Collaboration between Sponsors and CROs with a Study Level Metadata Repository

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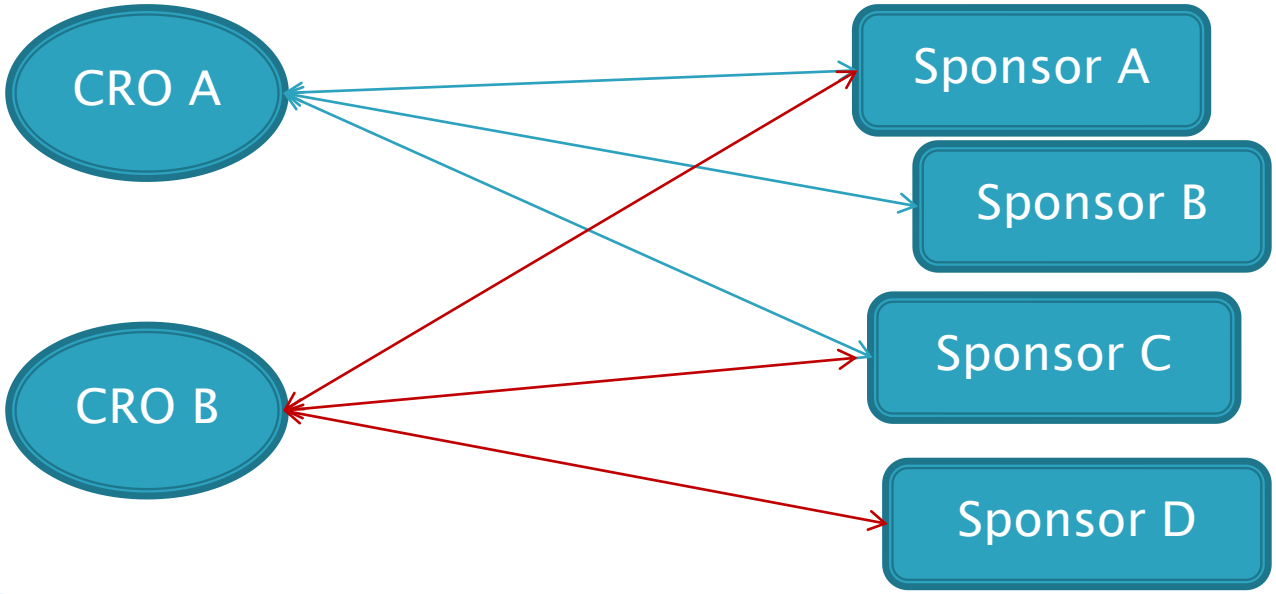
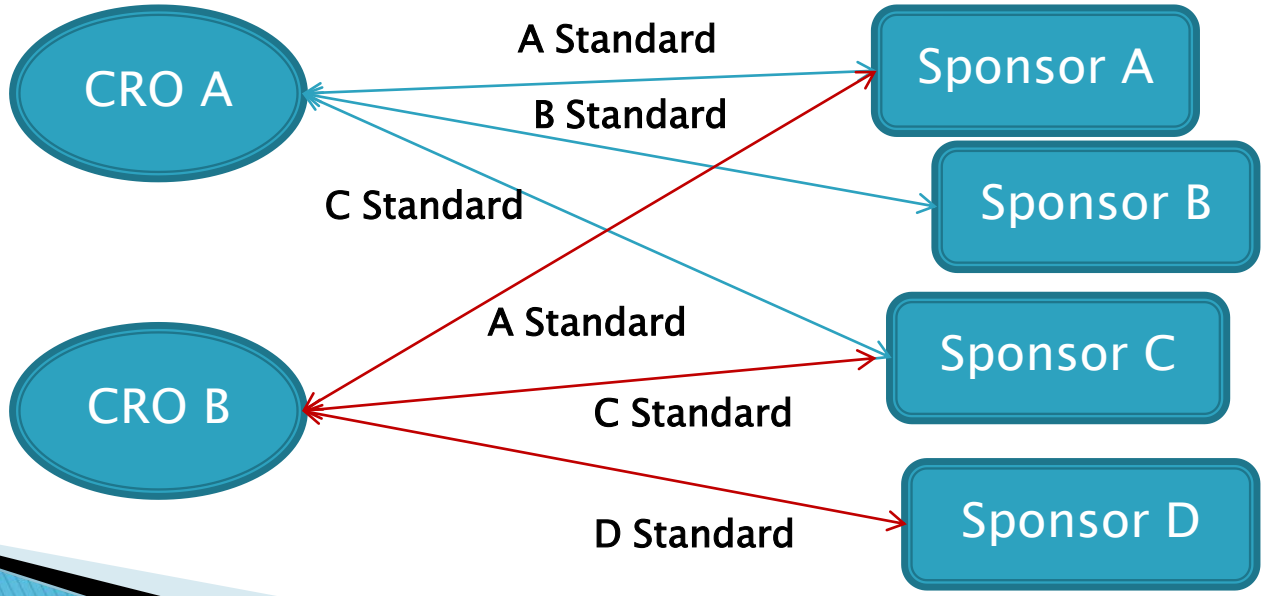
Introduction

- A Clinical Programmer at CRO touches several projects for creating the data package and the statistical reports (TFLs) simultaneously.



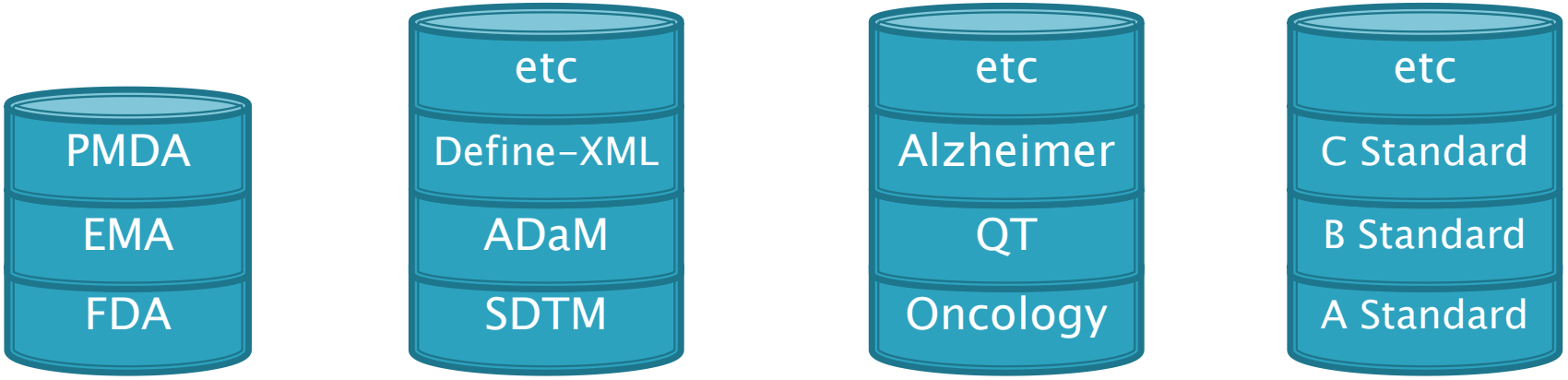
Introduction

- Each sponsor has a little different own standard, therefore a clinical programmer at CRO has to learn the each different sponsor's standard.



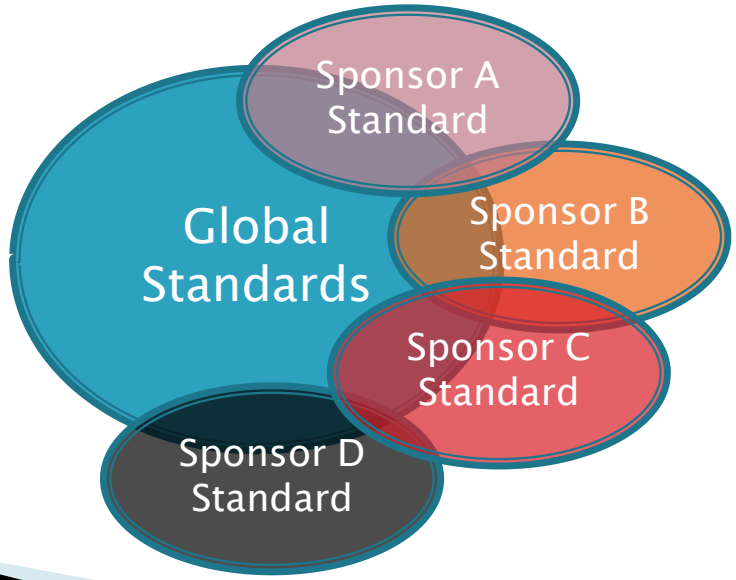
Introduction

Clinical programmers at CRO have to learn huge number of Standards including the regulatory guidance, fundamental CDISC Standards, Therapeutic Area Standards, and each sponsor's standards.



Problems

- Clinical programmer at CRO spend a long time for learning these standard and for understanding what differences are among each sponsor's standards.



Problems

- Clinical programmers at CRO sometimes have little confusion.

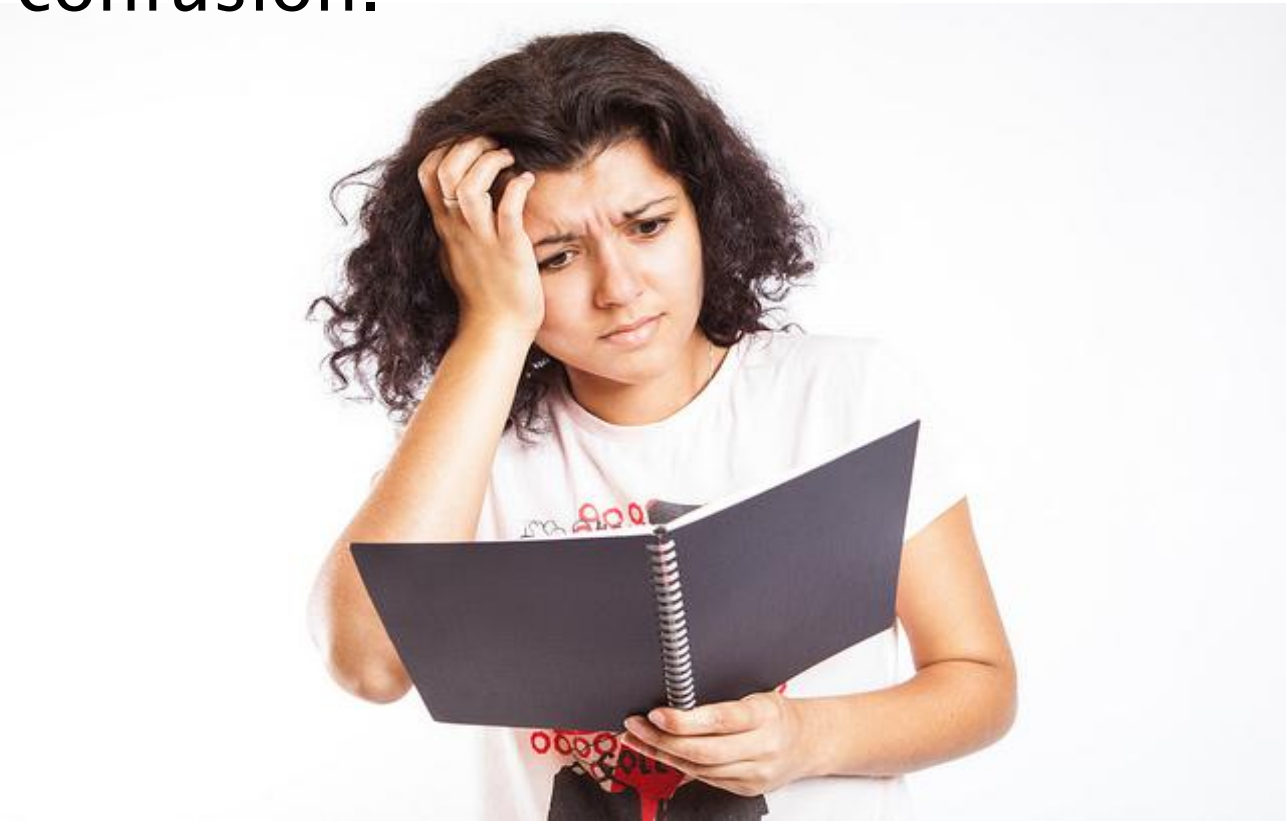


Photo by CollegeDegrees360

Problems

- Sponsor's standards include differences from CDISC Standards.
  - Different Controlled Terms
  - Different use case with SDTMIG and ADaMIG
  - Same term and different definition
  - Different term and same definition

Approaches to this problem

- It is considered two approaches to this problem.

- 1. All sponsors completely accepts the global standards.

- 2. Shorten time to learn the each different sponsor's standards with innovative methods

Our Approach

Proposal

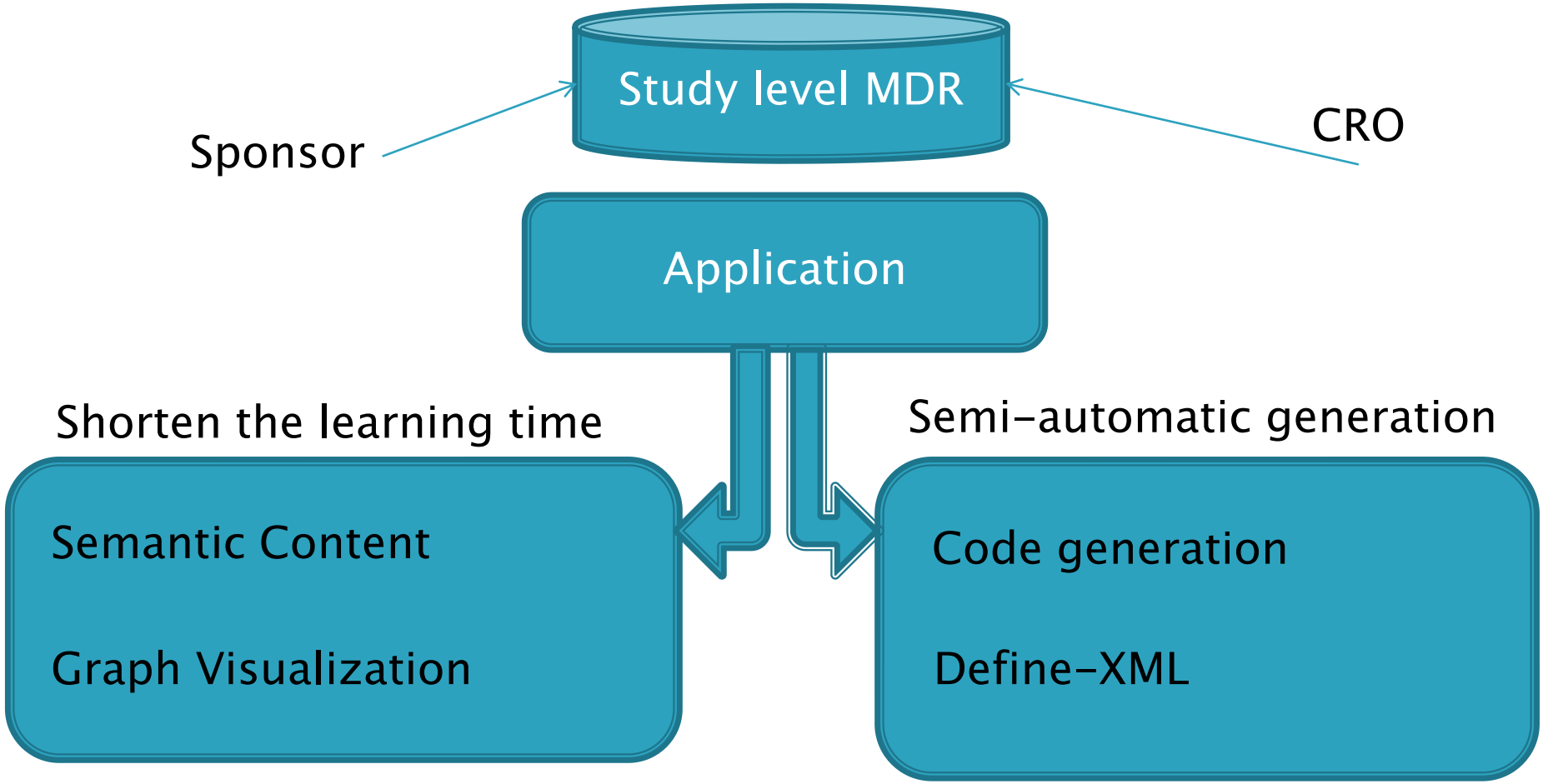
- In current situation, a clinical programmer at CRO learns sponsor specific standards with their guideline documents, metadata template, and their controlled terms.

- Our proposal is to realize shortened the learning time with Study Level Metadata Repository (MDR).

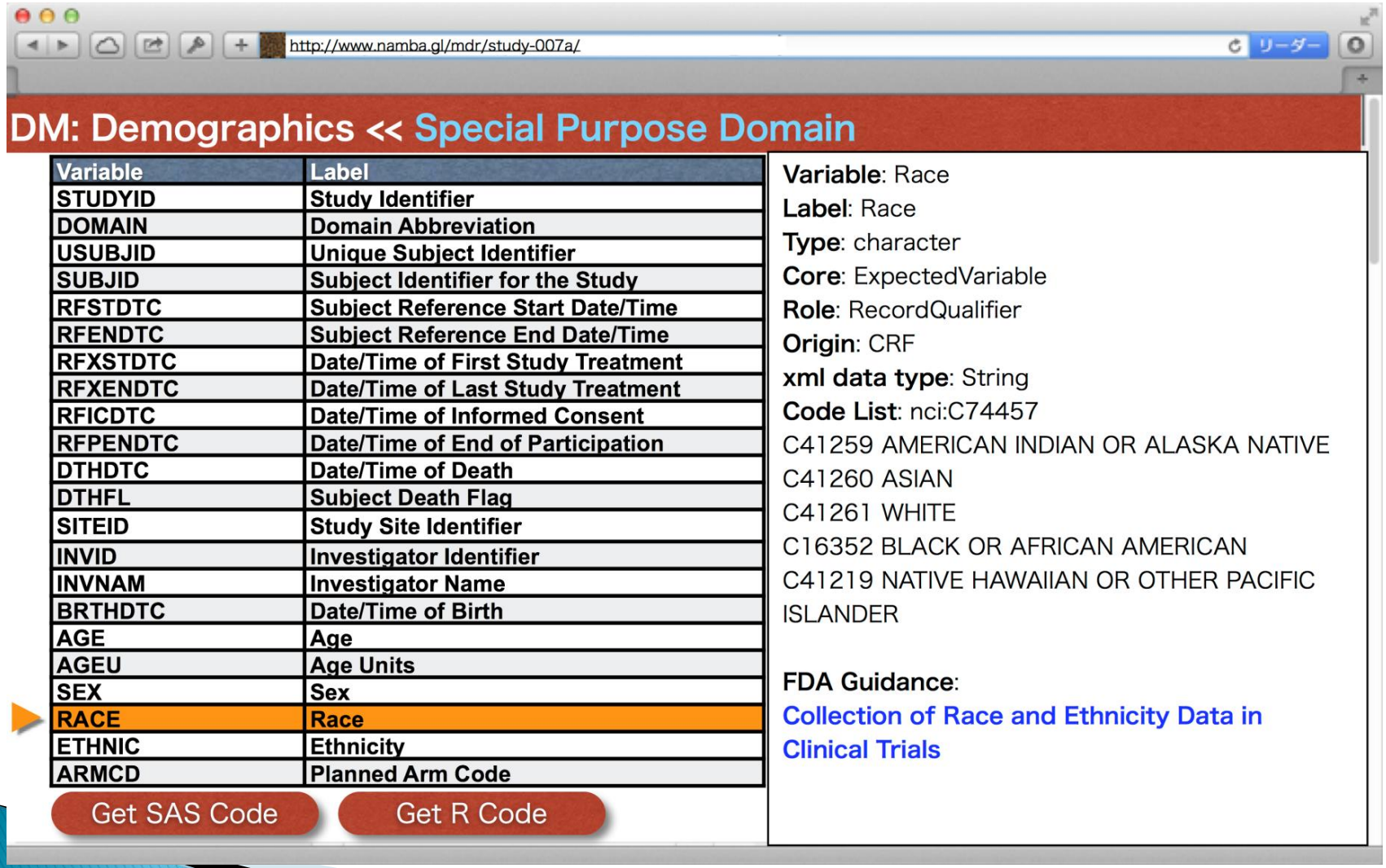
Proposal

- Using study level MDR:
  - Easy to understand metadata definition and the relationship among each metadata
  - semi-automatic generating a script code, which creates datasets and TFLs, and define.xml

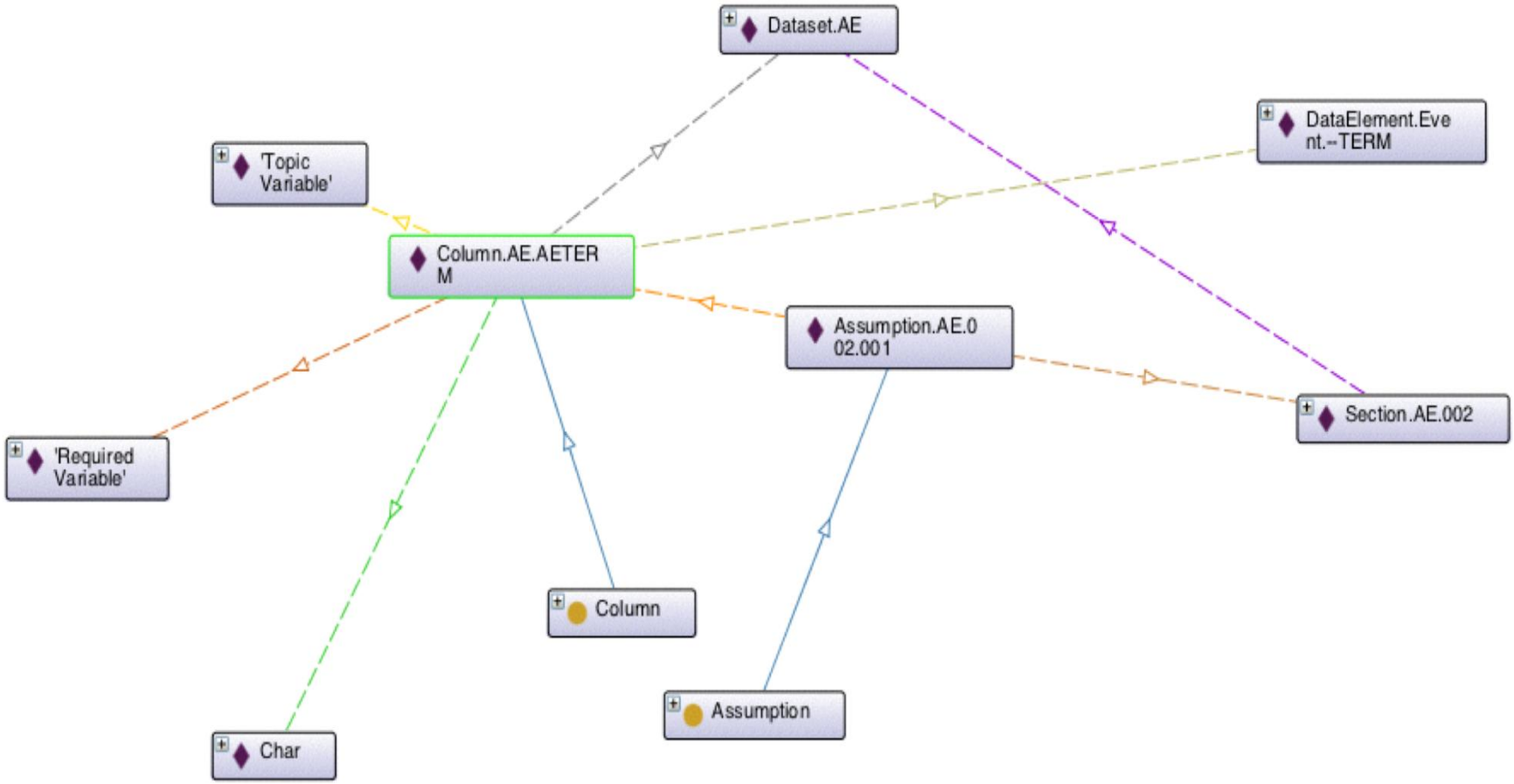
Collaboration with MDR



Semantic Content



Graph Visualization



Advantages of this concept

- Shorten the learning time
- Elevate a quality of data and TFLs

What should we do?

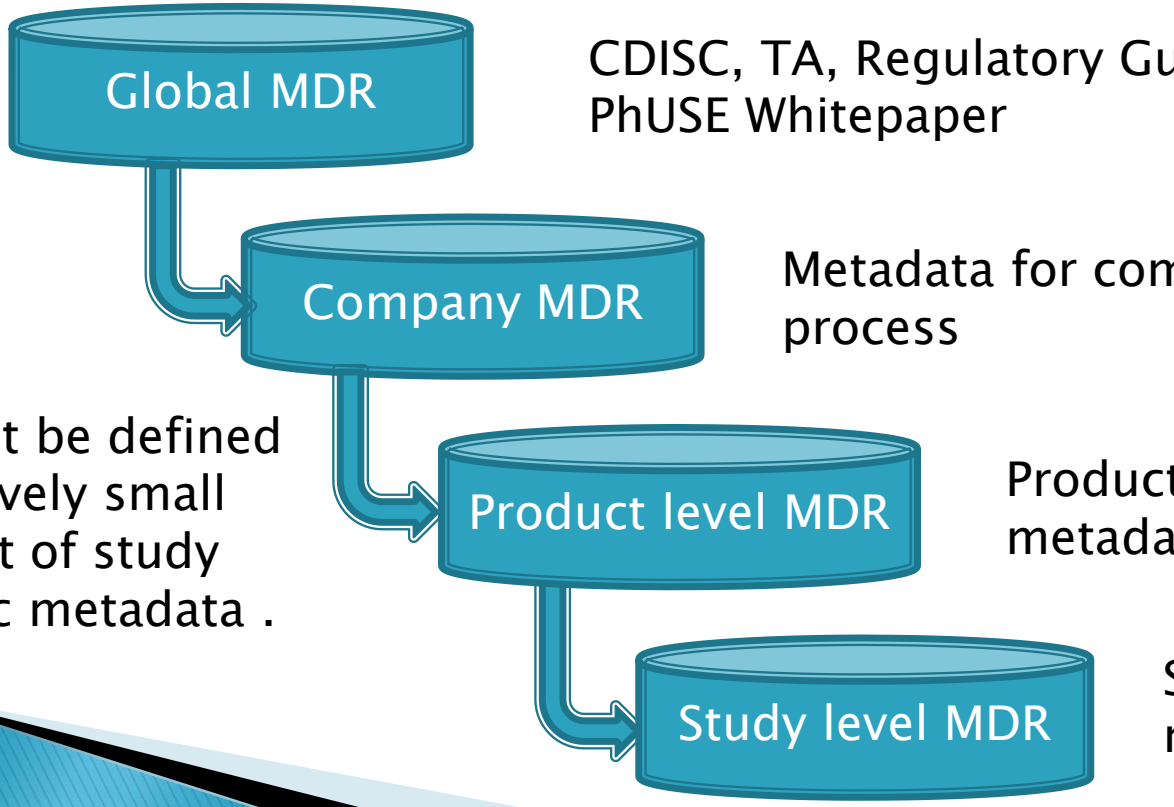
- Necessaries for this concept
  - Set up the MDR application
  - Implement the sponsor's metadata
  - Publish the sponsor's metadata to CRO
  - Metadata Governance

Study Level Metadata

- Dataset metadata
- Variable metadata
- Value and Parameter metadata
- Controlled Terminology
- Study Design
- Definition of computation
- Analysis Results Metadata

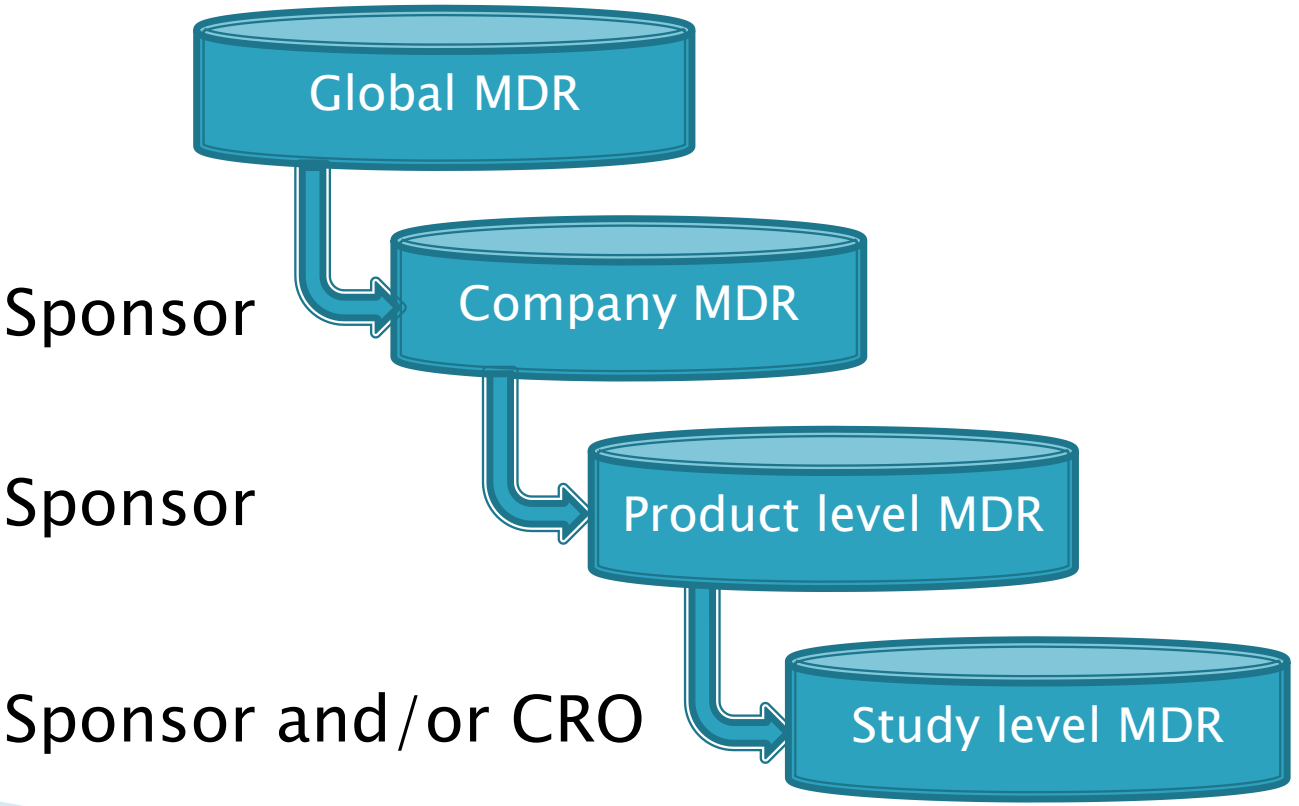
Hierarchy of MDR

- Metadata in Study level MDR might be to inherit metadata from upper level MDR



Metadata Governance

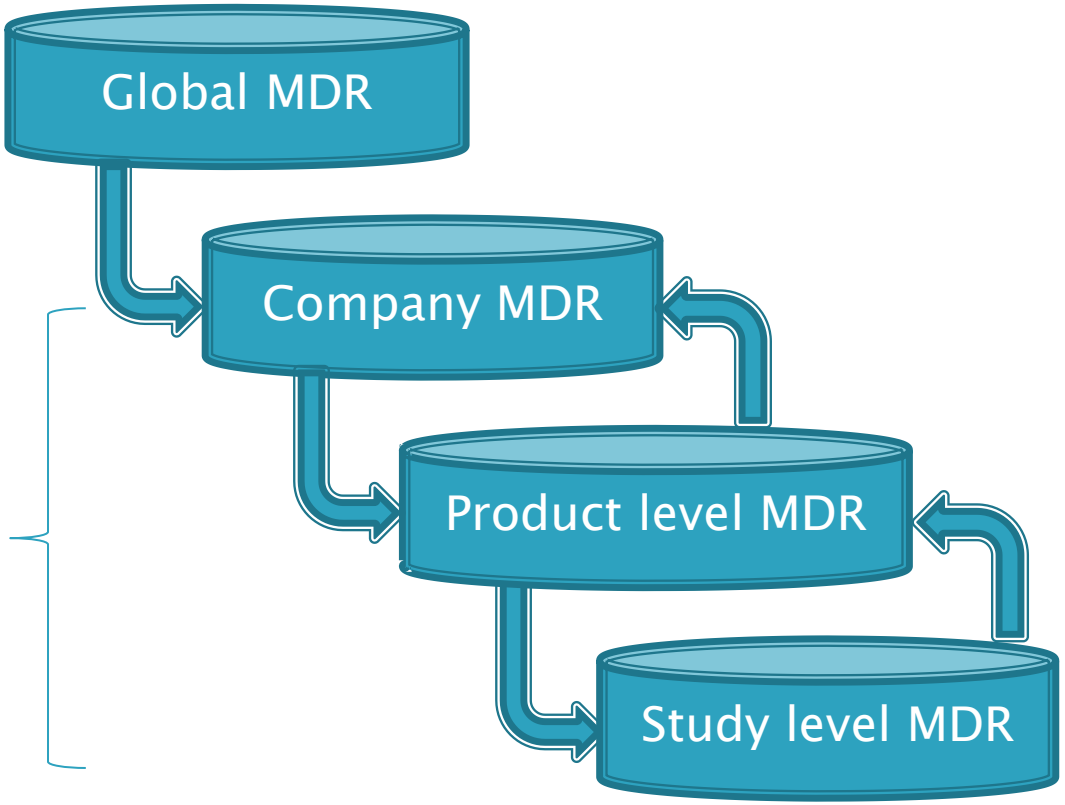
Who has responsibly to define the study level metadata?



Metadata Governance

A responsible person for each level MDR have to keep consistency throughout all level metadata.

Choose the metadata from upper level MDR
Feedback from lower level MDR



Metadata Driven Collaboration

Summary

- It was suggested a new concept for good collaboration with semantic technology based study level metadata between a sponsor and a CRO.

- We should be progressing the collaboration based on this concept.
- However, we have to discuss continuously regarding:
  - Features of MDR application
  - Metadata governance
  - Scope of study level metadata