



PHUSE EU Connect Hamburg

TT12

Pooling Studies Through Code Traceability

Hamdi Chouikha & Kornelius Neufeld

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Agenda

- // Pooling at Bayer
- // Verisian Pooler
 - // Pool Planner
 - // ADaM Planner
- // Outlook/ What is next?



Pooling at Bayer



Pooling at Bayer

- // Integrated analysis (IA) is the evaluation based on a database (GIAD) that contains several studies of a project/compound.
- // GIAD: **G**lobal **I**ntegrated **A**nalysis **D**atabase, also called “Pool”, where all the data of the single studies are stored in a standardized and harmonized way.
- // Challenges of IA
 - // different data sources and structures
 - // different study designs
 - // different approaches/derivations
- // Pooling concepts
 - // SDTM+ Pooling
 - // ADaM Pooling
- // Presentation of Joerg Guettner (PHUSE EU Connect Budapest 2012)
 - // https://phuse.s3.eu-central-1.amazonaws.com/Archive/2012/Connect/EU/Budapest/PAP_CD01.pdf

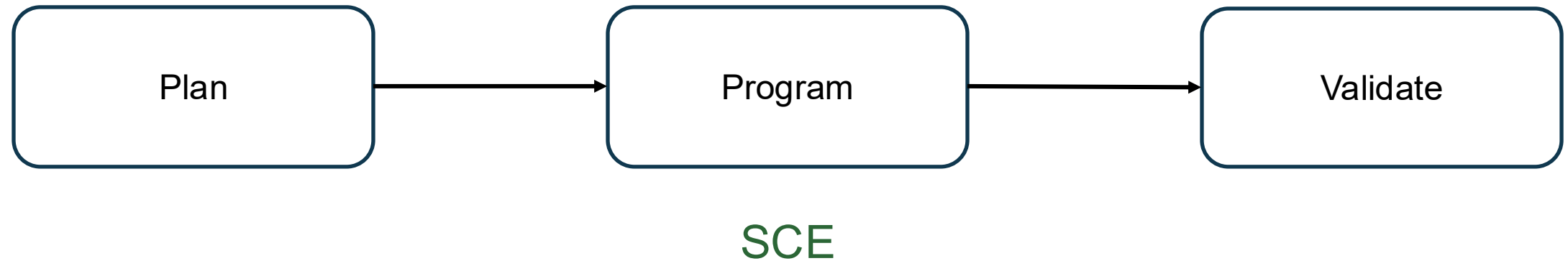


Verisian Pooler – Pool Planner



Verisian Pooler

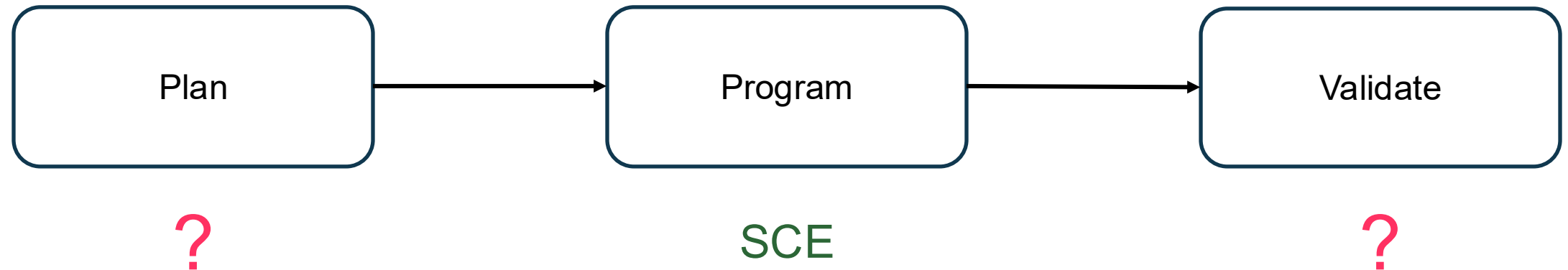
The end-2-end process





Verisian Pooler

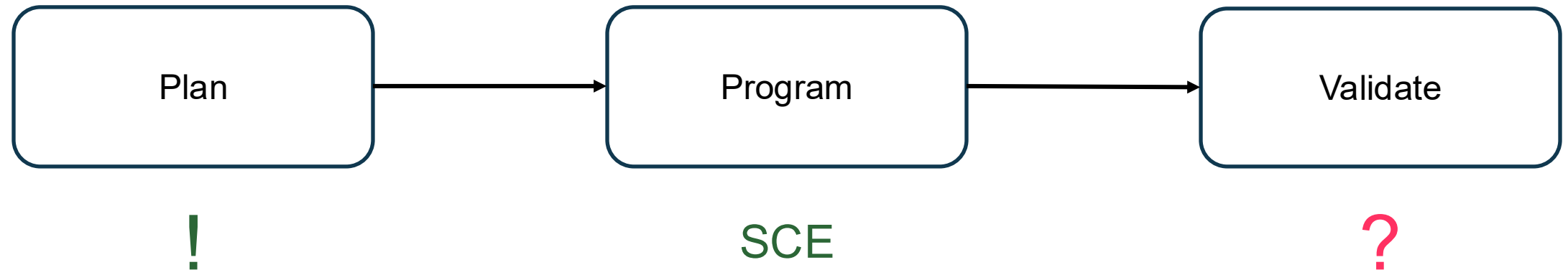
The end-2-end process





Verisian Pooler

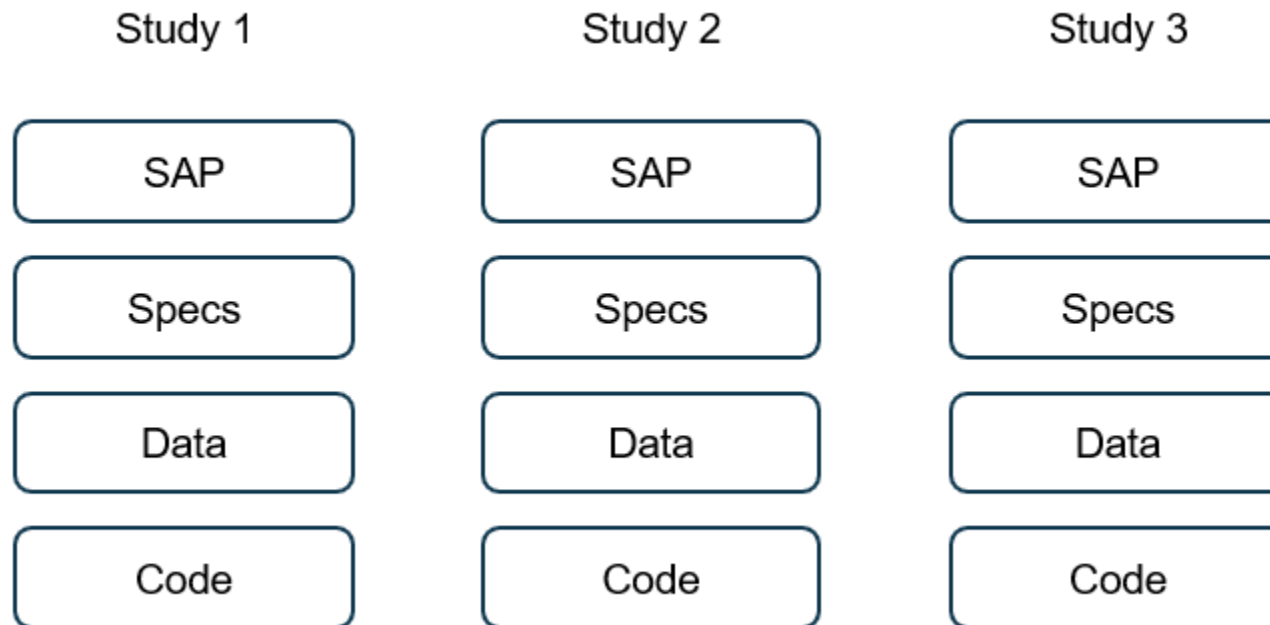
The end-2-end process





Verisian Pooler

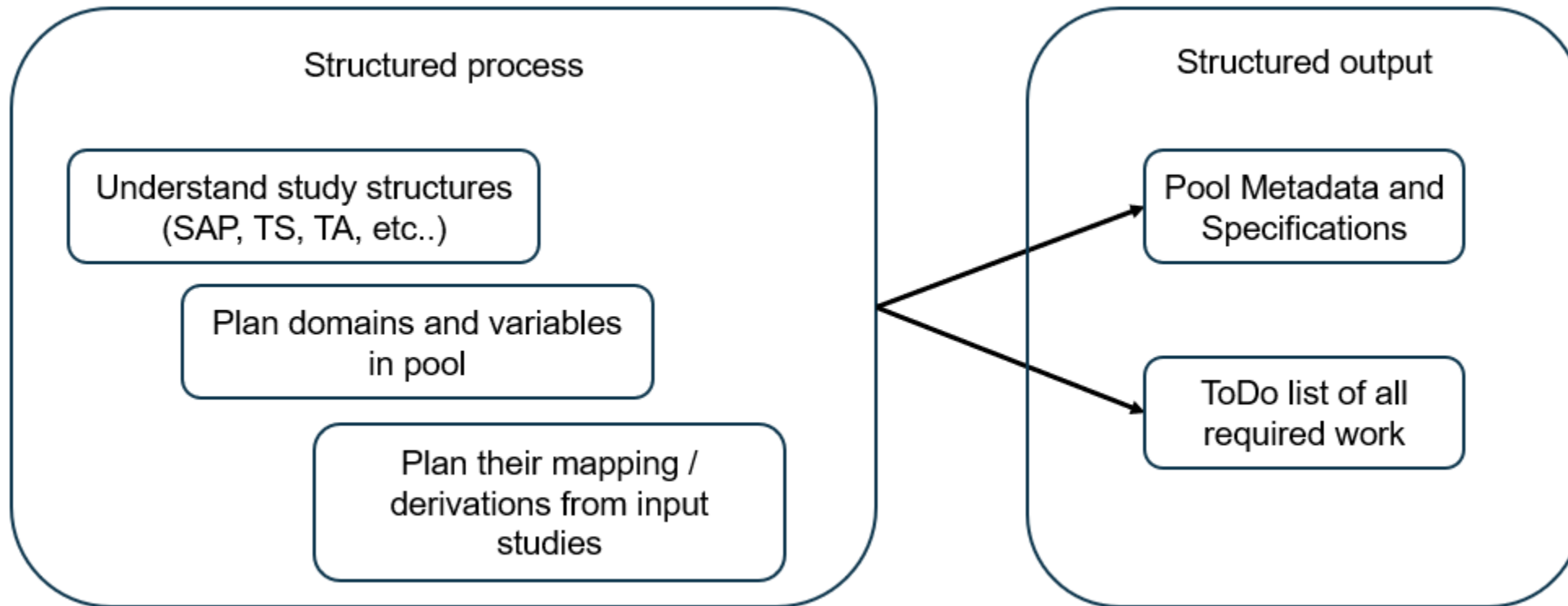
Pool Planning (SDTM+/ ADaM) – required information





Verisian Pooler

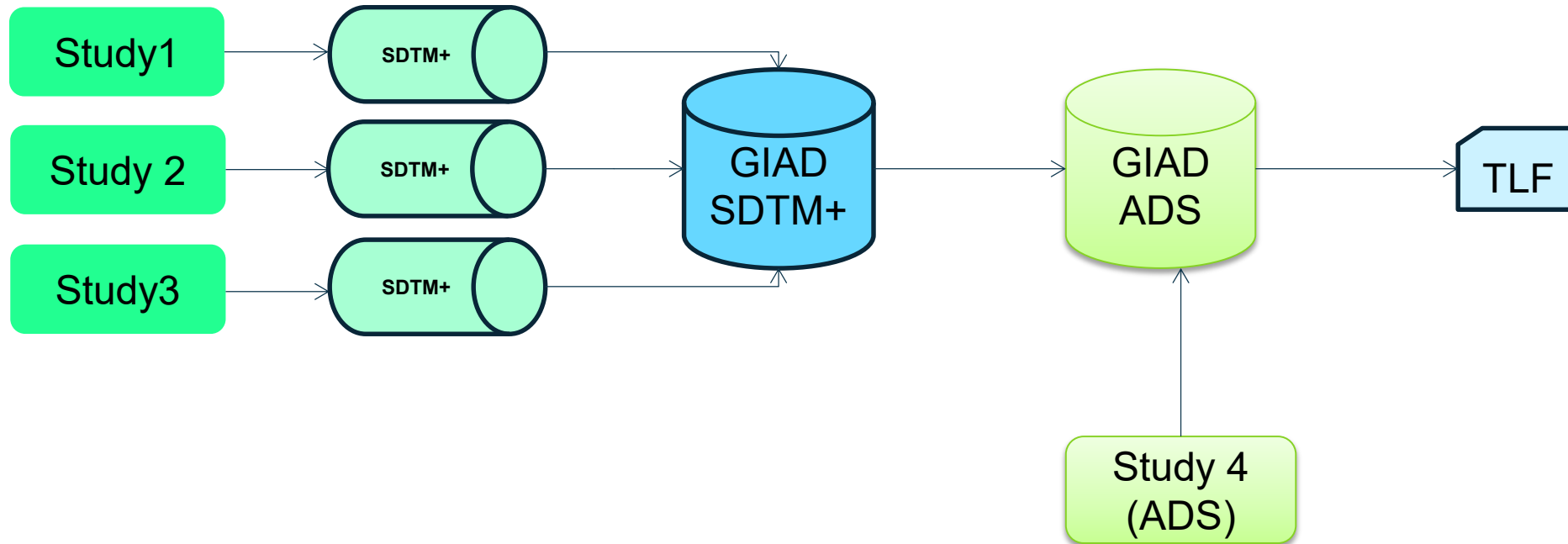
Pool Planning (SDTM+/ ADaM) – process and output





Verisian Pooler

Pooling use case: SDTM+ and ADaM pooling





Verisian Pooler

Trial Summary (TS) Comparison



Pool planning

Study pool planner - Target Pool - ADaM

Source Pool 21140

Highlight differences

Trial summary overview						
Source Pool 21140						
TSPARMCD	TSPARM	TSVAL	TSVALCD	TSVAL	TSVALCD	
CTCAEV	Common Terminology Criteria AE Version	4.03		5		5
MEDDRAV	MedDRA Version	23.1		27.0		
WHODDV	WHO-DD Version	2020SEP		2024MAR		
Actual Number of						



Verisian Pooler

Planning which data sets to include in the pool



Pool planning

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Planning

Datasets

Variables

Specification

Datasets planning

In progress (25)
Planned (0)
Excluded (0)

Q Search datasets...

Exclude from pool metadata

Plan	Dataset	Source Pool	21140	Variables overlap	Unresolved differences
☐	adae	✓	✓	23%	VARIABLE MISMATCH 200
☐	adcm	✓	✓	20%	VARIABLE MISMATCH 144
☐	adds	✓	✓	29%	VARIABLE MISMATCH 44
☐	addv	✗	✓	-	DATASET MISMATCH
☐	adegf	✗	✓	-	DATASET MISMATCH
☐	adegm	✓	✓	26%	VARIABLE MISMATCH 114
☐	adex	✓	✓	23%	VARIABLE MISMATCH 89
☐	adexp	✗	✓	-	DATASET MISMATCH
☐	adexsum	✗	✓	-	DATASET MISMATCH
☐	adlb	✓	✓	32%	VARIABLE MISMATCH 153
☐	adlbctc	✗	✓	-	DATASET MISMATCH



Verisian Pooler

Planning which data sets to include in the pool



Pool planning

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Datasets planning

In progress (10) Planned (0) Excluded (15)

Search datasets... Exclude from pool metadata

Plan	Dataset	Source Pool	21140	Variables overlap	Unresolved differences
☐	adae	✓	✓	23%	VARIABLE MISMATCH 200
☐	adcm	✓	✓	20%	VARIABLE MISMATCH 144
☐	adds	✓	✓	29%	VARIABLE MISMATCH 44
☐	adegm	✓	✓	26%	VARIABLE MISMATCH 114
☐	adex	✓	✓	23%	VARIABLE MISMATCH 89
☐	adlb	✓	✓	32%	VARIABLE MISMATCH 153
☐	adlnh	✓	✓	44%	VARIABLE MISMATCH 45
☐	adqsecog	✓	✓	24%	VARIABLE MISMATCH 112
☐	adsl	✓	✓	19%	VARIABLE MISMATCH 285
☐	advs	✓	✓	24%	VARIABLE MISMATCH 103

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Datasets planning

In progress (10) Planned (0) Excluded (15)

Excluded datasets are not considered in the final study pool metadata.
To exclude datasets, select them and use the "Exclude from pool metadata" button in the In progress datasets table.

Include in pool metadata

Dataset	Source Pool	21140
☐ addv	✗	✓
☐ adegf	✗	✓
☐ adexp	✗	✓
☐ adexsum	✗	✓
☐ adlbctc	✗	✓
☐ adpr	✗	✓
☐ adqsbpi	✗	✓
☐ adqsfact	✗	✓
☐ adrs	✗	✓



Verisian Pooler

Planning your pool data sets



Pool planning

Study pool planner - Target Pool - ADaM

pre_pool 21140PC

Trial summary

Planning

Datasets

Variables

Specification

Datasets

Search datasets...

adac

adcm

adds

adegf

adegm

adex

adexsum

adib

adlbctc

admin

adqsecog

adsl

adsv

adts

advs

Variables planning

In progress (48) Planned (3) Excluded (11)

Search variables...

Exclude from pool metadata

Copy from study

Plan	Variable	pre_pool	21140PC	Metadata similarity	Unresolved differences
☐	aperiod	✓	✗	-	VARIABLE MISMATCH
☐	aperiodc	✓	✗	-	VARIABLE MISMATCH
☐	aphase	✓	✗	-	VARIABLE MISMATCH
☐	astdt	✓	✓	83%	METADATA MISMATCH 2
☐	astdtf	✓	✓	83%	METADATA MISMATCH 2
☐	astdy	✓	✗	-	VARIABLE MISMATCH
☐	asttm	✓	✗	-	VARIABLE MISMATCH
☐	asttmf	✓	✗	-	VARIABLE MISMATCH
☐	dsactfun	✓	✗	-	VARIABLE MISMATCH
☐	dscat	✓	✓	50%	METADATA MISMATCH 6
☐	dscatn	✓	✗	-	VARIABLE MISMATCH
☐	dscdcaoth	✓	✗	-	VARIABLE MISMATCH
☐	dscdcause	✓	✗	-	VARIABLE MISMATCH
☐	dscdcusen	✓	✗	-	VARIABLE MISMATCH



Verisian Pooler

Planning your pool data sets



Pool planning

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Planning

Datasets

Variables

Specification

Search datasets...

adæ

adcm

adds

adegm

adex

adib

admh

adqsecog

adsl

advs

Variables planning

In progress (50) Planned (0) Excluded (12)

Search variables... Exclude from pool metadata Copy from study

Plan	Variable	Source Pool	21140	Metadata similarity	Unresolved differences
☐	adsname	✓	✓	92%	METADATA MISMATCH
☐	amendno	✓	✓	75%	METADATA MISMATCH
☐	aseq	✓	✓	83%	METADATA MISMATCH
☐	astdt	✓	✓	75%	METADATA MISMATCH
☐	astdtf	✓	✓	75%	METADATA MISMATCH
☐	dscat	✓	✓	83%	METADATA MISMATCH
☐	dsdecod	✓	✓	83%	METADATA MISMATCH
☐	dsdecodn	✓	✗	-	VARIABLE MISMATCH
☐	dsepreli	✓	✓	75%	METADATA MISMATCH
☐	dsivny	✓	✗	-	VARIABLE MISMATCH
☐	dsivryn	✓	✗	-	VARIABLE MISMATCH

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Planning

Datasets

Variables

Specification

Search datasets...

adæ

adcm

adds

adegm

adex

adib

admh

adqsecog

adsl

advs

Variables planning

In progress (50) Planned (0) Excluded (12)

A variable that has been excluded will not be considered in the final study pool metadata.
To exclude variables, select them and use the "Exclude from pool metadata" button in the **In progress** variables table.

Include in pool metadata

Variable	Source Pool	21140
☐ aperiod	✓	✗
☐ aperiodc	✓	✗
☐ aphase	✓	✗
☐ astdy	✓	✗
☐ asttm	✓	✗
☐ asttmf	✓	✗
☐ aterm	✗	✓
☐ dsactfun	✓	✗
☐ dscatn	✓	✗



Verisian Pooler

Planning your variables - metadata



Pool planning

Study pool planner - Target Pool - ADaM
Source Pool 21140

ADaM > adds > astdtf
Unresolved differences METADATA MISMATCH 3

</> Metadata Data Code

	Target Pool	Source Pool	21140
Label	Analysis Start Date Imputation Flag	Analysis Start Date Imputation Flag	Analysis Start Date Imputation Flag
Computation type	1	1	5
Computation name	=%_adamap_ref(refvar=ASTDT)	=%_adamap_ref(refvar=ASTDT)	
Computation description	If ASTDT is imputed, the following rules apply: If year is imputed set to Y, otherwise if month is imputed set to M, otherwise if day is imputed set to D. If nothing was imputed keep empty.	If ASTDT is imputed, the following rules apply: If year is imputed set to Y, otherwise if month is imputed set to M, otherwise if day is imputed set to D. If nothing was imputed keep empty.	If ASTDT is imputed, the following rules apply: If day is imputed set to D. If nothing was imputed keep empty.
Format			
Codelists			
Type	c	c	c
Length			
Notes			
Order number	39	39	15
Significant digits			

Save metadata
Mark as planned

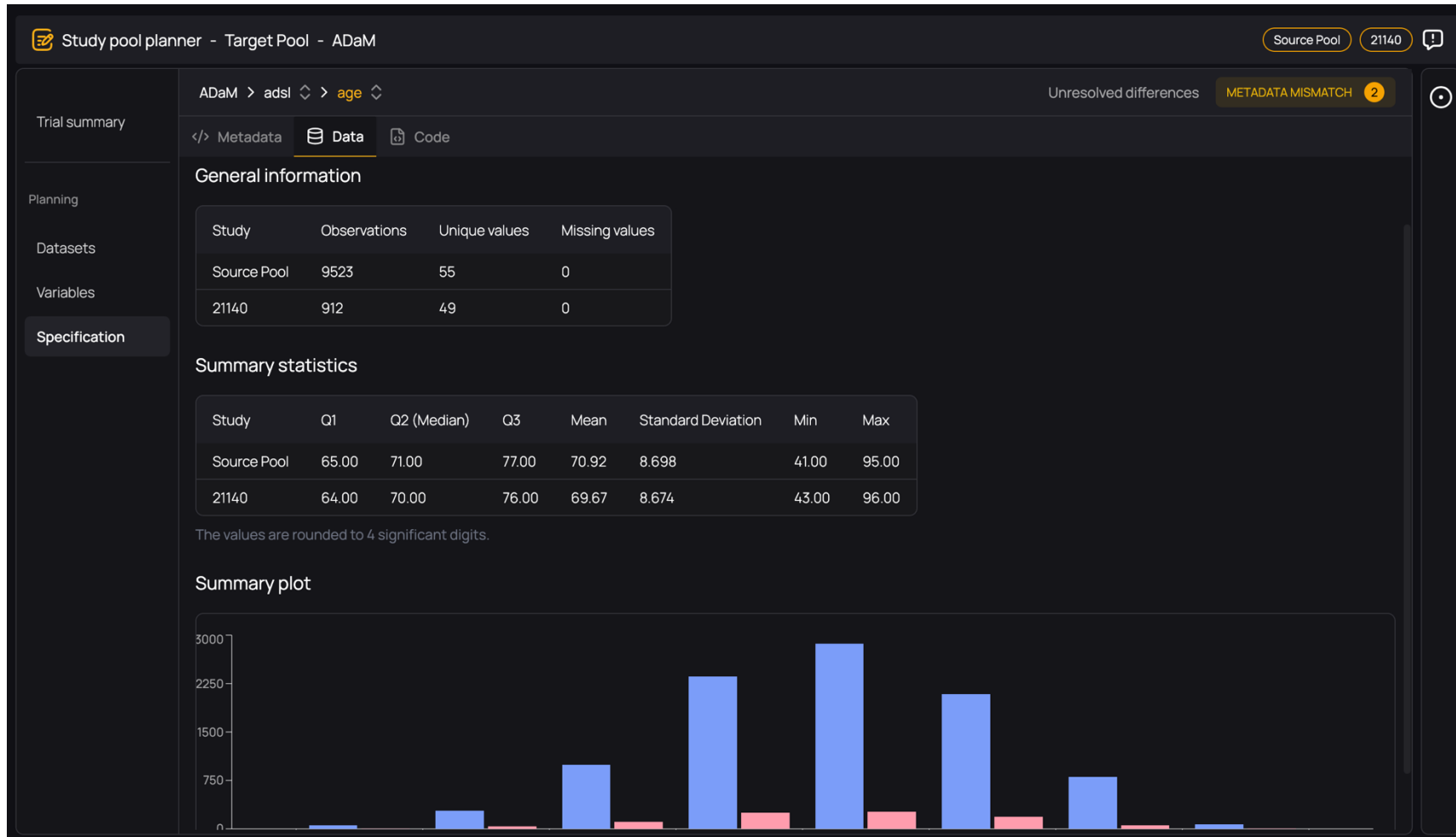


Verisian Pooler

Planning your variables - data



Pool planning





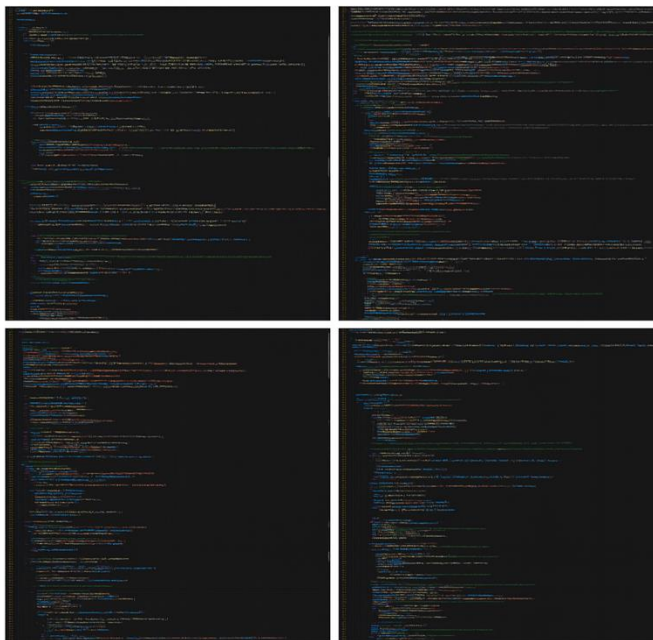
Verisian Pooler

Planning your variables - code

Health for all, Hunger for none



Pool planning



Study pool planner - Target Pool - ADaM

Source Pool 21140

Unresolved differences METADATA MISMATCH

ADaM > adds > astdtf

</> Metadata Data Code

Source Pool - Derivation

```
1 * #runall_ads1.log.sas;
2 %createADSDomain(adsDomain = ADDS, mergeads1=Y)
3
```

21140 - Derivation

```
33 aterm = substr(dsterm, 1, 1)||lowercase(substr(dsterm, 2));
34 aterm = tranwrd(aterm, 'covid', 'COVID');
35 aterm = tranwrd(aterm, 'psa', 'PSA');
36 end;
37 END;
38 /** ***** verisian: macro invocation start of
39 <date_imputation_mid> *****
40 *
41 * %date_imputation_mid(domain = DS , dttyp = ST)
42 *
43 ***** **/
43 if length(DSSTdtc) = 10 then do;
44   aSTdt = input(DSSTdtc, yymmdd10.);
45 end;
46 else if length(DSSTdtc) = 7 then do;
47   aSTdt = input(strip(DSSTdtc)||"-15", yymmdd10.);
48   aSTdtf = 'D';
49   if aSTdt>DCUTDT then aSTdt = DCUTDT;
50   if aSTdt>wdicdt. then do;
51     aSTdt = input(strip(DSSTdtc)||"-01", yymmdd10.);
52     if aSTdt>wdicdt. then put "WAR" "NING: check USUBJID WDI CD T
53       DSSTdtc" USUBJID WDI CD T DSSTdtc;
54   end;
55 end;
56 /** ***** verisian: macro invocation end of
57 <date_imputation_mid> *****
58 ***** **/
59 ;
60 RUN;
61 * d_adds.log.sas;
62 %late_ads_processing(adsdomain = ADDS)
```



Verisian Pooler

Planning your variables – process to complete metadata & ToDo list



Pool planning

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Planning

Datasets

Variables

Specification

Datasets

Search datasets...

adac

adcm

adds

adegm

adex

adib

admi

adqsecog

adsl

advs

Variables planning

In progress (47) Planned (3) Excluded (12)

Variables can be explicitly marked as planned once their metadata has been specified. Compare a variable in the In progress table to start planning its metadata.

Mark as not completed

Plan	Variable	Source Pool	21140
☐	aseq	✓	✓
☐	astdt	✓	✓
☐	astdtf	✓	✓

Study pool planner - Target Pool - ADaM

Source Pool 21140

Trial summary

Planning

Datasets

Variables

Specification

ADaM > adds > astdtf

No unresolved differences

</> Metadata Data Code

This variable has been marked as planned, but you can continue to edit its metadata.

	Target Pool	Source Pool	21140
Label	Analysis Start Date Imputation Flag	Analysis Start Date Imputation Flag	Analysis Start Date Imputation Flag
Computation type	1	1	5
Computation name	=%_admap_ref(refvar=	=%_admap_ref(refvar=ASTDT)	
Computation description	If ASTDT is imputed, the following rules apply: If year is imputed set to Y, otherwise if month is imputed set to M, otherwise if day is imputed set to D. If nothing was imputed keep empty.	If ASTDT is imputed, the following rules apply: If year is imputed set to Y, otherwise if month is imputed set to M, otherwise if day is imputed set to D. If nothing was imputed keep empty.	If ASTDT is imputed, the following rules apply: If year is imputed set to Y, otherwise if month is imputed set to M, otherwise if day is imputed set to D. If nothing was imputed keep empty.
Format			
Codelists			
Type	c	c	c

Save metadata Create work item for this variable

Search issues

Create issue

3 Open 1 Closed

Category	Severity	Assignees
Derive admh.adnam...	code	high
Derive adds.aseq (A...	code	high
Correct deri_way	metadata	high V

Create issue

Title

Derive adds astdtf (ADaM)

Description

Instructions:

Label: Analysis Start Date Imputation Flag

Computation type: 1

Category

Severity

Assignees

code high None

Create



Verisian Pooler

Outputs: Download metadata & track your ToDo list



Pool planning

ADAE	1	ADSNM	Dataset Name	C	5	X_ADSN	derived	Name of th	1	%_adamaj Req	1	A
ADAE	2	STUDID	#	#	#		SDTM			AE_STUDID #	1	A
ADAE	3	USUBID	#			Unique Par #	SDTM			AE_USUBID #	2	A
ADAE	4	AESQ	#				SDTM			AE_AESQ #		A
ADAE	5	AESQ	Analysis Set	N	5		derived	Calculated		4	%_adamaj Perm	A
ADAE	6	AESPID	#	#	#		SDTM			AE_AESPID #		A
ADAE	7	AESPID	#	#	#		SDTM			AE_AESPID #	3	A
ADAE	8	AELNKID	#	#	#		SDTM			AE_AELNKID #		A
ADAE	9	AETERM	#			Reported T #	SDTM			AE_AETERM #	6	A
ADAE	10	AETERM	#	#	#		SDTM	IF SUPPAC		AE_AETERM #		A
ADAE	11	AEMODIFY	#	#	#		SDTM			AE_AEMODIFY #		A
ADAE	12	AELTCD	#			Preferred T #	SDTM			AE_AELTCD #		A
ADAE	13	AELT	#	#	#		SDTM			AE_AELT #		A
ADAE	14	AELTCD	#	#	#		SDTM			AE_AELTCD #		A
ADAE	15	AELTCD	#			Preferred T #	SDTM			AE_AELTCD #		A
ADAE	16	AELT	#	#	#		SDTM			AE_AELT #		A
ADAE	17	AELTCD	#	#	#		SDTM			AE_AELTCD #		A
ADAE	18	AELTGT	#	#	#		SDTM			AE_AELTGT #		A
ADAE	19	AELTGT	#	#	#		SDTM			AE_AELTGT #		A
ADAE	20	AESOC	#	#	#		SDTM			AE_AESOC #		A
ADAE	21	AESOC	#	#	#		SDTM			AE_AESOC #		A
ADAE	22	AECAT	#	#	#		SDTM			AE_AECAT #		A
ADAE	23	AEBOSYS	#			Primary Sys #	SDTM			AE_AEBOSYS #		A
ADAE	24	AEBOSYS	#	#	#		SDTM			AE_AEBOSYS #		A
ADAE	25	AELC	#	#	#		SDTM			AE_AELC #		A
ADAE	26	AESV	#			Intensity	SDTM			AE_AESV #		A
ADAE	27	AESR	#	#	#		SDTM			AE_AESR #		A
ADAE	28	AESR	All Reasons Reason for C	200			derived	Concatenat		1	%_adamaj Perm	A
ADAE	29	AECN	#			Action Take #	SDTM			AE_AECN #		A
ADAE	30	AECN	#			Other Spec #	SDTM			AE_AECN #		A
ADAE	31	AEREL	#			Related to #	SDTM			AE_AEREL #		A
ADAE	32	AEREL	#			Outcome's #	SDTM			AE_AEREL #		A
ADAE	33	AESCON	#	#	#		SDTM			AE_AESCON #		A
ADAE	34	AESDISA	#	#	#		SDTM			AE_AESDISA #		A
ADAE	35	AESDTH	#	#	#		SDTM			AE_AESDTH #		A
ADAE	36	AESHOS	#	#	#		SDTM			AE_AESHOS #		A
ADAE	37	AESLIFE	#	#	#		SDTM			AE_AESLIFE #		A
ADAE	38	AETRITEM	#	#	#		SDTM	IF SUPPAC		AE_AETRITEM #		A
ADAE	39	AESMIE	#	#	#		SDTM			AE_AESMIE #		A
ADAE	40	AECNTRT	#			Concomita #	SDTM			AE_AECNTRT #		A
ADAE	41	AETOXGR	#	#	#		SDTM			AE_AETOXGR #		A
ADAE	42	AERELPR	#			Related to #	SDTM	IF SUPPAC		AE_AERELPR #		A
ADAE	43	ERELPR	#	#	#		SDTM			AE_ERELPR #		A

Issues

Study Wide

3

ADaM

3

SDTM

ADaM

adds

1

admh

1

adsl

1

Q Search Issues

+ New

3 Open 3 Closed

Module

Category

Severity

Entity

Assignees

Derive adsl.actarmcd (ADaM)

planning

code

high

ADaM ADSL ACTARMCD

Opened on 24 Oct 2025 by Damián Arquez

Derive adds.asstdt (ADaM)

planning

code

high

ADaM ADDS ASTDT

Opened on 24 Oct 2025 by Damián Arquez

Derive admh.adsname (ADaM)

planning

code

high

ADaM ADMH ADSNAME

Opened on 23 Oct 2025 by Damián Arquez

Showing 1 to 3 of 3 results

Page 1 of 1



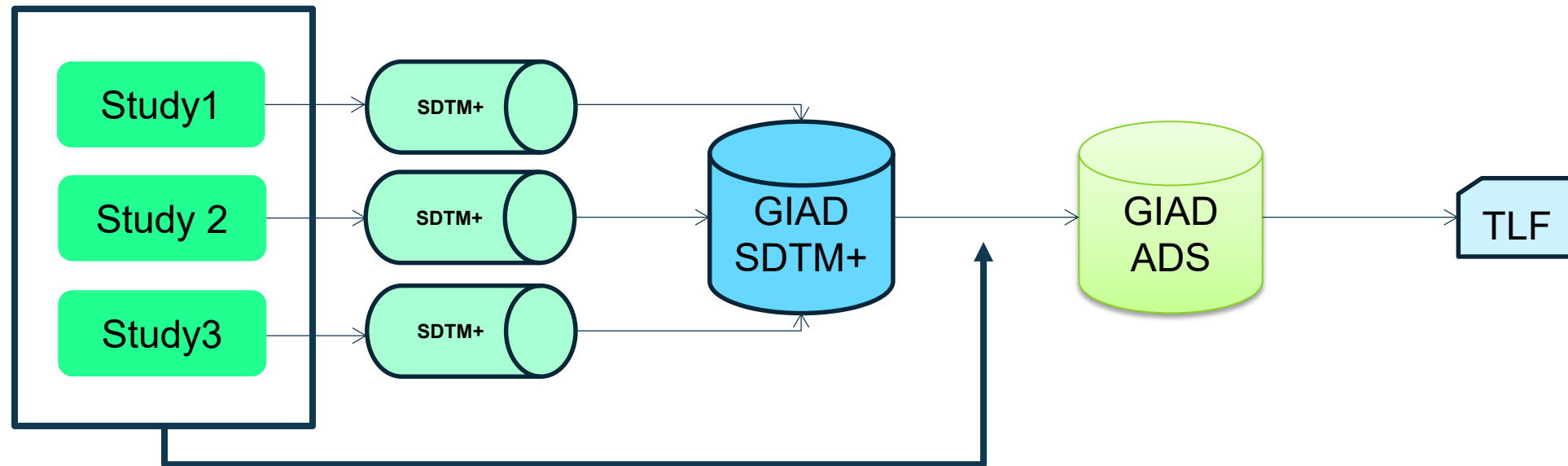
Verisian Pooler – ADaM Planner



Verisian Pooler

SDTM pool – re-using templates dynamically extracted from input studies

// SDTM+ pooling





Verisian Pooler

SDTM pool – re-using templates dynamically extracted from input studies



ADaM planning

Study pool planner - Target Pool - ADaM
34232
21140

TS
Planning

ADaM > adex > **adsname**

Target Pool

General

Label
Dataset Name

Origin

Role

Derivation

Computation type
1

Computation name
=_%_adamap_create_adsname

Computation description
Name of the analysis data set. Must be available in X_ADSNM-codelist

Data

Format

Codelists

Type
c

Length

Significant digits

Notes

See data comparison >

Save metadata
Mark as planned

Metadata
Data
Code

34232
21140

Label
Dataset Name

Origin

Role

Computation type
1

Computation name
=_%_adamap_create_adsname

Computation description
Name of the analysis data set. Must be available in X_ADSNM-codelist

Format

Codelists

Type
c

Length

Significant digits

Notes

Dataset Name

1

=_%_adamap_create_adsname

Name of the analysis data set. Must be available in X_ADSNM-codelist

c

Unresolved differences
METADATA MISMATCH

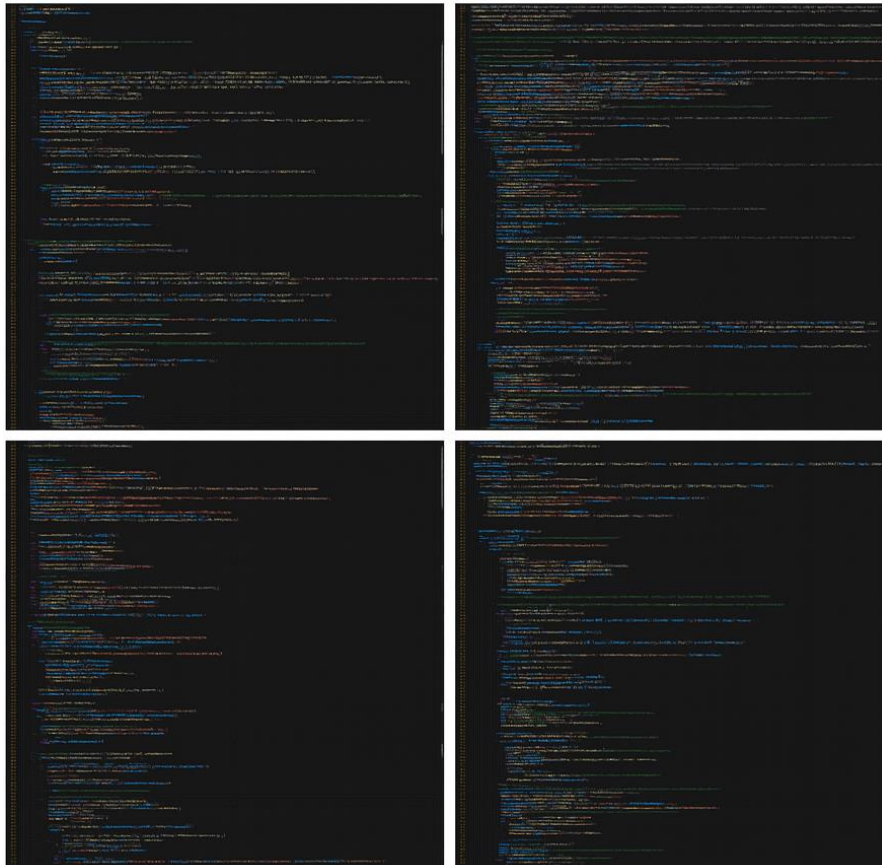


Verisian Pooler

SDTM pool – re-using templates dynamically extracted from input studies



ADaM planning



```
(Macro-Resolved) Show comments
Consent";
*...;
21   if not missing(WDICDTC) then WDICDT=input(WDICDTC,e8601da.);
22
23 RUN;
24
25 * d_adsl.log.sas;
26 %late_ads_processing(adsDomain = adsl)
27
28 * d_adds.log.sas;
29 %early_ads_processing(
30   adsDat = ADDS
31   , adsLib = WORK
32   , srcLib = WORK
33 )
34
35 * d_adds.log.sas;
36 DATA adds1;
37 *...;
38   ATTRIB ASTDT LENGTH=8 FORMAT=DATE9. LABEL="Analysis Start Date";
39   *...;
40   if length(DSSTdtc) = 10 then do;
41     aSTdt = input(DSSTdtc, yymmdd10.);
42     *...;
43   else if length(DSSTdtc) = 7 then do;
44     aSTdt = input(strip(DSSTdtc)||"-15", yymmdd10.);
45     *...;
46     if aSTdt>DCUTDT then aSTdt = DCUTDT;
47     if aSTdt>wdicdt. then do;
48       aSTdt = input(strip(DSSTdtc)||"-01", yymmdd10.);
49     *...;
50 RUN;
51
52 * d_adds.log.sas;
53 %late_ads_processing(adsdomain = ADDS)
54
```



Verisian Pooler

SDTM pool – re-using templates dynamically extracted from input studies



ADaM planning

The screenshot displays the Verisian Pooler interface, which is used for managing and deriving ADaM (Analysis Data Model) datasets. The interface is divided into several panels:

- Study pool planner - Target Pool - ADaM:** This panel shows the overall project structure. It includes a 'Trial summary' section with tabs for 'Metadata', 'Data', and 'Code'. Below this, there are two main sections for '34232 - Derivati...' and '21140 - Derivati...', each with a 'Show comments' button and a 'Data' icon. The 'Code' tab is active, showing SAS code snippets for both studies.
- Tracer:** This panel provides a detailed view of the data flow and transformations. It includes a 'Graph' section with 'Resolved', 'Original', 'Log', and 'Trace health' tabs. The 'Macro-Resolved' tab is selected, showing a flow diagram with nodes and edges. Below the graph, there is a 'Variable' section with columns for 'Name', 'I/O', 'Upstream', 'Downstream', 'Origins', and 'Destinations'. The variable 'chg' is highlighted, showing its inferred values (30, 60) and type (unknown).
- Issue Creation:** This panel allows users to create and manage issues. It includes a 'Search issues' section with a 'Create issue' button. Below this, there is a table of issues with columns for 'Open', 'Closed', 'Category', 'Severity', and 'Assignees'. The 'Create issue' form is also visible, showing fields for 'Title', 'Description', 'Category', 'Severity', and 'Assignees'.

A green arrow points from the 'Variable' section of the Tracer panel to the 'Create issue' form, indicating the integration between the data flow analysis and issue management.

SDTM pool – re-using templates dynamically extracted from input studies



ADaM planning

ADAE	1	ADNAME	Dataset Nbr	C	5	X_ADSZLN	derived	Name of th	1 - %_adama Req		A
ADAE	2	STUDYID	#	#	#		SOTM		AE-STUDYIDC	1	A
ADAE	3	USUBJID	#	Unique Per #	#		SOTM		AE-USUBJIDC	2	A
ADAE	4	AESQ	#	#	#		SOTM		AE-AESQ		A
ADAE	5	AESQ	Analysis Set	N	5		derived	Calculated	4 - %_adama Perm		A
ADAE	6	AEGRPID	#	#	#		SOTM		AE-AEGRPID		A
ADAE	7	AESPID	#	#	#		SOTM		AE-AESPID	3	A

Issues

Study Wide

3

ADaM

3

SDTM

ADaM

adds

1

admh

1

adsl

1

Q Search issues

+ New

3 Open 3 Closed

Module

Category

Severity

Entity

Assignees

Derive adsl.actarmcd (ADaM)

planning

code

high

ADaM

ADSL

ACTARMCD

Opened on 24 Oct 2025 by Damián Arquez

Derive adds.astdt (ADaM)

planning

code

high

ADaM

ADDS

ASTDT

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Derive admh.adsname (ADaM)

planning

code

high

ADaM

ADMH

ADSNAME

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Showing 1 to 3 of 3 results

Page 1 of 1

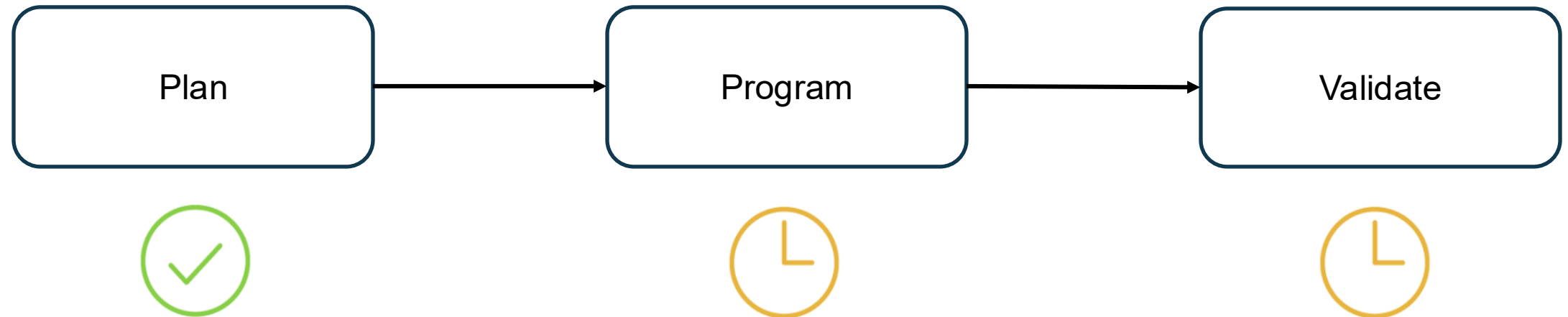


Outlook / What is next?



Verisian Pooler

The end-2-end process



////// *Health for all, Hunger for none*



bayer.com

Thank you!

hamdi.chouikha@bayer.com

kornelius.neufeld@bayer.com