

ADaM Spec Generator



ADaM Generator Tool (asg)

PHUSE 2021

Gustav Bernard, AD

Industry Standard Current vs Future

ADaM Specifications



Current

Excel

No Link between SDTM & ADaM

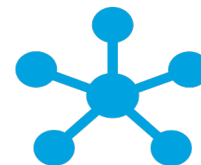
No Link to CDISC Library

- CDISC Standards
- CDISC Controlled Terminology

No Validation between Specification and Final ADaM Datasets

Define created from Specifications

Copy and Paste to include variables



Future

Application Based

Linked SDTM → ADaM

Connected to CDISC Library for:

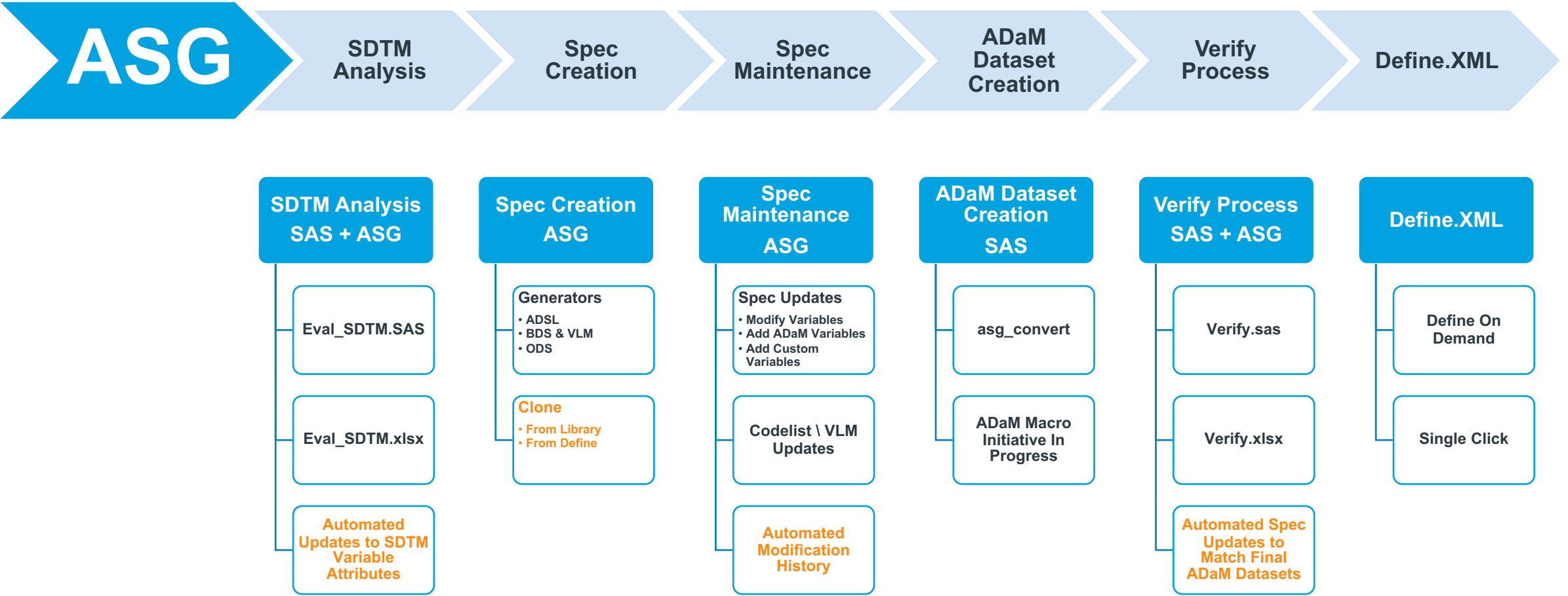
- IG from Library
- CTs from Library

Verification between Final ADaM Datasets and Specification

Define and Specification structure maintained simultaneously

Question based approach to including ADaM Variables

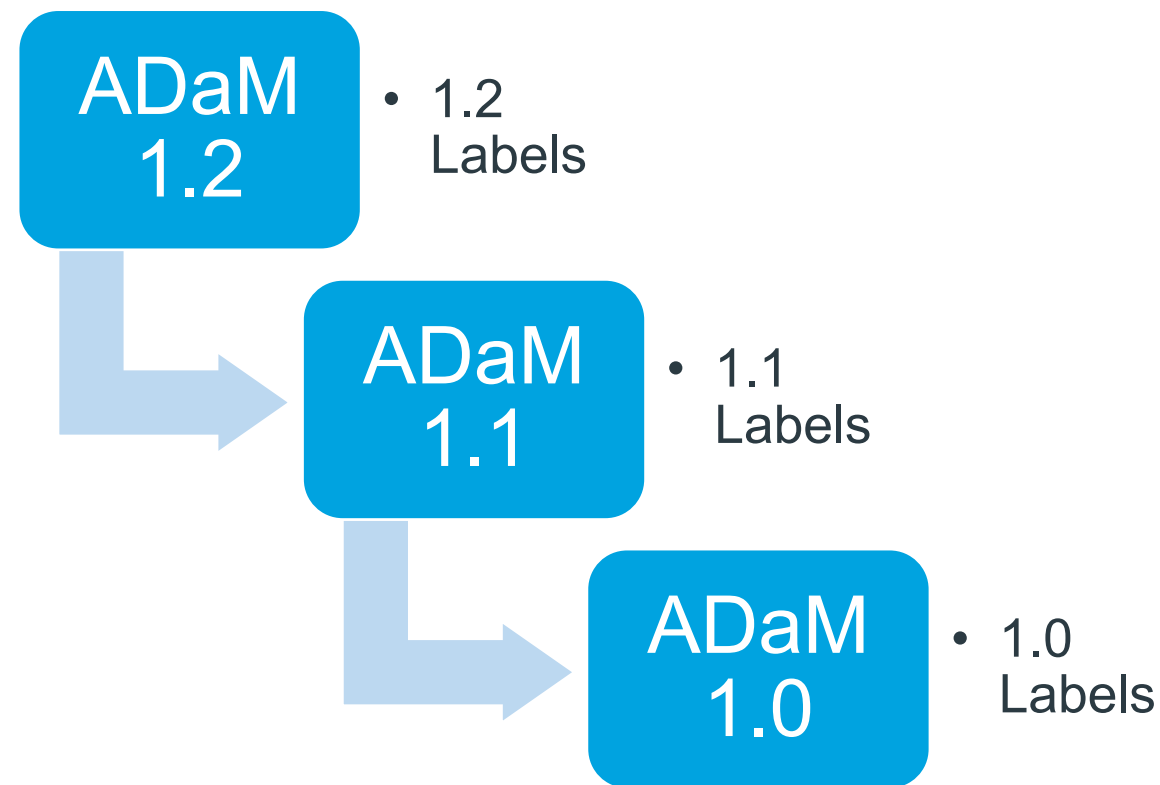
ASG Overview



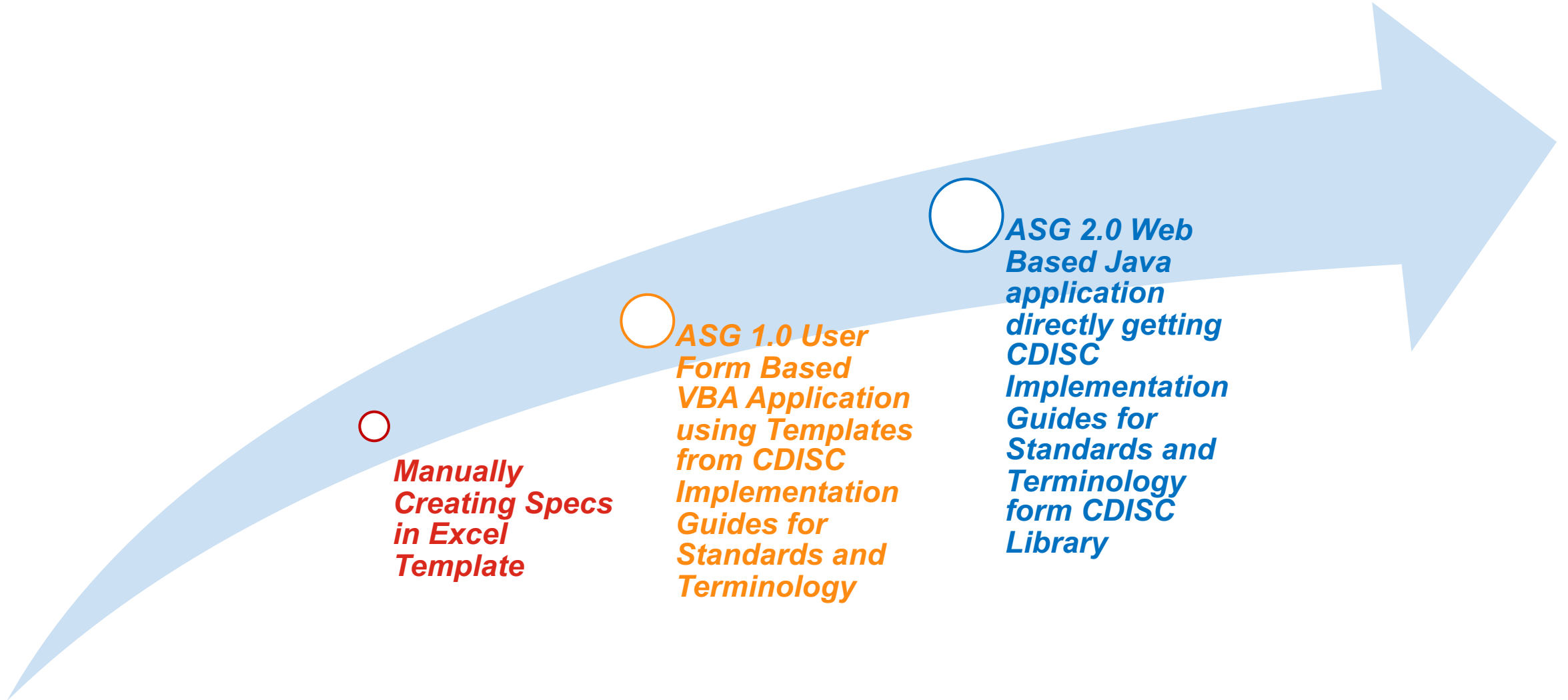
ASG

What Changes are found in ADaM Versions

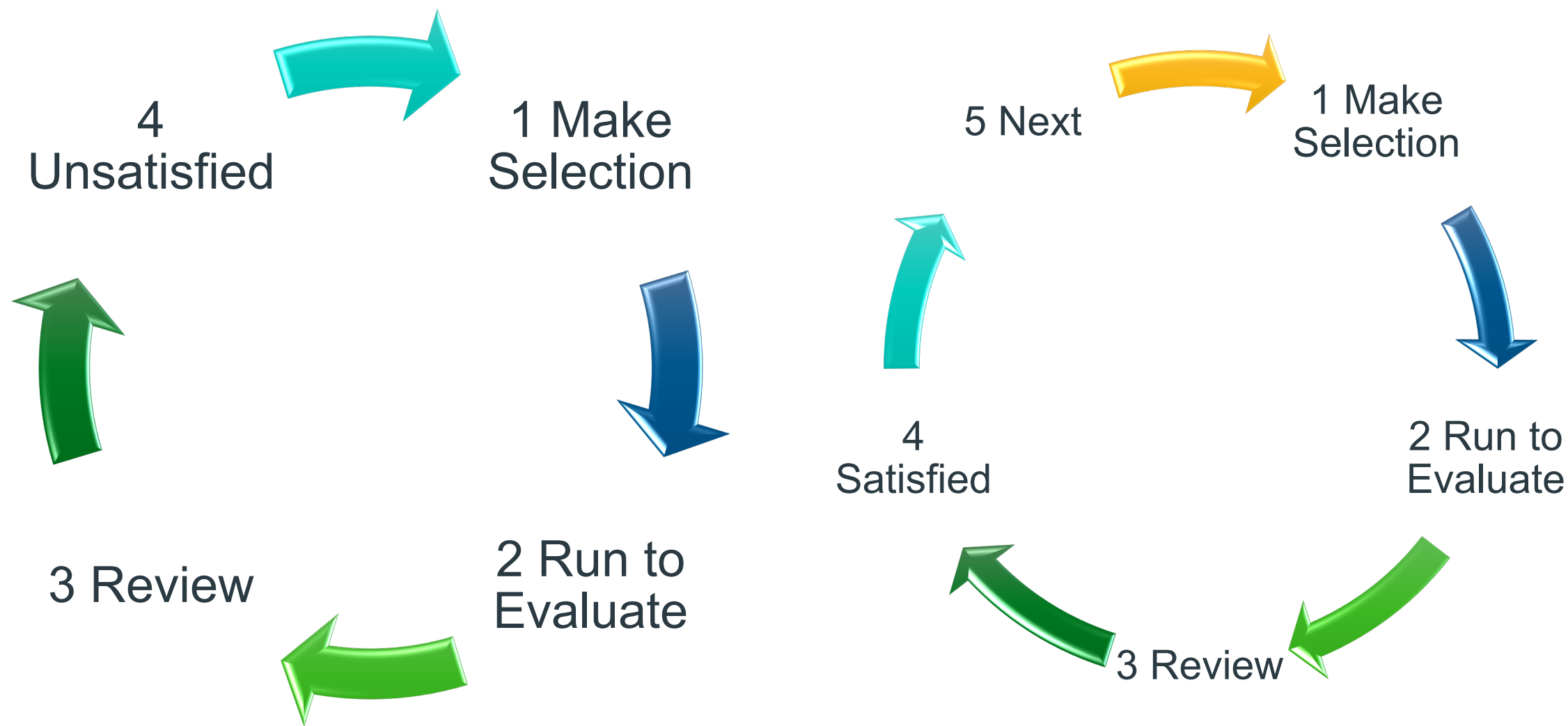
- New Variables Added
 - Older Versions set to be able select variables from Newer Sections
- Variable Label Changes
- ADaM 1.0 Follows ADaM IG 1.1, and Labels can be set to expected Labels released with IG 1.0
- ADaM 1.2 being implemented in ASG 2.0

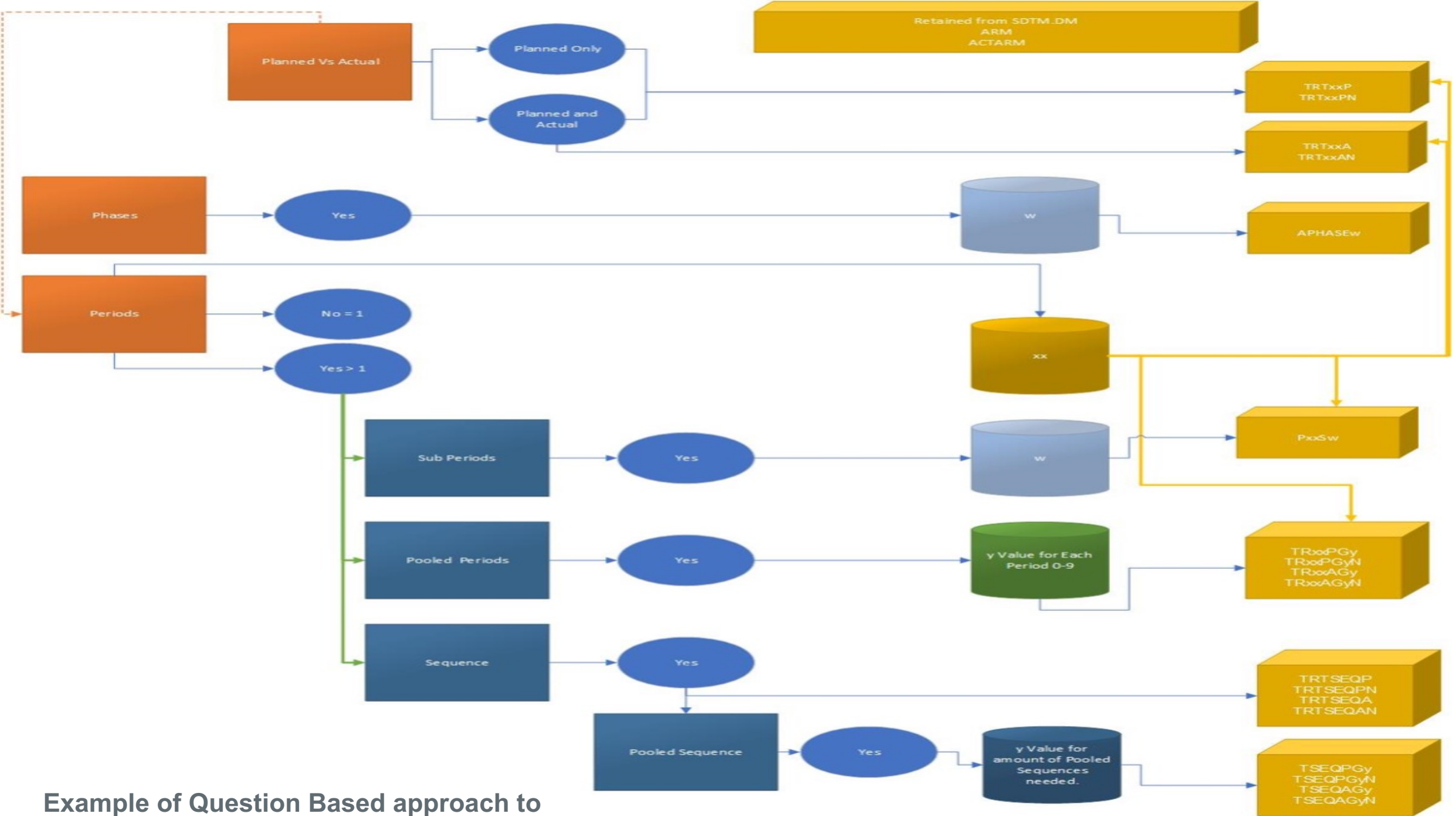


ADaM Generator Tool @iqvia



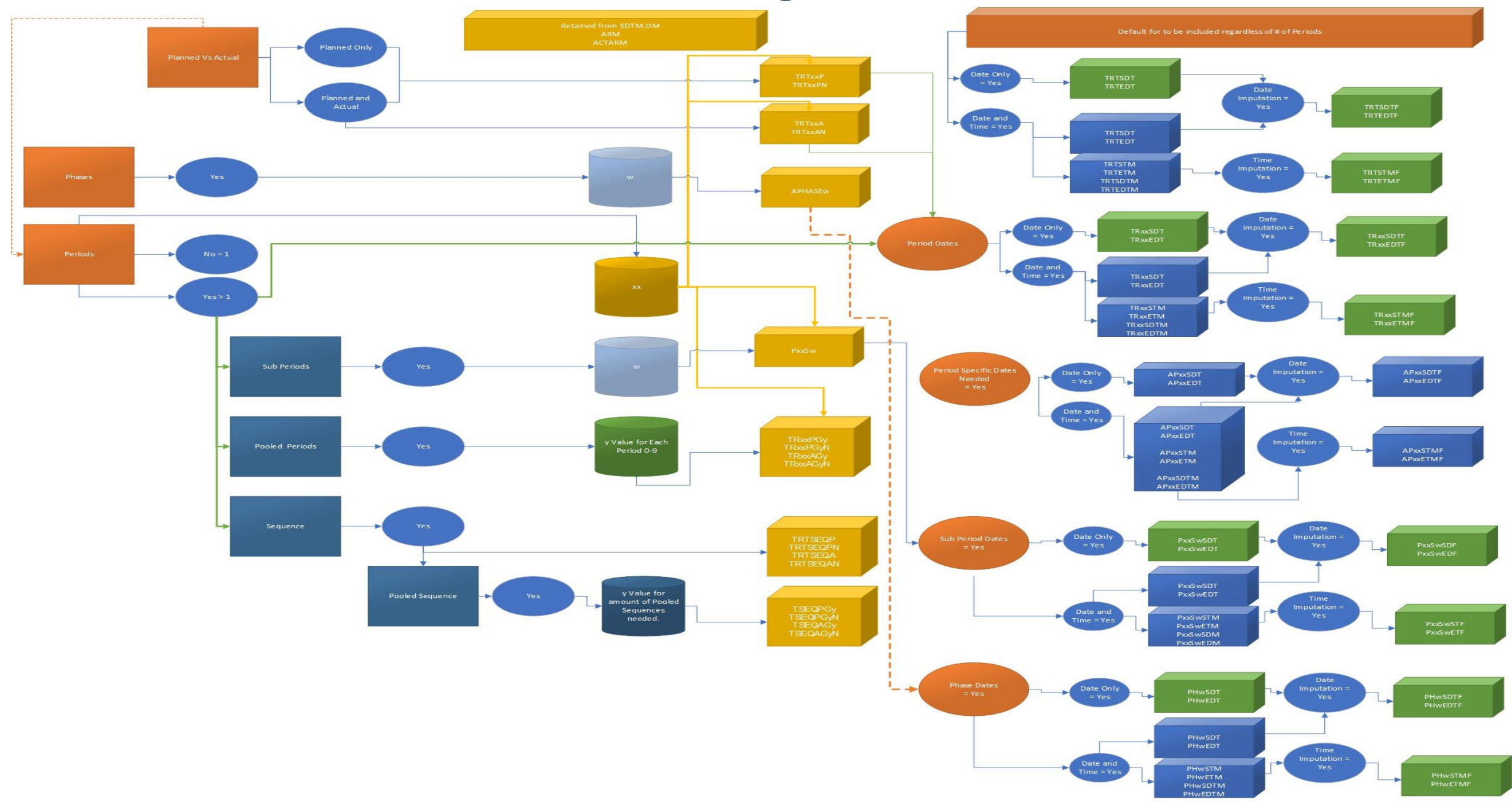
Question Based Approach to Creating ADaM Datasets





Example of Question Based approach to include Treatment Variables

Treatment variables and Dates Diagram



ASG 1.0 ADSL Treatment Design Screens

ASGSupport_TabTraining2021 - ADSL - Treatment Variables

BackADSL - Treatment Variables Step 3 of 9Exit

Does the Study Have Multiple Periods? Yes, 2 Levels

Info: This Selection will impact Both Design of ADSL and BDS Files.
The amount of PERIODS represents the XX placeholder.

Could the Planned and Actual Treatment Given Differ? Yes

Info: If No is Specified, only Planned Treatment variables will be added none of the Actual Treatment Variables will be created.

Could the study Require Grouping within the Treatment Period. No

Info: Pooled Treatment Periods

Sequence of Treatments Needed No

ADSL Dose Variables

Are Dosing Variables Needed? No

Progress:

Review variables in preview listbox and click 'Next' to continue.

RunNext

Preview Listbox:

Rule	Variable	Label
P	ARM	Description of Planned Arm
P	ARMCD	Planned Arm Code
P&A	ACTARM	Description of Actual Arm
P&A	ACTARMCD	Actual Arm Code
P1	TRT01P	Planned Treatment for Period 01
P1	TRT01PN	Planned Treatment for Period 01 (N)
P1P&A	TRT01A	Actual Treatment for Period 01
P1P&A	TRT01AN	Actual Treatment for Period 01 (N)
P2	TRT02P	Planned Treatment for Period 02
P2	TRT02PN	Planned Treatment for Period 02 (N)
P2P&A	TRT02A	Actual Treatment for Period 02
P2P&A	TRT02AN	Actual Treatment for Period 02 (N)

ASGSupport_TabTraining2021 - ADSL - Trial Dates

BackADSL - Trial Dates Step 4 of 9Exit

Study Treatment Periods 2

Click SDTM Analysis for Summary of SDTM Date/Time variables

SDTM Analysis

The following Questions refer to Variable/s Used for Creation of Treatment Start and End Date

Are both Date and Time available or only Date? Date and Time

Info: Data from SDTM DTC Analysis should be referenced for SDTM Date variable contents.

Is Imputation needed and what level? No Imputation Needed

Info: Partial Dates

Could the Study require Period Specific Dates that differ from the Treatment Period Dates. No

Info: Creates variables containing the start and end date of each period. APxxSDT/APxxSDTM/APxxEDT/APxxEDTM should only be created if Period windows are not the same as TRxxSDT/TRxxEDT Treatment windows.

ASGSupport_TabTraining2021 - ADSL - Subperiod and Phase Variables

BackADSL - Subperiod and Phase Variables Step 5 of 9Exit

Study Treatment Periods 2

Click SDTM Analysis for Summary of SDTM Date/Time variables

SDTM Analysis

The following Questions refer to Subperiod, and Phase Timing Variables

Are Subperiods Needed for Analysis? These are indicated with a w in the IG? Yes, 1 w Level

Is Phase subgrouping Needed for Analysis? These are indicated with a w in the IG, and are not by Period? No

Do you Need Timing Variables for SubPeriods and/or Phase Analysis? Yes

Are Date and Time available or only Date? Date and Time

Is Imputation needed and what level? No Imputation Needed

Preview Listbox:

Rule	Variable	Label
P1W1	P01S1	Description of Period 01 Subperiod 1
P1W1_D	P01S1SDT	Period 01 Subperiod 1 Start Date
P1W1_D	P01S1EDT	Period 01 Subperiod 1 End Date
P1W1_D_T	P01S1STM	Period 01 Subperiod 1 Start Time
P1W1_D_T	P01S1SDM	Period 01 Subperiod 1 Start Datetime
P1W1_D_T	P01S1ETM	Period 01 Subperiod 1 End Time
P1W1_D_T	P01S1EDM	Period 01 Subperiod 1 End Datetime
P2W1	P02S1	Description of Period 02 Subperiod 1
P2W1_D	P02S1SDT	Period 02 Subperiod 1 Start Date
P2W1_D	P02S1EDT	Period 02 Subperiod 1 End Date
P2W1_D_T	P02S1STM	Period 02 Subperiod 1 Start Time

Progress:

Review variables in preview listbox and click 'Next' to continue.

RunNext

Treatment, Treatment Timing, Subperiod & Phase Variables

Treatment Variables

Number of Periods (Period XX value) *

3

Affects design of both ADSL and BDS files.

- ☒ Planned Treatments
- ☒ Actual Treatments
- ☒ Include Treatment Timing

☒ Date ☒ Date Imputation

☒ Time ☐ Time Imputation
- ☒ Include Period Timing (If the study requires period specific dates that differ from the treatment period date)

☒ Date ☒ Date Imputation

☒ Time ☐ Time Imputation

Phase Selection

Study Grouping - Pooled Periods

Pooled Periods Default Value *

Set Value

Period	Pooled Periods
Period 1	0
Period 2	0
Period 3	0

Study Grouping - Subperiods

Subperiod Default Value *

2

Set Value

Period	Subperiod
Period 1	2
Period 2	1
Period 3	0

- ☐ Include Subperiod Timing

☐ Date ☐ Date Imputation

☐ Time ☐ Time Imputation

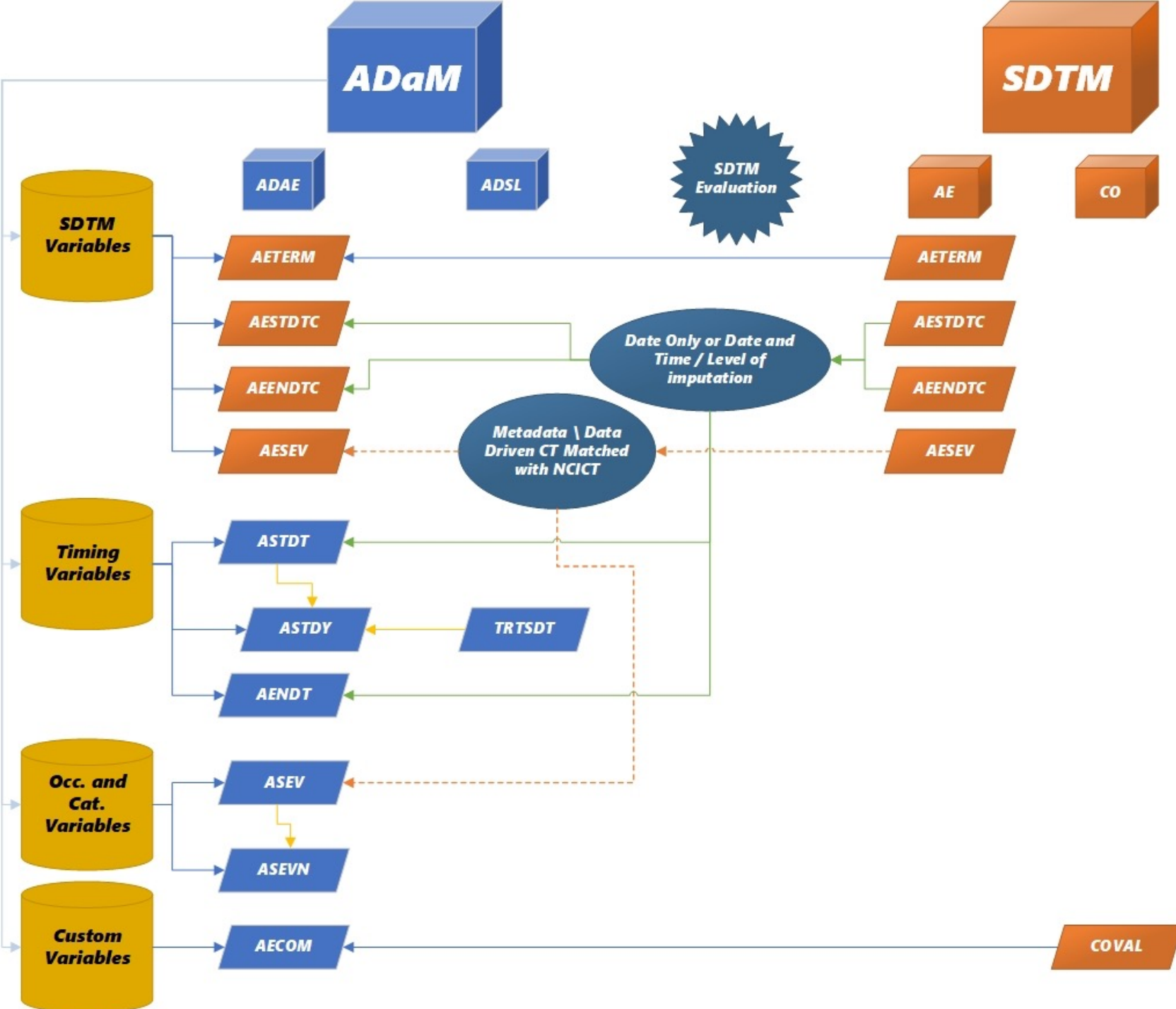
Study Grouping - Treatment Sequence Variables

- ☒ Sequence Variables Needed

Pooled Sequence Needed *

3

ASG 2.0
Web Based
Version of ASG
Treatment Design



Variable Mapping for ADaM Variables.

Some Variables will be Carried Forward from SDTM → ADaM

Some SDTM Variables will be evaluated for example all DTC variables will be evaluated to determine contents.

Data Driven Codelists will be created for a predetermined set of Variables.

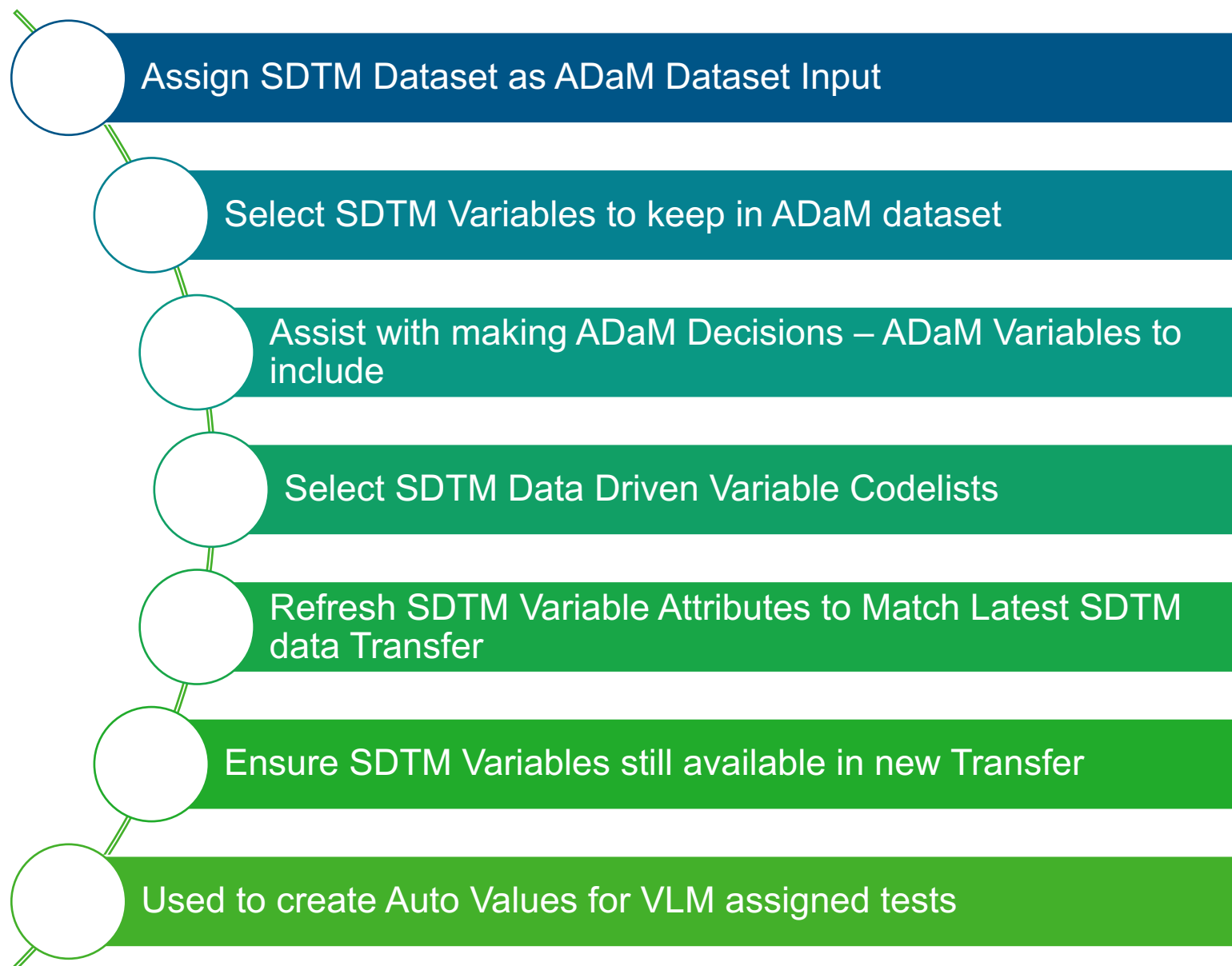
Dependencies to other ADaM Datasets and Variables.

SDTM Analysis

EvalSDTM.sas creates
EvalSDTM.xlsx



- ☐ Tab for SDTM Dataset Summary
- ☐ Tabs for DTC Analysis
- ☐ 1 Tab for Each SDTM Domain with CT Information
- ☐ 1 Tab for Each SDTM Domain with Variable + Supplemental Variable Information
- ☐ 1 Tab with VLM SDTM Information for All Domains
- ☐ 2 Tabs with Combined CT's for All Domains



ADaM Spec Generator [ASG] Process

Registering a New Project

The screenshot shows the ADaM Spec Generator (ASG) application window. The title bar reads "ADaM SPEC GENERator". The main header is a blue button labeled "ADaM Spec Generator" with an "Exit" button in the top right corner.

On the left, there are two instructional boxes:

- Start New Study:** To start an ADSL Specification for Study.
- Continue with an Existing Study:** Only Select if you have already Started or Completed creating ADSL using this Tool.

Below these are two radio buttons:

- ☒ Start a New Study
- ☐ Continue with an Existing Study

A callout "Start **New** Project" points to the "Start a New Study" radio button.

The main section is titled "Please Provide the following information". It contains several input fields:

- Sponsor:** A dropdown menu with "TAB Training" selected. A callout "Select or Enter Client Name" points to this field.
- ProjectID:** A dropdown menu with "GB0001" selected. A callout "Enter Project Code on Network Drive" points to this field.
- Indication:** A text box containing "Oncology". A callout "Indication of Trial" points to this field.
- User Name:** A text box containing "Gustav Bernard". A callout "Your Name and Surname" points to this field.
- Biostatistics Folder Location:** A text box with the instruction "Double Click Me to Browse. Select your Studies 'Biostatistics' Folder (Full UNC Path)". A callout "Double Click and Browse to your Studies Biostatistics folder." points to this field.
- Filename:** A text box containing "TAB Training_GB0001.xlsm".

At the bottom right, there is a blue button labeled "Start New Project" with a green play icon. A callout "Launch Project" points to this button.

A footer note states: "Excel will not be available during the use of the ADaM Spec Generator. If running from Desktop use SAS Grid Enviroment to Open Excel Documents. Desktop or SAS servers can be used to run the ADaM SPEC Generator."

Initial Start Screen

ADaM Spec Generator

User Name

Exit

Gustav Bernard

Link: ADaM IG 1.1

Path to Eval_SDTM Excel file:
[Double Click Me to Browse to Folder where EVAL_SDTM.xlsx is Located](#)

ADSL Generator

Clone Generator

SDTM Analysis

Create Study VBS Shortcut

Study Information

Define-XML Features

Select Define-XML Feature

Run

Files Needed:
SAP, TLF Shells,
SDTM Datasets,
EvalSDTM.sas & ADRG

Eval_SDTM.sas Macro needs to be run on SDTM datasets Prior to starting if available.

Import
Eval_SDTM.xlsx

ADSL Generator to
start Spec Creation
process.

Clone Generator to Start
a New Version within a
Study or to Copy from
Another Study.

Create Study
Specific ASG
Shortcut

ASG User Form (ADSL Generator)

Indicates Dataset Name and current step within the creation process.

Go Back to Previous Screen

Back

ADSL - Study Identifiers & Subject Demographics Step 1 of 9

Exit

Core Variables Required to be included in ADSL:

Variable	Label
STUDYID	Study Identifier
USUBJID	Unique Subject Identifier
SUBJID	Subject Identifier
SITEID	Study Site Identifier
AGE	Age
AGEU	Age Units
SEX	Sex
RACE	Race

Additional Variables To be Added Based on Questions:

Rule	Variable	Label
Site Grouping Needed	SITEGRy	Pooled Site Group y
Site Grouping Needed	SITEGRyN	Pooled Site Group y (N)
Region Grouping Needed	REGIONy	Geographic Region y
Region Grouping Needed	REGIONyN	Geographic Region y (N)
Age Group	AGEGRy	Pooled Age Group y
Age Group	AGEGRyN	Pooled Age Group y (N)
Race Grouping Needed	RACEGRy	Pooled Race Group y
Race Grouping Needed	RACEGRyN	Pooled Race Group y (N)

Site Grouping Variables Needed:

No

Region Grouping Variables Needed:

No

Age Grouping Variables Needed:

Yes, 1 Variable

Race Grouping Variables Needed:

Yes, 1 Variable

Do you need AGE? It is required if age is calculated differently than in SDTM.

No

Additional SDTM Variables To Include in ADSL:

☒ BRTHDTC (Date of Birth)

☐ COUNTRY

☐ ETHNIC

Progress:

Review variables in preview listbox and click 'Next' to continue.

Run

Next

Preview Listbox:

Core	SITEID	Study Site Identifier
Core	AGE	Age
Core	AGEU	Age Units
Core	SEX	Sex
Core	RACE	Race
AgeG1	AGEGR1	Pooled Age Group 1
AgeG1	AGEGR1N	Pooled Age Group 1 (N)
RaceG1	RACEGR1	Pooled Race Group 1
RaceG1	RACEGR1N	Pooled Race Group 1 (N)
BRTHDTC	BRTHDTC	Date/Time of Birth

List Box Required Variables

List Box with Optional Variables

Combo Boxes to be changed to included optional Variables

Check Boxes to be changed to included optional Variables

Preview List Box

Click Run to Preview Selection

Preview Populated

Back

ADSL - Study Identifiers & Subject Demographics Step 1 of 9

Exit

Core Variables Required to be included in ADSL:

Variable	Label
STUDYID	Study Identifier
USUBJID	Unique Subject Identifier
SUBJID	Subject Identifier for the Study
SITEID	Study Site Identifier
AGE	Age
AGEU	Age Units
SEX	Sex
RACE	Race

Additional Variables To be Added Based on Questions:

Rule	Variable	Label
Site Grouping Needed	SITEGRy	Pooled Site Group y
Site Grouping Needed	SITEGRyN	Pooled Site Group y (N)
Region Grouping Needed	REGIONy	Geographic Region y
Region Grouping Needed	REGIONyN	Geographic Region y (N)
AgeGroup	AGEGRy	Pooled Age Group y
AgeGroup	AGEGRyN	Pooled Age Group y (N)
Race Grouping Needed	RACEGRy	Pooled Race Group y
Race Grouping Needed	RACEGRyN	Pooled Race Group y (N)

Site Grouping Variables Needed:

No

Region Grouping Variables Needed:

No

Age Grouping Variables Needed:

Yes, 1 Variable

Race Grouping Variables Needed:

Yes, 1 Variable

Do you need AAGE? It is required if age is calculated differently than in SDTM.

No

Additional SDTM Variables To Include in ADSL?

☒ BRTHDTC (Date of Birth)

☐ COUNTRY

☐ ETHNIC

Progress:

Review variables in preview listbox and click 'Next' to continue.

Run

Next

Preview Listbox:

Core	SITEID	Study Site Identifier
Core	AGE	Age
Core	AGEU	Age Units
Core	SEX	Sex
Core	RACE	Race
AgeG1	AGEGR1	Pooled Age Group 1
AgeG1	AGEGR1N	Pooled Age Group 1 (N)
RaceG1	RACEGR1	Pooled Race Group 1
RaceG1	RACEGR1N	Pooled Race Group 1 (N)
BRTHDTC	BRTHDTC	Date/Time of Birth

Next Button Becomes available

Update Screen

Back

Update - ADSL Study Identifiers & Subject Demographics

Study Identifiers & Subject Demographics/

Exit

Select Variable to Edit:

*Suggested Edits

Derivation

Codelist

CT & Derivation

#	Variable	Label	Source	Origin	Codelist	Select an option f...
	STUDYID	Study Identifier	Predecessor	DM.STUDYID		
	USUBJID	Unique Subject Identifier	Predecessor	DM.USUBJID		
	SUBJID	Subject Identifier for the Study	Predecessor	DM.SUBJID		
	SITEID	Study Site Identifier	Predecessor	DM.SITEID		
	AGE	Age	Predecessor	DM.AGE		
©	AGEU	Age Units	Predecessor	DM.AGEU	(AGEU)	
©	SEX	Sex	Predecessor	DM.SEX	(SEX)	
©	RACE	Race	Predecessor	DM.RACE	(RACE)	

Source

Origin

Valid Origin for ADaM:
DOMAIN.VARIABLE
For Source: Predecessor or Assigned

Type

Display Format / Length

Codelist

View Codelists

Auto Populate

When Origin set to DOMAIN.VARIABLE
No Comment or Derivation needed.

Programming Derivation

Select an option from the ListBox Above

Define-XML Comment

ADRG = Analysis Data Reviewers Guide.
Set to ADRG page number.

ADRG

CDISC ADaM IG Comment

Next

Dropdown Box on the Top Right can be used to Edit Variables from different sections. Custom Variables can also be selected from there.

Update Screen will show after each section

Predecessor

Back

Update - ADSL Study Identifiers & Subject Demographics

Study Identifiers & Subject Demographics

Exit

Select Variable to Edit:

*Suggested Edits

Derivation

Codelist

CT & Derivation

*	Variable	Label	Source	Origin	Codelist	Select an option f...
	STUDYID	Study Identifier	Predecessor	DM.STUDYID		
	USUBJID	Unique Subject Identifier	Predecessor	DM.USUBJID		
	SUBJID	Subject Identifier for the Study	Predecessor	DM.SUBJID		
	SITEID	Study Site Identifier	Predecessor	DM.SITEID		
	AGE	Age	Predecessor	DM.AGE		
©	AGEU	Age Units	Predecessor	DM.AGEU	(AGEU)	
©	SEX	Sex	Predecessor	DM.SEX	(SEX)	
©	RACE	Race	Predecessor	DM.RACE	(RACE)	

Source

Predecessor

Origin

DM.AGE

Valid Origin for ADaM:
DOMAIN.VARIABLE
For Source: Predecessor or Assigned

Type

Num

Display Format / Length

8

Codelist

View Codelists

When Origin set to DOMAIN.VARIABLE
No Comment or Derivation needed.

Predecessor Variable Metadata

ADRG = Analysis Data Reviewers Guide.
Set to ADRG page number.

ADRG

CDISC ADaM IG
Comment

DM.AGE. If analysis needs require a derived age that does not match DM.AGE, then AAGE must be added.

Next

Dropdown Box on the Top Right can be used to Edit Variables from different sections. Custom Variables can also be selected from there.

Derived

Back

Update - ADSL Study Identifiers & Subject Demographics

Study Identifiers & Subject Demographics

Exit

Select Variable to Edit:

*Suggested Edits

Derivation

Codelist

CT & Derivation

AGE	Age	Predecessor	DM.AGE	
AGEU	Age Units	Predecessor	DM.AGEU	(AGEU)
SEX	Sex	Predecessor	DM.SEX	(SEX)
RACE	Race	Predecessor	DM.RACE	(RACE)
AGEGR1	Pooled Age Group 1	Derived	AGEGR	Explain...
AGEGR1N	Pooled Age Group 1 (N)	Assigned	AGEGRN	See Codelist for G...
RACEGR1	Pooled Race Group 1	Derived	RACEGR	Explain...
RACEGR1N	Pooled Race Group 1 (N)	Assigned	RACEGRN	See Codelist for G...
BRTHDTC	Date/Time of Birth	Predecessor	DM.BRTHDTC	

Source

Derived

Origin

Valid Origin for ADaM:
DOMAIN.VARIABLE
For Source: Predecessor or Assigned

Type

Char

Display Format / Length

20

Codelist

AGEGR

View Codelists

Codelist Needs to be Created.

Edit/Create Codelist

Auto Populate

When Origin set to DOMAIN.VARIABLE
No Comment or Derivation needed.

Programming Derivation

Explain...

Define-XML Comment

Pooled Age Group 1

ADRG = Analysis Data Reviewers Guide.
Set to ADRG page number.

ADRG

CDISC ADaM IG Comment

Character description of a grouping or pooling of the subject's age for analysis purposes. For example, AGEGR1 might have values of "<18", "18-65", and ">65"; AGEGR2 might have values of "Less than 35 y old" and "At least 35 y old".

Next

Dropdown Box on the Top Right can be used to Edit Variables from different sections. Custom Variables can also be selected from there.

From this screen, you can **update** the following:

- Source
- Origin
- Display Format/Length
- Codelist
- Programming
- Derivation
- Define-XML Comment

ADaM Spec Generator [ASG] Process

Initial ADaM Specification Creation – Start Screen

TAB Training_GB0001 - ADaM SPEC Generator

ADaM Spec Generator

User Name: Exit

Link: ADaM IG 1.1

Path to Eval_SDTM Excel file:

1 **BDS Generator** 2 **ODS Generator** **SDTM Analysis**

3 **VLM Generator** 4 **Clone Generator**

ADaM Modifications

Dataset Information

View/Edit Variables

Add ADaM Variables

View/Edit Codelists

ADaM Name:

Refresh ADSL Vars

Reselect/Add SDTM or ADSL Variables

Study Information

Refresh SDTM

Core ADSL Variables

ADaM Variable Order

Define-XML Features

Select Define-XML Feature Run

Files Needed:
SAP, TLF Shells,
SDTM Datasets,
EvalSDTM.sas & ADRG

Eval_SDTM.sas Macro needs to be run on SDTM datasets Prior to starting if available.

- After ADSL has been created **additional functionality** will be available from the Start Screen.
- During the **Creation Process** we will be using the following functionality.

- 1** **BDS Generator** – To create Basic Data Structure Datasets.
- 2** **ODS Generator** – To Create Occurrence and **ADaM Other** Data Structures.
- 3** **VLM Generator** to create VLM Entries for BDS domains.
- 4** **Clone Generator** is specification is cloned from the Library.

ADaM Spec Generator [ASG] Process

Initial ADaM Specification Creation – BDS \ ODS Initialize

TAB Training_GB0001 - BDS/ODS Generator

Back **Basic Data Structure - Initialize** **Exit**

Structure: Basic Data Structure

Dataset Name: ADEG **Custom Domain Names and Labels can be manually added.**

Dataset Label: ECG Analysis Dataset

Input Dataset(s)

☐	Standard	Name-Label	Class
☐	SDTM	DA - Drug Accountability **	Findings
☐	SDTM	DD - Death Details	Findings
☒	SDTM	EG - ECG Test Results **	Findings
☐	SDTM	FA - Findings About Events or Interventions **	Findings
☐	SDTM	FAAE - Findings About Adverse Events **	Findings
☐	SDTM	IE - Inclusion_Exclusion Criteria Not Met **	Findings
☐	SDTM	IS - Immunogenicity Specimen Assessments **	Findings
☐	SDTM	LB - Laboratory Test Results **	Findings
☐	SDTM	MI - Microscopic Findings **	Findings
☐	SDTM	PC - Pharmacokinetic Concentrations **	Findings
☐	SDTM	PE - Physical Examination **	Findings
☐	SDTM	QS - Questionnaire **	Findings
☐	SDTM	RP - Reproductive System Findings	Findings
☐	SDTM	RS - Disease Response **	Findings
☐	SDTM	SC - Subject Characteristics **	Findings

**** SDTM Dataset has both Domain and SUPPxx Domain.**

Next

For Both the BDS and ODS Generator the Specifications first Screen will ask the **Dataset Name, Label** will be auto populated if a common ADaM Domain is specified.

SDTM Input should also be specified here, usually each ADaM BDS and ODS domain will only have one SDTM input, but multiple can be selected if needed.

Custom Domain Names can be entered in the Dataset Name and Label Inputs.

ADaM Spec Generator [ASG] Process

Initial ADaM Specification Creation – VLM Generator Tabs

Parameter Value Level Metadata

Select DaM Domain: ADEG

1 VLM Template for Domain 2 Tests from SDTM Domain 3 PARAMCDs for Domain

Exit

- 1 The VLM **Template** for Domain will show any preidentified common derived ADaM PARAMCD's for a domain.
- 2 The **SDTM Tests** will show all the Unique Test Levels from the different findings SDTM Domains, a Unique test is a record with a Unique xxCAT, xxSCAT, xxTESTCD, xxTEST, xxSPEC, xxLOC, xxPOS, xxMETHOD, xxSTRESU and xxORRESU combination, and will take in consideration that only some of these will be available in most domains.
- 3 The PARAMCDs for Domain will show all Previously added **PARAMCDs** already added for Domain.

You can select a record from the VLM template or SDTM Tests and the VLM Metadata for PARAMCD will be populated, you can edit any of VLM Metadata and select **“Add PARAMCD”** to add to the VLM for the Study. PARAMCDs added to the Studies Parameter Value Level Metadata can be edited by selecting a PARAMCD from the List box, making the desired updates and then selecting **“Update PARAMCD”**.

“Delete PARAMCD” can be used to Delete a Previously added PARAMCD.

ADaM Spec Generator [ASG] Process

Initial ADaM Specification Creation – VLM Generator Add All from SDTM

Parameter Value Level Metadata

Select ADaM Domain: **ADEG** Exit

VLM Template for Domain **Tests from SDTM Domain** PARAMCDs for Domain

SDTM Input Domains: **EG** All SDTM Domains:

EG	<Missing>	<Missing>	HR	Heart Rate	BEATS/MIN	BEATS/MIN
EG	<Missing>	<Missing>	INTP	Interpretation	<Missing>	<Missing>
EG	<Missing>	<Missing>	PQPR	PQ/PR Interval	msec	msec
EG	<Missing>	<Missing>	QRS	QRS Interval	msec	msec
EG	<Missing>	<Missing>	QT	QT Interval	msec	msec
EG	<Missing>	<Missing>	QTCF	QTCF - Fridericia's Correction Formula	msec	msec
EG	<Missing>	<Missing>	RHYTHM	Rhythm	<Missing>	<Missing>
EG	<Missing>	<Missing>	RR	RR Duration	msec	msec

SDTM Variables and Values

TESTCD **HR** TEST **Heart Rate** CAT SCAT

SPEC LOC POS METHOD

STRESU ORRESU

STRESC ORRES STRESN SDTM Results Variable

ADaM Variables and Values for PARAMCD

PARAMCD PARAM Click Add All from SDTM

PARAMN Modify Parameter Variables

Variable

Origin Type Length

Codelist View/Edit Codelists

Derivation

Comment

Add All from SDTM Add PARAMCD Update PARAMCD VLM Show Data Form Next

Add All from SDTM

ADaM Spec Generator

Following PARAMCDs have been added to the study VLM.

- PARAMCD = HR and, Variable = AVAL
- PARAMCD = HR and, Variable = AVALC
- PARAMCD = INTP and, Variable = AVALC
- PARAMCD = INTP and, Variable = AVAL
- PARAMCD = PQPR and, Variable = AVAL
- PARAMCD = PQPR and, Variable = AVALC
- PARAMCD = QRS and, Variable = AVAL
- PARAMCD = QRS and, Variable = AVALC
- PARAMCD = QT and, Variable = AVAL
- PARAMCD = QT and, Variable = AVALC
- PARAMCD = QTCF and, Variable = AVAL
- PARAMCD = QTCF and, Variable = AVALC
- PARAMCD = RHYTHM and, Variable = AVALC
- PARAMCD = RHYTHM and, Variable = AVAL
- PARAMCD = RR and, Variable = AVAL
- PARAMCD = RR and, Variable = AVALC

OK

ADaM Spec Generator [ASG] Process

Initial ADaM Specification Creation – VLM Generator – Modify Parameter Variables

Modify Parameter Variables

Update PARAMCD Information

Select ADaM Domain: **ADEG** PARAMCD **HR**

PARAMCD	PARAM	PARAMN
HR	Heart Rate (BEATS/MIN)	1
INTP	Interpretation	2
PQPR	PQ/PR Interval (msec)	3
QRS	QRS Interval (msec)	4
QT	QT Interval (msec)	5
QTcF	QTcF - Fridericia's Correction Formula (msec)	6
RHYTHM	Rhythm	7
RR	RR Duration (msec)	8

PARAM **Heart Rate (BEATS/MIN)**

PARAMN **1**

1 Create codelist for PARAMCD, PARAM and PARAMN

Create PARAM CTs

Next

PARAM and PARAMN Updates will be made to All Entries for that PARAMCD in the VLM tab Regardless of Target Variable.

ADaM Spec Generator (ASG)

1 Parameter CT's Created: PARAMCD, PARAM and PARAMN

OK

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance – Dataset Information

Select **Dataset**

Delete or Rename Dataset.
ADSL can only be Recreated and not Deleted

Dataset Information

ADaM Datasets
ADSL
ADEG

ADaM Domain: ADEG

ADaM Spec Generator

User Name: Gustav Bernard Back

Label: ECG Analysis Dataset Class: Basic Data Structure

Sort: STUDYID,USUBJID,PARAMCD,PARAM,AVISITN Select Sort

Structure: One record per subject per analysis parameter per analysis timepoint.

SDTM Input: EG Change SDTM Input

ADaM Input

Filter: Where Clause

Additional Documentation

Delete ADaM Dataset Refresh ADSL Vars Reselect/Add SDTM or ADSL Variables
Rename ADaM Dataset Refresh SDTM
Recreate ADSL Restore Programming Comments

ADaM Variable Order Next

Select **Sort**
from List of Variables found in the Domain

Update Dataset Label, Structure, ADaM Input, Filter Criteria and Add Documentation by Editing Text Boxes.

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance - View/Edit Variables

1

ADSL
ADVS555
ADEG
ADAE
ADMH
ADLB
ADIE
ADPD
ADCM

Derivation
Codelist
Both

Dataset: ADPD

Section:

Variable:

User Name: Bernard, Gustav

2

Select Variable:

DDSEQ	Sequence Number	Predecessor	DD.DDSEQ
DDTESTCD	Death Detail Assessment Short Name	Predecessor	DD.DDTESTCD
DDTEST	Death Detail Assessment Name	Predecessor	DD.DDTEST
DDORRES	Result or Finding as Collected	Predecessor	DD.DDORRES
DDSTRESC	Character Result/Finding in Std Format	Predecessor	DD.DDSTRESC
ASEQ	Analysis Sequence Number	Derived	
TRTP	Planned Treatment	Derived	TRTP
TRTPN	Planned Treatment (N)	Assigned	TRTPN
TRTA	Actual Treatment	Derived	TRTA
TRTAN	Actual Treatment (N)	Assigned	TRTAN
ADT	Analysis Date	Derived	
ADY	Analysis Relative Day	Derived	
ATM	Analysis Time	Derived	
ADTM	Analysis Datetime	Derived	
AVISIT	Analysis Visit	Derived	AVISIT
AVISITN	Analysis Visit (N)	Assigned	AVISITN
ATPT	Analysis Timepoint	Assigned	ATPT
ATPTN	Analysis Timepoint (N)	Assigned	ATPTN
ATPTREF	Analysis Timepoint Reference	Derived	ATPTREF
PARAMN	Parameter (N)	Assigned	ADPD.PARAMN

3

STUDYID
USUBJID
SUBJID
SITEID
SEX
FASFL
SAFFL
ITTFL
DDSEQ
DDTESTCD
DDTEST
DDORRES
DDSTRESC
ASEQ
TRTP
TRTPN
TRTA
TRTAN
ADT
ADY
ATM
ADTM
AVISIT
AVISITN
ATPT
ATPTN
ATPTREF
PARAMN
PARAM
PARAMCD
PARCAT1
PARCAT1N
AVAL
AVALC

Source: Assigned

Origin:

Type: Num

Display Format / Length: 8

Add Custom Var

Codelist: ADPD.PARAMN

View Codelists

Codelist Added

Edit/Create Codelist

Delete Multiple

Auto Populate:

Delete Variable

Programming Derivation: See Codelist.

Variable Order

Define-XML Comment: Parameter Number in order to more easily sort and present as required

ADRG:

Update Var Across

CDISC ADaM IG Comment: A numeric representation of PARAM. Useful for ordering and programmatic manipulation. There must be a one-to-one mapping to PARAM within a dataset.

Next

ADPD Variables Loaded.

1 Select Dataset

2 Select Section or Variable

3 Select Variable to Edit

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance – Add ADaM Variables

Add Additional ADaM Variable(s)

Select ADaM Domain: **ADEG** User Name **Gustav Bernard** Select Additional Variables to keep

☐	AWRANGE	Analysis Window Valid Relative Range	Timing and Visit Variables	WINDOW	ADaM
☐	AWTARGET	Analysis Window Target	Timing and Visit Variables	WINDOW	ADaM
☐	AWTDIFF	Analysis Window Diff from Target	Timing and Visit Variables	WINDOW	ADaM
☐	AWLO	Analysis Window Beginning Timepoint	Timing and Visit Variables	WINDOW	ADaM
☐	AWHI	Analysis Window Ending Timepoint	Timing and Visit Variables	WINDOW	ADaM
☐	AWU	Analysis Window Unit	Timing and Visit Variables	WINDOW	ADaM
☒	BASE	Baseline Value	Variable Included in Domain	BASE	ADaM
☒	BASEC	Baseline Value (C)	Variable Included in Domain	BASEC	ADaM
☒	BASECAT1	Baseline Category 1	Baseline and Change from Baseline Variables	BASECAT1	ADaM
☒	BASECA1N	Baseline Category 1 (N)	Baseline and Change from Baseline Variables	BASECA1N	ADaM
☐	BASECAT2	Baseline Category 2	Baseline and Change from Baseline Variables	BASECAT2	ADaM
☐	BASECA2N	Baseline Category 2 (N)	Baseline and Change from Baseline Variables	BASECA2N	ADaM
☐	BASETYPE	Baseline Type	Baseline and Change from Baseline Variables	BASETYPE	ADaM
☒	CHG	Change from Baseline	Variable Included in Domain	CHG	ADaM
☐	CHGCAT1	Change from Baseline Category 1	Baseline and Change from Baseline Variables	CHGCAT1	ADaM
☐	CHGCAT1N	Change from Baseline Category 1 (N)	Baseline and Change from Baseline Variables	CHGCA1N	ADaM
☐	CHGCAT2	Change from Baseline Category 2	Baseline and Change from Baseline Variables	CHGCAT2	ADaM
☐	CHGCAT2N	Change from Baseline Category 2 (N)	Baseline and Change from Baseline Variables	CHGCA2N	ADaM
☒	PCHG	Percent Change from Baseline	Variable Included in Domain	PCHG	ADaM
☐	PCHGCAT1	Percent Chg from Baseline Category 1	Baseline and Change from Baseline Variables	PCHGCAT1	ADaM
☐	PCHGCA1N	Percent Chg from Baseline Category 1 (N)	Baseline and Change from Baseline Variables	PCHGCA1N	ADaM
☐	PCHGCAT2	Percent Chg from Baseline Category 2	Baseline and Change from Baseline Variables	PCHGCAT2	ADaM
☐	PCHGCA2N	Percent Chg from Baseline Category 2 (N)	Baseline and Change from Baseline Variables	PCHGCA2N	ADaM
☒	ABLFL	Baseline Record Flag	Variable Included in Domain	ABLFL	ADaM
☐	ABLFN	Baseline Record Flag (N)	Baseline and Change from Baseline Variables	ABLFN	ADaM
☐	ANRIND	Analysis Reference Range Indicator	Toxicity and Range Variables	ANRIND	3
☐	BNRIND	Baseline Reference Range Indicator	Toxicity and Range Variables	BNRIND	3
☐	ATOXGR	Analysis Toxicity Grade	Toxicity and Range Variables	TOX	3
☐	ATOXGRN	Analysis Toxicity Grade (N)	Toxicity and Range Variables	TOX_N	3
☐	BTOXGR	Baseline Analysis Toxicity Grade	Toxicity and Range Variables	B_TOX	3

Add Variables Next

Select ADaM Domain to Edit

ADSL Template will be loaded if ADSL Selected and BDS, BDS TTE or ODS Template will be selected if BDS, BDS TTE or ODS Domain is Selected.

Variables included in spec will be checked and highlighted and you wont be able to deselect these.

Select Any Variables from the list to be added.

Click **Add Variables** to Add Selected Variable(s) to the Spec.

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance – View Edit Codelists

Edit Study Codelists

Select Codelist to Modify: (Y)

Select Code to Edit:

Codelist	CODE	DECODE	ORDER	Codelist Name
(Y)	Y	Yes	1	Yes Only Response

To Add a New Term Select an Empty Row and Add New Term details below

Codelist Label: Yes Only Response

Code: Y

Decode: Yes

Order: 1

NCI Code

Codelist: C66742

Term: C49488

Codelist Used for the Following Variables or VLM Tests:

- (1) ADEG-ABLFL
- (2) ADEG-ANL01FL
- (3) ADEG-ONTRTFL
- (4) ADEG-LVOTFL

To Update a Codelist Click on the Row to update and make the needed updates in the Text Boxes.
To Add a Row Code Click on a Empty Row and just enter the details in the Text Boxes.

Remove

Next

Select Codelist

1

Edit any of these fields

Remove Row

Variables using selected Codelist.

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance – Refresh ADSL Vars

TAB Training_GB0001 - ADaM SPEC Generator

ADaM Spec Generator

User Name: Gustav Bernard Exit

Link: ADaM IG 1.1

Path to Eval_SDTM Excel file:
\\quintiles.net\Enterprise\Apps\sasdata\StatOpB\CSV\ADaM Spec Generator\Config\Template

SDTM Analysis

ADaM Modifications

Dataset Information

ADaM Name:

View/Edit Variables **Refresh ADSL Vars** **Reselect\Add SDTM or ADSL Variables**

Add ADaM Variables **View/Edit Codelists**

Study Information

Refresh SDTM **Core ADSL Variables** **ADaM Variable Order**

Define-XML Features

Select Define-XML Feature Run

Files Needed:
SAP, TLF Shells,
SDTM Datasets,
EvalSDTM.sas & ADRG

Eval_SDTM.sas Macro needs to be run on SDTM datasets Prior to starting if available.

5 Refresh ADSL Variables:
Checks if all ADSL Variables referenced in other domains is present in ADSL.

6 Reselect\Add SDTM or ADSL Variables:
Can be used from here to either add additional SDTM variables or select any Non Core ADSL variables to include in an Spec.

7 Reselect Core ADSL Variables
that will be Retained in Each of the BDS and ODS Domains.

8 Update the **order** in which variables will be presented in the spec.

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance – ADSL Core Variables

TAB Training_GB0001 - Modify ADSL Core Variables

Back **Update ADSL Core Variables** **Exit**

*Indicate Which Variables should be set to be Core Variables.
Variable carried forward in other Domains.*

☐ Variable	Label
☒ STUDYID	Study Identifier
☒ USUBJID	Unique Subject Identifier
☐ SUBJID	Subject Identifier for the Study
☐ SITEID	Study Site Identifier
☐ AGE	Age
☐ AGEU	Age Units
☐ SEX	Sex
☐ RACE	Race
☐ AGEGR1	Pooled Age Group 1
☐ AGEGR1N	Pooled Age Group 1 (N)
☐ AGEGR2	Pooled Age Group 2
☐ AGEGR2N	Pooled Age Group 2 (N)
☐ AAGE	Analysis Age
☐ BRTHDTC	Date/Time of Birth
☒ FASFL	Full Analysis Set Population Flag
☒ SAFFL	Safety Population Flag
☒ ITTFL	Intent-To-Treat Population Flag
☐ ARM	Description of Planned Arm
☐ ARMCD	Planned Arm Code
☐ ACTARM	Description of Actual Arm
☐ ACTARMCD	Actual Arm Code
☒ TRTO1P	Planned Treatment for Period 01
☒ TRTO1PN	Planned Treatment for Period 01 (N)

Progress:
Select ADSL Complete to complete ADSL Specification.

Run
Update Core Variables

Select **Core ADSL** variables to be retained in all ADaM domains. Then click Run to process, and Update Core Variables to implement change.

ADaM Spec Generator [ASG] Process

ADaM Specification Maintenance

Variable Order

Dataset or Section Variable Order Update

☐ Update Default BDS\ODS Section Order

☐ Update Dataset Variable Order within Each Section

☒ Update\Review Final Variable Order

Select ADaM Domain: **ADEG**

Specify New Row Number for Variable

1	STUDYID	ADSL Variable
2	USUBJID	ADSL Variable
3	FASFL	ADSL Variable
4	SAFFL	ADSL Variable
5	ITTFL	ADSL Variable
6	TRTO1P	ADSL Variable
7	TRTO1PN	ADSL Variable
8	TRTO1A	ADSL Variable
9	TRTO1AN	ADSL Variable
10	TRTSDTM	ADSL Variable
11	TRTEDTM	ADSL Variable
12	EGSEQ	Sequence Number SDTM Variables
13	EGTESTCD	ECG Test or Examination Short Name SDTM Variables
14	EGTEST	ECG Test or Examination Name SDTM Variables
15	EGORRES	Result or Finding in Original Units SDTM Variables
16	EGORRESU	Original Units SDTM Variables
17	EGSTRESC	Character Result/Finding in Std Format SDTM Variables
18	EGSTRESN	Numeric Result/Finding in Standard Units SDTM Variables
19	EGSTRESU	Standard Units SDTM Variables
20	ASEQ	Analysis Sequence Number Dataset Initialize
21	TRTP	Planned Treatment Record-level Variables
22	TRTPN	Planned Treatment (N) Record-level Variables
23	TRTA	Actual Treatment Record-level Variables
24	TRTAN	Actual Treatment (N) Record-level Variables
25	ASTDT	Analysis Start Date Timing and Visit Variables
26	ASTDY	Analysis Start Relative Day Timing and Visit Variables
27	AENDT	Analysis End Date Timing and Visit Variables
28	AENDY	Analysis End Relative Day Timing and Visit Variables
29	ASTTM	Analysis Start Time Timing and Visit Variables

Up

Down

Next

Options Available

1. Update Default ADLS \ BDS \ ODS Section Order
2. Update Dataset Variable order within Each Section
3. Update\Review Final Variable Order

Specify New Row Number for Variable can be used to speed up changing of variable order.

Variable Order that variables will be displayed in the spec and ADaM Dataset.

Verify Process

What's New

VLM Verify

- Will cross check and update PARCATs, PARAM, PARAMN against values found in ADaMs
- Will inform you if some parameters are missing from the VLM spec versus what is found in the ADaMs (normally we will expect all parameter to be included in the VLM)
- Will inform you if some parameters are in the VLM specs but not in the ADaMs, this is not necessarily an issue, but you might want to review those Parameters
- Allow you so sort the VLM by your preferred order.

Resizing Dataset

- This option will create a resized version of your ADaMs

Create XPT

- You will be able to convert ADaM sas dataset to xpt format within ASG Verify.

Importing the Verify Output

VLOG_ASG VLOG - ADaM SPEC Generator

ADaM Spec Generator

User Name: Exit

Link: ADaM IG 1.1

Path to Eval_SDTM Excel file:

BDS Generator ODS Generator SDTM Analysis
VLM Generator Clone Generator

ADaM Modifications

Dataset Information

View/Edit Variables Refresh ADSL Vars
Add ADaM Variables Reselect/Add SDTM or ADSL Variables
View/Edit Codelists

ADaM Name:

Study Information

Refresh SDTM
Core ADSL Variables
ADaM Variable Order

Define-XML Features

Run

Files Needed:
SAP, TLF Shells,
SDTM Datasets,
EvalSDTM.sas & ADRG

Eval_SDTM.sas Macro needs to be run on SDTM datasets Prior to starting if available.

Verify Specs vs Data (ASG_Verify.sas)
Click Run

Define-XML Features

Run

Browse to the Location of the
Verify.xlsx and select the file:

Please select Verify.xlsx

Solution Providers > General > ADaM > VBA > Dev > Config > Template > VERIFY

Name	Date modified	Type	Size
Data	6/27/2019 11:39 AM	File folder	
Specs	7/22/2019 1:28 PM	File folder	
Testing	7/30/2019 11:42 AM	File folder	
Validation	7/24/2019 4:02 PM	File folder	
Look	7/19/2019 1:11 PM	Microsoft Excel W...	50 KB
Verify Look	7/19/2019 3:47 PM	Microsoft Excel W...	50 KB
Verify	7/22/2019 1:36 PM	Microsoft Excel W...	49 KB
Verify_	6/5/2019 3:28 PM	Microsoft Excel W...	65 KB
VerifyLL	7/19/2019 3:32 PM	Microsoft Excel W...	50 KB

File name: Verify All Files

OK Cancel

From Define-XML Features

Click OK to Continue

Verify Process Auto Update Tab

Verify Specification vs ADaM SAS Datasets

Dataset Info

Dataset Updates **

Variable Info

Variable Update Info

Variable Updates **

Variable Codelists

VLM Info

VLM Update Info

VLM Updates **

VLM Codelists

☐	DATASET	VARIABLE	nLABEL	nTYPE	nFORMAT	nCodelist
☒	ADAE	ADYC		text	9	
☒	ADAE	AEACN		text	9	(ACN)
☒	ADAE	AEBODSYS		text	67	
☒	ADAE	AEDECOD		text	48	
☒	ADAE	AEDIS		text	48	
☒	ADAE	AEENDTC		text	48	
☒	ADAE	AEENRF		text	48	(STENRF)
☒	ADAE	AEOU		text	48	(OU)
☒	ADAE	AEREL		text	48	AEREL
☒	ADAE	AESEQ		integer	48	
☒	ADAE	AESE		text	48	(NY)
☒	ADAE	AESEV		text	48	(AESEV)
☒	ADAE	AESOC		text	48	
☒	ADAE	AESTDTC		text	48	
☒	ADAE	AETERM		text	48	
☒	ADAE	AOCCO9FL		text	48	
☒	ADAE	AOCCO10FL		text	48	
☒	ADAE	AOCCO11FL		text	48	
☒	ADAE	AOCCO12FL		text	48	
☒	ADAE	AOCCO13FL		text	48	
☒	ADAE	AOCCO14FL		text	48	
☒	ADAE	AOCCO15FL		text	48	
☒	ADAE	AOCCO16FL		text	48	
☒	ADAE	AREL		text	9	
☒	ADAE	ARELN		integer	9	
☒	ADAE	ASEV		text	8	

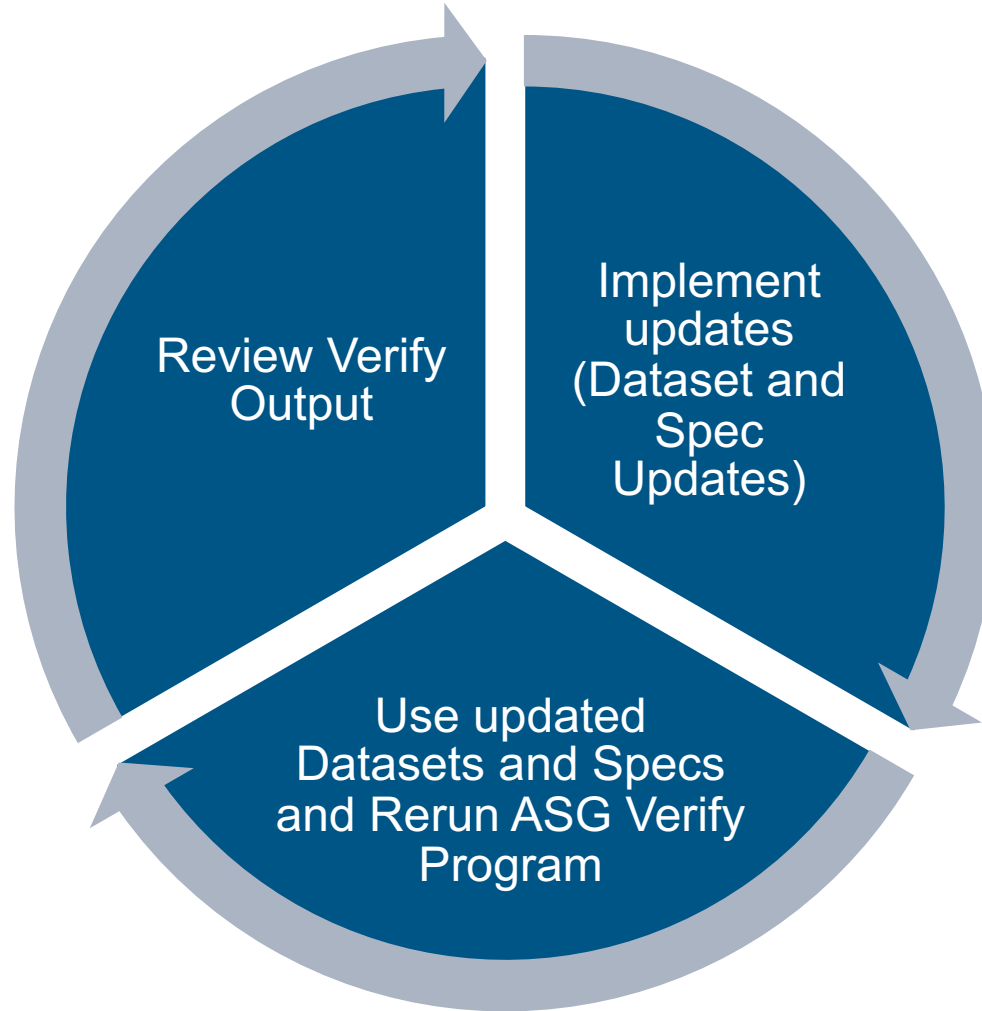
Click Run to update Specification to match ADaM variable attributes.

Click Run to Update Selected

Run

Dataset, Variable
and VLM **Updates**
**** tabs** can be used
to make automatic
updates the spec.

Verify Process



Auto Update can be used to update Specification.

Data Driven Codelist can be created using the Verify Process.

Hyperlinking

VARIABLE AND VLM LINKING

- Using the Manage Variable Level and VLM Links Form.
- From the Start Screen Select Manage Variable Level and VLM Links option from the Combobox.
- Note you might need to scroll down the selection list.
- Click Run.
- The ADRG and External Document Linking Form will show:

Define-XML Features

Manage Variable Level and VLM Links

Run

ASGSupport_Linking - ADaM Spec Generator [ASG] ADRG and External Document Linking

ADRG and External Document Links:

Dataset	Variable	PARAMCD	ADRG Page	Additional Document	Additional Document Page
ADAE	ANL01FL		add link	ctcae	5
ADAE	ONTRTFL		15	SHOW	12
ADAE	SMQ01CD		13		
ADAE	SMQ01SCH		15	SHOW	12
ADAE	TRTEMFL		12		
ADEQ	AVALC	INTP	77	SHOW	
ADQS	PARAMTYP		997		
ADQS	AVAL	BNSSAV0	dd		
ADQS	AVAL	BNSSBLU	dd		
ADRS	ANL02FL		9999	ctcae	2
ADRS	AVISIT		777	SHOW	2
ADRS	CRIT4		66	SHOW	2
ADRS	PARAMN			test	
ADRS	SEX		9999	ctcae	2
ADRS	TRTAN			ctcae	44
ADRS	AVAL	PANST0T		ctcae	2
ADRS	AVAL	PANSSP0S		ctcae	2
ADRS	AVAL	PANSSNEG		ctcae	2
ADRS	AVAL	PANSSGEN		ctcae	2
ADRS	AVAL	PANPOS5F		ctcae	2
ADRS	AVAL	PANNEG5F		ctcae	2
ADRS	AVAL	PANDIS5F		ctcae	2
ADRS	AVAL	PANH0S5F		ctcae	2
ADRS	AVAL	PANANX5F		ctcae	2
ADRS	AVAL	PANSTP0S		ctcae	2
ADRS	AVAL	PANSTDIS		ctcae	2
ADRS	AVAL	PANSTNAA		ctcae	2
ADRS	AVAL	PANSTNDE		ctcae	2
ADRS	AVAL	PANSTH0S		ctcae	2
ADRS	AVAL	PANSTANX		ctcae	2
ADRS	AVAL	PANSTDEP		ctcae	2
ADRS	AVAL	PANSTT0T		ctcae	2
ADSL	DCSREAS		55		

Add Additional Reference Document

☐ Add Variable Level Link
☐ Add VLM Level Link

Add Additional Variable or VLM Links

Next

ADaM Spec Generator [ASG] Process

Create Define-XML

Define-XML Features

Create Define-XML 2.0 (xml file)

Run

- From the Start Screen
- Select **Create Define-XML 2.0 (xml file)**
- From the Define-XML Features
- Click Run

Move Stylesheet from the Downloaded package folder to the Specification\ADaM folder prior to opening the define.xml in Internet Explorer. File Name: **define2-0-0.xsl**

You can **create** a new define-xml at **any time**.

VLOG_ASG VLOG - ADaM SPEC Generator

ADaM Spec Generator

User Name: Gustav Bernard **Exit**

Link: ADaM IG 1.1

Path to Eval_SDTM Excel file:
\\quintiles.net\enterprise\Organization\Biostatistics\Business Solutions\Solution Providers\General\ADaM\VBA\Dev\Config\Template

SDTM Analysis

BDS Generator ODS Generator
VLM Generator Clone Generator

ADaM Modifications

ADaM Name:

Dataset Information View/Edit Variables Refresh ADSL Vars
Add ADaM Variables Reselect/Add SDTM or ADSL Variables
View/Edit Codelists

Study Information

Refresh SDTM
Core ADSL Variables
ADaM Variable Order

Files Needed:
SAP, TLF Shells,
SDTM Datasets,
EvalSDTM.sas & ADRG

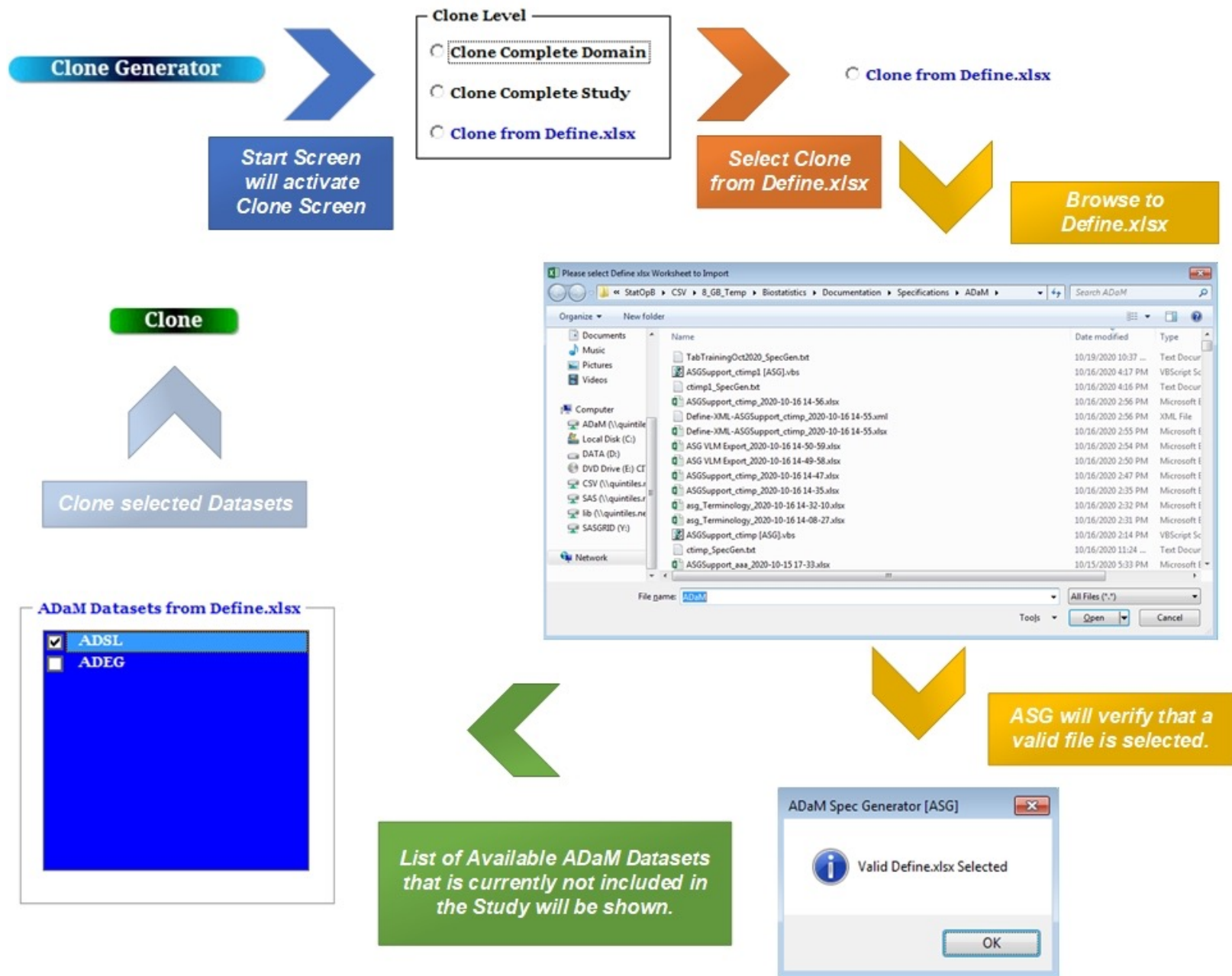
Define-XML Features

Create Define-XML 2.0 (xml file) **Run**

Eval_SDTM.sas Macro needs to be run on SDTM datasets Prior to starting if available.

define2asg

Process



Metadata Farm



Dataset Level Attributes



Variable Level Attributes



Variable Level Values



Parameter Level Values



Consistency Statistics



Create Data Driven IQVIA, Sponsor & Therapeutic Area Standards

- Standard ADaM Datasets
- Standard Variables by Domain
- Custom ADaM Variables
- Standard Variable Values
- Parameter Analysis
- BDS Categorization



Tips and Tricks

Plan your Spec Creation

Go Through	Go Through SAP and Shells for the Study
Assign	Assign ADSL to Resource most familiar to SAP and Shells
Evaluate	Evaluate SAP and Shells to determine List of ADaM Domains needed for Study
Determine	Determine Datasets as BDS or ODS
Classify	Classify BDS Datasets • Input for Dataset • Baseline Variables Needed • Criteria or CTCAE Variables Needed

Assign ODS datasets to the same Resource to spec.

Assign Similar BDS datasets to the same Resource

Tips and Tricks

Classify BDS ADaM Datasets



Inputs for Domain

- a) Parameters Assigned from SDTM Only
- b) Parameters Assigned from SDTM and New Derived Tests
- c) New Derived Parameters Only

Baseline Variables Needed

- a) Yes
- b) No

Criteria or CTCAE Variables Needed

- a) Yes
- b) No

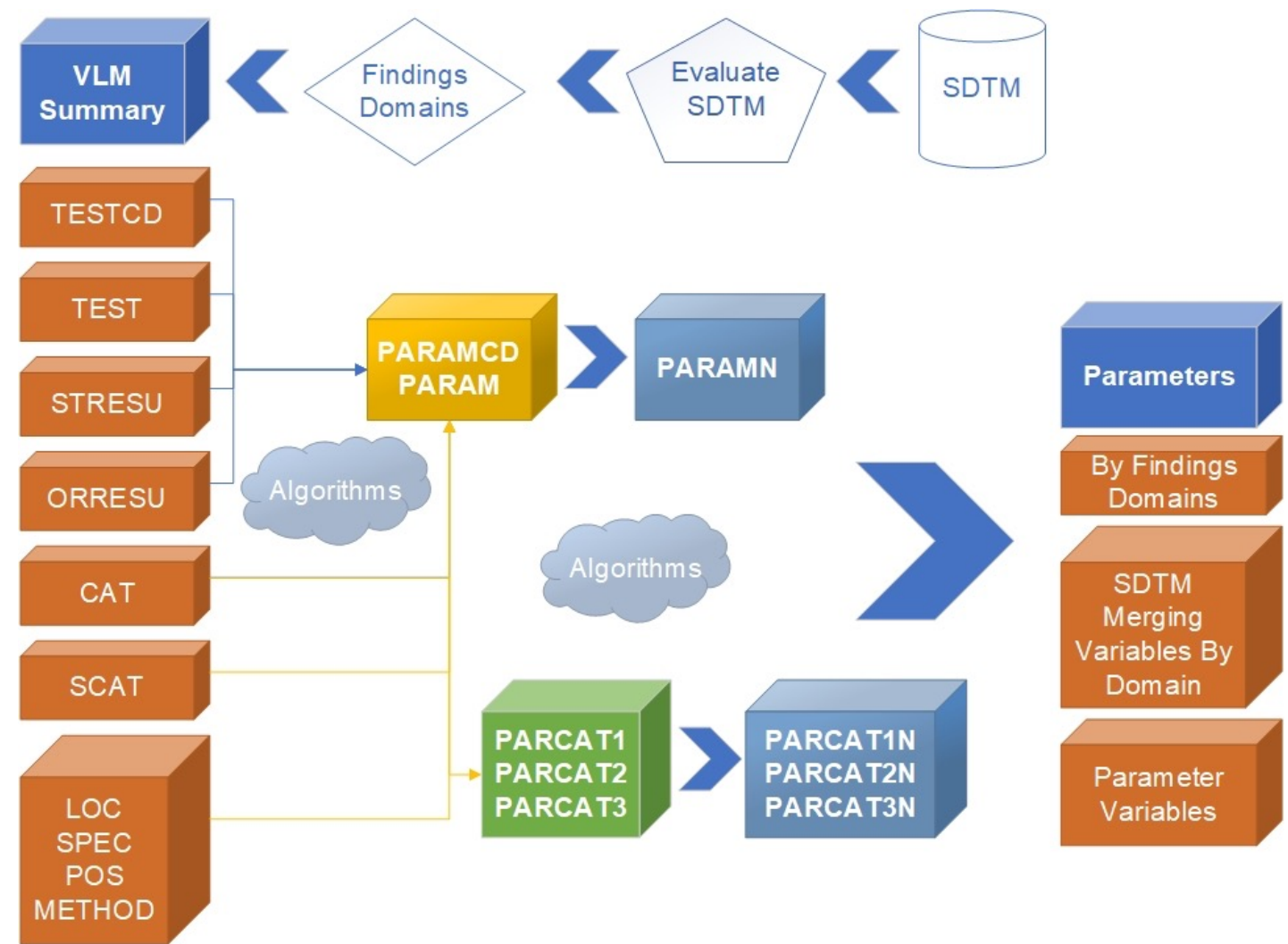
ADaM Generator Tool

ADaM Code Generator

- ADaM Automation SAS Macros
 - SDTM Input Macro
 - Datetime Macro
 - Assigned Variables Macro
 - ASGconvert Macro
 - Automated Flag Macro
 - ...
- ADaM Automation Processes
 - Parameters Process
 - CRITx Process
 - CTCAE Process

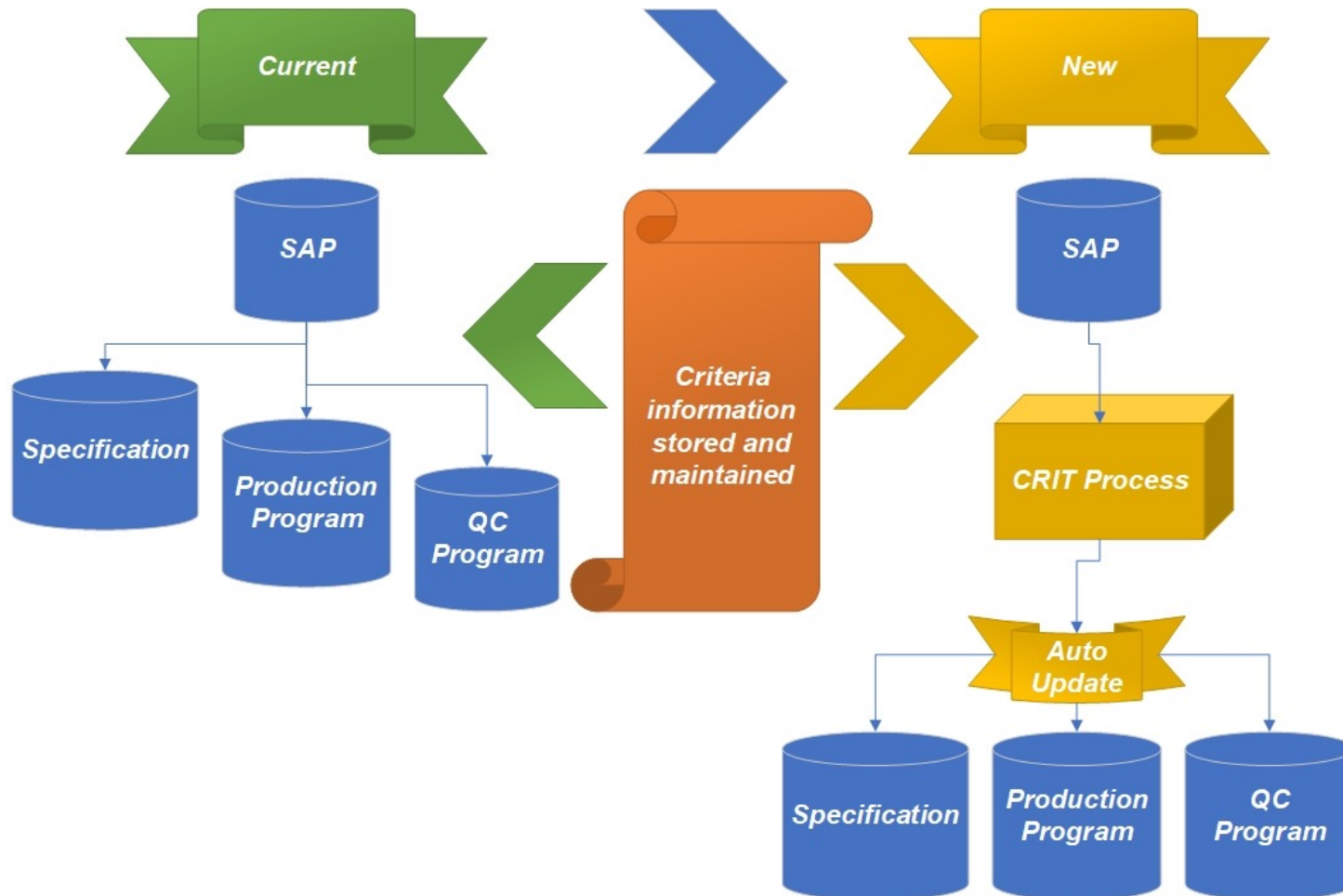
**Both New Processes and
Macros needed to be
introduced.**

Parameter Process



Automation Processes

CRIT Process



Process to Decrease the amount of Files that Store and Maintain Criteria information.

ADaM Generator Tool

- Gustav.Bernard@iqvia.com