

AD₁₁ - Manage TFLs Development in Life Science Analytics Framework 5.3 using SAS and R code

Jean Marc Ferran, Stijn Rogiers

PHUSE EU Connect 2020

Agenda

Manage TFLs Development in Life Science Analytics Framework 5.3 using SAS and R code

- The Business Case
- TLF module within SAS Life Science Analytics Framework 5.3
- Life Cycle Management Prototype
- Conclusion

The Business Case



Program Life-Cycle Management in LSAF

PHUSE SDE Utrecht 2019

10. October 2019, Nutricia Research

Bjarke Mirner Klein, Director of Statistical Operations (Ferring Pharmaceuticals)
Jean-Marc Ferran, Principal Consultant (Qualiance)



Derive Validation Status

Program Status



Status	Versioned	Checked out	Program Author signed	Program Approver signed
Rejected	Yes	No	Approve	Reject
Validated	Yes	No	Approve	Approve
Not yet started*	NA	NA	NA	NA
Ongoing	Yes / No	Yes	Yes / No	Yes / No
Draft not versioned	No	No	No	No
Draft versioned	Yes	No	No	No
Ready for validation	Yes	No	Approve	No
Signed not versioned	No	No	Yes / No**	Yes / No**

* Available in Programming Plan but not in LSAF
** At least one has to be yes



Derive Validation Status

Potential Issues



Issue	Description
1	Program author signed as 'Reject'
2	Program author and program approver is the same
3	Program approver signed before program author
4	Program approver missing in Programming Plan but present in LSAF
5	Program author is missing in Programming Plan but present in LSAF
6	Programmer checked in not signed as Program author
7	Program approver has signed but program author has not signed
8	Programming Plan author is different from actual in LSAF
9	Programming Plan approver is different from actual in LSAF
10	Program not listed in Programming Plan
11	Unknown issue



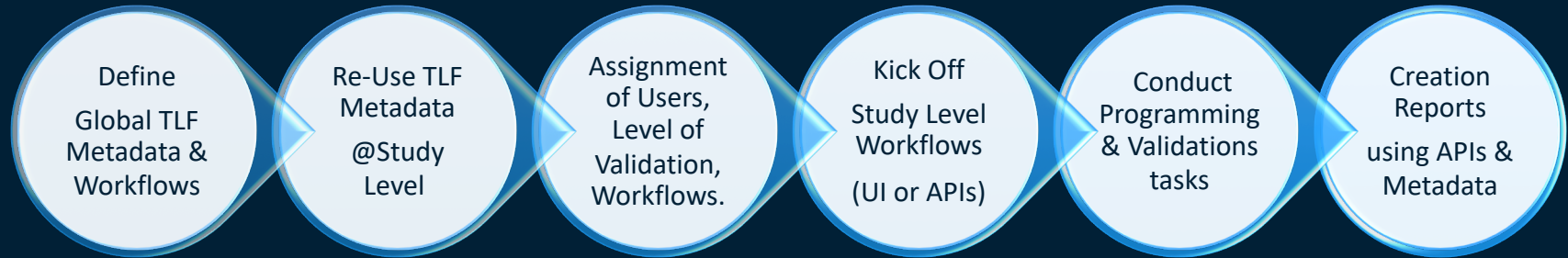
Ferring Study Dashboard



Program	Title	Current Version	Programmer	Programmer Designated	Validator	Validator Designated	Validator Designated	Validation Date	Total Versions	Status	Last Validated
ca0_cocaine.aas	Create form-submitters	1.1	an	Approve	10Sep2019 09:16:41	scas	Approve	10Sep2019 09:20:38	1	Validated	1.1
ca0_dj_adm.aas	Copy required ACRF datasets from the	1.2	an	Approve	10Sep2019 09:16:41	scas	Approve	10Sep2019 09:20:38	1	Validated	1.2
ca1_adm.aas	Address Event	1.1	an	Approve	08Sep2019 08:11:57	ajsa	Approve	08Sep2019 11:45:34	1	Validated	1.1
ca1_adm.aas	Disposition	1.1	ajsa	Approve	08Sep2019 11:19:51	an	Approve	08Sep2019 12:37:28	1	Validated	1.1
ca1_adm.aas	Pregnancy	1.1	scas	Approve	08Sep2019 11:17:29	an	Approve	08Sep2019 12:37:28	1	Validated	1.1
ca2_adm.aas	Pregnancy Loss	1.1	scas	Approve	08Sep2019 11:17:29	an	Approve	08Sep2019 12:37:28	1	Validated	1.1
ca2_adm.aas	Neonate	1.1	an	Approve	08Sep2019 08:11:57	ajsa	Approve	08Sep2019 11:45:34	1	Validated	1.1
ca2_adm.aas	Early pregnancy loss - subjects with	1.0	scas	Approve	08Sep2019 12:19:59	an	Approve	08Sep2019 13:37:00	1	Validated	1.0
ca2_adm.aas	Ongoing pregnancy - Full Analysis Set	1.0	ajsa	Approve	08Sep2019 13:34:38	an	Approve	08Sep2019 13:37:00	1	Validated	1.0
ca2_adm.aas	Neonate health at 4 weeks after birth	1.0	scas	Approve	08Sep2019 12:19:59	an	Approve	08Sep2019 13:36:59	1	Validated	1.0
ca2_adm.aas	Neonate health at 4 weeks after birth - all	1.0	an	Approve	08Sep2019 12:44:19	ajsa	Approve	08Sep2019 13:36:59	1	Validated	1.0
ca2_adm.aas	Neonate characteristics at birth - all	1.0	scas	Approve	08Sep2019 12:24:16	ajsa	Approve	08Sep2019 13:36:59	1	Validated	1.0
ca2_adm.aas	Neonate for no live birth	1.0	ajsa	Approve	08Sep2019 12:27:43	an	Approve	08Sep2019 13:37:00	1	Validated	1.0

Flow of activities

Overview



LSAF 5.3 and the TLF module

Global TLF Metadata


SAS® Life Science Analytics Framework - Tables, Listings, Figures (TLF)

General Study TLFs

Details

Tables, Listings & Figures

13 TLFs

<input type="checkbox"/>	Results	Enable Auto Flow * 	Section ↑	Type *	Identifier *	Name *	Description	program name	Title_1	Title_2	Title_3	Title_4	Title_5	Footnote_1	Footnote_2	Footnote_3	Footnote_4
<input type="checkbox"/>	0	No ▾	1 - Subject Dis...	Table ▾	1	Subject Dis...	All Randomized	SubjectDisposition.sas	Table 1.0	Subject Dis...	Number (%)			[1] Randomized	[2] ITT Subjects	[3] Modified ITT	[4] Subject 148K
<input type="checkbox"/>	0	No ▾	2 - Protocol V...	Table ▾	2	Protocol Vio	Intent-to-Treat	ProtocolViolations.sas	Table 2.0	Protocol Viol	Number (%)			Note: Only one			
<input type="checkbox"/>	0	No ▾	3 - Pill Compli...	Table ▾	3	Pill Complia	Intent-to-Treat	PillCompliance.sas	Table 3.0	Pill Compliar	Number (%)			[1] First pill sh...	[2] Second pill s		
<input type="checkbox"/>	0	No ▾	4 - Demograp...	Table ▾	4	Demographi	Intent-to-Treat	DemographicCharact...	Table 4.0	Demographi	Number (%)						
<input type="checkbox"/>	0	No ▾	5 - Clinically ...	Table ▾	5	Clinically Sig	Intent-to-Treat	PreexistingConditions	Table 5.0	Clinically Sig	Number (%)			Note: A clinical			
<input type="checkbox"/>	0	No ▾	6 - Vital Signs ...	Table ▾	6	Vital Signs s	Intent-to-Treat	VitalSignRandomization.s	Table 6.0	Vital Signs s							
<input type="checkbox"/>	0	No ▾	7 - Summary ...	Table ▾	7	Summary of	Intent-to-Treat	PriorMedications.sas	Table 7.0	Summary of	By WHO-On	Number (%)		Note: Prior Med			
<input type="checkbox"/>	0	No ▾	7 - Summary ...	Table ▾	7.1	Summary of	Intent-to-Treat	ConcomitantMedicatio...	Table 7.1	Summary of	By WHO-On			Note: Concomits			
<input type="checkbox"/>	0	No ▾	8 - Summary ...	Table ▾	8	Summary of	Intent-to-Treat	AdverseEvents.sas	Table 8.0	Summary of	By MedDRA			Note: Subjects r			
<input type="checkbox"/>	0	No ▾	8 - Summary ...	Table ▾	8.1	Summary of	Intent-to-Treat	DiscontinuationAdvers...	Table 8.1	Summary of	By MedDRA			Note: Subjects r			
<input type="checkbox"/>	0	No ▾	9 - Summary ...	Table ▾	9	Summary of	Intent-to-Treat	SeriousAdverseEvent	Table 9.0	Summary of	By MedDRA			Note: Subjects r			
<input type="checkbox"/>	0	No ▾	9 - Summary ...	Table ▾	9.1	Listing of Inc	Intent-to-Treat	SeriousAdverseEvent	Table 9.1	Listing of Inc				[1] Maximum Int	[2] Action Taken	[3] Drug Relate	[4] Outcome: Rx
<input type="checkbox"/>	0	No ▾	10 - Subject ...	Table ▾	10	Subject Rep	Intent-to-Treat	ReportedSymptoms.s	Table 10.0	Subject Rep	Number (%)			Note: Percentag			

Configurable Global TLF Metadata

Life Cycle Management Prototype



Define your Study-Level TLF Metadata (re-use from global/previous study)

All sections
Standard type: Analysis Standard model: Analysis Standard Base standard name: ADaM

11 TLFs

Results	Enable Auto Flow *	Section	Type *	Identifier *	Name *	Description	program name	Title_1	User Assignment 1	User Assignment 2	User Assignment 3	Level of Validation
<input type="checkbox"/> 2	Yes		Table	RD.Table_14-3.01	Table 14-3.01	Primary Endpoint Analysis: ADAS-Cog - Sum	Table 14-3.01	Primary Endpo	Jean-Marc Ferran (qu...	Stijn Rogiers (sbxsro)	Stijn Rogiers (sbxsro)	QC Review
<input type="checkbox"/> 1	Yes		Table	RD.Table_14-5.02	Table 14-5.02	Incidence of Treatment Emergent Serious Ad	Table 14-5.02	Incidence of Tn	Stijn Rogiers (sbxsro)	Jean-Marc Ferran (qu...	Jean-Marc Ferran (qu...	QC Review
<input type="checkbox"/> 1	Yes		Table	RD.Table_14-6.02	Table 14-6.02	Incidence of Treatment Emergent Serious Ad	Table 14-6.02	Incidence of Tn	Kevin Clark (keclar)	Adam LaManna (adia...	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.03	Table 14-6.03	Incidence of Treatment Emergent Serious Ad	Table 14-6.03	Incidence of Tn	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.04	Table 14-6.04	Incidence of Treatment Emergent Serious Ad	Table 14-6.04	Incidence of Tn	Adam LaManna (adia...	Sandeep Juneja (saju...	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.05	Table 14-6.05	Incidence of Treatment Emergent Serious Ad	Table 14-6.05	Incidence of Tn	Sandeep Juneja (saju...	Kevin Clark (keclar)	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.06	Table 14-6.06	Incidence of Treatment Emergent Serious Ad	Table 14-6.06	Incidence of Tn	Ben Bocchicchio (beb...	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.07	Table 14-6.07	Incidence of Treatment Emergent Serious Ad	Table 14-6.07	Incidence of Tn	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...	Ben Bocchicchio (beb...	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.08	Table 14-6.08	Incidence of Treatment Emergent Serious Ad	Table 14-6.08	Incidence of Tn	Adam LaManna (adia...	Sandeep Juneja (saju...	Ben Bocchicchio (beb...	Self-Verification
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.09	Table 14-6.09	Incidence of Treatment Emergent Serious Ad	Table 14-6.09	Incidence of Tn	Adam LaManna (adia...	Sandeep Juneja (saju...	Ben Bocchicchio (beb...	Self-Verification
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.10	Table 14-6.10	Secondary Endpoint Analysis: EQ5D Summa	Table 14-6.10	Secondary Enc	Jean-Marc Ferran (qu...	Stijn Rogiers (sbxsro)	Sandeep Juneja (saju...	Self-Verification

Programmer,
Validator
and Reviewer
Assignment

Life Cycle Management Prototype

Define your Study-Level TLF Metadata (re-use from global/previous study)

All sections
Standard type: Analysis Standard model: Analysis Standard Base standard name: ADaM

11 TLFs

Results	Enable Auto Flow *	Section	Type *	Identifier *	Name *	Description	program name	Title_1	User Assignment 1	User Assignment 2	User Assignment 3	Level of Validation
<input type="checkbox"/> 2	Yes		Table	RD.Table_14-3.01	Table 14-3.01	Primary Endpoint Analysis: ADAS-Cog - Sum	Table 14-3.01	Primary Endpo	Jean-Marc Ferran (qu...)	Stijn Rogiers (sbxsro)	Stijn Rogiers (sbxsro)	QC Review
<input type="checkbox"/> 1	Yes		Table	RD.Table_14-5.02	Table 14-5.02	Incidence of Treatment Emergent Serious Ad	Table 14-5.02	Incidence of Tn	Stijn Rogiers (sbxsro)	Jean-Marc Ferran (qu...)	Jean-Marc Ferran (qu...)	QC Review
<input type="checkbox"/> 1	Yes		Table	RD.Table_14-6.02	Table 14-6.02	Incidence of Treatment Emergent Serious Ad	Table 14-6.02	Incidence of Tn	Kevin Clark (keclar)	Adam LaManna (adia...)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.03	Table 14-6.03	Incidence of Treatment Emergent Serious Ad	Table 14-6.03	Incidence of Tn	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.04	Table 14-6.04	Incidence of Treatment Emergent Serious Ad	Table 14-6.04	Incidence of Tn	Adam LaManna (adia...)	Sandeep Juneja (saju...)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.05	Table 14-6.05	Incidence of Treatment Emergent Serious Ad	Table 14-6.05	Incidence of Tn	Sandeep Juneja (saju...)	Kevin Clark (keclar)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.06	Table 14-6.06	Incidence of Treatment Emergent Serious Ad	Table 14-6.06	Incidence of Tn	Ben Bocchicchio (beb...)	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.07	Table 14-6.07	Incidence of Treatment Emergent Serious Ad	Table 14-6.07	Incidence of Tn	Preetesh Parikh (prpari)	Ben Bocchicchio (beb...)	Ben Bocchicchio (beb...)	QC Review
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.08	Table 14-6.08	Incidence of Treatment Emergent Serious Ad	Table 14-6.08	Incidence of Tn	Adam LaManna (adia...)	Sandeep Juneja (saju...)	Ben Bocchicchio (beb...)	Self-Verification
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.09	Table 14-6.09	Incidence of Treatment Emergent Serious Ad	Table 14-6.09	Incidence of Tn	Adam LaManna (adia...)	Sandeep Juneja (saju...)	Ben Bocchicchio (beb...)	Self-Verification
<input type="checkbox"/> 0	Yes		Table	RD.Table_14-6.10	Table 14-6.10	Secondary Endpoint Analysis: EQ5D Summa	Table 14-6.10	Secondary Enc	Jean-Marc Ferran (qu...)	Stijn Rogiers (sbxsro)	Sandeep Juneja (saju...)	Self-Verification

Level of
Validation

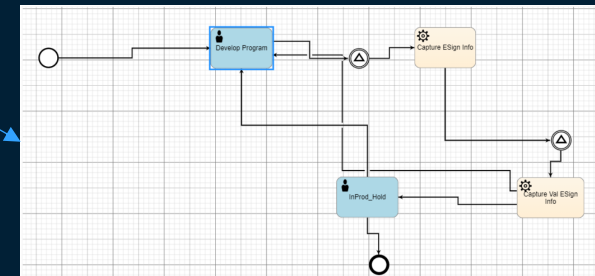
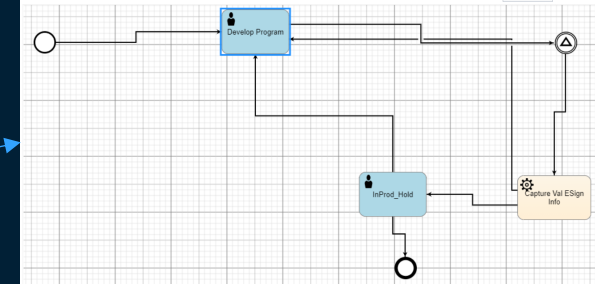
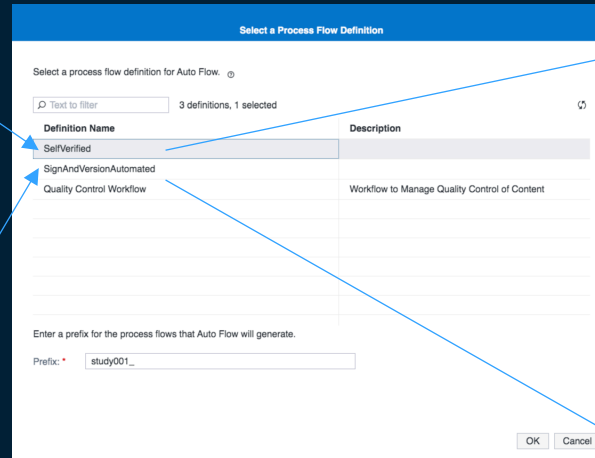
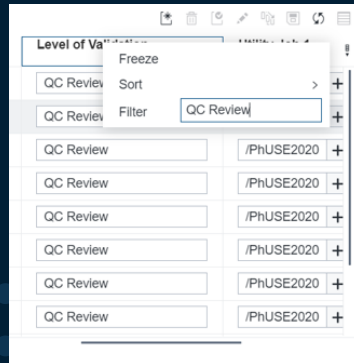
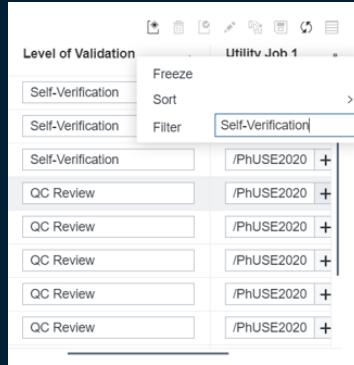
Life Cycle Management Prototype

Export TLF Metadata using APIs

```
program_complete_status_report.sas create_studymetadata.sas x +
Code Log Results Submission Inputs Submission Outputs
20
21 %lsaf_getstudyid(LSAF_PATH=&lsafstudy);
22 %put &_lsafStudyId_;
23
24 %lsaf_getstudystandards(
25   lsaf_studyid=%str(&_lsafStudyId_),
26   sas_dsname=work.lsafgetstudystandards
27 );
28
29 data _null_;
30   set work.lsafgetstudystandards end=end;
31   call symputx('modelid' || strip(put(_n_,8.)), modelid);
32   call symputx('standardname' || strip(put(_n_,8.)), name);
33   call symputx('basestandardname' || strip(put(_n_,8.)), basestandardname);
34   call symputx('basestandardversion' || strip(put(_n_,8.)), basestandardversion);
35   if end then call symputx('nstandards', _n_);
36 run;
37
38 %macro export_metadata(location);
39
40   %local i base_std;
41
42   %do i = 1 %to &nstandards;
43
44     %put &i &&modelid&i &&basestandardname&i &&standardname&i &&basestandardversion&i;
45
46     %let base_std = %lowcase(&&basestandardname&i);
47
48     %lsaf_exportstudydetails(
49       lsaf_studyid=%str(&_lsafStudyId_),
50       lsaf_location=&location,
51       lsaf_path=%str(&lsafstudy/Dev/metadata/&base_std/studydetails),
52       lsaf_overwrite=1
53     );
54
55
56     %if &location=WORKSPACE %then %do;
57       %lsaf_exportstudytablestows(
58         lsaf_studyid=%str(&_lsafStudyId_),
59         lsaf_basestandardname=&&basestandardname&i,
60         lsaf_modelid=%str(&&modelid&i))
```

Life Cycle Management Prototype

Create Workflows for each Output using AutoFlow (or API) functionality



Development of workflows done in Eclipse
(bpmn standard is required)

Life Cycle Management Prototype

Create Workflows for each Output using AutoFlow (or API) functionality

SAS® Life Science Analytics Framework - Process Flows

Text to filter 11 process flows

QUERY PARAMETERS					Status	Name	Context	Creation Method	Process Flow Definition	Owner	Modified By	Date Modified
Status:	(any status)					study001_Table 14-3.01	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
Name:						study001_Table 14-5.02	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
Context:	/PhUSE2020/Drug001/IND001/Study001					study001_Table 14-6.02	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
Process flow definition:						study001_Table 14-6.03	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
Creation method:	(any method)					study001_Table 14-6.04	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
Owner:	(any user)					study001_Table 14-6.05	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Jean-Marc Ferran	Jean-Marc Ferran	Sep 14, 2020, 10:00 P...
						study001_Table 14-6.06	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
						study001_Table 14-6.07	/PhUSE2020/Drug001/I...	TLF Auto Flow	SignAndVersionAutoma...	Ben Bocchicchio	Ben Bocchicchio	Sep 8, 2020, 3:47 PM ...
						study001_Table 14-6.08	/PhUSE2020/Drug001/I...	TLF Auto Flow	SelfVerified	Jean-Marc Ferran	Jean-Marc Ferran	Sep 14, 2020, 9:59 PM ...
						study001_Table 14-6.09	/PhUSE2020/Drug001/I...	TLF Auto Flow	SelfVerified	Jean-Marc Ferran	Jean-Marc Ferran	Sep 14, 2020, 9:27 PM ...
						study001_Table 14-6.10	/PhUSE2020/Drug001/I...	TLF Auto Flow	SelfVerified	Jean-Marc Ferran	Jean-Marc Ferran	Sep 14, 2020, 9:59 PM ...

Different Workflow
for each
Level of Validation

Life Cycle Management Prototype

Automated actions triggered from e-Signature using Jobs within Workflow

SAS Life Science Analytics Framework - Process Flows

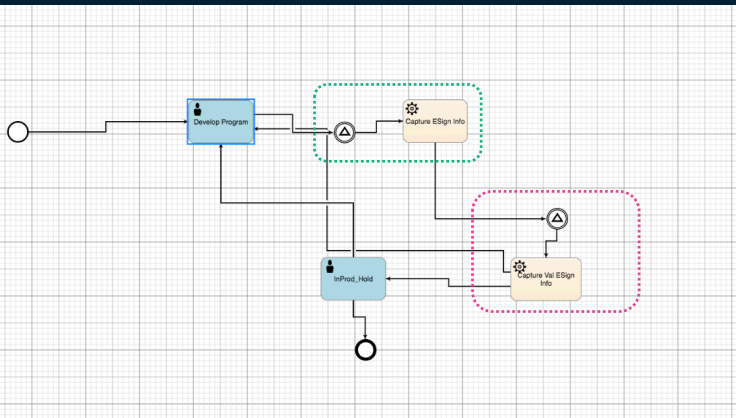
study001__Table 14-3.01

Details
Flow Setup
Process Data
Current
Completed
Attachments

List Diagram

Text to filter 6 items, 1 selected

ID	Name	Type	Details	Due Date	Priority	Complexity
A_Develop_Program	Develop Program	User	Jean-Marc Ferran		Medium	Medium
B_1_ESign_File	ESign File	Intermediate Event-Signal	/PHUSE2020/Drug001/IND001/Study001/Dev/programs/Tab			
B_2_RunJob	Capture ESign Info	System Job Wait	read_pl_metadata_init_prj.job			
D_1_Val_ESign	SignalCatchEvent	Intermediate Event-Signal	/PHUSE2020/Drug001/IND001/Study001/Dev/programs/Tab			
D_2_Val_RunJob	Capture Val ESign Info	System Job Wait	read_pl_metadata_qc_prj.job			
E_Hold	InProd_Hold	User	Stijn Rogiers		Medium	Medium



SAS Life Science Analytics Framework - Repository

/PHUSE2020/Drug001/IND001/Study001/Prod/programs

Text to filter 6 items

Type	Name	Size	Modified By	Date Modified	Signed
Table	Table_14-3.01.sas	639 bytes	Ben Bocchiechio	Aug 27, 2020, 9:54 PM GMT+02:00	✓
Table	Table_14-3.01.sas	2.02 KB	Ben Bocchiechio	Aug 27, 2020, 9:54 PM GMT+02:00	✓
Table	Table_14-3.01.sas	639 bytes	Ben Bocchiechio	Sep 3, 2020, 11:19 PM GMT+02:00	✓
Table	Table_14-3.01.sas	2.02 KB	Ben Bocchiechio	Sep 3, 2020, 11:19 PM GMT+02:00	✓
Table	Table_14-3.01.sas	639 bytes	Ben Bocchiechio	Sep 8, 2020, 3:29 PM GMT+02:00	✓
Table	Table_14-3.01.sas	2.02 KB	Ben Bocchiechio	Sep 8, 2020, 3:29 PM GMT+02:00	✓

Properties Permissions

Name: Table 14-3.01.sas

Description: ProdReady

Content type: application/x-sas

Type: SAS Program

Size: 2.02 KB

Version: -

Created by: Ben Bocchiechio

Programs are automatically moved from Dev to Prod and Description (status) is updated

Life Cycle Management Prototype

Workflow documents reason for changes after validation

SAS® Life Science Analytics Framework - Process Flows

study001__Table 14-6.09

Details
Flow Setup
Process Data
Current
Completed
Attachments

Text to filter 1 item, 1 selected

Status	ID	Name	Type	Assignee	Due Date	Priority	Complexity
<input checked="" type="checkbox"/>	E_Hold	InProd_Hold	User	Jean-Marc Ferran		Medium	Medium

Complete Task

ID: E_Hold

Name: InProd_Hold

Comment:

Actual hours: 0

Completion Data

Choose2: * ReDefine Specific... (none) End ReDefine Specifications

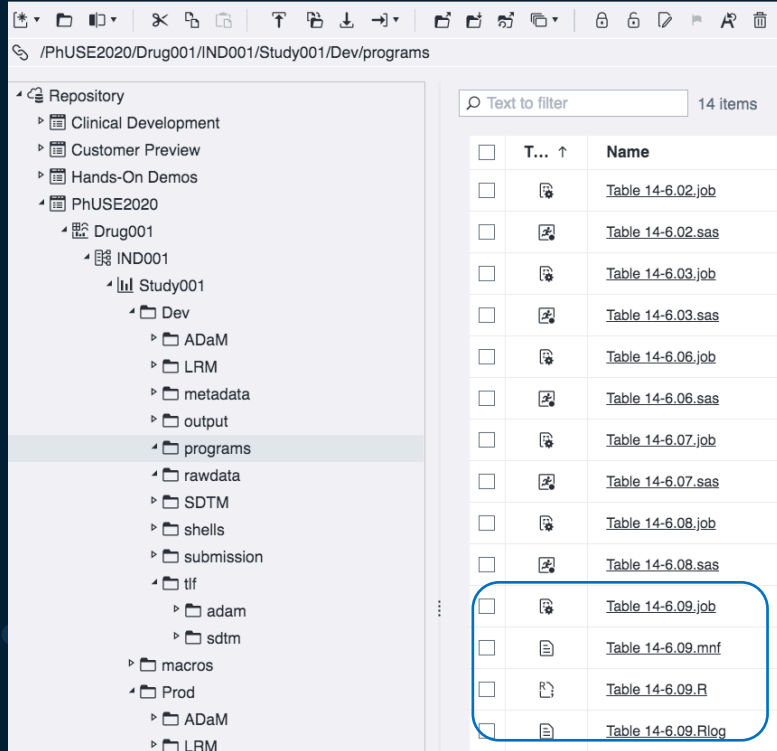
Complete **Cancel**

R programs and jobs can be integrated and follow same Life-Cycle Management

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Life Cycle Management Prototype















R programs and jobs can be integrated and follow same Life-Cycle Management

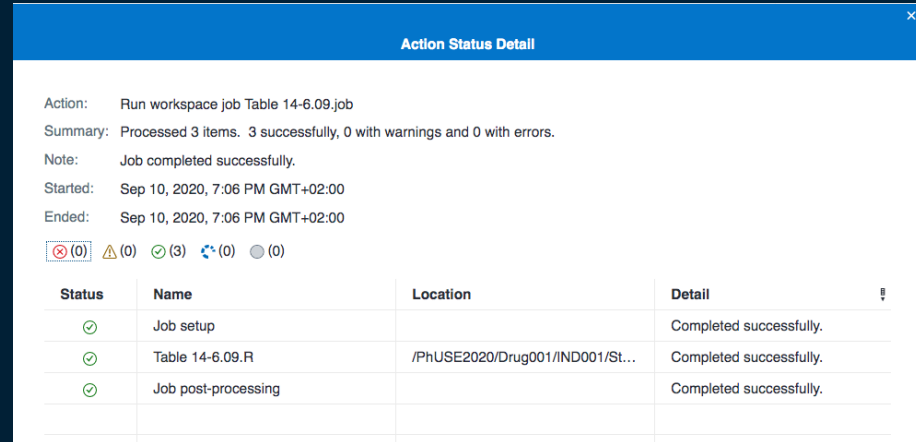


Repository

- Clinical Development
- Customer Preview
- Hands-On Demos
- PhUSE2020
 - Drug001
 - IND001
 - Study001
 - Dev
 - ADaM
 - LRM
 - metadata
 - output
 - programs
 - rawdata
 - SDTM
 - shells
 - submission
 - ttf
 - adam
 - sdtm
 - macros
 - Prod
 - ADaM
 - LRM

Text to filter 14 items

	T... ↑	Name
<input type="checkbox"/>		Table 14-6.02.job
<input type="checkbox"/>		Table 14-6.02.sas
<input type="checkbox"/>		Table 14-6.03.job
<input type="checkbox"/>		Table 14-6.03.sas
<input type="checkbox"/>		Table 14-6.06.job
<input type="checkbox"/>		Table 14-6.06.sas
<input type="checkbox"/>		Table 14-6.07.job
<input type="checkbox"/>		Table 14-6.07.sas
<input type="checkbox"/>		Table 14-6.08.job
<input type="checkbox"/>		Table 14-6.08.sas
<input type="checkbox"/>		Table 14-6.09.job
<input type="checkbox"/>		Table 14-6.09.mnf
<input type="checkbox"/>		Table 14-6.09.R
<input type="checkbox"/>		Table 14-6.09.Rlog



Action Status Detail






Action: Run workspace job Table 14-6.09.job




Summary: Processed 3 items. 3 successfully, 0 with warnings and 0 with errors.

Note: Job completed successfully.

Started: Sep 10, 2020, 7:06 PM GMT+02:00

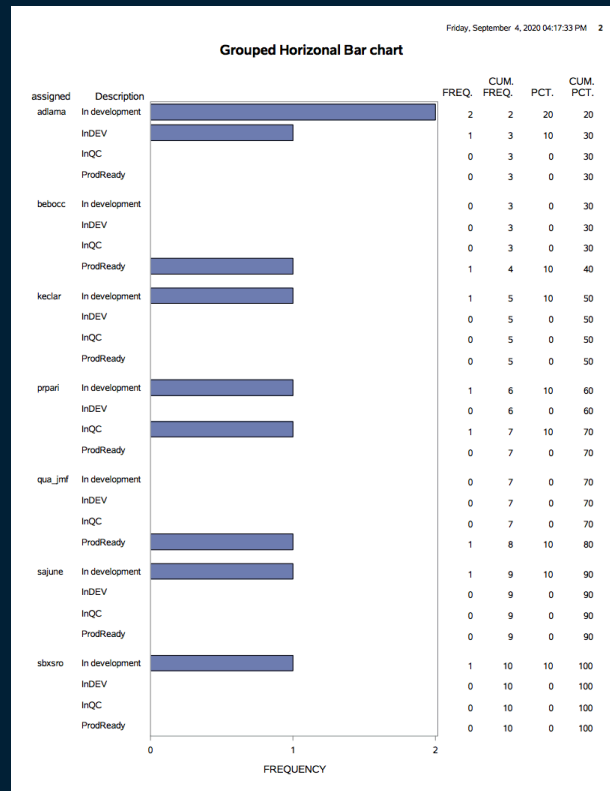
Ended: Sep 10, 2020, 7:06 PM GMT+02:00

 (0)  (0)  (3)  (0)  (0)

Status	Name	Location	Detail
	Job setup		Completed successfully.
	Table 14-6.09.R	/PhUSE2020/Drug001/IND001/St...	Completed successfully.
	Job post-processing		Completed successfully.

Life Cycle Management Prototype

Reporting using the APIs



Life Cycle Management Prototype

Reporting using the APIs (Example code)

```
program_complete_status_report.sas x +
[Icons]
Code Log Results Submission Inputs Submission Outputs
1 libname rpt_data "&_sasws_/PhUSE2020/Drug001/IND001/Study001/Dev/metadata/adam/";
2
3 %let loop =0;
4
5 data temp(keep=name assigned);
6   set rpt_data.adam_tlf nobobs=nobs;
7   r_loc = tranwrd(job, 'sdd://', '');
8   r_loc2 = tranwrd(r_loc, '%', ' ');
9   name = strip(program_name) || ".sas";
10  assigned = tranwrd(user_assignment_1, "User::", '');
11 run;
12
13
14 %lsaf_getchildren( lsaf_path=PhUSE2020/Drug001/IND001/Study001/Dev/programs, sas_dsname=work.lsafGetChildrenD, lsaf_recursive=1 );
15
16 data prg_d(keep= name version description lastmodifiedby);
17   set work.lsafGetChildrenD;
18   where strip(itemType) = "sas:sasprogram" and iscontainer ne 1;
19   location = 'DEV';
20 run;
21
22 %lsaf_getchildren( lsaf_path=PhUSE2020/Drug001/IND001/Study001/Prod/programs, sas_dsname=work.lsafGetChildrenP, lsaf_recursive=1 );
23
```

Conclusion



Manage TFLs Development in Life Science Analytics Framework 5.3
using SAS and R code

Conclusions



Manage TFLs Development in Life Science Analytics Framework 5.3 using SAS and R code

- TLF module can be used for planning purpose AND to capture outputs metadata.
 - ✓ TLF module can be configured
 - ✓ Export output metadata to a SAS dataset (using API or UI) to support the reporting of each TLF

Conclusions



Manage TFLs Development in Life Science Analytics Framework 5.3 using SAS and R code

- TLF module can be used for planning purpose AND to capture outputs metadata.
- **It is possible to manage outputs supported by both SAS and R code**
 - ✓ Integrated within SAS Life Science Analytics Framework; no need to work outside system for dev. nor execution
 - ✓ Traceability and Reproducibility for both SAS and R programs

Conclusions



Manage TFLs Development in Life Science Analytics Framework 5.3 using SAS and R code


- TLF module can be used for planning purpose AND to capture outputs metadata.
- It is possible to manage outputs supported by both SAS and R code
- **Setting up of Workflows can be automated using APIs and tailored to each company's internal process**
 - ✓ Workflow can be triggered on eSign activities & trigger next steps accordingly (e.g. move from DEV to PROD area)
 - ✓ It is possible to document after the validation state is reached any reason for change (e.g. change of specs)






Note: It is not possible to write back into the TFL module. Custom reporting is still required. Work in progress.

Documentation for your reference

LSAF APIs



SUPPORT



SUPPORT / SAMPLES & SAS NOTES

SUPPORT

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Usage Note 65943: SAS® Life Science Analytics Framework Macro API 2.3 - Release Notes

Details Downloads About **Rate it**

The SAS® Life Science Analytics Framework Macro API 2.3 is available for use with SAS® Life Science Analytics Framework Java API 2.3.

The table below summarizes the enhancements for this release.

For a detailed list of added and modified macros, see the SAS® Life Science Analytics Framework Macros 2.3 Changes Spreadsheet located on the Downloads tab of this SAS Note.

Functional Area	Description
	Updated all macros that produce a data set to set the default data set name if the user sets the parameter to blank.
AuditService	New service with macro to support audit history query functionality.
AuthenticationService	Created new service for existing macros that support connection to an LSAF session. Macros now associated with this service: <ul style="list-style-type: none">lsaf_loginlsaf_logout
GlobalPrivilegeService	Macros added: <ul style="list-style-type: none">lsaf_getuserswithglobalprivilege
JobService	Macros added: <ul style="list-style-type: none">lsaf_getjobrunasownerlsaf_setjobrunasowner
JobSubmissionService	Macros added: <ul style="list-style-type: none">lsaf_getjobmanifestinfolsaf_getjobmanifestinputs

<https://support.sas.com/kb/65/943.html>

<https://support.sas.com/kb/57/862.html>



*Thank you for your
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Ben Bocchicchio,
Sandeep Juneja,
Bill Gibson.*

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Any Questions ?

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