Nuts and Bolts of SAS Patient Safety User Interface

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Topics

- Introduction to SAS Patient Safety
  - Workflow
  - User Interface
  - Architecture
- Using Model-View-Controller
- Custom Portlets
  - Descriptions
  - Implementation
Safety Signal: WHO Definition

“Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.”

SAS Patient Safety

Relevant features:

- Provides automated drug safety signal generation at product-event level
- Provide guided analysis to understand signals
- Provides further analysis on product-AE pair
- Provides alerts through customizable dashboard
- Exports for ad hoc analysis
Four Keys to Safety Analysis

- Integration
- Quality data
- Batch analysis
- Monitoring

Data Integration and Automation

- Signal algorithms
- Data mining
- Text mining
- Exploration

Signal and Hypothesis Generation

- Guided analysis
- Ad hoc analysis
- Medical review
- Planned studies

Safety Signal Analysis

- Monitoring
- Triage
- Auditing
- Optimization

Safety Signal Management
Signal Detection Web Interface

Currently:

- Zero footprint interface
- Personalized dashboards
- Easy review of signal results
- Drill-down to supporting analysis and detail
- Supports post-marketing and clinical adverse event signal detection for both human and animal data
- Grouped analysis using terminologies such as MedDRA.
- Data exploration
SAS Patient Safety Web User Interface Workflow – Signal Results Analysis

ENTRY

Summary Dashboard

Product and Group Signal Summary

SI Journal Manager

Drugs-Drug Interaction Analysis Component

Drug-Syndrome Interaction Analysis Component

Ad Hoc Analysis

Advanced Search Facility

Text Mining Subsystem

Admin Tools

GRP Safety Reports (clinical trial data)

Product-AE Dashboard

AE Signal Summary

MedDRA Preferred Term (PT)
MedDRA HLT and GHLT
MedDRA System Organ Class (SOC)
SMQ, SSMQ* and CMQ**

Product-AE Analysis Selector

Case List

Case Profile Viewer (clinical trial data)

Case Detail

ENTRY

ENTRY

* SSMQ = Sponsor Standardized MedDRA Query
** CMQ = Custom MedDRA Query
Drill down on Mobic
### Adverse Event Signal Summary for MOBIC

**PRODUCT NAME:** MOBIC (N=26244)

**GENDER:** ALL

**AGE GROUP:** ALL

**REPORT INTERVAL:** 2004 - 2008

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<th>Adverse Event (MEDDRA Term)</th>
<th>Number of Cases</th>
<th>Expected Event Count</th>
<th>Reporting Ratio</th>
<th>Total Event Count</th>
<th>Total Case Count</th>
<th>Reporting Rate</th>
<th>Adjusted Residual Score</th>
<th>Proportional Reporting Rate</th>
<th>Reporting Odds Ratio</th>
<th>IC-2SD Score (BCPWIN) (FLAG=0.001)</th>
<th>EBGM Score (MGPS) (FLAG=2)</th>
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Click on EBGM score
SAS Patient Safety…

- Is based on SAS 9.2 technology
- Utilizes a model-view-controller pattern of workflow
- Depends on WIP services and SAS foundation services
- Is registered in the metadata server
- Generates web contents using data from safety detail data store (DDS) and data marts
- Uses the JDBC driver to connect to the SAS Workspace server to retrieve the data
- Generates some reports and output using SAS stored processes in the SAS stored process server
- Authenticates through SAS Logon Manager to direct a successful logon to the appropriate page
Architecture Topology

Client Tier
- SMC
- SAS DI Studio
- SAS Logon Manager
- SAS ID Portal
- SASPS Web App
- SAS STP Web App

Middle Tier
- Web Application Server: JBoss
- SAS Patient Safety Web Components
- SAS WIP Services & Applications
- SAS Foundation Services

Server Tier
- SAS Metadata Server
- SAS Workspace Server
- SAS Stored Process Server
- SAS Patient Safety DDS

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Flexibility with Model-View-Controller (MVC)

- MVC uses stored processes that are:
  - Perfect fit for MVC
  - Offer flexibility to add new reports (pages) quickly
  - Take advantage of full capability of SAS

- MVC enables flexible workflow

- MVC offers reusability (through services)

- MVC can run as an app within the SAS Portal
  - Taking advantage of Portal services
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Version 3

4/24/2009
Customizable Portlets

Portlet content can be rendered in many ways.

- HTML-based content
- A bar chart generated from a SAS stored process
- A table from a JSP page
- A Flash-based content from a Flex component in an external web application
- Or other kinds of web contents, such as PDF or plain text files.

- Portlets are changed by type or by content.
Combine Portlet Types
Change Portlet Type

Customize SAS Patient Safety Dashboard:

Select a Patient Safety Dashboard to display:

- Monitored Events Dashboard

Customize SAS Patient Safety Dashboard:

Select a Patient Safety Dashboard to display:

- Monitored Events Dashboard
- Top 10 Signal Scores Dashboard
- Monitored Products Dashboard
- Top 10 Signal Changes Dashboard
- PDF Doc
- TXT Doc
- HTML Doc

OK  Cancel
Change Portlet Content
Steps to Implementing Portlets

- Establish Web Infrastructure Platform Integration
- Integrate with SAS Logon Manager
- Implement Portlet as:
  - A Local Portlet in the SAS ID Portal
  - An intra frame (iFrame)
- Create content for Portlet
- Add Portlet type to the content selection list
Web Infrastructure Platform Integration (WIP)

- Provided in 9.2
- Enables integration and use of:
  - SAS Portal services and applications
- Can be consumed in custom Portlets
- Documented and available on SAS web site
  - See references
References at //support.sas.com:

- Developing Custom Portlets
  /rnd/itech/doc9/portal_dev/portlets/dg_portlets.html

- SAS Web Infrastructure Platform
  /documentation/cdl/en/itechov/60309/HTML/default/a003288350.htm

- Web Application Administration Guide: SAS Web Infrastructure Platform
  /documentation/cdl/en/biwaag/61238/HTML/default/a003267716.htm

- Foundation Services
  /documentation/cdl/en/itechov/60309/HTML/default/a003260773.htm

- Stored Processes
  /documentation/cdl/en/itechov/60309/HTML/default/a003260785.htm