

Get SMART to Stay in CONTROL and Avoid KAOS: Signal Management for Adverse Events in Real Time

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Disclaimer

The views expressed here are those of the authors and not necessarily those of the institutions which employ them

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- JMP Discussion Forum

Agenda

- Definitions
- Introduction
- Overview
- Demo
- Technical Bits
- Conclusions
- Key Learnings

Definitions



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Definitions

- **Adverse Event (AE):**

- Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related

- Examples:

- NAUSEA
- VOMITING
- HEADACHE
- HEART ATTACK
- MALARIA
- ANAEMIA

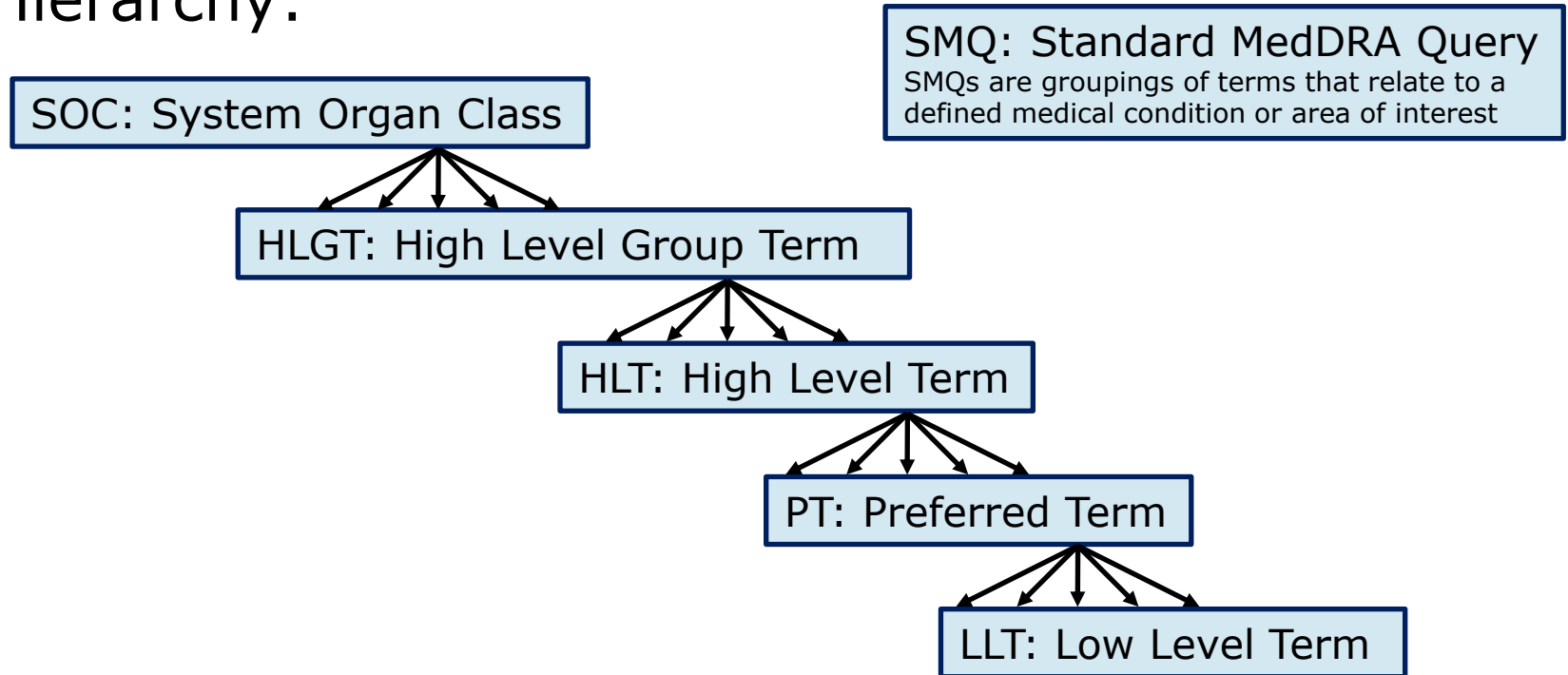
Definitions

- **Positive Rechallenge:**

- Drug administered
- Adverse event occurs
- Drug withheld for a time
- Drug administered again (rechallenge)
- Adverse event occurs again (positive rechallenge)

Definitions

- **MedDRA** - **M**edical **D**ictionary for **R**egulatory **A**ctivities
- Standardizes medical terminology used to classify adverse event information
- Hierarchy:



Definitions

MedDRA Hierarchy

- **SOC**: System Organ Class (26 terms)
- **HLGT**: High Level Group Term (335 terms)
- **HLT**: High Level Term (1,700 terms)
- **PT**: Preferred Term (21,000 terms)
- **LLT**: Lowest Level Term (65,000 terms)

Partial Sample MedDRA Hierarchy for Preferred Term = HEADACHE

Verbatim Term	LLT Name	PT Name	HLT Name	HLGT Name	SOC Name
SEVERE PALPITATIONS IN THE HEAD	HEAD THROBBING	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
FEELING OF FULLNESS IN HEAD	FULLNESS HEAD	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
SEVERE HEAD PRESSURE	HEAD PRESSURE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
FUZZY HEADACHE	HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
TEMPOROMANDIBULAR JOINT HEADACHE	TEMPORAL HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
EPIISODES OF HEADACHE PRIOR TO REACHING ORGASM	HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
PRE-EXITING HEAD PAIN	HEAD PAIN	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
NITROGLYCERIN INDUCED HEADACHE	DRUG-INDUCED HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
PAIN IN BRAIN	PAIN HEAD	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
RELAPSED PAIN IN BRAIN	PAIN HEAD	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
ELECTRICAL SHOOTING PAINS IN HER HEAD	HEAD PAIN	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
OCCASIONAL BREAKTHROUGH HEADACHE	INTERMITTENT HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
INTERMITTENT PAIN IN FOREHEAD	FOREHEAD HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
HEADACHE PAROXYSMAL	HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
UNABLE TO LAY ON LEFT SIDE OF HEAD DUE TO HEAD PAIN	HEAD PAIN	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
ORTHOSTATIC POSITIONAL HEADACHE	HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
FRONTOTEMPORAL BILATERAL CEPHALEA	CEPHALGIA	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
PRESSURE HEADACHE THAT WAS WORSE THAN A MIGRAINE	HEAD PRESSURE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
CHRONIC HEADACHE WITH SUPERIMPOSED MIGRAINES	CHRONIC HEADACHES	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
ICE PICK HEADACHE	ICE PICK HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
INCREASE IN BREAKTHROUGH HEADACHE	HEADACHE AGGRAVATED	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS
SEVERE BASAL HEADACHE	HEADACHE	HEADACHE	HEADACHES NEC	HEADACHES	NERVOUS SYSTEM DISORDERS

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Definitions

- **DME:** Designated Medical Event
- Adverse events which are
 - Rare
 - Serious
 - More likely to be associated with a high drug-attributable risk

Definitions

Alert: An automated, system-generated, notification indicating that either a pre-defined statistical threshold has been met, or a specific case characteristic has been identified

Definitions

Signal: “...information that suggests a *new potentially causal association, or a new aspect of a known association*, between an intervention and an event(s), either adverse or beneficial, that is judged to be of *sufficient likelihood to justify verificatory action.*”

- CIOMS VIII, in EMA guideline for good pharmacovigilance practices, Module IX—Signal management

Definitions

A signal is therefore a hypothesis together with supporting data and arguments.

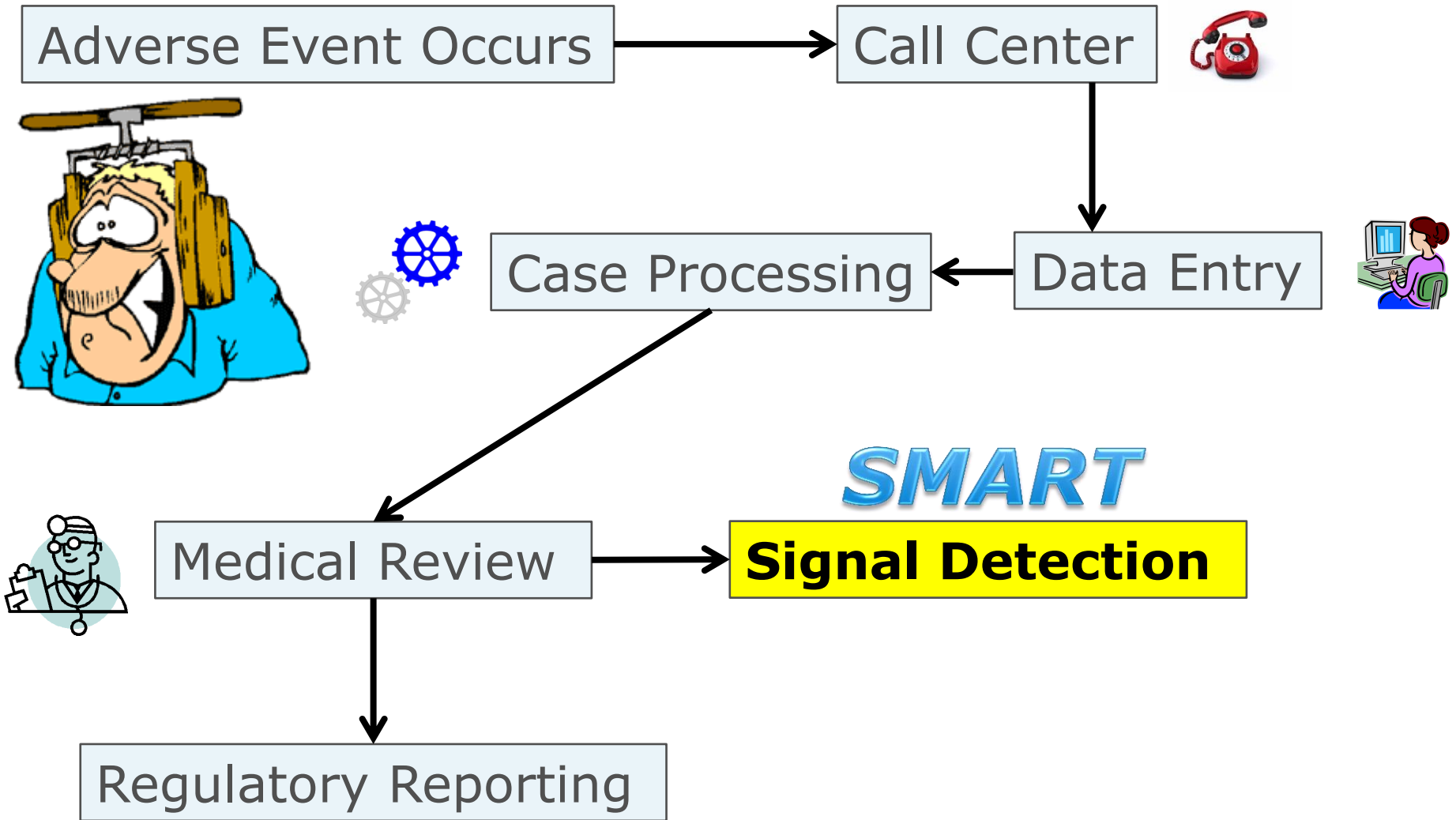
A signal is not only *uncertain* but also *preliminary* in nature: the situation may change substantially over time one way or another as more information is gathered.

Definitions

Case: information about adverse events experienced by a person while taking a drug

- Unique ID #
- Dates (occurrence, receipt, etc.)
- Demographics (gender, age, etc.)
- Adverse Event(s)
- Drug(s)
- Narrative

Safety Data Processing



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Introduction



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Introduction

- **SMART**: Decision support tool for signal detection/management
- **S**ignal **M**anagement for **A**dverse Events in **R**eal **T**ime
- Monitor product safety data
- Alert appropriate staff
- Analyze and assess/evaluate case data and basic trends for resultant alerts
- Document reviewer comments and signoff
- Manage workload
- Generate reports

Real-Time Surveillance – Why?

- Regulations require frequent monitoring of available safety data
- Maximize capabilities to proactively identify new safety risks
- Complete transparency from alert to final assessment
- Deliver industry-leading real-time signal detection platform

Real-Time Surveillance – Why?

- Improve timeliness of signal detection
- Improve sensitivity and specificity of methods
- Streamline processes and improve documentation
- Improve efficiency

SMART Overview



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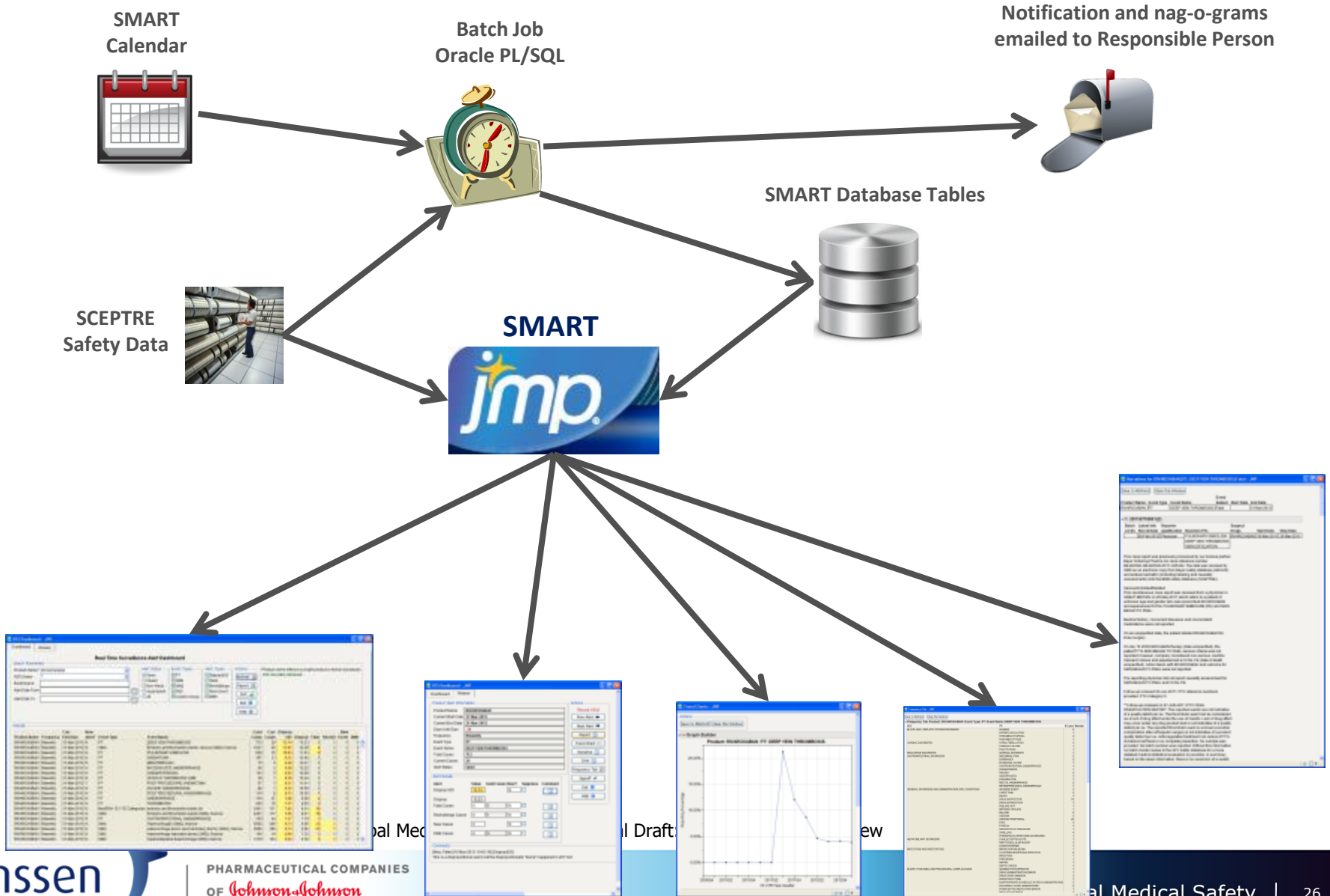
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SMART System Overview

- SMART: custom application which uses multiple linked interfaces to accomplish the following objectives:
 - Create and manage AE groups for queries
 - Schedule, customize, and edit real-time surveillance queries
 - Batch job sends email to surveillance physician when alerts are found
 - Review, Triage and Analyze alerts
 - Document comments and signoff review of alerts
 - Suppress recurring alert types which, based on clinical judgment and product knowledge, do not require continued medical review
 - Manage overall surveillance strategy across all products
- Developer notes
 - JMP 11: user interface, reports, graphs
 - Oracle PL/SQL package: backend logic
 - Oracle tables: data storage

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SMART System Architecture



Sample Notification

The screenshot shows an Outlook window titled "SMART Run log for 24-Jun-2014 - Message (HTML)". The email is from smart@its.jnj.com, sent on Tue 6/24/2014 9:04 AM. The subject is "SMART Run log for 24-Jun-2014".

The email body contains the following text:

Dear [redacted],

The Real Time Surveillance batch job found the following alerts:

Product Name	# Alerts	Frequency
[redacted]	3	4 Weeks
[redacted]	6	4 Weeks
[redacted]	14	4 Weeks
[redacted]	42	4 Weeks
[redacted]	13	4 Weeks
[redacted]	24	4 Weeks
[redacted]	19	4 Weeks
[redacted]	7	4 Weeks
[redacted]	22	4 Weeks
[redacted]	18	4 Weeks
[redacted]	2	4 Weeks
[redacted]	10	4 Weeks
[redacted]	1	4 Weeks

To view these alerts in detail use the SMART menu in JMP.

The email footer shows the sender's name "smart@its.jnj.com" and a social network connection prompt.

Sample Nag-o-gram

SMART Alert Reminders for 14-May-2015 - Message (HTML)

From: smart@its.jnj.com Sent: Thu 5/14/2015 10:14 PM

To:

Cc:

Subject: SMART Alert Reminders for 14-May-2015

Dear [redacted],

You have several alerts that are either due within 7 days or are past due:

Product	Due Date	Alert Status	# Alerts
[redacted]	19-May-2015	Open	3
[redacted]	19-May-2015	Open	3
[redacted]	19-May-2015	Open	9
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	13
[redacted]	19-May-2015	Open	18
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	1
[redacted]	19-May-2015	Open	1
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	7
[redacted]	19-May-2015	Open	2
[redacted]	19-May-2015	Open	6

To view these alerts in detail use the SMART menu in JMP.

smart@its.jnj.com

Connect to social networks to show profile photos and activity updates of your colleagues in Outlook. Click here to add networks.

There are no items to show in this view.

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SMART Algorithm

- SMART is designed to provide an early warning (alert) for the following reporting situations:
 - An AE or AE Group shows an increase in reporting percentage over time (**T**ime **F**eatures **A**nalysis)
 - A product is disproportionately reported with an adverse event (AE) or AE group (**IC025** = Information Component of BCPNN > 0*)
 - An AE is reported with a **F**atal outcome for a product
 - An AE is reported with a positive **R**echallenge for a product
 - An AE is **N**ewly reported with a product
 - A product is reported with a **D**esignated Medical Event (DME)
 - An AE is reported which has a 50% or greater probability of representing a safety signal (**C**LASP)
 - An AE is reported that is a user-defined Event of Interest (**E**VOI)

* Bayesian Confidence Propagation Neural Network, semi-empirical approximation

What is TFA?

- Time Features Analysis (TFA)
 - Monitor changes in reporting percentages for drug-event pairs over time
 - When “rules” are “broken”, a TFA alert is generated.

TFA Rules

- A method for identifying reporting percentage “behaviors” of a drug-event pair by a single alert.
 - Spike
 - Upward trend
 - Upward shift
- Each week of data since the last review will be evaluated against the TFA rules (e.g. a product with a biweekly review frequency will have 2 evaluation weeks)
- Historical data aggregated into time periods of:
 - 2 weeks
 - 4 weeks
 - 8 weeks

TFA Rules

- There are 3 rules applied to each of the time periods:

- **Spike**

- Only evaluated if there is more than 1 case for a drug-event pair in the evaluation week
- Reporting percentage in the most recent time period (i.e. last 2, 4, 8 weeks) is greater than the average of the last 12 time periods plus 3x the standard deviation of the last 12 time periods

- **Shift**

- Reporting percentages of the last 5 time periods (totaling 10, 20, 40 weeks for the 2, 4, 8 week time periods, respectively) are greater than the reporting percentage over the past 12 time periods (24 week, 48 week, 96 week reporting percentage for the 2, 4, 8 week time periods, respectively)

- **Trend**

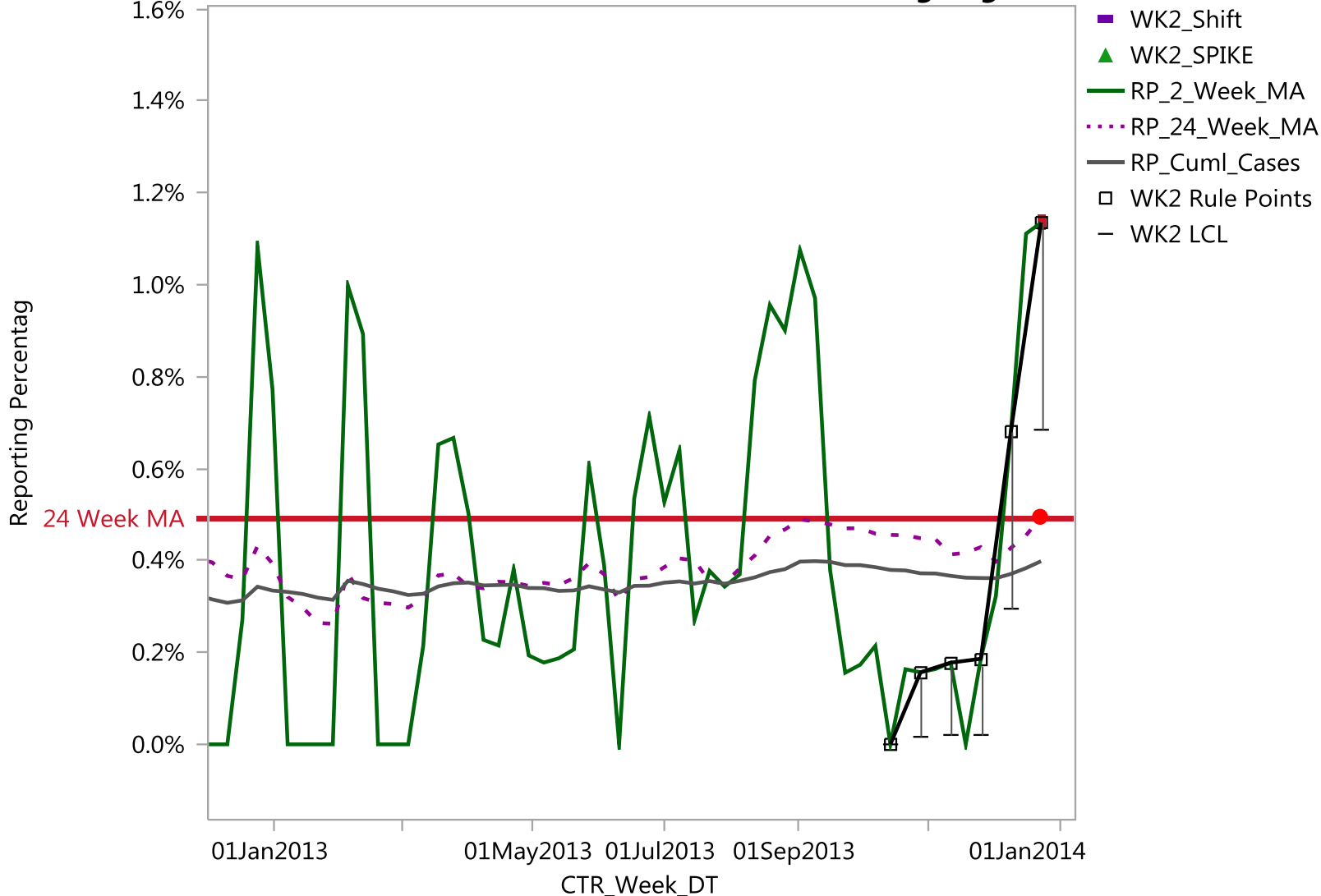
- Reporting percentages of the last 5 time periods are consecutively greater than the preceding time period

New TFA Rules

- TFA TREND and SHIFT rules modified
- Use 90% confidence limits to reduce the number of “spurious” TFA alerts.
- TREND rule:
 - Latest 5 time periods are each successively greater than preceding time period
 - Lower 90% confidence limit (LCL) of latest time period is greater than comparator moving average
- SHIFT rule:
 - Lower 90% confidence limit (LCL) from latest 5 time periods are all greater than comparator moving average

TREND Rule Example

Product: DALTSTRONG PT: PARAESTHESIA 2/24 Wk Moving Avg



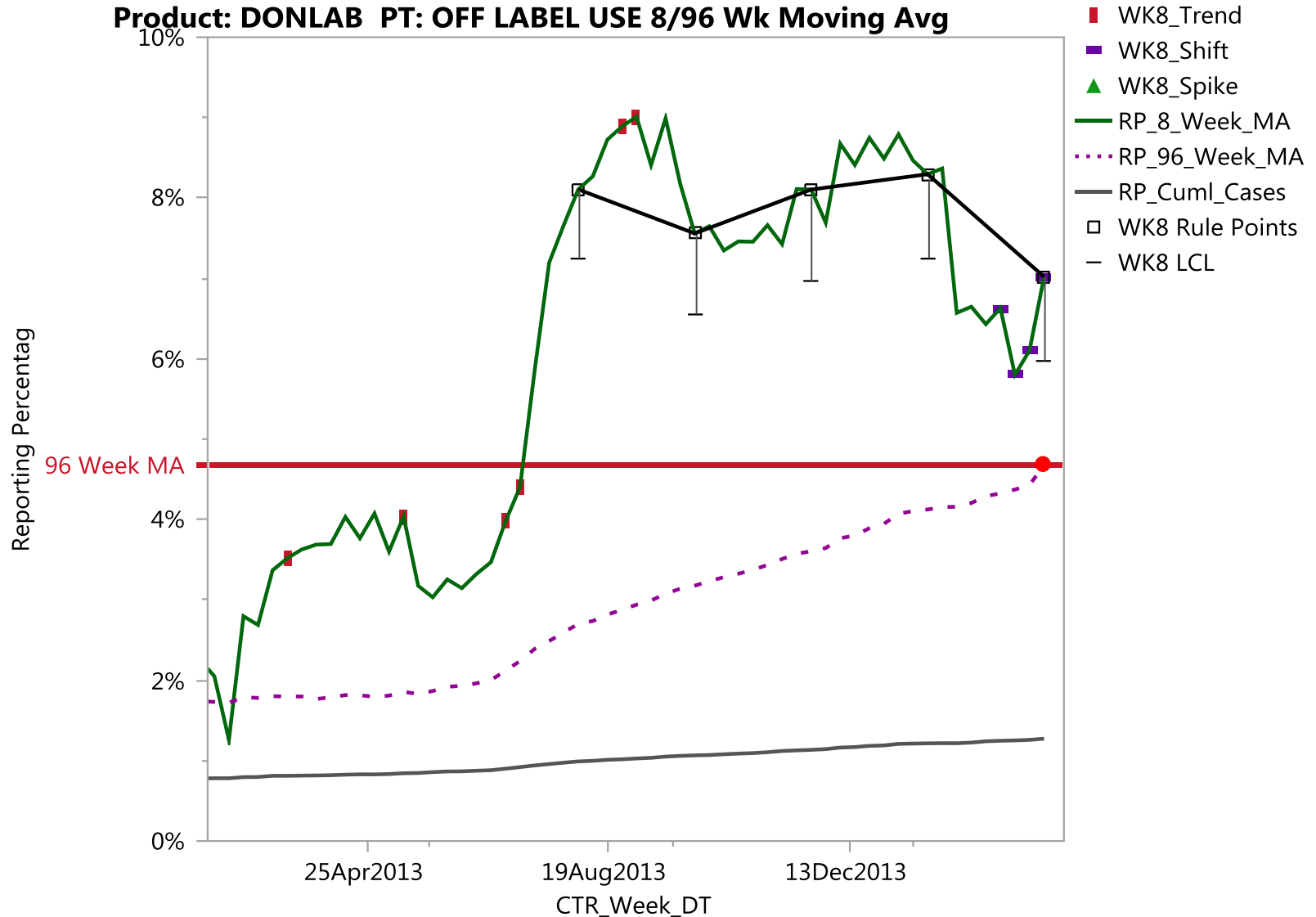
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SHIFT Rule Example

Product: DONLAB PT: OFF LABEL USE 8/96 Wk Moving Avg



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What is CLASP?

- **C**ase **L**evel **A**tttribute **S**ystematic **P**rioritization
- CLASP model developed on case-level attributes of historical data
- Model deployed on future data to make predictions
- CLASP score
 - 0: not an alert, given past behavior
 - 1: high probability that this is an alert, given past behavior

CLASP Model Schematic

Attributes for drug-event cases

HAS_LAB_INFO	IS_SERIOUSCASE
HAS_DRUG_START	IS_EVENT_SERIOUS
HAS_DRUG_END	IS_EVENT_NOT_CORELABELED
HAS_DOSE_REGIMEN	IS_PEDIATRIC
HAS_EVENT_START	IS_ELDERLY
HAS_EVENT_END	IS_POSITIVE_RECHALLENGE
HAS_PATIENTAGE	IS_POSITIVE_DECHALLENGE
HAS_PATIENTSEX	IS_POSITIVE_ESTLATENCY
HAS_ESTLATENCY	IS_POSITIVE_ESTRECOVERY
HAS_ESTRECOVERY	IS_REPCAUSALITY_POSSIBLE
HAS_DRUGOUTCOME	IS_REPCAUSALITY_PROBABLE
HAS_EVENTOUTCOME	IS_REPCAUSALITY_VERYLIKELY
HAS_PATIENTHISTORY	IS_PHYSICIAN_VERYLIKELY
HAS_SOCIALHISTORY	IS_OTHERHEALTH_VERYLIKELY
HAS_DRUGINDICATION	IS_PHARMACIST_VERYLIKELY
HAS_OTHERDRUGS	IS_REPCAUSALITY_NOTPROVIDED
HAS_OTHERSUSPECT_DRUGS	IS_REPCAUSALITY_DOUBTFUL
IS_LIT_MULTIPLE	IS_REPCAUSALITY_NOTRELATED
IS_PHARMA_DRUG	IS_PHYSICIAN_NOTRELATED
IS_CONSUMER_DRUG	IS_OTHERHEALTH_NOTRELATED
IS_LITERATURECASE	IS_PHARMACIST_NOTRELATED
IS_MEDICALLYCONFIRMED	IS_NEGATIVE_ESTLATENCY
IS_PRIMREPORTER_COMPANYREP	IS_NEGATIVE_ESTRECOVERY
IS_PRIMREPORTER_CONSUMER	IS_NARRATIVELENGTH_ABOVEHRESH
IS_PRIMREPORTER_LAWYER	IS_NEGATIVE_RECHALLENGE
IS_PRIMREPORTER_OTHERHEALTH	IS_NEGATIVE_DECHALLENGE
IS_PRIMREPORTER_PATIENT	IS_DRUG_INDICATIONEVENT
IS_PRIMREPORTER_PHARMACIST	IS_OTHERDRUG_INDICATIONEVENT
IS_PRIMREPORTER_PHYSICIAN	IS_HISTORYEVENT
IS_PRIMREPORTER_MEDICALPROF	IS_EVENT_OFINTEREST
IS_DRUGOUTCOME_DOSEINCREASED	IS_CONFOUNDED
IS_DRUGOUTCOME_DOSEREDUCED	Q_CATEGORY_IS_1
IS_DRUGOUTCOME_DOSE_NOTCHANGED	Q_CATEGORY_IS_2
IS_DRUGOUTCOME_DRUGWITHDRAWN	Q_CATEGORY_IS_3
IS_DRUGOUTCOME_NA	Q_CATEGORY_IS_4
IS_DRUGOUTCOME_UNKNOWN	Q_CATEGORY_IS_5
IS_FATALCASE	numCases_INV = 1/total # cases in series



0: Not an alert
1: Alert

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Attributes used to generate CLASP alerts

HAS_LAB_INFO	IS_SERIOUSCASE
HAS_DRUG_START	IS_EVENT_SERIOUS
HAS_DRUG_END	IS_EVENT_NOT_CORELABELED
HAS_DOSE_REGIMEN	IS_PEDIATRIC
HAS_EVENT_START	IS_ELDERLY
HAS_EVENT_END	IS_POSITIVE_RECHALLENGE
HAS_PATIENTAGE	IS_POSITIVE_DECHALLENGE
HAS_PATIENTSEX	IS_POSITIVE_ESTLATENCY
HAS_ESTLATENCY	IS_POSITIVE_ESTRECOVERY
HAS_ESTRECOVERY	IS_REPCAU_SALITY_POSSIBLE
HAS_DRUGOUTCOME	IS_REPCAU_SALITY_PROBABLE
HAS_EVENTOUTCOME	IS_REPCAU_SALITY_VERYLIKELY
HAS_PATIENTHISTORY	IS_PHYSICIAN_VERYLIKELY
HAS_SOCIALHISTORY	IS_OTHERHEALTH_VERYLIKELY
HAS_DRUGINDICATION	IS_PHARMACIST_VERYLIKELY
HAS_OTHERDRUGS	IS_REPCAU_SALITY_NOTPROVIDED
HAS_OTHERSUSPECT_DRUGS	IS_REPCAU_SALITY_DOUBTFUL
IS_LIT_MULTIPLE	IS_REPCAU_SALITY_NOTRELATED
IS_PHARMA_DRUG	IS_PHYSICIAN_NOTRELATED
IS_CONSUMER_DRUG	IS_OTHERHEALTH_NOTRELATED
IS_LITERATURECASE	IS_PHARMACIST_NOTRELATED
IS_MEDICALLYCONFIRMED	IS_NEGATIVE_ESTLATENCY
IS_PRIMREPORTER_COMPANYREP	IS_NEGATIVE_ESTRECOVERY
IS_PRIMREPORTER_CONSUMER	IS_NARRATIVELENGTH_ABOVETHRESH
IS_PRIMREPORTER_LAWYER	IS_NEGATIVE_RECHALLENGE
IS_PRIMREPORTER_OTHERHEALTH	IS_NEGATIVE_DECHALLENGE
IS_PRIMREPORTER_PATIENT	IS_DRUG_INDICATIONEVENT
IS_PRIMREPORTER_PHARMACIST	IS_OTHERDRUG_INDICATIONEVENT
IS_PRIMREPORTER_PHYSICIAN	IS_HISTORYEVENT
IS_PRIMREPORTER_MEDICALPROF	IS_EVENT_OFINTEREST
IS_DRUGOUTCOME_DOSEINCREASED	IS_CONFOUNDED
IS_DRUGOUTCOME_DOSEREDUCED	Q_CATEGORY_IS_1
IS_DRUGOUTCOME_DOSE_NOTCHANGED	Q_CATEGORY_IS_2
IS_DRUGOUTCOME_DRUGWITHDRAWN	Q_CATEGORY_IS_3
IS_DRUGOUTCOME_NA	Q_CATEGORY_IS_4
IS_DRUGOUTCOME_UNKNOWN	Q_CATEGORY_IS_5
IS_FATALCASE	numCases_INV = 1/total # cases in series

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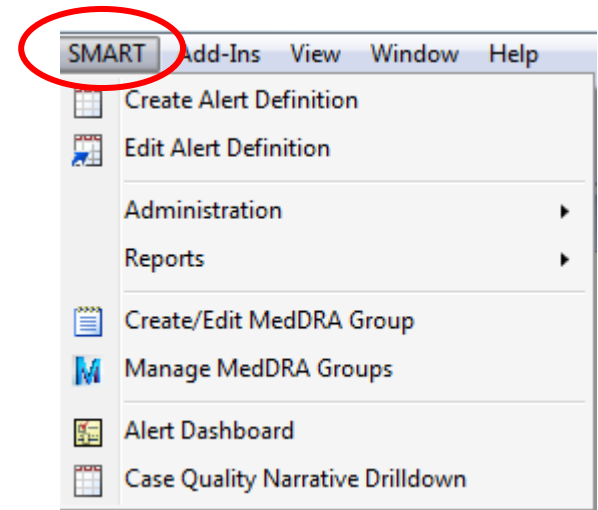
SMART Options

- **Create Alert Definition:** schedule and customize new real-time surveillance alert queries
- **Edit Alert Definition:** edit existing real-time surveillance alert queries
- **Administration *submenu*:** Add user/edit existing user
- **Reports *submenu*:** various summary reports
- **Custom MedDRA Groups:** creation and maintenance of AE Groups
- **Manage MedDRA groups:** rename groups or set group status to active/inactive
- **Alert Dashboard:** searchable, cumulative record of all alerts for each unique alert query
- **Alert Review:** supports analysis and documentation of alerts as well as suppression of recurring alerts which, based on clinical judgment and product knowledge, do not require continued medical review.

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JMP SMART Menu

- SMART capabilities can be accessed through the SAS/JMP SMART menu:
- Create Alert Definition
- Edit Alert Definition
- Administration
- Reports
- Create/Edit MedDRA Group
- Manage MedDRA Groups
- Alert Dashboard
- Case Quality Narrative Drilldown



→ This is where users spend most of their time

Alert Dashboard

- Make search selections
- Click **Refresh**
- Click on a spreadsheet row to switch to the **Review** tab for that alert
 - Brings up the **Review** screen
 - Shows all information for the selected spreadsheet row

Alert Dashboard

SMART Dashboard - JMP

Dashboard Review

SMART: Real Time Surveillance Alert Dashboard

Search Parameters

Product Name* ASD Owner Event Name Alert Date From Alert Date To

Alert Status: Open, Under Review, Closed, Signal, Non-Alerts, Suppressed, All

Event Types: PT, DME, SMQ, PQC, Custom

Alert Types: TFA, Disprop025, Fatal, Rechallenge, New Event, DME, Clasp, EVOI

Actions: Refresh, Report, Sort, Exit, Help

*Product name refers to a single product or family of products
778 record(s) retrieved

Results

Product Name	Curr End Date	Due Date	New Alert?	Event Type	Event Name	Cuml Cases	Curr Cases	Disprop			Fatal	Rechall	New			
								TFA	025	Disprop			Event	DME	CLASP	EVOI
PRONAP	18-May-2014	17-Jun-2014	Y	PT	EYE ALLERGY	1	1	0	0.07	0.92	0	0	1	0	0	0
PRONAP	18-May-2014	17-Jun-2014	Y	PT	APPLICATION SITE INFECTION	1	1	0	0.01	0.17	0	0	1	0	0	1
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	DRUG DEPENDENCE	387	15	7	2.24	2.52	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	INCORRECT DRUG ADMINISTRATION DURATION	1178	15	3	4.64	4.96	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	SNEEZING	146	2	2	2.20	2.66	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	Y	PT	ACCIDENTAL EXPOSURE TO PRODUCT BY CHILD	28	2	2	0.40	0.62	0	0	0	0	1	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	PAIN IN JAW	167	4	1	5.25	6.26	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	OROPHARYNGEAL DISCOMFORT	66	2	1	4.61	6.12	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	COLD SWEAT	228	2	1	2.87	3.31	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	ERYTHEMA	836	2	1	1.20	1.29	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	DRUG INTOLERANCE	59	3	1	1.02	1.38	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	Y	PT	MYOCARDIAL INFARCTION	94	2	1	0.66	0.83	0	0	0	0	0	2
PRONAP	15-Jun-2014	15-Jul-2014	Y	PT	HICCUPS	662	9	0	13.24	14.47	0	1	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	DEPENDENCE	1467	1	0	11.18	11.87	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	ABNORMAL DREAMS	1355	4	0	9.85	10.47	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	TOBACCO USER	68	1	0	9.33	12.26	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	NIGHTMARE	711	2	0	6.25	6.79	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	THROAT IRRITATION	1576	5	0	6.08	6.44	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	INTENTIONAL PRODUCT MISUSE	2538	11	0	5.35	5.60	0	0	0	0	0	0
PRONAP	15-Jun-2014	15-Jul-2014	N	PT	CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	85	1	0	5.28	6.77	0	0	0	0	0	0

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Alert Review

SMART Dashboard - JMP
Dashboard | Review

Product Alert Information

Product Name:

Current Start Date:

Current End Date:

Due Date:

Frequency:

Event Type:

Event Name:

Alert Status:

Signal Triage:

Case Count Summary

Period	Total Cases	Cases	Report %	Serious	% Serious	Listed	% Listed
Curr	219	15	6.85	14	93.33	15	100
Prev	225	17	7.56	16	94.12	16	94.12
13 Wks	824	44	5.34	38	86.36	43	97.73
Year	3718	52	1.4	44	84.62	50	96.15
Cuml	56436	387	0.69	266	68.73	303	78.29

Alert Details

Alert	Value	Cuml Cases	New?	Suppress	Comment
TFA	7		N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
Disprop 025	2.24		N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
Disprop	<input type="text" value="2.52"/>				
Fatal Cases	<input type="text" value="0"/>	<input type="text" value="0"/>	N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
Rechallenge Cases	<input type="text" value="0"/>	<input type="text" value="0"/>	N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
New Cases	<input type="text" value="0"/>		N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
DME Cases	<input type="text" value="0"/>	<input type="text" value="0"/>	N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
CLASP Alert	<input type="text" value="0"/>		N	<input type="button" value="▶"/>	<input type="button" value="📄"/>
EVOI	<input type="text" value="0"/>	<input type="text" value="0"/>	N	<input type="button" value="▶"/>	<input type="button" value="📄"/>

Actions

Record 683/778

Comments

[Mroz, Peter] [18-May-2015 13:40:32] [Disprop025]
Continue to monitor

[Mroz, Peter] [18-May-2015 13:40:08] [TFA]
Continue to monitor

SMART Demo

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PHARMACEUTICAL COMPANIES
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Narrative Drilldown



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Actions

Save to MSWord  Word Cloud  Close this Window 

Product Name	Event Type	Event Name	Event Subset	Start Date	End Date
INCHDOX PT		WRONG PATIENT RECEIVED MEDICATION	All	30-Dec-2013	26-Jan-2014

1. 2005148071(1)

Batch Lot #s	Latest Info Recvd Date	Reporter qualification	Reaction PTs	Suspect Drugs	Start Date	Stop Date	Case Status
3323CP	16-Jan-2014	Patient	WRONG PATIENT RECEIVED MEDICATION THERAPEUTIC RESPONSE UNEXPECTED		01-Apr-2005		Reporting

AER (2005148071) was migrated from the Johnson & Johnson ARISg Consumer Safety Database into the Johnson & Johnson SCEPTRE Safety Database on 19-FEB-2011.

A 75-YEAR-OLD FEMALE CONSUMER HAS BEEN USING 1ML OF [REDACTED] TWICE DAILY SINCE APR2005 (DATE UNSPECIFIED) FOR BALDING. SHE STATED THAT THE PRODUCT WORKS GREAT. AS OF 29OCT2005 PRODUCT USE WAS CONTINUED.

Additional information was received from the patient on 16-JAN-2014.

This report concerns an 85-year-old female. The patient's weight was not reported.

The patient was treated with [REDACTED] topical, batch 3323CP, unspecified formulation) "dropper full twice a day," initiated on APR-2005 for hair regrowth (wrong patient received medication).

On an unspecified date, the patient reported that she had been using the product for the past 20 years and that it has done a wonderful job (unexpected therapeutic benefit).

The dose of [REDACTED] was not changed.

The outcome for wrong patient received medication and unexpected therapeutic benefit were not reported.

This case is a duplicate of 20140110976.

2. 20131117187(2)

Batch Lot #s	Latest Info Recvd Date	Reporter qualification	Reaction PTs	Suspect Drugs	Start Date	Stop Date	Case Status
L0093D3B;2992RD	21-Jan-2014	Patient	INCORRECT DOSE ADMINISTERED DRUG INEFFECTIVE FOR UNAPPROVED INDICATION WRONG PATIENT RECEIVED MEDICATION DRUG INEFFECTIVE PRODUCT QUALITY ISSUE PRODUCT CONTAINER ISSUE				Reporting

This spontaneous report was received from a 60 year old female patient reporting on herself from Canada: 015947717A.

The patient's weight was 129 pounds and height was not reported.

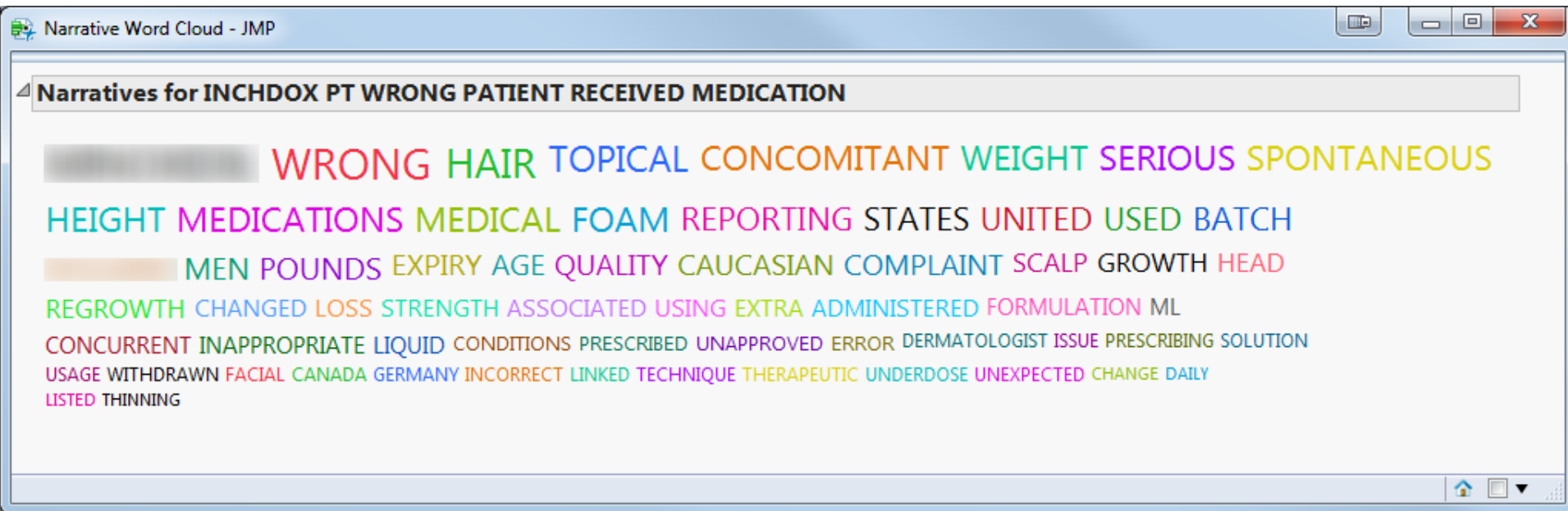
The patient's medical history was not reported.

The patient was treated with [REDACTED] 5% (foam, topical, batch L0093D3B, expiry APR-2014) (foam, topical, batch 2992RD) initiated on an unspecified date for hair loss in front of head. Concomitant medications were not reported.

It was reported that, it did not work for her (lack of effect). Initially, it came out as foam. Then after a week it was coming out as a liquid (product quality issue). Later completely stopped coming out. The pumps initially worked and then totally stopped dispensing (product

Narrative Word Cloud

- Text size indicates word frequency
- Color differentiates words



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Case Quality Drilldown



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Case Quality Drilldown

- Case Quality score (0-5)
- Case Quality category (Low, Med-Low, Medium, Med-High, High)
- Subset of CLASP attributes indicative of case quality
- Narrative drilldown

Case Quality Attributes

Case Attributes for CLASP Quality Score

Primary reporter is a physician, pharmacist, or other health care professional

Patient sex is reported

Patient age is reported

Patient medical history is reported

Patient social history (e.g., alcohol or tobacco use) is reported

Patient laboratory data are reported

Drug indication is reported

Drug outcome is reported

Drug start date is reported

Drug end date is reported

Drug dose and regimen are reported

Other drugs are reported

Other suspect drugs are reported

Event start date is reported

Event end date is reported

Event outcome is reported

Combination: Both drug and event outcome are reported

Combination: Both drug and event start dates are reported

Case Quality Scoring

Category Specifications and Case Scoring

Quality Category	Quality Score	Critical Case Information (first step in assessing score)*	No. Quality Attributes within Case
High	> 4.0 to 5.0	Pos. Rechall	13 to 18
Med-High	> 3.0 to 4.0		10 to 12
Medium	> 2.0 to 3.0		7 to 9
Med-Low	> 1.0 to 2.0		4 to 6
Low	0 to 1.0	Neg. Latency; Multi-patient literature	0 to 3

**If critical case information is available, cases are immediately categorized accordingly. Otherwise, case quality attributes are counted to derive the case score and category*

Case Quality Output

CLASP Quality Scores for ERYTHEMA - JMP

File Edit Tables Rows Cols DOE Analyze Graph PVAR SNAP PVS Surveillance Tcols SMART Add-Ins View Window Help

CLASP Quality Scores ... 21.0 Cols

Start Date: 02-Dec-2013
End Date: 29-Dec-2013

Q Category	Q Score	Report Number	Ver	Drug Generic Name	DRank	Reaction PT	ERank	Core Label	Characteristics	Fatal	Lit.	Primary Reporter	Reported Causality	Latency	Recovery
1 High	4.15	20131201196	0		1	ERYTHEMA	2	LABELED	[Spont; S-Event]	No	No	Other Health Professional	Probable	83	*
2 High	4.15	20131202542	0		1	ERYTHEMA	1	UNLABELED	[Spont; NS-Event]	No	No	Physician	Possible	485	0
3 High	4.15	20131212877	0		1	ERYTHEMA	2	LABELED	[Spont; S-Event]	No	No	Other Health Professional	Possible	1457	*
4 Med-High	4	20131209409	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Patient	Possible	304	0
5 Med-High	4	20131210171	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Patient	Possible	366	*
6 Med-High	4	20131209529	0		1	ERYTHEMA	4	LABELED	[Spont; NS-Event]	No	No	Pharmacist	Possible	232	*
7 Med-High	4	20131202540	1		1	ERYTHEMA	1	LABELED	[Spont; S-Event]	No	No	Physician	Possible	776	*
8 Med-High	4	20131203126	0		1	ERYTHEMA	5	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
9 Med-High	4	20131210187	0		1	ERYTHEMA	1	LABELED	[Spont; S-Event]	No	No	Other Health Professional	Probable	*	*
10 Med-High	3.65	20131108015	0		1	ERYTHEMA	5	LABELED	[Spont; NS-Event]	No	No	Consumer or Other Non Health Professional	Possible	138	*
11 Med-High	3.65	20130900191	2		1	ERYTHEMA	6	LABELED	[Spont; NS-Event]	No	No	Other Health Professional	Possible	*	*
12 Med-High	3.65	20131201686	0		1	ERYTHEMA	2	LABELED	[Spont; S-Event]	No	No	Other Health Professional	Probable	*	*
13 Med-High	3.35	20131200192	0		1	ERYTHEMA	3	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
14 Med-High	3.35	20131211921	0		1	ERYTHEMA	2	LABELED	[Spont; S-Event]	No	No	Physician	Possible	*	*
15 Medium	3	20131202510	0		1	ERYTHEMA	3	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
16 Medium	3	20131106964	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Patient	Doubtful	*	*
17 Medium	3	20131206319	0		1	ERYTHEMA	1	LABELED	[Spont; NS-Event]	No	No	Patient	Possible	703	*
18 Medium	2.65	20131208285	1		1	ERYTHEMA	4	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
19 Medium	2.65	20131211914	2		1	ERYTHEMA	3	LABELED	[Spont; S-Event]	No	Yes	Physician	Not Related	*	*
20 Medium	2.35	20131116497	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Patient	Possible	*	*
21 Med-Low	2	20131112693	0		1	ERYTHEMA	1	UNLABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
22 Med-Low	2	20131203193	1		1	ERYTHEMA	1	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
23 Med-Low	1.65	20131208215	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Consumer or Other Non Health Professional	Possible	*	*
24 Med-Low	1.35	20131103568	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Pharmacist	Possible	*	*
25 Med-Low	1.35	20131202742	0		1	ERYTHEMA	3	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
26 Low	1	20131203192	0		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	No	Physician	Possible	*	*
27 Low	1	20131210806	1		1	ERYTHEMA	2	LABELED	[Spont; NS-Event]	No	Yes	Physician	Possible	*	*
28 Low	1	20131206391	0		1	ERYTHEMA	3	LABELED	[Spont; S-Event]	No	No	Other Health Professional	Possible	*	*

Columns (22/0)

- Q Category
- Q Score
- Case ID
- Report Number
- Ver
- Drug Generic Name
- DRank
- Reaction PT
- ERank
- Core Label
- Characteristics
- Fatal
- Lit.
- Primary Reporter
- Reported Causality
- Latency
- Recovery
- Dechallenge
- Rechallenge
- Suspect Drugs
- Confound Ind/His

Rows

- All rows: 28
- Selected: 0
- Excluded: 0
- Hidden: 0
- Labelled: 0

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Case Quality Narrative Drilldown

CLASP Quality Scores for PT ERYTHEMA - JMP

File Edit Tables Rows Cols DOE Analyze Graph PVAR SNAP PVS Surveillance Tools SMART Add-Ins View Window Help

Start Date: 02-Dec-2013
End Date: 29-Dec-2013

Columns (22/0)

- Q Category
- Q Score
- Case ID
- Report Number
- Ver
- Drug Generic Name
- DRank
- Reaction PT
- ERank
- Core Label
- Characteristics
- Fatal
- Lit.
- Primary Reporter
- Reported Causality
- Latency
- Recovery
- Dechallenge
- Rechallenge
- Suspect Drugs
- Confound Ind/His

Rows

- All rows: 28
- Selected: 14
- Excluded: 0
- Hidden: 0
- Labelled: 0

Q Category	Q Score	Report Number	Ver	DRank	Reaction PT	ERank	Core Label	Characteristics
1 High	4.15	20131201196	0			1	ERYTHEMA	[Spont; S-Even]
2 High	4.15	20131202542	0			1	ERYTHEMA	[Spont; NS-Ev]
3 High	4.15	20131212877	0			1	ERYTHEMA	[Spont; NS-Ev]
4 Med-High	4	20131209409	0			2	LABELLED	[Spont; S-Even]
5 Med-High	4	20131210171	0			2	LABELLED	[Spont; NS-Ev]
6 Med-High	4	20131209529	0			2	LABELLED	[Spont; NS-Ev]
7 Med-High	4	20131202540	1			4	LABELLED	[Spont; NS-Ev]
8 Med-High	4	20131203126	0			1	ERYTHEMA	[Spont; NS-Ev]
9 Med-High	4	20131210187	0			1	ERYTHEMA	[Spont; S-Even]
10 Med-High	3.65	20131108015	0			5	LABELLED	[Spont; NS-Ev]
11 Med-High	3.65	20130900191	2			6	LABELLED	[Spont; NS-Ev]
12 Med-High	3.65	20131201686	0			2	LABELLED	[Spont; S-Even]
13 Med-High	3.35	20131200192	0			3	LABELLED	[Spont; NS-Ev]
14 Med-High	3.35	20131211921	0			2	LABELLED	[Spont; S-Even]
15 Medium	3	20131202510	0			3	LABELLED	[Spont; NS-Ev]
16 Medium	3	20131106964	0			2	LABELLED	[Spont; NS-Ev]
17 Medium	3	20131206319	0			1	LABELLED	[Spont; NS-Ev]
18 Medium	2.65	20131208285	1			4	LABELLED	[Spont; NS-Ev]
19 Medium	2.65	20131211914	2			3	LABELLED	[Spont; S-Even]
20 Medium	2.35	20131116497	0			2	LABELLED	[Spont; NS-Ev]
21 Med-Low	2	20131112693	0			1	UNLABELED	[Spont; NS-Ev]
22 Med-Low	2	20131203193	1			1	LABELLED	[Spont; NS-Ev]
23 Med-Low	1.65	20131208215	0			2	LABELLED	[Spont; NS-Ev]
24 Med-Low	1.35	20131103568	0			2	LABELLED	[Spont; NS-Ev]
25 Med-Low	1.35	20131202742	0			3	LABELLED	[Spont; NS-Ev]
26 Low	1	20131203192	0			2	LABELLED	[Spont; NS-Ev]
27 Low	1	20131210806	1			2	LABELLED	[Spont; NS-Ev]
28 Low	1	20131206391	0			3	LABELLED	[Spont; S-Even]

SMART Add-Ins View Window Help

- Create Alert Definition
- Edit Alert Definition
- Administration
- Reports
- Create/Edit MedDRA Group
- Manage MedDRA Groups
- Alert Dashboard
- Case Quality Narrative Drilldown

Drilldown to narratives for selected rows in the case quality table

Case Quality Narrative Drilldown Output

CLASP Quality Scores for PT ERYTHEMA (Narratives) - JMP

Actions: Save to MSWord Word Cloud Close this Window

1. 20131108015(0)

DRank	ERank	Event	Q Category	Q Score	Batch Lot #s	Latest Info Recvd Date	Reporter qualification	Reaction PTs	Suspect Product	Co-suspect Medications
1	5	ERYTHEMA	Med-High	3.65		14-Nov-2013	Consumer or Other Non Health Professional	OFF LABEL USE INFUSION RELATED REACTION COUGH HYPERHIDROSIS ERYTHEMA		

This spontaneous report was received from a patient's mother and concerns her 9-year-old son from Mexico; local case ID: MEX967/2013. Initial information was processed along with the additional information received on 14-NOV-2013. The patient's height was not reported and weight was 35 kilograms. The patient's medical history included uveitis. The patient's history of drug allergies was not reported. The patient was treated with (lyophilized powder, intravenous) (dose unspecified) initiated on 26-JUN-2013 for uveitis (off label use). Concomitant medications were not reported. On 11-NOV-2013, when the infusion began, the patient presented a forced cough, had sweating and was very red. It was stated that "he was very bad". The treatment was suspended. Treatment with was withdrawn. The patient had recovered from cough, sweating and redness on 11-NOV-2013 and off-label use on 12-NOV-2013. This report was not serious.

2. 20131200192(0)

DRank	ERank	Event	Q Category	Q Score	Batch Lot #s	Latest Info Recvd Date	Reporter qualification	Reaction PTs	Suspect Product	Co-suspect Medications
1	3	ERYTHEMA	Med-High	3.35		02-Dec-2013	Physician	BLOOD PRESSURE INCREASED PRURITUS ERYTHEMA		

This spontaneous report was received from a physician and concerns a male patient of unspecified age from New Zealand: Local case ID: ANZ0414812. The patient's height and weight were not reported. The patient's concurrent conditions included ankylosing spondylitis and Crohn's disease. The patient was treated with (lyophilized powder, intravenous) 10 mg once every 8 weeks, initiated on an unspecified date for ankylosing spondylitis and Crohn's disease. Concomitant medications included hydrocortisone and loratadine. On an unspecified date (after on 3rd infusion), the patient had experienced blood pressure was raised and redness in face. Infusion stopped then restarted. On 4th infusion, dose of was reduced to 5 mg once every 4 weeks. However the patient developed an itchy as well as redness in face. Infusion was stopped. It was reported that Crohn's symptoms had improved and gastroenterologist would like to continue with infusions. The dose of was reduced. The patient had not recovered from raised blood pressure, itchy and redness in face. This report was not serious.

3. 20131201196(0)

DRank	ERank	Event	Q Category	Q Score	Batch Lot #s	Latest Info Recvd Date	Reporter qualification	Reaction PTs	Suspect Product	Co-suspect Medications
1	2	ERYTHEMA	High	4.15		02-Dec-2013	Other Health Professional	HYPERSENSITIVITY		

Technical Bits

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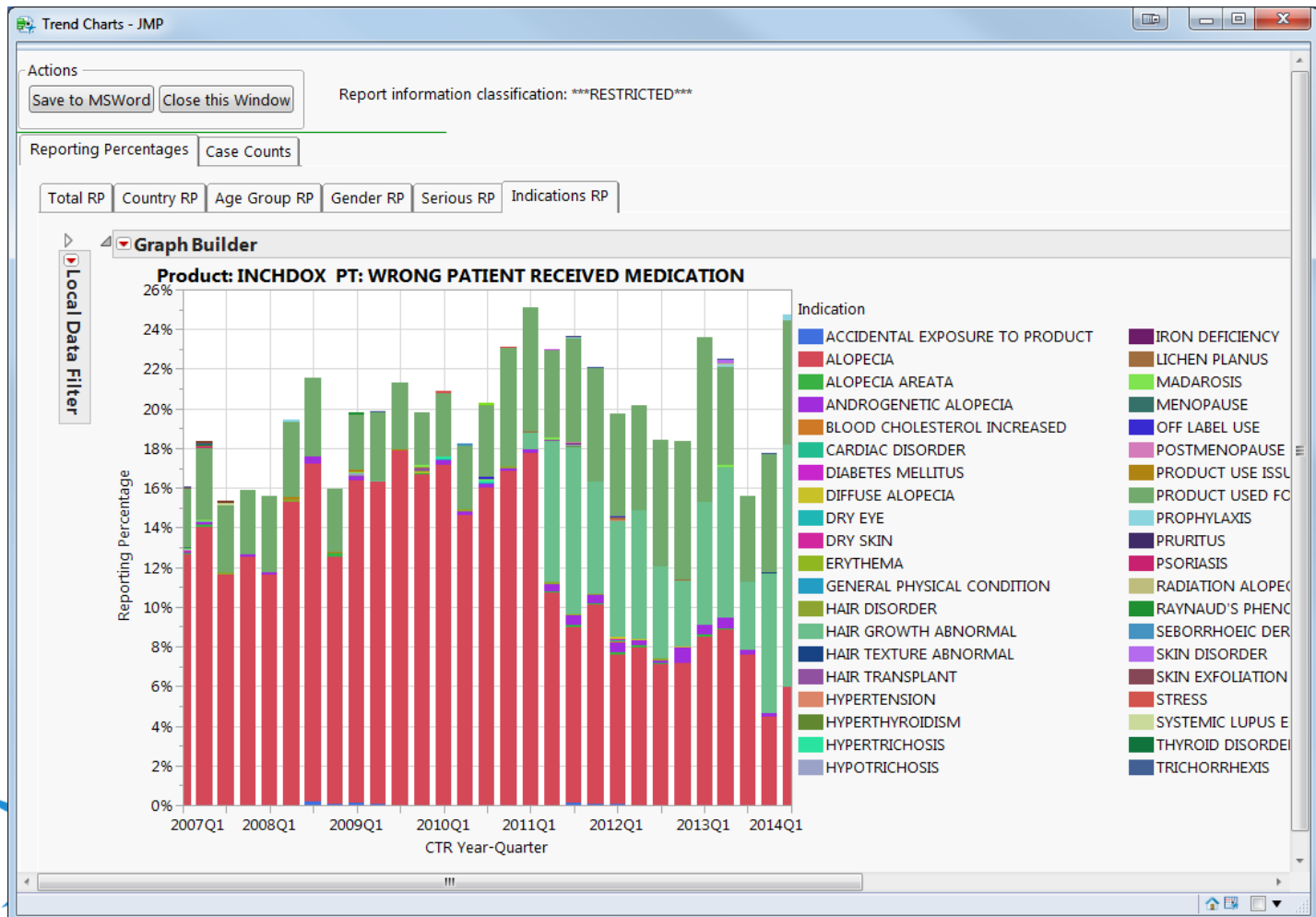
PHARMACEUTICAL COMPANIES
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Technical Bits

- Trend charts with tabbed interface and local data filters
- Moving averages in SQL
- DSN-less ODBC connection to Oracle
- User interface tips

Trend Charts

- Tabbed interface to easily show 12 charts
- Local data filter for all stacked bar charts



Each graph is an expression

```
// Plot Country
ctryrp_expr = expr(
  current_data_table(rts_strat_chart_dt);
  trend_chart_ctryrp = Graph Builder(
    Show Control Panel( 0 ),
    Variables(
      X( :Name( "CTR Year-Quarter" ) ),
      Y( :Reporting Percentage ),
      Overlay( :Country ) ),
    Elements(Bar( X, Y, Legend( 3 ), Bar Style( "Stacked" ), Summary Statistic( "Sum" ) ) ),
    SendToReport(
      Dispatch( {}, "CTR Year-Quarter", ScaleBox,
        {Min( min_date ), Max( max_date ), Interval( "Month" ), Inc( x_increment ),
        Minor Ticks( 0 ), Show Major Grid( 1 ), Rotated Labels( "Automatic" )} ),
      Dispatch( {}, "Reporting Percentage", ScaleBox, {Show Major Grid( 1 )} ),
      Dispatch( {}, "graph title", TextBox, {Set Text( rts_chart_title )} ),
    )
  );

// Add data filter for country
ldf_ctryrp = trend_chart_ctryrp << Local Data Filter( Add Filter( columns( :Country ),
  Display( :Country, Size( 204, 194 ), List Display ), ) );

ldf_ctryrp << (Filter Column( :Country ) << Order by Count( 1 ));

);
```


Tabs Within Tabs

```
trend_win = new window("Trend Charts",
    .
    .
    .
    trend_output = tab box(
        "Reporting Percentages",
        tab box(
            "Total RP", rp_expr,
            "Country RP", ctryrp_expr,
            "Age Group RP", agerp_expr,
            "Gender RP", sexrp_expr,
            "Serious RP", serrp_expr,
            "Indications RP", indrp_expr,
            "Approval Number RP", ndarp_expr
        ),
        "Case Counts",
        tab box(
            "Total CC", cc_expr,
            "Country CC", ctry_expr,
            "Age Group CC", age_expr,
            "Gender CC", sex_expr,
            "Serious CC", ser_expr,
            "Indications CC", ind_expr,
            "Approval Number CC", nda_expr,
        ),
    )
);
```

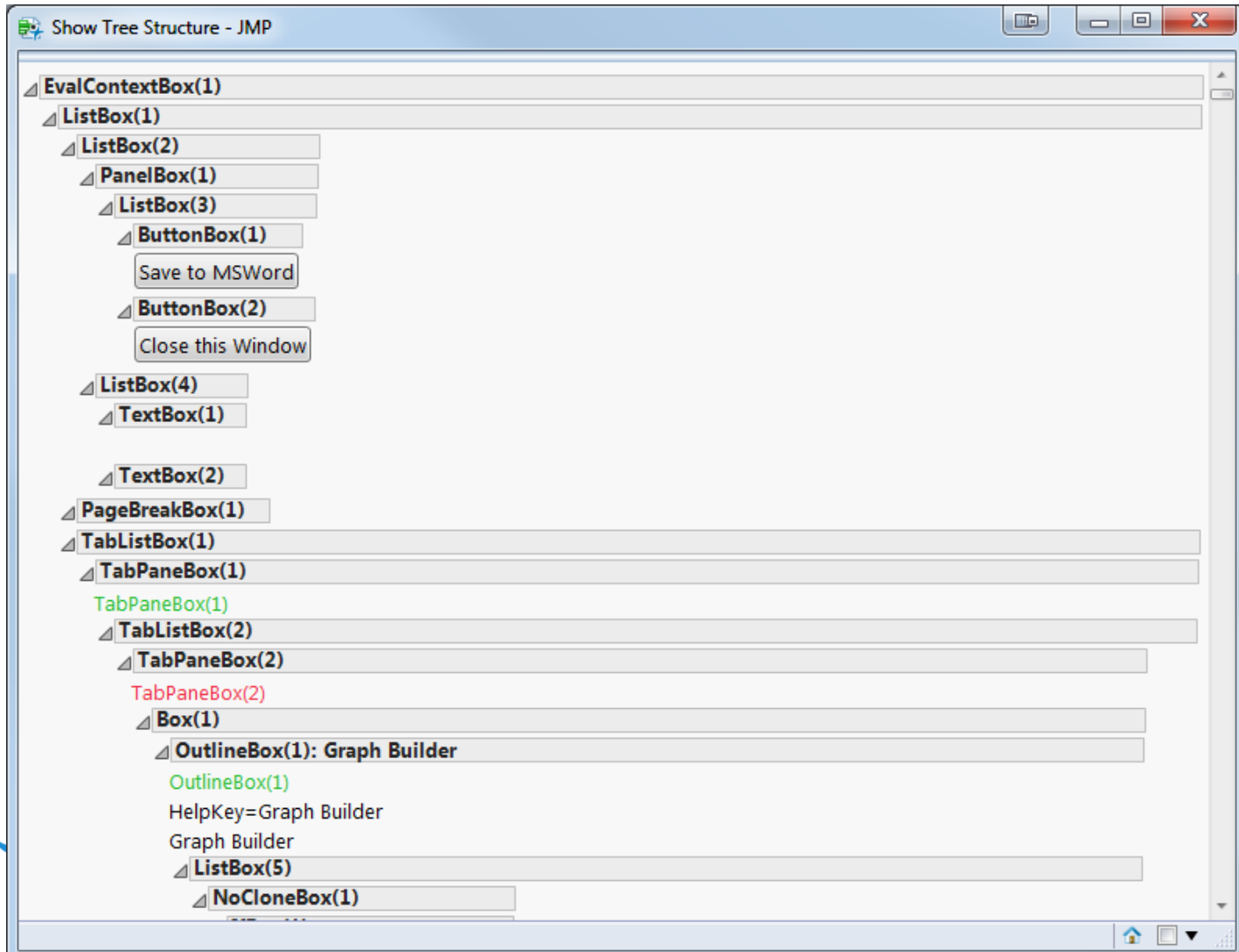
Close All Data Filters Initially

```
trend_win[Outline Box ( 2 )] << Close ( 1 );  
trend_win[Outline Box ( 4 )] << Close ( 1 );  
trend_win[Outline Box ( 6 )] << Close ( 1 );  
trend_win[Outline Box ( 8 )] << Close ( 1 );  
trend_win[Outline Box ( 10 )] << Close ( 1 );  
trend_win[Outline Box ( 12 )] << Close ( 1 );
```

```
trend_win[Outline Box ( 15 )] << Close ( 1 );  
trend_win[Outline Box ( 17 )] << Close ( 1 );  
trend_win[Outline Box ( 19 )] << Close ( 1 );  
trend_win[Outline Box ( 21 )] << Close ( 1 );  
trend_win[Outline Box ( 23 )] << Close ( 1 );  
trend_win[Outline Box ( 25 )] << Close ( 1 );
```

Find Data Filter using Tree Structure

```
trend_win << show tree structure;
```



Moving Averages in SQL

-- Calculate moving average for the last 30 records.

```
SELECT cust_no, curr_month, curr_invoice,  
       AVG(curr_invoice)  
       OVER (PARTITION BY cust_no ORDER BY curr_month  
            ROWS 30 PRECEDING) moving_avg  
FROM my_orders
```

Moving Averages in SQL

```
SELECT a.calendar_id, a.alert_name, a.ctr_week_dt, a.ctr_week, a.event_type, a.event_name,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 1 preceding AND CURRENT ROW) AS a_2_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 1 preceding AND CURRENT ROW) AS ab_2_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 3 preceding AND CURRENT ROW) AS a_4_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 3 preceding AND CURRENT ROW) AS ab_4_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 7 preceding AND CURRENT ROW) AS a_8_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 7 preceding AND CURRENT ROW) AS ab_8_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 12 preceding AND CURRENT ROW) AS a_13_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 12 preceding AND CURRENT ROW) AS ab_13_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 23 preceding AND CURRENT ROW) AS a_24_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 23 preceding AND CURRENT ROW) AS ab_24_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 47 preceding AND CURRENT ROW) AS a_48_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 47 preceding AND CURRENT ROW) AS ab_48_week_ma,
       avg(a.a_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 95 preceding AND CURRENT ROW) AS a_96_week_ma,
       avg(a.ab_cases) over (PARTITION BY a.calendar_id, a.alert_name, a.event_type, a.event_name ORDER BY
a.ctr_week ROWS BETWEEN 95 preceding AND CURRENT ROW) AS ab_96_week_ma
```

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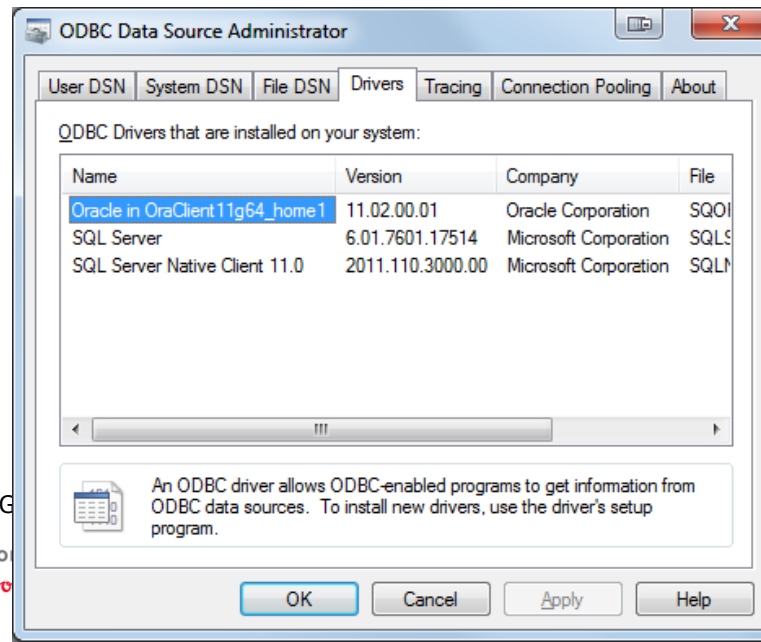
Oracle ODBC DSN-Less Connection

- Control Panel > Administrative Tools > Data Sources (ODBC)
- Check **Drivers** tab for name of Oracle driver
- Use driver name in connection string

dsn_string =

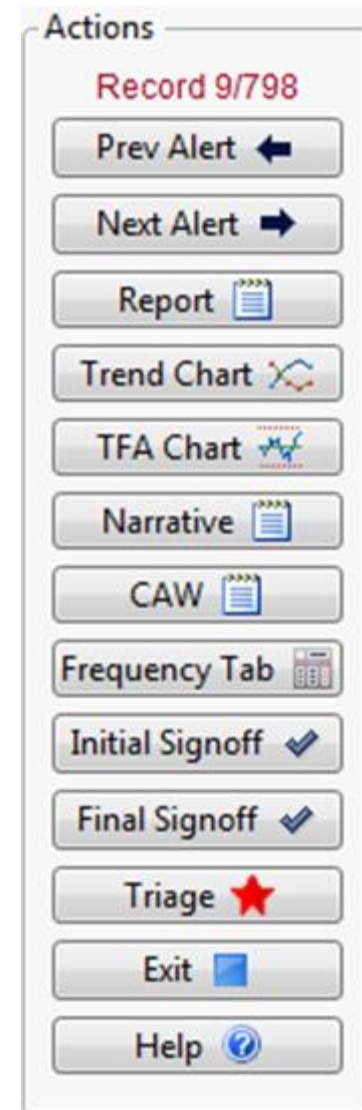
```
"Driver={Oracle in OraClient11g64_home1};  
Dbq=database_name;UID=username;PWD=password;"
```

- **database_name** alias found in TNSNAMES.ORA



User Interface Tips

- Application Builder great for prototyping
- Keep things lined up (users can detect pixel differences!)
- Use **Panel Box** to organize things, label sections
- Use **Lineup Box** to line things up
- Use icons on buttons



Global Medical Safety -- Confidential Draft: Subject to further review

SMART: Create New Alert Definition

Enter parameters for new product alert

Alert Definition Name

ASD Owner

Define Alert Types

Alert Type	Run Frequency	Review Period End Date
<input type="checkbox"/> Time Features Analysis (TFA)	4 Weeks	<input type="text"/>
<input type="checkbox"/> IC025 (Disproportionality)		
<input type="checkbox"/> Fatal		
<input type="checkbox"/> Rechallenge		
<input type="checkbox"/> New		
<input type="checkbox"/> CLASP		
<input type="checkbox"/> Custom MedDRA Group		
<input type="checkbox"/> Demographic Alerts		
<input type="checkbox"/> DME	1 Day	<input type="text"/>
<input type="checkbox"/> Event of Interest (EVOI)		

Periodic Reminder Alerts

Alert Type	Run Frequency	Review Period End Date
<input type="checkbox"/> Data Mining	6 Months	<input type="text"/>
<input type="checkbox"/> Observational Data Review	6 Months	<input type="text"/>
<input type="checkbox"/> Text Mining Review	6 Months	<input type="text"/>
<input type="checkbox"/> Social Media Review	6 Months	<input type="text"/>
<input type="checkbox"/> Eudravigilance Review	6 Months	<input type="text"/>
<input type="checkbox"/> Other	6 Months	<input type="text"/>

Other Description:

Comments

Product Search Term	<input type="text"/>	Selected Values
Product Names	<input type="text"/>	
Dosage Forms (if none are selected, all will be used)		
Custom MedDRA Groups	<ul style="list-style-type: none"> (Mroz, Peter) PQC 17.1 (Mroz, Peter) PQC 18.0 (Mroz, Peter) Topics (Mroz, Peter) Renal and Hepatic (Mroz, Peter) Renal and Hepatic Events (Mroz, Peter) thrombocytopenia (Mroz, Peter) MedDRA Categories 	<ul style="list-style-type: none"> Custom MedDRA Group Alerts (TFA, IC) Custom Event of Interest Alerts (PT-based)

Set Status

Active

Inactive

Actions

Save Exit Help

Saved?

Conclusions

- SMART has met all of our objectives
- “Real-time” monitoring every 2, 4 or 8 weeks
- Surveillance physicians proactively identify new safety risks
- Transparency from alert to final assessment
- Industry-leading real-time signal detection platform
- Improved timeliness of signal detection
- Improved sensitivity and specificity of methods
- Streamlined processes and improve documentation
- Improved efficiency
- JMP + Oracle an excellent combination

Conclusions (why I like JMP)

- JMP Script Language (JSL)
- Application Builder: Easy interface design
- Graph Builder
- Datasets: easy to use table structure
- Oracle connection
- Tabulate
- Rich statistical platforms and functions
- Add-ins:
 - Easy menu development
 - Easy deployment

Key Learnings

- Listen to your users
- Listen some more
- Keep listening!
- Don't say no right away
- Show prototypes
- Users don't know what they want until they see what they don't want



Key Learnings

- KISS
- Consistency
- Catchy name (SMART better than IRTSS)
- Give users ability to
 - Create
 - Edit
 - Configure
 - Report

Questions???



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