



Upgrade your library from CDASH 1.1 to CDASH 2.0

Presented by Sandra Latorre
Data Integration Specialist, Business & Decision Life Sciences

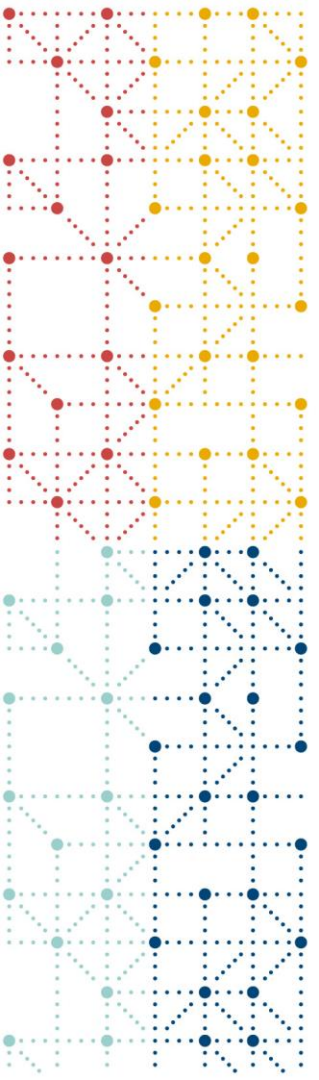


GUf CDISC 24 juin 2019



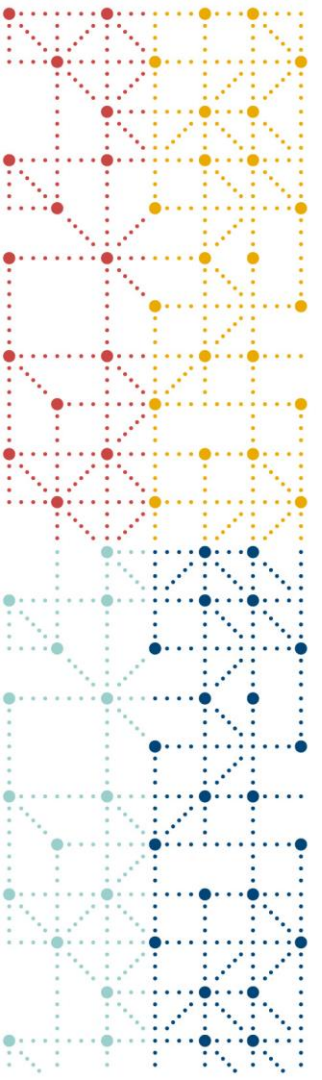
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



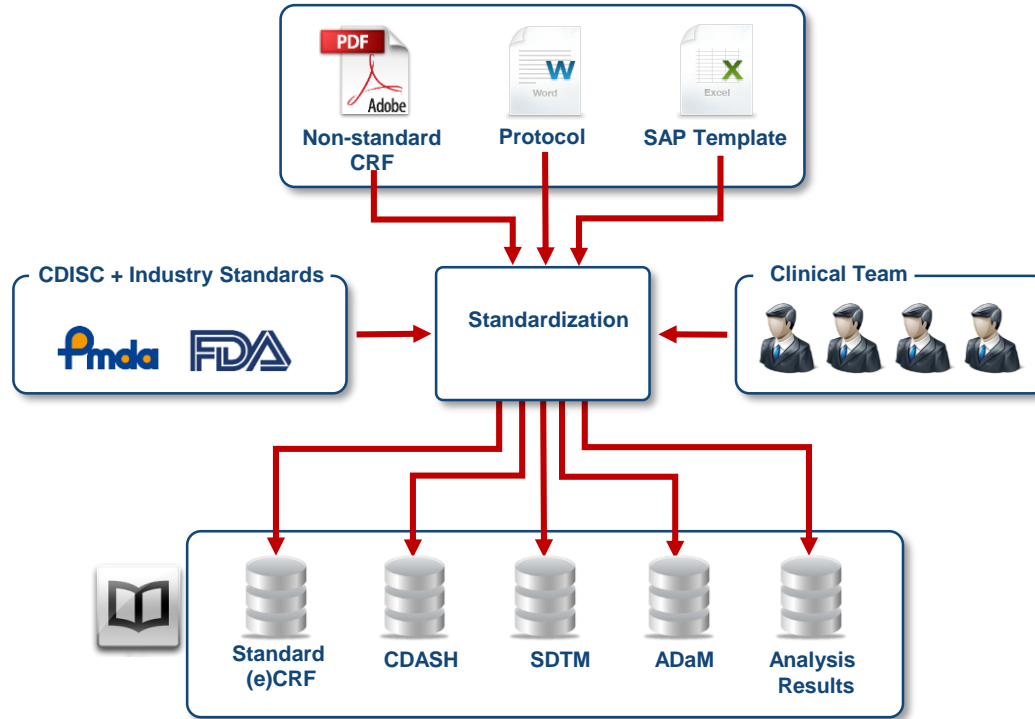
Agenda

1. Introduction
2. CDASH v2.0: exploring the updates
3. Library Upgrade
4. Conclusion
5. Q&A





Introduction

Sponsor CDISC-compliant Library



Sponsor CDISC-compliant Library

- **Content: CDASH, SDTM, ADaM...**
- **Input: CDISC/Industry/Sponsor**
- **Format: from simple Excel**  **to complex MDR** 
- **Links**
- **Processes**
- **→ As many Libraries as sponsors**

Sponsor CDISC-compliant Library

- CDASH Version 1.1 →
Version 2.0 25 Sep 2017

- Consequences on your company?

Who? 'Governance board'

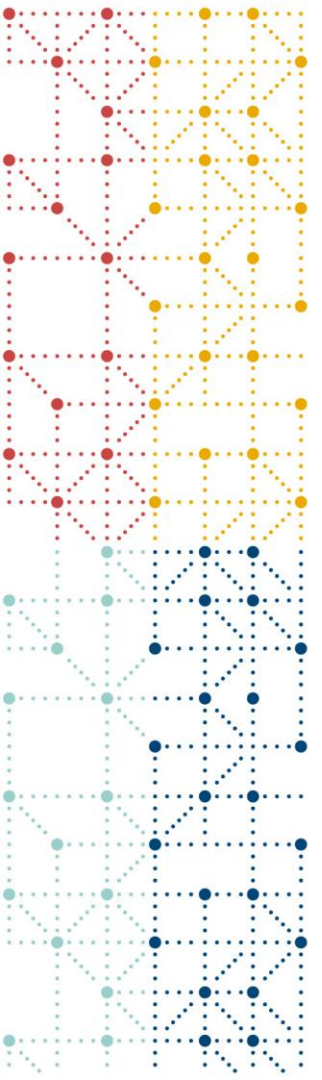
How? Governance process

What? Perform a gap analysis

When? Timelines

→ Impact analysis → Decision





CDASH v2.0: exploring the updates



Exploring CDASH updates

- **Gap analysis**

- Evaluate discrepancies between current library and new CDASH

- **Challenge**

- CDASH v 2.0***

- High level changes

- Content updates

- « Revision history »: good starting point but not all changes are listed

High Level Changes

Before



Now



→ *Impact on library?*

More Flexibility

- **Question Text/Prompt: customizable**

What [is/was] the outcome (of the event/event topic) ?	Outcome
--	---------

What was the outcome? ✓

What is the outcome? ✓

What is the outcome of the migraine? ✓

What was the outcome of the adverse event? ✓

Outcome ✓

→ **Implement this type of change may help reducing waiver requests from CRO**

More Guidance

- **Model to create new variables**

CDASH model v1.0: New document to model variables for any domain you would like

Interventions	N/A	36	-- REASOC	Reason for Occur Value	An explanation of why a scheduled intervention did not occur.
---------------	-----	----	--------------	---------------------------	--

- **Detailed instructions on custom variables**

Example: If the mapping to SDTM is similar, but not direct “C” can be included before the root variable name to indicate a “collected” version of the variable to which that data will map.

Anatomical Location	<input type="checkbox"/>	Left Arm
EXLOC EXCLOC	<input type="checkbox"/>	Right Arm

EXLOC	EXLAT
ARM	LEFT

→ **Implementation in library: enhances consistency, traceability**

EC / EX

- Alignment with SDTM IG 3.2

Was study treatment administered? <i>(Defaulted)</i> ECCOCUR	<u>N</u>
Study Treatment Category <i>(Defaulted)</i> ECCAT	<u>MISSED DOSE</u>
Study Treatment Name <i>(Defaulted)</i> ECTRT	Sponsor Defined
Line Number ECSPID	_____
What was the intended dose date? ECSTDTC ECSTDAT	__/__/____
Reason Treatment Not Administered SUPPEC.QVAL WHERE QNAM = "ECREASOC" ECREASOC	_____



- Library upgrade is strongly recommended

CDASH Attributes

- **New Structure**

- Example of deleted attribute: 'BRIDG'
- Example of new attribute: 'CDASHIG Variable Label'

→ **Library implementation**

- Valuable but complex depending on system (what about adding a new attribute?)

CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text
PRCSTAT	Procedure Collected Completion Status	The variable used to indicate that data are not available by having the site recording a sponsor-defined value (e.g., Not Collected/Not Evaluated/Not Assessed/Not Available/Not Answered)	Was the procedure data collected?

Attributes Values

- **Changes not listed**

→ **Programmatic assessment of changes between CDASH v1.1 and CDASHIG v2.0**

Example: SCPERF

Old prompt

~~Any Subject Characteristics?~~

Misleading

New prompt

Subject Characteristics Collected

Other content changes

- **Also reworked:**

- Best practice
- Conformance rules

- Low
- Medium
- High



No fundamental changes but reorganized and clarified

- Medium
- Low
- High



→ Full evaluation of new CDASH needed
Read documentation!



Future updates (under review)

- **CDASH model 1.1**
 - **CDASH IG 2.1**
 - **Still aligned with SDTM 3.2**
 - **Addition of domains**
MB, MS, TU, TR, RS, AP--
 - **Updated Example aCRFs:**
 - « CRF Maker Tool »
 - Associated Metadata
- Similar to Therapeutic Area User Guides (TAUGs)

Future updates: new CRF template

Title: Demographics

Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc.) in this format (DD-MON-YYYY).

Birth Date

BRTHDAT **BRTHDTC**

Record the appropriate sex (e.g., F (Female), M (Male)).

What is the sex of the subject?

SEX

- Male
- Female
- Unknown
- Undifferentiated

<From SEX codelist>

Study participants should self-report ethnicity, with ethnicity being asked about before race.

Do you consider yourself Hispanic/Latino or not Hispanic/Latino?

ETHNIC

- Hispanic or Latino
- Not Hispanic or Latino
- Not Reported

<From ETHNIC codelist>

Study participants should self-report race, with race being asked about after ethnicity.

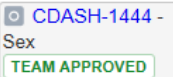
Which of the following five racial designations best describes you? (More than one choice is acceptable.)

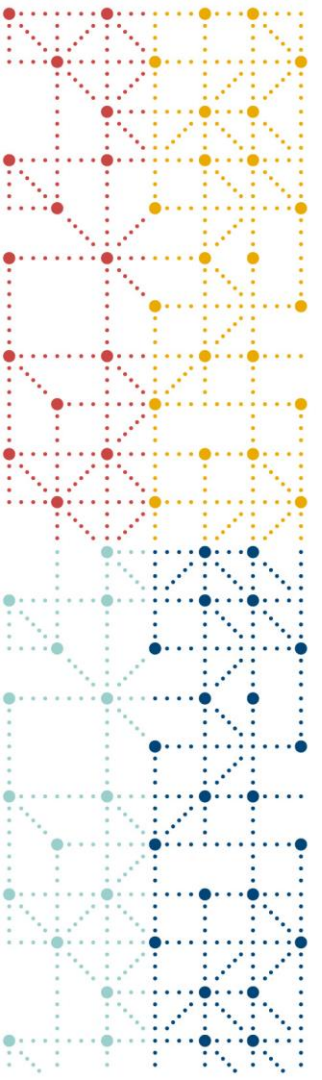
RACE

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

<From RACE codelist>

Future updates: Example Metadata

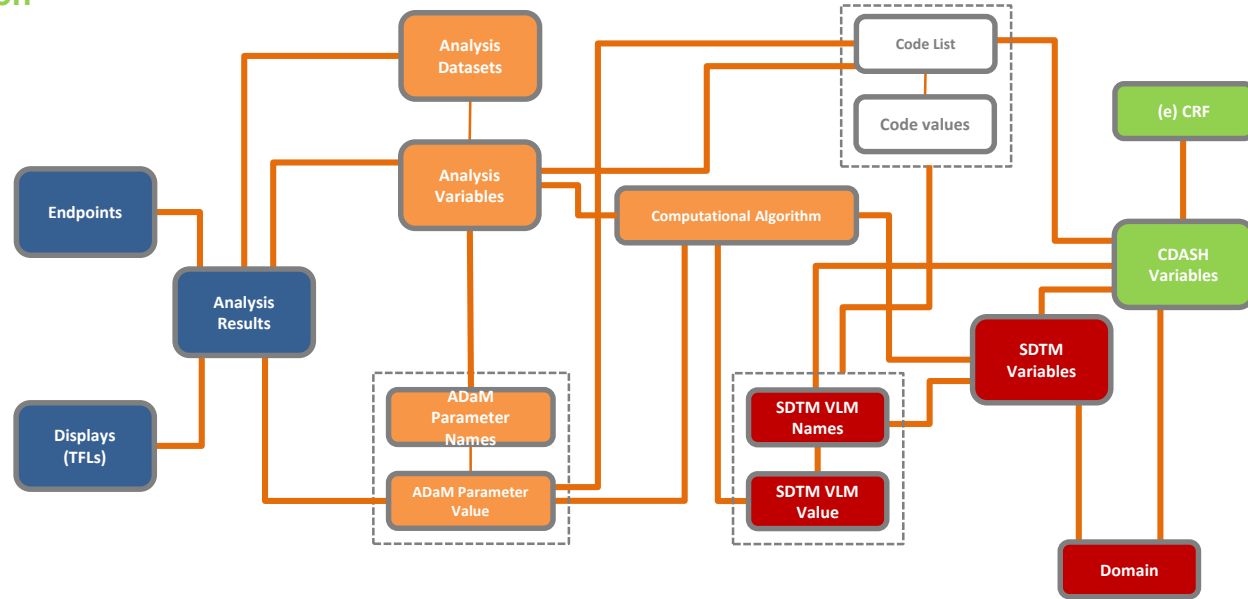
CDASH Variable	Order	Question Text	Prompt	CRF Completion Instructions	Type	SDTMIG Target	SDTM Variable Mapping	Controlled Terminology Code List Name	Permissible Values	Pre-specified Value	Query Display	List Style	Hidden
BRTHDAT	1	What is the subject's date of birth?	Birth Date	Record the date of birth to the level of precision known (e.g., day/month/year, year, month/year, etc.) in this format (DD-MON-YYYY).	Date	BRTHDTC							
SEX	2	What is the sex of the subject?	Sex	Record the appropriate sex (e.g., F (Female), M (Male)).	Text	SEX		(SEX)	Male; Female; Unknown; Undifferentiated 			radio	
ETHNIC	3	Do you consider yourself Hispanic/Latino or not Hispanic/Latino?	Ethnicity	Study participants should self-report ethnicity, with ethnicity being asked about before race.	Text	ETHNIC		(ETHNIC)	Hispanic or Latino; Not Hispanic or Latino; Not Reported			radio	
RACE	4	Which of the following five racial designations best describes you? (More than one choice is acceptable.)	Race	Study participants should self-report race, with race being asked about after ethnicity.	Text	RACE		(RACE)	American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White			check	



Library Upgrade

Impact Analysis: Semantic Linking

Data Collection
SDTM
ADaM
Analysis



In an MDR, an impact analysis functionality can help



Impact Analysis: Points to Consider

- **System in use (MDR)**
- **Impact on partner CROs**
- **Training needs**
- **Budget**
- **Resources**
- **Timelines**



Impact Analysis: Specifics

- **Specificity of this CDASH release: Complex evaluation**
- **Can be evaluated per type of gap instead of a whole**
(no need to expect a big release of CDASH v2.0-compliant library version)
- **No regulatory requirements, so nothing is critical but all is « nice to have »: implement because you will benefit from it, not because it's written**



Implementation Decisions

- Company specific
- Effort (see Impact Analysis) vs expected benefits
 - enhanced traceability,
 - consistency,
 - communication,
 - quality of data,
 - easiness of SDTM programming...
- Go/No go
- Priorities



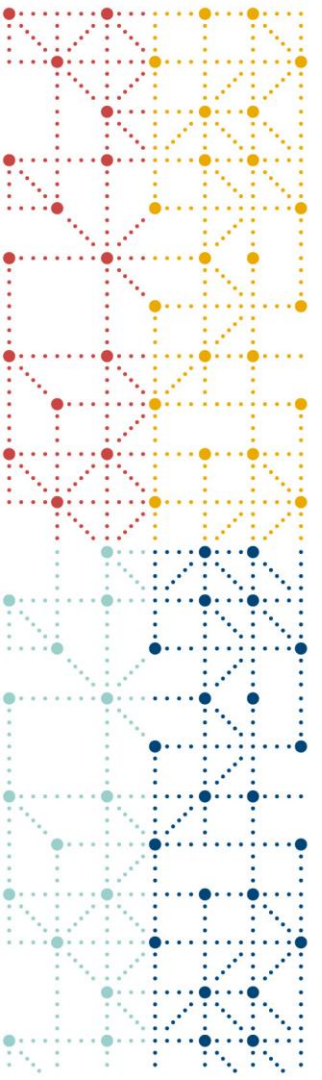
Implementation Plan: example

1st step → Full training of librarians on new CDASH

2nd step → Allow customization of question texts

3rd step → Align custom variable names to CDASH variable naming rules

4rd step → Align CDASH attribute values



Conclusion

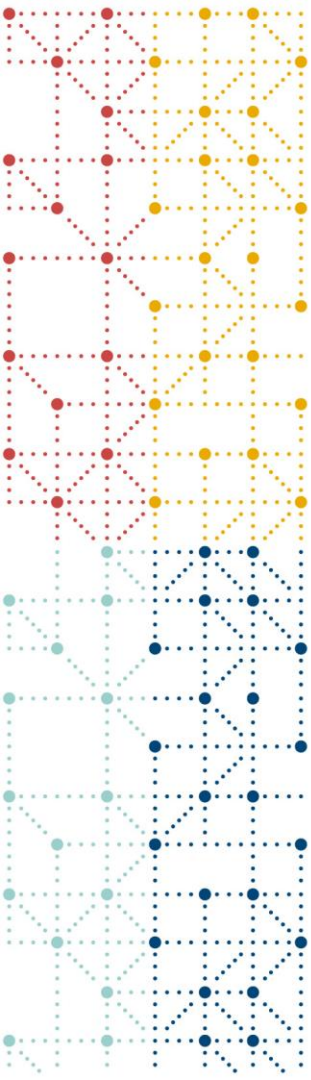


Conclusion

CDASH new version

- It's here, take advantage of it
- No urgency, no submission requirement
- Enhances traceability with SDTM 3.2
- Involve governance board, apply steps: gap analysis - impact analysis - decision

Everybody who works with SDTM should use CDASH



Thank You!

Sandra Latorre

sandra.latorre@businessdecision.be

cdisc

Business & Decision
Life Sciences