

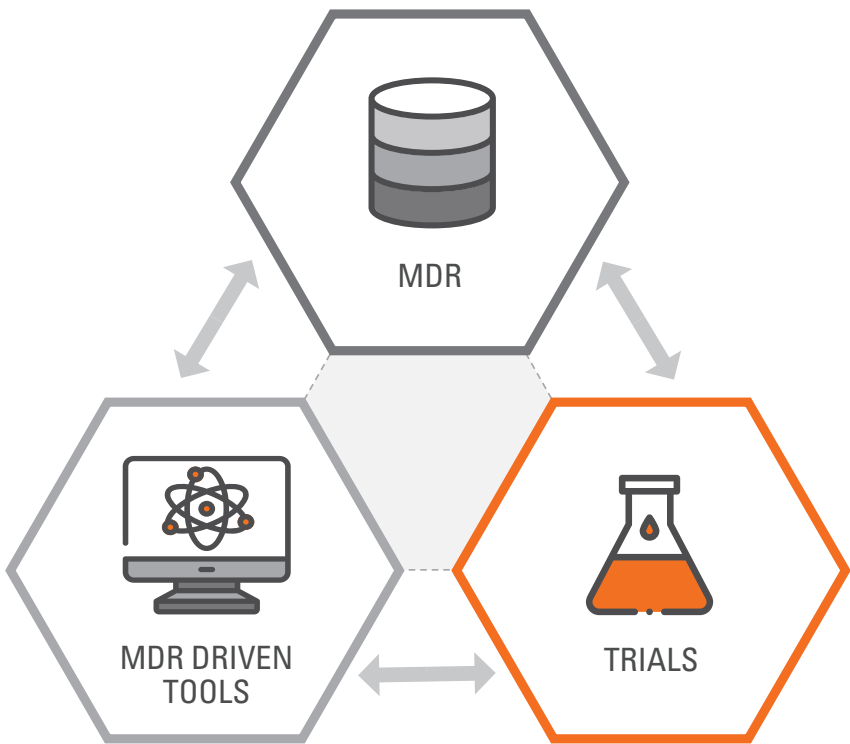
CDISC Library Try-out:

From Implementation to Evaluation of the API

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CDISC Library promises linked data and a REST API to deliver CDISC standards metadata for software applications to automate standards-based processes.

This poster will share the journey of the CDISC Library case study for one of our in-house developed tools. To test and demonstrate the implementation of the CDISC Library, we used our TS (Trial Summary information) dataset creation tool. The TS dataset creation tool enables the Clinical Data Manager to create the TS dataset for a trial, necessary for submission to the authorities. The Clinical Data Manager is able to add trial summary parameters which are based on the CDISC controlled terminology.



Case study: Trial Summary



OLD PROCESS

- Create TS dataset manually using Excel file
- Prone to error due to the nature of the TS dataset: a lot of values are controlled by terminology



IMPROVED PROCESS

- + Trial summary tool: in-house developed MDR driven application
- + User guided in creating TS records
- + Values controlled by the link with the MDR (impossible to provide incorrect values)

WHAT IS TRIAL SUMMARY

- Trial Summary (TS domain) is part of the SDTM Trial Design domains
- Describes characteristics:
 - Trial Phase
 - Trial objectives
 - Protocol title



EXAMPLE OF A TS RECORD CREATED WITH THE TRIAL SUMMARY TOOL:					
TSPARMCD	TSPARM	TSVAL	TSVALCD	TSVCDREF	TSVCDVER
ADAPT	ADAPTIVE DESIGN	Y	C49488	CDISC	2019-06-28

TSPARM & TSPARMCD

- Link with MDR: CDISC SDTM IG and controlled terminology
- User selects the parameters from a list
- Correct labels populated automatically
- For FDA submissions, check Technical Conformance Guide for required parameters

TSVAL & TSVALCD

- Populating TSVAL is a bit more complicated
- Next to the SDTM IG, the TS Codetable Excel file should be used. (can be found on the controlled terminology page of the CDISC website in the Codetable Mapping section)
- Based on this file, the user is only presented with the applicable values for that specific parameter

TSVCDREF & TSVCDVER

- Automatically populated by the Trial Summary tool. The user doesn't need to think about these two parameters
- Linking the tool with the MDR ensures that the tool exactly knows which version of the CDISC terminology was used to populate the values for TSVAL and TSVALCD

CDISC Library – API calls

CAN THE LINK WITH OUR MDR IN THE TS TOOL BE REPLACED WITH CDISC LIBRARY API CALLS?



ARE NEEDED STANDARDS AVAILABLE IN CDISC LIBRARY?

- SDTM v1.4, v1.7
- SDTMIG v3.2, v3.3
- Controlled Terminology



CAN WE USE API REQUESTS IN STEAD OF OUR MDR?

- Yes, to a certain extent we can use API call to retrieve the necessary information needed in the TS tool
- Check our paper for more information about the actual API call made for this case study



IS MORE LINKED METADATA AVAILABLE?

- No, more linked metadata is not yet available
- To populate TSVAL correctly, we still need to download the TS codetable Excel from the CDISC website and implement it in our Tool

Metadata Centric

1. MDR

- Metadata Repository is the master source of metadata containing multiple metadata libraries, including client libraries
- Structure is based on the define.xml, containing all domains, variables, valuelists, codelists, comments and computational methods

2. MDR DRIVEN TOOLS

- In-house developed applications linked to the MDR and to the trial specific metadata
- Achieve end to end automation of the SDTM workflow
- Tool examples:
 - Annotation tool
 - SDTM mapping tool
 - Trial Summary creator

3. TRIALS

- At SDTM database setup, the complete set of applicable metadata library is copied from the MDR
- Make the metadata specific to the trial

CONCLUSION

- With the CDISC 360 concept, CDISC Library and API technology, I believe CDISC has laid the foundations for automatized standards-based processes
- The more linked metadata becomes available in the CDISC Library, the better software it will deliver
- By only making use of the CDISC Library API in our TS tool, we can't provide the same functionalities yet (case study performed in June 2020)
- For this case study I don't see much differences/benefits yet in using the old way, the CDISC share vs the CDISC library



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