PP15 – PHUSE CSS 2025

An e-Submission Jigsaw when the Answer is Not in a CDISC IG

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Introduction

To begin the jigsaw, start with the framework.

- Consult the study data standard catalogs of the relevant regulatory agencies
- Decide on the respective CDISC standard versions
- Consider regulatory agency specific CDISC implementation preferences, e.g., FDA's Study Data Technical Conformance Guide (sdTCG)
- Consider other relevant resources

Other Resources

- **Study Data Standards Resources | FDA**
  sdTCG and various Tech Specs
- **Therapeutic Areas | CDISC**
  TAUGs
- **Knowledge Base | CDISC**
  Articles, Examples Collection, Known Issues
- **Standards Timeline | CDISC**
  Overview of expected major changes per standard
- **Deliverables | PHUSE**
  White papers, templates
- **Archive Page | PHUSE, Conference Proceedings – PharmaSUG, Interchange Presentations | CDISC**
  Conference presentations or papers with a preview of new draft concepts

Communication/Confirmation

Ever heard *"Ask your reviewer"*? Consider laying out implementation plans together with the respective rationale for going beyond the IGs and asking for confirmation.

- Study Data Standardization Plan (SDSP),
  Section 5. Non-Conformance to Supported Standards Justification

ADaM

Compared to SDTM, ADaM is more generic and thus more flexible to address analysis needs not described in a published ADaM document in an ADaM compliant way.

- **Non-standard variables can be added if there is no fitting standard one available.**
- **Class ADaM Other can be used when none of the standard data structures work.**

Example topics not covered in published ADaM Documents yet

- **Effects of SDTM DC and LC on ADaM**
  → Might be addressed in CDISC Knowledge Base Articles
- **Estimands**
  → PHUSE whitepaper expected
- **Safety Tables and Figures Integrated Guide published by the FDA**
  → CDISC ADaM publication expected on laboratory displays
  → eTFL Portal in the CDISC Knowledge Base

SDTM

Assume the study allows for rescreening of subjects and it includes laboratory data.

Quotes from FDA sdTCG	SDTM Implementation Implications	SDTMIG v3.4 Compliant
If a single subject is screened and/or enrolled more than once in a study, then the subject's SUBJID should be different for each unique screening or enrollment. For a study with multiple screenings and/or multiple enrollments per subject, SUBJID should be included in other related domains besides DM even though it may cause validation errors.	SUBJID in multiple domains	No
For subjects with multiple enrollments within a single study, the primary enrollment should be submitted in DM. Additional enrollments should be included in a custom domain with a similar structure to DM.	"Custom domain" DC	No
For clinical studies, submit two separate domains for lab results. The LB domain should contain SI units in LBSTRESU for the SI results in the LBSTRESC and LBSTRESN fields. An additional custom domain called LC structured identically to LB should contain conventional units in –STRESU for the results in conventional units in the – STRESC and –STRESN variables.	Custom domain LC	Yes

Does a deviation from the SDTMIG have to be a showstopper, particularly when a deviation from the standard is asked for?

Documentation

Once informed data modelling decisions are taken, focus on clearly documenting it.

- SDTM define.xml and cSDRG
- ADaM define.xml and ADRG

Document	SDTM	ADaM
define.xml	Dataset / Variable Comments	
	IsNonStandard Attribute	
cSDRG/ADRG	**Multiple Datasets affected?** → Section Overview – Additional Content of Interest	
	Dataset which goes beyond the IGs? → Subsection in Subject/Analysis Data Descriptions Section	
	Thorough explanations of resulting P21 issues → Section Data Conformance Summary – Issues Summary	

Prerequisites for High Quality Documentation

→ Clear understanding of what is done and why
→ Ability to differentiate between what is within/outside the limits of published IGs

Conclusion

High quality documentation is the key.
It ensures that the final SDTM and ADaM packages provide the full picture of the study, where all the puzzle pieces fit together nicely.