# 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

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# 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

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# The Business Case

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## 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)

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## 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

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## 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 | Progam 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 in LSAF |
| 9 | Programming Plan approver is diffrent from actual in LSAF |
| 10 | Program not listed in Programming Plan |
| 11 | Unknown issue |

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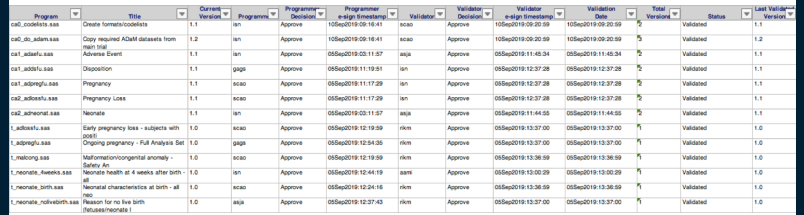
## Ferring Study Dashboard



| Program | Title | Current Version | Programmer | Programmer Decision | Programmer e-sign timestamp | Validator | Validator Decision | Validator e-sign timestamp | Validation Date | Total Versions | Status | Last Validated Version |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ca0_codelists.sas | Create formats/codelists | 1.1 | isn | Approve | 10Sep2019:09:16:41 | scao | Approve | 10Sep2019:09:20:59 | 10Sep2019:09:20:59 | 2 | Validated | 1.1 |
| ca0_do_adam.sas | Copy required ADaM datasets from main trial | 1.2 | isn | Approve | 10Sep2019:09:16:41 | scao | Approve | 10Sep2019:09:20:59 | 10Sep2019:09:20:59 | 2 | Validated | 1.2 |
| ca1_adaefu.sas | Adverse Event | 1.1 | isn | Approve | 05Sep2019:03:11:57 | asja | Approve | 05Sep2019:11:45:34 | 05Sep2019:11:45:34 | 2 | Validated | 1.1 |
| ca1_addsfu.sas | Disposition | 1.1 | gags | Approve | 05Sep2019:11:19:51 | isn | Approve | 05Sep2019:12:37:28 | 05Sep2019:12:37:28 | 2 | Validated | 1.1 |
| ca1_adpregfu.sas | Pregnancy | 1.1 | scao | Approve | 05Sep2019:11:17:29 | isn | Approve | 05Sep2019:12:37:28 | 05Sep2019:12:37:28 | 2 | Validated | 1.1 |
| ca2_adlossfu.sas | Pregnancy Loss | 1.1 | scao | Approve | 05Sep2019:11:17:29 | isn | Approve | 05Sep2019:12:37:28 | 05Sep2019:12:37:28 | 2 | Validated | 1.1 |
| ca2_adneonat.sas | Neonate | 1.1 | isn | Approve | 05Sep2019:03:11:57 | asja | Approve | 05Sep2019:11:44:55 | 05Sep2019:11:44:55 | 2 | Validated | 1.1 |
| t_adlossfu.sas | Early pregnancy loss - subjects with poi#1 | 1.0 | scao | Approve | 05Sep2019:12:19:59 | rkm | Approve | 05Sep2019:13:37:00 | 05Sep2019:13:37:00 | 1 | Validated | 1.0 |
| t_adpregfu.sas | Ongoing pregnancy - Full Analysis Set | 1.0 | gags | Approve | 05Sep2019:12:54:35 | rkm | Approve | 05Sep2019:13:37:00 | 05Sep2019:13:37:00 | 1 | Validated | 1.0 |
| t_malcong.sas | Malformation/congenital anomaly - Safety An | 1.0 | scao | Approve | 05Sep2019:12:19:59 | rkm | Approve | 05Sep2019:13:36:59 | 05Sep2019:13:36:59 | 1 | Validated | 1.0 |
| t_neonate_4weeks.sas | Neonate health at 4 weeks after birth - all | 1.0 | isn | Approve | 05Sep2019:12:44:19 | aami | Approve | 05Sep2019:13:00:29 | 05Sep2019:13:00:29 | 1 | Validated | 1.0 |
| t_neonate_birth.sas | Neonatal characteristics at birth - all neo | 1.0 | scao | Approve | 05Sep2019:12:24:16 | rkm | Approve | 05Sep2019:13:36:59 | 05Sep2019:13:36:59 | 1 | Validated | 1.0 |
| t_neonate_nolivebirth.sas | Reason for no live birth (fetuses/neonate l | 1.0 | asja | Approve | 05Sep2019:12:37:43 | rkm | Approve | 05Sep2019:13:37:00 | 05Sep2019:13:37:00 | 1 | Validated | 1.0 |



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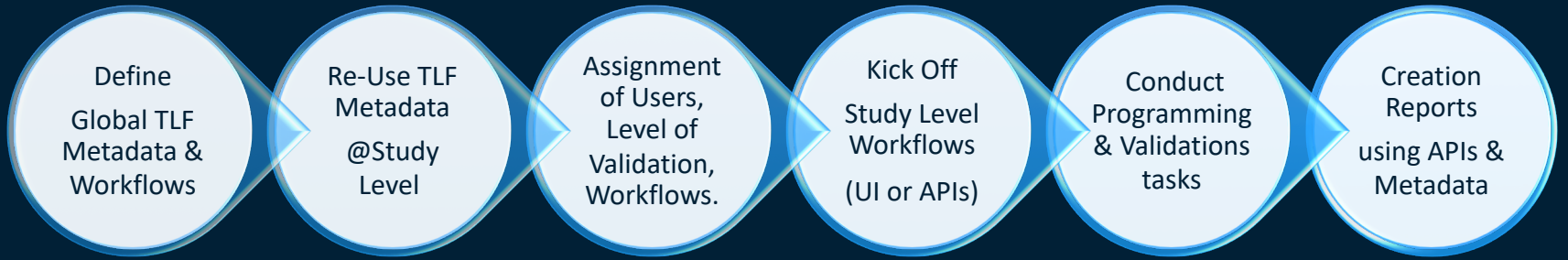
# Flow of activities

## Overview

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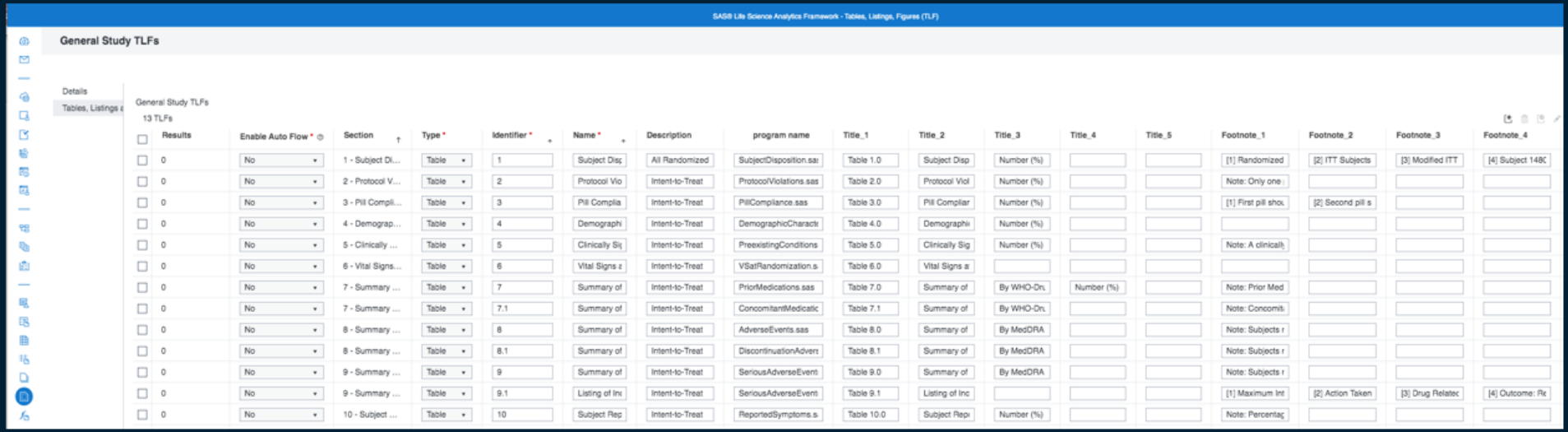
# LSAF 5.3 and the TLF module

## Global TLF Metadata




Configurable Global TLF Metadata

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# Life Cycle Management Prototype

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## 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2 | Yes | | Table | RD.Table_14-3.0 | Table 14-3.01 | Primary Endpoint Analysis: ADAS-Cog - Sumi | Table 14-3.01 | Primary Endpo | Jean-Marc Ferran (qu… | Stijn Rogiers (sbxsro) | Stijn Rogiers (sbxsro) | QC Review |
| 1 | Yes | | Table | RD.Table_14-5.02 | Table 14-5.02 | Incidence of Treatment Emergent Serious Adv | Table 14-5.02 | Incidence of Tr | Stijn Rogiers (sbxsro) | Jean-Marc Ferran (qu… | Jean-Marc Ferran (qu… | QC Review |
| 1 | Yes | | Table | RD.Table_14-6.02 | Table 14-6.02 | Incidence of Treatment Emergent Serious Adv | Table 14-6.02 | Incidence of Tr | Kevin Clark (keclar) | Adam LaManna (adla… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.03 | Table 14-6.03 | Incidence of Treatment Emergent Serious Adv | Table 14-6.03 | Incidence of Tr | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.04 | Table 14-6.04 | Incidence of Treatment Emergent Serious Adv | Table 14-6.04 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.05 | Table 14-6.05 | Incidence of Treatment Emergent Serious Adv | Table 14-6.05 | Incidence of Tr | Sandeep Juneja (saju… | Kevin Clark (keclar) | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.06 | Table 14-6.06 | Incidence of Treatment Emergent Serious Adv | Table 14-6.06 | Incidence of Tr | Ben Bocchicchio (beb… | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.07 | Table 14-6.07 | Incidence of Treatment Emergent Serious Adv | Table 14-6.07 | Incidence of Tr | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.08 | Table 14-6.08 | Incidence of Treatment Emergent Serious Adv | Table 14-6.08 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | Self-Verification |
| 0 | Yes | | Table | RD.Table_14-6.09 | Table 14-6.09 | Incidence of Treatment Emergent Serious Adv | Table 14-6.09 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | Self-Verification |
| 0 | Yes | | Table | RD.Table_14-6.10 | Table 14-6.10 | Secondary Endpoint Analysis: EQ5D Summar | Table 14-6.10 | Secondary Enc | Jean-Marc Ferran (qu… | Stijn Rogiers (sbxsro) | Sandeep Juneja (saju… | Self-Verification |

Programmer,
Validator
and Reviewer
Assignment

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# 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 2 | Yes | | Table | RD.Table_14-3.0 | Table 14-3.01 | Primary Endpoint Analysis: ADAS-Cog - Sumi | Table 14-3.01 | Primary Endpo | Jean-Marc Ferran (qu… | Stijn Rogiers (sbxsro) | Stijn Rogiers (sbxsro) | QC Review |
| 1 | Yes | | Table | RD.Table_14-5.02 | Table 14-5.02 | Incidence of Treatment Emergent Serious Adv | Table 14-5.02 | Incidence of Tr | Stijn Rogiers (sbxsro) | Jean-Marc Ferran (qu… | Jean-Marc Ferran (qu… | QC Review |
| 1 | Yes | | Table | RD.Table_14-6.02 | Table 14-6.02 | Incidence of Treatment Emergent Serious Adv | Table 14-6.02 | Incidence of Tr | Kevin Clark (keclar) | Adam LaManna (adla… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.03 | Table 14-6.03 | Incidence of Treatment Emergent Serious Adv | Table 14-6.03 | Incidence of Tr | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.04 | Table 14-6.04 | Incidence of Treatment Emergent Serious Adv | Table 14-6.04 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.05 | Table 14-6.05 | Incidence of Treatment Emergent Serious Adv | Table 14-6.05 | Incidence of Tr | Sandeep Juneja (saju… | Kevin Clark (keclar) | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.06 | Table 14-6.06 | Incidence of Treatment Emergent Serious Adv | Table 14-6.06 | Incidence of Tr | Ben Bocchicchio (beb… | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.07 | Table 14-6.07 | Incidence of Treatment Emergent Serious Adv | Table 14-6.07 | Incidence of Tr | Preetesh Parikh (prpari) | Ben Bocchicchio (beb… | Ben Bocchicchio (beb… | QC Review |
| 0 | Yes | | Table | RD.Table_14-6.08 | Table 14-6.08 | Incidence of Treatment Emergent Serious Adv | Table 14-6.08 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | Self-Verification |
| 0 | Yes | | Table | RD.Table_14-6.09 | Table 14-6.09 | Incidence of Treatment Emergent Serious Adv | Table 14-6.09 | Incidence of Tr | Adam LaManna (adla… | Sandeep Juneja (saju… | Ben Bocchicchio (beb… | Self-Verification |
| 0 | Yes | | Table | RD.Table_14-6.10 | Table 14-6.10 | Secondary Endpoint Analysis: EQ5D Summai | Table 14-6.10 | Secondary Enc | Jean-Marc Ferran (qu… | Stijn Rogiers (sbxsro) | Sandeep Juneja (saju… | Self-Verification |

Level of Validation

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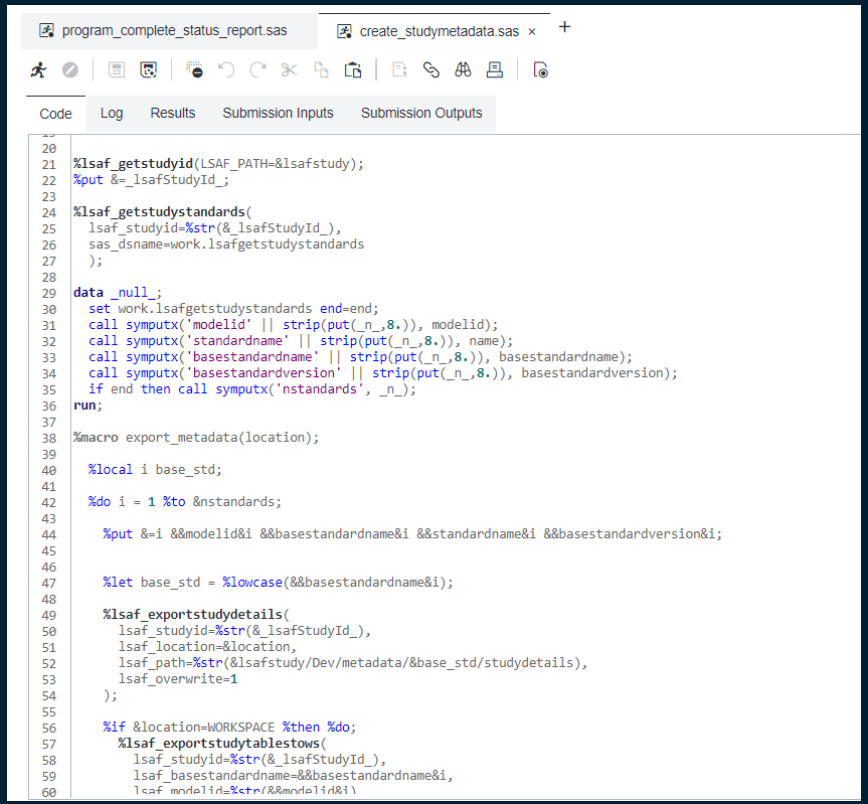
# Life Cycle Management Prototype

## Export TLF Metadata using APIs

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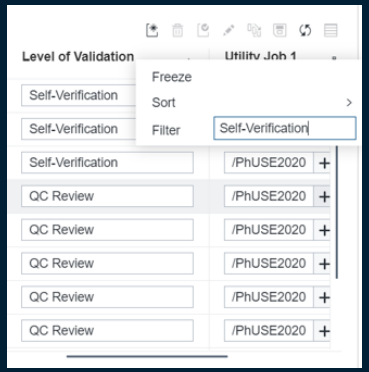
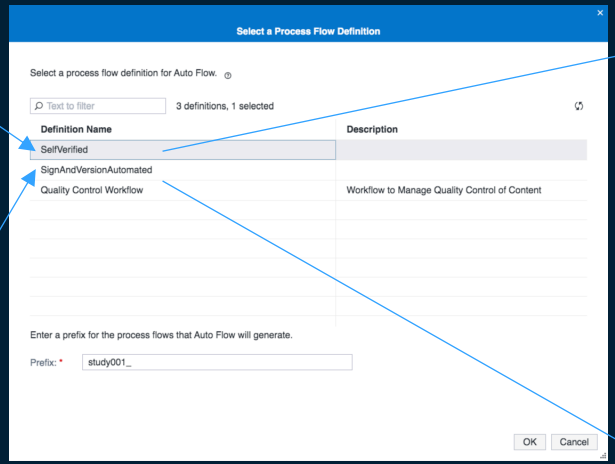
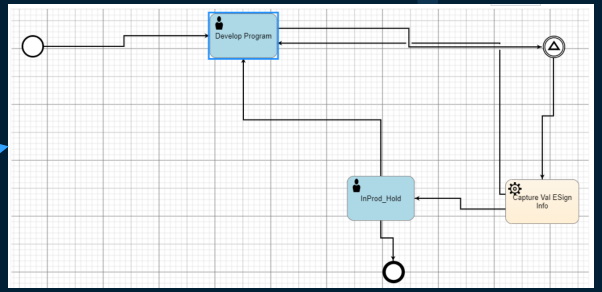
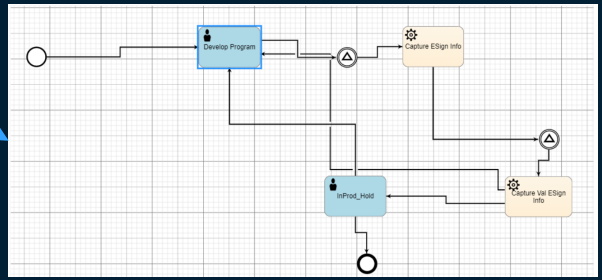
# Life Cycle Management Prototype

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






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

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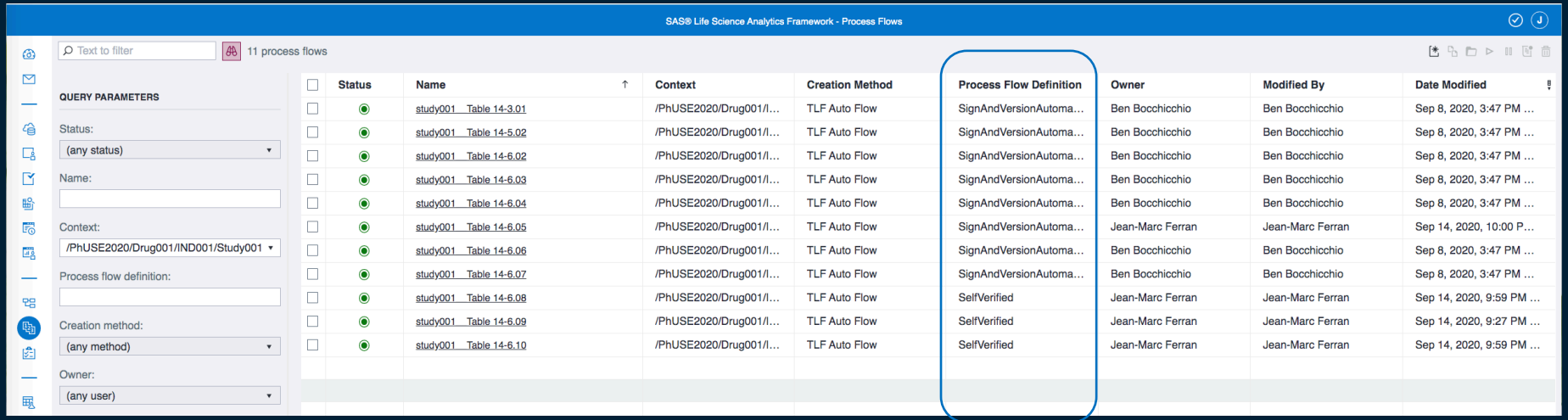
# Life Cycle Management Prototype

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




Different Workflow
for each
Level of Validation

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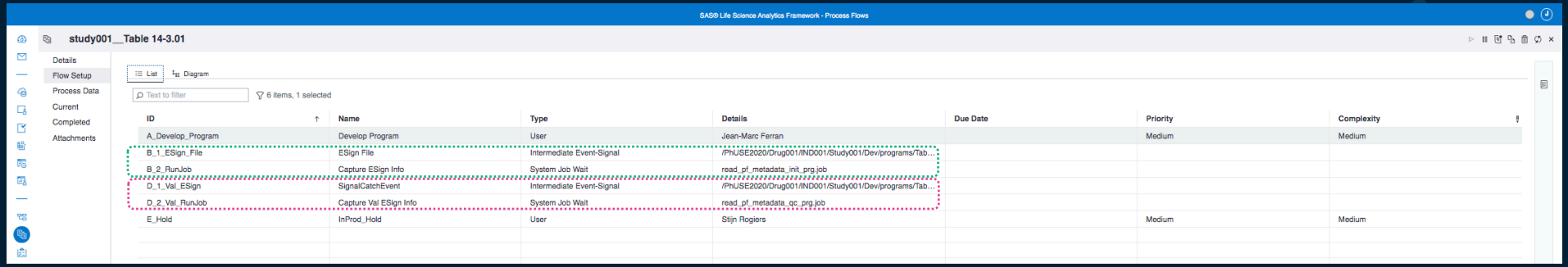
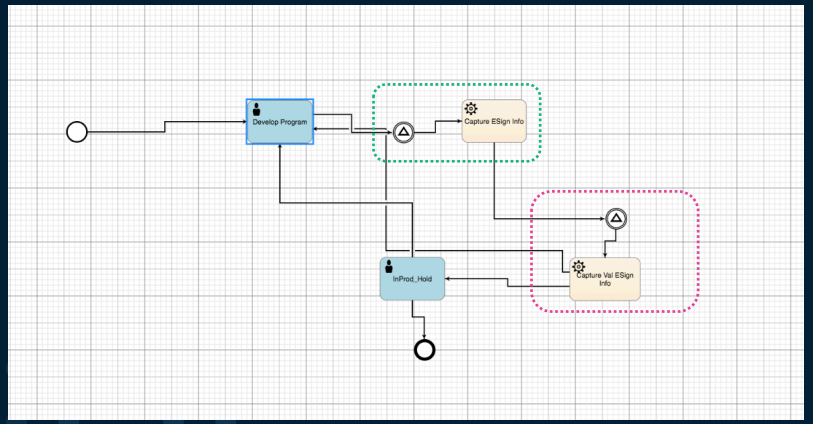
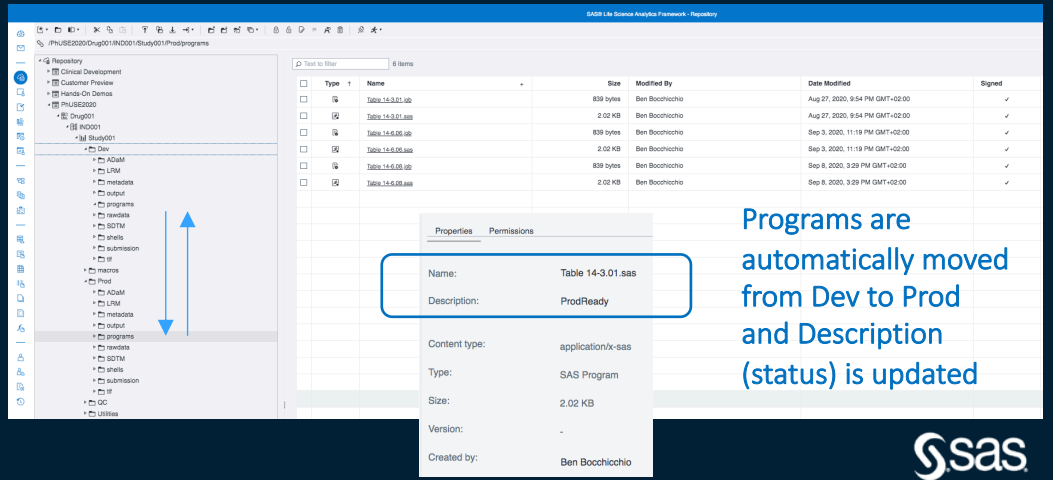
# Life Cycle Management Prototype

## Automated actions triggered from e-Signature using Jobs within Workflow




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

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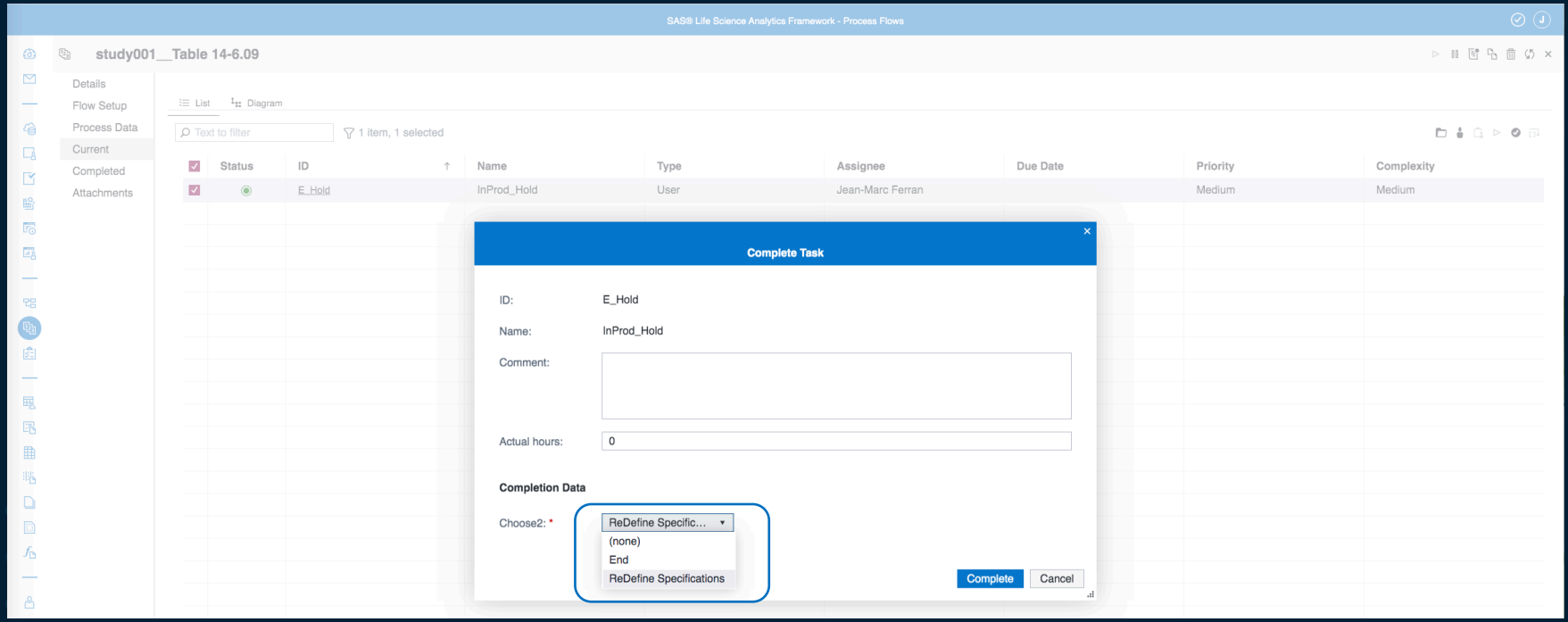
# Life Cycle Management Prototype

## Workflow documents reason for changes after validation

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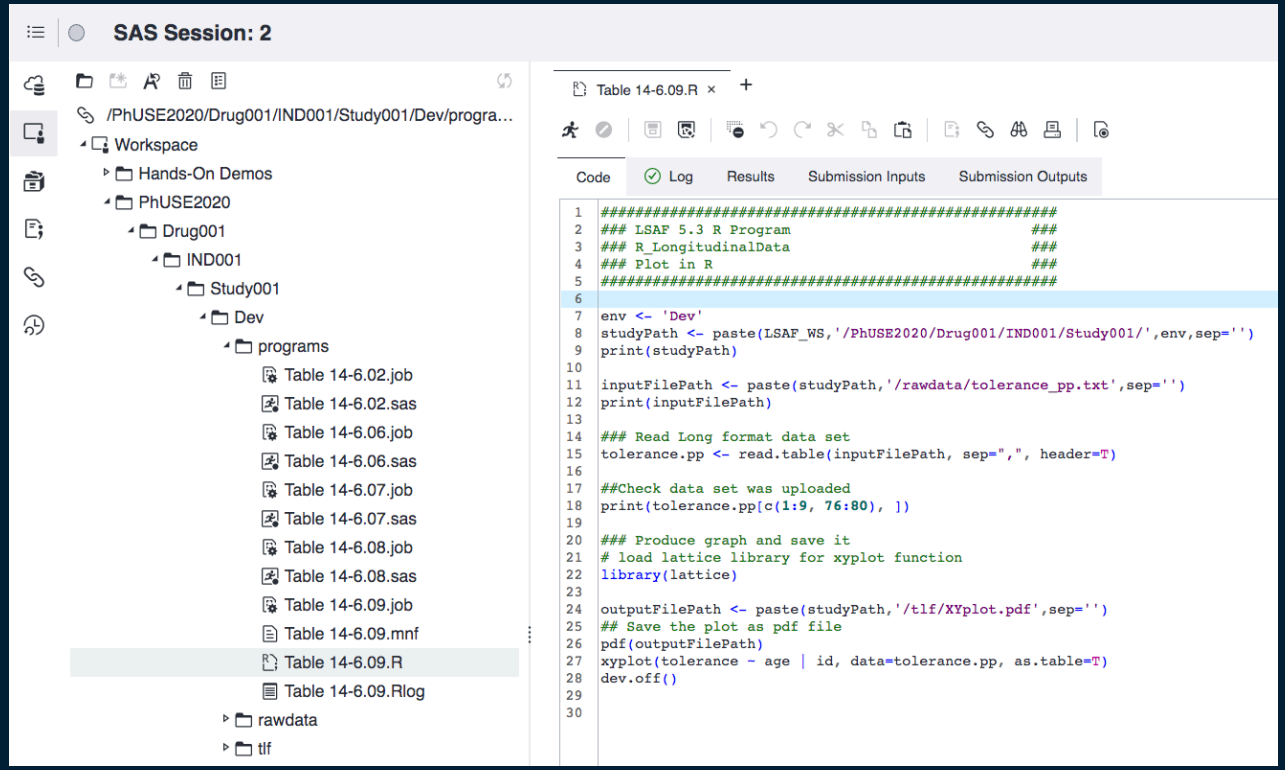
# Life Cycle Management Prototype

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

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# Life Cycle Management Prototype

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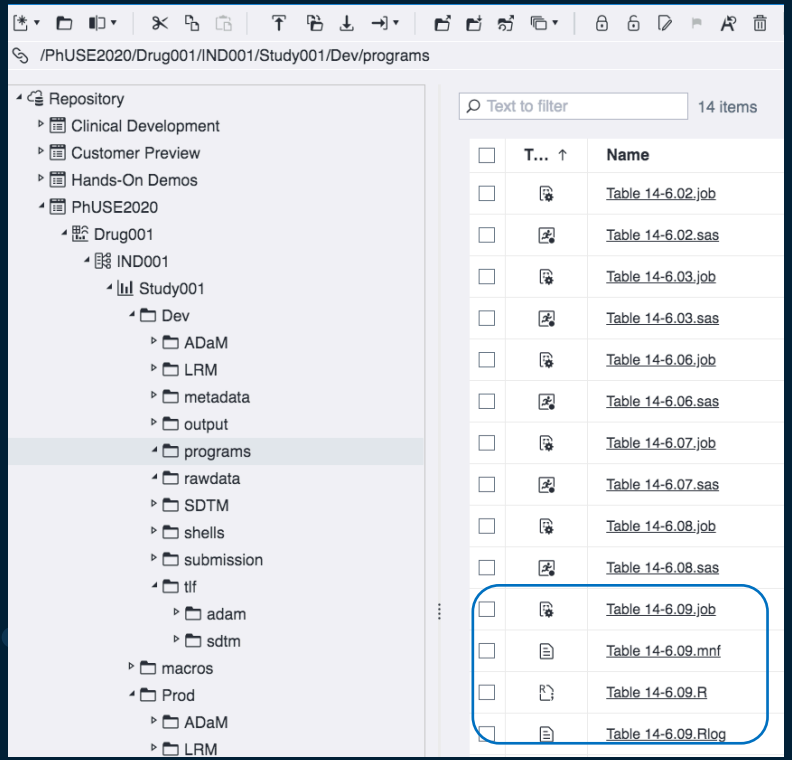
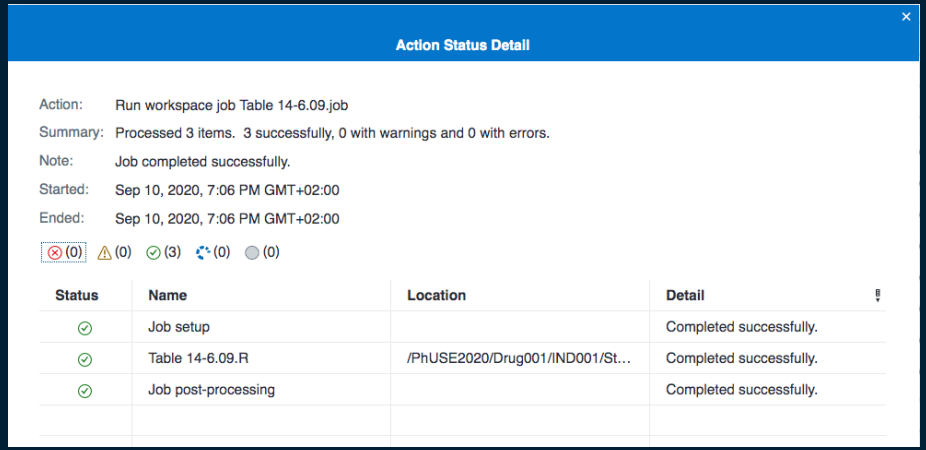
R programs and jobs can be integrated and follow same Life-Cycle Management

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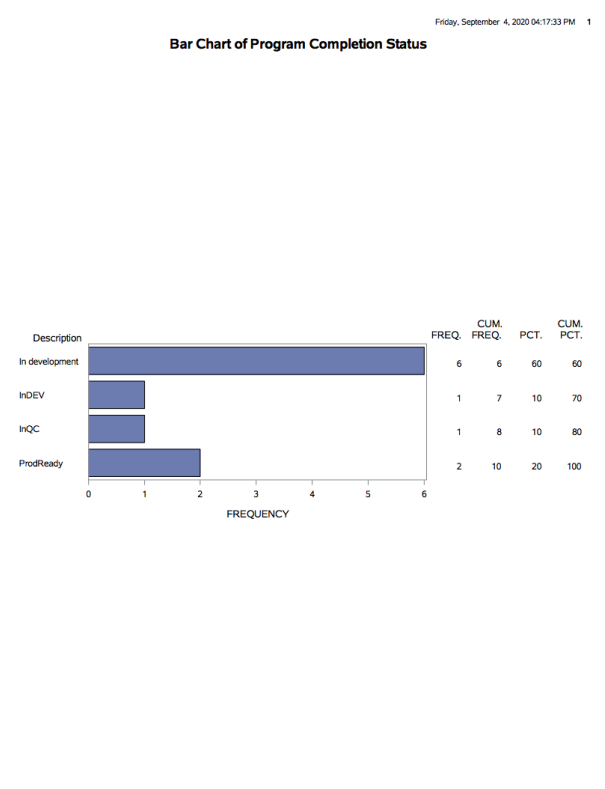
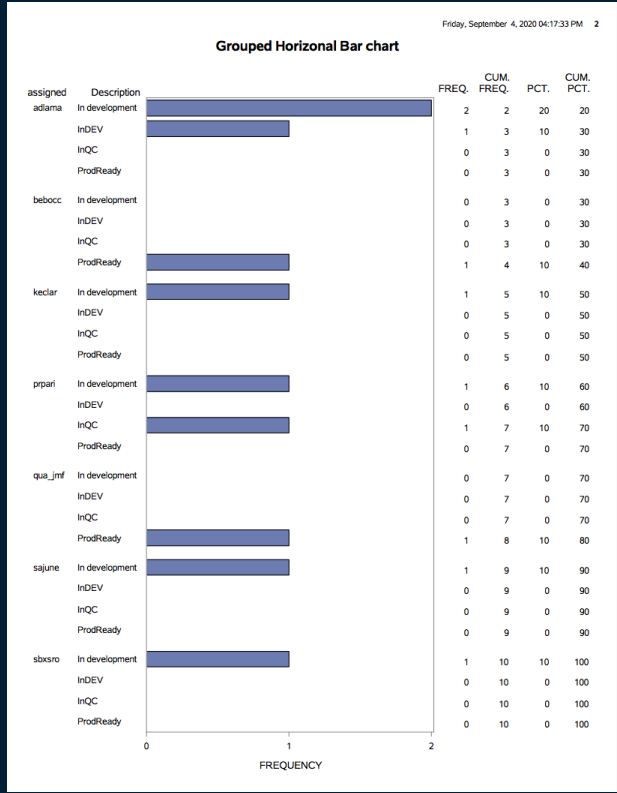
# Life Cycle Management Prototype

## Reporting using the APIs

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# Life Cycle Management Prototype

## Reporting using the APIs (Example code)

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program_complete_status_report.sas ×

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 nobs=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
```

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# Conclusion

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

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# Conclusions

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## 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

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# 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 Reproducability for both SAS and R programs

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# Conclusions

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## 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.*

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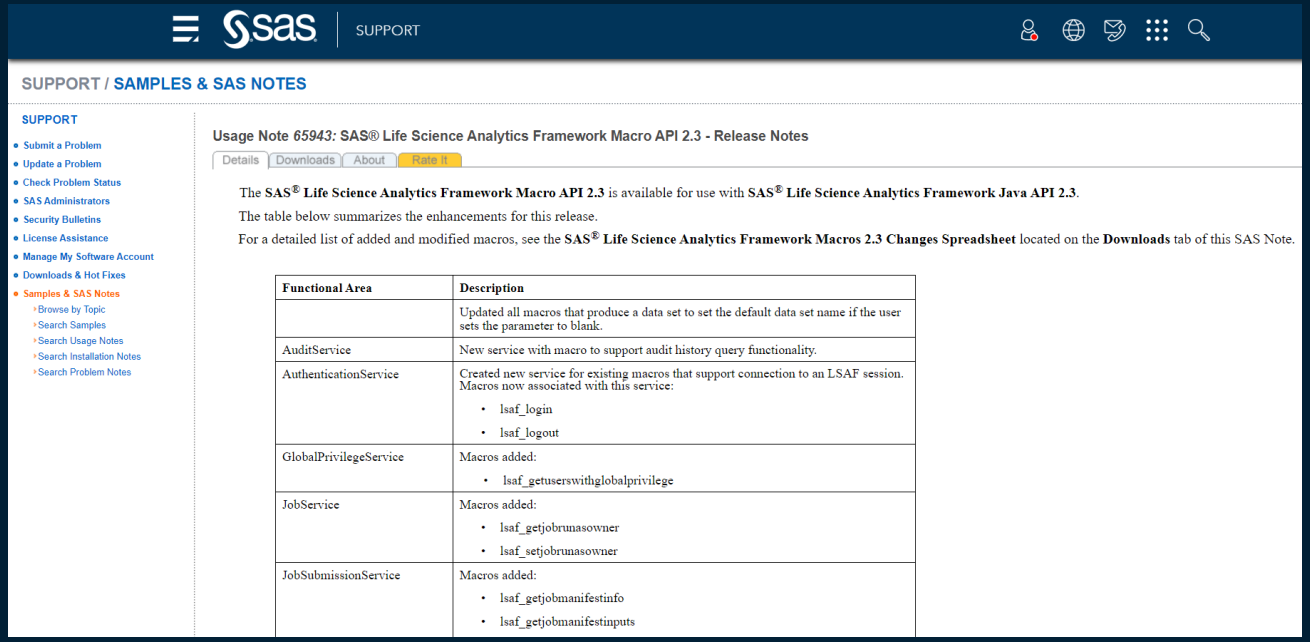
# Documentation for your reference

## LSAF APIs



SUPPORT

SUPPORT / SAMPLES & SAS NOTES

SUPPORT

- Submit a Problem
- Update a Problem
- Check Problem Status
- SAS Administrators
- Security Bulletins
- License Assistance
- Manage My Software Account
- Downloads & Hot Fixes
- Samples & SAS Notes
  - Browse by Topic
  - Search Samples
  - Search Usage Notes
  - Search Installation Notes
  - Search Problem Notes

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:<br>• lsaf_login<br>• lsaf_logout |
| GlobalPrivilegeService | Macros added:<br>• lsaf_getuserswithglobalprivilege |
| JobService | Macros added:<br>• lsaf_getjobrunasowner<br>• lsaf_setjobrunasowner |
| JobSubmissionService | Macros added:<br>• lsaf_getjobmanifestinfo<br>• lsaf_getjobmanifestinputs |

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

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

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*Thank you for your great contribution @*

*Ben Bocchicchio,*

*Sandeep Juneja,*

*Bill Gibson.*

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# Any Questions ?

https://www.linkedin.com/in/jeanmarcferran/
jmf@qualiance.dk

https://www.linkedin.com/in/stijnrogiers/
stijn.rogiers@sas.com

sas.com

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