



When you need
to be sure

SGS Pharma, Clinical Research

DS03 - Qualitative ADaM datasets and define.xml without using ADaM specs

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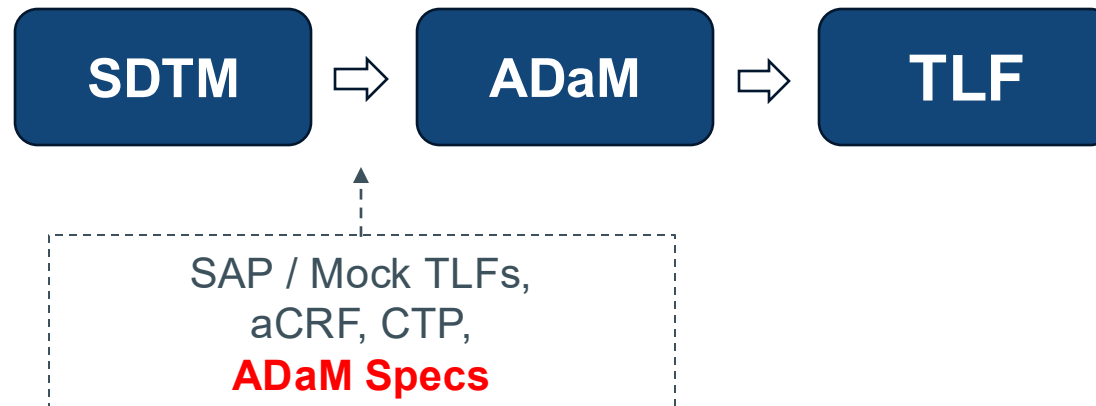
Agenda

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- 01 Introduction
 - 02 Process with ADaM specs
 - 03 Challenges
 - 04 Process without ADaM specs
 - 05 Advantages
 - 06 Conclusion

ADaM Specifications

Definition

A **study-specific** data model definition, outlining how **analysis datasets** in CDISC ADaM are derived from CDISC SDTM, detailing dataset **structure**, **content** and **derivation logic**.



ADaM Specifications

Dataset Name	Dataset Description	Dataset Structure	Key Variables of Dataset	Class of Dataset
<u>ADSL</u>	Subject-Level Analysis Dataset	One record per subject	STUDYID, USUBJID	SUBJECT LEVEL ANALYSIS DATASET
<u>ADVS</u>	Analysis of Vital Signs Test Results	One record per vital sign measurement per analysis visit per subject	STUDYID, USUBJID, PARAM, AVISITN, VSDTC	BASIC DATA STRUCTURE
<u>ADEFF01</u>	Analysis of Efficacy Assessments	One record per efficacy assessment per analysis visit per subject	STUDYID, USUBJID, PARAM, AVISITN, VSDTC	BASIC DATA STRUCTURE

Dataset name	Variable sequence	Variable name	Variable label	Variable type	Variable length	Display format	Codelist	Source / Derivation
ADSL	6	AGE	[sdm]	[sdm]	[sdm]			DM.AGE
ADSL	7	AGEU	[sdm]	[sdm]	[sdm]			DM.AGEU
ADSL	8	AGEGR1	Pooled Age Group 1	Char	40		{AGEGR}	Derived: '< 65 years (REFERENCE)' when DM.AGE < 65, '>= 65 years' when DM.AGE >= 65.
ADSL	9	SEX	[sdm]	[sdm]	[sdm]			DM.SEX
ADSL	10	CHILDPOT	[testcd]	[testcd]	[testcd]			RP.RPORRES where RPTSTCD='CHILDPOT'

CodeList Name	CodeList Value	CodeList Label
AGEGR	< 65 years (REFERENCE)	
AGEGR	>= 65 years	

domainList	ADSL	ADAPER	ADAE	ADCM	ADEG	ADIS	ADLB01	ADLB02	ADLB03	ADPC	ADVS	ADEFF01	CodeList
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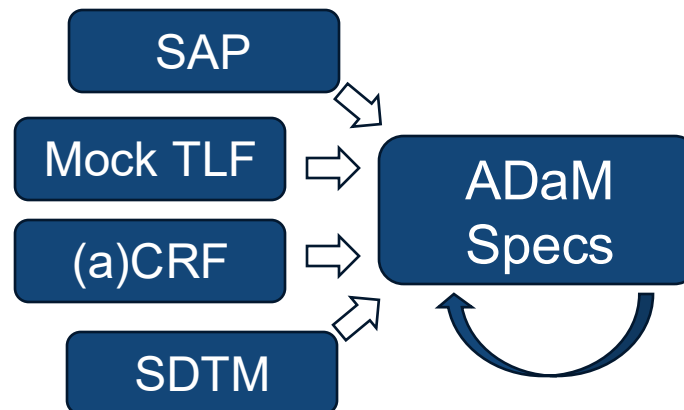
Process with ADaM Specs

1 Create study-specific ADaM specs

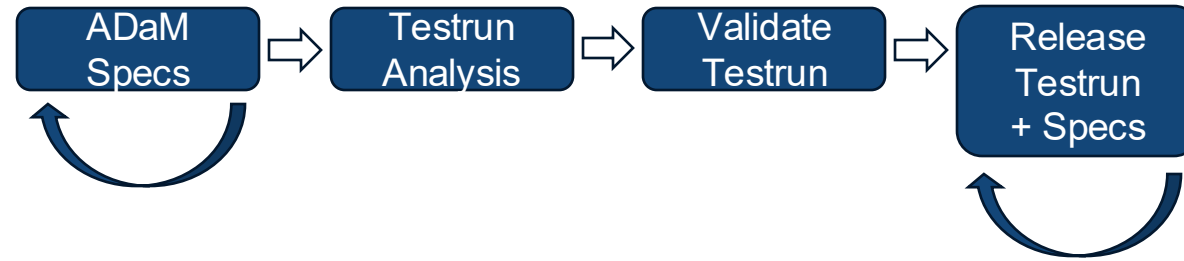
- Based on SAP, mock TLFs, (a)CRF, SDTM metadata
- Specify domains, variables, values

2 Client review of ADaM specs

- Implement client comments prior to onset of programming activities



Process with ADaM Specs



3 Develop Testrun Analysis (ADaMs + TLFs)

- Based on ADaM specs, SAP, mock TLFs, (a)CRF, CTP, ...

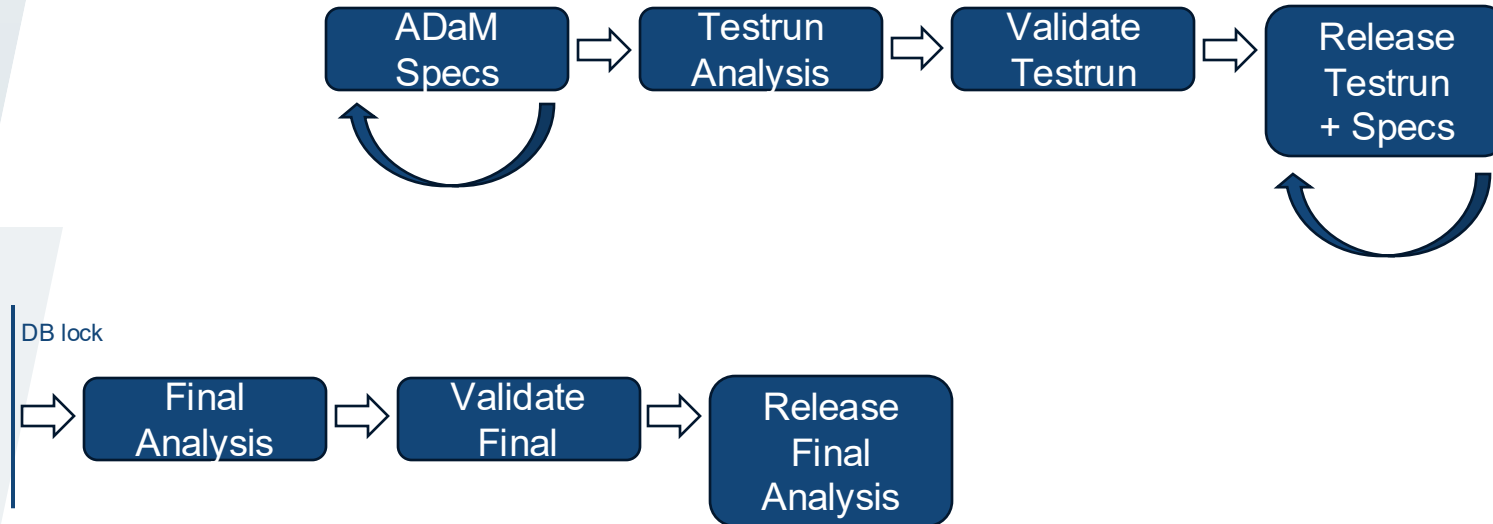
4 Validate Testrun Analysis

- Same info as developer (SAP + ADaM specs)

5 Release Testrun Analysis + ADaM specs to client

- Client review of Testrun Analysis

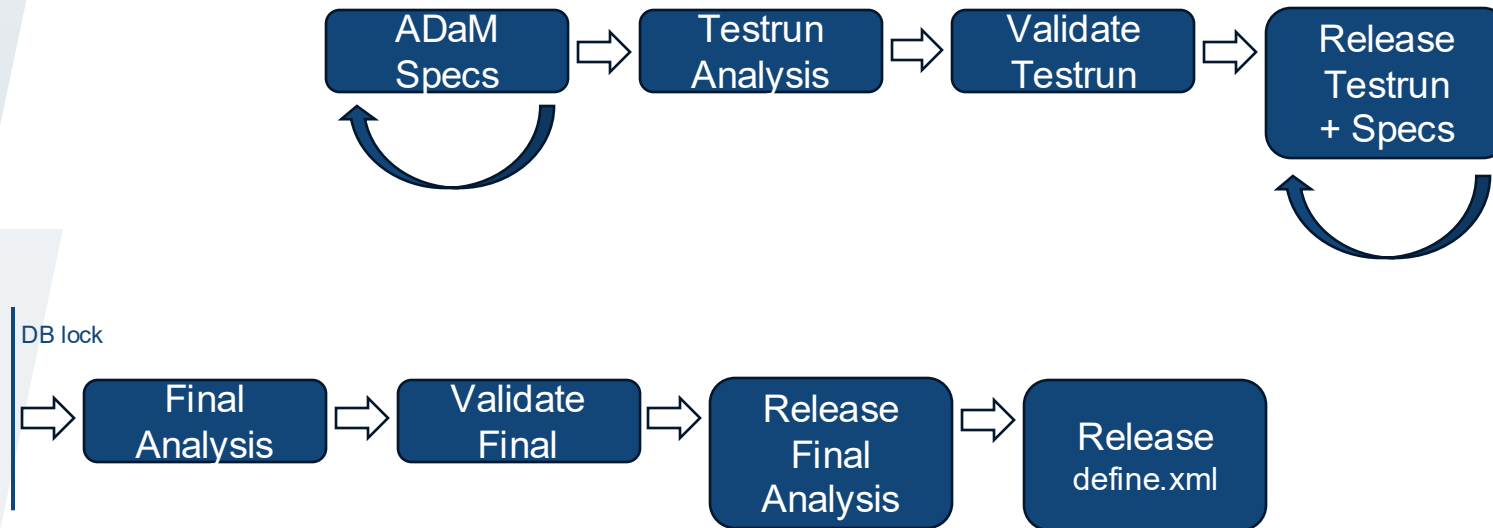
Process with ADaM Specs



6 After DB lock:

- Develop, Validate and Release Final Analysis

Process with ADaM specs



6 After DB lock:

- Develop, Validate and Release Final Analysis

7 define.xml:

- Created after the final analysis using ADaM specs as input

Our situation

CRO

- Multiple clients
- Cover all Therapeutic Areas/indications
- High volume of complex studies

Biostatistics Department

- Early onset of programming activities
- Limited source data
- Late involvement in clinical development program



Challenges



Initial creation: time consuming

- ✗ Theoretical thinking about the ADaM dataset design
- ✗ Study data not yet or partly available



During programming: maintenance

- ✗ Changes in SDTM domains, variables, values
- ✗ Changes due to SAP updates
- ✗ Derivation algorithms



Limited reusability

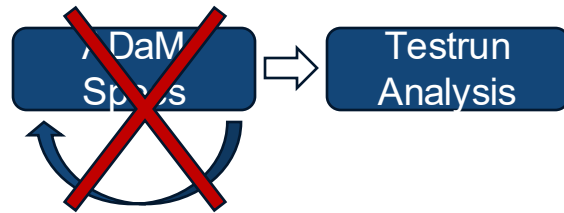
- ✗ Snapshot of certain CDISC standard and terminology
- ✗ Not up-to-date with latest standards and terminology

SGS Process without ADaM specs



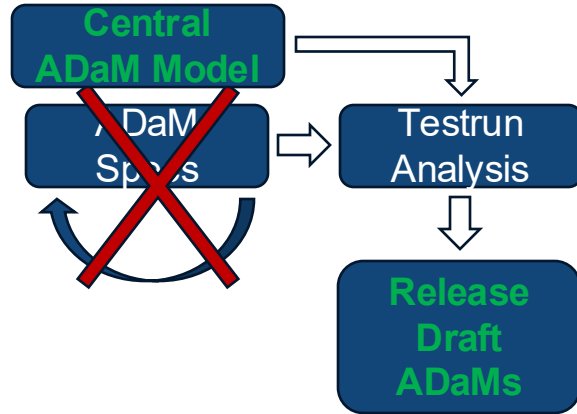
1 Do not create ADaM specs

SGS Process without ADaM specs



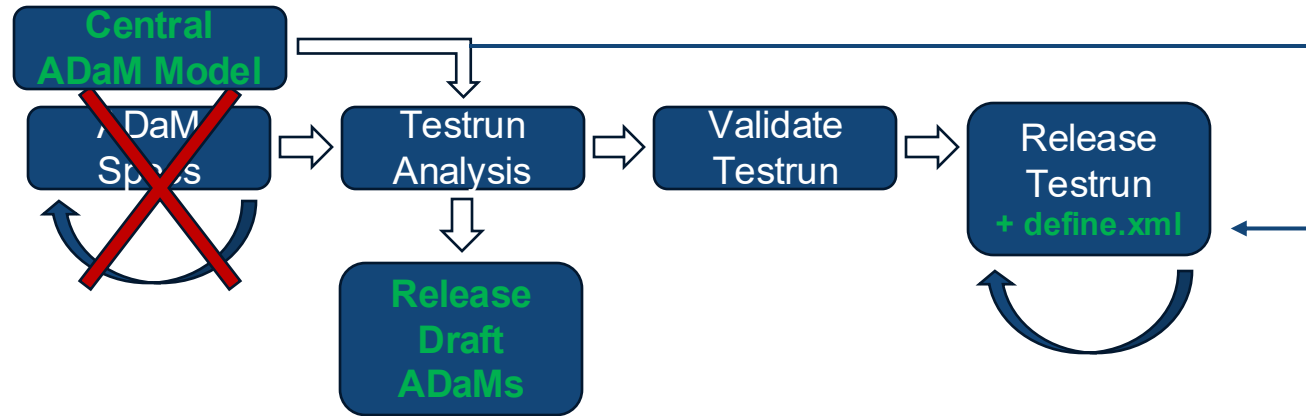
- 1 Do not create ADaM specs
- 2 Develop testrun analysis (ADaMs + TLFs)
 - Based on ~~ADaM specs~~, SAP, mock TLFs, (a)CRF, ...

SGS Process without ADaM specs



- 1 Do not create ADaM specs
- 2 Develop testrun analysis (ADaMs + TLFs)
 - Based on **central ADaM Model**, SAP, mock TLFs, (a)CRF, ...
- 3 Release Draft AdaM Datatsets

SGS Process without ADaM specs



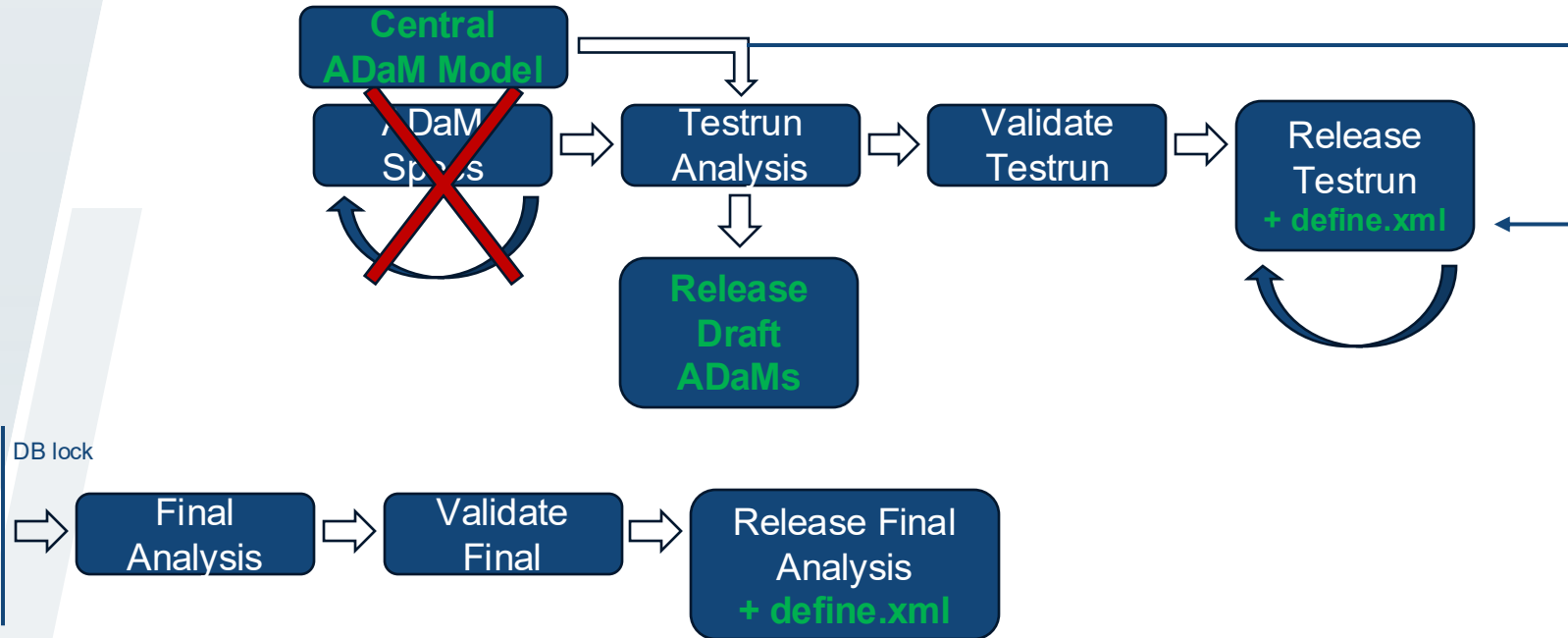
4 Validate testrun analysis

- Derivation algorithms defined independently

5 Release testrun analysis + define.xml to client

- Create define.xml including derivation algorithms
- Client review of testrun analysis and define.xml

Process without ADaM specs



6 After DB lock:

- Develop, validate and release final analysis
- Re-run define.xml

Central ADaM model

Dataset Name	Generic Domain	Dataset Description	Class of Dataset
domain	generic	name	class

Dataset	Variable name	Variable sequence	Variable Subsequence	Variable name	Variable superseded	Variable needed	Variable label
ADAE	domain	seq	subseq	name	superseded	needed	label
ADAPER	ADSL	1		STUDYID			[sdtm]
ADCE	ADSL	2		PART	[shared]	[shared]	Part
ADCM	ADSL	3		COHORT	SUBJGR*		Cohort
ADDA	ADSL	4		STAGE	[shared]	[shared]	Stage
ADDS	ADSL	5		USUBJID			[sdtm]
ADDS	ADSL	6		SUBJID			[sdtm]
ADDS	ADSL	7	1	SUBJGR*	[shared]	[shared]	Pooled Subject Group *
ADDS	ADSL	7	2	SUBJGR*N	[shared]		
ADDV	ADSL	8		SCID			
ADEC	ADSL	9		RFSTDTC			
ADEG	ADSL	10		RFENDTC			
	ADSL	11		SITEID			
	ADSL	12	1	SITEGR*			
	ADSL	12	2	SITEGR*N			
	ADSL	13		INVID			
	ADSL	14		INVNAM			
	ADSL	15		BRTHDTC			
	ADSL	16		BRTHDT			
	ADSL	17		BRTHDTM			
	ADSL	18		AGE			[sdtm]
	ADSL	19		AGEU			[sdtm]
	ADSL	20		AAGE		AAGEU AAGEU	Analysis Age
	ADSL	21		AAGEU		AAGE	Analysis Age Unit

CodeList Name	CodeList Long Name
AEACNN	Action Taken with Study Treatment (N)
AEOUTN	Outcome of Event (N)
AEREL##	Causality for Item ##
AEREL##N	Causality (N) for Item ##
AERELN	Causality (N)
AESERN	Seriousness (N)
AESEVN	Severity/Intensity Scale for Adverse Events (N)
AETOXGRN	Toxicity Grade for Adverse Events (N)
AGEGR**	Age Group **
AGEGR**N	Age Group ** (N)
BRTHDTC	Datetime of Birth

Central ADaM model



Maintenance

Training

All ...

Domains

Variables

Codelists

Up-to-date

Versions

History

Client



Variable length/label



Additional validation



define.xml

Advantages of SGS Approach



High-quality ADaM

- **Actual** instead of expected data
- Derivation algorithm **verified independently**
- Automated checks with **central model**



Increased Efficiency

- No ADaM specs creation or maintenance
 - **Earlier programming** onset
 - **Define.xml** based on central model and analysis datasets

Advantages of SGS Approach



Engaging for programmers

- Derivations based on SAP and source data
- Discussion **developer/validator** optimizes approach



Metadata

- More **complete and accurate**
- **Earlier** availability of define.xml

Our Personal Experience



Clients initially request to create ADaM specs

- Explain our alternative process
- 100% acceptance



Several years with all current clients

- Efficient process for internal as well as client validation
- High-quality ADaM datasets
- Reduced timelines during testrun and final analysis

Client feedback

*“Their commitment to open communication between sponsor and CRO programmers, treating us as one team, ensures **clarity** and efficient **problem-solving** during ADaM creation. By developing specifications dynamically alongside the code, we gain **early visibility** into draft deliverables, allowing for **proactive** feedback and continuous improvement, a far more **effective** process than static upfront specifications.”*

Head of Statistical Programming at **argenx** 

Conclusion



Predefined, study-specific ADaM specs pose significant challenges

... especially for complex studies



Using a central ADaM model instead offers more flexibility and efficiency



This process has been finetuned over years to the satisfaction of clients

... as well as programmers

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