



# ACDM24 Conference

Exploring the transition from  
Define xml 2.0 to 2.1



# Transition eased!

More Detailed approach towards

- Multiple standards & Controlled Terminology coherence
- Redefined Origin mapping
- Previous version (2.0) errata fixes
- SENDIG Support (Non-Clinical Studies)
- Additional updates

# Mandatory in the Submission Context Rule

- Dataset keys & Description
- Addition of Domain Variable to mention the specific guideline been used (For SDTM & SEND)
- Submission of SAS XPT files
- No data values in a dataset variable (with proper explanation of data not been collected)
- Origin of all the variables
- Class & Subclass (in ADaM Submissions) information

# 1. References to versions of content standards

## Define xml 2.0

✘ def:StandardName attribute

### Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	<a href="#">Trial Arms</a>	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	<a href="#">ta.xpt</a>	

## Define xml 2.1

✔ Included Standards and Standard elements

### Standards for Study CDISC01\_1

Standard	Type	Status	Documentation
SDTMIG 3.1.2	IG	Final	The CDISC01 study was modeled on a very old SDTMIG and no attempt was done yet to upversion it to a newer SDTMIG
SDTMIG 3.2	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTM IG 3.2
SDTMIG-MD 1.0	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTMIG-MD 1.0. The XS Domain is expected to reference the device used with variable SPDEVID.
CDISC/NCI SDTM 2011-12-09	CT	Final	Assuming the CT was not upversioned for this study
CDISC/NCI SDTM 2015-12-18	CT	Final	The CT version applicable for the new Domain is the 2015-12-18 version
CDISC/NCI DEFINE-XML 2023-06-30	CT	Final	This is the CDISC CT Package 54 (2023-06-30) associated to the CDISC Define-XML Specification Version 2.1.6.

# 1. References to versions of content standards

Standards for Study CDISC01\_1

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- Any other therapeutic guides
- Multiple SDTM Guidelines (eg: For Integration study purpose, any domains from latest SDTM versions)

**Addition of new column “Standard” (Recommended by P21) in *Datasets Sheet*.**

# 2. Controlled Terminology definitions

## Standards for Study CDISC-Sample

Standard	Type	Status	Documentation
ADaMIG 1.1	IG	Final	
CDISC/NCI ADaM 2017-09-29	CT	Final	ADaM specific CT is applicable for a few variables only.
CDISC/NCI SDTM 2018-06-29	CT	Final	SDTM CT is applicable for variables copied from SDTM to ADaM.
CDISC/NCI DEFINE-XML 2023-06-30	CT	Final	This is the CDISC CT Package 54 (2023-06-30) associated to the CDISC Define-XML Specification Version 2.1.6.

**Addition of new column “Terminology” (Recommended by P21) in Codelists Sheet.**

### Domain Abbreviation (DM) [C66734] [CDISC/NCI SDTM 2011-12-09]

Permitted Value (Code)	Display Value (Decode)
DM [C49572]	Demographics

### Domain Abbreviation (EC) [C66734] [CDISC/NCI SDTM 2015-12-18]

The Domain codelist was updated when SDTMIG 3.2 became production. Referencing a newer CT version that includes the revised codelist

Permitted Value (Code)	Display Value (Decode)
EC [C49587]	Exposure as Collected

*Description text for codelist can be added*

# 3. Dataset definitions

Datasets

Dataset	Description	Class - SubClass	Structure	Purpose	Keys	Documentation	Location
<a href="#">ADSL</a> [ADaMIG 1.1]	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	STUDYID, USUBJID	Screen Failures are excluded since they are not needed for this study analysis. See referenced dataset creation program and ADRG <a href="#">adsl.sas</a> Analysis Data Reviewer's Guide [6]	<a href="#">adsl.xpt</a>
<a href="#">ADQSADAS</a> [ADaMIG 1.1]	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per analysis visit per analysis date	Analysis	STUDYID, USUBJID, PARAMCD, AVISIT, ADT	See referenced dataset creation program and ADRG <a href="#">adqsadas.sas</a> Analysis Data Reviewer's Guide [Section 2.1]	<a href="#">adqsadas.xpt</a>
<a href="#">ADAE</a> [ADaMIG 1.1]	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE - ADVERSE EVENT	one record per subject per adverse event	Analysis	STUDYID, USUBJID, AETERM, ASTDT, AESEQ	See SAS program <a href="#">adae.sas</a>	<a href="#">adae.xpt</a>

Addition of new column “*Subclass*” (Recommended by P21) in *Datasets* Sheet.

# 4. Considerations with Origin

## Addition of key attributes: **Type** & **Source**

- Expected to be managed and published with CDISC Controlled Terminology **in non-extensible codelists.**
- For SEND Datasets – only “Type” attribute is used
- Addition of new column “**Source**” in *Variables* and *Value level* Sheets

### Deprecation

Origin values “CRF” and “eDT” removal

### Addition

- Origin values “Collected” and “Not Available” addition
- New Source values
  - Subject
  - Investigator
  - Vendor
  - Sponsor

Used in Legacy datasets (not provided by Organization)

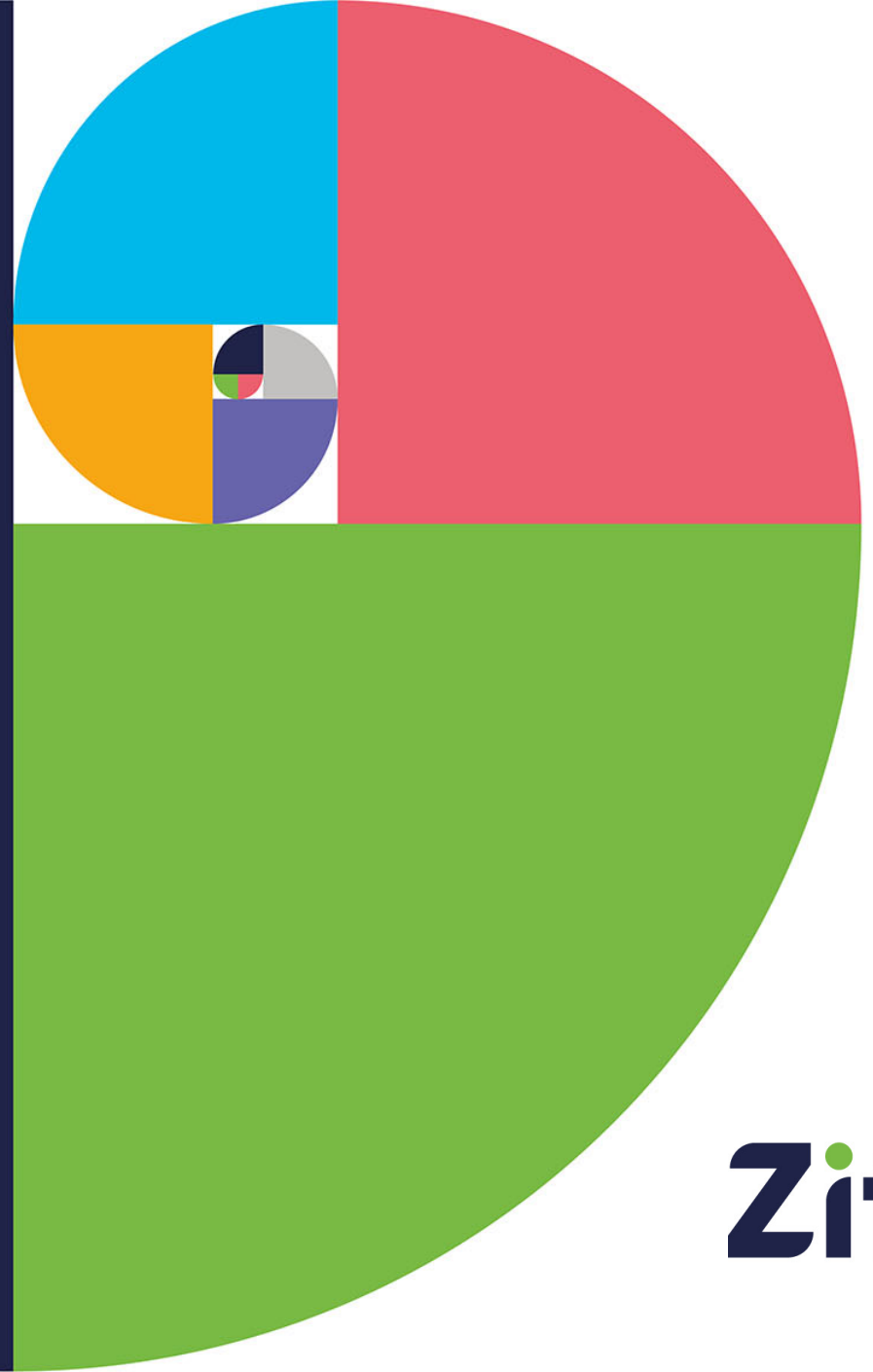
# 4. Considerations with Origin - Clinical Studies

Define xml 2.0	Define xml 2.1		Use cases
	Type	Source	
CRF	Collected	Subject / Investigator	<i>Subject case</i> : EHR, ePRO in Registry, RWE studies <i>Investigator case</i> : Information collected directly from CRF
eDT		Vendor	Laboratory & ECG assessments results, Pharmacokinetic concentrations and its parameters
Derived	Derived	Vendor	Scores derived based on the results from external Lab vendors (Eg: Cumulative Pain score)
		Sponsor	Baseline, Study day derivations For all ADaM Variables
Assigned	Assigned	Vendor	Confirmatory analyses done by third party based on result values (Eg: Confirmation of tumor based on the response)
		Sponsor	Predefined Codelist values (eg: --TESTCD, DOMAIN) For all ADaM Variables
Protocol	Protocol	Sponsor	Methods used for lab assessments & Specimen collection information, the mode of administration planned for study drug
Predecessor	Predecessor		SDTM Variables retention in ADaM Domains

# 5. Additional Updates

- If a submission dataset has no values collected till the end of the trial, “[No Data]” will be captured in “Datasets” sheet
- Alias Element allows for SAS variables or dataset names longer than 8 characters – to support legacy dataset submission.
- The def:Context attribute on the ODM root element has the value
  - Submission – Intended for a regulatory submission
  - Other - Not intended for a regulatory submission

Thank you!



**Zifo.**