

MOVING THE CLINICAL ANALYTICAL ENVIRONMENT INTO THE CLOUD



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AGENDA

- Move towards cloud analytical environment
- SAS Drug Development
- Move from SAS Drug Development to Life Science Analytics Framework
- Evolution from centralized to a distributed collaborative environment.

Analytics is and will be more than ever the *driving force* for all *decisions* related to moving forward a new therapy towards the patient, from *clinical trial design and optimization*, over *operations* to *analyzing the clinical data* and finally *assessing the value* of the therapy for patient communities by *analyzing effectiveness in a real-world setting*, combining with many available secondary data sources.

Why moving towards Cloud 'analytical' environment

- Platform, Infrastructure and Software as a service.
- Maintenance externally, focus internally on R&D.
- Collaboration (*see functionalities*)

Important functionalities / features of an analytical environment

- Collaboration
 - accessible to all stakeholders; internally and externally (geographically remote)
- Integrated Approach
 - managing, analyzing, reporting, and reviewing clinical research information in the same analytical environment
- Secure Repository / Work Area
 - editing / development of files in work <private> area; prevention of accidental modification
 - data from repository accessible for multiple users at same time; all versions available in repository (see also change history)
- Enhanced folder structure / user access
 - restricted folder permissions and clear system privileges
- Managing change history of all files
 - version control and signature capabilities (*transparency*); audit trail (*traceability*)
 - differentiate between programs that are under development, have been validated, or were used for specific production runs
- Workflows
 - ability to schedule work tasks
 - process orchestration - things can be automated, certain activity can initiate other activity to make sure things are happening as anticipated and users are notified
- Compliance / Industry Expectations
 - improving program flexibility & maintaining regulatory compliance at same time

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT



What is SAS Drug Development ?

SAS Drug Development provides an *integrated system for managing, analyzing, reporting, and reviewing clinical research information*. By exposing legacy and ongoing research data through a *secure*, dashboard-driven *web* portal, SAS Drug Development provides key researchers with *direct access* to their clinical research content, data managers with a library of CDISC data standards, and executive management teams with the business intelligence needed to make informed decisions about their entire portfolio of clinical research programs.

Clearly organized and searchable, SAS Drug Development exposes regulated content through a *highly configurable, clinically-intuitive user interface*. In addition, SAS Drug Development provides a *high-performance application programming interface (API)* and an *expanding suite of web services* that together enable eClinical applications to access the objects managed in SAS Drug Development while *maintaining a complete audit history*.

Combining these features with SAS Drug Development's *robust version control system* enables study sponsors, development partners, contract research organizations (CRO), as well as compliance and regulatory stakeholders, to reach and sustain new levels of confidence about the accuracy and integrity of their research content.

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Dashboard

Global Messaging

User messages & notifications

User tasks & assignments

Job scheduling & history

Work Items (Workflow) and deliverables

Recently accessed files, projects and documents with quick links.

SAS Sessions (monitoring & administration)

SAS Sessions

State	Session	Submission Item	Started	Ended	Type
☐	14	convert_sas7bdat2xpt.sas	Sep 24, 2015 11:15 AM GMT+0200		SAS session editor
☐	13	account.sas	Sep 24, 2015 11:14 AM GMT+0200		SAS session editor
☒	12	create_AE.job - account.sas (1/1)	Sep 24, 2015 10:57 AM GMT+0200	Sep 24, 2015 10:57 AM GMT+0200	Workspace job
☒	10	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:50 PM GMT+0200	Sep 22, 2015 07:50 PM GMT+0200	Workspace job
☒	8	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:47 PM GMT+0200	Sep 22, 2015 07:47 PM GMT+0200	Workspace job
☒	7	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:45 PM GMT+0200	Sep 22, 2015 07:45 PM GMT+0200	Workspace job
☒	6	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:44 PM GMT+0200	Sep 22, 2015 07:44 PM GMT+0200	Workspace job
☒	5	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:40 PM GMT+0200	Sep 22, 2015 07:40 PM GMT+0200	Workspace job
☒	4	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:39 PM GMT+0200	Sep 22, 2015 07:40 PM GMT+0200	Workspace job
☒	2	create_AE.job - account.sas (1/1)	Sep 22, 2015 07:24 PM GMT+0200	Sep 22, 2015 07:24 PM GMT+0200	Workspace job
☒	1	create_AE.job - account.sas (1/1)	Jun 13, 2014 11:14 AM GMT+0200	Jun 13, 2014 11:14 AM GMT+0200	Workspace job

Repository and Workspace

Repository

Workspace

Organization level

Project level

Analysis level

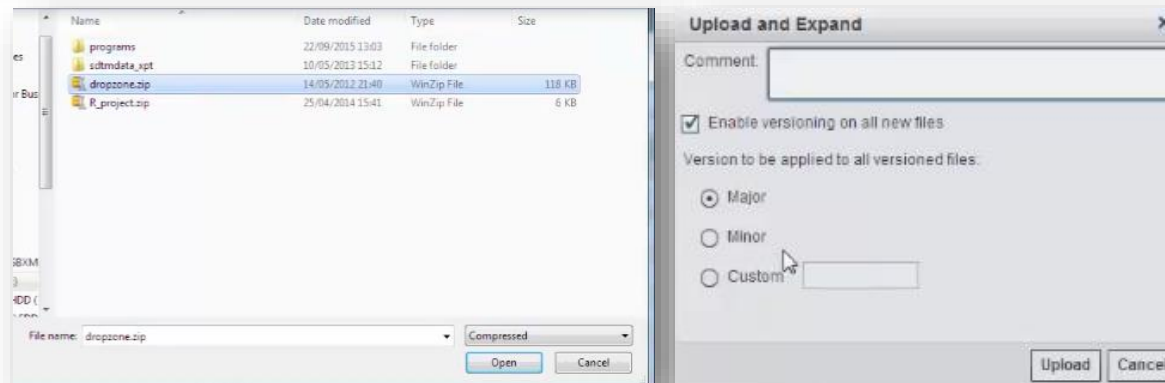
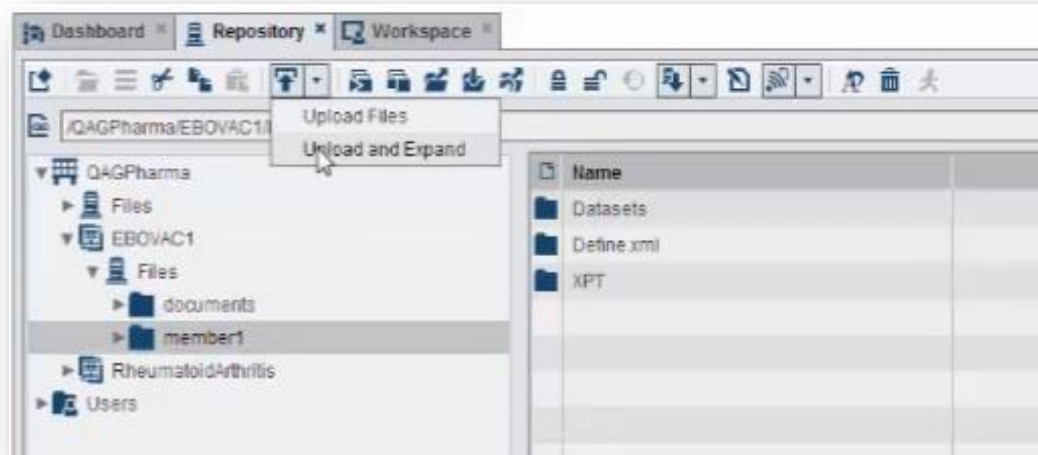
Files

Recent Files

- **Repository:** This is where master copies of files and programs are stored.
 - **Workspace:** This is where you store working copies of files, programs, and results.
- Note:** Files and SAS data sets must be present in the Workspace to enable programs to read them.

SAS DRUG DEVELOPMENT TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Upload Files / Upload & Expand (versioning)



SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Version History and Manage Extended Attributes

Version History

File name:

aecount.sas

File location:

/QAGPharma/EBOVAC1/Files/programs/aecount.sas

Version history:

Text to filter

Version	Signed	Version...	Date Ve...	Comment
1.0		Mark La...	24 sept...	

Properties

Name:

aecount.sas

Description:

Size:

1092

Content type:

application/x-sas

Created by:

Mark Lambrecht

Date created:

24 september 2015 15:16 GMT+

Modified by:

Mark Lambrecht

Date modified:

24 september 2015 15:16 GMT+

Properties modified by:

Mark Lambrecht

Properties date modified:

24 september 2015 15:23 GMT+

Locked:

No

Open

Cancel

Manage Extended Attributes

Organization

Project

Analysis

Folder

▼ File

PDF

SAS Data Set

SAS Job

SAS Program

User

Work Item

Task

Inherited attributes:

Label	Type	Attribute
Name	Character	System
Description	Character	System
Size	Numeric	System
Content type	Character	System
Created by	Character	System
Date created	Date	System
Modified by	Character	System
Date modified	Date	System
Properties modified by	Character	System
Properties date modified	Date	System
Locked	Boolean	System

Extended attributes:

Label	Type
	Character
	Numeric
	Character
	Date
	Boolean

Enable/Disable Versioning

The screenshot shows a file explorer window with a tree view on the left. The 'jobs' folder is selected, and its context menu is open. The menu items are: 'New folder', 'Open', 'Set State', 'Cut', 'Copy', 'Paste', 'Upload', 'Download', 'Enable Versioning', 'Disable Versioning' (highlighted), 'Check Out', and 'Check In'. The 'Users' pane on the left shows the 'root' user is selected.

Event Subscription (by subscriber/by event)

e.g. you want to be triggered (via email or/and SDD message) if versioning is disabled/enabled on a specific location.

Event Subscription By Subscriber

Subscriber: Stijn Rogiers

Location: /QAGPharma/EBOVAC1/Files/jobs/create_accounts.job

Event	Subscribe	Cascade	Group Subscription	Inherited From
File				
Attributes Updated	☐			
Check In	☐			
Check Out	☐			
Deleted	☐			
Downloaded	☐			
Job Run	☐			
Locked	☐			
Moved	☐			
Renamed	☐			
Scheduled Job Run	☐			
Signed	☐			
Undo Check Out	☐			
Unlocked	☐			
Uploaded	☐			
Versioning Disabled	☒			
Versioning Enabled	☐			
General				
Default Owner Changed	☐			
Default Permissions Upda...	☐			
Owner Changed	☐			
Permissions Updated	☐			

OK Cancel

Event Subscription By Event

Location: /QAGPharma/EBOVAC1/Files/jobs/create_accounts.job

Event	Subscriber	Cascade
File	There are no sub	
Attributes Updated		
Check In		
Check Out		
Deleted		
Downloaded		
Job Run		
Locked		
Moved		
Renamed		
Scheduled Job Run		
Signed		
Undo Check Out		
Unlocked		
Uploaded		
Versioning Disabled		
Versioning Enabled		
General		
Default Owner Changed		
Default Permissions Updated		
Owner Changed		
Permissions Updated		

Subscribers through inheritance:

Subscriber	Inherited From
There are no sub	

OK Cancel

My Account

General
Account
Preferences
General
Repository
Subscriptions
Views
SAS Session
Event Subscriptions

Receive notifications via:

☐ E-mail
☒ Message

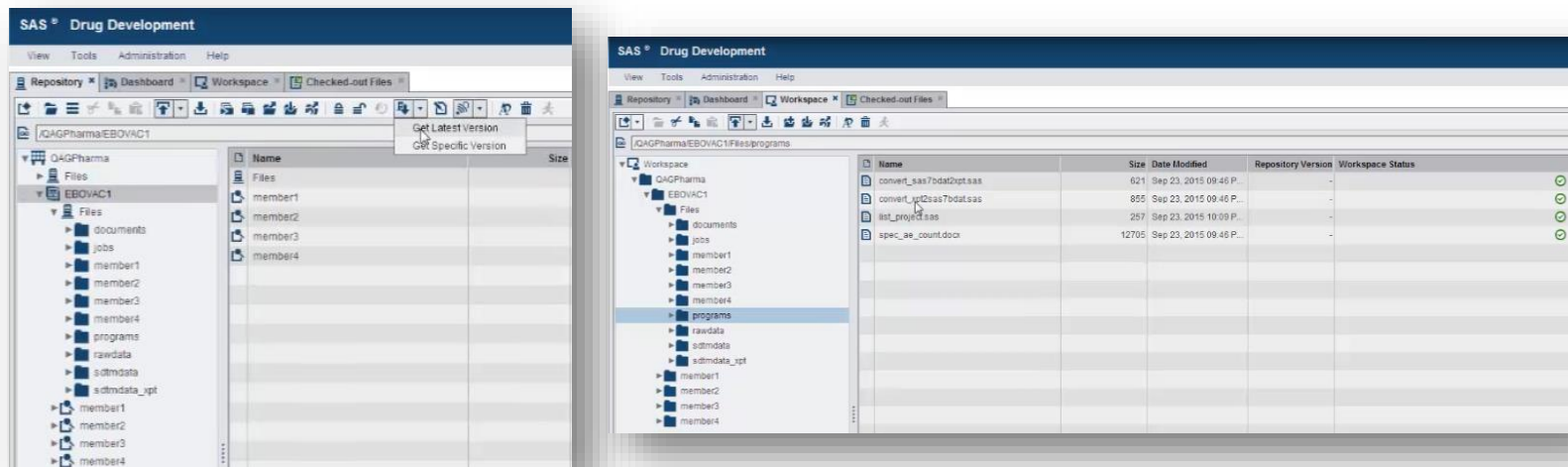
SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Copy files from the repository to your workspace

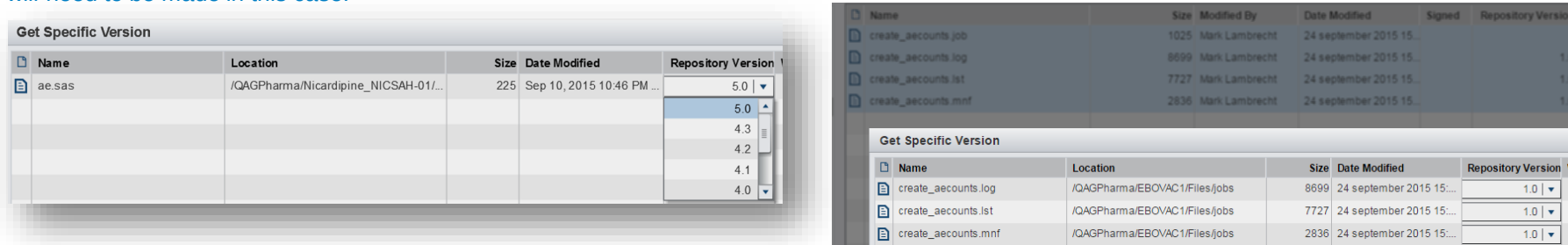
1. Get Latest Version

The folders and files (selected in repository) are copied to your personal workspace. There is NO locking taking place in the repository.



2. Get Specific Version

Only a specific version is being copied to your workspace. This can also be used for copying multiple files – a selection per versioned file will need to be made in this case.

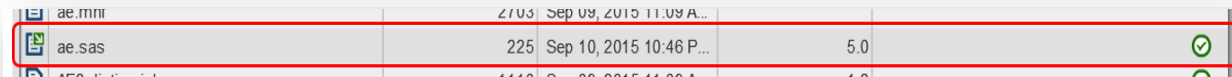


SAS DRUG DEVELOPMENT TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Copy files from the repository to your workspace

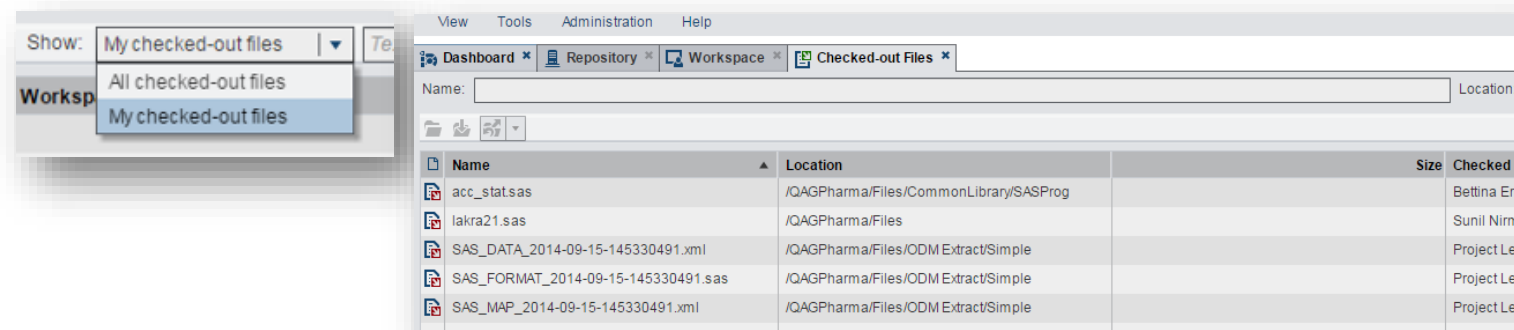
3. Check Out

For Editing, “Check Out” can be used. The underlying folders / files (if available) are copied automatically to your personal workspace. It always takes latest version of file(s); similar to ‘Get Latest Version’. Folders/files are however locked in repository.



ae.mml	2703	Sep 09, 2015 11:09 A...		
ae.sas	225	Sep 10, 2015 10:46 P...	5.0	✓
AEQ-destination	1440	Sep 09, 2015 11:09 A...	1.0	✓

Overview of Checked-Out Files.



Worksp Show: My checked-out files | Te

Dashboard * Repository * Workspace * Checked-out Files *

Name: Location:

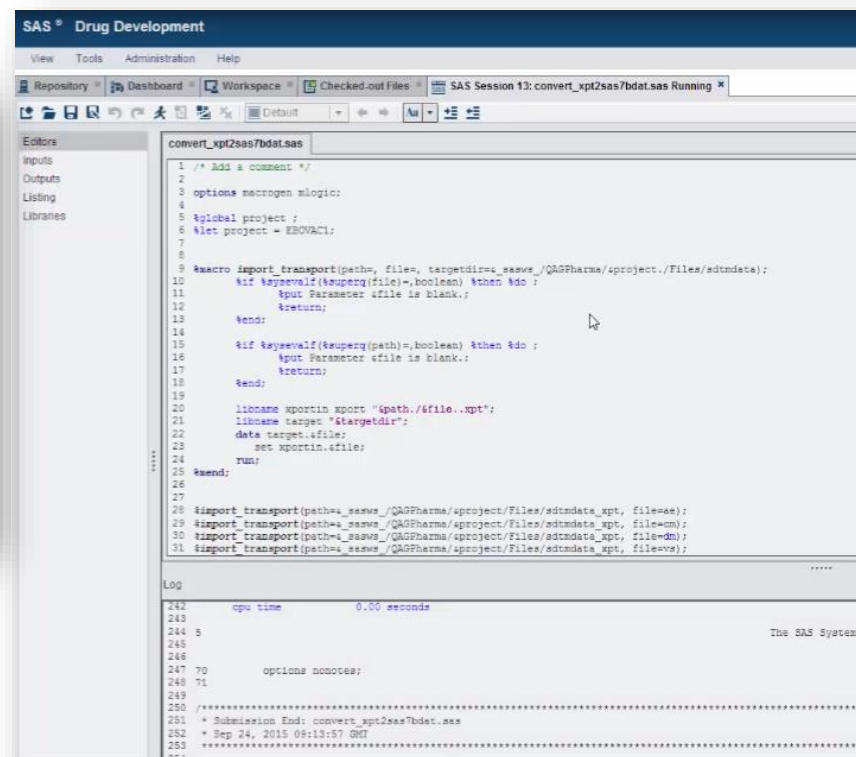
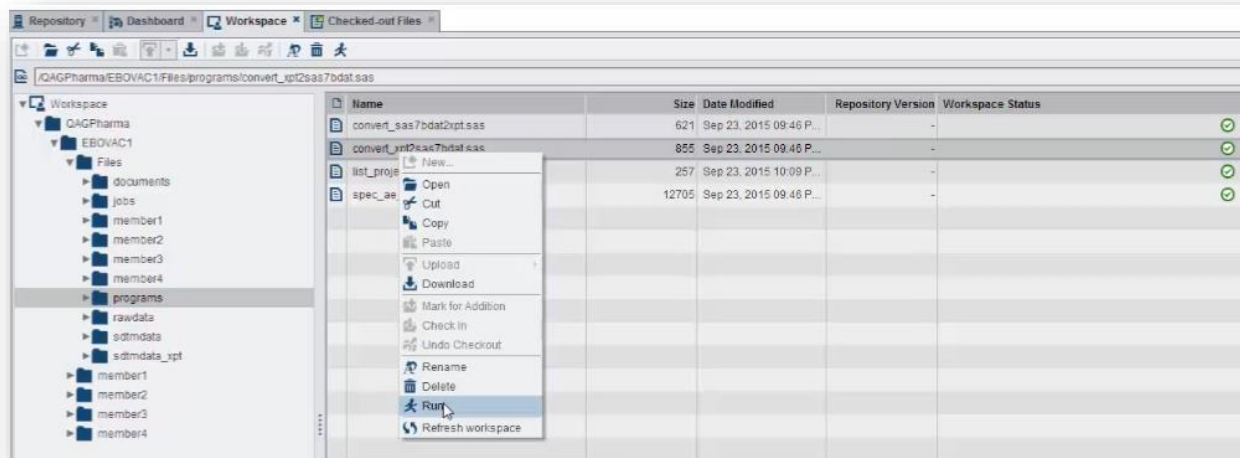
Name	Location	Size	Checked Out by
acc_stats.sas	/QAGPharma/Files/CommonLibrary/SASProg		Bettina Ern
lakra21.sas	/QAGPharma/Files		Sunil Nirm
SAS_DATA_2014-09-15-145330491.xml	/QAGPharma/Files/ODM Extract/Simple		Project Lea
SAS_FORMAT_2014-09-15-145330491.sas	/QAGPharma/Files/ODM Extract/Simple		Project Lea
SAS_MAP_2014-09-15-145330491.xml	/QAGPharma/Files/ODM Extract/Simple		Project Lea

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Integrated SAS Development/Execution environment (SAS Session / Editor) – SAS Program

SAS Session Management: SAS sessions support **multiple Editor windows**. This enables you to have more than one program open at a time.



All files must be referenced in your SAS program(s) by prepending all paths with special **SAS macro variable “&_SASWS_”**. This provides SAS with the physical location of your personal Workspace.

```
myprogram.sas*
1 libname testlib "&_SASWS_/"
```

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

SAS Session - Real time feedback (Inputs, Outputs, Listing, Libraries)

Inputs

Name	Library	Location	Date Modified	Size
account.sas - Sep 24, 2015 11:15 AM GMT+0200				
ae.sas7bdat	TEST	IQAGPharmaEBOVAC1Files\sdm	Sep 24, 2015 11:13 AM GMT+0200	294912
ae	WORK			294912
accounts.sas7bdat	TEST	IQAGPharmaEBOVAC1Files\sdm	Sep 24, 2015 11:15 AM GMT+0200	131072
sas.mact	WORK			0

Outputs

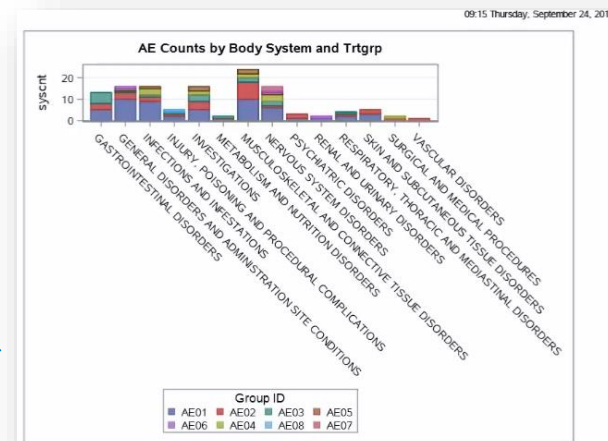
Name	Library	Location	Date Modified	Size	Repository Version
ae.pdf					
ae	WORK	IQAGPharmaEBOVAC1Files\sdm	Sep 24, 2015 11:15 AM GMT+0200	89686	
accounts.sas7bdat	TEST	IQAGPharmaEBOVAC1Files\sdm	Sep 24, 2015 11:15 AM GMT+0200	131072	
sas.mact	WORK			0	
sas.mact	WORK			0	

Listing

Line	Code	AEGRID	sysct
1	GAstrointestinal disorders	AE01	5
2	GAstrointestinal disorders	AE02	3
3	GAstrointestinal disorders	AE03	5
4	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AE01	10
5	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AE02	3
6	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AE03	1
7	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AE05	1
8	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AE06	1
9	INFECTIONS AND INFESTATIONS	AE01	9
10	INFECTIONS AND INFESTATIONS	AE02	2
11	INFECTIONS AND INFESTATIONS	AE03	1
12	INFECTIONS AND INFESTATIONS	AE04	3
13	INFECTIONS AND INFESTATIONS	AE05	1
14	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	AE01	2

Libraries

Name	Size	Description	Modified
AE	294912		Sep 24, 2015 11:13 AM GMT+0200
ACCOUNTS	131072		Sep 24, 2015 11:15 AM GMT+0200
DM	1146880		Sep 24, 2015 11:13 AM GMT+0200
DM	131072		Sep 24, 2015 11:13 AM GMT+0200
YS	2369296		Sep 24, 2015 11:13 AM GMT+0200

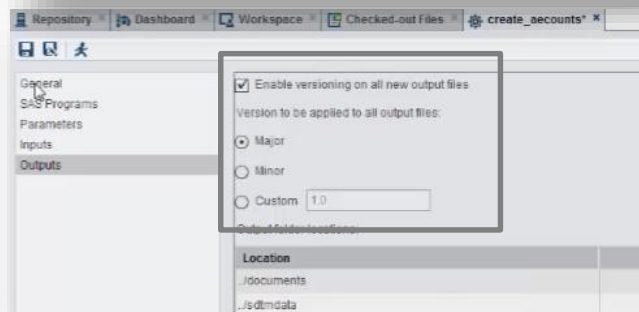
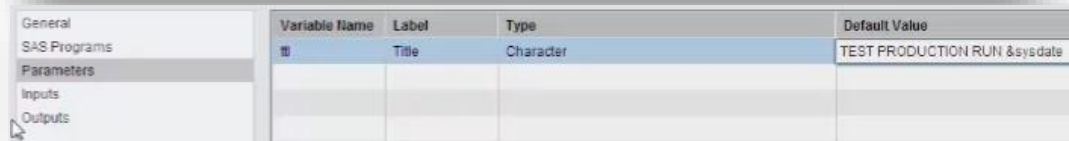
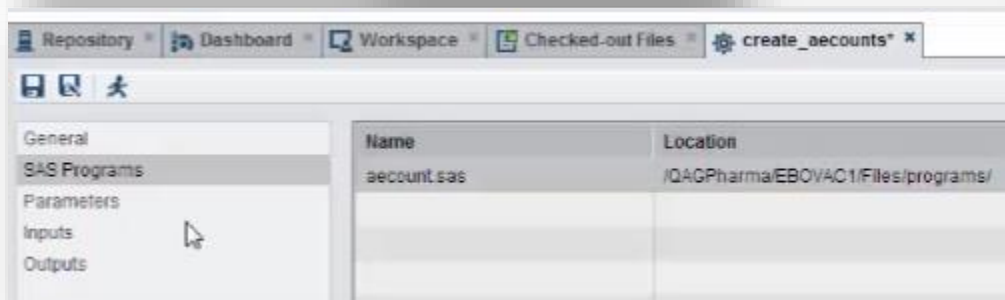
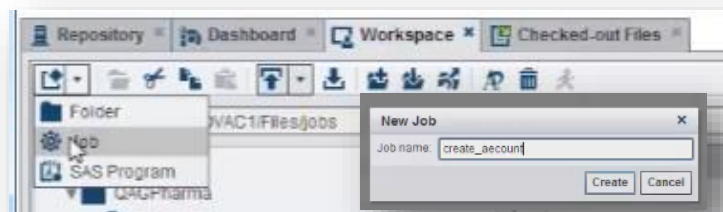


SAS DRUG DEVELOPMENT

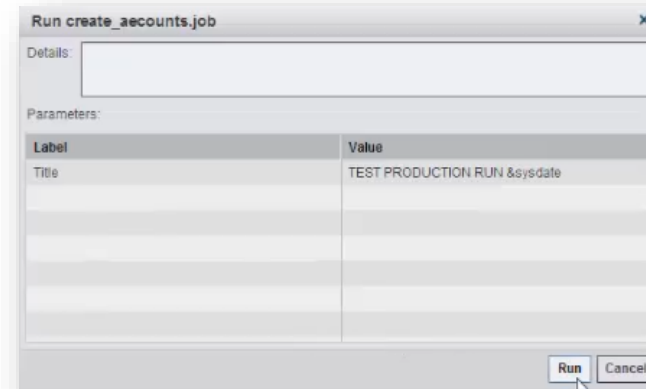
TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Integrated SAS Development/Execution environment (SAS Session / Editor) – Job

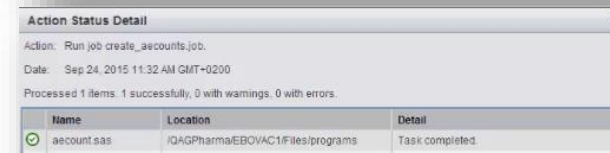
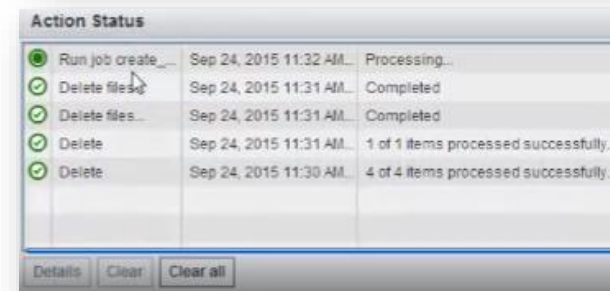
JOB creation



Save & Run Job



Action Status



Result after running a Job (SAS Session) – Manifest File

The manifest (XML) file contains all the information regarding a specific JOB run/execution.

- ✓ *General Info*
- ✓ *SAS programs*
- ✓ *Parameters*
- ✓ *Inputs*
- ✓ *Outputs*
- ✓ *Log*
- ✓ *Listing*



The screenshot shows the SAS Workspace browser interface. On the left, a tree view displays the workspace structure under the path 'QAGPharma/EBOVAC1/Files/jobs'. The 'jobs' folder is selected, showing subfolders 'documents', 'jobs', 'member1', 'member2', 'member3', 'member4', 'programs', 'rawdata', 'sdmdata', and 'sdmdata_xpt'. On the right, a table lists the files in the 'jobs' folder. The file 'create_accounts.mnf' is highlighted with a red box.

Name	Size	Date Modified	Repository Version	Workspace Status
create_accounts.job	1024	Sep 24, 2015 11:32 A...		
create_accounts.log	8385	Sep 24, 2015 11:32 A...		
create_accounts.lst	7727	Sep 24, 2015 11:32 A...		
create_accounts.mnf	2825	Sep 24, 2015 11:32 A...		

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Manifest File Example

Dashboard * Repository * Workspace * create_accounts (1.0) *

General

SAS Programs

Parameters

Inputs

Outputs

Log

Listing

Manifest Details

Name: create_accounts

Version: 1.0

Location: /QAGPharma/EBOVAC1/Files/jobs

Job Details

Name: create_accounts

Version: -

Owner: Mark Lambrecht

Run-as owner: No

Location: /QAGPharma/EBOVAC1/Files/jobs

Details:

Run Details

Type: Published

Submitted date: 24 september 2015 15:17 GMT+0200

Submitted by: Mark Lambrecht

Initiated from: Interactive

Completed date: 24 september 2015 15:17 GMT+0200

Completed status: Job completed successfully.

SAS® Drug Development

View Tools Administration Help

Dashboard * Repository * Workspace * create_accounts (1.0) *

General

SAS Programs

Parameters

Inputs

Outputs

Log

Listing

Status

Name

Location

aeaccount.sas

/QAGPharma/EBOVAC1/Files/programs

Label

Variable Name

Value

Title

FINAL PRODUCTION RUN &sysdate

Name

Location

Version

Referenced SAS Program

aeaccounts.sas7bdat

/QAGPharma/EBOVAC1/Files/dtmdata

-

/QAGPharma/EBOVAC1/Files/programs/aeaccount.sas

ae.sas7bdat

/QAGPharma/EBOVAC1/Files/dtmdata

-

/QAGPharma/EBOVAC1/Files/programs/aeaccount.sas

Versioning was enabled on all new output files.

Major versions were applied to all output files.

Name

Location

Version

Referenced SAS Program

graph.pdf

/QAGPharma/EBOVAC1/Files/documents

1.0

/QAGPharma/EBOVAC1/Files/programs/aeaccount.sas

create_accounts.lst

/QAGPharma/EBOVAC1/Files/jobs

1.0

create_accounts.log

/QAGPharma/EBOVAC1/Files/jobs

1.0

1 1 The SAS System 13:17 Thursday, September 24, 2015

2

3 NOTE: Copyright (c) 2002-2012 by SAS Institute Inc., Cary, NC, USA.

4 NOTE: SAS (r) Proprietary Software 9.4 (TS1M1 MCS3170)

5 Licensed to R&D PACKAGE VALIDATION, Site 70187988.

6 NOTE: This session is executing on the Linux 2.6.32-279.2.1.el6.x86_64 (LIN X64) platform.

1

2

3 * Submission Start: aeaccount.sas

4 * Sep 24, 2015 13:17:06 GMT by shxmal

5

6 Title is : FINAL PRODUCTION RUN 24SEP15

7

8

9

10

Obs

AEBOODSYS

AEGRPID

syscnt

1

GASTROINTESTINAL DISORDERS

AE01

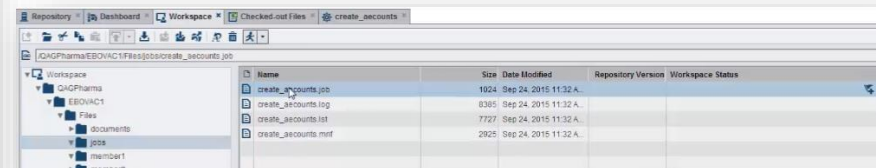
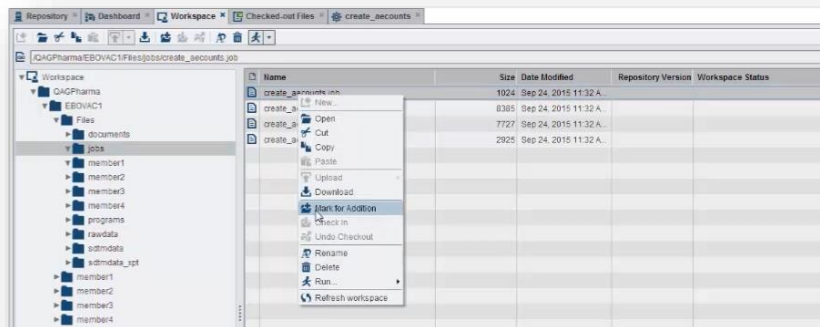
5

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

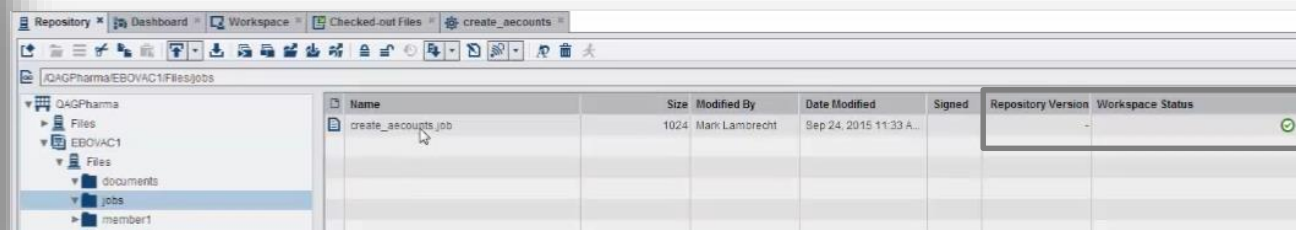
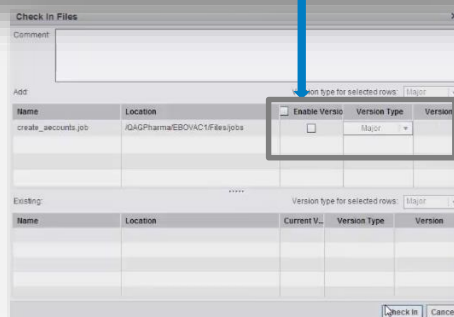
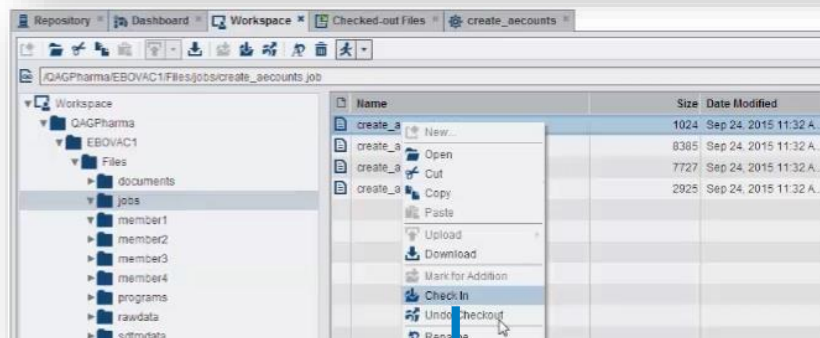
Move file(s) from Workspace into Repository

'Mark For Addition'
(Only for new files /
not yet available in
repository).

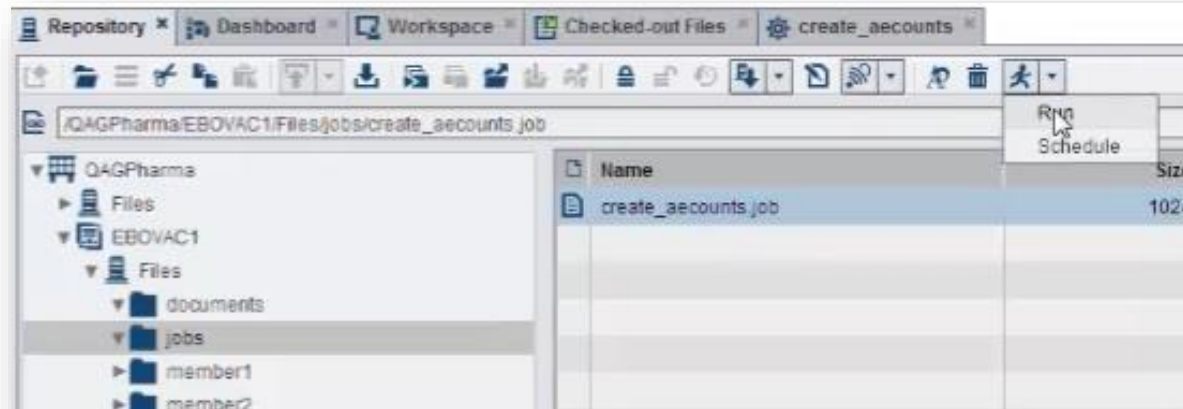


'Check In' (already
existing files in
repository).

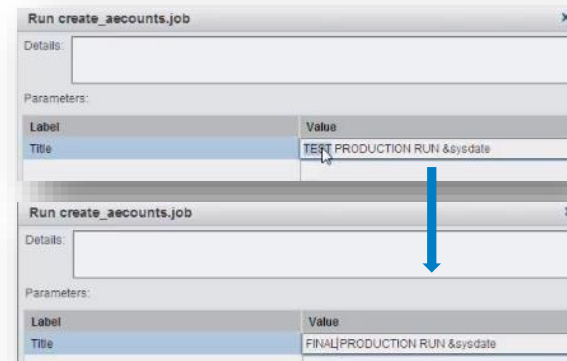
Save the program to
a corresponding
(repository) directory
in your Workspace
first before using
Check In feature.



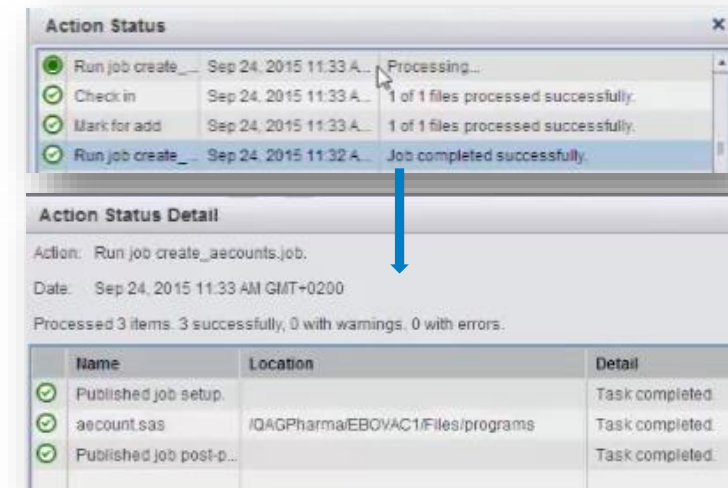
Running Job in Repository



Run Job



Action Status



SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Audit Trail

Audit history with pre/post change information.

The screenshot displays the SAS Drug Development Audit History interface. The top navigation bar includes 'View', 'Tools', 'Administration', and 'Help'. The 'Administration' menu is open, showing 'Audit History', 'Extended Attributes', and 'Users'. The left sidebar shows a tree view of the repository structure, including 'QAGPharma', 'EBOVAC1', 'Files', 'documents', and 'jobs'. The main content area shows the 'Audit History' tab with search filters for Object, Name, Location, Action, and Date. The search results show 187 records found. The table below lists the audit records.

Object	Name	Location	Action	Acted On By (User Name)	Date Acted On
Project	EBOVAC1	QAGPharma	Member added	sbxmal (Mark Lambrecht)	Sep 24, 2015 11:12:14 AM GMT+0200
Project	EBOVAC1	QAGPharma	Member removed	sbxmal (Mark Lambrecht)	Sep 24, 2015 11:01:18 AM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:49 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:49 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:49 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:47 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis removed	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:40 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis removed	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:33 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis removed	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:28 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis removed	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:23 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:04 PM GMT+0200
Project	EBOVAC1	QAGPharma	Analysis added	sbxmal (Mark Lambrecht)	Sep 23, 2015 09:34:04 PM GMT+0200

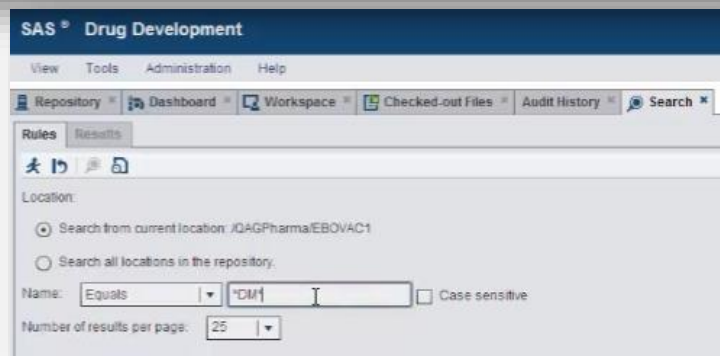
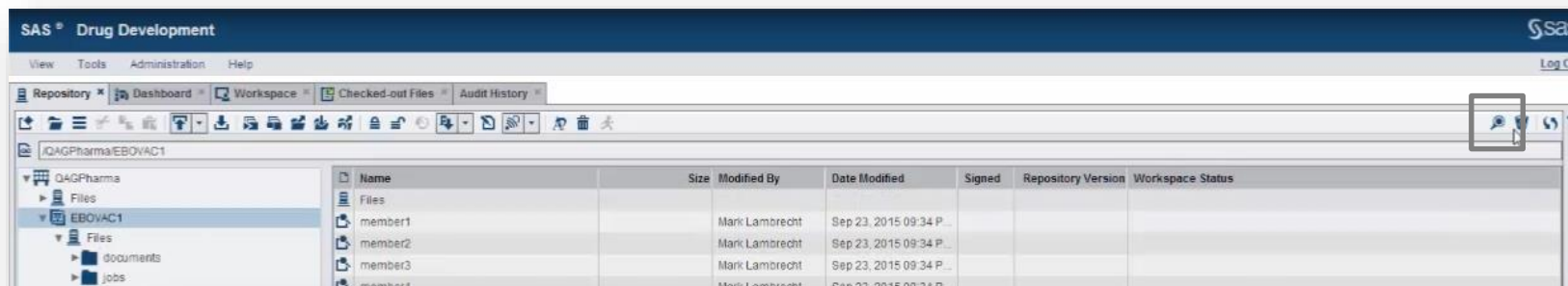
Details:

Attribute	From	To
Member		projlead8

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Search in Repository



Name	Location	Type
DMADS.xpt	/QAGPharma/EBOVAC1/Files/member1/XPT	File
dm.sas7bdat	/QAGPharma/EBOVAC1/Files/sdtmdata	SAS Data Set
dm.xpt	/QAGPharma/EBOVAC1/Files/sdtmdata_xpt	File

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Data Explorer

The screenshot displays the SAS Data Explorer interface, showing two overlapping windows. The top window displays a table with columns: Obs, STUDYID, DOMAIN, USUBJID, SUBJID, RFSTDTC, RFENDTC, SITEID, and INVID. The bottom window displays a table with columns: Obs, BRTHDTC, AGE, AGEU, SEX, RACE, ETHNIC, ARMCD, ARM, COUNTRY, and DMDTC. Both windows have a left-hand menu for selecting columns and a bottom status bar showing row and column counts.

Top Window: REPOSITORY.DM.DATASET

Obs	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	SITEID	INVID
1	NIC001	DM	011-001	011001	2007-10-12T23...	2007-10-24T10...	011	1
2	NIC001	DM	011-002	011002	2007-10-14T16...	2007-10-21T10...	011	1
3	NIC001	DM	011-003	011003	2007-11-10T18...	2007-11-23T19...	011	1

Bottom Window: REPOSITORY.DM.DATASET

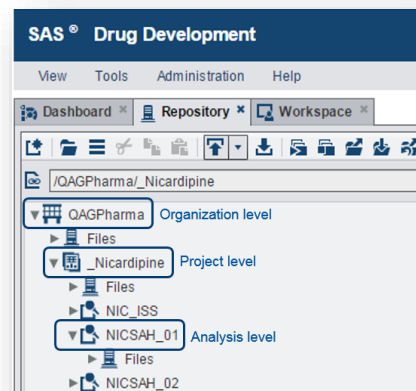
Obs	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM	COUNTRY	DMDTC
1	1988-10-24	19	YEARS	M	WHITE		PLA	PLACEBO	USA	2007-10-12
2	1983-10-14	26	YEARS	M	WHITE		PLA	PLACEBO	USA	2008-11-24
3	1980-01-05	29	YEARS	M	OTHER		PLA	PLACEBO	USA	2008-02-03
4	1979-12-19	29	YEARS	M	BLACKORAFRI...		NIC15	NICARDIPINE	USA	2008-03-26
5	1989-10-30	19	YEARS	M	WHITE		NIC15	NICARDIPINE	USA	2008-09-04
6	1984-01-26	26	YEARS	M	WHITE		NIC15	NICARDIPINE	USA	2009-01-26
7	1981-09-12	28	YEARS	M	WHITE					
8	1981-09-11	27	YEARS	M	OT					
9	1982-12-20	26	YEARS	M	OT					
10	1984-01-16	26	YEARS	M	OT					
11	1988-12-17	19	YEARS	M	W					
12	1983-01-27	27	YEARS	M	W					
13	1981-01-26	29	YEARS	M	AS					
14	1980-01-07	29	YEARS	M	W					
15	1980-11-27	29	YEARS	M	W					
16	1981-01-16	28	YEARS	M	W					
17	1985-02-12	24	YEARS	M	W					
18	1985-06-01	24	YEARS	M	W					
19	1981-10-20	28	YEARS	M	W					
20	1990-08-08	19	YEARS	M	W					
21	1982-02-02	26	YEARS	M	W					
22	1981-03-02	28	YEARS	M	W					
23	1981-03-03	28	YEARS	M	WHITE					
24	1991-01-07	19	YEARS	M	WHITE		PLA	PLACEBO	USA	2009-02-20
25	1981-01-07	29	YEARS	M	WHITE		NIC15	NICARDIPINE	USA	2009-06-11

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

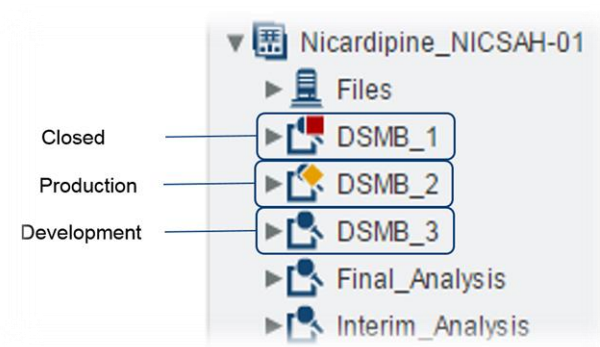
Metadata management using Context, Context State & API

Hierarchy with three types of contexts: **Organization**, **Project**, **Analysis Level**.



Each context has a Files container under which users may create their own folder hierarchy.

Context State: **Dev**, **Prod** and **Closed**.



Production: an informational indicator that the programs within the context have been through the development cycle and are ready for production use

Closed: indicates that the context is no longer in use, and the context is locked, and only certain actions are available to users.

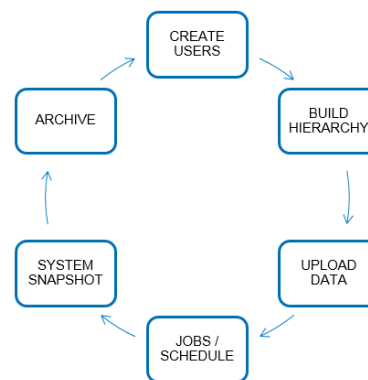
SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

Metadata management using Context, Context State & API (Cont'd)

API

The SAS Drug Development API consists of both *Java and SAS Macro* based interfaces designed to facilitate the development of applications that can *extend, automate, or drive SAS Drug Development functionality*



JAVA API SERVICES (1.7.1)

User Management	UserService, GlobalPrivilegeAssignmentService
Context Management	OrganizationService, ProjectService, AnalysisService
Membership Management	MembershipService
Group Management	GroupService
Role Management	RoleDefinitionService, PrivilegeService, RoleAssignmentService
File Management	RepositoryResourceService, BatchRepositoryResourceService, WorkspaceResourceService, BatchWorkspaceResourceService, AclService, SignatureService
Job Management	JobService, JobExecutionService
Schedule Management	ScheduleService
Subscription Management	SubscriptionService
Work Items	WorkItemService
Recycle Bin	RecycleBinService
Audit	AuditService
Application management	ApplicationInformationService, TypeService

SAS MACRO API 1.4

Context Management	Create / Delete / Rename Project or Analysis
Membership Management	Get / Exists / Add / Remove Members
Group Management	Get / Exists / Create / Delete Group Get / Exists / Add / Remove Group Member
Role Management	Get / Exists / Create / Delete Context Role Assign / UnAssign / AssignExits for Inherited Roles
Role Privilege(s)	Get default list of Context Privileges Get / Exists / Add / Remove Context Role Privilege
Role Membership	Get / Exists / Add / Remove Role Member
File Management	Get / Exists / Version / Create / Delete / Copy / Move / Rename /
ACLs (Permissions)	Get / Update File Permissions Get / Update Owner
Sync Management	Get Sync Status Download Latest copy from Repository to Workspace
User Management	Get / Exists / Create / Delete / Lock / Unlock User Assign / Deny Privilege(s) or Group Assignment(s)
Job Management	Job Exists / Retrieve / Execute
Subscription Management	Get List of Subscriptions
Recycle Bin Management	Retrieve Recycle Bin Items Delete Recycle Bin Items
PC Only	Upload / Download Data from SAS Drug Development

Metadata management using Context, Context State & Macro API (Cont'd)

- API SAS Macros can be used to store metadata about file versions used for a snapshot, which can be used to easily retrieve those versions later, eliminating the need to create an additional copy of data and programs.
- The `sasdrugdev_getchildren` API macro will return, in a SAS dataset, metadata about the objects within the path specified in the macro call. This is however not sufficient.

`%sasdrugdev_getchildren`

Obs	path	name	objectType	isContainer	description	versionLabel	isVersioned
1	/QAGPharma/N...	Production	sas.folder	1			0
2	/QAGPharma/N...	ae.job	sas.job	0		1.2	1
3	/QAGPharma/N...	ae.sas	sas.sasprogram	0		5.0	1
4	/QAGPharma/N...	ae_listing.sas	sas.sasprogram	0		3.2	1
5	/QAGPharma/N...	AE2_listing.job	sas.job	0		1.2	1

- Using `sasdrugdev_getjob` API macro's (see list below) will provide you also the metadata from all of the jobs that have been used in the Analysis.

`%sasdrugdev_getjobinfo`

`%sasdrugdev_getjobinputs`

`%sasdrugdev_getjoboutputs`

`%sasdrugdev_getjobparameters`

`%sasdrugdev_getjobtasks`

Metadata management using Manifest file

- If standard practice at your company is to always specify only the exact inputs and programs, including their versions, for jobs then using the getjob macros could provide a useful set of information. However, if these precise values are not consistently defined in all jobs, the information you can get from the getjob macros will be limited. You also will not be able to trace either the parameter values used or the outputs created by the job.
- The **SAS XML Libname Engine** can be used to read manifest files, but it will be necessary to use an **XML map** so that the structure of the manifest can be properly understood by **SAS as a set of datasets**. The structure of all manifest files in SAS Drug Development are the same; this means you can generate an XML map using one manifest file, and that **XML map can then be used when reading all manifest files**.

```
filename qsmnf "&_sasws_/QAGPharma/Nicardipine_NICSAH-01/DSMB_2/Files/SDTM/Programs/Production/Create_qs.mnf";

filename map "&_sasws_/QAGPharma/Nicardipine_NICSAH-01/DSMB_2/Files/Specifications/manifest.map";

libname qsmnf xmlv2 xmlmap=map;
```

Retrieve Files

- This can be done manually by selecting the file to retrieve, selecting the menu item to get version, and selecting **Get Specific Version**. If you've however stored the snapshot metadata in a SAS dataset, the **sasdrugdev_syncfiletoworkspace** macro conveniently gets the specific version of the files you need into your workspace.

```
Untitled.sas*
1 $sasdrugdev_syncfiletoworkspace(sdd_path=/QAGPharma/Nicardipine_NICSAH-01/DSMB_2/Files/Listings/Programs/Production/ae.sas,sdd_version=2.1);
```

See also recent SAS White Paper: “*Metadata Snapshots: How SAS Drug Development API Macros Can Help (Melissa R. Martinez)*”

SAS DRUG DEVELOPMENT

TRANSPARENCY AND TRACEABILITY USING SAS DRUG DEVELOPMENT

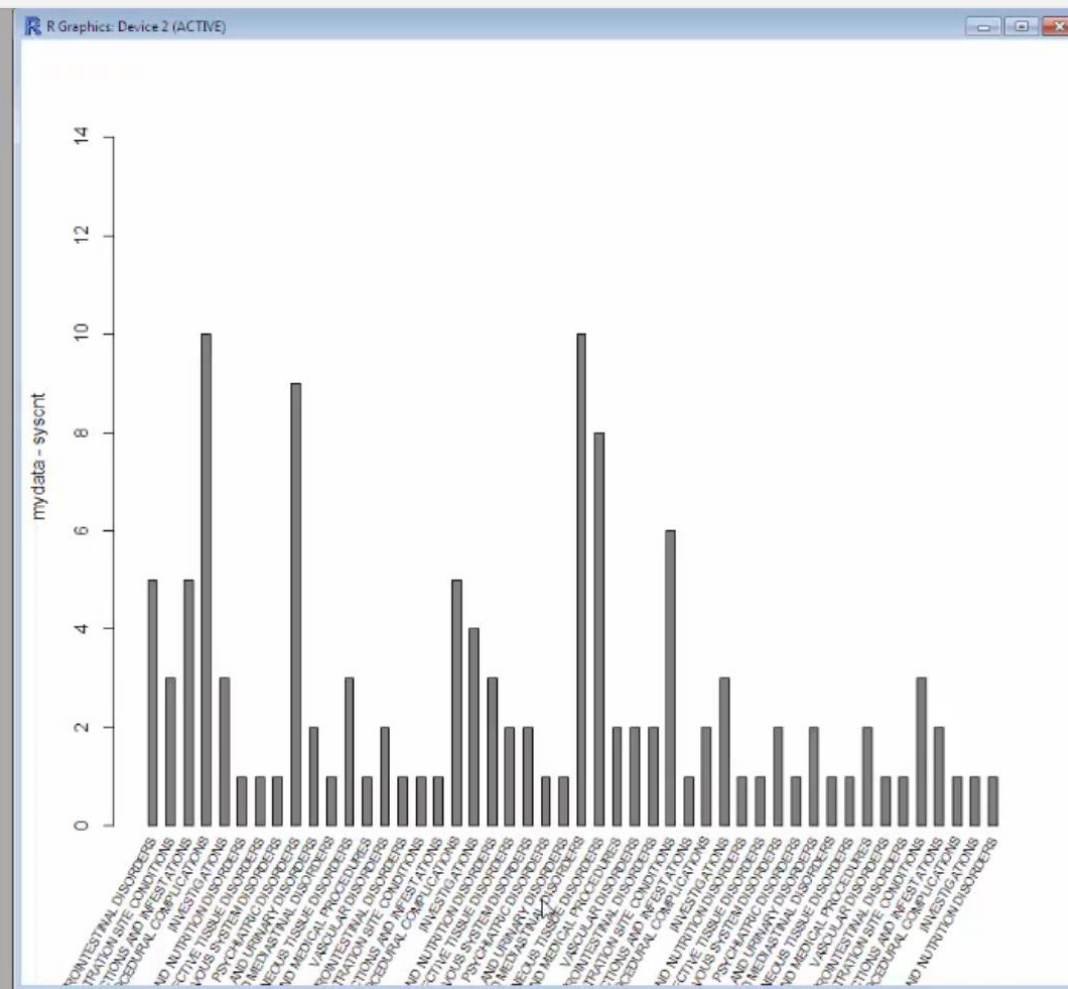
Using R with SAS Drug Development Repository (example)

```
R Console
> summary(mydata)

          aebodsys      aegrpid
NERVOUS SYSTEM DISORDERS      : 7      AE02 :13
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: 5      AE01 :11
INFECTIONS AND INFESTATIONS    : 5      AE03 : 9
INVESTIGATIONS                 : 5      AE04 : 5
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS      : 5      AE05 : 5
INJURY, POISONING AND PROCEDURAL COMPLICATIONS      : 4      AE06 : 3
(Other)                        :17      (Other): 2

      sysent
Min.   : 1.000
1st Qu.: 1.000
Median : 2.000
Mean   : 2.604
3rd Qu.: 3.000
Max.   :10.000

> sysent.order<-order(mydata$sysent, decreasing=TRUE)
> mydata.sysent<-mydata[sysent.order,]
> barplot(mydata$sysent)
> par(mar=c(7, 4, 2, 2) + 0.2)
> end_point = 0.5 + nrow(mydata) - 1
> barplot(mydata$sysent, col="grey50", main="", ylab="mydata - sysent", ylim=c(0, 14))
> text(seq(1.5, end_point, by=2), par("usr")[3]-0.25, srt=60, adj=1, xpd=TRUE, s
```



Using R and RStudio on SAS hosted Environment is very similar to using R on your local PC.

R packages can be imported by the customer. Some packages however do not run without additional software on SAS hosted environment (SAS Technical Support will support customer).

MOVE FROM SAS DRUG DEVELOPMENT TO LIFE SCIENCE ANALYTICS FRAMEWORK



SAS LIFE SCIENCE ANALYTICAL FRAMEWORK

MOVE FROM SAS DRUG DEVELOPMENT TO LIFE SCIENCE ANALYTICS FRAMEWORK

What's new ? (Main themes)



Current situation:

- SAS Drug Development 4.5
- Clinical Data Integration 2.6
- Clinical Standards Toolkit 1.7

Future:

- Life Science Analytical Framework

SAS LIFE SCIENCE ANALYTICAL FRAMEWORK

MOVE FROM SAS DRUG DEVELOPMENT TO LIFE SCIENCE ANALYTICS FRAMEWORK

What's new ? (New SAS Session Editor / shared with SAS Studio)

The screenshot displays the SAS Life Science Analytics Framework interface. On the left, a 'Repository' pane shows a hierarchical view of files and folders, including 'QAGPharma', 'Nicardipine', 'NICSAH_Study_001', 'ADAM Data', 'Analysis Data', 'Documents', 'EDC Data', 'Jobs', 'Programs', 'Rawdata', 'Reports', 'SDTM Data', 'NICSAH_Study_002', 'NICSAH_Study_003', 'NICSAH_Study_004', 'PatientProfile', 'Therapeutic Areas', 'X_FRX_CV', and 'Users'. The main area is divided into two panes. The top pane, titled 'Untitled.sas *', contains SAS code for setting up the programming environment, including options for formatting, locale, and paths for SAS data and user profiles. The bottom pane, titled 'Session Log', shows the output of the SAS initialization process, including the total process time, real time, and CPU time.

```
1 /*SAS programming environment
2 *your program goes here
3 */
4
5 options nofmterr ls=200;
6 options dtreset;
7 options locale=EN_US;
8 %let _SDDUSR_=%bquote(bigibs);
9 %let _SASWS_ = %nrstr("/sddshared/SASWorkspaces/bigibs");
10 %let _SASWS_ = %qsubstr(&_SASWS_, 2, %length(&_SASWS_) - 2);
11
12 %let _SASUSRWS_ = %nrstr("/sddshared/SASWorkspaces/bigibs/Users/bigibs");
13 %let _SASUSRWS_ = %qsubstr(&_SASUSRWS_, 2, %length(&_SASUSRWS_) - 2);
14
15 proc p
```

Procedures list:

- PROC FIM
- PROC PMENU
- PROC POWER
- PROC PRESENT
- PROC PRINCOMP
- PROC PRINQUAL
- PROC PRINT
- PROC PRINTTO
- PROC PROBIT

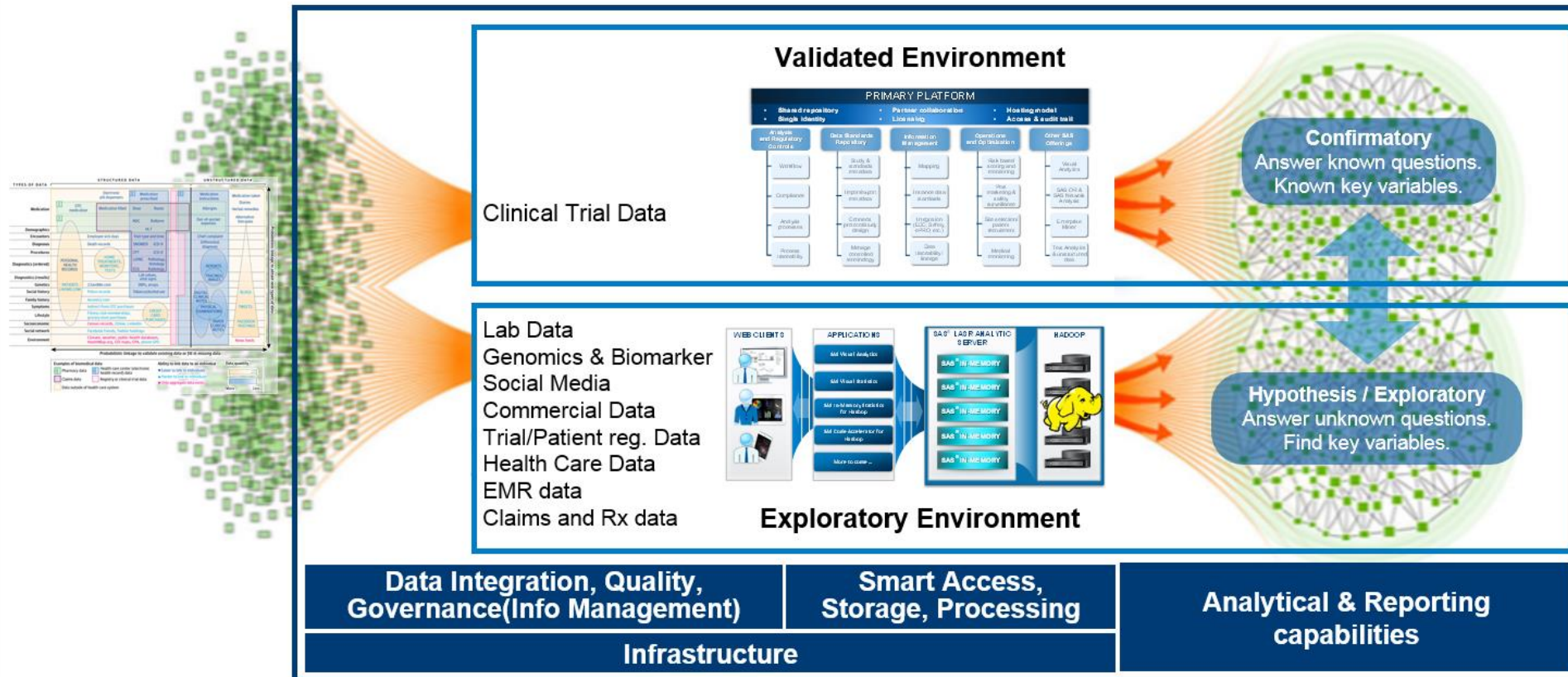
Session Log:

```
33
34
35
36
37 NOTE: SAS Initialization used (Total process time):
38     real time      0.01 seconds
39     cpu time       0.02 seconds
40
```

ANALYTICAL ENVIRONMENT

THE BIGGER PICTURE

And don't forget, it's only the 'validated' environment ... (the bigger picture)



FROM CENTRALIZED TO DISTRIBUTED COLLABORATIVE ENVIRONMENT



EVOLUTION

FROM CENTRALIZED TO DISTRIBUTED COLLABORATIVE ENVIRONMENT.

Collaborative Research Environment

- Problem statement
 - Research in health care is evolving past traditional clinical studies towards accessing new types of data, integrating disparate information and aggregating all of this for on-demand access by new researcher populations.
- Proposal
 - Proposed is the creation of an environment that will be the foundation for the next generation of clinical research and the dissemination of health care innovation.
 - The environment proposed will enable isolated areas of the clinical research ecosystem to share information, ideas, and results while collaborating with individuals anywhere in the world on the analyses of these data.

EVOLUTION

FROM CENTRALIZED TO DISTRIBUTED COLLABORATIVE ENVIRONMENT.

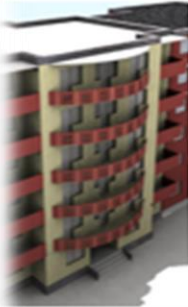
Overview of shared instance (Multiple Project Environment) proposal



“House” model

- Own the instance, whether living there or not.
- Pay for all infrastructure
- Pay for all utilities
- Pay for any maintenance
- Pay for upgrades

Photo credit: <http://youneverheardofartidivell.com/2012/03/03/home-sweet-home/>



“Apartment” model

- Rent an apartment for length needed
- Landlord pays for infrastructure and upkeep
- Pay for portion of utilities
- Landlord pays for maintenance and upkeep
- If upgrade is done, landlord pays for benefit of all tenants

EVOLUTION

FROM CENTRALIZED TO DISTRIBUTED COLLABORATIVE ENVIRONMENT.

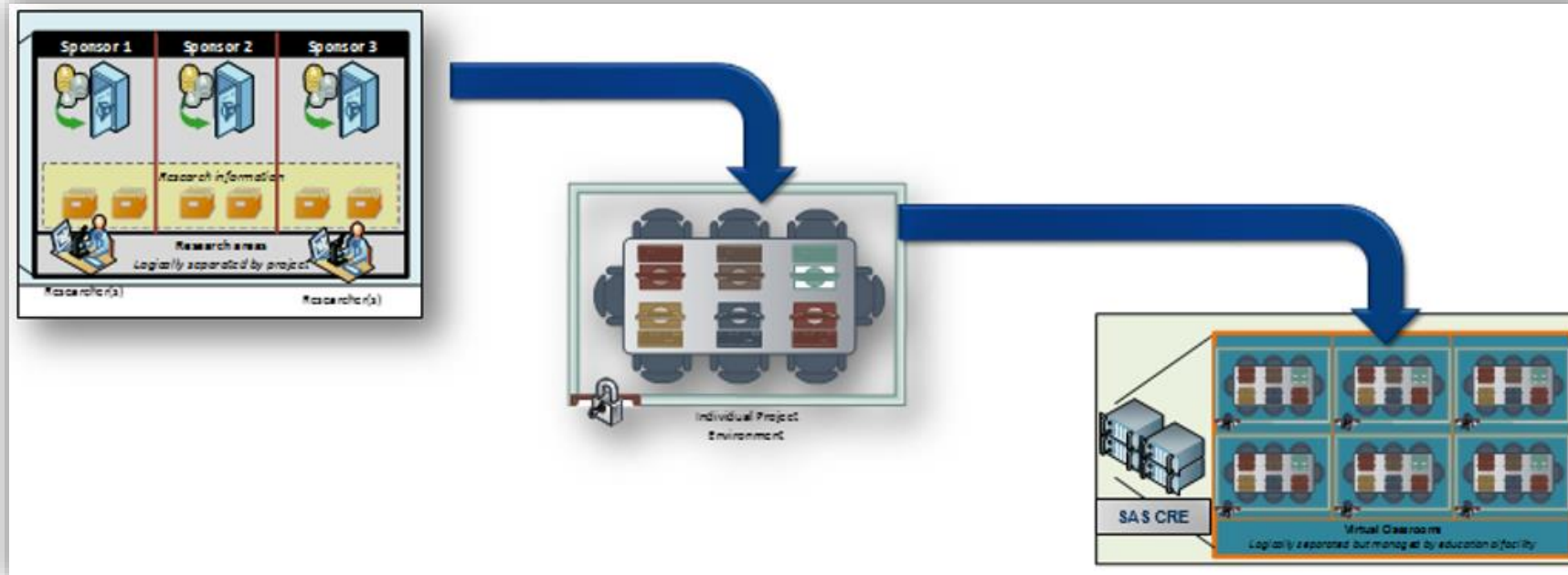
“Apartment” model details

Apartment analogy	CRE equivalent
Building security	CRE Environment limits access to the environment to only those that should get into the environment
Private, individual units	Each Project is logically separated from each other so that users can only see their area and aren't aware of nor have access to any other Project. A Sponsor may have multiple Projects in the CRE. The CRE supports multiple Sponsors.
Various apartment sizes	Ability to support projects for different size research teams
Variable length leases	Can have access to a project for the length of time needed and can extend if needed
Building common areas	Hardware, software, licensing, network access, etc. are used across all projects and costs are distributed based use
Scalable infrastructure	Able to quickly scale up storage, users or processing capability as needed by the research team
Building upgrades	If requested and approved, new features can be added to the environment that will benefit all users
On-site apartment manager	All administration, monitoring, hosting and back-ups managed centrally by SAS. If system has any issues, admin team is available 24/7.
Concierge services	Tech-support available to researchers to answer questions or help address problems

EVOLUTION

FROM CENTRALIZED TO
DISTRIBUTED COLLABORATIVE ENVIRONMENT.

Multiple Project Environment



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