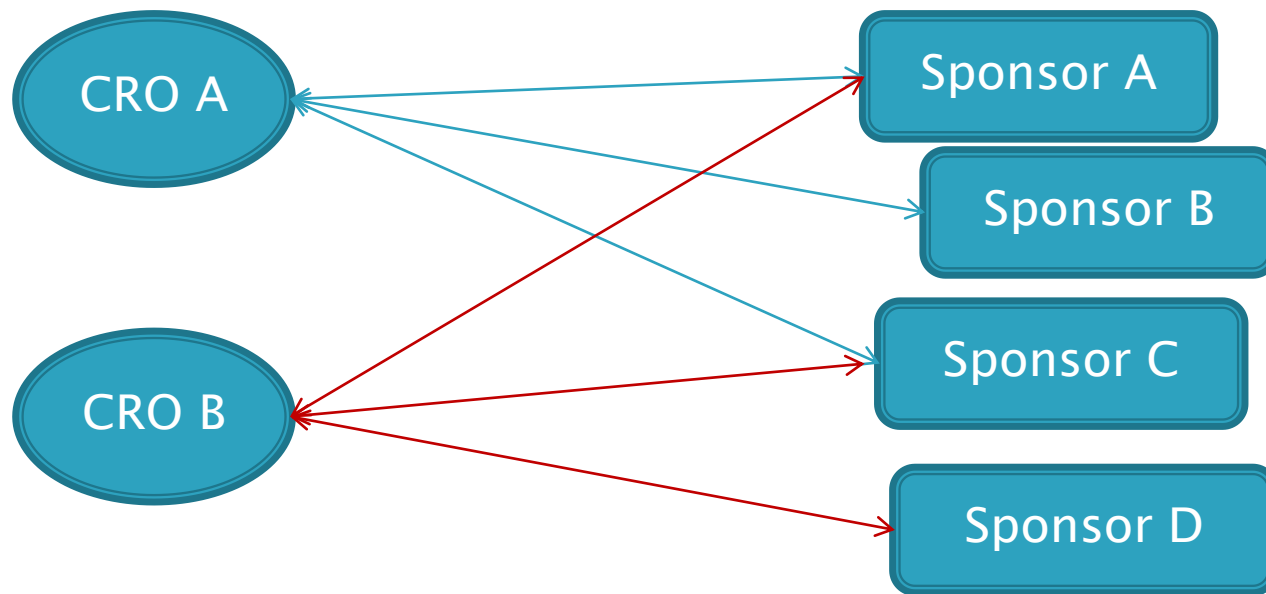


Collaboration between Sponsors and CROs with a Study Level Metadata Repository

Masami Ohchi, ACRONET

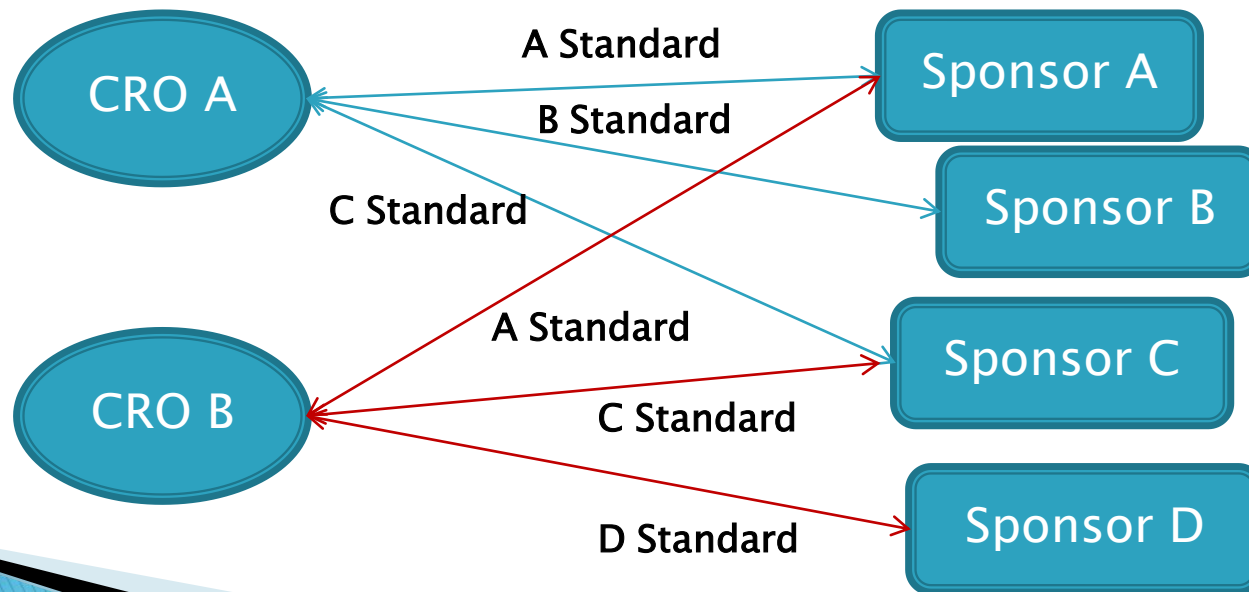
Introduction

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



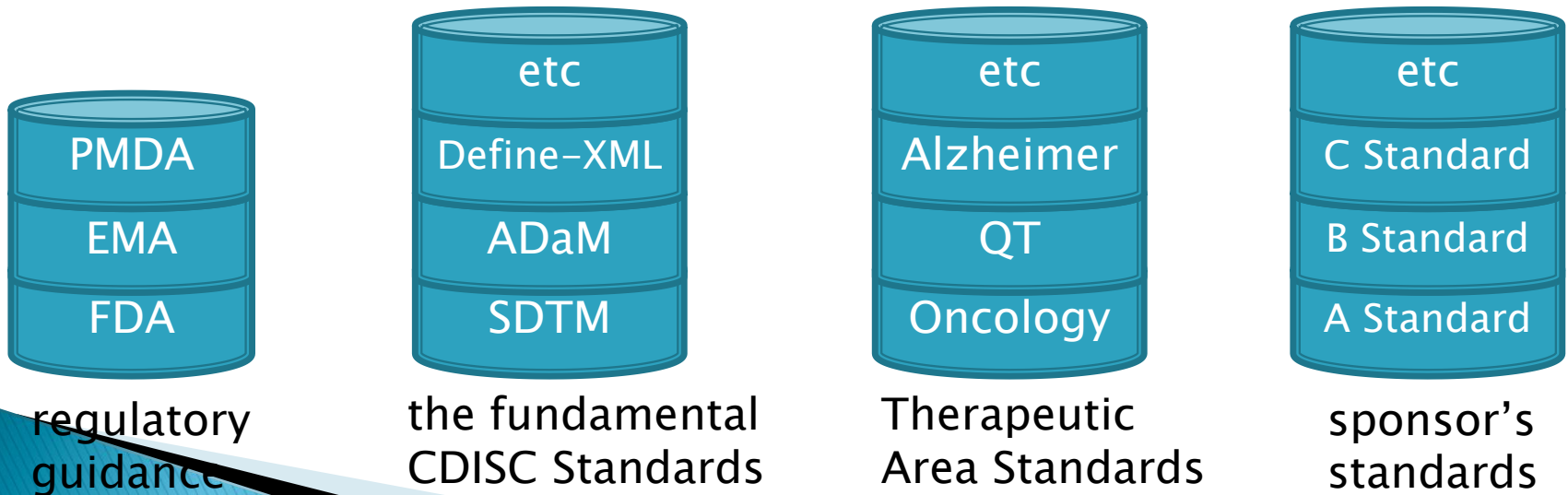
Introduction

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



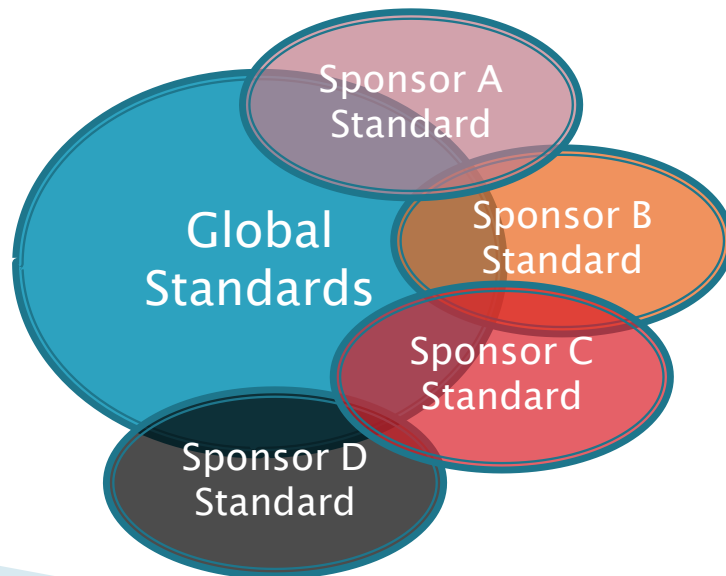
Introduction

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

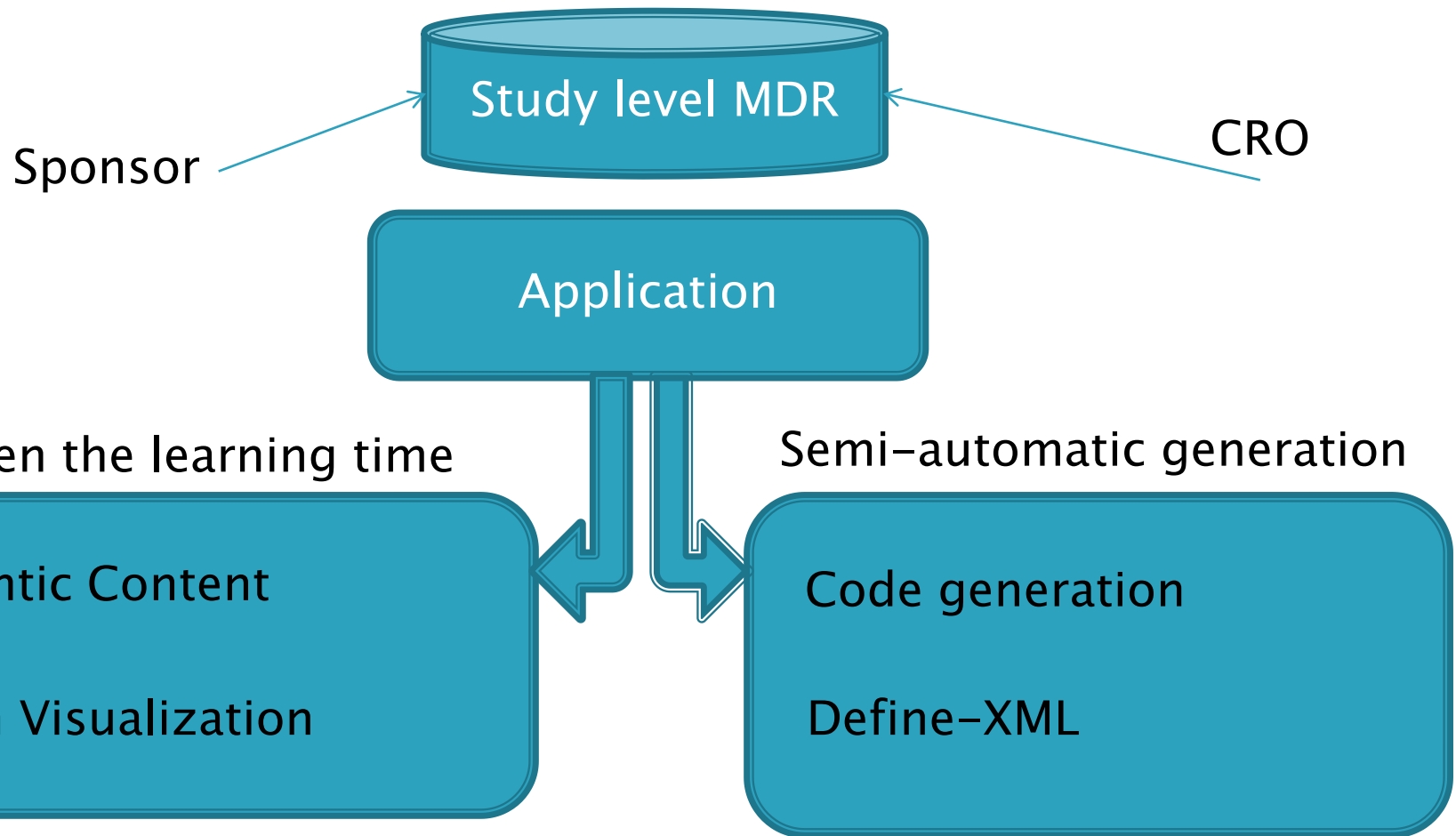
Proposal

- ▶ 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

http://www.namba.gl/mdr/study-007a/ リーダー

DM: Demographics << Special Purpose Domain

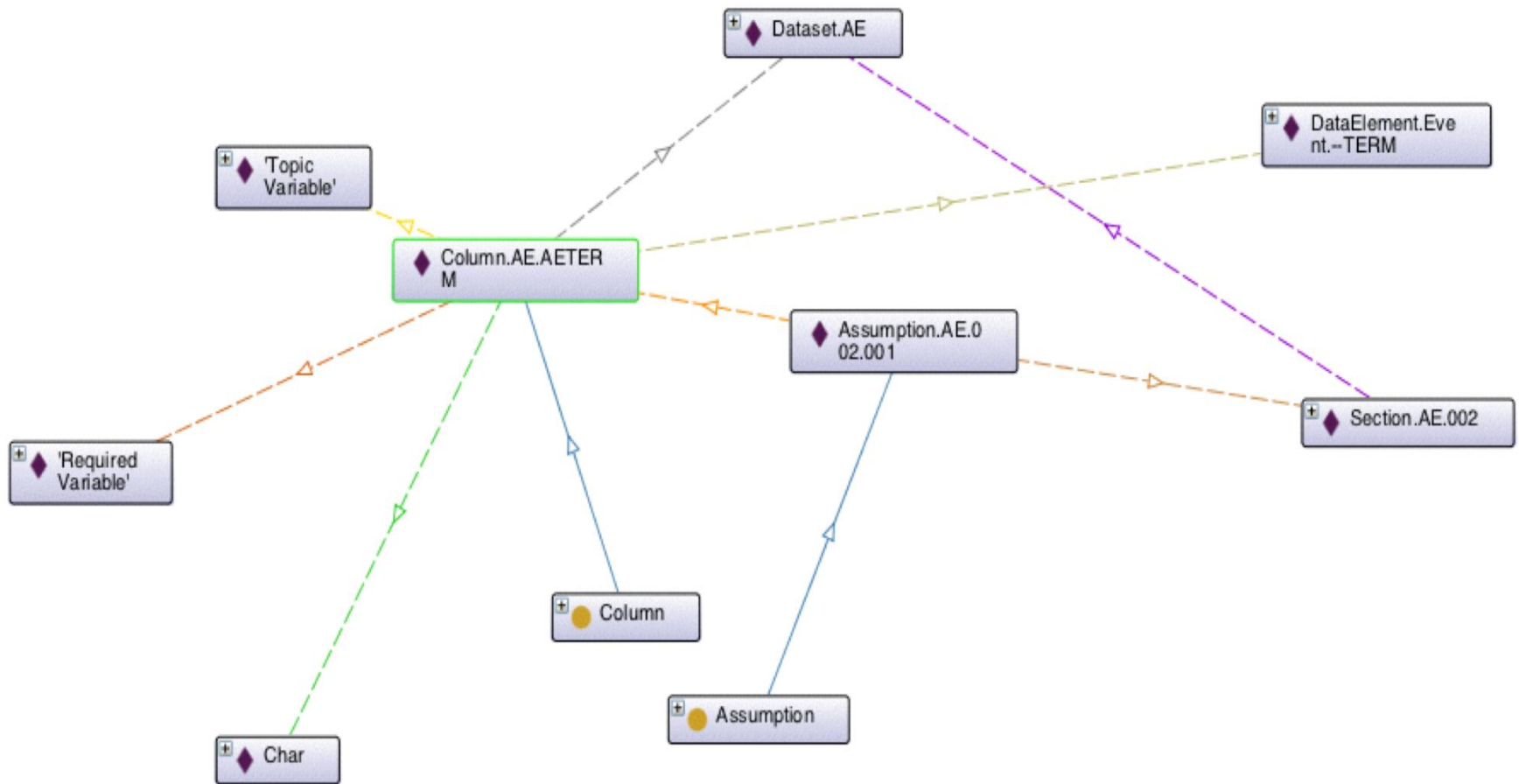
Variable	Label
STUDYID	Study Identifier
DOMAIN	Domain Abbreviation
USUBJID	Unique Subject Identifier
SUBJID	Subject Identifier for the Study
RFSTDTCT	Subject Reference Start Date/Time
RFENDTCT	Subject Reference End Date/Time
RFXSTDTCT	Date/Time of First Study Treatment
RFXENDTCT	Date/Time of Last Study Treatment
RFICDTCT	Date/Time of Informed Consent
RFPENDTCT	Date/Time of End of Participation
DTHDTCT	Date/Time of Death
DTHFL	Subject Death Flag
SITEID	Study Site Identifier
INVID	Investigator Identifier
INVNAM	Investigator Name
BRTHDTCT	Date/Time of Birth
AGE	Age
AGEU	Age Units
SEX	Sex
RACE	Race
ETHNIC	Ethnicity
ARMCD	Planned Arm Code

Variable: Race
Label: Race
Type: character
Core: ExpectedVariable
Role: RecordQualifier
Origin: CRF
xml data type: String
Code List: nci:C74457
C41259 AMERICAN INDIAN OR ALASKA NATIVE
C41260 ASIAN
C41261 WHITE
C16352 BLACK OR AFRICAN AMERICAN
C41219 NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER

FDA Guidance:
[Collection of Race and Ethnicity Data in Clinical Trials](#)

Get SAS Code Get R Code

Graph Visualization



Advantages of this concept

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

What should we do?

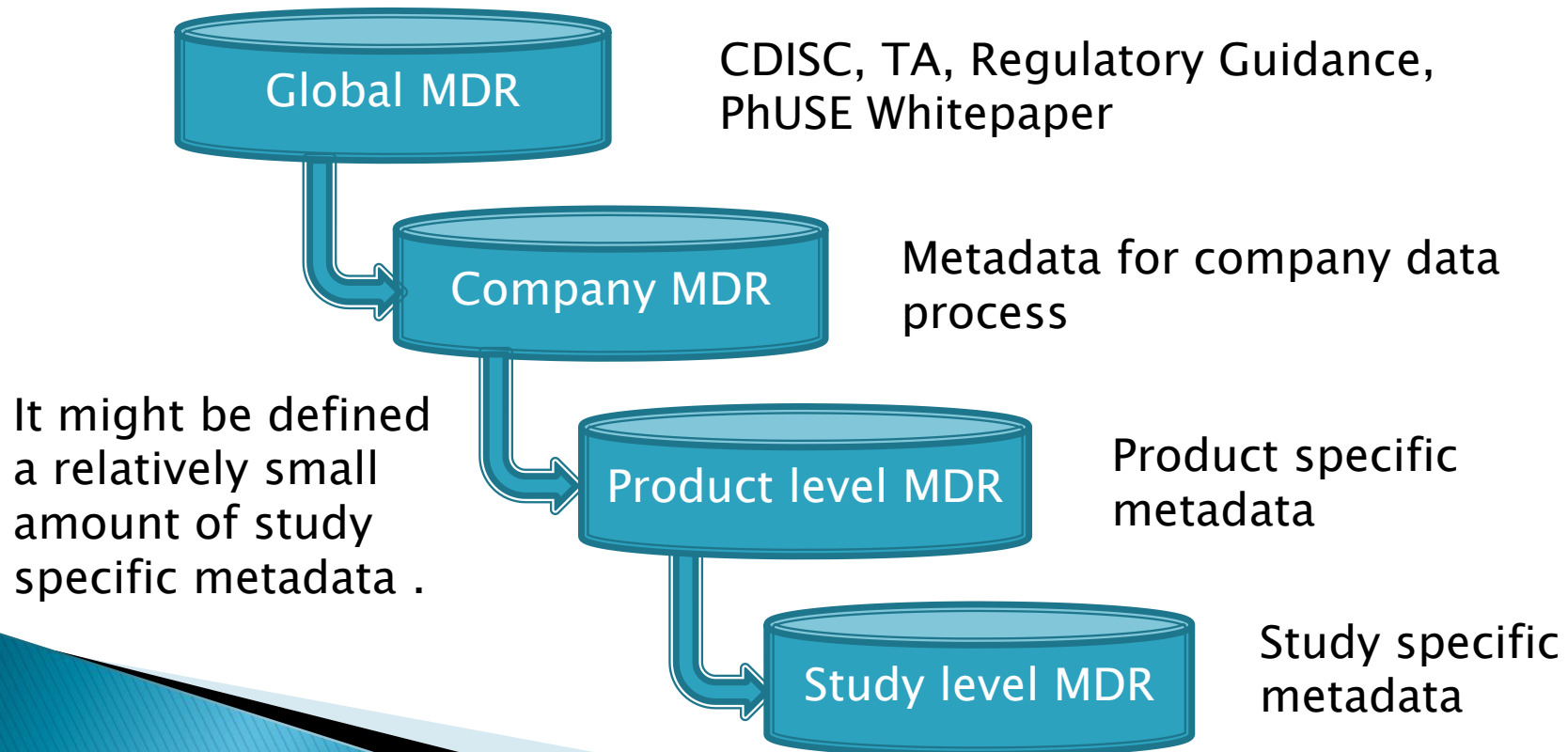
- ▶ Necessaries for this concept
 - Set up the MDR application
 - Implement the sponsor's metadata
 - Publish the sponsor's metadata to CRO
 - Metadata Governance

Study Level Metadata

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

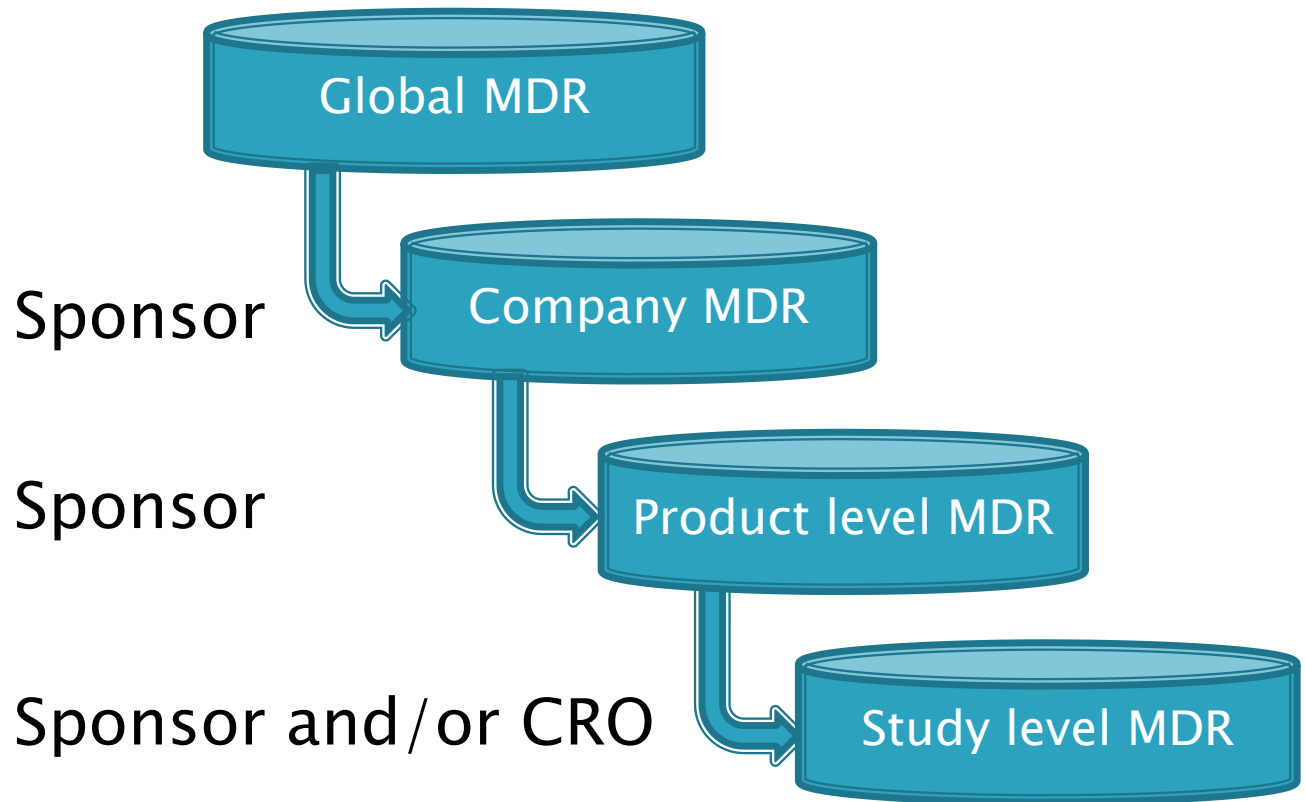
Hierarchy of MDR

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



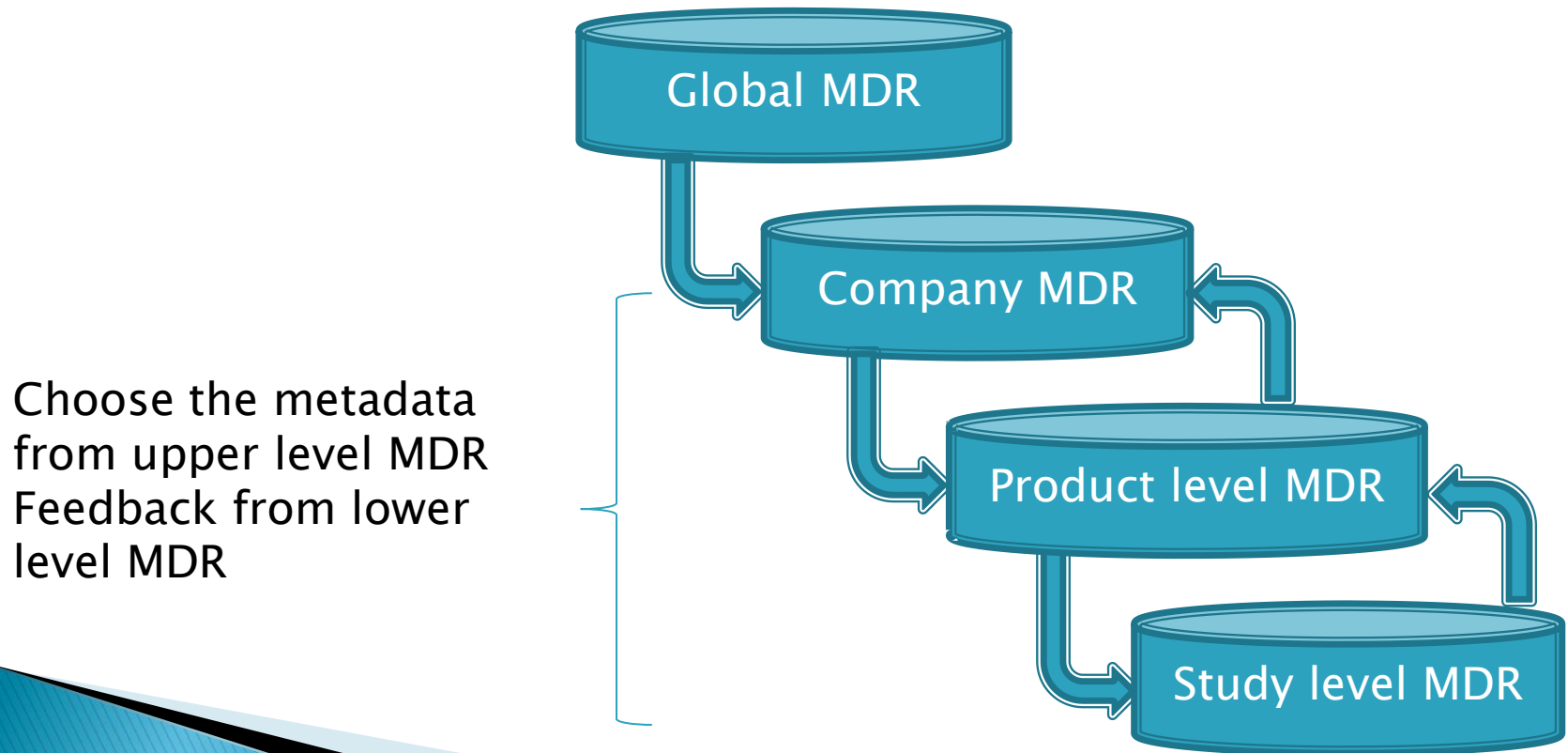
Metadata Governance

Who has responsibility to define the study level metadata?

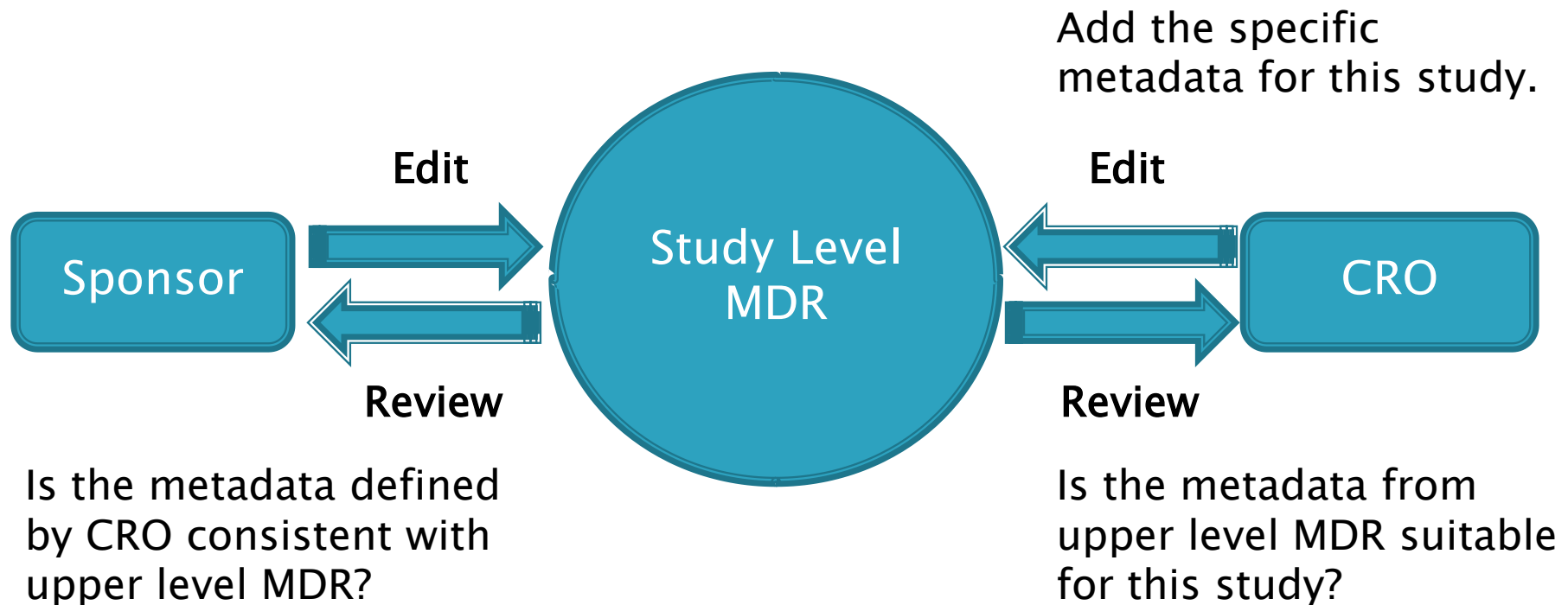


Metadata Governance

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



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