



GlaxoSmithKline

SAS Drug Development (SDD)

Meeting the challenges of Globalisation

PhUSE Brussels Single Day Event (SDE)

April 2010

Francois Torche, LACO for GSK Biologicals

Agenda

- Introduction
 - Background
 - Business Drivers
 - Why SAS Drug Development?
- GSK Business Implementation
 - Repository
 - System Administration
 - Programming & Execution
- A few words about Infrastructure...
- Conclusion

Agenda

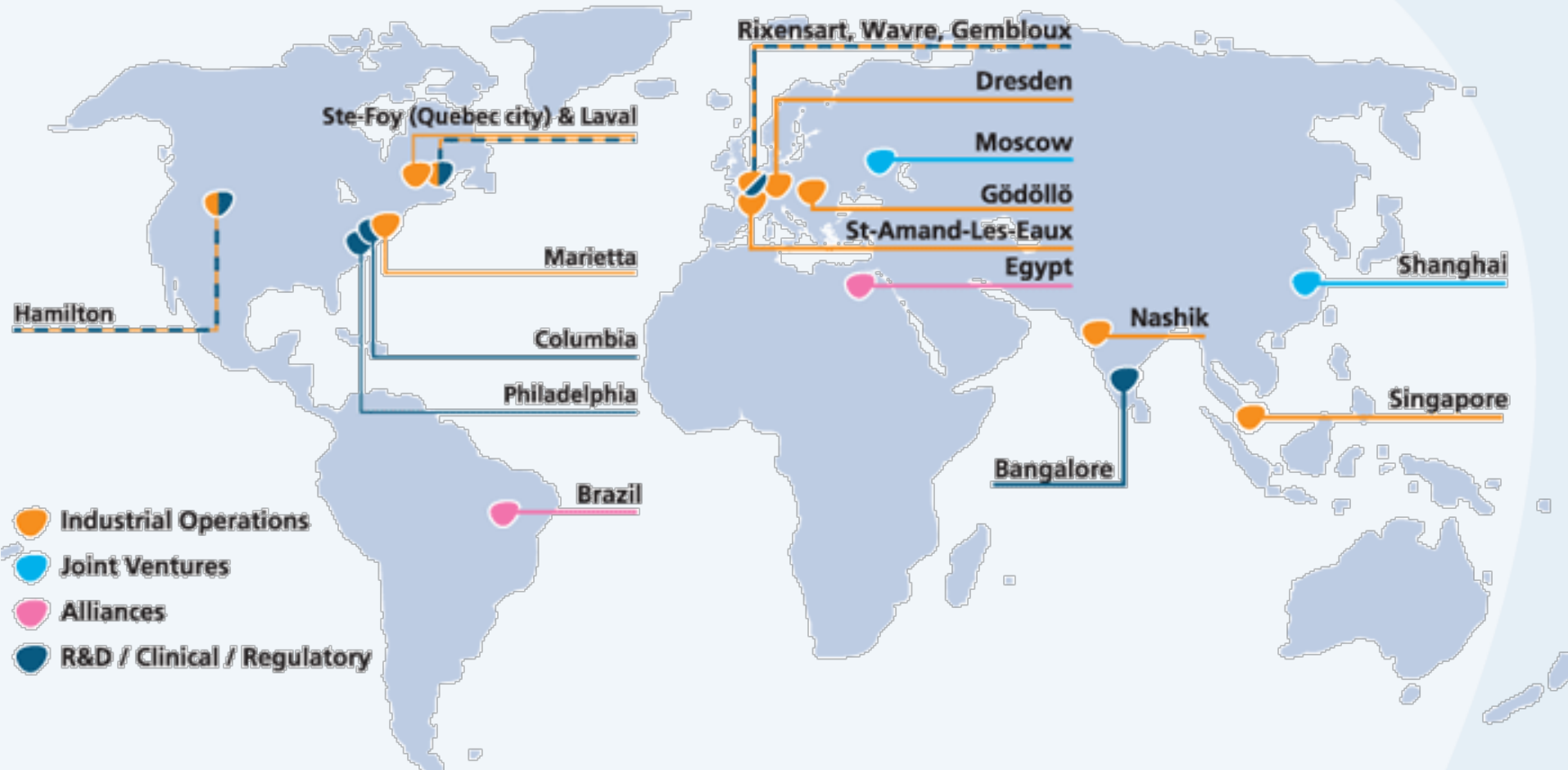
- **Introduction**
 - **Background**
 - **Business Drivers**
 - **Why SAS Drug Development?**
- *GSK Business Implementation*
 - *Repository*
 - *System Administration*
 - *Programming & Execution*
- *A few words about Infrastructure...*
- *Conclusion*

GSK Biologicals today

- 1.4 billion vaccine doses
- Over 30 marketed vaccines available worldwide
- Over 20 vaccines in clinical development
- 11,200 employees worldwide
- Over 200 ongoing studies and overall more than 240,000 subjects enrolled



Global Network



Business Drivers - Globalisation & Externalisation

- Data management and biostatistics activities in Belgium, India and in the US.
- Increasing number of external partnerships
- Challenges:
 - Improve communication between sites/functions
 - Facilitate the content management
 - Harmonize the processes
 - Increase productivity / keep quality standard
 - Secure the data respecting business & authorities requirements
 - Avoid the installation and the maintenance of the SAS software on hundreds of machines
 - License fee per machine
 - Not all managed by GSK Biologicals

Externalize our activities...
Centralize the control

Why SAS Drug Development?

- SAS is an industry standard
- Minimize the integration efforts: GSK Biologicals has a large set of standard and reusable SAS programs (macros)
- SAS Drug Development is a centralized and secured web-based platform
 - **Platform:** it's a files repository and a set of tools to execute SAS programs and browse SAS datasets (*native integration of the SAS processing within the application*).
 - **Web-based:** no need for specific client applications (other than JRE 1.5), accessible worldwide
 - **Centralized:** unique source of data for all users. No more data synchronization process across the organization.
 - **Secured:** Possibility to create groups of users and assign permissions on a granular basis (per project, per study, per function), audit trail.

Agenda

- *Introduction*
 - *Background*
 - *Business Drivers*
 - *Why SAS Drug Development?*
- **GSK Business Implementation**
 - **Repository**
 - **System Administration**
 - **Programming & Execution**
- *A few words about Infrastructure...*
- *Conclusion*





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You must log in to access this system.

UserID:	TORCHE
Password:	
Log in Reset	



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PhUSE
PhUse Brussels SDE, April 2011

Actions

						New	Loader
☐	Item	Size	Owner	Type	Created	Modified	Modified by
☐	adverse.sas7bdat	601 KB	admin	sasDataTable	4/26/11 9:20:58 AM GMT	4/26/11 9:21:03 AM GMT	TORCHE
☐	Demo API.sas	3 KB	admin	process	4/26/11 11:39:01 AM GMT	4/26/11 11:39:01 AM GMT	TORCHE
☐	Demo Libname.sas	2 KB	admin	process	4/26/11 11:32:10 AM GMT	4/26/11 11:32:10 AM GMT	TORCHE
☐	Demo PhUSE.jobxml	1 KB	admin	job	4/26/11 11:13:27 AM GMT	4/26/11 11:13:27 AM GMT	TORCHE
☐	Demo PhUSE.tbvxml	5 KB	admin	tableView	4/26/11 9:44:38 AM GMT	4/26/11 9:44:38 AM GMT	TORCHE
☐	demo.sas7bdat	97 KB	admin	sasDataTable	4/26/11 9:20:59 AM GMT	4/26/11 9:21:03 AM GMT	TORCHE
☐	demo.xls	175 KB	admin	document	4/26/11 12:49:49 PM GMT	4/26/11 12:49:49 PM GMT	TORCHE
☐	DEMO_SAMPLE.sas	4 KB	admin	process	4/26/11 9:21:00 AM GMT	4/26/11 11:15:47 AM GMT	TORCHE
☐	expo_gn.sas7bdat	136 KB	admin	sasDataTable	4/26/11 12:49:18 PM GMT	4/26/11 12:49:23 PM GMT	TORCHE
☐	NICSAH001_protocol.doc	31 KB	admin	document	4/26/11 9:20:59 AM GMT	4/26/11 9:20:59 AM GMT	TORCHE

Done

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PhUSE

Actions

	Name	Size	Owner	Type	Created	Modified	Loader
	adverse.sas7bdat	601 KB	admin	sasDataTable	4/26/11 9:20:58 AM GMT	4/26/11 9:21:03 AM GMT	TORCHE
	demo.sas7bdat	97 KB	admin	sasDataTable	4/26/11 9:20:59 AM GMT	4/26/11 9:21:03 AM GMT	TORCHE
	demo.xls	175 KB	admin	document	4/26/11 9:36:48 AM GMT	4/26/11 9:36:48 AM GMT	TORCHE
	DEMO_SAMPLE.sas	4 KB	admin	process	4/26/11 9:21:00 AM GMT	4/26/11 9:21:00 AM GMT	TORCHE
	expo_gn.sas7bdat	136 KB	admin	sasDataTable	4/26/11 9:33:35 AM GMT	4/26/11 9:33:39 AM GMT	TORCHE
	NICSAH001_protocol.doc	31 KB	admin	document	4/26/11 9:20:59 AM GMT	4/26/11 9:20:59 AM GMT	TORCHE

Done

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Loader

Load

Cancel

☐ Overwrite existing non-versioned file(s)

File:

Browse...

Done

 **Advanced Loader** [-] [] [X]

#	Name	Version	Location	Type	Convert To	
1	demo.sas7b...	<version no...	/GSKBIO/US...	SAS7BDAT	XLS	demo.xls

Source:



Dest.:

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📄 Audit Trail results for demo.xls

Export

Printer Friendly Version

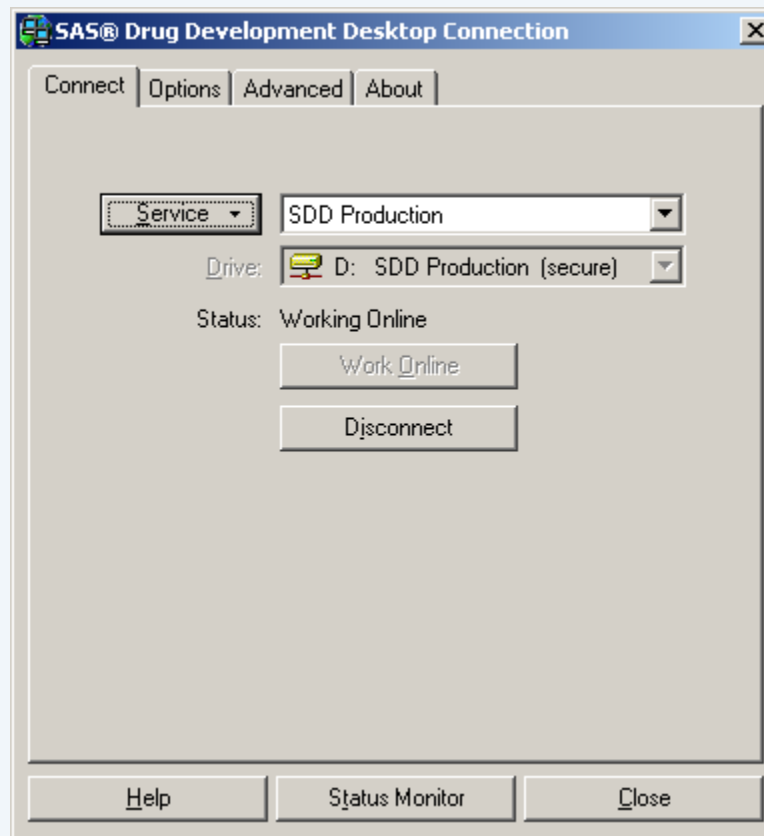
OK

Matches: 1 - 3 of 3

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User	Action	Date ▾	Description
TORCHE	Entity Updated	4/27/11 7:55:20 AM GMT	User TORCHE updated the object "/GSKBIO/USERS/PhUSE/demo.xls".
TORCHE	File Updated	4/27/11 7:55:20 AM GMT	User TORCHE saved a new file to "/GSKBIO/USERS/PhUSE/demo.xls".
TORCHE	Entity Created	4/26/11 12:49:49 PM GMT	User TORCHE created a new document, "/GSKBIO/USERS/PhUSE/demo.xls".

Done



F:\GSKBIO\USERS\PhUSE

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Back

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Folders

Address F:\GSKBIO\USERS\PhUSE

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My Computer

RIXWL-82589 (C:)

SDD Training on 'XythosDrive' (F:)

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XPSharedApp on 'Wavoffaxp01' (H:)

Copfull on 'Rixsffs08' (M:)

Dmstat on 'Rixsffs09' (N:)

Public on 'Wavoffpub01' (P:)

Clinrd on 'Rixsffs09' (Q:)

DVD-RAM Drive (R:)

Bds on 'Rixsffs09' (S:)

Fxt77129\$ on 'Rixsfwn139' (U:)

Biometric on 'Rixsffs05' (V:)

Safety_dm on 'Rixsfwn017' (X:)

Name	Size	Type	Date Modified
adverse.sas7bdat	601 KB	SAS Data Set	26/04/2011 11:21
Demo API.sas	3 KB	SAS System Program	26/04/2011 13:39
Demo Libname.sas	2 KB	SAS System Program	26/04/2011 13:32
Demo PhUSE.jobxml	1 KB	JOBXML File	26/04/2011 13:13
Demo PhUSE.tbvxml	5 KB	TBVXML File	26/04/2011 11:44
demo.sas7bdat	97 KB	SAS Data Set	26/04/2011 11:21
demo.xls	175 KB	Microsoft Office Exc...	27/04/2011 09:55
DEMO_SAMPLE.sas	4 KB	SAS System Program	26/04/2011 13:15
expo_gn.sas7bdat	136 KB	SAS Data Set	27/04/2011 09:54
NICSAH001_protocol.doc	31 KB	Microsoft Office Wo...	26/04/2011 11:21

10 objects

1.02 MB

Local intranet

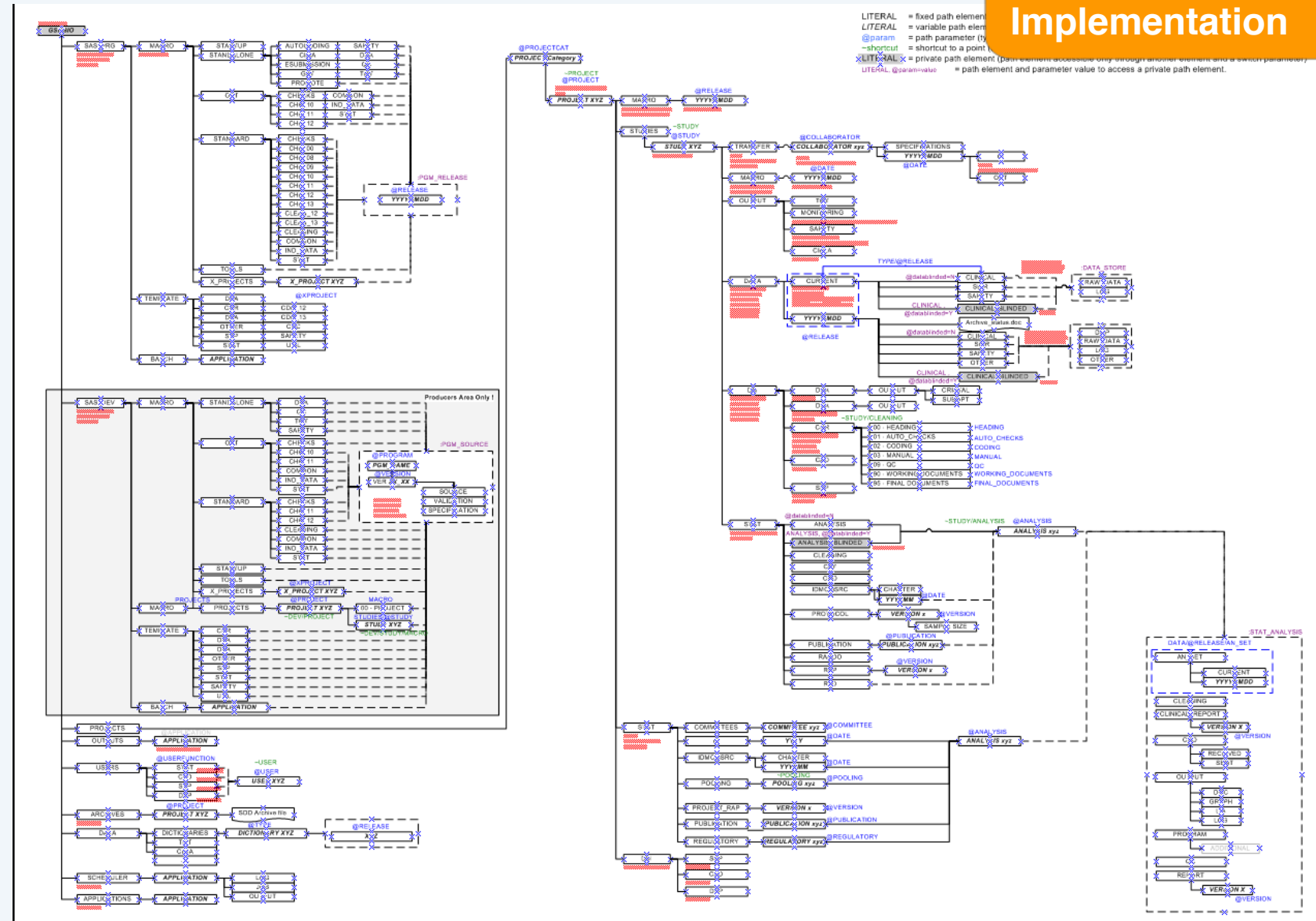
Repository Structure

Objectives

Before SDD	With SDD
Each function is working on a different file server	One environment shared by all functions no matter where they are located
There is no access restriction at the project or study level	Access restrictions at the study level but also within a study, at the function level.

Repository Structure

Implementation



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⊕📁BACKUP_RESTORE

⊕📁DATA

⊕📁OUTPUTS

⊖📁PROJECTS

⊖📁CLINICAL

⊕📁4PN (236918)

⊕📁DHER2-AS15 (719125)

⊕📁DTPA 0.3 (BOOSTRIX) (776423)

⊕📁DTPA-HBV-IPV=HIB-MENC-TT

⊕📁DTPA-IPV (INFANRIX-IPV) (213503)

⊕📁FLU NG

⊕📁FLU Q-PAN H1N1-AS03

⊕📁FLU-AS25

⊕📁HPV (580299)

⊕📁IPV ALUM

⊖📁MENACWY-TT (134612)

⊕📁DM

⊕📁MACRO

⊕📁STAT

⊖📁STUDIES

⊕📁107386_ESFU

⊕📁107392

⊕📁109067

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📁109067

MENACWY-TT-035

Actions

						New	Loader
☐	Name /	Size	Owner	Type	Created	Modified	Modified by
☒	📁 DATA	24272 KB	admin	folder	8/12/10 6:12:03 AM GMT	8/12/10 6:12:03 AM GMT	TORCHE
☒	📁 DM	59824 KB	admin	folder	8/12/10 6:08:10 AM GMT	8/12/10 6:08:10 AM GMT	TORCHE
☒	📁 MACRO	215 KB	admin	folder	8/12/10 6:12:43 AM GMT	8/12/10 6:12:43 AM GMT	TORCHE
☒	📁 OUTPUT	0 KB	admin	folder	8/12/10 6:12:47 AM GMT	8/12/10 6:12:47 AM GMT	TORCHE
☒	📁 STAT	55894 KB	admin	folder	8/12/10 6:10:34 AM GMT	8/12/10 6:10:34 AM GMT	TORCHE
☒	📁 TRANSFER	0 KB	admin	folder	8/12/10 6:10:33 AM GMT	8/12/10 6:10:33 AM GMT	TORCHE

Done🔒

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4PN (236918)

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DHER2-AS15 (719125)

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DTPA 0.3 (BOOSTRIX) (776423)

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DTPA-HBV-IPV=HIB-MENC-TT

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DTPA-IPV (INFANRIX-IPV) (213503)

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FLU NG

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FLU Q-PAN H1N1-AS03

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FLU-AS25

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HPV (580299)

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IPV ALUM

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MENACWY-TT (134612)

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DM

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MACRO

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STAT

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STUDIES

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📁 Object Permissions for 109067

MENACWY-TT-035

Edit

Cancel

Current Object

New Objects

Name	Type	Read	Write	Delete	Manage
Owner (admin)	User	✓	✓	✓	✓
ADM	Group	✓	✓	✓	✓
DSP	Group	✓			
GAT	Group	✓			
MGT	Group	✓			
S_109067	Group	✓			
STAT	Group	✓			
Users with Accounts	Group				

Done

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📁 OUTPUTS

📁 PROJECTS

📁 CLINICAL

📁 4PN (236918)

📁 DHER2-AS15 (719125)

📁 DTPA 0.3 (BOOSTRIX) (776423)

📁 DTPA-HBV-IPV=HIB-MENC-TT

📁 DTPA-IPV (INFANRIX-IPV) (213503)

📁 FLU NG

📁 FLU Q-PAN H1N1-AS03

📁 FLU-AS25

📁 HPV (580299)

📁 IPV ALUM

📁 MENACWY-TT (134612)

📁 DM

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📁 Object Permissions for DM

✎✎

✎✎

Current ObjectNew Objects

Name	Type	Read	Write	Delete	Manage
Owner (admin)	User	✓	✓	✓	✓
ADM	Group	✓	✓	✓	✓
DSP	Group	✓			
GAT	Group	✓			
MGT	Group	✓			
S_109067_CDC	Group	✓			
S_109067_CDR	Group	✓			
S_109067_DEA	Group	✓			
S_109067_SSP	Group	✓			
Users with Accounts	Group				

Done🔒

Repository Structure

Lessons Learned

	
•Flexibility •Security •Audit trail •SDD Desktop Connection	•Unstable with large volumes of data transfered •Trash can •Audit trail •Versioning

System Administration

Quick Tour



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🔍 Users

Manage the system users

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UserID

Find

Include

☒ Active

☐ Inactive

☐ Retired users

Clear

Matches: 1 - 15 of 24

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Defined Users: 25

Licensed Users: 25

UserID	First name	Middle name	Last name	Status	Created	New Loader Modified
admin	Installer		Account	active	9/11/09 7:29:15 PM GMT	1/20/11 9:56:29 AM GMT
DARK_VADOR	Xavier		Deflorenne	active	8/10/10 7:29:37 AM GMT	9/14/10 1:37:51 PM GMT
DARKVADOR	Xavier		Deflorenne	active	8/10/10 6:39:53 AM GMT	3/11/11 9:56:32 AM GMT
DAVISTER	Cedric		Davister	active	10/27/09 4:43:23 PM GMT	1/27/11 6:26:21 AM GMT
DEFLORENNE	Xavier		Deflorenne	active	10/27/09 4:42:18 PM GMT	4/14/11 12:41:39 PM GMT
GATHY	Gregory		Gathy	active	3/24/10 10:33:07 AM GMT	11/16/10 7:32:47 AM GMT
snoatf	Andrew		Fagan	active	3/3/11 10:53:35 AM GMT	3/8/11 8:30:40 PM GMT
TECH_SASSUPPORT	Tech Account		SAS Support	active	4/29/10 2:23:21 PM GMT	3/2/11 3:29:51 PM GMT
TECH_SMS	Tech Account		SMS	active	4/8/10 7:26:22 AM GMT	3/27/11 12:05:12 PM GMT
TESTUSER1	Xavier		Deflorenne	active	11/23/09 10:48:46 AM GMT	9/14/10 1:37:56 PM GMT
TORCHE	Francois		Torche	active	10/27/09 4:39:32 PM GMT	3/23/11 1:30:43 PM GMT
TRAINEE1	Train		User1	active	12/9/09 10:14:23 AM GMT	4/8/11 8:43:49 AM GMT
TRAINEE10	Train		User10	active	2/10/10 10:00:41 AM GMT	3/31/11 7:37:56 AM GMT
TRAINEE2	Train		User2	active	2/1/10 1:41:43 PM GMT	4/8/11 8:40:17 AM GMT

Done

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Global Groups

Manage the global groups

OK

Actions

Group /	Description
☐ ADM	SDD Role: Administrators
☐ Baseline Test Group	For testing group functionality
☐ BCSP	SDD Role: Safety (Central)
☐ CDC	SDD Role: Clinical Data Coordinators
☐ CDM	SDD Role: Clinical Data Managers
☐ CDR	SDD Role: Clinical Data Reviewers
☐ CIPLA	SDD Role: CIPLA users
☐ DEA	SDD Role: Data Entry
☐ DSP	SDD Role: Standard Team
☐ EXS	CLINICAL-TEST IS3
☐ GAD	SDD Role: Global Application Developers
☐ GAT	SDD Role: Global Application Team
☐ GSM	SDD Role: Global Study Managers
☐ MGT	Management
☐ MON	SDD Role: Monitors
☐ P_0001	CLINICAL-MENACWY-TT (134612)

New

Done

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Object Permissions for PhUSE

PhUse Brussels SDE, April 2011

Add Group(s)

Find groups by

Name

phuse

Find

Clear

OK

Cancel

Matches: 1 - 15 of 316 Page: 1 of 22

Group Name	Type	Description
☐ Baseline Test Group	Group	For testing group functionality
☐ BCSP	Group	SDD Role: Safety (Central)
☐ CDC	Group	SDD Role: Clinical Data Coordinators
☐ CDM	Group	SDD Role: Clinical Data Managers
☐ CDR	Group	SDD Role: Clinical Data Reviewers
☐ CIPLA	Group	SDD Role: CIPLA users
☐ DEA	Group	SDD Role: Data Entry
☐ DSP	Group	SDD Role: Standard Team
☐ EXS	Group	CLINICAL-TEST IS3
☐ GAD	Group	SDD Role: Global Application Developers
☐ GAT	Group	SDD Role: Global Application Team
☐ GSM	Group	SDD Role: Global Study Managers
☐ MGT	Group	Management
☐ MON	Group	SDD Role: Monitors
☐ P_0001	Group	CLINICAL-MENACWY-TT (134612)

⏪ ⏩ 1 2 3 4 5 6 7 8 9 10 11 → ⏩

Done

F:\GSKBIO\USERS\PhUSE\Demo API.sas - Notepad++

File Edit Search View Encoding Language Settings Macro Run TextFX Plugins Window ?

Demo API.sas

```
1
2 %sasdrugdev_login(url=https://sddmercator.sas.com/sddremote,sdduserid=TRAINER,sddpassword=***);
3
4 %sasdrugdev_createuser(sdduserid=,sddpassword=,sddfirstname=,sddlastname=,sddemail=);
5
6 %sasdrugdev_createsddcontainer(sddpath=, type=folder);
7
8 %sasdrugdev_fileexists(sddpath=);
9
10 %sdd_updateuser(sdduserid=, sddpassword=);
11
12 %sdd_setcontainerperms(dsname=work._containerperms_, recurse=NONE, keepGroup=_NONE_);
```

Normal text file 383 chars 405 bytes 12 lines Ln : 12 Col : 86 Sel : 0 (0 bytes) in 0 ranges Dos/Windows ANSI INS

System Administration

Objectives

- Automate the administration of the system
- Minimum/No manual intervention
- Use GSK clinical systems accounts management database to update SDD
 - Users
 - Studies
 - Permissions

System Administration

Implementation

- In-house development: SMS (SDD Management System)
- Set of SAS programs using the **SDD Remote API (1)**:
 - Create project and study folders based on a template
 - Assign/remove permissions on folders
 - Create users
 - Create/delete groups
 - Add/Delete users to groups
 - Reset password
 - Synchronize with GSK servers (data, macros)
- All actions based on a GSK Oracle database (ACCOUNT)

(1): SAS wrote GSK specific macros to expose some missing features

SAS Drug Development - Mozilla Firefox

File Edit View History Bookmarks Tools Help

https://sddmercator.sas.com/p21/mainScreen.do

SAS Drug Development

You are logged in as: Francois Torche

Settings Tools Admin Help Search

Search

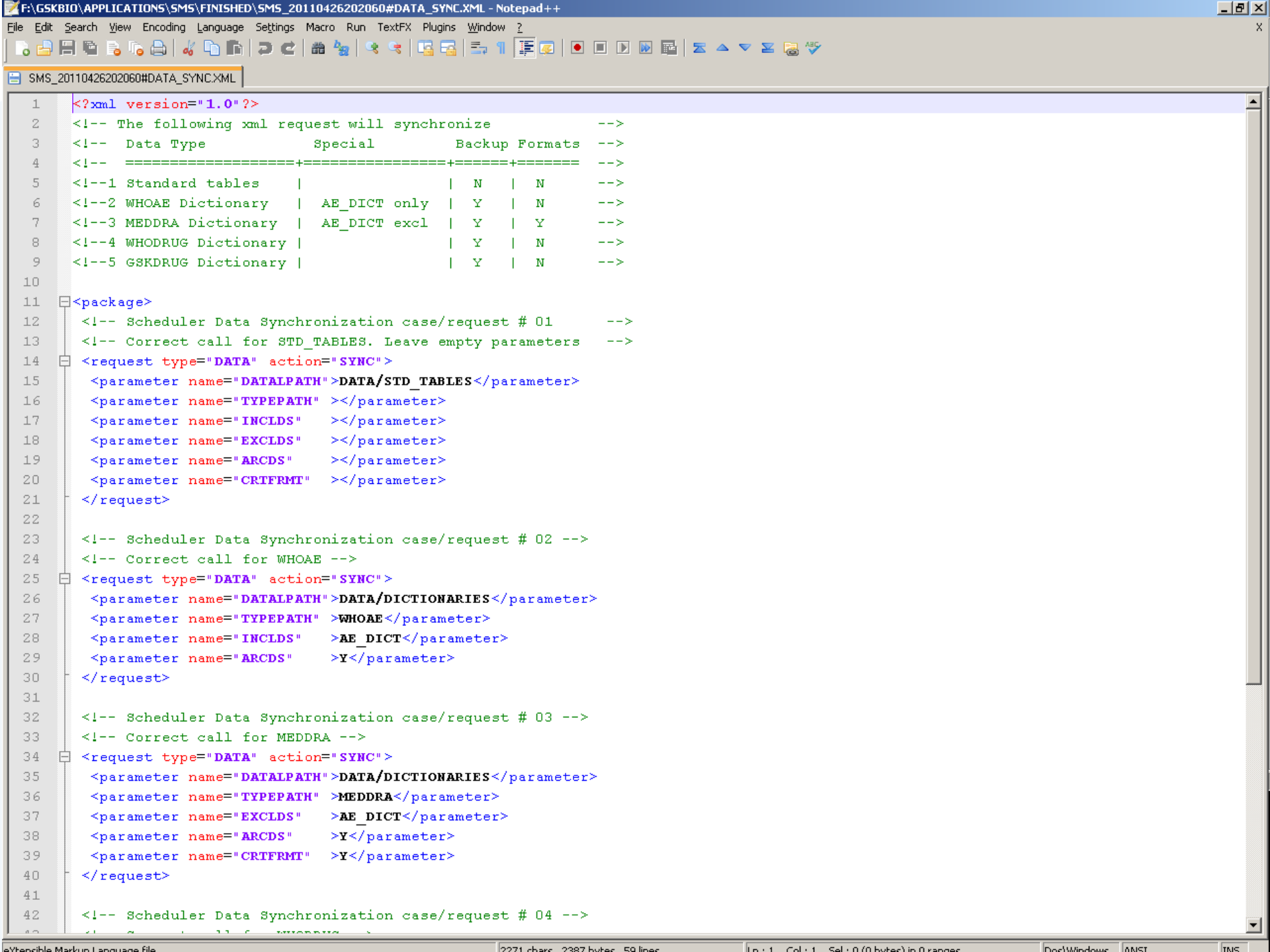
Logout

Home / GSKBIO / APPLICATIONS / SMS

SMS

Actions					New	Loader	
☐	Name	Size	Owner	Type	Created	Modified	Modified by
☒	DATA	33604 KB	admin	folder	8/3/10 6:41:59 AM GMT	8/3/10 6:41:59 AM GMT	DEFLORENNE
☐	FINISHED	52 KB	admin	folder	12/17/09 11:20:20 AM GMT	12/18/09 10:19:29 AM GMT	DEFLORENNE
☐	INBOX	0 KB	admin	folder	12/17/09 11:20:09 AM GMT	12/17/09 11:20:18 AM GMT	DEFLORENNE
☐	MODELS	20 KB	admin	folder	12/18/09 11:13:31 AM GMT	12/18/09 11:13:44 AM GMT	DEFLORENNE
☐	ONGOING	0 KB	admin	folder	12/17/09 1:09:39 PM GMT	12/17/09 1:09:46 PM GMT	DEFLORENNE
☐	REPORTS	86 KB	admin	folder	9/3/10 7:58:24 AM GMT	9/3/10 7:58:28 AM GMT	DEFLORENNE
☐	TESTING	5950 KB	admin	folder	2/23/10 1:01:19 PM GMT	2/23/10 1:01:25 PM GMT	DEFLORENNE

Done



SDD login

Choose your instance:

☒ Development

☐ Production

User display:

☒ Show Userids only

☐ Show Full name (slow!)

Userid:

Password:

SDD Management System - GUI 0.1

Groups

Group name:

All Groups:

Blind Groups:

Current Group: ADM

DEFLORENNE
GATHY
TECH_SMS
TESTUSER1
TORCHE
admin

System Administration

Lessons Learned



- Ability to automate all tasks in SAS programs or Java applications (Remote API)



- Missing functions in the API
- External Authentication (JNLP)
- Backup / restore
- SDD groups administrative window

Programming & Execution

Quick Tour



- Demography
 - SUBJID
 - SITEID
 - INVNAME
 - WEIGHT
 - HEIGHT
 - STUDYID
 - COUNTRY
 - BIRTHDT
 - SEX
 - RACE
 - AGE
 - TRTGRP
 - TRTCD
- User-generated columns

#	SUBJID	SITEID	INVNAME	WEIGHT	HEIGHT	STUDYID	COUNTRY	BIRTHDT	SEX	RACE	AGE	TRTGRP	TRTCD
1	11001	01	011A	82	182	NICSAH1	UNITED ST...	24OCT1968	Male	Caucasian	18	Placebo	0
2	11002	01	011A	78	172	NICSAH1	UNITED ST...	20JUL1908	Male	Caucasian	79	NIC .15	2
3	11003	01	011A	103	187	NICSAH1	UNITED ST...	03JAN1941	Male	Caucasian	46	NIC .15	2
4	11004	01	011A	60	157	NICSAH1	UNITED ST...	18SEP1915	Female	Caucasian	72	Placebo	0
5	11005	01	011A	53	157	NICSAH1	UNITED ST...	10JUL1907	Female	Caucasian	80	Placebo	0
6	11006	01	011A	55	165	NICSAH1	UNITED ST...	11AUG1934	Female	Caucasian	53	Placebo	0
7	11007	011A	011A	98	182	NICSAH1	UNITED ST...	27MAR1944	Male	Caucasian	43	NIC .15	2
8	11008	01	011A	53		NICSAH1	UNITED ST...	28NOV1931	Female	Caucasian	56	NIC .15	2
9	11009	011A	011A	68	170	NICSAH1	UNITED ST...	25JUN1922	Female	Caucasian	65	NIC .15	2
10	11010	011A	011A	58		NICSAH1	UNITED ST...	06APR1943	Female	Caucasian	44	Placebo	0
11	11011	011A	011A	60	160	NICSAH1	UNITED ST...	05NOV1960	Female	Caucasian	27	NIC .15	2
12	11012	01	011A	65	170	NICSAH1	UNITED ST...	07OCT1954	Female	Caucasian	33	Placebo	0
13	11013	011A	011A	65	163	NICSAH1	UNITED ST...	09JAN1924	Female	Caucasian	64	Placebo	0
14	11014	01	011A	86	182	NICSAH1	UNITED ST...	15FEB1941	Male	Caucasian	47	Placebo	0
15	11015	011A	011A	105	187	NICSAH1	UNITED ST...	25APR1933	Male	Caucasian	54	NIC .15	2
16	11016	011A	011A	53	154	NICSAH1	UNITED ST...	18JUL1953	Female	Black	34	NIC .15	2
17	11017	011A	011A	56	165	NICSAH1	UNITED ST...	11SEP1926	Female	Caucasian	61	Placebo	0
18	11018	011A	011A	83	180	NICSAH1	UNITED ST...	09OCT1957	Male	Caucasian	30	NIC .15	2
19	11019	011A	011A	62	162	NICSAH1	UNITED ST...	01APR1925	Female	Caucasian	63	Placebo	0
20	11020	011A	011A	58		NICSAH1	UNITED ST...	21OCT1941	Female	Caucasian	46	NIC .15	2
21	11021	011A	011A	70	170	NICSAH1	UNITED ST...	01MAY1925	Female	Caucasian	63	NIC .15	2
22	11022	011A	011A	78	193	NICSAH1	UNITED ST...	14NOV1949	Male	Caucasian	38	Placebo	0
23	11023	011A	011A	83	182	NICSAH1	UNITED ST...	26OCT1942	Male	Black	45	NIC .15	2
24	11024	011A	011A	99	187	NICSAH1	UNITED ST...	26AUG1934	Male	Caucasian	54	Placebo	0
25	11025	011A	011A	100		NICSAH1	UNITED ST...	31MAY1944	Male	Caucasian	44	Placebo	0
26	11026	011A	011A	53	157	NICSAH1	UNITED ST...	18DEC1954	Female	Caucasian	33	Placebo	0
27	11027	011A	011A	74	182	NICSAH1	UNITED ST...	19JAN1932	Male	Caucasian	56	NIC .15	2
28	11028	011A	011A	76		NICSAH1	UNITED ST...	14OCT1922	Female	Caucasian	65	NIC .15	2
29	11029	011A	011A	50	160	NICSAH1	UNITED ST...	26APR1942	Female	Caucasian	46	NIC .15	2
30	11030	011A	011A	110	182	NICSAH1	UNITED ST...	20AUG1915	Male	Caucasian	73	NIC .15	2
31	11031	011A	011A	64	182	NICSAH1	UNITED ST...	25MAR1943	Male	Caucasian	45	Placebo	0
32	11032	011A	011A	50	157	NICSAH1	UNITED ST...	03JUN1919	Female	Oriental	69	Placebo	0
33	11033	011A	011A	66	162	NICSAH1	UNITED ST...	09JUL1941	Female	Caucasian	47	NIC .15	2
34	11034	011A	011A	60	172	NICSAH1	UNITED ST...	29MAY1939	Female	Caucasian	49	NIC .15	2
35	11035	011A	011A	98		NICSAH1	UNITED ST...	18FEB1924	Female	Caucasian	64	Placebo	0
36	11036	011A	011A	58	190	NICSAH1	UNITED ST...	22MAY1925	Male	Caucasian	63	Placebo	0
37	11037	011A	011A	72	187	NICSAH1	UNITED ST...	28NOV1951	Male	Caucasian	37	NIC .15	2
38	11038	011A	011A	70	167	NICSAH1	UNITED ST...	20AUG1934	Female	Caucasian	54	NIC .15	2
39	11039	011A	011A	107	180	NICSAH1	UNITED ST...	13AUG1951	Male	Caucasian	37	Placebo	0
40	11040	011A	011A	51	157	NICSAH1	UNITED ST...	28OCT1925	Female	Caucasian	63	Placebo	0
41	11041	011A	011A	53	157	NICSAH1	UNITED ST...	14AUG1945	Female	Caucasian	43	Placebo	0
42	11042	011A	011A	59	175	NICSAH1	UNITED ST...	26MAY1944	Female	Caucasian	44	Placebo	0
43	11043	011A	011A	54	167	NICSAH1	UNITED ST...	01JAN1949	Female	Black	40	NIC .15	2
44	11044	011A	011A	76	142	NICSAH1	UNITED ST...	06JUN1934	Female	Caucasian	54	NIC .15	2

Rounding: OFF. Total Rows: 906 Filtered Rows: 906 Variables: 13 Excluded Rows: 0 Excluded Cells: 0

Add Remove



Local File System
SAS Drug Development Domain

Process Editor - DEMO_SAMPLE.sas- <version not available> (/GSKBIO/USERS/PhUSE) from SAS Drug Development Domain

```
1 %LET _sddday_ = https://sddmercator.sas.com/webdav;
2 %LET macromode = 4;
3
4 %setstart;
5 %init_global;
6
7 %LET biost_id = 109067;
8 |
9 %LET an_name = FINAL;
10
11 %GLOBAL batch;
12 %LET batch=SAMPLE_BATCH;      * Name of the batch ;
13
14 %LET data_blinded = Y ;
15
16 %LET rep_in=;
17 %setref(outref=rep_in,ref=rep_in,resource=(category=~STUDY/ANALYSIS)); * Main directory ;
18 %setref(outref=rep_in,ref=rep_in,path=%sddav&reproot/USERS/SDD TRAINING/TRAINEE1); * Main directory ;
19 %PUT rep_in=%rep_in;
20
21 * Defines reference to log file ;
22 %LET mylog=;
23 %setref(outref=mylog,ref=mylog,pref=%rep_in.,path=LOG/&batch..log,type=FILE,newdir=Y);
24
25 * Defines reference to output file ;
26 %LET myprn=;
27 %setref(outref=myprn,ref=myprn,pref=%rep_in.,path=LIS/&batch..lst,type=FILE,newdir=Y);
28
29 * Starts redirection of log and output ;
30 %prtlogto(log=%mylog.,print=%myprn.);
31
32 %libmacro();
33 %ct_lib(16FEB2009);
34
35 *proc print data = LIB_DATA.DEMOG;
36 *run;
37
38 data test;
39 x =1;
40 run;
41 proc print; run;
42
43 %prtlogto;
44 %det_err(out=mylog*,user=STAT);
45
```



Run of New Job on Wed Apr 27 11:06:47 CEST 201

New Report **OUTPUTS NOT SAVED**

- System Files
 - Process parameter values
 - SAS log
 - SAS output
 - SDD process (with defaults)
 - SDD process (selected)

Messages

Process Editor - Demo SDD Parameter.sas-<version not available>(/GSKBIO/USERS/PhUSE) from SAS Drug Development Domain

```
1 DATA _NULL_;
2   DO i = 1 TO &loop;
3     PUT "Hello PhUSE attendees!";
4   END;
5 RUN;
```

Parameters							
#	Var Name	Type	Label	Enabled	Required	Default	Tabna
1	*LOG*	SAS log	SAS log	☐	☐	SAS Log File	System Files
2	*LST*	SAS output	SAS output	☐	☐	SAS Output File	System Files
3	SDDPARMS	Process parameter va...	Process par...	☐	☐	SAS v9 Data Set (PC, Unix)	System Files
4	*PGM*	SAS program	SAS program	☐	☐	SAS Program File	System Files
5	LOOP	Text field	Text field	☒	☒		Parameters

Up
Down

Schedule [X]

 Schedule name: /GSKBIO/USERS/PhUSE/Demo PhUSE.jobxml

Schedule Options

Schedule Job: Start date:

Once [v] April 26, 2011 [calendar icon]

Schedule Job Once

Start time: 1:18 PM [time picker]

OK Cancel

Programming & Execution

Objectives

- No or minimal changes in our processes:
 - Standard and specific macros
 - In-house versioning and SAS macros life cycle systems
 - All parameters defined at execution-time
- All SAS programs developed and executed on the platform

- Challenges:
 - UNIX operating system
 - WEBDAV files system
 - Authentication required at each FILENAME/LIBNAME
 - Not all files SAS functions supported (e.g.:FEXIST)
 - Log & output redirected to a temporary location
- Changes:
 - Set of “tool” macros to manage all Files I/O functions
 - No direct calls to FILENAME/LIBNAME, CALL SYSTEM, PROC EXPORT, etc.
 - Any SAS program MUST use the tools macros
 - OS specificities isolated in +/- 10 macros
- SDD versioning, check-in and check-out features not used in GSK Biologicals



FS_COPY.SAS

```

118  **** Internal macros ****
119  ****
120
121  %MACRO fs_copy_ff;
122      %IF &srcaccess.=DISK AND &tgtaccess.=DISK %THEN %DO;
123          %IF &hostsystype.=PC %THEN %DO;
124              %LET sourcepath=%SYSFUNC(TRANSLATE(&srcfullpath.,\,/));
125              %LET targetpath=%SYSFUNC(TRANSLATE(&tgtfullpath.,\,/));
126
127              %SYSEXEC copy /Y &dq.&sourcepath.&dq. &dq.&targetpath.&dq.;
128
129              %IF &sysrc. NE 0 %THEN
130                  %LET copyrc=3;
131              %ELSE
132                  %LET copyrc=0;
133          %END;
134      %ELSE %IF &hostsystype.=UNIX %THEN %DO;
135          %SYSEXEC cp &sq.&srcfullpath.&sq. &sq.&tgtfullpath.&sq.;
136
137          %IF &sysrc. NE 0 %THEN
138              %LET copyrc=3;
139          %ELSE
140              %LET copyrc=0;
141          %END;
142      %ELSE %DO;
143          %LET copyrc=4;
144      %END;
145  %END;
146  %ELSE %IF &srcaccess.=DISK AND &tgtaccess.=WEBDAV %THEN %DO;
147      %IF &hostsystype.=PC %THEN
148          %LET sourcepath=%SYSFUNC(TRANSLATE(&srcfullpath.,\,/));
149      %ELSE
150          %LET sourcepath=&srcfullpath.;
151
152      /* disk - webfav (file) : source file to target file and target cannot exist ;
153
154      %sasdrugdev_fileexists(sddpath=%STR(&tgtrelpath.));
155      %IF &_sddrc_. NE -4 AND &_sddrc_. NE 1 %THEN %DO;
156          %LET copyrc=3;
157          %GOTO m_exit_fsncpyff;
158      %END;
159
160      %IF (&_sddrc_ = 0) OR (&_sddrc_ = 1) %THEN %DO;

```

Programming

Lessons Learned



- All I/O centralized in a small set of programs
- Ability to make our SAS processes multiplatform and transparent for the end-user
- Remote API
- Data Explorer



- Poor WEBDAV implementation in SAS 9.2
- Significant amount of work to adapt existing SAS programs to SDD specificities

- Challenges:
 - GUI vs execution-time
 - “Please wait” window
 - No view on the assigned libraries
- Conclusions:
 - The process editor cannot replace the local SAS environment
 - Need to access SDD resources from local PC
- Consequences:
 - SAS 9.2 still installed locally together with SDD remote API macros
 - Local development
 - Final execution (production) in SDD
 - Bad performances



- Lightweight software
- Faster than VPN for external partners
- User can run SAS programs in sequence (Jobs)
- User can schedule his/her jobs



- No access to the assigned libraries (except SASWORK and SASHELP)
- No vision on the running process
- Unstable
- Slow

Agenda

- *Introduction*
 - *Background*
 - *Business Drivers*
 - *Why SAS Drug Development?*
- *GSK Business Implementation*
 - *Repository*
 - *System Administration*
 - *Programming & Execution*
- **A few words about Infrastructure...**
- *Conclusion*

Infrastructure

- In-house vs SAAS
- US hosting (Cary) vs EU hosting (Amsterdam)
- Local vs Central
- Network is key
 - Internet connection for your end-users
 - B2B for transfers between GSK and SAS servers
 - SAS/CONNECT dramatically improves transfer rates

GSK Environments

	Sandbox	Development	Production
Location	Cary, NC	Amsterdam, NL	Amsterdam, NL
Purpose	-Test SAS patches and hotfixes	-Validate SAS patches and hotfixes -Training -Development/Validation of SAS programs for the maintenance of the system (creation of users, folders, etc.)	-Development of standard and study specific SAS programs -Execution of batches, review of the outputs
Validation	No	Yes	Yes
# users	5	20	250+

The network connections

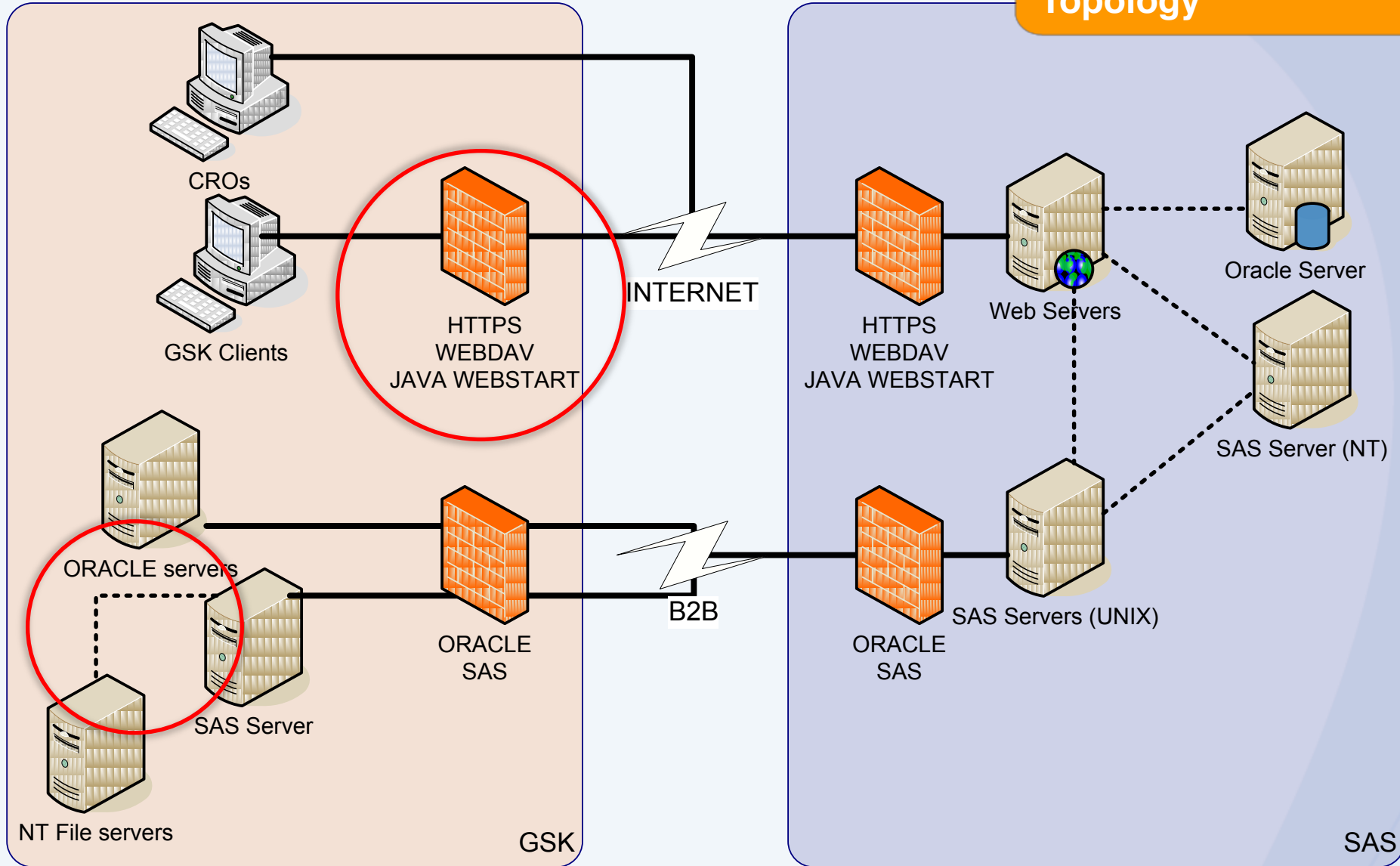
Measures

	Local	VPN (Cary) (~40Mbits)	VPN (Amst.) (~40Mbits)	2xE1 (4Mbits)
20.000 records	1 s	20 s	2 s	7 s
600.000 records	12 s	300 s	60 s	90 s
SAS/CONNECT 20.000 records	5 s	15 s	5 s	8 s
SAS/CONNECT 600.000 records	27 s	80 s	43 s	53 s

- Conclusions:
 - VPN is faster than a leased line
 - Greater standard deviation in the VPN results
 - Leased line more secured
 - Easier setup of the VPN
 - SAS/CONNECT improves the transfer rates

The network connections

Topology



Agenda

- *Introduction*
 - *Background*
 - *Business Drivers*
 - *Why SAS Drug Development?*
- *GSK Business Implementation*
 - *Repository*
 - *System Administration*
 - *Programming & Execution*
- *A few words about Infrastructure...*
- **Conclusion**

Key messages: SDD is live...

Pros	Cons
Centralized repository	Incomplete programming environment
Better performances for external partners	WEBDAV implementation
Easier unblinding process to work with external collaborators	
System Administration (API)	
Data Explorer	

Overall: great potential to be confirmed...

Potential to be confirmed: SDD 4.x

- Our expectations:
 - A good and performant programming environment
 - Keep the nice features:
 - Repository accessible from windows explorer
 - API to automate administrative tasks
 - Jobs scheduling
 - Data explorer
- Still in development... early adopter program:
 - Our objectives:
 - Assess the impacts to migrate to 4.x
 - Identify bugs
 - Identify important missing or incomplete features
 - Timelines are dependent on SAS, target date to start the implementation could be Q3 2011



Thank you!

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GlaxoSmithKline