



QUALIANCE

DH09

Managing Programs Development Life-Cycles in LSAF

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Agenda

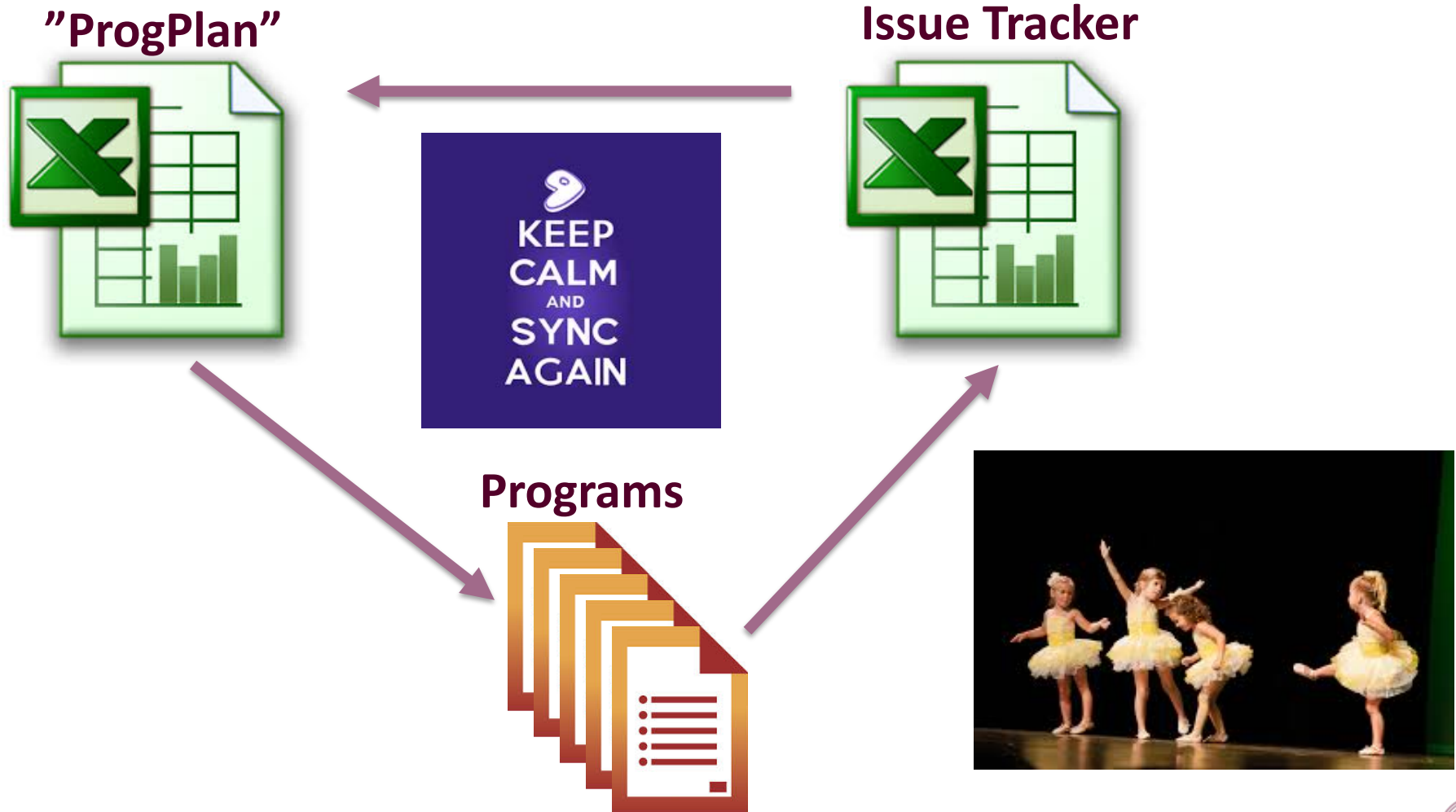
- Business Case
- LSAF Features
- Life-Cycle Example in LSAF
- Tackling Dependencies

Agenda

- **Business Case**
- LSAF Features
- Life-Cycle Example in LSAF
- Tackling Dependencies

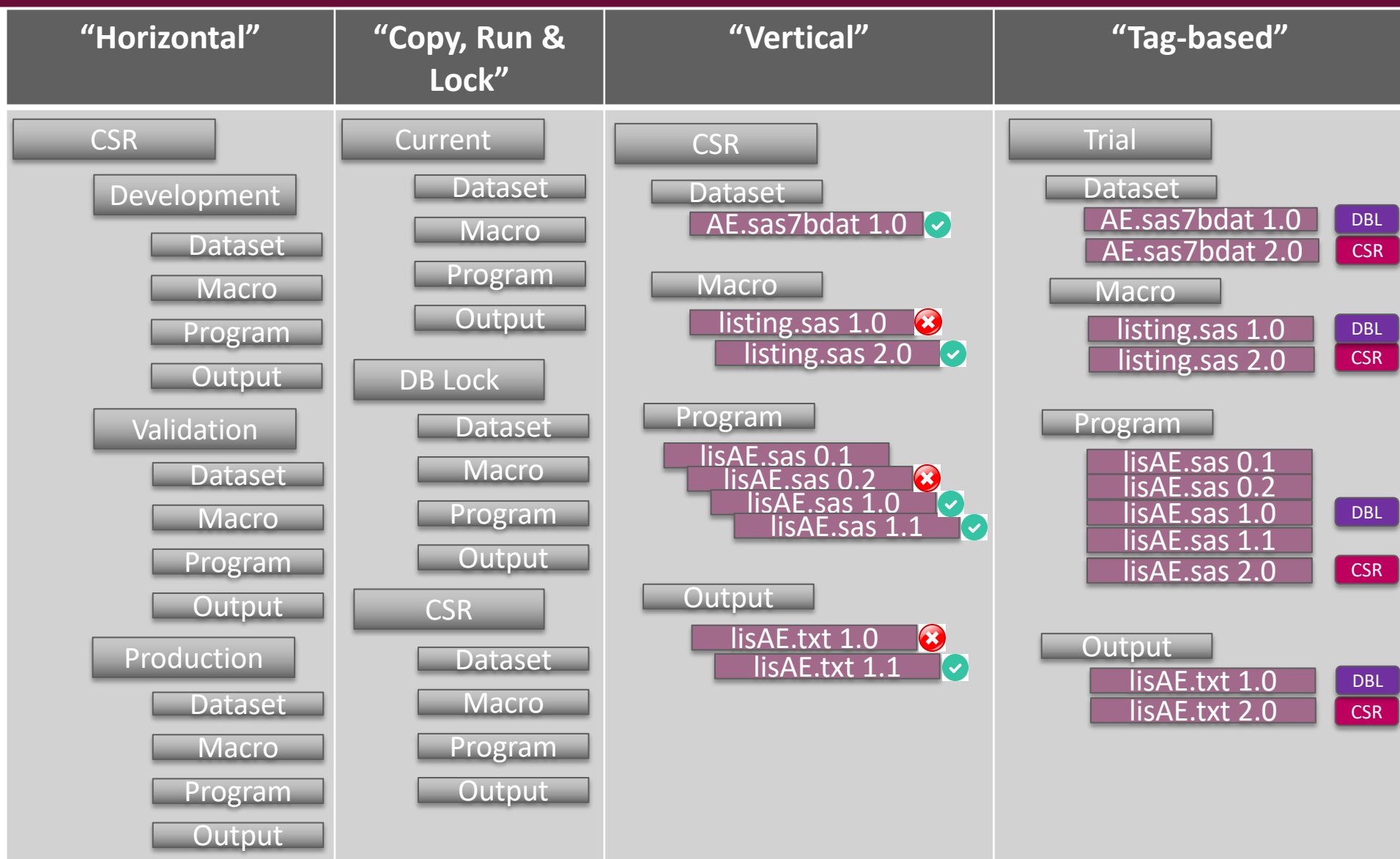
Business Case (1)

Tracking Statuses & Issues using MS Excel



Business Case (2)

Life Cycle Management Industry Examples



Agenda

- Business Case
- **LSAF Features**
- Life-Cycle Example in LSAF
- Tackling Dependencies

LSAF Features (1)

Main Interface in LSAF 4.5, 4.6 and 4.7

The screenshot displays the SAS Drug Development LSAF interface. The top navigation bar includes 'View', 'Tools', 'Administration', and 'Help'. The 'Repository' tab is selected, showing a file tree on the left and a file list in the center. The file list has columns for Name, Size, Modified By, and Date Modified. The right sidebar shows the 'Properties' panel with 'Permissions' and 'Users or Groups' sections.

Annotations on the interface:

- Repository / Workspace**: Points to the 'Repository' and 'Workspace' tabs.
- Check-in/out**: Points to the 'Check-in/out' icon in the toolbar.
- Versioning**: Points to the 'Versioning' icon in the toolbar.
- eSign**: Points to the 'eSign' icon in the toolbar.

Name	Size	Modified By	Date Modified
adae.sas7bdat	262144	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adanti.sas7bdat	2621440	Jean-Marc Ferran	Sep 08, 2014 09:55 P...
adbl.sas7bdat	786432	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adcm.sas7bdat	262144	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adds.sas7bdat	294912	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
ademb1.sas7bdat	1835008	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
ademb2.sas7bdat	2097152	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adex.sas7bdat	393216	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adimpl.sas7bdat	524288	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adinj.sas7bdat	2359296	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
admh.sas7bdat	262144	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adohss.sas7bdat	262144	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adpgloss.sas7bdat	655360	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adpreg.sas7bdat	786432	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adsl.sas7bdat	163840	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adsl2.sas7bdat	262144	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adsv.sas7bdat	573440	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adtvu.sas7bdat	1048576	Jean-Marc Ferran	Aug 22, 2014 11:27 A...
adv.sas7bdat	1179648	Jean-Marc Ferran	Aug 22, 2014 11:27 A...

Permissions

Current **Default**

Owner: Jean-Marc Ferran

Users or Groups:

- Owner
- Members
- Analysis_JM_Programmer

LSAF Features (2)

Versioning in LSAF

Check In Files

Comment: This is the first version

Add: Version type for selected rows: Major

Name	Location	Enable Version	Version Type	Version
mypgm.sas	/ SAS/ Study_Sample/ 03_Study_Report...	☒	Major	1.0
			Major	
			Minor	
			Custom	

Existing: Version type for selected rows: Major

Name	Location	Current ...	Version Type	Version

Check In Cancel

- Possibility to enable and disable versioning
- New versions created at check-in and check-out or when files are overwritten
- Each time a user modifies a program under versioning, a new version is created as next Major, Minor or Custom version.

LSAF Features (3)

eSignature in LSAF

The screenshot displays the LSAF eSignature interface. It features two 'Sign Files' windows and a 'Version History' window.

Sign Files (Left Window):

- Reason: Approve
- Signatory role: Approver
- Comment: Approver
- Sign the following files:

Name	Location	Sign...	Version
mypgm.sas	/SAS/Study_Sample/03_Study_Report/Files/30_O...		1.1

Sign Files (Right Window):

- Reason: Approve
- Signatory role: Approve
- Comment: Reject
- Comment: This version is ready for QC
- Sign the following files:

Name	Location	Sign...	Version
mypgm.sas	/SAS/Study_Sample/03_Study_Report/Files/30_O...		1.1

Version History:

File name: mypgm.sas
File location: /SAS/Study_Sample/03_Study_Report/Files/30_Output_Programs/mypgm.sas

Version history:

Version	Signed	Versioned By	Date Modified	Size	Comment
1.1		Jean-Marc Ferran	May 03, 2018 11:...	23 bytes	This is my 2nd version...version 1.1
1.0		Jean-Marc Ferran	May 03, 2018 11:...	16 bytes	This is my first version

Signed:

Reason	User ID (Display Na...	Role	Date
Reject	ferranje (Jean-Marc ...	Reviewer	May 03, 2018 11:1...
Approve	ferranje (Jean-Marc ...	Clinical Programmer	May 03, 2018 11:0...

- Versions can be eSigned with different roles and reasons
- Roles and reasons can be customized
- **eSignatures are not carried forward from one version to the next**

LSAF Features (4)

Using the LSAF APIs...

%LSAF_GETCHILDREN and %LSAF_GETVERSION

name	versionLabel	isCheckedOut	isLocked	is Signed	createdBy	dateCreated	lastModifiedBy	lastModified
program1.sas	1.0	0	0	1	dev_jfe	11MAY16:08:29:28	dev_jfe	Wed May 11 08:29:28 GMT 2016
program2.sas	1.0	0	0	1	dev_jfe	11MAY16:08:29:29	dev_jfe	Wed May 11 08:29:29 GMT 2016
program3.sas	2.0	0	0	1	dev_jfe	11MAY16:08:29:29	ext_training_018	Wed May 11 14:15:02 GMT 2016
program3.sas	1.0	0	0	1	dev_jfe	11MAY16:08:29:29	dev_jfe	Wed May 11 08:29:29 GMT 2016
program4.sas	1.0	0	0	1	dev_jfe	11MAY16:08:29:29	dev_jfe	Wed May 11 08:29:29 GMT 2016
program5.sas	2.0	0	0	0	ext_training_016	11MAY16:13:27:34	ext_training_018	Wed May 11 13:43:37 GMT 2016
program5.sas	1.0	0	0	1	ext_training_016	11MAY16:13:27:34	ext_training_016	Wed May 11 13:27:34 GMT 2016

%LSAF_GETSIGNATURES

name	versionLabel	userId	reason	role	comment	date Signed
program1.sas	1.0	ext_training_016	Approve	Reviewer		11MAY16:13:23:43
program1.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:39
program2.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program2.sas	1.0	ext_training_017	Approve	Approver		11MAY16:13:39:59
program3.sas	2.0	ext_training_018	Approve	Clinical Programmer		11MAY16:14:15:36
program3.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program3.sas	1.0	ext_training_016	Reject	Reviewer		11MAY16:13:26:01
program4.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program5.sas	1.0	ext_training_016	Approve	Statistical Programmer		11MAY16:13:29:35
program5.sas	1.0	ext_training_017	Approve	Reviewer		11MAY16:13:40:58



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- Business Case
- LSAF Features
- **Life-Cycle Example in LSAF**
- Tackling Dependencies

Life-Cycle Example in LSAF (1)

Computing Program Status

name	versionLabel	isCheckedOut	isLocked	is Signed	createdBy	dateCreated	lastModifiedBy	lastModified
program1.sas	1.0	0	0	1	dev_jfe	11MAY16:08:29:28	dev_jfe	Wed May 11 08:29:28 GMT 2016
program2.sas	1.0	0	0	1				
program3.sas	2.0	0	0	1				
program3.sas	1.0	0	0	1				
program4.sas	1.0	0	0	1				
program5.sas	2.0	0	0	0				
program5.sas	1.0	0	0	1				

name	versionLabel	userId	reason	role	comment	date Signed
program1.sas	1.0	ext_training_016	Approve	Reviewer		11MAY16:13:23:43
program1.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:39
program2.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program2.sas	1.0	ext_training_017	Approve	Approver		11MAY16:13:39:59
program3.sas	2.0	ext_training_018	Approve	Clinical Programmer		11MAY16:14:15:36
program3.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program3.sas	1.0	ext_training_016	Reject	Reviewer		11MAY16:13:26:01
program4.sas	1.0	dev_jfe	Approve	Statistical Programmer		11MAY16:08:30:38
program5.sas	1.0	ext_training_016	Approve	Statistical Programmer		11MAY16:13:29:35
program5.sas	1.0	ext_training_017	Approve	Reviewer		11MAY16:13:40:58



#	Status	Status Description
1	Not Started	Program is in ProgPlan but not in LSAF
2	Draft not versioned	Program is in LSAF but not versioned
3	Draft versioned	Versioned and last version is not signed
4	Ready for validation	Last version is signed by Programmer as "Approve"
5	Failed validation	Last version is signed by Validator as "Reject"
6	Validated	Last version is also signed by Validator as "Approve"



Life-Cycle Example in LSAF (2)

Reporting Exceptions

#	Exceptions reported as Issues
1	Programmer and Validator are the same
2	Only Validator has signed
3	Program is not in ProgPlan

#	Exceptions reported as Warnings
1	Programmer who last modified and Signing Programmer are different
2	Validator eSigns before the Programmer
3	Program is checked-out
4	Program has validated or failed validation status but program is not referenced in Issue Tracker
5	Program has validated status but program still has open issues in Issue Tracker

Life-Cycle Example in LSAF (3)

Validation Status Dashboard

Indicates whether the program exist in the ProgPlan or was created on the go

Programmer Initials who last modified the program

Programmer Initials and Signature Date based on eSign info

Status computed for last version in LSAF based on eSign info

Validator Initials and Signature Date based on eSign info

Versions program is eSigned

ProgPlan

Programming & Validation

19_06_2016

LSAF

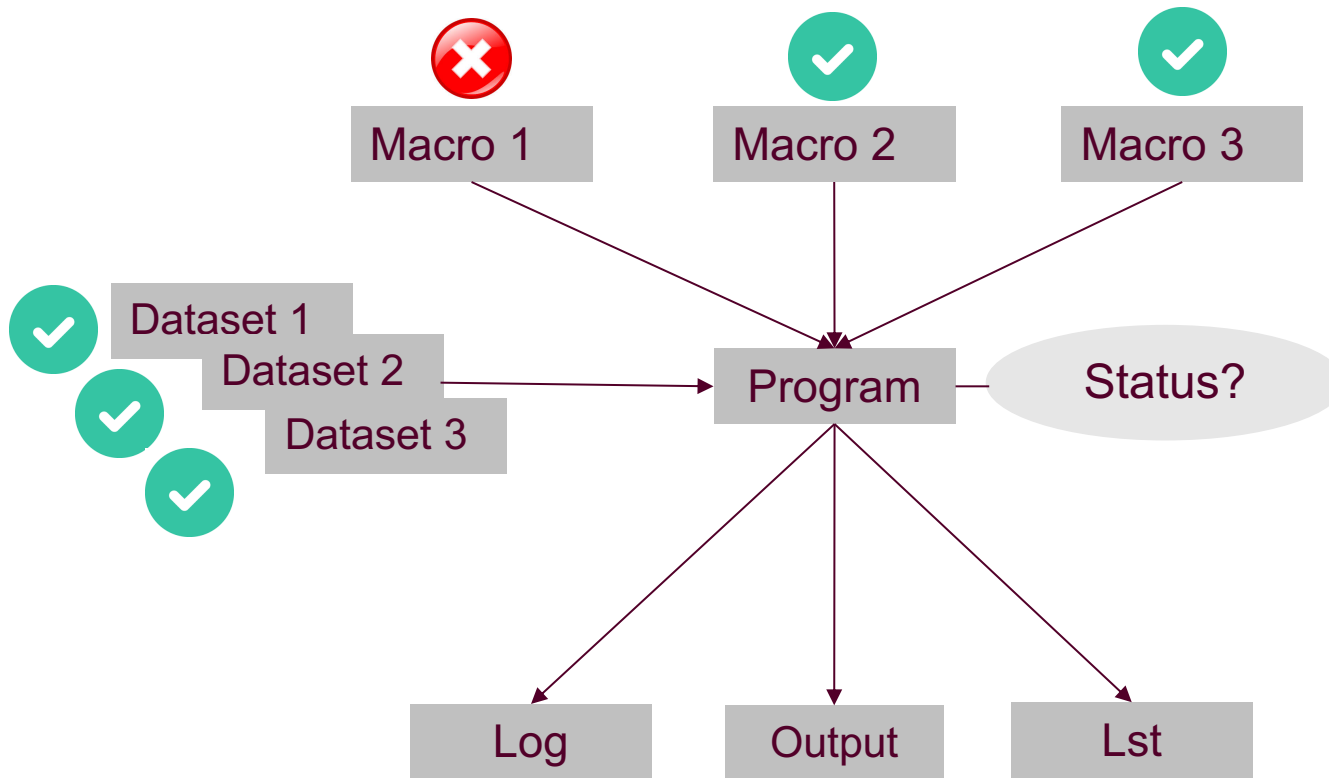
In ProgPlan (Y;N)	Category	Title	Program	Output File	Last Modified By	Programmer	Programmer Date Signed	Latest Version	Status	Validator	Validator Dates Signed	Iterations	Is Checked Out (Y;N)	Warning
Y	demog	Disposition Events	t_adds	t_adds_S_1	dev_jfe		.	1.0	Draft and versioned: Checked-out		.	1	Y	2: Program is checked-out
N	demog		t_adds_jfe		dev_jfe		.		Draft and not versioned		.	.	N	
N	demog		t_base		dev_jfe		.	1.0	Issue: Validation but Programming not confirmed	ext_training_016	19AUG16:08:33:05	1	N	
Y	demog	Subject Disposition	t_disp	t_disp	dev_jfe	ext_training_016	10JUN16:14:17:21	1.0	Validated	ext_training_018	10JUN16:14:28:58	1	N	0: Programmer who last modified and signing programmer are different
Y	demog	Subject Disposition by trial site	t_grpdisp	t_grpdisp	dev_jfe	ext_training_016	10JUN16:14:17:21	1.0	Validated	ext_training_018	10JUN16:14:28:58	1	N	4: Issue(s) not closed in Validation Report
N	demog		t_mw2		dev_jfe		.	1.0	Draft and versioned		.	.	N	
Y	efficacy	Number of fertilised oocytes (ANCOVA models)	it1_ademb2	it1_ademb2_21	ext_training_017	ext_training_017	10JUN16:14:26:26	1.1	Validated	dev_jfe	10JUN16:14:34:57	2	N	3: Program is not referenced in Validation Report
Y	efficacy	Number of fertilised oocytes (ANOVA models)	it2_ademb2	it2_ademb2	ext_training_017	ext_training_017	10JUN16:14:26:26	1.1	Validated	dev_jfe	10JUN16:14:34:57	2	N	
Y	efficacy	Number of fertilised oocytes (Summary Tables)	t_ademb2	t_ademb2_2_2	dev_jfe		.	1.1	Draft and versioned		.	1	N	
Y	efficacy	Number of fertilised oocytes (Summary Tables)	t_ademb2	t_ademb2_3_2	dev_jfe		.	1.1	Draft and versioned		.	1	N	
N	efficacy		t_ademb2_v2		dev_jfe		.		Draft and not versioned		.	.	N	
Y	pdl	Subject Disposition with Respect to Analysis Set	L_anapop	L_ANAPOPOP	dev_jfe		.	1.5	Draft and versioned		.	5	N	
Y	pdl	Body Measurements	L_bodymeas	L_BODYMEAS			.		Not started		.	.	.	
Y	pdl	Demographics and Baseline Characteristics	L_demog	L_DEMOG	dev_jfe	ext_training_016	10JUN16:14:20:32	1.0	Validated	ext_training_018	10JUN16:14:30:46	1	N	0: Programmer who last modified and signing programmer are different
Y	pdl	Subject Discontinuation According to Study Flow	L_discon	L_DISCON	dev_jfe	dev_jfe	18AUG16:15:02:40	1.1	Ready for validation		.	2	N	
Y	pdl	Major protocol deviations - ITT	L_protdev	L_PROTDEV	dev_jfe	dev_jfe	18AUG16:13:56:19	1.0	Validated	ext_training_018	10JUN16:14:30:47	1	N	1: Validation before Programming
Y	safety	Outcome of Individual Assays	t_adanti	t_adanti			.		Not started		.	.	.	
Y	safety	Pregnancy Loss	t_adpgloss	t_adpgloss			.		Not started		.	.	.	

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- Business Case
- LSAF Features
- Life-Cycle Example in LSAF
- **Tackling Dependencies**

Tackling Dependencies (1)

How to consider status of dependent artefacts?



Tackling Dependencies (2)

What is a Job?

The screenshot shows the SAS Job Manager interface with the 'Inputs' tab selected. The 'SAS programs' section contains a table with one entry: 'test_jmf.sas' located at '/SAS/Tenuto_0/Files/50 Study Report/50 Output Programs' with the 'Latest' version. The 'Input file and folder locations' section contains a table with two entries: 'adsl_temp.sas7bdat' and 'macro1.sas', both located at '/SAS/Tenuto_0/Files/50 Study Rep...' with 'Latest' and '1.1' versions respectively. The 'Include Subfolders' column has checkboxes for each entry.

Name	Location	Version
test_jmf.sas	/SAS/Tenuto_0/Files/50 Study Report/50 Output Programs	Latest

Name	Location	Include Subfolders	Version
adsl_temp.sas7bdat	/SAS/Tenuto_0/Files/50 Study Rep...	☐	Latest
macro1.sas	/SAS/Tenuto_0/Files/50 Study Rep...	☐	1.1

- Executes SAS programs as a background process
- Represents a single SAS session with a shared WORK library
- Lists all inputs and outputs
- Inputs can be specified as “Latest” or pointing to a specific version
- **Jobs information can be read using LSAF APIs**
- Produce a job manifest with all execution information

The screenshot shows the 'Manifest Details' tab for a job named 'parameters'. The 'General' section shows the job name, version (1.0), and location (/SAS/Files/output). The 'Job Details' section shows the job name, version (-), owner (SAS User), run-as owner (No), location (/SAS/Files), and details. The 'Run Details' section shows the job type (Published), submitted date (Nov 7, 2013 09:59 AM GMT-0500), submitted by (SAS User), initiated from (Interactive), completed date (Nov 7, 2013 10:00 AM GMT-0500), and completed status (Job completed successfully).

General	
Name:	parameters
Version:	1.0
Location:	/SAS/Files/output

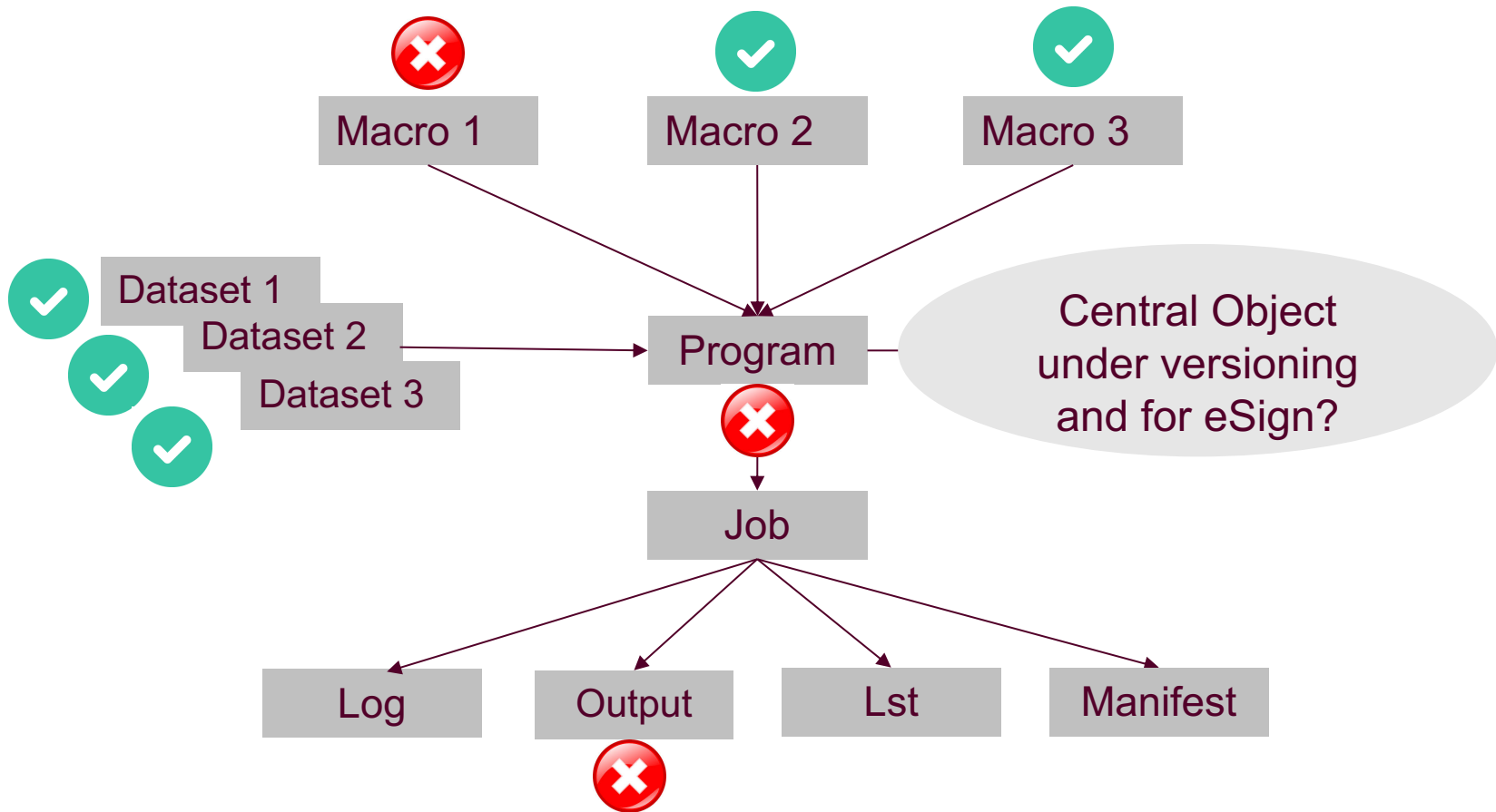
Job Details	
Name:	parameters
Version:	-
Owner:	SAS User
Run-as owner:	No
Location:	/SAS/Files
Details:	

Run Details	
Type:	Published
Submitted date:	Nov 7, 2013 09:59 AM GMT-0500
Submitted by:	SAS User
Initiated from:	Interactive
Completed date:	Nov 7, 2013 10:00 AM GMT-0500
Completed status:	Job completed successfully.



Tackling Dependencies (3)

Expand Validation Status to Inputs and Outputs



Conclusion

- **Status information is computed** from programmer and validator eSignatures:
 - All operational information is **programmatically retrievable** using LSAF APIs
 - **Cannot be out of Sync** with "ProgPlan" by Design!
- **Inadvertent changes** will result in a new version with status Draft or the deletion of eSignatures if the program is not under versioning.
- **Human errors can easily be tracked** in the system and reported.
- Process assumes that **users turn on versioning** at the latest when code is ready for validation.
- **Metrics on programming iterations needed** can be captured and provide feedback to management on team performance, standard program needs or training.
- Concepts can be extended to **tackle dependencies by analysing jobs** and their manifests

Thanks!

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