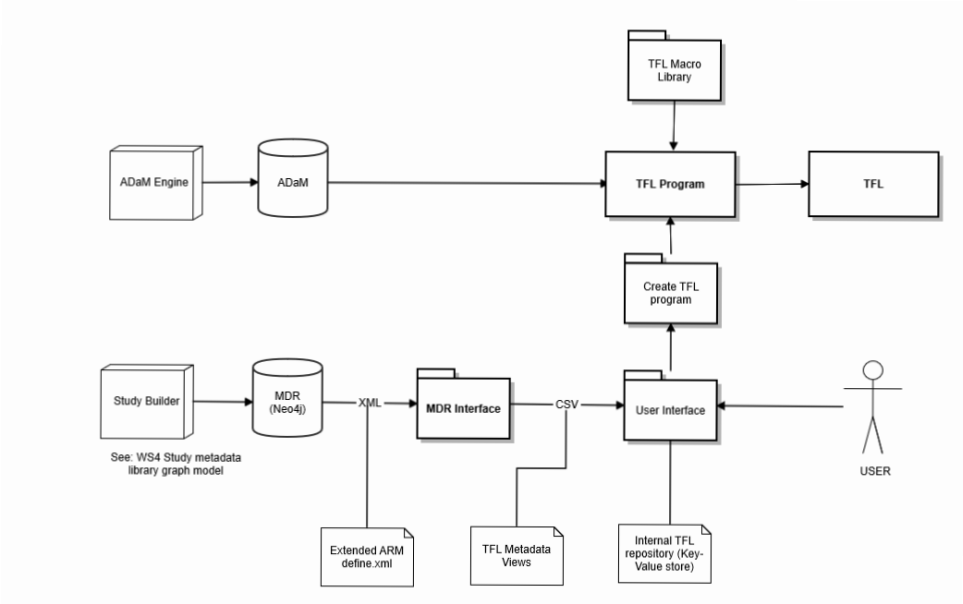
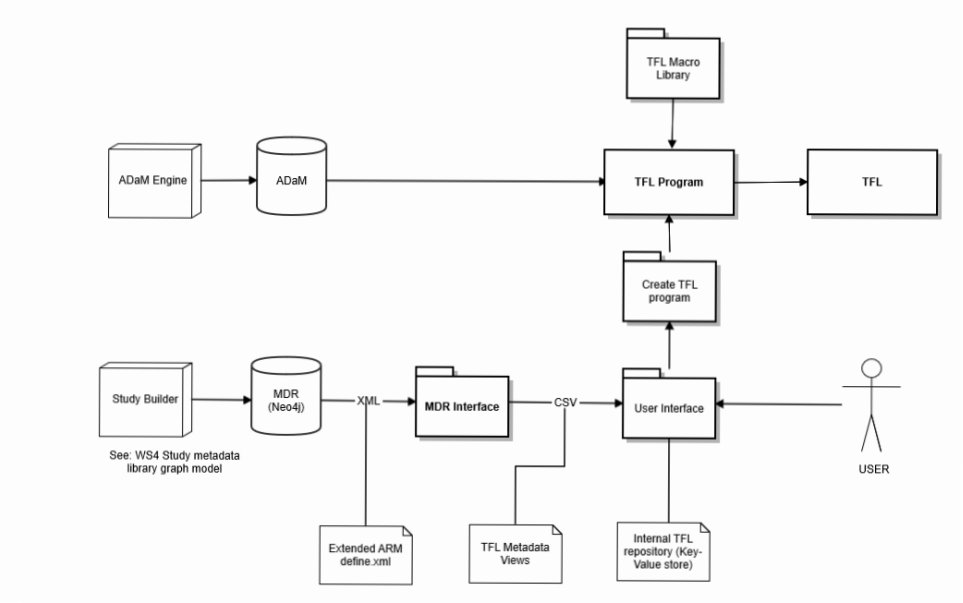

TFL Macro Library
ADaM Engine
ADaM
TFL Program
TFL
Create TFL program
Study Builder
MDR (Neo4j)
XML
MDR Interface
CSV
User Interface
USER
See: WS4 Study metadata library graph model
Extended ARM define.xml
TFL Metadata Views
Internal TFL repository (Key-Value store)


TFL Macro Library
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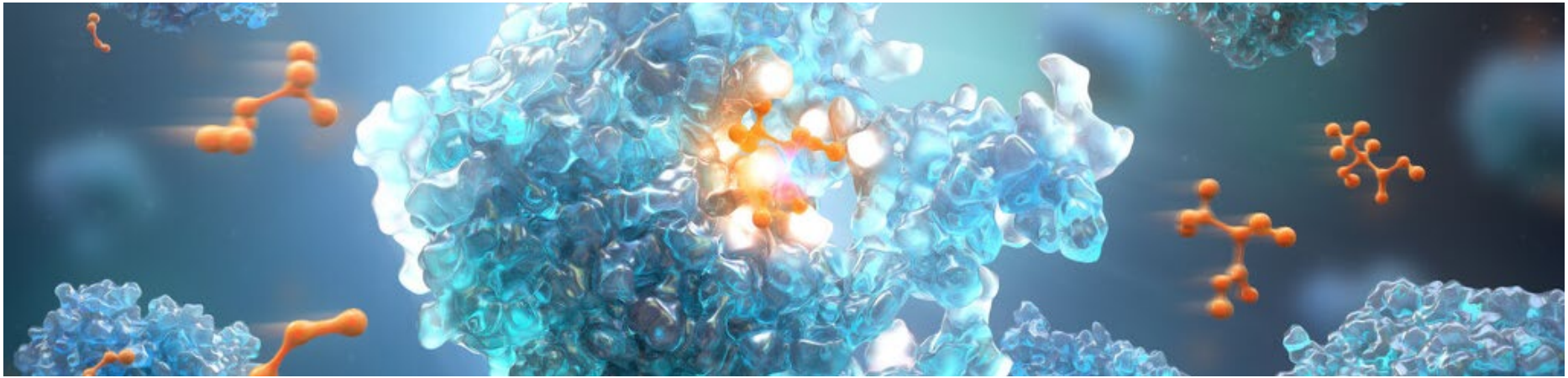
CDISC360 – WS6 TFL Automation

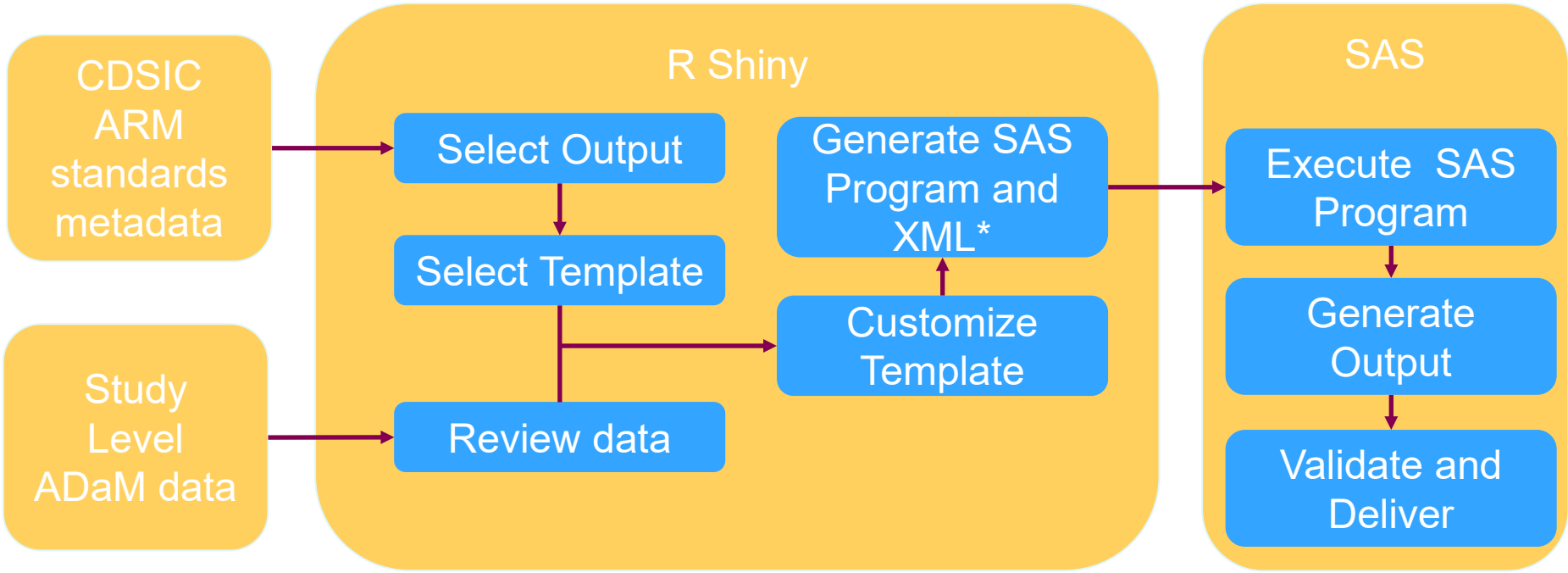
End to end process map

Prasanna Murugesan on behalf of TFL Automation team

24Feb2020



CDISC360 – WS6 TFL Automation



* - XML can be combined with ADaM Define

CDISC360 – WS6 TFL Automation

CDISC ARM standards metadata

Study	Analysis	Group	Filename	Type	Order	DisplayID	DisplayVersion	StyleID
CDISC	CDISC 360	Safety	tdemog_saf	rtf	1	T14111_SAF_DEMOG	1	table_rtf
CDISC	CDISC 360	Safety	tae_soc_pt_saf	rtf	2	T14131_SAF_AE2TIER	1	table_rtf
CDISC	CDISC 360	Safety	tmace_edpt_fas	rtf	2	T1421_FAS_EFF	1	table_rtf

1 Output | Display | Style | Results | WhereClause | TFL Metadata View list

DisplayID	DisplayVersion	Population_ Dataset	Population_ Variable	Population_ Comparator	Population_ Value	AcrossVar	AcrossOrdFmt	DisplayName	DisplayTitle
T14111_SAF_DEMOG	1	adsl	SAFFL	EQ	Y	TRTA	trtord	Table 14.1.1.1	Demographic characteristics (SAF)

2 Output | Display | Style | Results | WhereClause | TFL M ...

DisplayID	ID	Version	ResultDescription	ResultFmt
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	"Age (years)"	
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	n	xxx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Mean	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	SD	xx.xx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Min	xx
T14111_SAF_DEMOG	T14111_01_SAF_D	1	Q25	xx.x

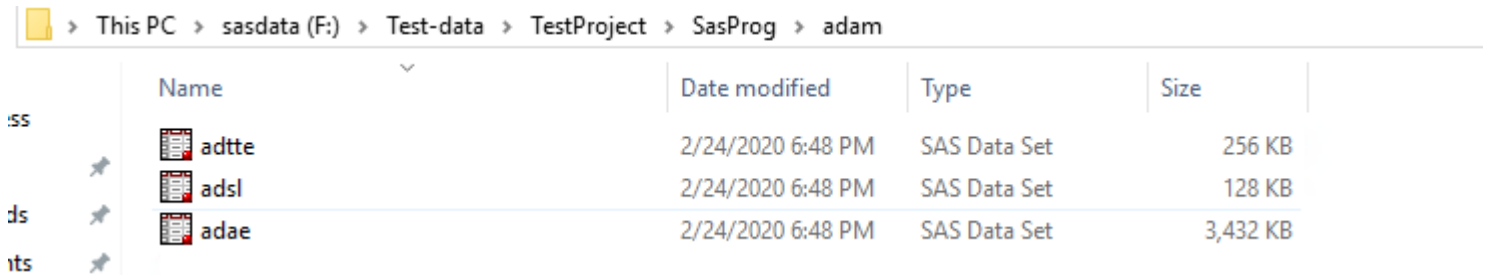
3 Output | Display | Style | Results | Whe ...

DisplayName	WhereClauseID	Dataset	WhereClause_Variable	WhereClause_Comparator	WhereClause_Value
Table 14.1.1.1	_01_SAF_DEMOG_01	adsl	AGE		
Table 14.1.1.1	_02_SAF_DEMOG_01	adsl	AGEGR1	eq	15<= to <30 years
Table 14.1.1.1	_02_SAF_DEMOG_02	adsl	AGEGR1	eq	30<= to <45 years
Table 14.1.1.1	_02_SAF_DEMOG_03	adsl	AGEGR1	eq	>=45 years
Table 14.1.1.1	_03_SAF_DEMOG_01	adsl	SEX	eq	M
Table 14.1.1.1	_03_SAF_DEMOG_02	adsl	SEX	eq	F

4 ... | Display | Style | Results | WhereClause | TFL Mc ...

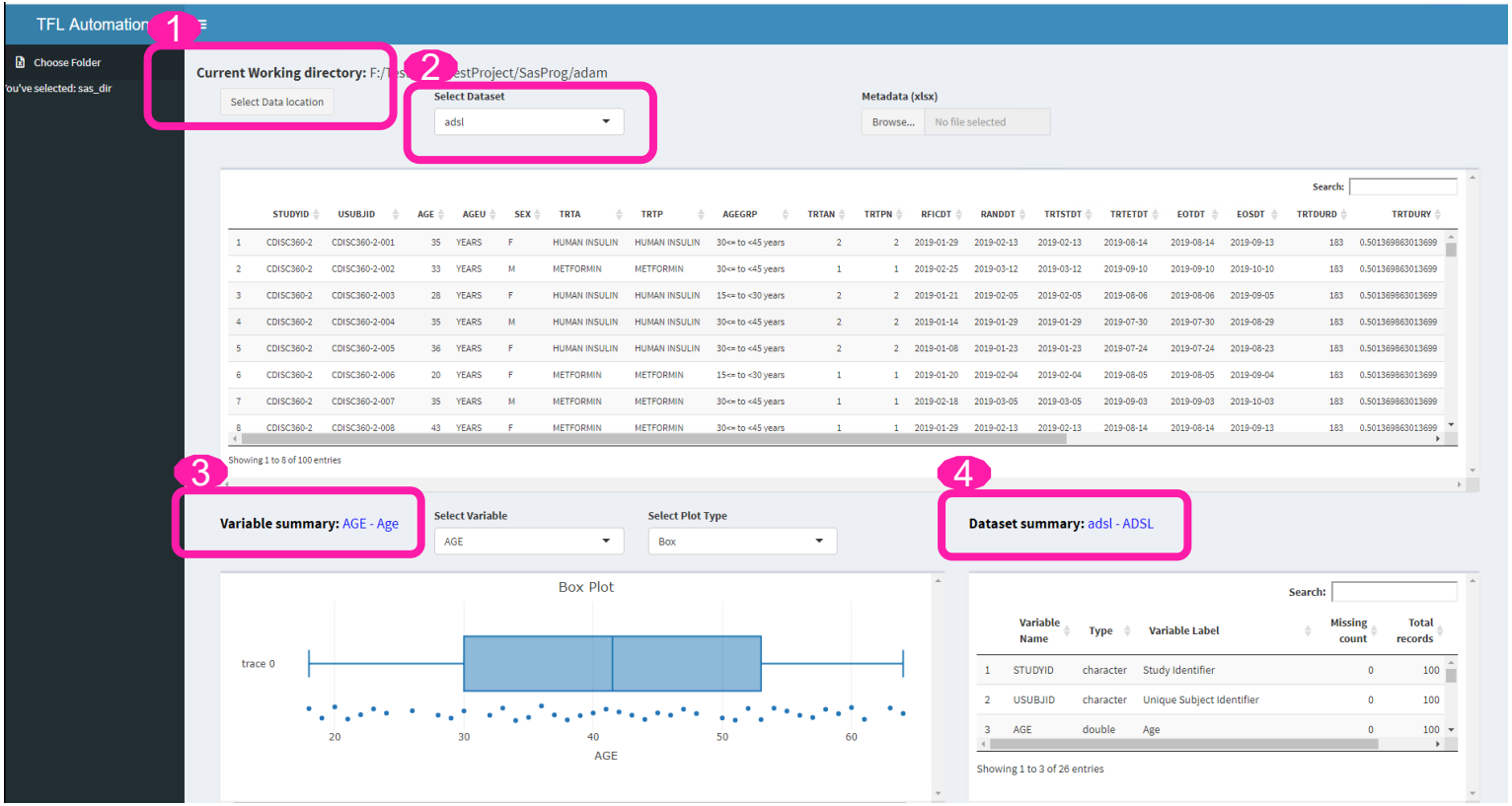
CDISC360 – WS6 TFL Automation

Study Level ADaM data



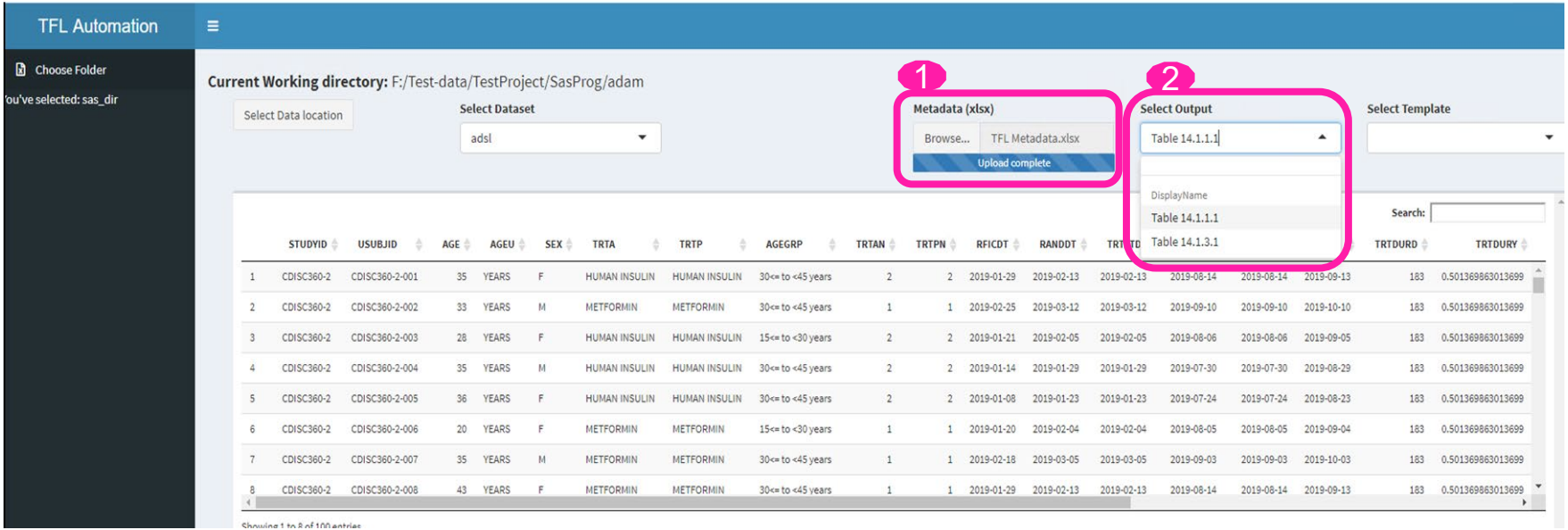
CDISC360 – WS6 TFL Automation

Review data



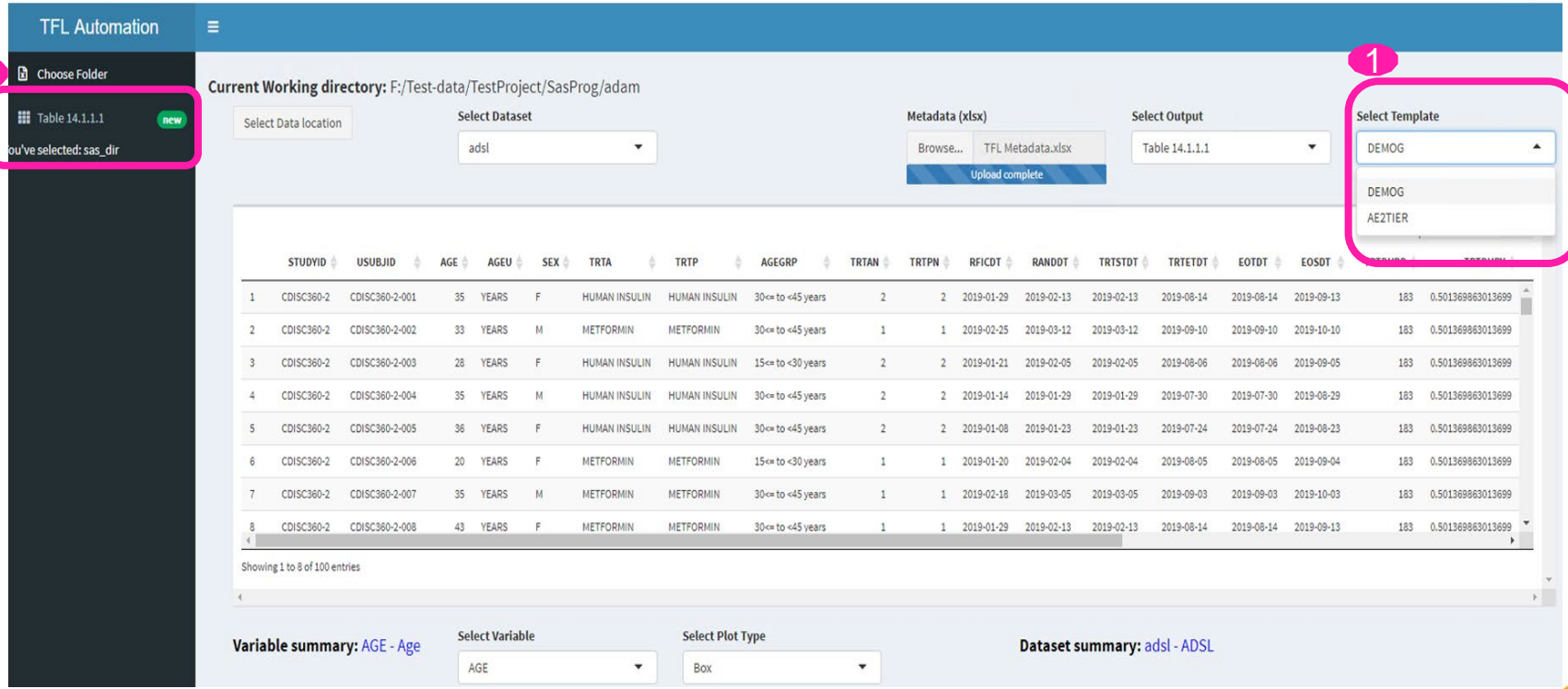
CDISC360 – WS6 TFL Automation

Select Output



CDISC360 – WS6 TFL Automation

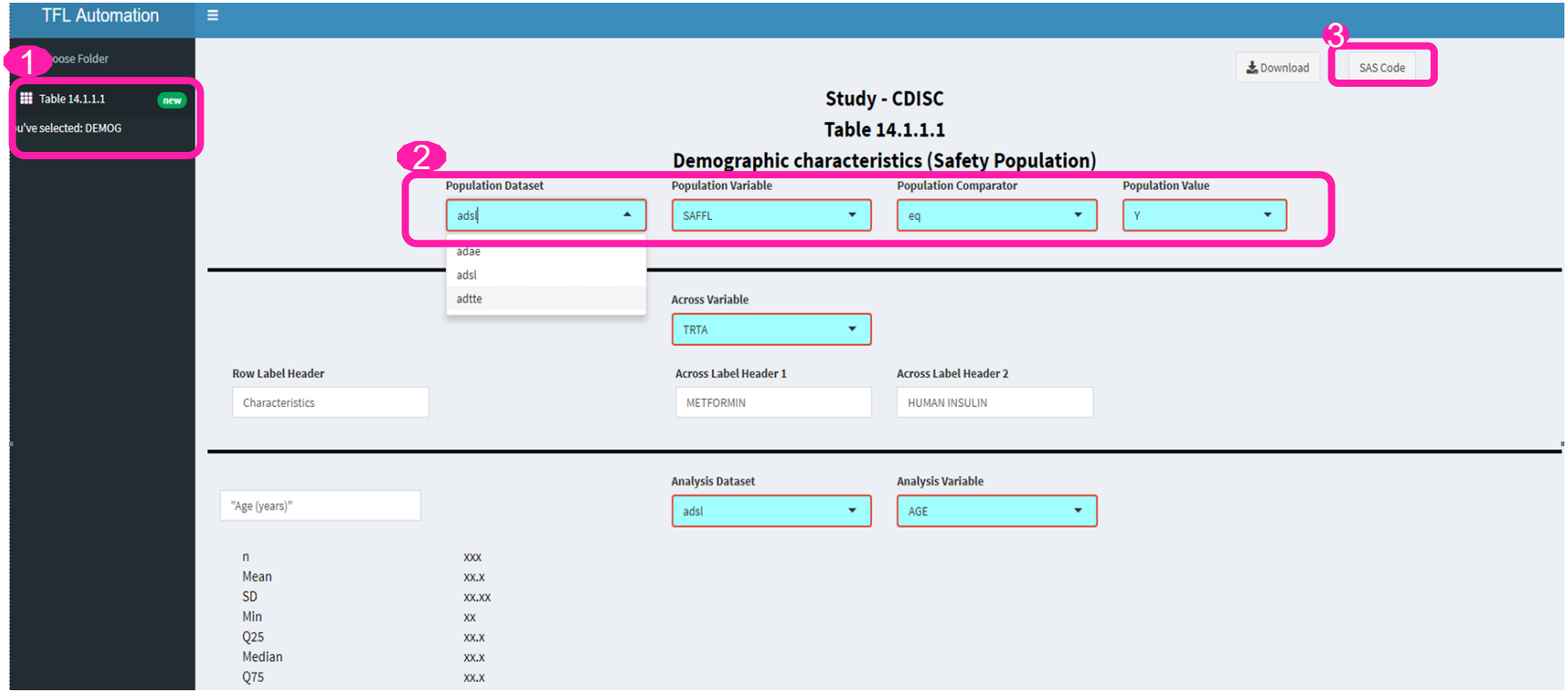
Select Template



CDISC360 – WS6 TFL Automation

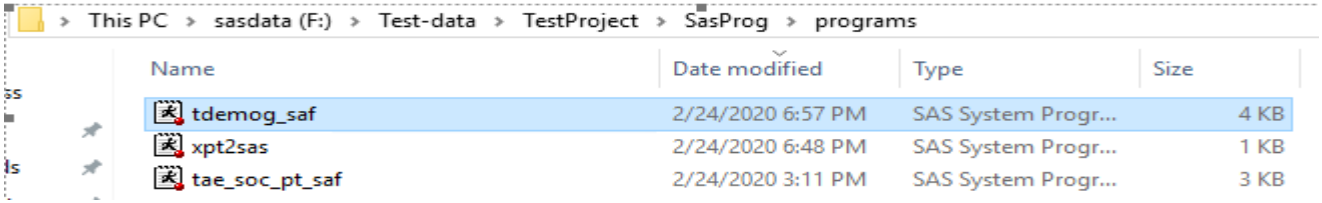
Customize Template

Generate SAS Program and XML



CDISC360 – WS6 TFL Automation

Execute SAS Program




```
/*************************************************************************************************************
*                                  Cdisc 360 - TFL programming
* Program Name          :  tdemog_saf
* Author                :  vikram.kasarala
* Creation Date         :  Mon Feb 24 18:57:23 2020
* Purpose               :  Table 14.1.1.1 Demographic characteristics (Safety Population)
* Data sets used        :
* Modification History  :
* Modification History  :
* Modification History  :
* Modification History  :
*************************************************************************************************************/


%include " F:\Test-data\TestProject\SasProg\macros\setup.sas ";

%pop(pop_dsn      =  adsl
    ,pop_out      =  T14111_SAF_DEMOG
    ,pop_var      =  SAFFL
    ,pop_comp     =  eq
    ,pop_value    =  Y
    ,AcrossVar    =  TRTA
    ,AcrossOrdFmt =  trtord
     );

%stats (s_dsn  =  T14111_SAF_DEMOG
       ,s_sec  =  T14111_01_SAF_DEMOG
```

CDISC360 – WS6 TFL Automation

Review Output

Study – CDISC

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN N=54	HUMAN INSULIN N=46
Age (years)		
n	54	46
Mean	38.2	44.4
SD	15.13	12.43
Min	18	18
Q25	24.0	35.0
Median	36.0	45.0
Q75	48.0	56.0
Max	64	63
Age Group - n (%)		
15 - <30 years	18 (33.3)	6 (13.0)
30 - <45 years	18 (33.3)	16 (34.8)
>=45 years	18 (33.3)	24 (52.2)
Gender - n (%)		
Male	27 (50.0)	22 (47.8)
Female	27 (50.0)	24 (52.2)

This page contains documentation on the WS6 TFL Metadata and how it uses and extends ARM Define.xml.

The working assumption is that the TFL Engine receives its metadata as an extended ARM Define-XML which is then converting into a set of tables (referred to as the TFL Metadata Views).

File
Microsoft Word Document WS6_TFL_define_XML_Elements.docx
Microsoft Word Document WS6_TFL_define_XML_Specification_Template.docx
JPEG File DemogDefineArmXML.JPG
JPEG File DemogDefineArmOutput.JPG
JPEG File Table14_1_1_1.JPG
File Demog_Table_Shell.rtf
PDF File Demog_Table_Shell.pdf
PDF File Demog_Table_Shell_Annotated.pdf
PDF File Demog_Table_Shell_Annotated_Display.pdf
PDF File Demog_Table_Shell_Annotated_BB.pdf
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views.xlsx
PDF File Demog_Table_Shell_Annotated_SM.pdf

Background to WS6 TFL Metadata Tables

• The WS6 TFL automation task team has put together TFL metadata tables which is based on the CDISC ARM standards. These metadata tables could be considered as “ARM++” and has enhancements to the current CDISC ARM standards. These additional elements were required to facilitate TFL automation.

• Currently the TFL metadata is managed locally to WS6. To realise end-to-end processing of metadata will require an interface (i.e. an API prototype) between the WS6 automation engines and the metadata repository.

Aim of the TFL metadata review

1. Finalize the structure/convention of the newly added elements. Is this in line with the current CDISC ARM specification?
2. Decide if, where, and or how the TFL metadata fits into the concept modelling. Does this need to be fully end-to-end?, or partial?, or outside the scope altogether? What additional information is needed from WS6? Etc.
3. Identify any changes that WS6 need to make to the TFL metadata for it to be used for concept modelling and MDR storage - feedback on naming, description, structure, meaning, etc. Also, are there alternative standards that we could or should be using for the “non-standard metadata”?
4. Decide how we want to interface the TFL automation engine with the MDR – standards based API? REST? Other? Can automation engine write to MDR? Currently TFL automation engine does not have local storage – there was an assumption that these would be written back to the MDR – do we need to do this for POC? Should we have one “automation API” that all of SDTM/ADAM/TFL engines use or will each engine have its own? Etc.

Files included in this review

File	Description
WS6_Demog_Table_Shell_Annotated.pdf	A table shell annotated with TFL View Metadata. Read this first.
WS6_TFL_define_XML_Elements.docx	A proposed ARM++ hierarchy that reflects the structure of the metadata read from the MDR.
WS6_TFL_Metadata_Views.xlsx	This file describes the 'flat' TFL View Metadata schema (see Red 'TFL Metadata View list' sheet), and the mapping (bindings) to the ARM++ The other sheets in this file contain test metadata used by the POC

File
PDF File WS6_Demog_Table_Shell_Annotated.pdf
Microsoft Word Document WS6_TFL_define_XML_Elements.docx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views.xlsx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views_lexjansen_20200618.xlsx
Microsoft Word Document TFL-metadata-review-comments.docx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views_20200727.xlsx
Microsoft Word Document TFL-metadata-review-20200727.docx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views_20200729.xlsx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views_20200810.xlsx
Microsoft Excel Spreadsheet WS6_TFL_Metadata_Views_20200812.xlsx
PDF File Demog_Table_Shell_Annotated_Updated_DSK.pdf

Although the TFL Metadata is stored centrally in the Neo4j database, within the TFL Automation, the TFL Metadata Interface (see architecture diagram) provides a set of table views (in csv format) to the user interface.

This approach was taken for two main reasons:

a) to provide a more 'automation ready' view of the metadata than using the 'raw' ARM define.xml format, and

b) it disconnects the user interface and automation programming from the central metadata library

The TFL Metadata Views are delivered in CSV (comma separated value) format.

NOTE that it is the programmer and metadata creator responsibility to ensure that the data conforms (e.g. no commas in titles, etc.). It is not expected that production quality robustness checking will be built into the application.

TFL Metadata View list

The Output view contains all the output files (e.g. a RTF file) and lists the TFL (i.e. the Display) that are in the Output file. There can be more than one Display in an Output.

The Display view contains each of the TFL, and associated metadata (title, footers, etc.), and a Display is composed of 1 or more Result.

A Result is an an atomic analysis that is applied to the source (filtering the data using the WhereClause), and applying a 'PROC STATS' to produce the part of the Table/Figure/Listing

All the metadata is contained in the following views:

Metadata view table	Description	Structure
Output	The contents and format of each output (which displays, file format, etc.)	One record per Output per Display
Display	List of all Displays - both generic library Display and study-specific (using in 1 or more Output)	One record per Display per Version
Style	Stylesheet parameters associated with Outputs	One record per Style per parameter
Result	All result metadata required to describe the anlaysis and create display in output	One record per Result
WhereClause	All the component parts of a where clause used to filter data	One record per where clause component

TFL Metadata Views

Metadata view	Fieldname	Description	must be populated?	Examples	Related table
Output	Study	Name of the study this output is part of	Y		
Output	Analysis	Identifier of the analysis that this output is part of	Y	CSR_Primary, CSR_Interim1, IDMC_2020Q1, etc.	
Output	Group	Used to group output files together	Y	Topline, Efficacy, etc.	
Output	Filename	The name of the file (without extension). No pathname	Y	F11010, topline, efficacy, etc.	
Output	Type	Output file type (format)	Y	pdf, rtf, etc.	
Output	Order	Order of the display in Output	Y	1,2,3.. or A, B, C, etc.	
Output	DisplayID	Display that is contained in this Output	Y	F11010_ITT_XYZ, L12150_SS_AEsFatalPI	Display
Output	DisplayVersion	Version of the display to include in Output	Y	1,2,3.. etc.	Display
Output	StyleID	The StyleID used for this output	N	efficacy_pdf, table_rtf, figure_pdf, etc.	Style
Metadata view	**Fieldname**	**Description**	**must be populated?**	**Examples**	**Related table**
Display	ID	ID of this display (TFL)	Y	F11010_ITT_XYZ, L12150_SS_AEsFatalPI	
Display	Version	Version number of this display	Y	1,2,3.. etc.	
Display	Population_Dataset	Dataset used to derive ‘big N’ for this TFL	Y	ADSL	
Display	Population_Filter	Conditional logic used to filter dataset for ‘big N’	Y	ITTFL=”Y”, SAFFL=”Y”	

Display	DisplayName	Display name/number	Y	Table 14.1.1.1	
Display	DisplayTitle	Display title, usually combined with DisplayName	Y	Baseline characteristics (ITT)	
Display	Title1	Title1 for this TFL	N		
Display	Title2	Title2 for this TFL	N		
Display	Title3	Title3 for this TFL	N		
Display	Title4	Title4 for this TFL	N		
Display	RowLabelHeader	Text for left-column header for tables.	N	text for ‘header0’ above table row labels (left column)	
Display	Header1	Header1 for this TFL	N	Column header text here	
Display	Header2	Header2 for this TFL	N	Enter text as displayed on column header..	
Display	Header3	Header3 for this TFL	N	or use e.g. {VAR1} markup which is interpreted..	
Display	Header4	Header4 for this TFL	N	..by the automation program	
Display	Footer1	Footer1 for this TFL	N	[1] the footer text as displayed on TFL	
Display	Footer2	Footer2 for this TFL	N	[2] numbering should be included in text	
Display	Footer3	Footer3 for this TFL	N	which means that numbering is optional	
Display	Footer4	Footer4 for this TFL	N		
Display	Document	Document ID associated with this TFL	N		Document
Metadata view	**Fieldname**	**Description**	**must be populated?**	**Examples**	**Related table**
Style	ID	unique identifier for this style	Y	pdf_style	Output
Style	ElementName	Name of the style element (e.g. a SAS ODS Style element)	Y	TitleFont, link_colour, left_margin, body_align, etc.	
Style	ElementValue		N	Courier New', 12pt, Bold	
Metadata view	**Fieldname**	**Description**	**must be populated?**	**Examples**	**Related table**
Result	DisplayID	Display ID that this result is a part of	Y		Display
Result	ID	ID of this result	Y		
Result	Version	Version of this result	Y	1,2,3..etc.	
Result	ResultDescription	Description of the result	N	Number of events	
Result	Reason	Reason the result is included in analysis	N	Specified in SAP	
Result	Purpose	Purpose of doing this analysis	N	Primary outcome measure	
Result	Dataset	The analysis dataset where data is sourced	Y		
Result	WhereClauseID	ID of the where clause used to filter dataset	N		WhereClause
Result	Variable	Analysis variable used to derive the result	Y	AVAL	
Result	AcrossVar	Variable used to summarise data by (e.g. columns)	Y	TRT01P	
Result	AcrossOrdFmt	Format ID that turns AcrossVar into column order	Y		Format
Result	Documentation	Document ID associated with this result	N		Document
Result	ProgrammingCodeContext	Software environment used to compute the result	Y	SAS 9.4, R 3.5.3, etc.	
Result	ProgrammingCode	Name of programming function (macro) used to derive result	Y	Tmpl_Tab_Cat_nSubject, etc.	
Metadata view	**Fieldname**	**Description**	**must be populated?**	**Examples**	**Related table**
WhereClause	ID	where clause identifier	Y	ADAE.ANL06FL.EQ.Y	
WhereClause	Dataset	source dataset	Y	ADAE	
WhereClause	Variable	variable to consider	Y	ANL06FL	
WhereClause	Comparator	operator to apply to Variable and Value	Y	EQ	
WhereClause	Value	value for comparison with variable	Y	"Y"	