

Business & Decision Life Sciences

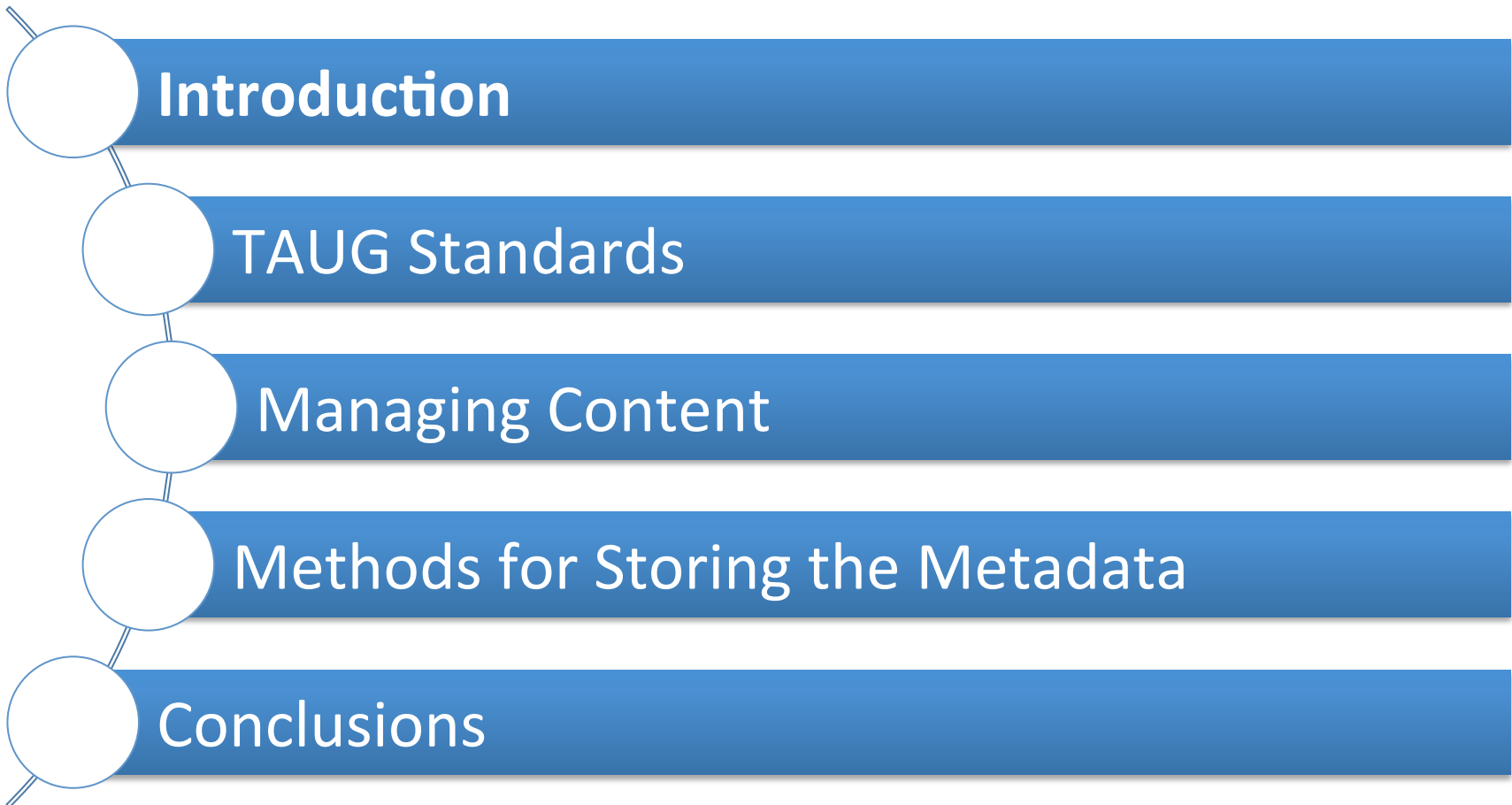
Is Your Clinical Data Standards Library Ready for Change? – Adapting to Therapeutic Area Specific Standards

Lauren Shinaberry

13 October 2014



Is Your Clinical Data Standards Library Ready for Change?

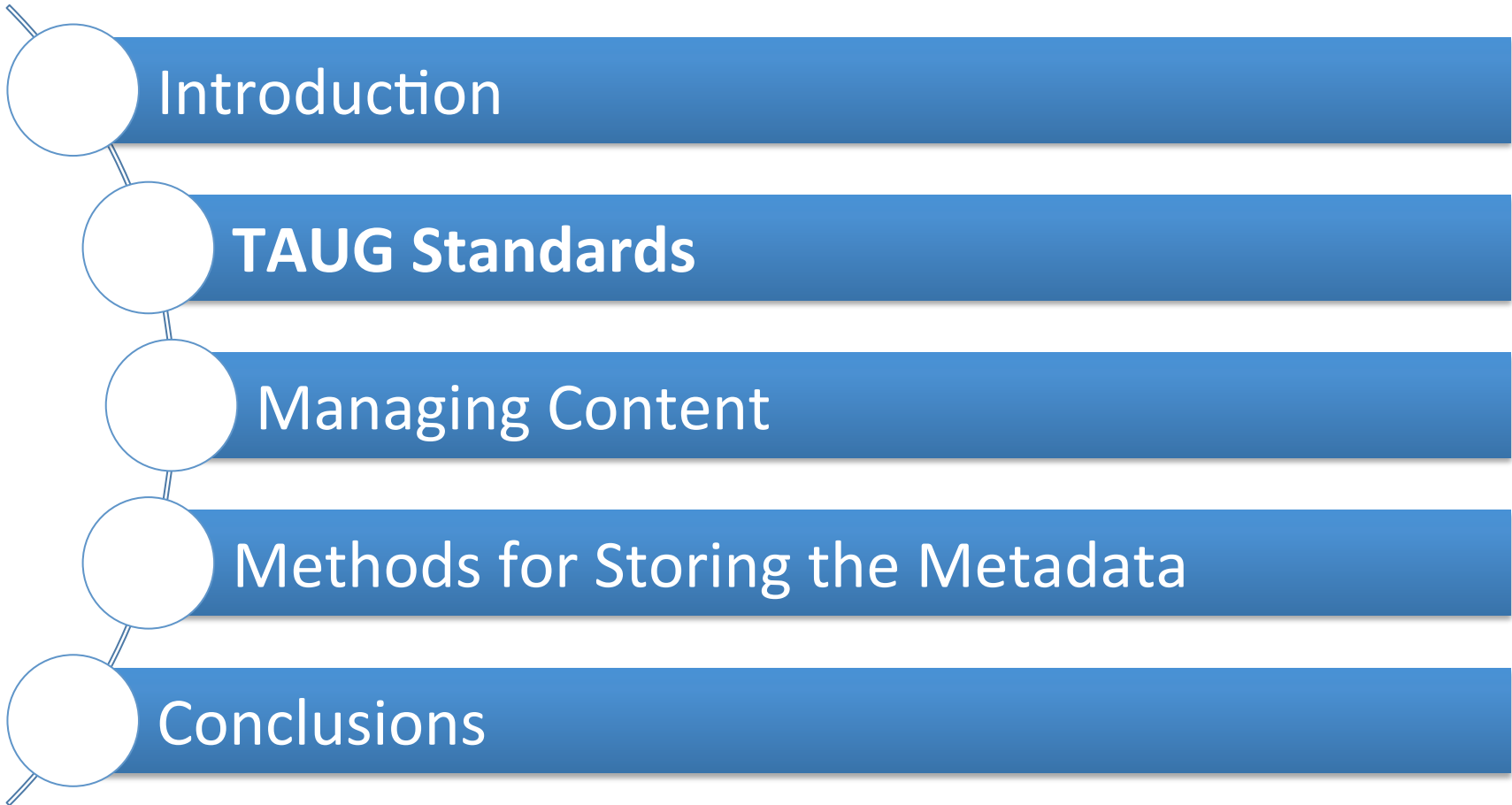


Introduction



- **Brief overview of current, ongoing and planned Therapeutic Area User Guides (TAUGs) from CFAST**
- **Description of TA standards development and why it matters to your library**
- **Past-present-future state of storing standard metadata**
- **Recommendations for best practices**

Is Your Clinical Data Standards Library Ready for Change?



TAUG Standards



Program Overview – September 2014 Approved Therapeutic Area Standards Projects

Therapeutic Area	Coordinating Organization(s)	Proposal Approval Date	Stage 0	Stage 1	Stage 2	Stage 3a	*Stage 3b	*Stage 3c
	Project Manager		Scoping & Planning	Concept Modeling	Standards Development	Internal Review	Public Review	**Projected Publication
CV Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	July	Sep	Nov	Feb	May	Q314
Diabetes v1	TCB Rachael Zirkle	Apr 13	May	Aug	Dec	Apr	May	Q314
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	Jul	Sept	Q414
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Sept	Oct	Nov			Q215
Chronic Hepatitis C Virus v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Oct	Nov	Q414
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	Jul	Aug	Oct	Nov	Q115
Breast Cancer v1	TCB Pam Harvey	Nov 13	Aug	Sept	Nov			2015
Influenza v1	C-PATH Laura Butte	Feb 14	May	Jul	Aug	Sept	Oct	Q414
Dyslipidemia v1	TCB John Glover	Dec 13	May	Sept	Oct			Q115
COPD v1	TCB John Glover	Nov 13	Aug	Oct	Dec			Q315

Key | Stage completed | Stage ongoing | All months reflect when stage is, or is projected to be, completed.

*The Stage3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publically available.

** Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

September 19, 2014



List of planned TA standards and release dates available on website:

<http://www.cdisc.org/therapeutic>



TAUG Process



- Development requires understanding of the clinical aspects of the data that is unique to the area
- Approach developed by CDISC: good model for development of internal TA standards
- Process: starts with defining scope/clinical concepts (not with SDTM data)

Therapeutic Area	Coordinating Organization(s)	Proposal Approval Date	Stage 0	Stage 1	Stage 2	Stage 3a	*Stage 3b	*Stage 3c
	Project Manager		Scoping & Planning	Concept Modeling	Standards Development	Internal Review	Public Review	**Projected Publication
CV Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	July	Sep	Nov	Feb	May	Q314

Concept maps



CDISC Therapeutic Area Data Standards: User Guide for Alzheimer's Disease (Version 2.0)

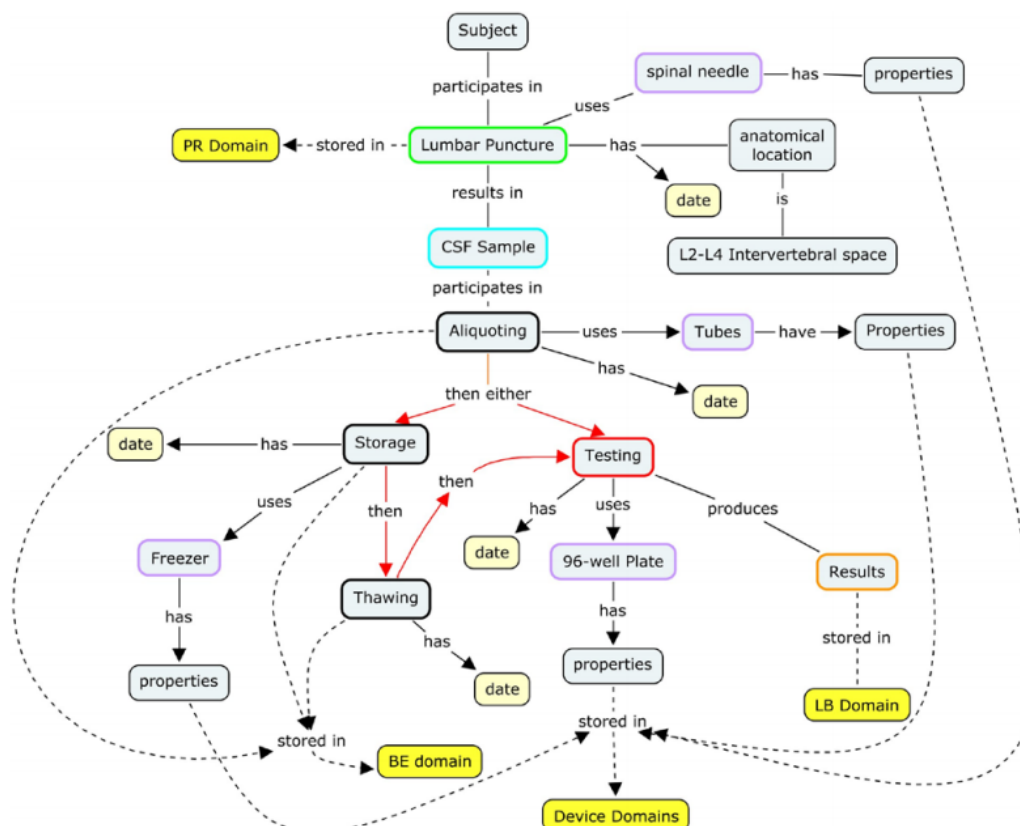
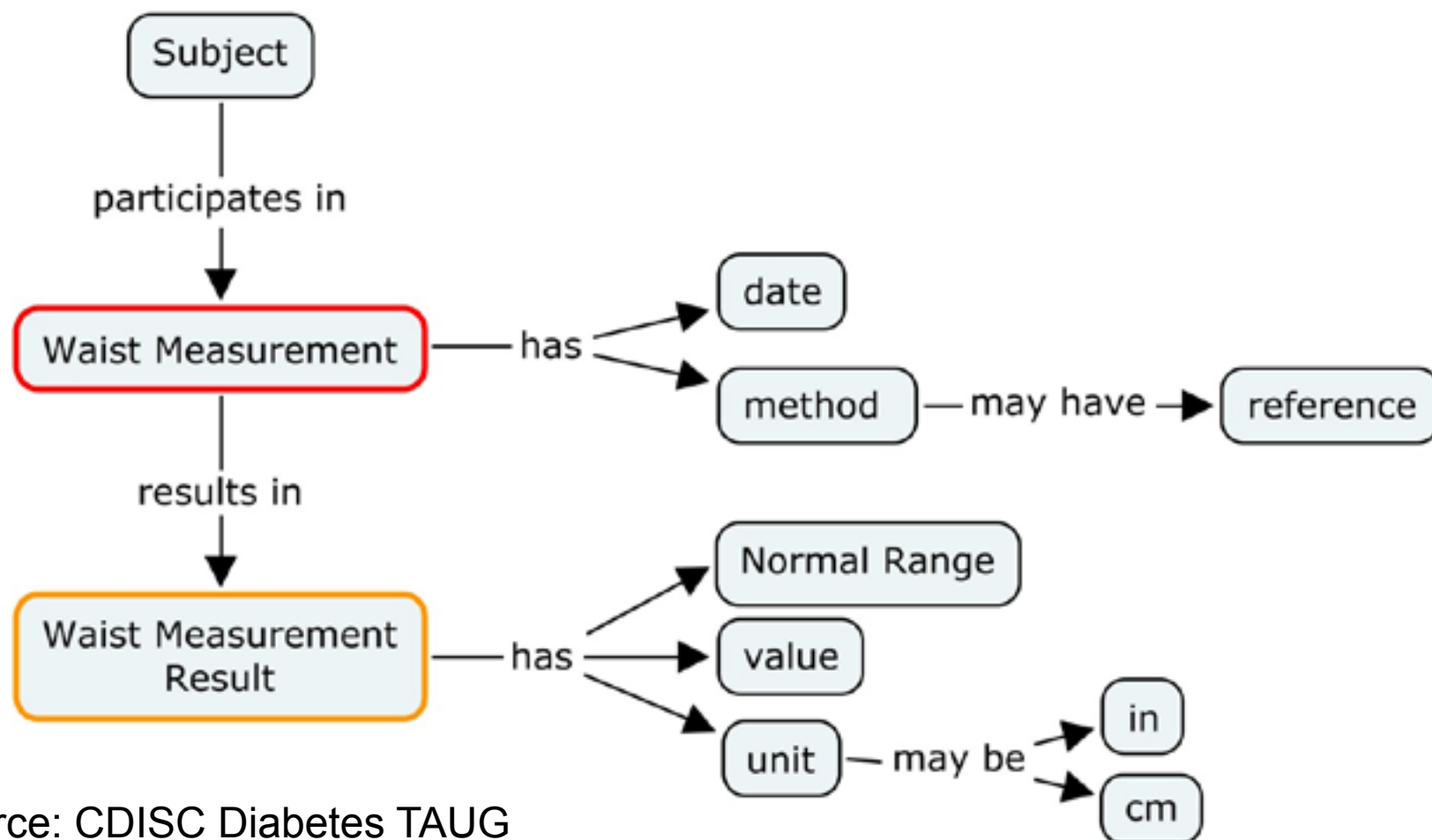


Figure 3.1: CSF Sampling and Processing

Concept maps



Source: CDISC Diabetes TAUG

Applying TAUGs to your libraries

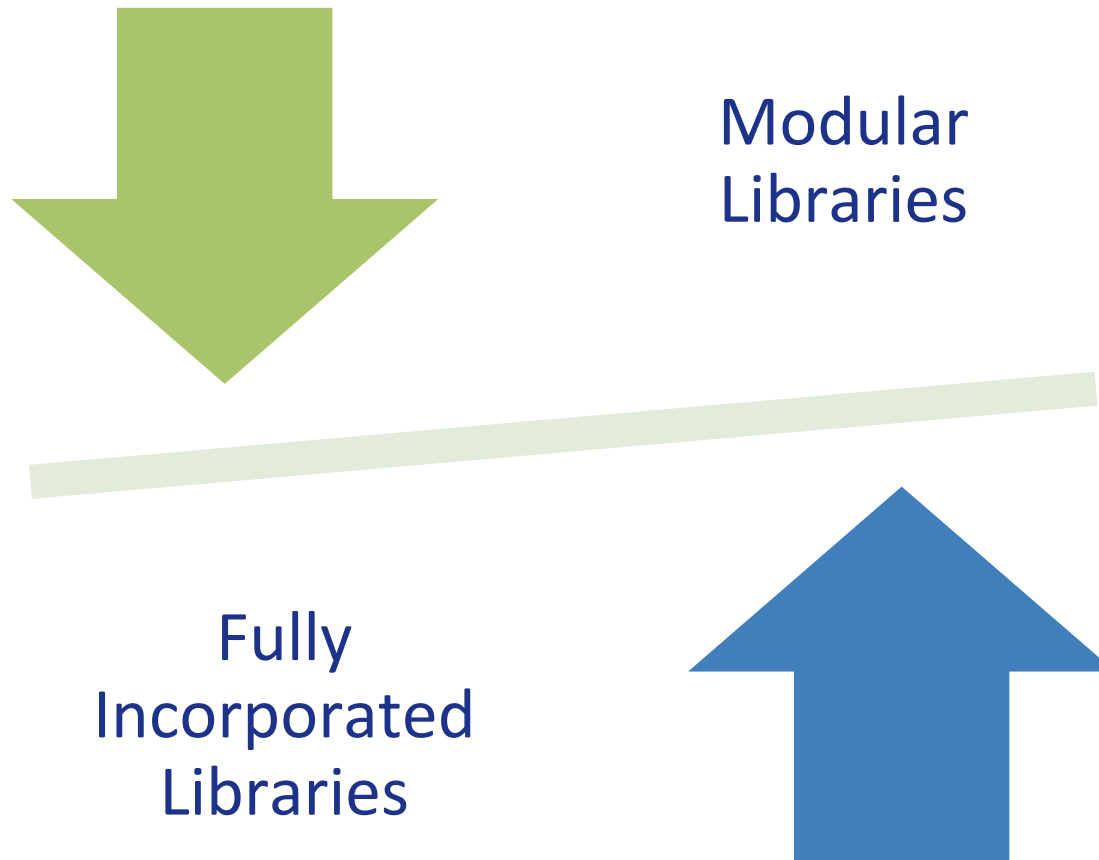


- Supplement the foundational Standards, do not replace them
- **For the sponsor:**
how to adapt to the forecasted changes
without increasing the administrative burden?

Is Your Clinical Data Standards Library Ready for Change?



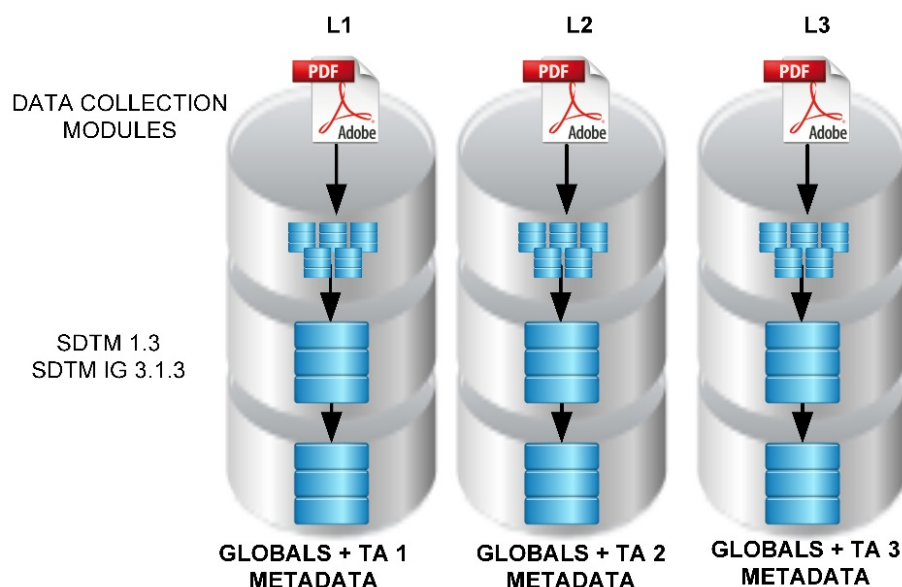
Managing Content



Fully Incorporated Content



DATA STANDARDS LIBRARY

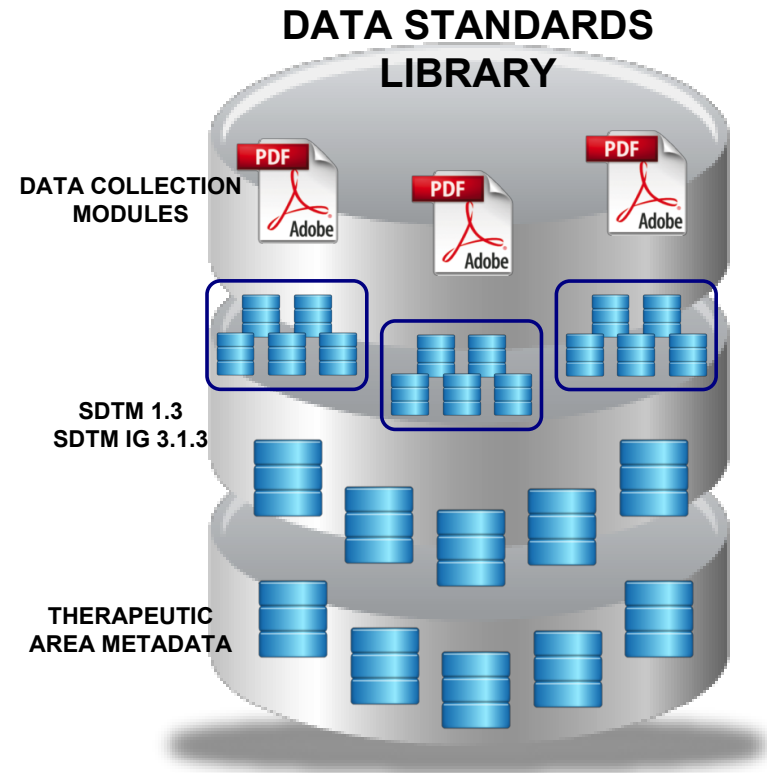


Multiple standalone libraries that incorporate all globally applicable standards with the TA-specific standards

Modular Content



A single global library
that is complemented
with discrete
TA-specific libraries



Benefits and drawbacks



Fully incorporated

- Benefits: contains both global standards + TA standards in one single library → simplifies end-user experience; single place to reference for standards needed
- Drawbacks: difficulties for the management of libraries; duplicates global content → high risk of inconsistencies, high effort to make updates in global

Modular

- Benefits: more efficient for librarians to manage updates in one central repository
- Drawbacks: difficulty for end-users to know how to use multiple libraries

Ideal solution?



- For governance and management, would allow the independent libraries proposed in the second approach
- For end users, would present the metadata in a consolidated “single library” view, as it would appear with first approach

Is Your Clinical Data Standards Library Ready for Change?



Evolution of metadata storage



Relational
Databases

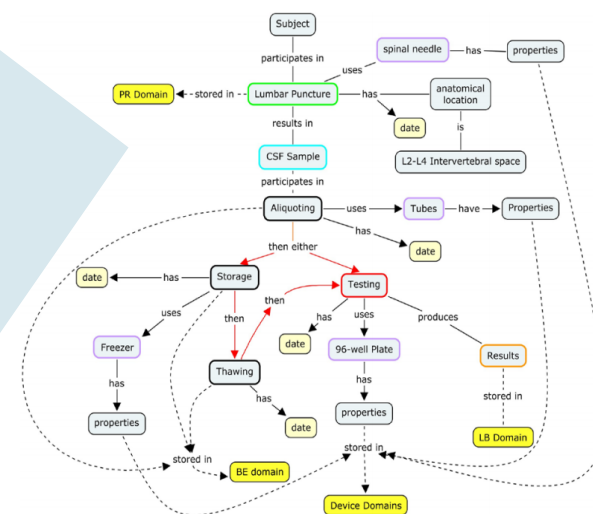
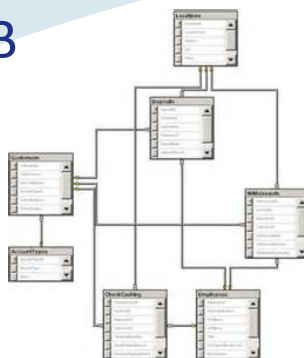
RDB

Spreadsheets

Domain Prefix	Variable Name	Variable Label	Type	Controlled Terms, Code list, or Format	Role
AE	AE TERM	Reported Term for the Adverse Event	Char		Topic
AE	AE SEV	Seriously/Intensity	Char	AESEV	Record Qualifier
AE	AE REL	Causality	Char		Record Qualifier
AE	AE OUT	Outcome of Adverse Event	Char	OUT	Record Qualifier

Resource
Description Framework

RDF



Methods for Storing the Metadata



Traditional methods

- Excel spreadsheets or other document-based processes
- In a simple file server environment or through a versioned document management system
- **Drawbacks:**
 - Two-dimensional representation
 - Requires extensive manual effort to maintain
 - Difficult for end users to understand how to implement
 - Little control over the proper use of the content

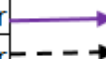
Domain Prefix	Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role
AE	AETERM	Reported Term for the Adverse Event	Char		Topic
AE	AESEV	Severity/Intensity	Char	AESEV	Record Qualifier
AE	AEREL	Causality	Char	*	Record Qualifier
AE	AEOUT	Outcome of Adverse Event	Char	OUT	Record Qualifier

Methods for Storing the Metadata



VARIABLES				
Name	Label	Type	Codelist	Role
AETERM	Reported Term for the Adverse Event	Char		Topic
AESEV	Severity/Intensity	Char	AESEV	Record Qualifier
AETOXGR	Standard Toxicity Grade	Char		Record Qualifier
...	...	...	...	...

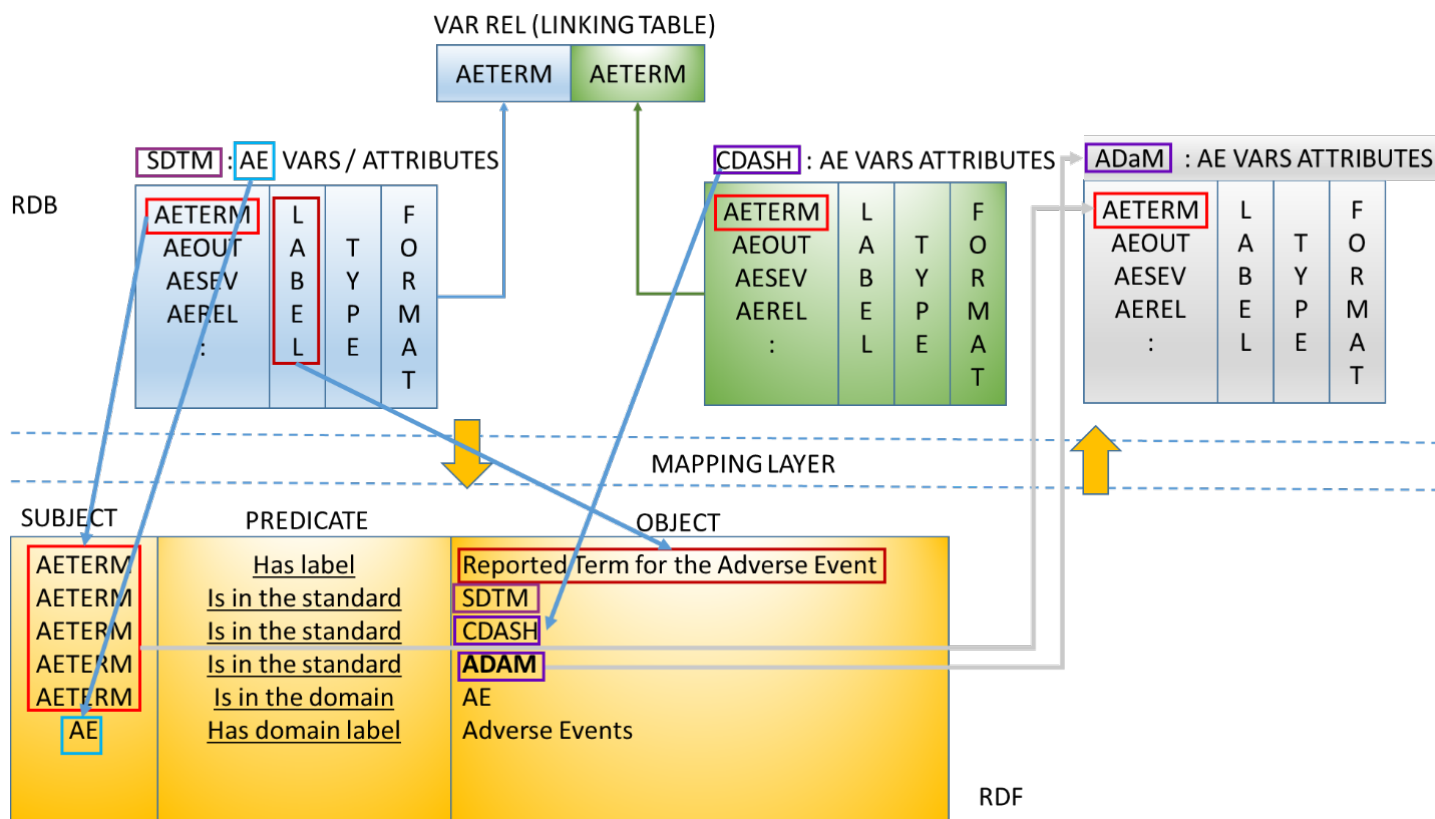
THERAPEUTIC AREA	
Name	Description
COPD	Chronic Obstructive Pulmonary Disease
ONCO	Oncology
...	...



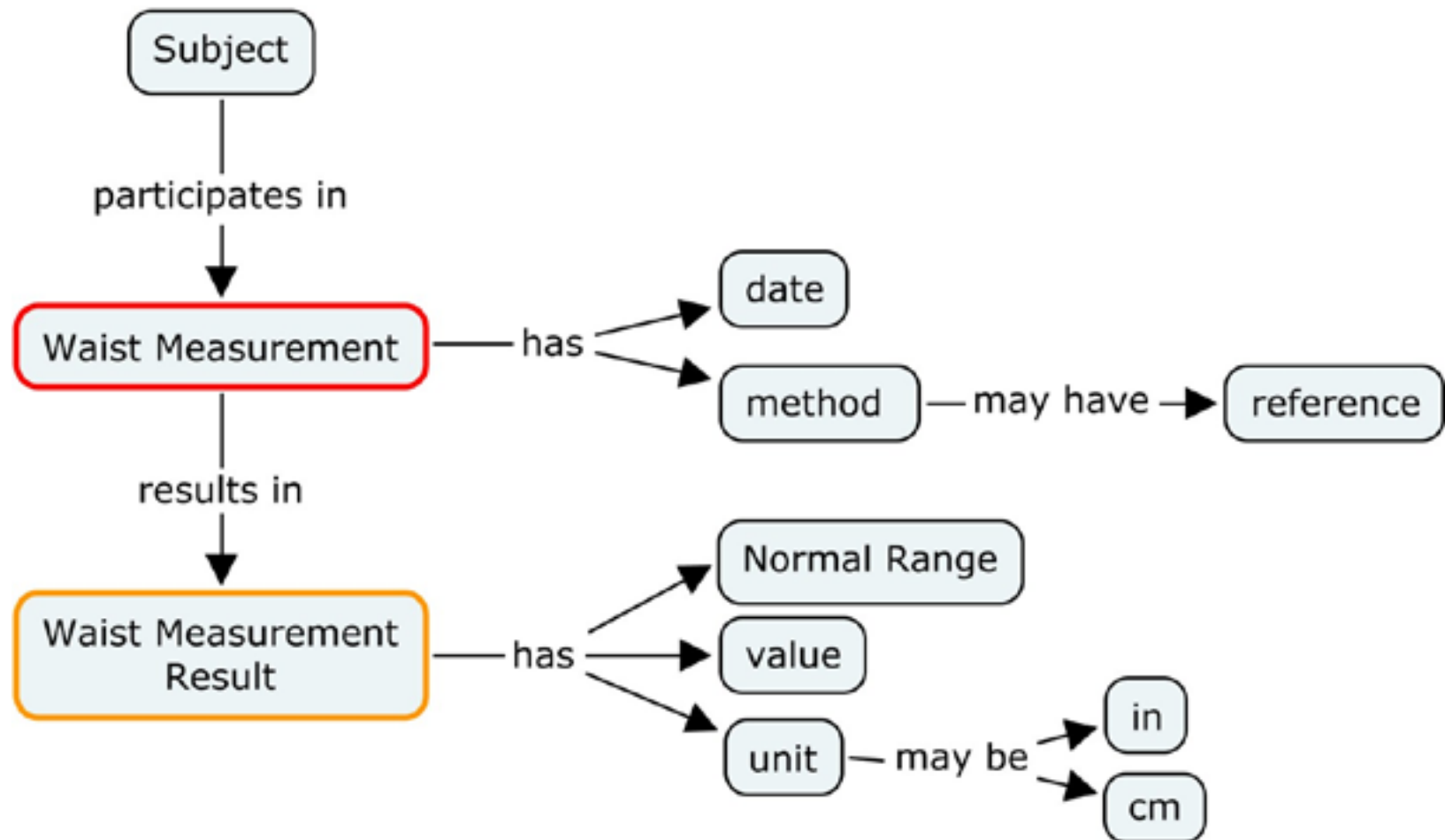
Relational Databases

- Can link specific items in your library to one or more TAs
- Allows more robust querying capability
- Avoids duplication and inconsistencies
- Changes to the concepts may require structural changes
- Relationships between items is hidden in linking of tables

Methods for Storing the Metadata



Concept maps & RDF



Source: CDISC Diabetes TAUG

Learn more about RDF



- There are many good discussions of RDF and CDISC standards on the PhUSE website and wiki
 - Semantic Technology Working Group
 - <https://github.com/phuse-org/rdf.cdisc.org>
 - And others...

▣ **rdf.cdisc.org**

FDA/PhUSE Semantic Technology Project

Representing Existing CDISC Standards in RDF

▣ **Introduction**

The FDA/PhUSE Semantic Technology project investigates how formal semantic standards can support the clinical and non-clinical trial data life cycle from protocol to submission. Within this project, several teams work on dedicated tasks to execute this investigation. The first outcome and deliverable of this project is the representation of existing CDISC standards in RDF, including representations of the following CDISC standards:

- CDASH 1.1
- SDTM 1.2 and SDTM Implementation Guide 3.1.2
- SDTM 1.3 and SDTM Implementation Guide 3.1.3
- SEND Implementation Guide 3.0
- ADaM 2.1 and ADaM Implementation Guide 1.0
- Controlled Terminology

Today, CDISC publishes these standards in a paper based format and partly in Excel, which makes it difficult to consistently represent and process this information. The RDF representation addresses both issues by providing at the same time a formal model, a machine readable representation, and an exchange format. Accordingly, we have decided not to reproduce a lot of paper based documentation. This document provides only a few pointers, other than that the RDF models are self-describing and we therefore encourage you to use

Methods for Storing the Metadata



CDISC-CFAST development of TA standards

- Mirrors the modular approach
- Designed to supplement foundational standards, do not replace them
- Only include implementation specific to the area, do not duplicate standard domains that are not TA-specific

Methods for Storing the Metadata



CDISC SHARE platform

- Organizes metadata in a discrete way rather than duplicating metadata that do not require TA-specific implementations
- Will be offering metadata in RDF format in the near future

Is Your Clinical Data Standards Library Ready for Change?



Conclusions



- TA standards should be seen as complementary to the global metadata, not a replacement
- Optimum method for managing the metadata of both global and TA standards would mirror this relationship
- Industry is evolving from two-dimensional spreadsheets to more complex data modeling
 - End-user needs to have easy to use interaction regardless of the storage approach
- The processes for developing TA standards supports the use of these more traditional data modeling

Thank you for your attention.

Join us for a coffee at our stand.

London, United Kingdom, 13 OCT 2014





Lauren Shinaberry | Project Manager | Lauren.Shinaberry@businessdecision.com

Business & Decision Life Sciences
Sint-Lambertusstraat 141 rue Saint-Lambert
B-1200 Brussels
T: +32 2 774 11 00
F: +32 2 774 11 99
lifesciences@businessdecision.com
<http://www.businessdecision-lifesciences.com/>