
  To assemble data mining counts and statistics that can be compared over time, Argus Signal Management includes 23 data mining runs. All runs are refreshed as part of preparing a monthly signal management update.

- **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.

About Argus Signal Management

Argus Signal Management is the Signal Management feature of Oracle Empirica Signal, as used with your Oracle Argus Mart database.

Your Oracle Argus Mart database is refreshed regularly through the Argus Mart ETL.

An Oracle Empirica Signal user with Manage Signal Configurations and Create Data Mining Run permissions refreshes the statistics reported by Signal Management. The statistics include report counts (N) and EB05, EBGM, and EB95 scores.

These release notes describe:

- Database restrictions that identify subpopulations or types of cases within the Argus database.

- Data mining runs that are used to produce scores reported by Signal Management.

- Options available to display the Argus data and generated statistics in Signal Management.

Argus Signal Management Configuration

The Argus Signal Configuration defaults can be modified by your organization.

Attribute	Argus Signal Management Default
Name	Argus Signal Configuration
Description	Argus Signal Management Configuration
Type	Interactive
Default signal view	Open/potential signals - new cases 1M
Topic workflow configuration	-
Topic product field	-
Disable default view	No (unchecked)
Disable review period	No (unchecked)
Disable private comment	Yes (checked)
Data configuration for all reports	ARGUS (S)
Data configuration for 2D runs	Argus Spontaneous (S)
Data configuration for 3D runs	Argus Spontaneous (S+C)
Drug variable	(Drug/derived) Preferred PSUR Product Name
Event variable for 2D runs	(Event/Narrow SMQ) PT_plus_Narrow_SMQ
Event variable for 23D runs	(Event) PT
Stratification variables	(Case/derived) STANDARD_STRATA
Subset variable for signal history	(Case/derived) Subset_Month
Subset variable for Nsince counts	(Case/derived) Last Significant Update Month
Project for data mining runs	Argus Signal Mgmt
Publish data mining runs	No (unchecked)
Allow reviewers to manage their drugs' reference data	Yes (checked)

Standard Argus Subpopulations

The Signal Management feature of Oracle Empirica Signal reports the results of statistical analysis of all spontaneous records in the Argus database.

For comparison, it also reports the results of statistical analyses performed only on reports with certain shared characteristics within the database: for example, reports involving elderly reports only, or reports with a fatal outcome only.

To identify different subpopulations and types of cases in the Argus 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	(Case/derived) AgeGroup4 equals '18_64'
Elderly	(Case/derived) AgeGroup4 equals '65_above'
Fatal	(Case/derived) Fatal YN = 'Y'
Female	(Case/derived) Patient Gender equals 'F'

Population	Default Query
Male	(Case/derived) Patient Gender equals 'M'
Pediatric	(Case/derived) AgeGroup4 equals '00_17'
Serious	(Case/derived) Seriousness YN equals 'Y'
Study	(Case) Report type in 'Sponsored Trial', 'Post Marketing Surv.'

Case Scoring

Argus Signal Management supports Case Scoring.

A case score indicates how well populated a report is for a given product-event combination.

The case score is computed as the product of scores for the following categories:

- Event seriousness
- Product-event combination listedness
- Product-event combination causality
- Medical confirmation
- Case completeness

Oracle Empirica Signal computes the scores for the categories as follows:

Category	Variable	Computation
Event seriousness	Fatal Life-threatening Serious	If the event is fatal or life-threatening—5, or If the event is serious—3, or If none of the previous scenarios apply—1
Product-event combination listedness	Unlisted	If the event is listed on the drug/product label—3 If the event is not listed on the drug/product label—1

Category	Variable	Computation
Product-event combination causality (for Sponsored Trial cases)	Case type Reporter related Reporter unrelated Company related Company unrelated Rechallenge positive Dechallenge positive	If the report is reporter related and company related—8, or If the report is reporter related or company related, and • The rechallenge positive is yes or dechallenge positive is yes—8, or • The rechallenge positive is no and dechallenge positive is no—4, or If the report is reporter unrelated and company unrelated—.25, or If the report is reporter unrelated or company unrelated—1, or If none of the previous scenarios apply—.5
Product-event combination causality (for Post Marketing Survey and Compassionate Use cases)	Case type Reporter related Reporter unrelated Company related Company unrelated Rechallenge positive Dechallenge positive	If the report is reporter related or company related, and • The rechallenge positive is yes—8, or • The dechallenge positive is yes—4, or • The rechallenge positive is no and dechallenge positive is no—2, or If the report is reporter unrelated and company unrelated—.25, or If the report is reporter unrelated or company unrelated—1, or If none of the previous scenarios apply—.5
Product-event combination causality (for Spontaneous and Literature cases)	Case type Reporter related Reporter unrelated Company related Company unrelated Rechallenge positive Dechallenge positive	If the report is not company related or missing, and • If rechallenge positive is yes—8, or • If dechallenge positive is yes—4, or • If neither rechallenge positive nor dechallenge positive are yes—2 If none of the previous scenarios apply—.25
Product-event combination causality (for cases of any type that is not listed in a previous row)	-	.5

Category	Variable	Computation
Medical confirmation	-	If the report is medically confirmed—2, or
		If the report is not medically unconfirmed or missing—1
Case completeness	-	If the report has medical confirmation, drug start date, and event onset date defined, and
		• If the report has patient gender, patient age, drug dose, drug indication, PT unevalauble, and event outcome defined—3, or
		• If the previous scenario does not apply—2 If the report is missing medical confirmation, drug start date, or event onset date—1

• Thresholds
  Thresholds are used in the Significant Case Score views. All thresholds are connected via OR (any one signals).

Thresholds

Thresholds are used in the Significant Case Score views. All thresholds are connected via OR (any one signals).

Period	Period Sum	Period Average	Cumulative Average
1 Month	144	--	144
3 Months	288	--	144
6 Months	422	144	144
12 Months	566	144	144

Standard Data Mining Runs

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

The following types of runs are included:

• Data mining runs to produce disproportionality scores and report counts for the Argus data set. These runs are incorporated into the drug-event combinations table.

• Data mining runs to determine new or follow-up 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.

All of the standard data mining runs for Signal Management are MGPS runs that are limited to the set of monitored drugs. These runs are assigned to the project referenced in the Signal Management Configuration. This project is named `Argus Signal Mgmt` by default.

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

If custom terms are identified for Signal Management, the run details provide information on the custom terms.

In the descriptions that follow, values in angle brackets come from your organization's Argus Signal Configuration.

- Data Mining Runs Producing Disproportionality Scores
  Data mining runs are performed to produce the disproportionality scores for drug-event terms. This process includes one run computed using all reports in Argus, another for spontaneous reports, and another for study reports.

- Data Mining Runs to Determine "New" Cases
  The cumulative subset runs are performed to determine "new" cases relative to prior time periods.

- Data Mining Runs Producing SOC, HLT Disproportionality Scores
  A pair of data mining runs is performed to compute disproportionality scores at the SOC and HLT levels of the MedDRA hierarchy using spontaneous reports in Oracle Argus Mart.

- Data Mining Runs for Viewing Interactions
  A 3D data mining run is used to investigate Drug-Drug-Event interactions.

Data Mining Runs Producing Disproportionality Scores

Data mining runs are performed to produce the disproportionality scores for drug-event terms. This process includes one run computed using all reports in Argus, another for spontaneous reports, and another for study reports.

There are data mining runs that correspond to the following areas of interest:

- Argus - All
- Argus - Spontaneous
- Argus - Study
- Argus - Spontaneous Adult
- Argus - Spontaneous Elderly
- Argus - Fatal
- Argus - Spontaneous Female New
- Argus - Spontaneous Male
- Argus - Spontaneous Pediatric

- Argus - Serious

Argus - All

Field	Description
Run Name:	Argus - All
Configuration:	<Data configuration for all reports>
Database Restriction:	None
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for signal history>Cumulative: YesOrder: ForwardLabels: [<5 years ago>] [<4 years ago>] [<3 years ago>] [<2 years ago>] [<1 year ago>]
	[<9 months ago>] [<6 months ago>]
	[<3 months ago>] [<2 months ago>] [<1 month ago>] [<most recent month>]
Strata Variables:	<Stratification variables>
Min Count:	1
PRR and ROR:	Includes non-stratified PRR and ROR; Counts are based on cases; Yates correction applied

Argus - Spontaneous

Field	Description
Run Name:	Argus - Spontaneous
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Spontaneous reports; <Drug variable> and <Event variable for 2D runs>; Cumulative subset by <Subset variable for signal history>; Minimum count=1; stratified using <Stratification variables>; includes unstratified PRR and ROR; includes hierarchy information.
Database Restriction:	None
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for signal history>Cumulative: YesOrder: ForwardLabels: [<5 years ago>] [<4 years ago>] [<3 years ago>] [<2 years ago>] [<1 year ago>]
	[<9 months ago>] [<6 months ago>]
	[<3 months ago>] [<2 months ago>] [<1 month ago>] [<most recent month>]
Strata Variables:	<Stratification variables>
Min Count:	1
Dimensions:	2

Field	Description
PRR and ROR:	Includes non-stratified PRR and ROR; Counts are based on cases; Yates correction applied
Fill in Hierarchy Values:	Yes
Exclude Single Itemtypes:	Yes
Fit Separate Distributions:	Yes
Limit Results To:	Set of drugs that are being monitored for Signal Management

Argus - Study

Field	Description
Run Name:	Argus - Study
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Study reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR.
Database Restriction:	(Case) Report type in 'Sponsored Trial', 'Post Marketing Surv.'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Adult

Field	Description
Run Name:	Argus - Spontaneous Adult
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>

Field	Description
Description:	Adult reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) AgeGroup4 equals '18_64'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Elderly

Field	Description
Run Name:	Argus - Spontaneous Elderly
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Elderly reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) AgeGroup4 equals '65_above'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Fatal

Field	Description
Run Name:	Argus - Fatal
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Fatal reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) Fatal YN = 'Y'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Female New

Field	Description
Run Name:	Argus - Spontaneous Female New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed female reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) Patient Gender equals 'F'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min Count:	1

Field	Description
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 drugs that are being monitored for Signal Management

Argus - Spontaneous Male

Field	Description
Run Name:	Argus - Spontaneous Male
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Male reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) Patient Gender equals 'M'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Pediatric

Field	Description
Run Name:	Argus - Spontaneous Pediatric
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>

Field	Description
Description:	Pediatric reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) AgeGroup4 equals '00_17'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Serious

Field	Description
Run Name:	Argus - Serious
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Serious reports; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; stratified using <Stratification variables>; no PRR or ROR
Database Restriction:	(Case/derived) Seriousness YN equals 'Y'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Data Mining Runs to Determine "New" Cases

The cumulative subset runs are performed to determine "new" cases relative to prior time periods.

- Argus - All New
- Argus - Spontaneous New
- Argus - Study New
- Argus - Spontaneous Elderly New
- Argus - Fatal New
- Argus - Spontaneous Female New
- Argus - Spontaneous Male New
- Argus - Spontaneous Pediatric New
- Argus - Serious New
- Argus - Increased Frequency

Argus - All New

Field	Description
Run Name:	Argus - All New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Count of new or changed reports, including non-spontaneous thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	None
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min Count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in Hierarchy Values:	No
Exclude Single Itemtypes:	Yes

Field	Description
Fit Separate Distributions:	Yes
Limit Results To:	Set of drugs that are being monitored for Signal Management

Argus - Spontaneous New

Field	Description
Run Name:	Argus - Spontaneous New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed spontaneous reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	None
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Study New

Field	Description
Run Name:	Argus - Study New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>

Field	Description
Description:	Count of new or changed study reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case) Report type in 'Sponsored Trial', 'Post Marketing Surv.'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Elderly New

Field	Description
Run Name:	Argus - Spontaneous Elderly New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed elderly reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) AgeGroup4 equals '65_above'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None

Field	Description
Min 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 drugs that are being monitored for Signal Management

Argus - Fatal New

Field	Description
Run Name:	Argus - Fatal New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Count of new or changed reports with fatal outcomes thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) Fatal YN = 'Y'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Female New

Field	Description
Run Name:	Argus - Spontaneous Female New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed female reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) Patient Gender equals 'F'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Male New

Field	Description
Run Name:	Argus - Spontaneous Male New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed male reports thru end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) Patient Gender equals 'M'
Item Variables:	<Drug variable>, <Event variable for 2D runs>

Field	Description
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels: ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous Pediatric New

Field	Description
Run Name:	Argus - Spontaneous Pediatric New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Count of new or changed pediatric reports through end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR.
Database Restriction:	(Case/derived) AgeGroup4 equals '00_17'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels: ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min Count:	1
Dimensions:	2
PRR and ROR:	No PRR or ROR
Fill in Hierarchy Values:	No
Exclude Single Itemtypes:	Yes

Field	Description
Fit Separate Distributions:	Yes
Limit Results To:	Set of drugs that are being monitored for Signal Management

Argus - Serious New

Field	Description
Run Name:	Argus - Serious New
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for all reports>
Description:	Count of new or changed serious reports through end of <yyyymm> using cumulative subset by <Subset variable for Nsince counts>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	(Case/derived) Seriousness YN equals 'Y'
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for Nsince counts>Cumulative: YesOrder: ForwardLabels:
	ChgsSince[<1 month ago>]
	ChgsSince[<3 months ago>]ChgsSince[<6 months ago>]
	ChgsSince[<1 year ago>]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Argus - Increased Frequency

Field	Description
Run Name:	Argus - Increased Frequency
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>

Field	Description
Description:	Count of new reports in most recent year, prior year, and prior to 24 months, subset by <Subset variable for signal history>; <Drug variable> and <Event variable for 2D runs>; Minimum count=1; no PRR or ROR
Database Restriction:	-
Item Variables:	<Drug variable>, <Event variable for 2D runs>
Subset:	Variable: <Subset variable for signal history>Cumulative: NoLabels:
	[<1 year ago>], for example [201409–201508]
	[<13-24 months ago>], for example [201309–201408][<Prior 25+ months>], for example [1990-1999–201308]
Strata Variables:	None
Min 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 drugs that are being monitored for Signal Management

Data Mining Runs Producing SOC, HLT Disproportionality Scores

A pair of data mining runs is performed to compute disproportionality scores at the SOC and HLT levels of the MedDRA hierarchy using spontaneous reports in Oracle Argus Mart.

These are used in the Spontaneous signal set used in Argus Signal Management.

- Argus - Spontaneous, SOC
- Argus - Spontaneous, HLT

Argus - Spontaneous, SOC

Field	Description
Run Name:	Argus - Spontaneous, SOC
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Spontaneous reports; <Drug variable> and (Event) SOC Abbrev; Minimum count=1; stratified using <Stratification variables>; unstratified PRR and ROR

Field	Description
Database Restriction:	None
Item Variables:	<Drug variable>, (Event) SOC Abbrev
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Argus - Spontaneous, HLT

Field	Description
Run Name:	Argus - Spontaneous, HLT
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 2D runs>
Description:	Spontaneous reports; <Drug variable> and (Event) HLT; Minimum count=1; stratified using <Stratification variables>; unstratified PRR and ROR
Database Restriction:	None
Item Variables:	<Drug variable>, (Event) HLT
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

Data Mining Runs for Viewing Interactions

A 3D data mining run is used to investigate Drug-Drug-Event interactions.

- Argus - 3D, Spontaneous

Argus - 3D, Spontaneous

Field	Description
Run Name:	Argus - 3D, Spontaneous
Run Type:	MGPS
Project:	Argus Signal Mgmt
Configuration:	<Data configuration for 3D runs>
Description:	<Drug variable> and <Event variable for 3D runs>; 3D; Minimum count=5; stratified using <Stratification variables>; no PRR or ROR; includes hierarchy information.
Database Restriction:	None
Item Variables:	<Drug variable>, <Event variable for 3D runs>
Subset:	None
Strata Variables:	<Stratification variables>
Min 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 drugs that are being monitored for Signal Management

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

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

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

- 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. 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.

- Standard Signal Supplemental Views

  The Supplemental Views include the following for each review period (1Month shown here).

- Standard Signal Sets

  There are two standard signal sets: Spontaneous and All.

Standard Alert Types

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

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

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

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

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

Products Page

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

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

The Products page appears and contains:

- **Products By drop-down and cards:** Using the Products By drop-down list, you can group the products you are tracking by product group, category,

complexity, organization, or assigned reviewer. The grouping is reflected in the cards displayed below the Products By drop-down. For each grouping, there is a card that includes all products as well as the individual elements of the grouping. You can move back and forth through the cards with the dots below them or the right-arrow at the right. Selecting a card updates the graphic details panel and filters the Products table.

• **Products table:** Below the cards is a table containing the individual products that match the Products By filter. If you select the All card, all monitored products appear. If you select a product group card, only the products in that group appear. The graphic details on the right update to match the selection.

• **Graphic details panel:** To the right of the Products By panel and the Products table is a summary panel of either the selected Products By card or the selected Product. The panel contains sections that can be expanded or collapsed. The sections available depend on the selected item and the signal configuration. The Tracked Alerts and Informational Alerts sections are always available. The Open Topics section is available if your signal configuration is integrated with 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 Argus Signal Management-specific alert columns that you can display in the Products table in default order.

Products Column	Description
Drug	Drug Term.
SDR	Number of unlisted events with new reports and EB05 >= 2.
Fatal	Number of events with new fatal reports since the prior period.
DME	Number of designated medical events with new reports since the prior period.
TME	Number of intensively monitored events (targeted medical events) with new reports since the prior period.
Pediatric	Number of events from spontaneous reports newly exceeding threshold [EB05(peds)>=2 and EB05(peds)>EB95(adult)] since the prior period (where peds = ages 0 through 17, and adult = ages 18 through 64).
Elderly	Number of events from spontaneous reports newly exceeding threshold [EB05(elderly)>=2 and EB05(elderly)>EB95(adult)] since the prior period (where adult = ages 18 through 64, and elderly = ages 65 and above).
New	Number of events with new reports since the prior period.
Serious	Number of events with new serious reports since the prior period.
Female	Number of events from spontaneous reports newly exceeding threshold [EB05(female)>=2 and EB05(female)>EB95(male)] since the prior period.

Products Column	Description
Male	Number of events from spontaneous reports newly exceeding threshold [EB05(male)>=2 and EB05(male)>EB95(female)] since the prior period.
Interaction	Number of events from spontaneous reports newly exceeding threshold [INTSS>2] since the prior period.

Product-Event Combinations Page

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

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

2. Click a product name or an alert count.
   The Product-Event Combinations page appears. This page contains:

   • **Product Summary information (across the top and always on display):** Product statistics appear here and include the product name, product group, percentage reviewed gauge, reviewed tracked alerts/total tracked alerts, and the number of pending alerts, open topics (only available if the selected signal configuration is integrated with Topics), and comments. Under the product name is the selected Products By card.

   • **System Organ Class (SOC) cards:** The cards represent the alerts grouped by MedDRA system organ class. The counts represent tracked alerts Reviewed/Total. Selection of a card filters the Product-Event Combinations table.

   • **Product-Event Combinations table:** Lists the product-event details for the selected product. The number of product-event combinations appears in a row above the table and includes the total number of product-event combinations, the sort order, and the number of rows per page and the page number.
   By default, each tab represents an alert. The rows and columns displayed in the tab's table are defined by the alert's view and further filtered by the card selection. You can add tabs and customize the columns.

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

Standard Comments

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

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

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

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

4. (Optional) If your system supports free text comments, enter additional detailed comments.

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

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

Standard Signal Views

A signal view is a predefined set of columns and sorting preferences. 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 Signal Management. You can also create your own views. 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** on the Product-Event Combinations **Header Action menu** ( ).

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, create a new view from the existing view and 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, select the **DME tab**, select **Save as View** from the **Header Action menu** (⋮), add the new tab using the **Add Tab** menu, and 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 organized into two categories:

• Product Alerts

• Supplemental Views

The Product Alerts category includes the following for each review period (1Month shown here). These represent the user-accessible alert type views.

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

Standard Signal Supplemental Views

The Supplemental Views include the following for each review period (1Month shown here).

Name	Description
All events 1M	All events reported for the selected drug.
Closed/dismissed signals 1M	Events for the selected drug, for which the associated comment or topic state indicates that the signal has been explicitly closed.
DMEs and TMEs 1M	All designated medical events and targeted medical events reported for the selected drug.
New spontaneous cases 1M	Events reported for the selected drug, for which there have been one or more new spontaneous reports since the last review period.
New study cases 1M	Events reported for the selected drug, for which there have been one or more new study reports since the last review period.
Open/potential signals 1M	Events reported for the selected drug, for which one of the following is true: • There is a comment indicating an open signal. • There is an associated topic that is not closed. • EB05 >=2; the event is unlisted; if present, the comment is not one of the comments indicating signal closure; if present, the topic is not in a final state.
Open/potential signals with new cases 1M	Events reported for the selected drug, with new reports in the last review period for which one of the following is true: • There is a comment indicating an open signal. • There is an associated topic that is not closed. • EB05 >=2; the event is unlisted; if present, the comment is not one of the comments indicating signal closure; if present, the topic is not in a final state.
Recently reviewed 1M	Events reported for the selected drug, for which 'Submit Review' action has recently occurred.
Significant case score 1M	Events reported for the selected drug with new reports in the last review period for which Period Sum Case Score >= 144 or Cumulative Average Case Score >= 144
SMQs and custom terms 1M	SMQs and custom terms for the selected drug.

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

| Name	Description
Increased frequency	Listed drug-event combinations with increased frequency of spontaneous reports.

Standard Signal Sets

There are two standard signal sets: Spontaneous and All.

- **Spontaneous** — signal set reflects results from the Argus - Spontaneous run.

- **All** —signal set reflects results from the Argus - All run.

To view a confidence interval trend graph and other information about a combination on the Product-Event Combinations page, click **View Signal History**.

Information for the two standard signal sets displays in Signal History as follows:
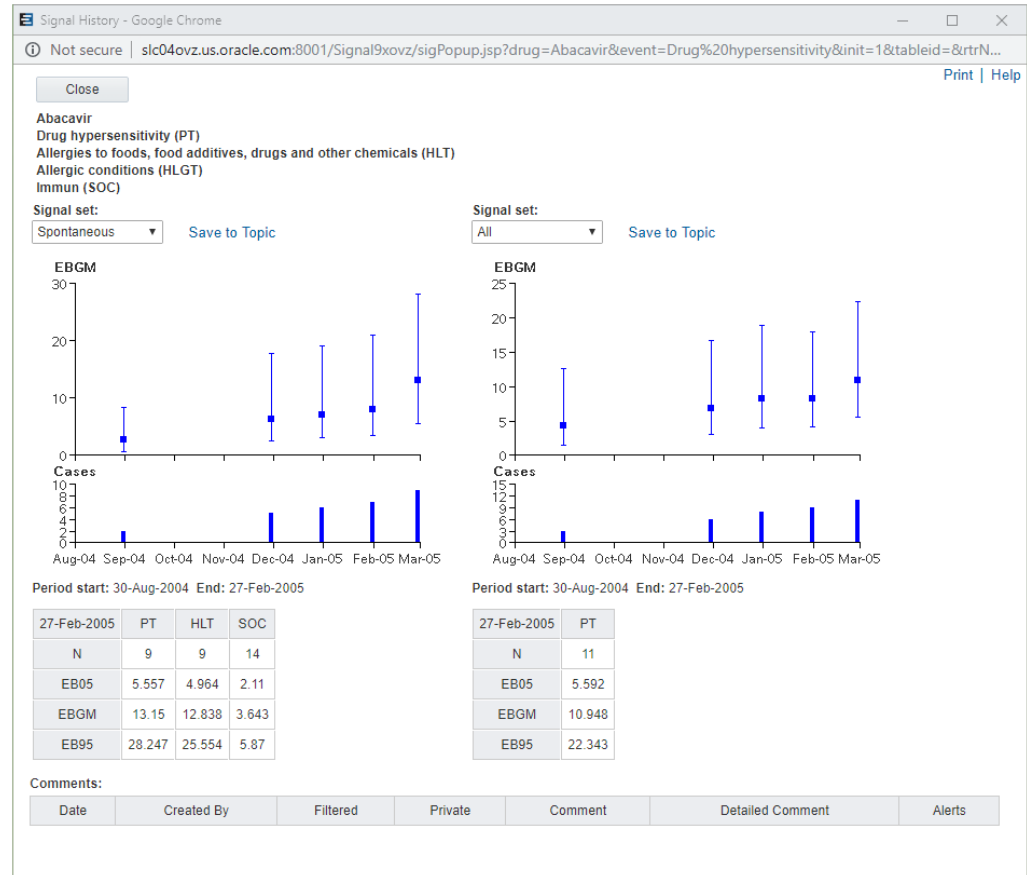
The Spontaneous Signal Set includes HLT and SOC scores in the View Signal History window. The Sector Map and Age Group/Gender Breakdown graphs can be displayed for the Spontaneous Signal Set.

7
Corrected Issues

- 22011001 - Preferred PSUR Product Name variable references wrong table
  Previously, in the ARGUS (S) data configuration shipped with Oracle Argus Mart 8.0, the (Drug/derived) Preferred PSUR Product Name variable referenced a wrong table.

- 29179497 - SIGNALDRUGCOLVIEW entries for NEW alert reference wrong views
  Previously, views assigned for the New column in Drug Overviews were incorrectly using the views for Open/potential signals - new cases.

22011001 - Preferred PSUR Product Name variable references wrong table

Previously, in the ARGUS (S) data configuration shipped with Oracle Argus Mart 8.0, the (Drug/derived) Preferred PSUR Product Name variable referenced a wrong table.

This issue has been fixed. The (Drug/derived) Preferred PSUR Product Name variable correctly references the SM_PRODUCT_S table.

29179497 - SIGNALDRUGCOLVIEW entries for NEW alert reference wrong views

Previously, views assigned for the New column in Drug Overviews were incorrectly using the views for Open/potential signals - new cases.

This issue has been fixed. The New column in the Products table uses the views for the New cases alert.

8

Known Issues

- 16391714 - Oracle Empirica Signal does not support Argus Mart multi-tenant deployment
  Multi-tenant deployments are not supported with Oracle Empirica Signal.

- 21915410 - Selecting non-default view for SMC before first refresh throws error
  If the Default View changes before the first Argus Signal Management refresh, an error occurs.

- 22456788 - Auto-Assign Reviewers with Argus SMC references wrong variables
  When using Auto-Assign Reviewers, even though 'N' counts are also listed, only 'N since' counts can be used.

16391714 - Oracle Empirica Signal does not support Argus Mart multi-tenant deployment

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If the Default View changes before the first Argus Signal Management refresh, an error occurs.

22456788 - Auto-Assign Reviewers with Argus SMC references wrong variables

When using Auto-Assign Reviewers, even though 'N' counts are also listed, only 'N since' counts can be used.