

CDISC News

Presented by Monika Kawohl



Strength through Collaboration

Define-XML v2.0 (March 2013)

- Draft Define-XML v2.0 → Final Define-XML v2.0
 - Schema: Minor Changes Only
 - Stylesheet: Major Improvements
 - SDTM & ADaM samples based on Define-XML v1.0 samples

ADaM-IG 1.0 Date of document generation: 2013-03-03T14:47:00
Stylesheet version: 2013-03-04

Analysis Data Reviewer's Guide
 ▶ Analysis Datasets
 ▶ Parameter Value Level Metadata
 ▶ Controlled Terminology
 ▶ Analysis Derivations
 ▶ Comments

Analysis Datasets for Study CDISC-Sample (ADaM-IG 1.0)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADSL	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	USUBJID	adsl.xpt	Screen Failures are excluded since they are not needed for this study analysis
ADQSADAS	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per analysis visit per analysis date	Analysis	USUBJID, PARAMCD, AVISIT, ADT	adqsadas.xpt	See referenced dataset creation program and Analysis Data Reviewer's Guide, Section 2.1 adqsadas.sas Analysis Data Reviewer's Guide

Go to the [top](#) of the define.xml

Subject-Level Analysis (ADSL) [Location: [adsl.xpt](#)]

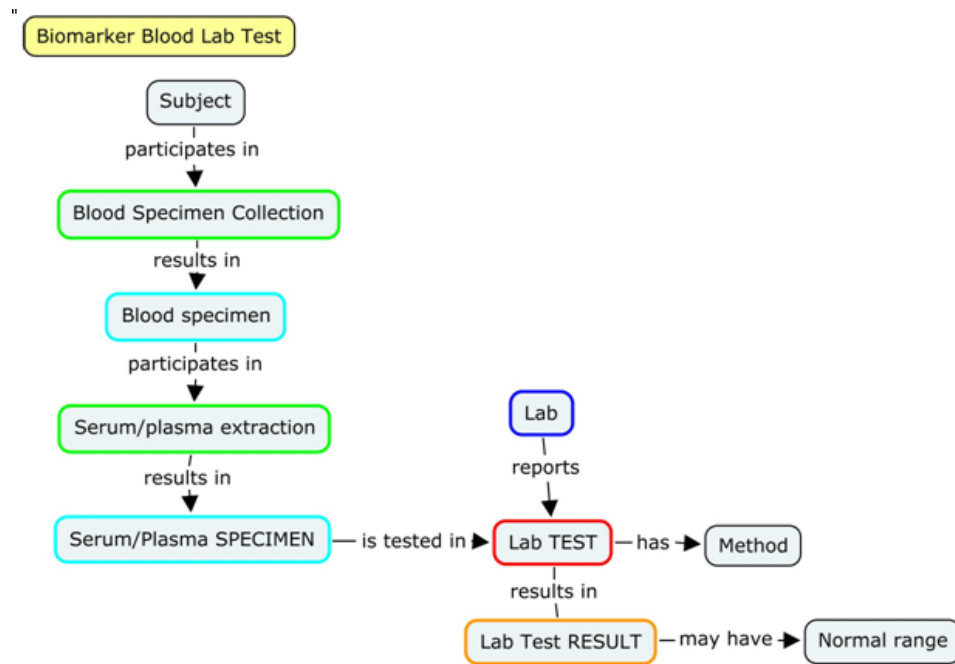
Variable	Label	Type	Length / Display Format	Controlled Terms or Format	Source/Derivation/Comment
STUDYID	Study Identifier	text	12		Predecessor: DM.STUDYID
USUBJID	Unique Subject Identifier	text	11		Predecessor: DM.USUBJID
SUBJID	Subject Identifier for the Study	text	4		Predecessor: DM.SUBJID
SITEID	Study Site Identifier	text	3		Predecessor: DM.SITEID
SITEGR1	Pooled Site Group 1	text	3		Derived: refer to SAP, Section 7.1 - if not pooled then SITEGR1=SITEID. If pooled, SITEGR1 will be 900
ARM	Description of Planned Arm	text	20	["Placebo", "Xanomeline Low Dose", "Xanomeline High Dose"]	Predecessor: DM.ARM

Terminology Update 12-Apr-2013

- SDTM
- SEND
- Questionnaires
 - New terms
 - Deleted terms (no copyright permission)
- Clinical Data Element Glossary

Therapeutic Area Standards Development

- New Process
- Pilot: Asthma
- Use of concept maps



- Taped Webinar on TA Asthma available on YouTube

Other Updates since February

- Polycystic Kidney Disease TA User Guide
 - Version 1.0 for Provisional Use (Feb-2013)
- SDTM v1.3/SDTMIG v3.1.3 Metadata Spreadsheet
 - Available in the Member's Only Area (Mar-2013)
- OpenCDISC v1.4 (Mar-2013)
- FDA/PhUSE CSS (Mar-2013)
 - Study Data Reviewer's Guide Template
- Technical Plan Project Schedule (Mar-2013)

Coming Soon: Draft SDTM IG 3.1.4 Batch 3

- SDTM v1.4
 - Associated Persons Guide
 - New material related to exposure
 - Other new domains
-
- Final SDTMIG v3.1.4 is planned for this summer