



Upgrade your library from CDASH 1.1 to CDASH 2.0

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Business & Decision
Life Sciences



Introduction



CDASH v2.0: exploring the updates



Library Upgrade



Conclusion



Q&A





Introduction



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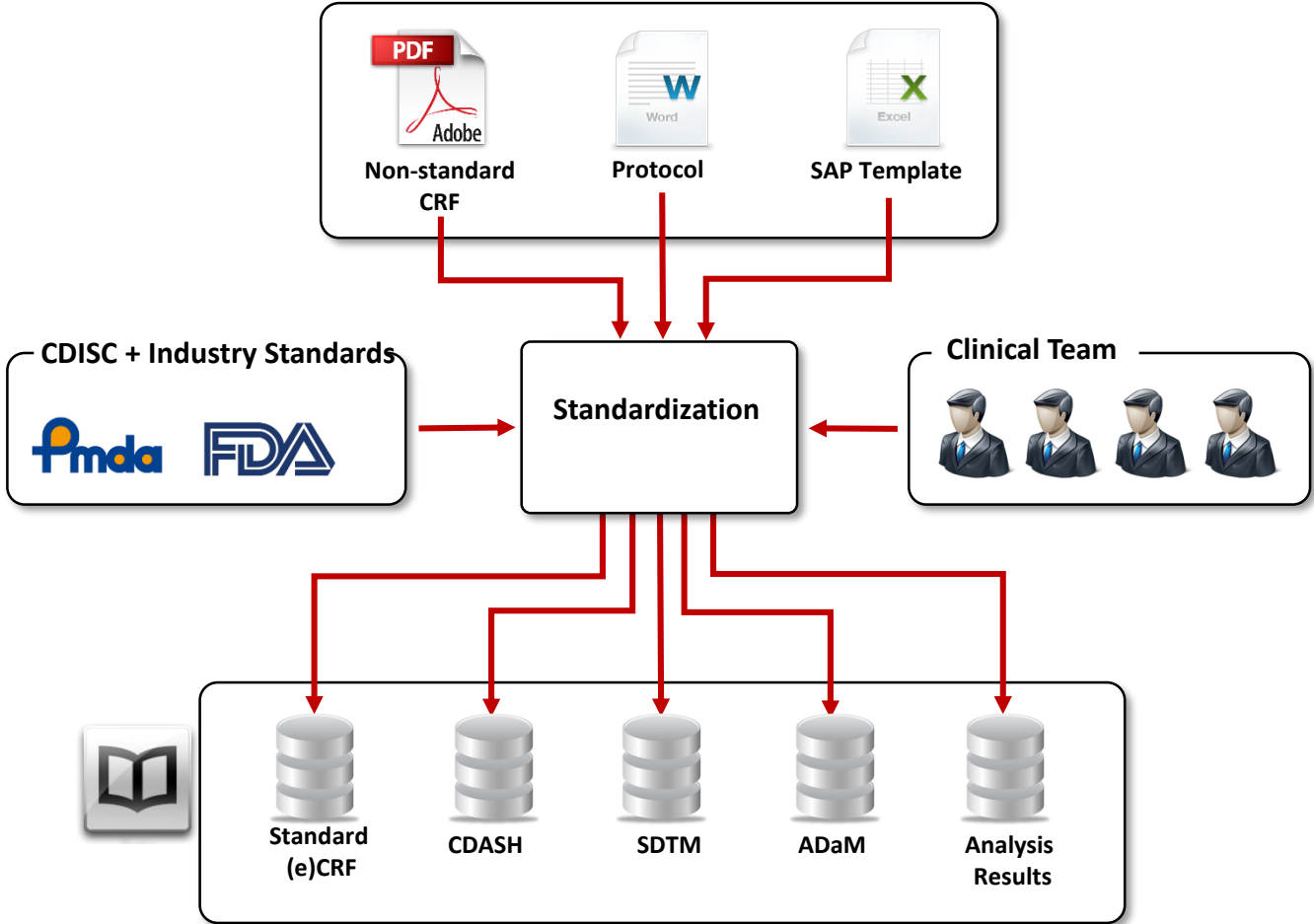
Conclusion



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

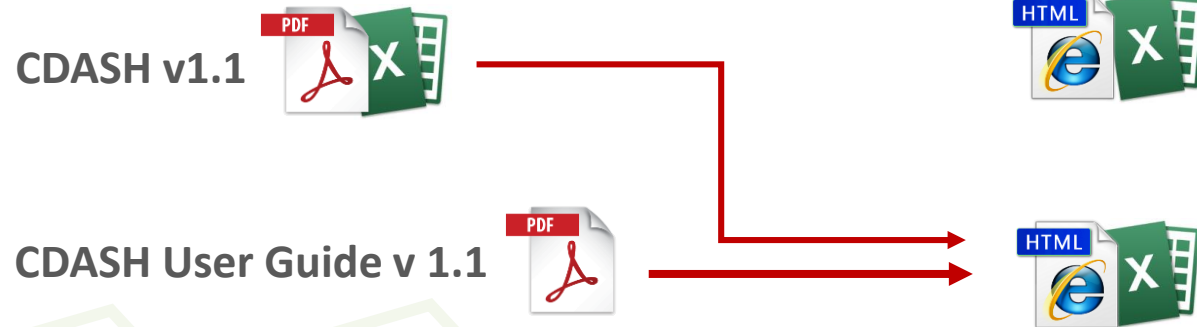
→ High level changes

→ Content updates

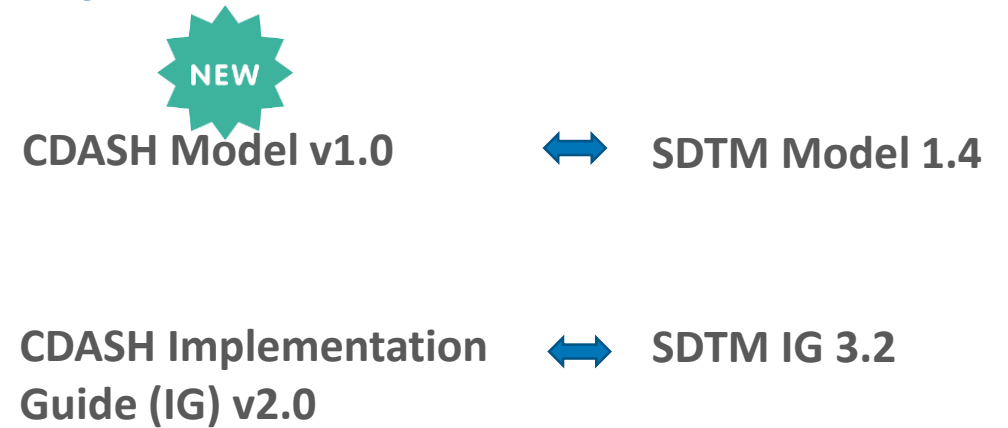
→ list of differences provided by CDISC: only high level ('major')

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

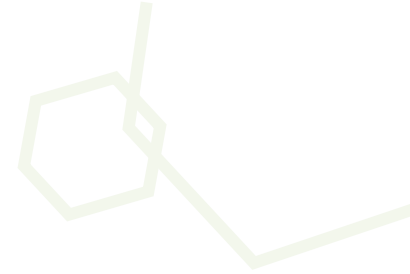
Example: If the mapping to SDTM is similar, but not direct "C" can be included before the root variable name to indicate a "collected" version of the variable to which that data will map.

Anatomical Location	<input type="checkbox"/>	Left Arm
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? (Defaulted) ECOCCUR	<u>N</u>
Study Treatment Category (Defaulted) ECCAT	<u>MISSED DOSE</u>
Study Treatment Name (Defaulted) 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

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	Excel
CDASH IG	2.0	Pending Final Curation	Excel

Need a bit of workaround due to new structure



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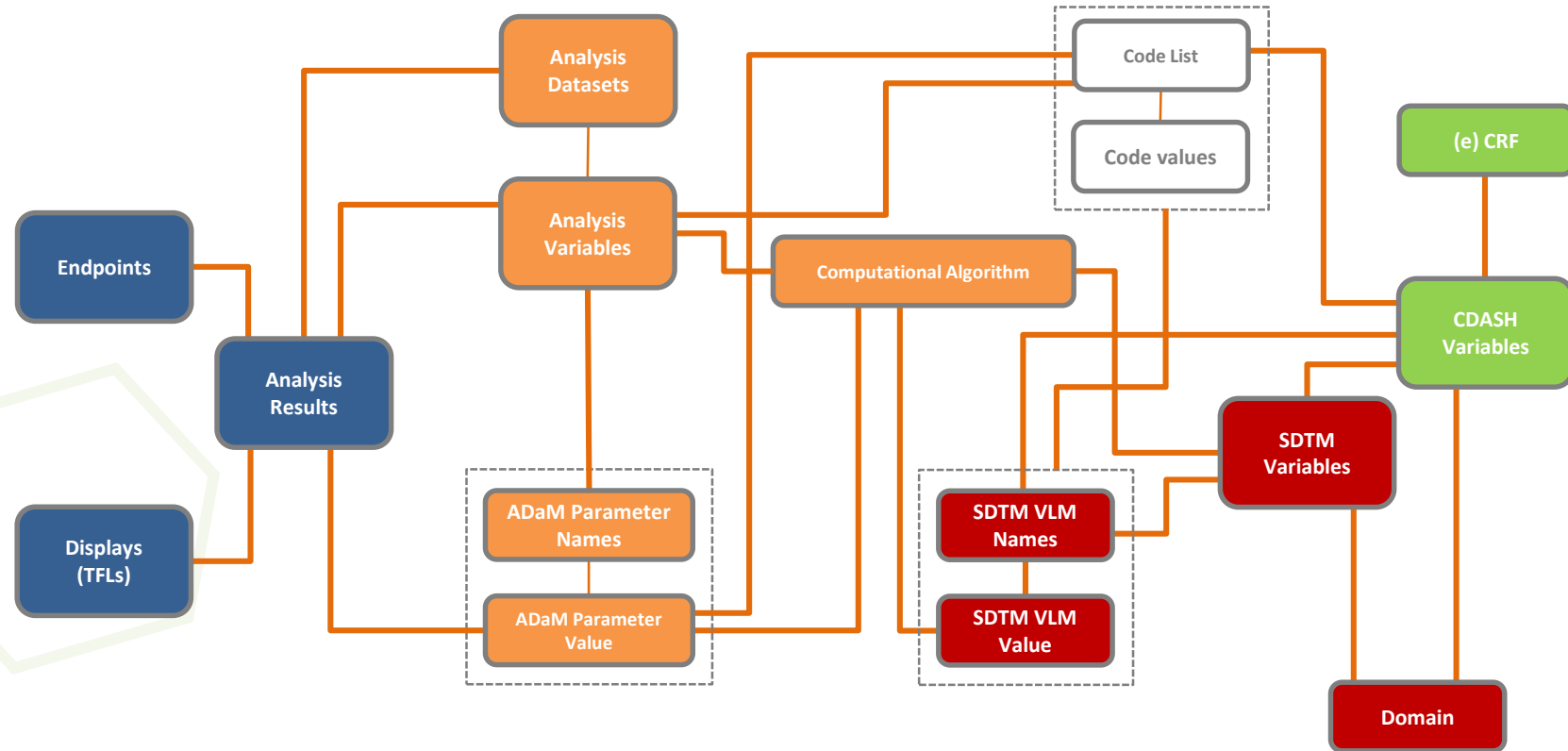
Impact Analysis: Semantic Linking

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

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*



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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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