



**THE
POWER
TO KNOW®**

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.”

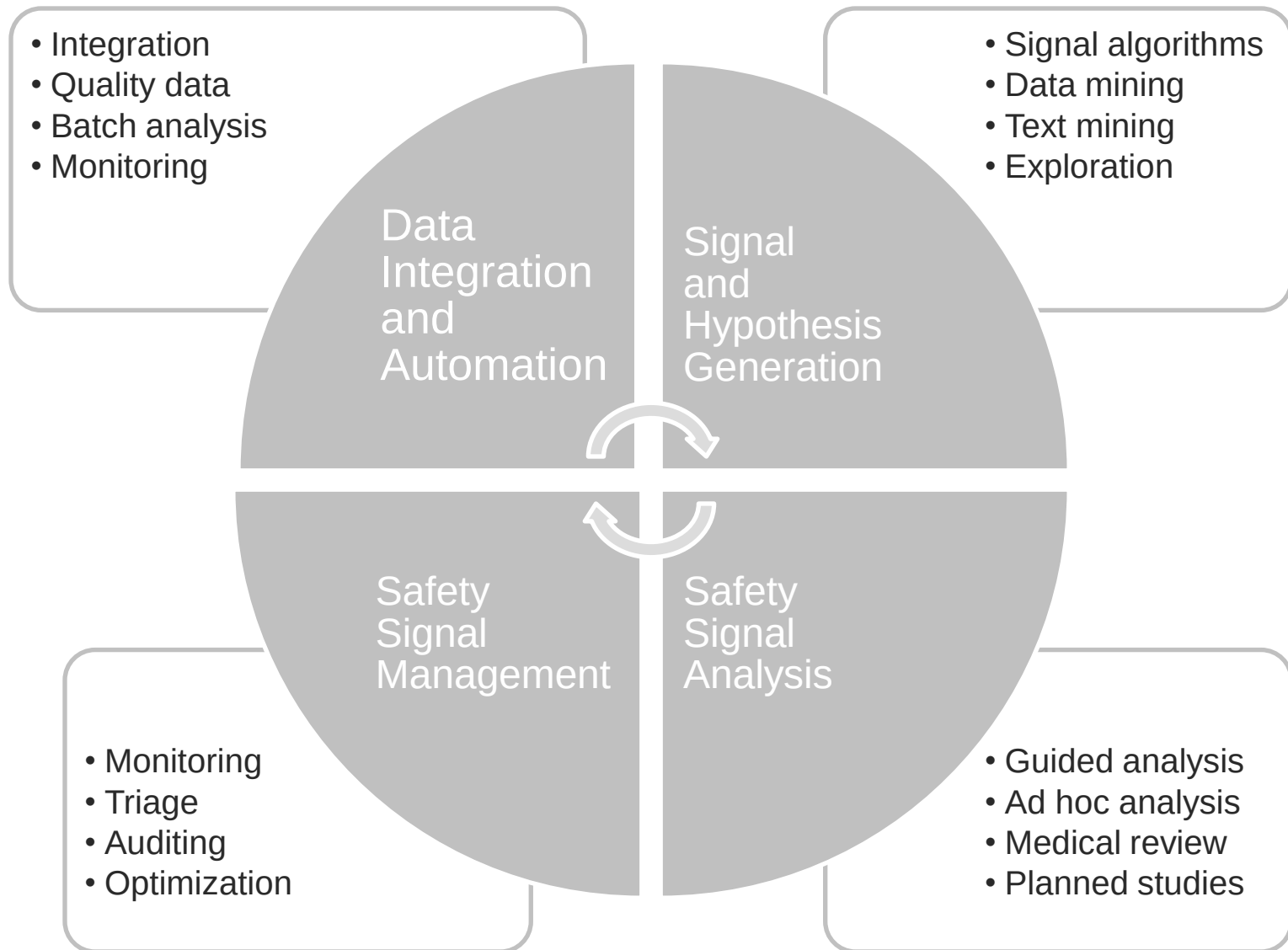
Biriell, I. E. (1994). Harmonisation in Pharmacovigilance. *Drug Safety* , 10:93-102.

SAS Patient Safety

Relevant features:

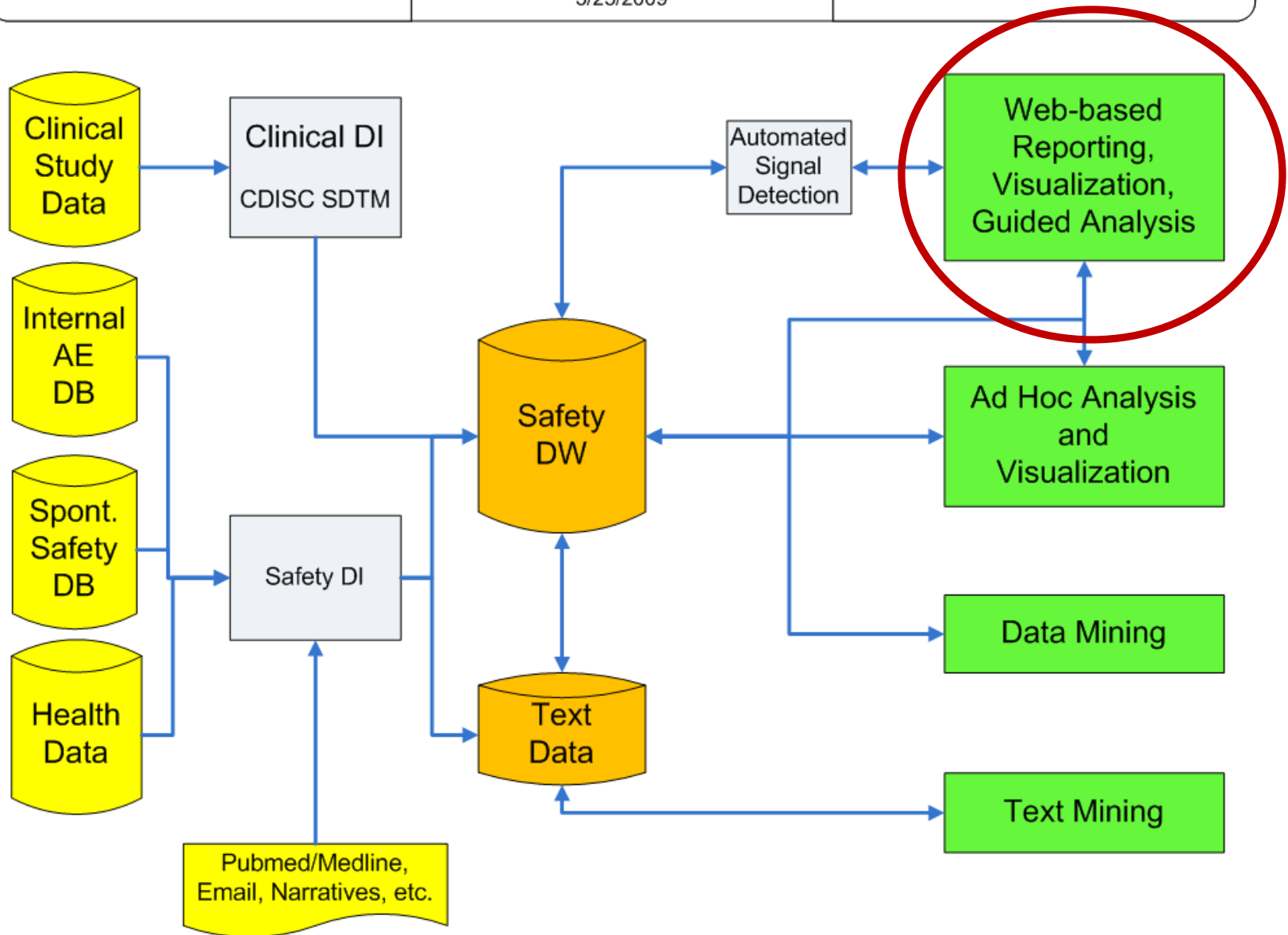
- Provides automated drug safety signal generation at product-event level
- Provide guided analysis to understand signals
- Provides further analysis on product-AE pair
- Provides alerts through customizable dashboard
- Exports for ad hoc analysis

Four Keys to Safety Analysis



Safety Data Functional Architecture

3/25/2009

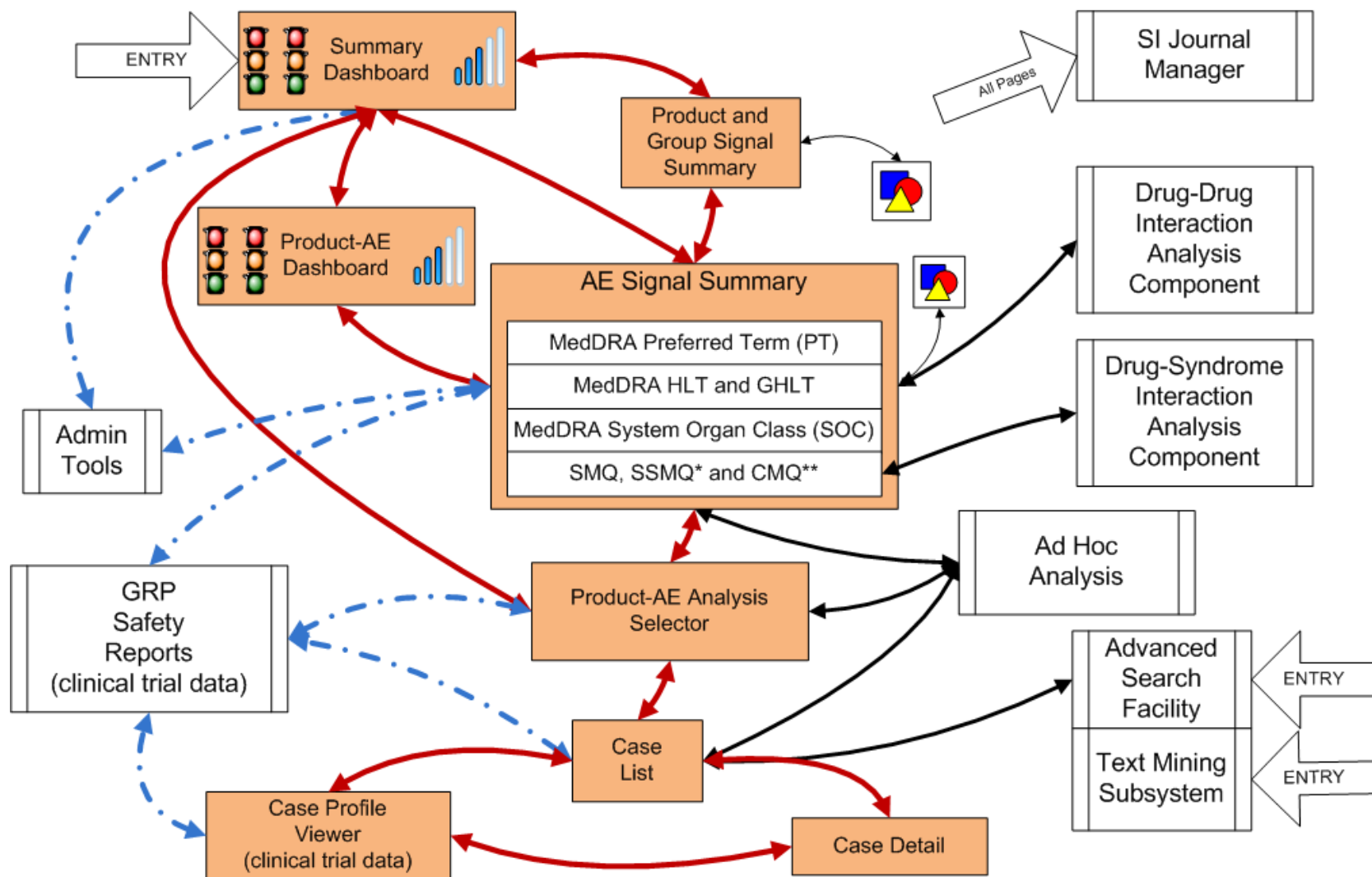


Signal Detection Web Interface

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

Version 3



* SSMQ = Sponsor Standardized MedDRA Query ** CMQ = Custom MedDRA Query

http://feec6850e.na.sas.com:8080/Portal/backToMain.do

File Edit View Favorites Tools Help

Google G Go Bookmarks Popups okay Check AutoLink AutoFill Send to Settings

SAS Information Delivery Portal

Portal Administrator Options Search Log Off sasdemo Help

SAS® Portal

SAS Patient Safety Web Application - Human Data SAS Patient Safety Web Application - Animal Data Development Home Development & Testing Page Test Page NewTest TestPage

Sticky: SPS Analyst Group

SAS Patient Safety Dashboard Portlet

Shared: SPS Analyst Group

My Products - Ranked by Composite Score

Product	Composite Score
TERIL	115
MOBIC	85
EPIVIR	55
PREDNISONE	40

Drill down on Mobic

Customize SAS Patient Safety Dashboard...

SAS Patient Safety Report Portlet

Shared: SPS Analyst Group

My Products Counts
(Last Update: Jan 19, 2009)

Product	Total PT	Total Reports	New Reports	% Change
EPIVIR	1207	162	67	41.35
AXID	234	112	37	33.06
ZYPREXA	467	56	37	66.07
VIOXX	2214	304	167	54.93
MOBIC	1505	102	61	59.80

Customize Report Portlet...

SAS Patient Safety Task Collection Portlet

Shared: SPS Analyst Group

SAS Patient Safety Task Collection (created by SAS Demo User):

Customize Task Collection...

SAS Patient Safety Dashboard Portlet

Shared: SPS Analyst Group

Watch List

Adverse Event	Adjusted Residuals
EPIVIR/PYREXIA	2.7
VIOXX/ULCER	2.4
VIOXX/EMBOLISM	2.2
ZYPREXA/PANCREATITIS	2.0
ZYPREXA/OVERDOSE	1.9
ARICEPT/DYSPNOEA	1.1
EPIVIR/HEPATITIS	0.8
ARICEPT/DIZZINESS	0.6
ARICEPT/FALL	0.5
EPIVIR/ASCITES	0.4

Customize SAS Patient Safety Dashboard...

Administrator Tool

User: SAS Demo User
Time: Thu Feb 05 08:58:05 EST 2009

Start SAS Patient Safety Administration Console

SAS Patient Safety User Profile Portlet

Shared: SPS Analyst Group

User: SAS Demo User
Time: Thu Feb 05 08:58:05 EST 2009

Start SAS Patient Safety User Profile Manager (Tree)
Start SAS Patient Safety User Profile Manager (Menu)

Local intranet 100%

http://eec6850e.na.sas.com:8080/SASPatientSafety/Controller?action=drill_down&type=rpt01&indexdrug=MOBIC&PRODUCT_TYPE=BRAND&CASE_TYPE=ALL&SPECIES_DESC=ALL

File Edit View Favorites Tools Help

Google

http://eec6850e.na.sas.com:8080/SASPatientSafety/...

Settings

Page Tools

Portal -> Product Signal

SAS Patient Safety - Signal Detection

SAS

File View

Add to MyProducts

Adverse Event Signal Summary for MOBIC

PRODUCT NAME: MOBIC (N=26244)
GENDER : ALL
AGE GROUP : ALL
REPORT INTERVAL: 2004 - 2008

Adverse Event (MEDDRA)	MEDDRA Term Count (N)	Number of Cases	Expected Event Count(E)	Reporting Ratio (Events)	Total Event Count	Total Case Count	Reporting Rate (Events)	Signal Algorithms (Events)						Event Signal Score	(Cases)	Reported	Date Event Last Reported
								Adjusted Residual Score (FLAG=2)	Proportional Reporting Rate (FLAG=3)	Reporting Odds Ratio (FLAG=2)	IC-2SD Score (BCPNN) (FLAG=0.001)	EBGM Score (MGPS) (FLAG=2)					
INTERSTITIAL LUNG DISEASE	105	105	12.20	8.607	504	488	0.2083	0.138	10.116	10.162	2.632	8.480	4	4	683.157	15JAN04	24FEB2008
PHARMACEUTICAL PRODUCT COMPLAINT	90	90	29.88	3.012	1101	1034	0.0817	-0.825	3.422	3.430	1.337	3.020	4	4	141.811	11FEB04	29FEB2008
MELAENA	73	73	10.48	6.962	441	423	0.1655	-0.057	7.625	7.644	2.237	6.840	4	4	350.801	06JAN04	26MAR2008
GASTRIC ULCER	70	70	15.09	4.639	770	730	0.0909	-0.428	3.844	3.852	1.430	4.600	4	4	133.995	16MAR04	26MAR2008
RHEUMATOID ARTHRITIS	70	70	15.39	4.549	686	644	0.1020	-0.446	4.368	4.377	1.586	4.520	4	4	163.350	24FEB04	17MAR2008
RENAL IMPAIRMENT	66	66	13.72	4.809	720	693	0.0917	-0.395	3.879	3.886	1.428	4.770	4	4	128.201	12JUL04	04DEC2007
PNEUMOCYSTIS JIROVECI PNEUMONIA	59	59	4.16	14.195	220	215	0.2682	0.594	14.086	14.116	2.763	13.960	4	4	525.035	15JAN04	12NOV2007
OSTEONECROSIS	58	58	14.72	3.940	638	592	0.0909	-0.577	3.844	3.850	1.385	3.920	4	4	111.010	23MAY05	24MAR2008
INJECTION SITE PAIN	57	57	7.22	7.894	256	238	0.2227	0.058	11.010	11.032	2.528	7.690	4	4	403.354	29MAR04	25MAR2008
HAEMATEMESIS	56	56	11.55	4.847	586	564	0.0956	-0.387	4.061	4.068	1.443	4.790	4	4	116.948	06JAN04	20MAR2008
INJECTION SITE IRRITATION	47	47	4.17	11.269	154	147	0.3052	0.382	16.885	16.913	2.806	10.920	4	4	488.073	29MAR04	25MAR2008
DISSEMINATED INTRAVASCULAR COAGULATION	45	45	6.15	7.315	394	376	0.1142	-0.011	4.956	4.963	1.612	7.100	4	4	125.931	13APR04	20NOV2007
DUODENAL ULCER	41	41	5.23	7.834	327	318	0.1254	0.051	5.511	5.518	1.699	7.570	4	4	132.434	16APR04	27FEB2008
OSTEOMYELITIS	39	39	8.63	4.518	323	294	0.1207	-0.449	5.279	5.285	1.634	4.460	4	4	118.961	29DEC04	24MAR2008
GASTRIC ULCER HAEMORRHAGE	38	38	4.12	9.228	212	207	0.1792	0.200	8.395	8.405	2.104	8.860	4	4	203.201	09JUL04	04DEC2007
INJECTION SITE FRYTHEMA	38	38	4.95	7.670	211	200	0.1801	0.032	8.443	8.454	2.110	7.390	4	4	204.481	29MAR04	25MAR2008

Click on EBGM score

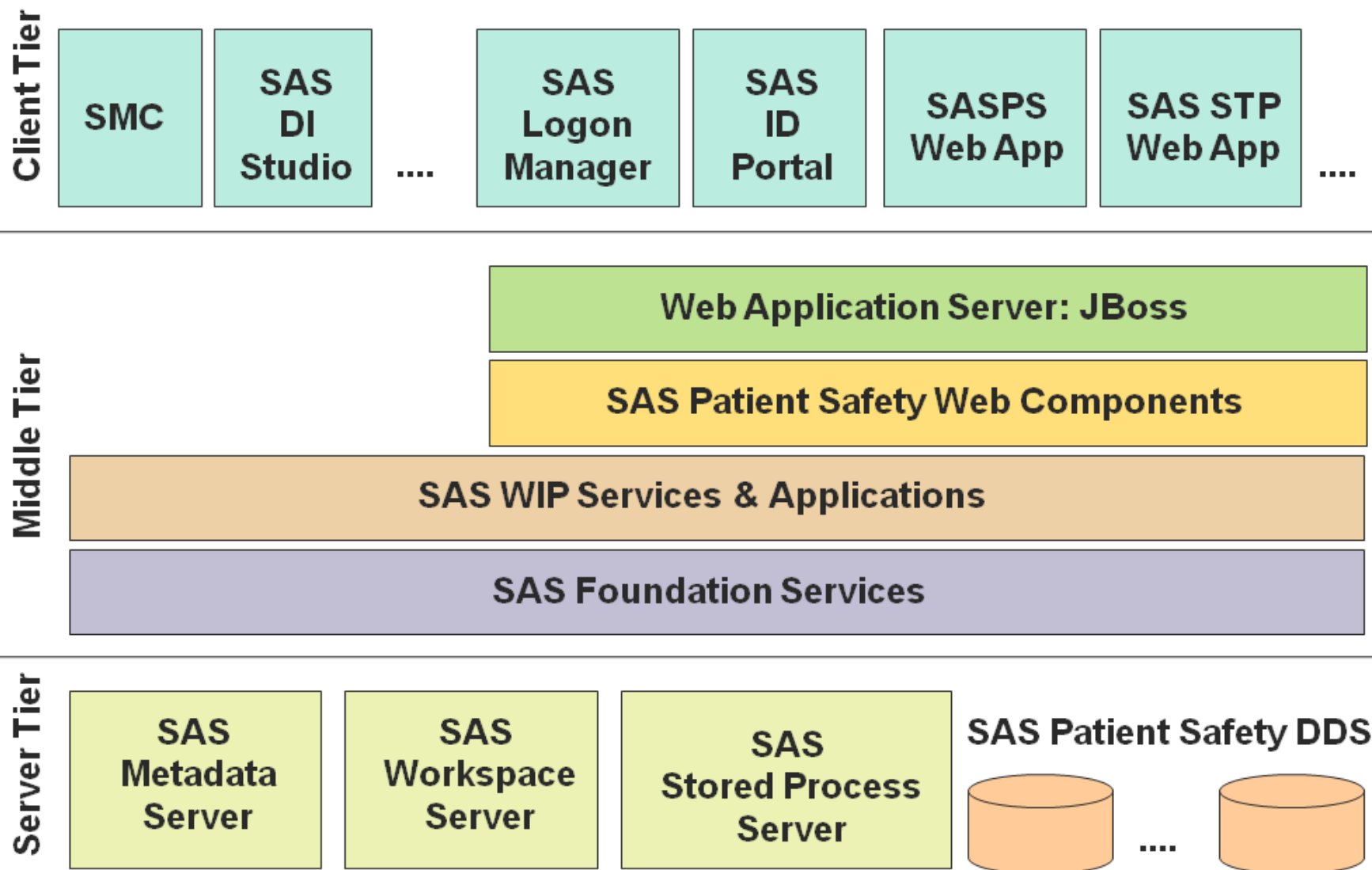
Local intranet

100%

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

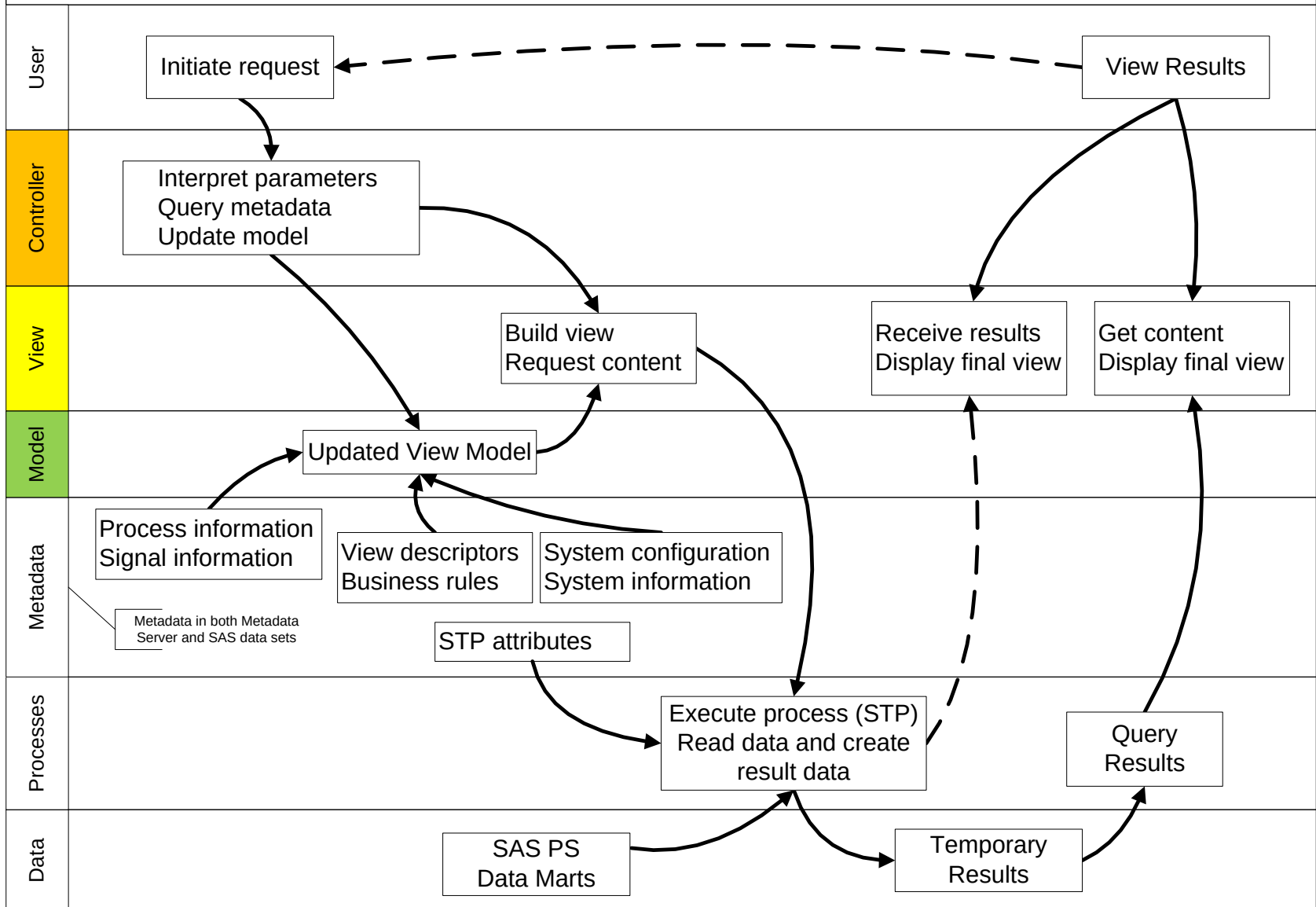
Architecture Topology



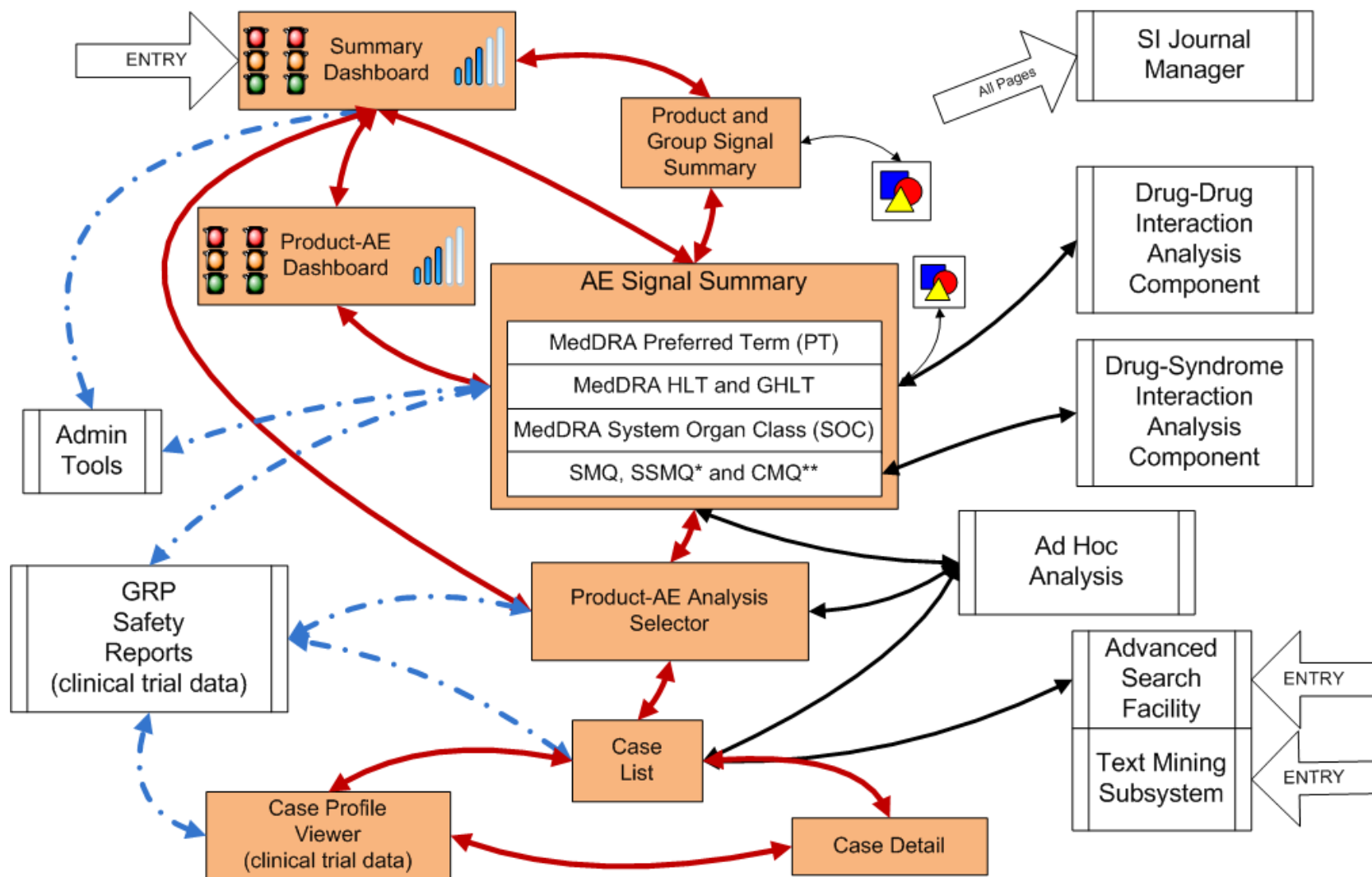
Flexibility with Model-View-Controller (MVC)

- 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

Patient Safety MVC



Version 3



* SSMQ = Sponsor Standardized MedDRA Query ** CMQ = Custom MedDRA Query

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

Options

Search

Log Off Eric Brinsfield

Help

SAS® Portal

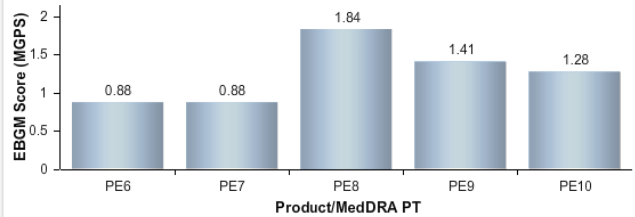
SAS Patient Safety

Home

Monitored Events Dashboard

Shared: SASPS Analysts

Monitored Events (EBGM Score (MGPS))

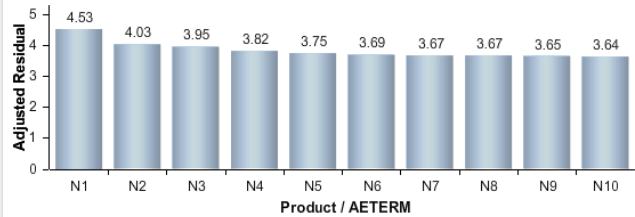


Product/MedDRA PT	EBGM Score (MGPS)
PE6	0.88
PE7	0.88
PE8	1.84
PE9	1.41
PE10	1.28

Top 10 Signal Scores

Persistent: SASPS Analysts

Top 10 Signal Scores (Adjusted Residual)



Product / AETERM	Adjusted Residual
N1	4.53
N2	4.03
N3	3.95
N4	3.82
N5	3.75
N6	3.69
N7	3.67
N8	3.67
N9	3.65
N10	3.64

Monitored Products

Shared: SASPS Analysts

My Monitored Products Counts
(Last Update: July 19, 2009)

Product	Total AE	Total Reports	New Reports	% Change
EPIVIR	1,207	162	67	41.35
AXID	467	56	37	66.07
VIOXX	2,214	304	167	54.93
MOBIC	1,505	102	61	59.80
ALINIA	1,211	92	64	59.20

Products 1 - 5 of 17

Top 10 AE Changes Dashboard

Shared: SASPS Analysts

Top 10 Changes Since Last Month

Product AE	Total Reports	New Reports	% Changes	GAM Score
EPIVIR	1,207	162	67	41.35
AXID	467	56	37	66.07
VIOXX	2,214	304	167	54.93
MOBIC	1,505	102	61	59.80
ALINIA	1,211	92	64	59.20

Products 1 - 5 of 17

SAS Patient Safety Task Collection Portlet

Shared: SASPS Analysts

SAS Patient Safety Task Collection (created by Eric Brinsfield):

Product Summary

Change Portlet Type

Help

Edit Portlet • SAS Patient Safety Dashboard

Customize SAS Patient Safety Dashborad:

Select a Patient Safety Dashboard to display:

Monitored Events Dashboard

OK Cancel

Customize SAS Patient Safety Dashborad:

Select a Patient Safety Dashboard to display:

Monitored Events Dashboard

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

SAS Patient Safety Dashboard

Top 10 Signal Scores (Adjusted Residual)

Adjusted Residual

4.53 4.03 3.95 3.82 3.75 3.69 3.67 3.67 3.65 3.64

N1 N2 N3 N4 N5 N6 N7 N8 N9 N10

Top 10 Signal Scores Shared: SASPS Analysts

Monitored Events (Adjusted Residual)

Myproducts List

Rank	Prod	AETerm	Score	Method	Prod Type	Age	Sex	View
N1	VITR	TOXIC AN	3.92	ADJRESIDU	BRAND		ALL	AETERM
N2	AMPH	TOXIC AN	3.92	ADJRESIDU	BRAND		ALL	AETERM
N3	ALIN	GASTROEN	3.80	ADJRESIDU	BRAND		ALL	AETERM
N4	CLAF	NEUROTO	3.74	ADJRESIDU	BRAND		ALL	AETERM
N5	SUPR	PSEUDOME	3.69	ADJRESIDU	BRAND		ALL	AETERM
							ALL	AETERM
							ALL	AETERM

Top 10 Signal Scores Shared: SASPS Analysts

Top 10 Signal Scores (Adjusted Residual)

Customization

- Signal Method...
- Group Level...
- Product Type...

Signal Algorithms (Events)

- ☒ Adjusted Residual Score
- ☐ Proportional Reporting Rate
- ☐ Reporting Odds Ratio
- ☐ IC-2SD Score (BCPNN)
- ☐ EBGM Score (MGPS)

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>



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