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cdisc

CDASH 2.0

WHAT, WHY AND HOW?

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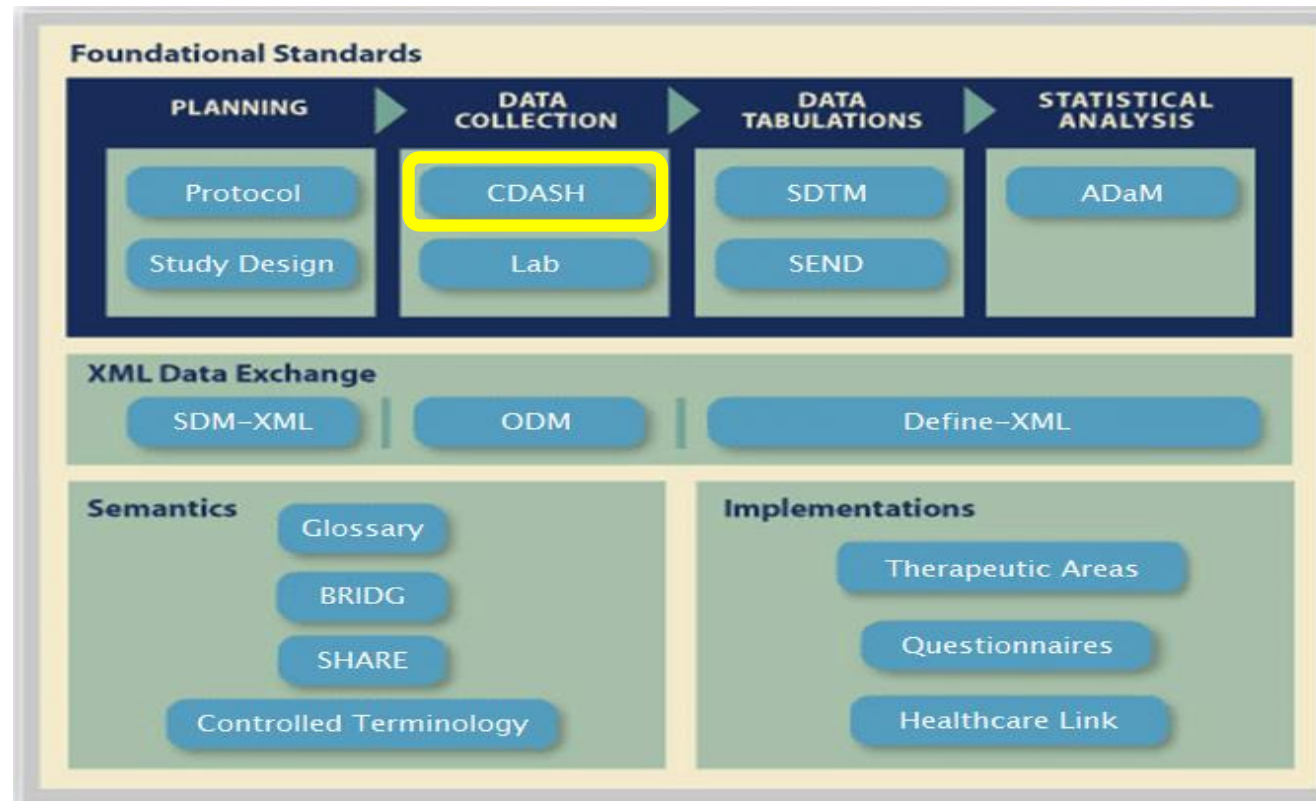
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What is CDASH? - Definition

Clinical **D**ata **A**quisition **S**tandards **H**armonization



Note: Not mandatory but strongly recommended



What is CDASH?

- A set of documents
- CDASH establishes a standard way to collect data in a similar way across studies and Sponsors
- Standards that “face” the site
- Collaboration among data management, programming, statisticians, clinical et al
- Metadata that support data capture design for SDTM reporting datasets



What's news?

CDASH 2.0

CDASH Model v1.0

CDASHIG v2.0

CDASHIG metadata tables


released 20 Sep 2017



CDASH Model v. 1.0

- **New** standard that describes the root metadata for data collection variables and questions (by observation class)
- Harmonized with SDTM v1.4

CDASH Model v1.0



Clinical Data Acquisition Standards Harmonization Model

Version 1.0

Prepared by the
CDISC CDASH Team

Notes to Readers

This is Version 1.0 of the Clinical Data Acquisition Standards Harmonization Model.

Revision History

Date	Version
2017-09-20	1.0 Final

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CDASH Model v. 1.0 – Root variables

SDTM Class	CDASH Variable	CDASH Variable Label	Maps to the SDTM Variable	Mapping Instructions
Events	--YN	Any [Event]	N/A	Does not map to an SDTM variable. The SDTM this field is NOT SUBMITTED.
Events	--TERM	Reported Term	--TERM	Maps directly to the SDTM variable listed in the "SDTM Variable".
Events	--MODIFY	Modified Term	--MODIFY	Maps directly to the SDTM variable listed in the "SDTM Variable".
Events	--LLT	Lowest Level Term	--LLT	Maps directly to the SDTM variable listed in the "SDTM Variable". The sponsor is expected to pre-code the event utilizing the Define-XML extension and an Origin column in the define metadata document.

Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel



CDASH Model v. 1.0 – Question text & Prompt

Question text and prompt are parametrized to provide more flexibility

Question Text	Prompt
Has the subject had any [intervention topic(s)] (after/before) [study-specific time frame] (after/before [study-specific time frame])?; [Was/Were] (there) any [intervention topic(s)] [taken/performed/used/collected] (after/before) study-specific time frame)?	Any [Intervention Topic]
What [is/was] the (type of) [treatment/intervention topic]?; [If other is selected], [explain/specify/provide more details]	[Treatment/Intervention]; [Specify Other/ Explain/Specify Details [Treatment/Intervention]
What [is/ was] the [treatment/ intervention topic] ?	[Intervention Topic]

Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel



CDASHIG V. 2.0 - IG + Metadata tables

- The document combines guide text and the metadata tables
- Updated Best Practices Recommendations section
- Updated Conformance Rules section
- All previous published domains are updated

- CDASH Domains are published similar to SDTM Domains
 - Description
 - Specification (**NEW!!!** Metadata tables)
 - Assumptions
 - CRF Examples (**NEW!!!**)



CDASH v1.1 vs. CDASHIG v2.0

CDASH V1.1	CDASHIG V2.0
16 Domains (+2 “Common” fields tables)	24 Domains (Header fields integrated)
Metadata tables in PDF	Metadata tables published from SHARE (Currently XLS only Future - ODM, RDF, CSV)
No Model	Model Metadata published from SHARE (Currently XLS only Future - ODM, RDF, CSV)
Domains published alphabetically	Domains organized alphabetically within Observation Class
No CRF examples included in the standard	CRF examples for many domains are included in the CDASHIG
Metadata table had 8 components (some overloaded)	Metadata includes 18 components, including SDTM mappings

Source: 2018 European Interchange – CDASH: What’s New in CDASH v2? by Peter Van Reusel



CDASHIG v2.0 – Metadata tables

Observation class and Domain

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition
Events	AE	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.
Events	AE	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.

Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel



CDASHIG v2.0 – Metadata tables

Data Collection Scenario – different CDASHIG variables

ECG Test Results

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Data Type	CDASHIG Core
Findings	EG	Central Reading with Investigator Assessment	/A	16	EGEVAL	ECG Evaluator	The role of the person who provided the evaluation.	Who provided the information?; Who was the evaluator?	[Evaluator/Reporter]	Char	0
Findings	EG	Central Reading with Investigator Assessment	/A	17	INTP_EGORRES	ECG Interpretation	Overall interpretation of the result of the measurement or finding.	What was the interpretation of the ECG?	Interpretation	Char	0
Findings	EG	Local Reading	/A	17	EGCLSIG	Clinical Significance	An indication whether ECG results were clinically significant.	Was the ECG clinically significant?	Clinically Significant	Char	0

Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel



CDASHIG v2.0 – Metadata tables

Implementation Options: explanation of how to implement horizontal data collection when the SDTM target is in a vertical structure (also in Model V1.0)

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition
Findings	VS	Denormalized	Horizontal-Example	1	TEMP_VSORRES	Temperature	Result of the vital signs measurement as originally received or collected.
Findings	VS	Denormalized	Horizontal-Example	2	TEMP_VSORRESU	Temperature Unit	The unit of the result as originally received or collected.
Findings	VS	Denormalized	Horizontal-Example	3	TEMP_VSCLSIG	Temperature Clinical Significance	An indication whether the temperature result was clinically significant.



Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel

CDASHIG v2.0 – Metadata tables

SDTMIG Mapping instructions

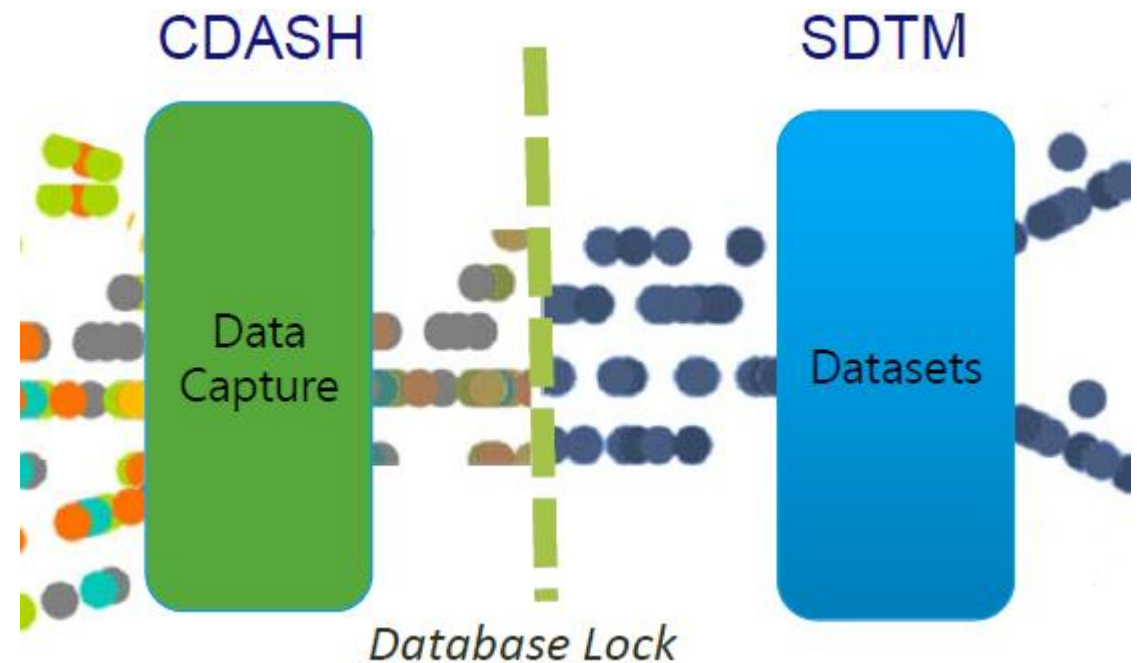
SDTMIG Target	Mapping Instructions
STUDYID	Maps directly to the SDTMIG variable listed in the column with the heading "SDTMIG Target".
DM.SITEID	Maps directly to the SDTMIG variable listed in the column with the heading "SDTMIG Target".
DM.SUBJID	Maps directly to the SDTMIG variable listed in the column with the heading "SDTMIG Target".

Source: 2018 European Interchange – CDASH: What's New in CDASH v2? by Peter Van Reusel



CDASH vs. SDTM

- CDASH mirrors SDTM wherever it can
- Different scope & requirements
- Standard CDASH variables for any additional data



CDASH vs. SDTM

CDASH and SDTM are in fact very similar:

- **86%** of CDASH maps directly with SDTMIG variables or a standard mapping is included (e.g. dates)
 - 67% of CDASH v2.0 maps directly to SDTMIG variables
- **14%** are different for a reason
 - CDASH is optimized for data capture, investigator site activities & data quality
 - SDTM is optimized for tabulation, analysis dataset creation, & data submission

Different requirements, different approaches, but with the same end in mind.



Why CDASH?

- Set up new studies faster and with higher quality
- Aggregate our collected data and learn more from it
- CDASH CRFs are traceable to SDTM, by design
- CDASH helps to standardize the SDTM creation process



How CDASH?

A Menarini Ricerche example

Who we are:

- 10 people in Biostatistics and Data Management Unit of Clinical Science Department – Menarini Ricerche

this means:

- Close contact between Biostat and DM
- eCRF setup and build completely in house and in the same location (Florence)
- eCRF programmer and SDTM programmer can work together



How CDASH?

A Menarini Ricerche example

- EDC system: Medidata RAVE
- Global Library V. 1.0
- Global Librarian (designated DM)
- Library with forms created following CDASH 2.0 and standard across studies
- Standard SDTM specification across studies only for the forms part of Global Library
- Standard Jobs in SAS Clinical Data Integration (work in progress!!!)



RAVE – Global Library

Architect MEN Global Vol. 1 Version 1.0 Forms Medical Hist...

Medical History Preview Save Cancel Go Back

Num	Name	Label	Format	Active
+	MHYN	Were any medical con...	\$1	✓
+	MHTERM	Medical History Term	\$200	✓
+	MHSTDAT	Start Date	dd- MMM- yyyy	✓
+	MHONGO	Ongoing	1	✓
+	MHENDAT	End Date	dd- MMM- yyyy	✓

+ Add New

Variable

VarOID: Find New

Format:

Dictionary: +

Unit Dictionary: +

Coding Dictionary: Apply Variable

Field

Field Name:

Field OID:

Field Num:

Subject: Subject
Page: Medical History

Were any medical conditions or events reported? Yes No

#	Medical History Term	Start Date	Ongoing	End Date
1	Data	Data	Data	Data

Add a new Log line

[Printable Version](#) [Icon Key](#)

CRF Draft 2 - Page Generated: 08 Feb 2019 10:05:28 Greenwich Standard Time

Save Cancel

Close Preview

Were any medical conditions or events reported?



