SDRG from the template to the submission document

Experience Sharing

Jacques Lanoue

Statistical Reporting

NOVARTIS

Agenda

- The client
- Phuse SDRG Package
  - Present the sections of the reviewer's guide
- The process we followed to complete the SDRG
- Retrospective & Prospective

NOVARTIS

The client

- Sponsor Interpretation of the SDTM IG
- Not familiar with sponsor controlled terminology
  - ARM, Epoch, Element
- Custom Domains

NOVARTIS

Phuse SDRG Package

SDRG Completion Guideline Purpose

The purpose of this document is to provide sponsors with a clear, concise set of instructions that facilitates the consistent development of the SDRG from the Study Data Reviewer's Guide Template. In addition to the SDRG Completion Guideline, SDRG examples are available as an additional reference.

Guideline V1.1

SDRG Template

Examples

NOVARTIS

Sections of the reviewer's guide

- Introduction
  - Purpose
  - Acronyms
  - Study Data Standards code lists and Dictionary Inventory
- Protocol Description
  - Protocol Number and Title
  - Protocol Design
  - Trial Design Datasets

Sections of the reviewer's guide

- Subject Data Description
  - Overview
  - Annotated CRF
  - SDTM Subject Domains
    - List all subject-related datasets included in the submission alphabetically by domain code.

Sections of the reviewer's guide

Subject Data Description (continued)

- List all subject-related datasets included in the submission alphabetically by domain code.

Example:

Dataset – Dataset Label	Efficacy	Safety	Other	SUPP--	Related Using RELREC	Observation Class
AE - Adverse Events		X		X	CM, DS	Events
CE - Clinical Events	X					Events
CM - Concomitant Medications	X	X		X	AE, FA	Interventions
CO - Comments			X			Special Purpose
DM - Demographics			X	X		Special Purpose
DS - Disposition			X		AE	Events
EX - Exposure			X	X		Interventions
FA - Findings About	X	X			CM, MH	Findings
LB - Laboratory Test Results	X	X				Findings
LB1 - Hematology		X				Findings
LB2 - Chemistry		X				Findings
LB3 - Biomarkers	X					Findings
MH - Medical History				X	FA	Events
...						

NOVARTIS

Sections of the reviewer's guide

Subject Data Description (continued)

- Description of each data domain
  - Description of custom domains or organization of content
  - A table of all Supplemental Qualifiers for a given domain
- Data Conformance Summary
  - Conformance Inputs
    - Validator Version
    - Was the define.xml validated along with the data
- Issues Summary
- Appendix

NOVARTIS

The process we followed to complete the SDRG

A Team work effort

Statistics

- Study Design
- Study Data Status
- Inclusion/Exclusion

Governance

- SDTM Version
- Domain assumptions
- Sponsor defined domains

Programming

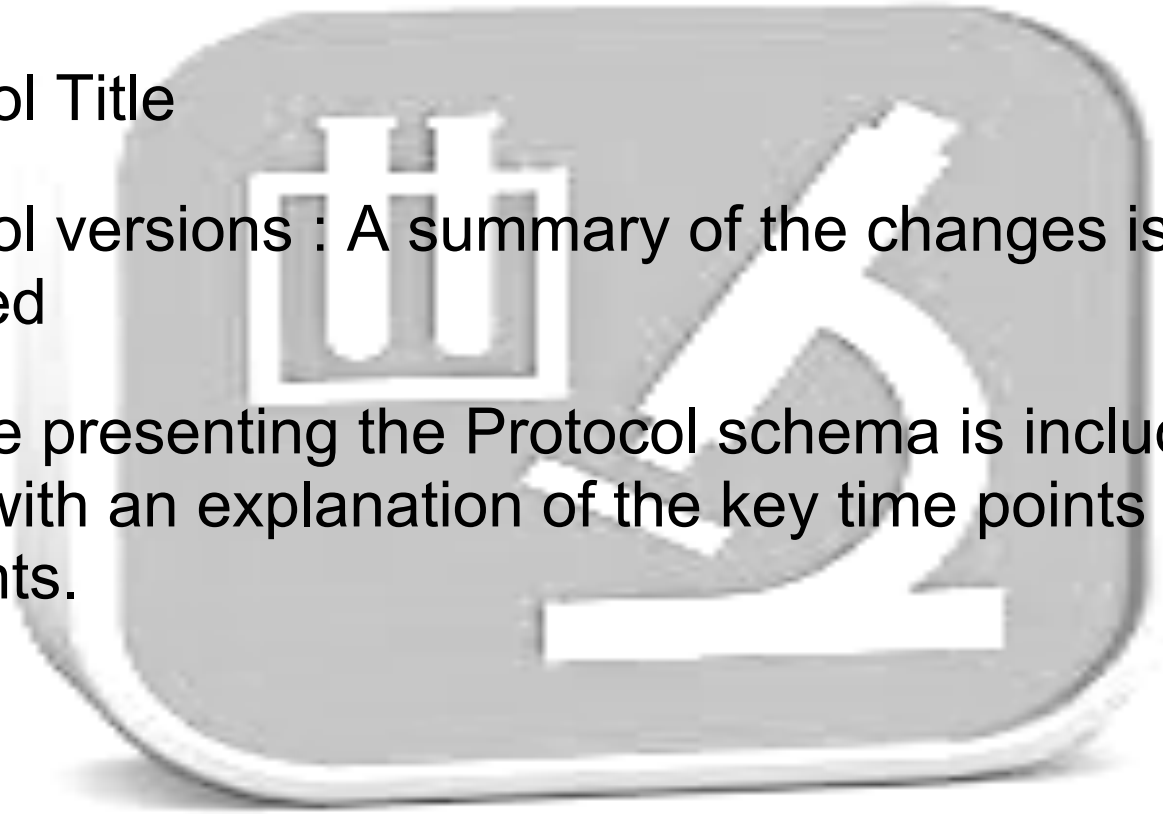
- Study specific data organization
- OpenCDISC Findings

NOVARTIS

The process we followed to complete the SDRG

Protocol Description

- Protocol Number
- Protocol Title
- Protocol versions : A summary of the changes is provided
- A figure presenting the Protocol schema is included along with an explanation of the key time points and elements.

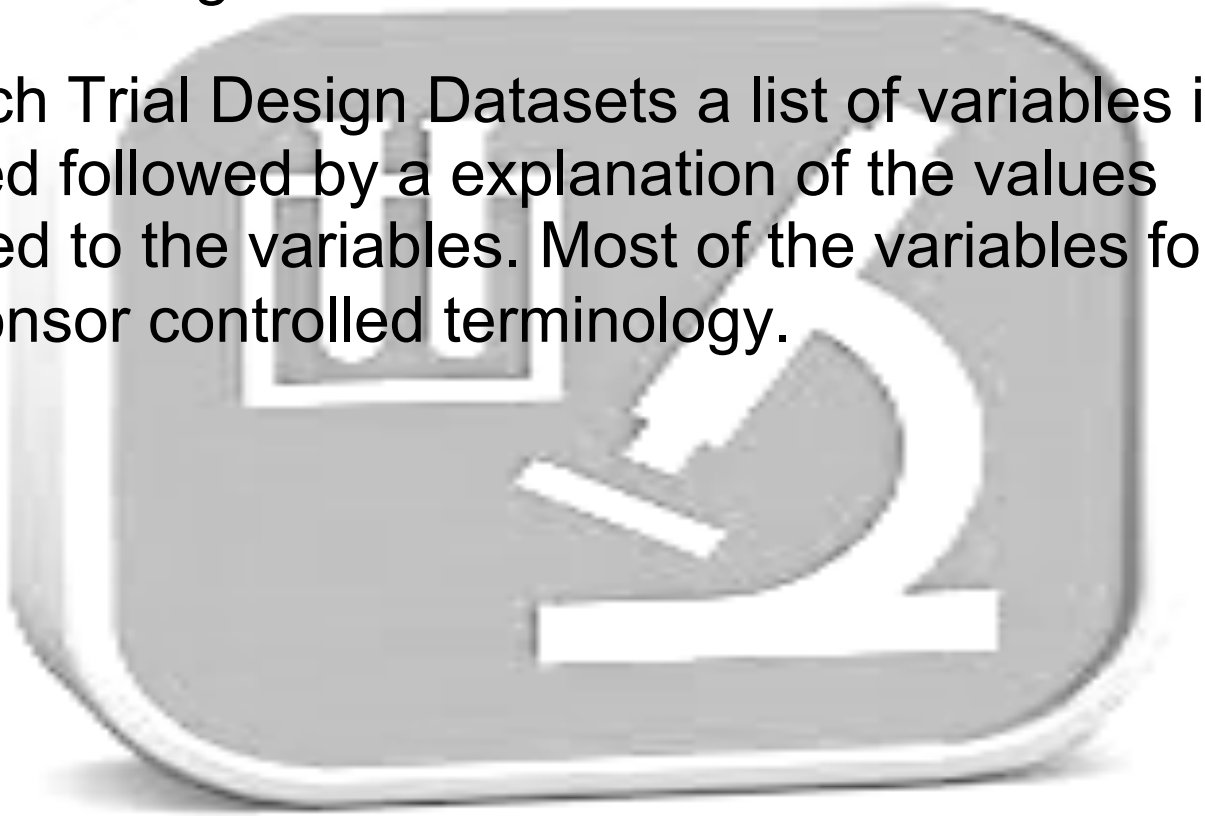


NOVARTIS

The process we followed to complete the SDRG

Trial Design Datasets

- The Trial Design Datasets are listed in a table
- For each Trial Design Datasets a list of variables is provided followed by a explanation of the values assigned to the variables. Most of the variables follow the sponsor controlled terminology.



NOVARTIS

The process we followed to complete the SDRG

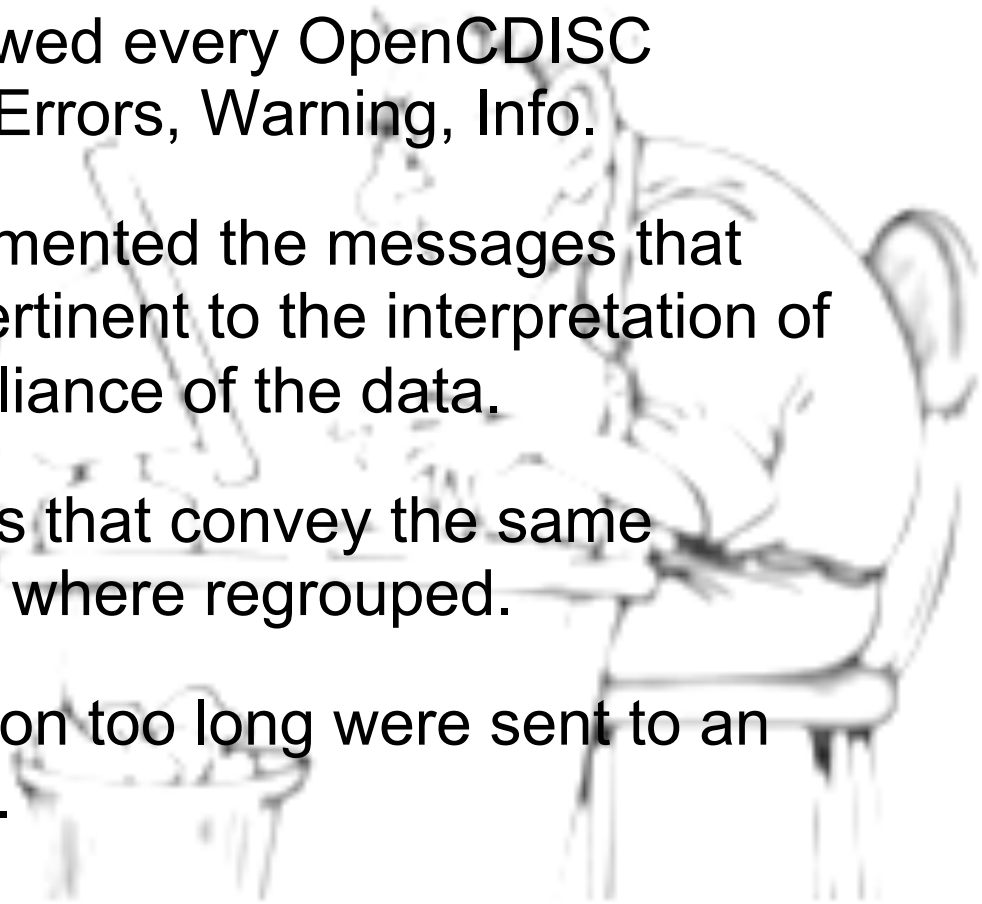
Subject Data Description

- For each domain, we provided a short description of the domain.
- Each assumption for the domain was review to identify when clarifications could be necessary.
- Structural variables, --CAT, --SCAT, --GRPID, --REFID where described to help the reviewer navigate the structure of the data.
- We also describe some element of traceability when data was captured with legacy terms but submitted in compliance with CDISC Controlled Terminology.

The process we followed to complete the SDRG

Data Conformance Summary

- We reviewed every OpenCDISC findings: Errors, Warning, Info.
- We documented the messages that seems pertinent to the interpretation of the compliance of the data.
- Messages that convey the same message where regrouped.
- Explanation too long were sent to an appendix.



NOVARTIS

Retrospective

Phuse SDRG Package

- We found the package to be complete and ready to use.
- The example provided give a good idea of the level of explanation needed to be included in the SDRG.

Prospective

- For future projects, we are building on the provided template adding instructions to the template for consistency across our projects.
- The completed SDRG are a good source of information to improve the our SDTM Implementation.

NOVARTIS

Phuse SDRG Core Team

Link and References

Helena Sviglin, FDA
Douglas Warfield, FDA
Gail Stoner GStoner@its.jnj.com, J&J
Joanna Koft joanna.koft@biogenidec.com, Biogen Idec
Scott Bahlavooni scottab@gene.com, Genentech
John Brega, Pharmastat

- Phuse wiki Study Data Reviewer's Guide Project

NOVARTIS

References

Jacques Lanoue

Associate Director Programming, CVM Franchise

Novartis Pharmaceuticals Corporation

IIS Statistical Programming

jacques.lanoue@novartis.com

NOVARTIS