



*Upgrade your library  
from CDASH 1.1 to CDASH 2.0*

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*Sandra Latorre 5th July 2018*

Business & Decision  
Life Sciences



*Introduction*



*CDASH v2.0: exploring the updates*



*Library Upgrade*



*Conclusion*



*Q&A*





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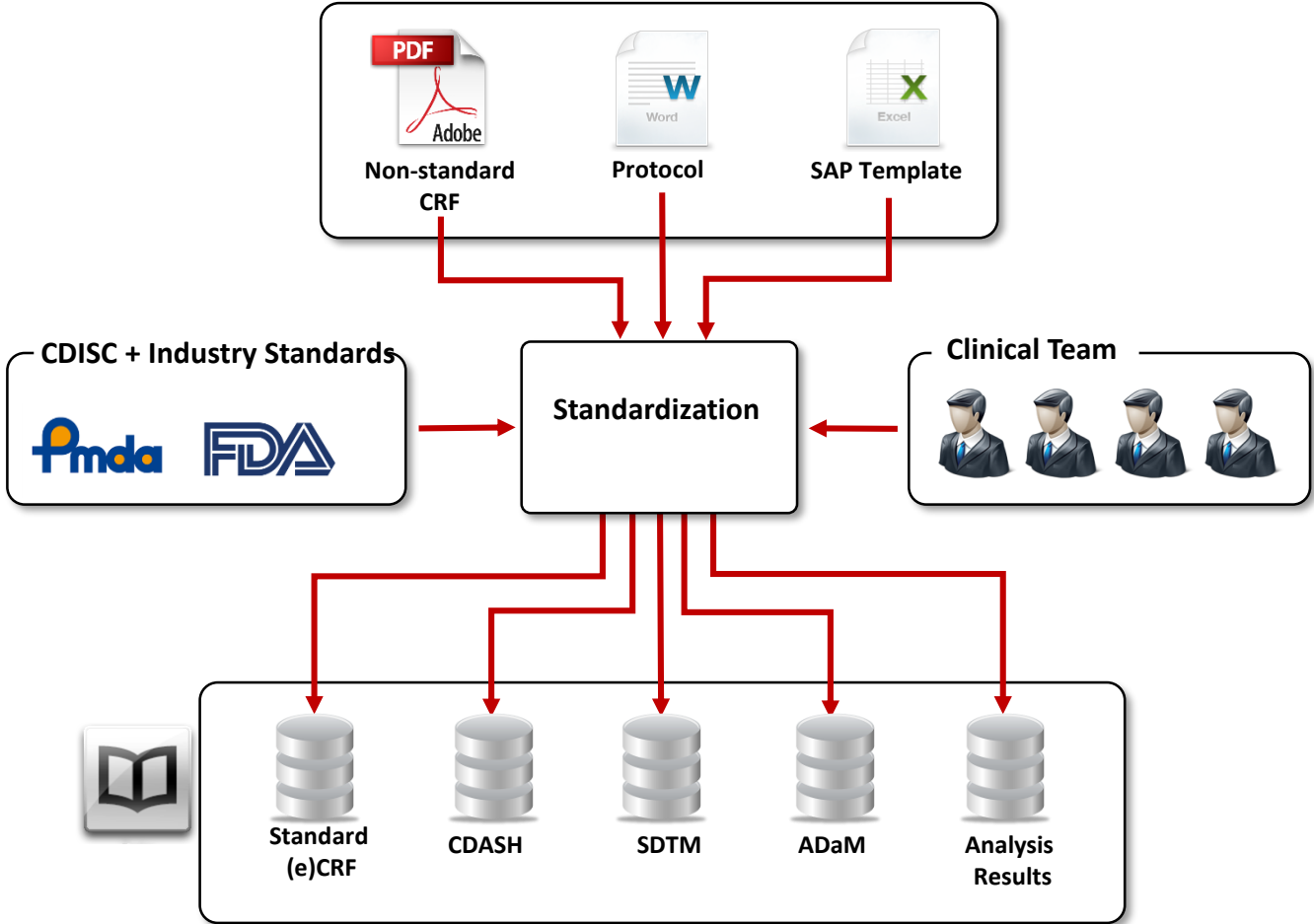
*Conclusion*



*Q&A*



# 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**

# Release of new CDASH version

❏ *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*





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# Exploring CDASH updates

## ■ *Gap analysis*

→ Evaluate discrepancies between current library and new CDASH

## ■ *Challenge*

### *CDASH v 2.0*

→ High level changes

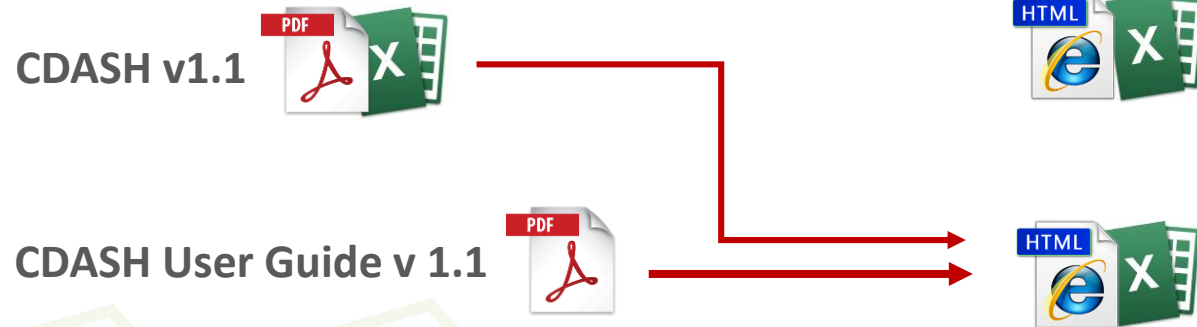
→ Content updates

→ list of differences provided by CDISC: only high level ('major')

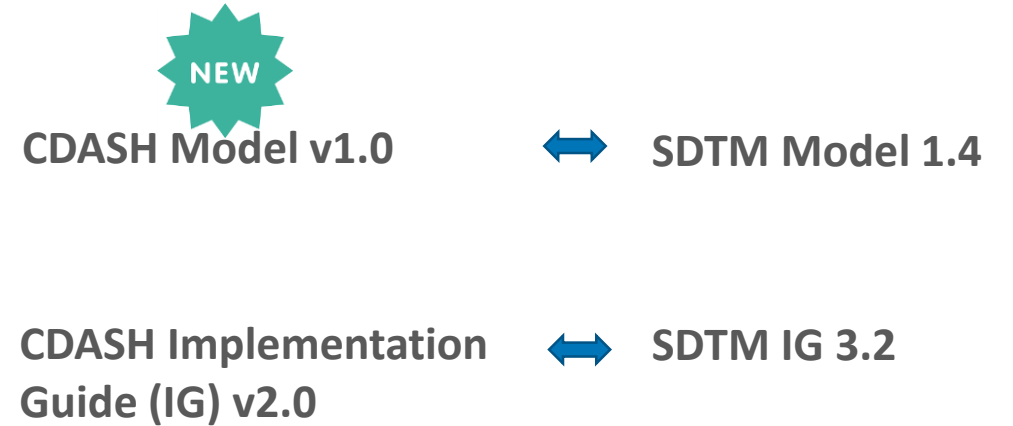


# High Level Changes

## Before



## Now



Controlled Terminology

TAUG releases

*Impact on library?*

# Revision History

## ■ **Source: CDASH IG v2.0**

### **High level changes**

#### **Structural changes**

- Organized by class and domain (align with SDTMIG)
- List of attributes removed and attributes added → new Excel structure ?

#### **Content changes**

- Updated existing domains (no detail provided) ?
- Added domains CE, DD, EC, HO, MI, PC, PR, RP, SR ?
- Updated attributes for every CDASHIG variable ?
- More flexibility in Question Text and Prompt ?
- ECPDOSE, ECPDOSU, and ECPOCCUR were deprecated ?
- Common Identifier Variables were added to each of the Domains

#### **Revision History doesn't list all the changes ?**

- Go through all documentation

# 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.
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## Detailed instructions on custom variables

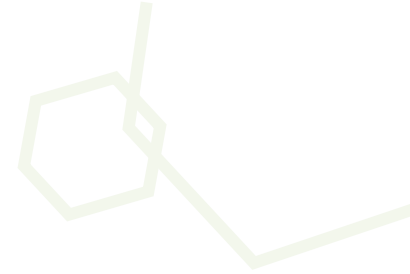
Example: If the mapping to SDTM is similar, but not direct "C" can be included before the root variable name to indicate a "collected" version of the variable to which that data will map.

Anatomical Location	<input type="checkbox"/>	Left Arm
<b>EXLOC</b> 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? (Defaulted) <b>ECOCCUR</b>	<u>N</u>
Study Treatment Category (Defaulted) <b>ECCAT</b>	<u>MISSED DOSE</u>
Study Treatment Name (Defaulted) <b>ECTRT</b>	Sponsor Defined
Line Number <b>ECSPID</b>	_____
What was the intended dose date? <b>ECSTDTC</b> <b>ECSTDAT</b>	-- / -- / --
Reason Treatment Not Administered <b>SUPPEC.QVAL WHERE QNAM = "ECREASOC"</b> <b>ECREASOC</b>	_____

## Library upgrade is strongly recommended

# Content changes: What Revision History doesn't say

## ■ **Also reworked:**

- Best practice
- Conformance rules

***No fundamental changes but reorganized and clarified***

***→ Full evaluation of new CDASH needed***

- Low
- Medium
- High



- Medium
- Low
- High



# CDASH Attributes

## ■ *New Structure*

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

## ■ *Library implementation*

- Valuable but complex depending on system

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

## ■ Programmatic assessment of changes between CDASH v1.1 and CDASH v2.0

*Need to use Excel files but « pending final curation »*

CDASH Model	1.0	Pending Final Curation	<a href="#">Excel</a>
CDASH IG	2.0	Pending Final Curation	<a href="#">Excel</a>

*Need a bit of workaround due to new structure*





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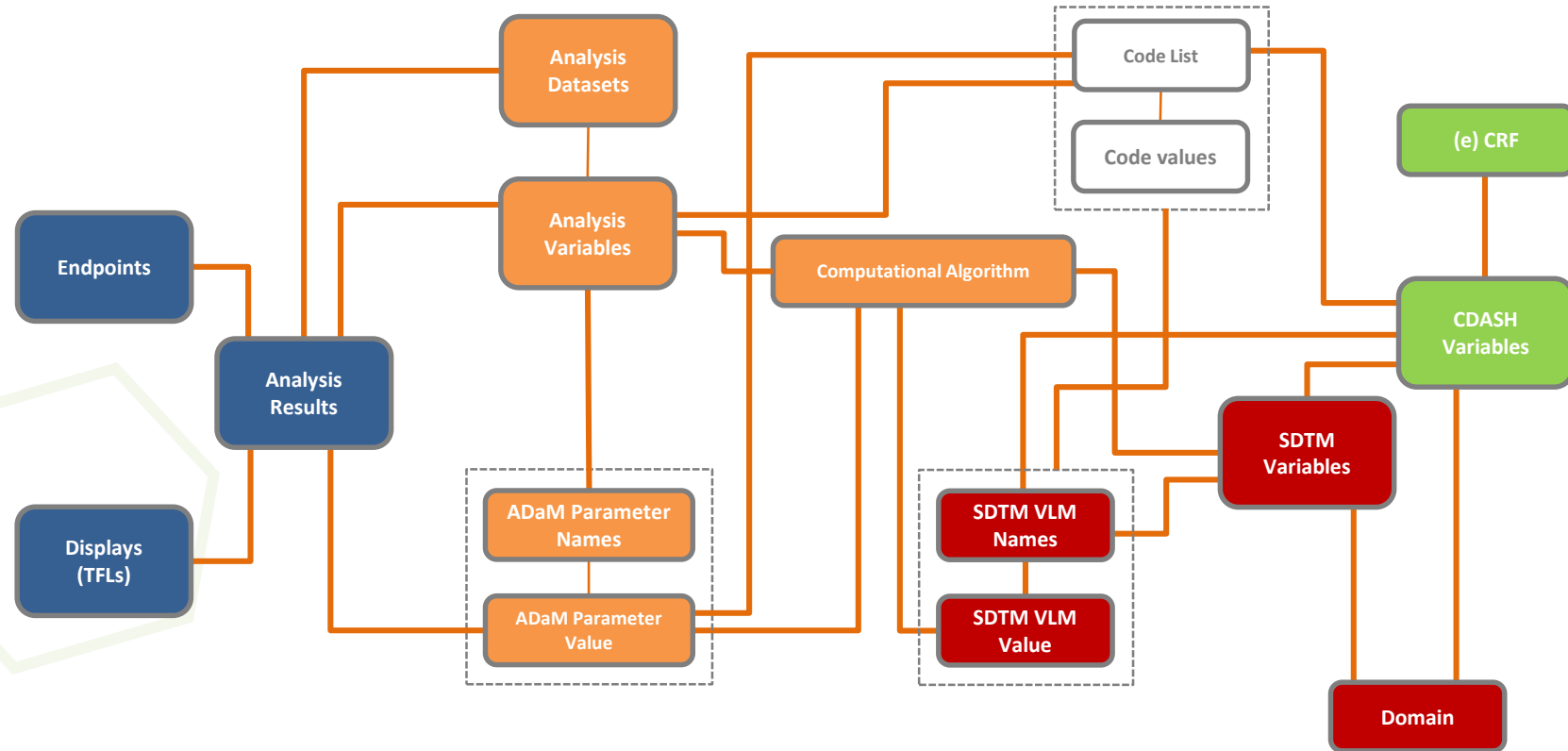
# Impact Analysis: Semantic Linking

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

**1<sup>st</sup> step** → *Full training of librarians on new CDASH*

**2<sup>nd</sup> step** → *Allow customization of question texts*

**3<sup>rd</sup> step** → *Align custom variable names to CDASH variable naming rules*

**4<sup>rd</sup> step** → *Align CDASH attribute values*



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# 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





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# Business & Decision Life Sciences

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 **Business  
& Decision**

