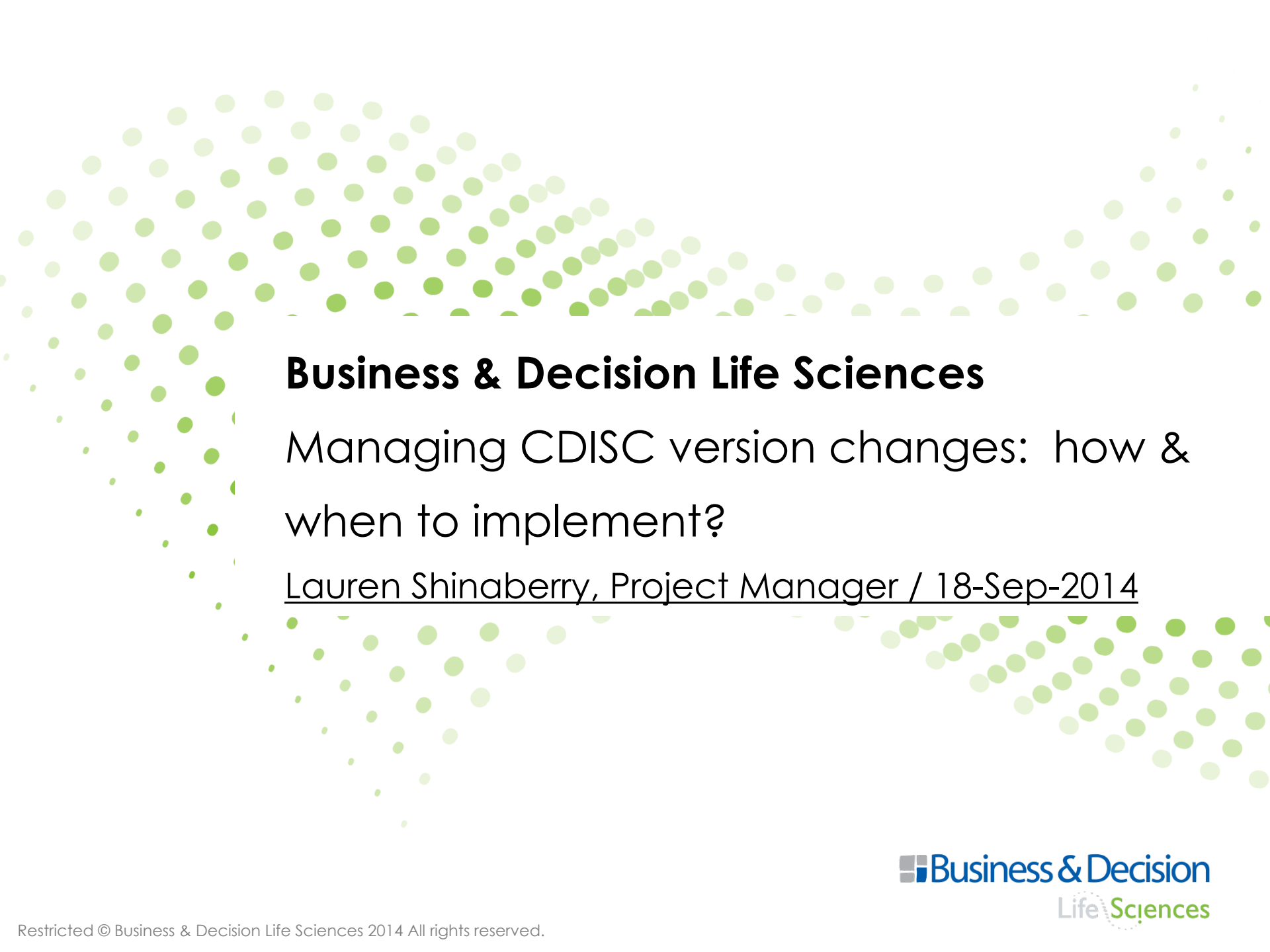


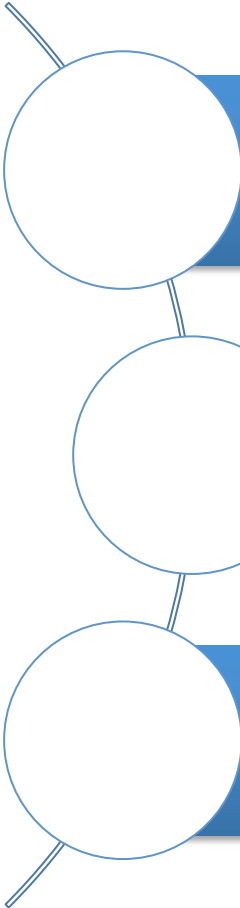


Business & Decision Life Sciences

Managing CDISC version changes: how & when to implement?

Lauren Shinaberry, Project Manager / 18-Sep-2014

Overview

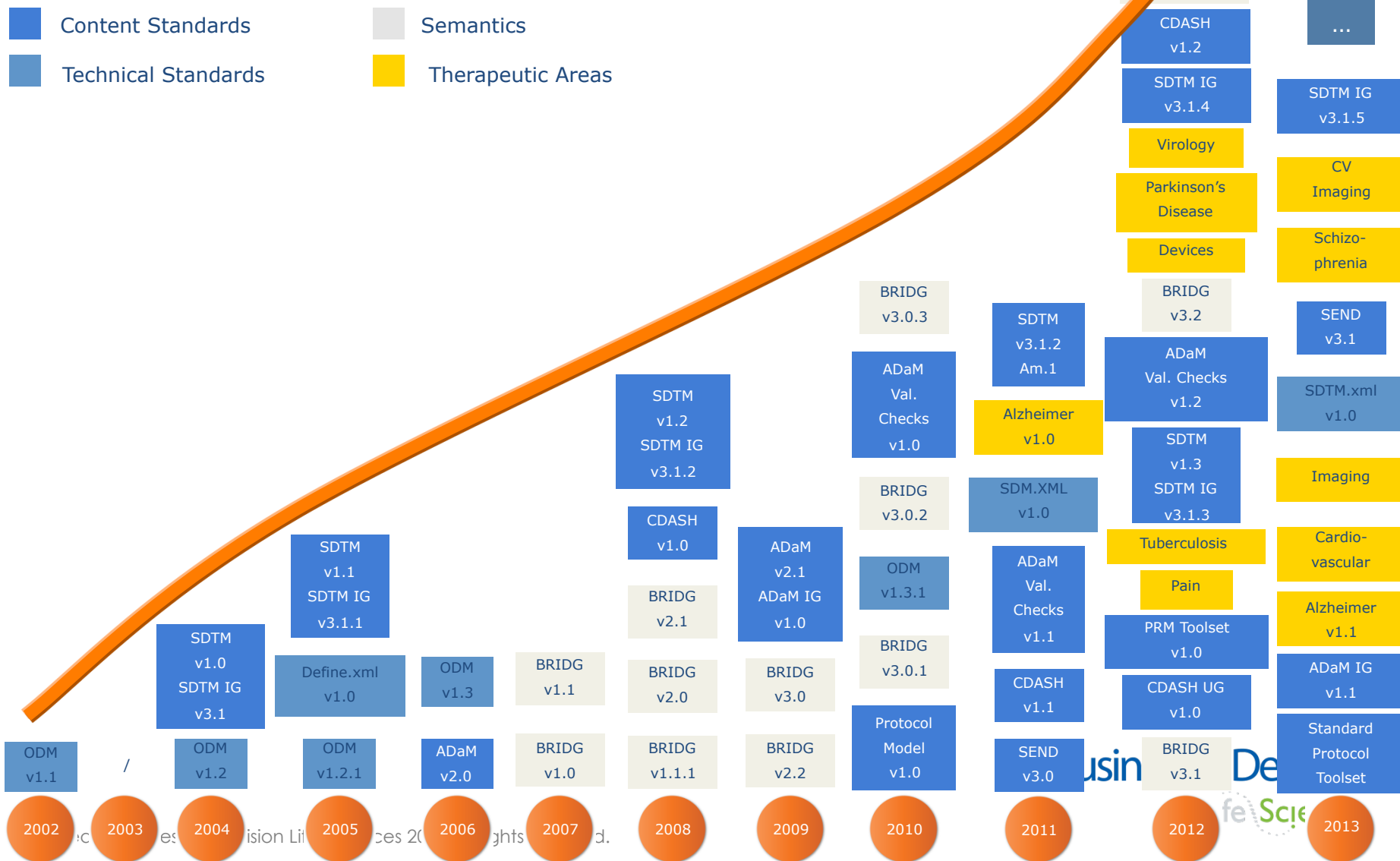


Introduction

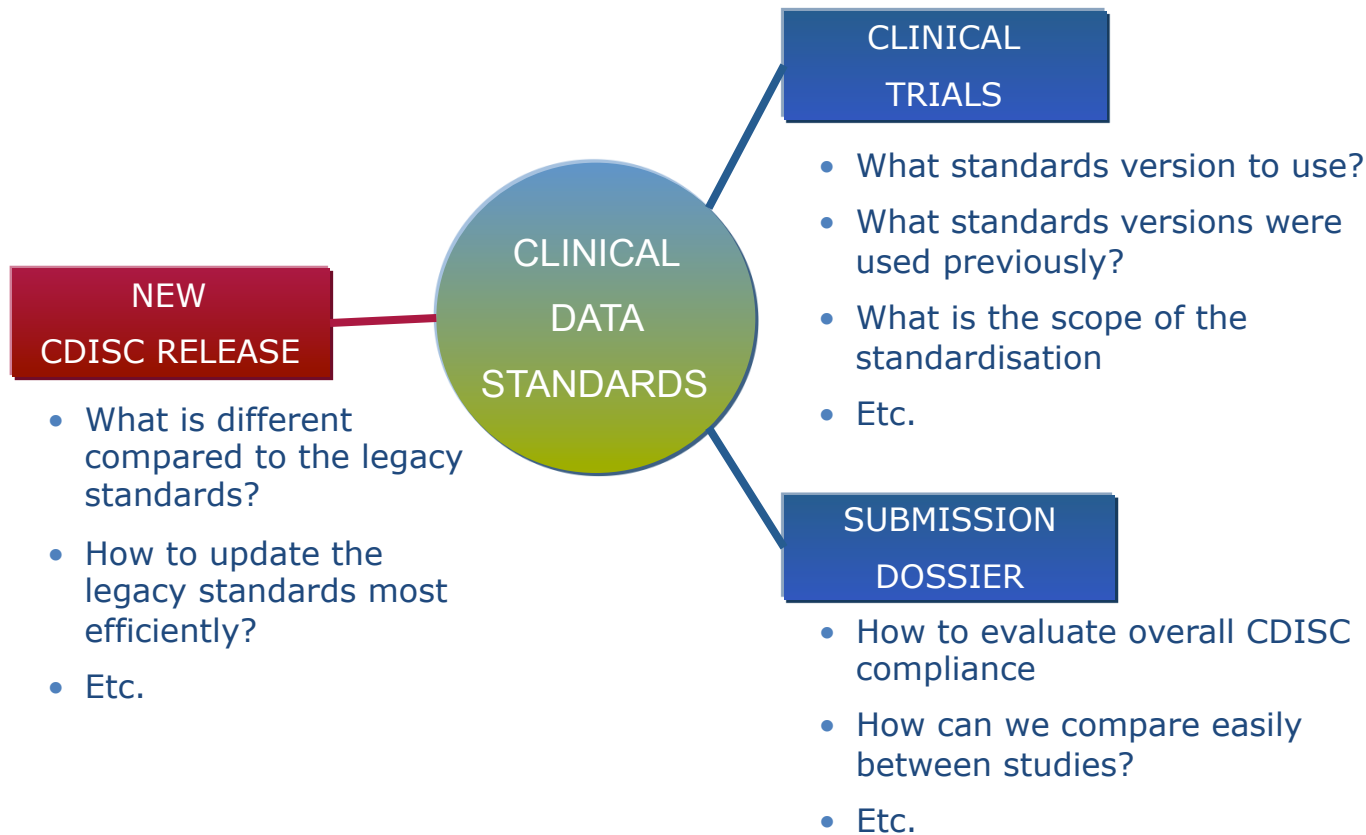
Case Study: effort comparison

Case Study: managing end-to-end versioning in a metadata repository

CDISC models evolution over time

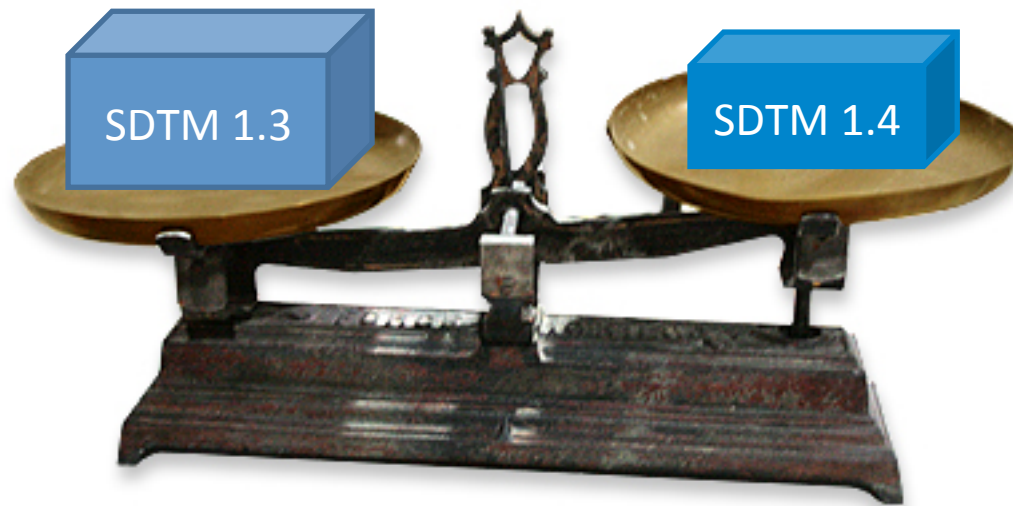


More complex and increasing challenges



Up-versioning

- How do you weigh the potential costs?
- How much of an impact is there on existing study data?



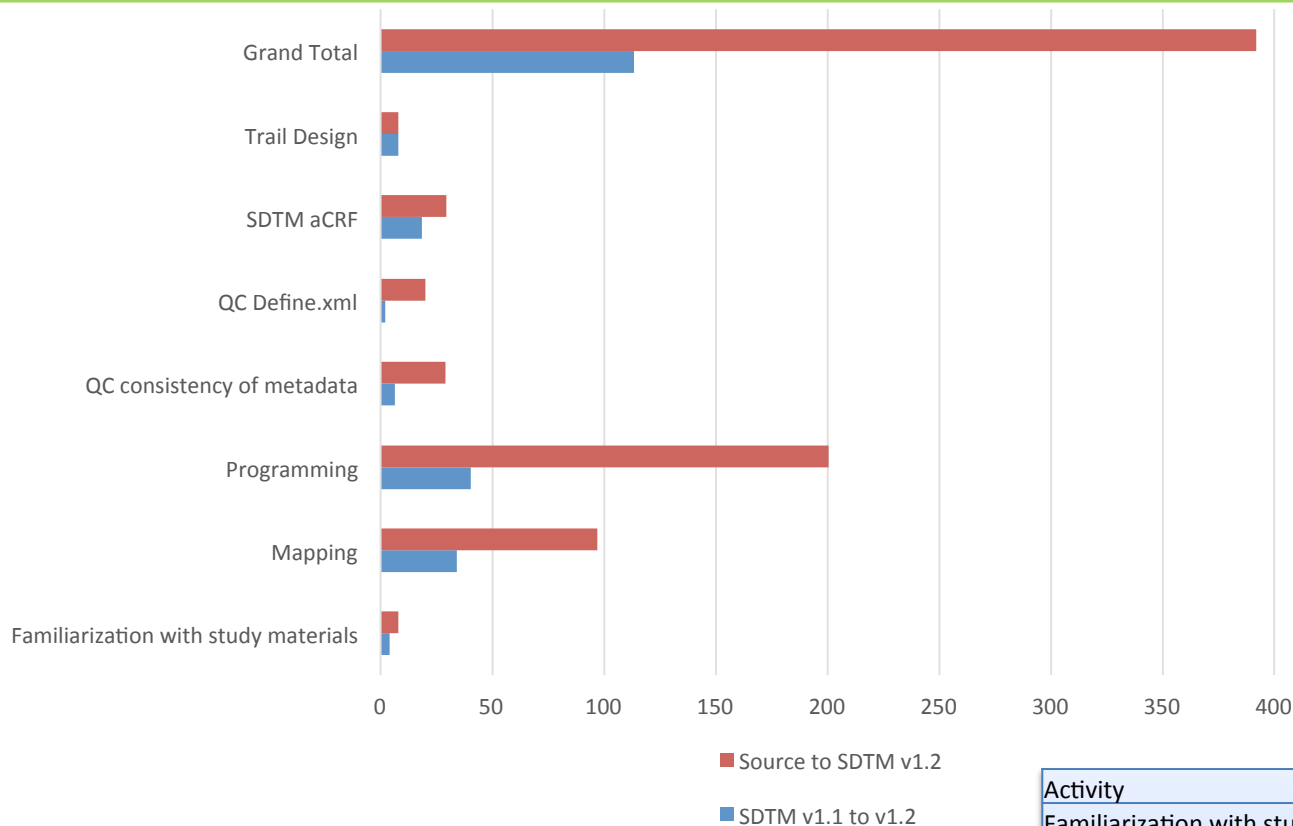
Overview

- Case study: effort comparison
 - Converting data from one version of SDTM to another
 - Converting data directly from source to new version of SDTM
- Case study: managing end-to-end versioning in a metadata repository
 - Allows for tracking interdependent changes across CDISC standards
 - Facilitates comparisons between different versions of libraries as well as at the study level

Case Study: Effort comparison

- Two Phase III studies
- Same compound and indication
- Comparable number of SDTM datasets created
- Converted to SDTM v1.2
 - One study was already in SDTM v1.1
 - One study was converted from source

Significant Reduction



Activity	Percent Reduction
Familiarization with study materials	50%
Mapping	65%
Programming	80%
QC consistency of metadata	78%
QC Define.xml	90%
SDTM aCRF	37%
Trail Design	0%
Total Reduction in Effort	71%

Case study: managing your metadata

- Previous case study only included up-versioning for SDTM
- End-to-end implementations require the ability to manage complex versioning and relationships between standards
- Using concept of Active From and Active To dates allows retrieval of CDASH and SDTM standards at any point in time
- Linking metadata in study metadata repository allows impact analysis

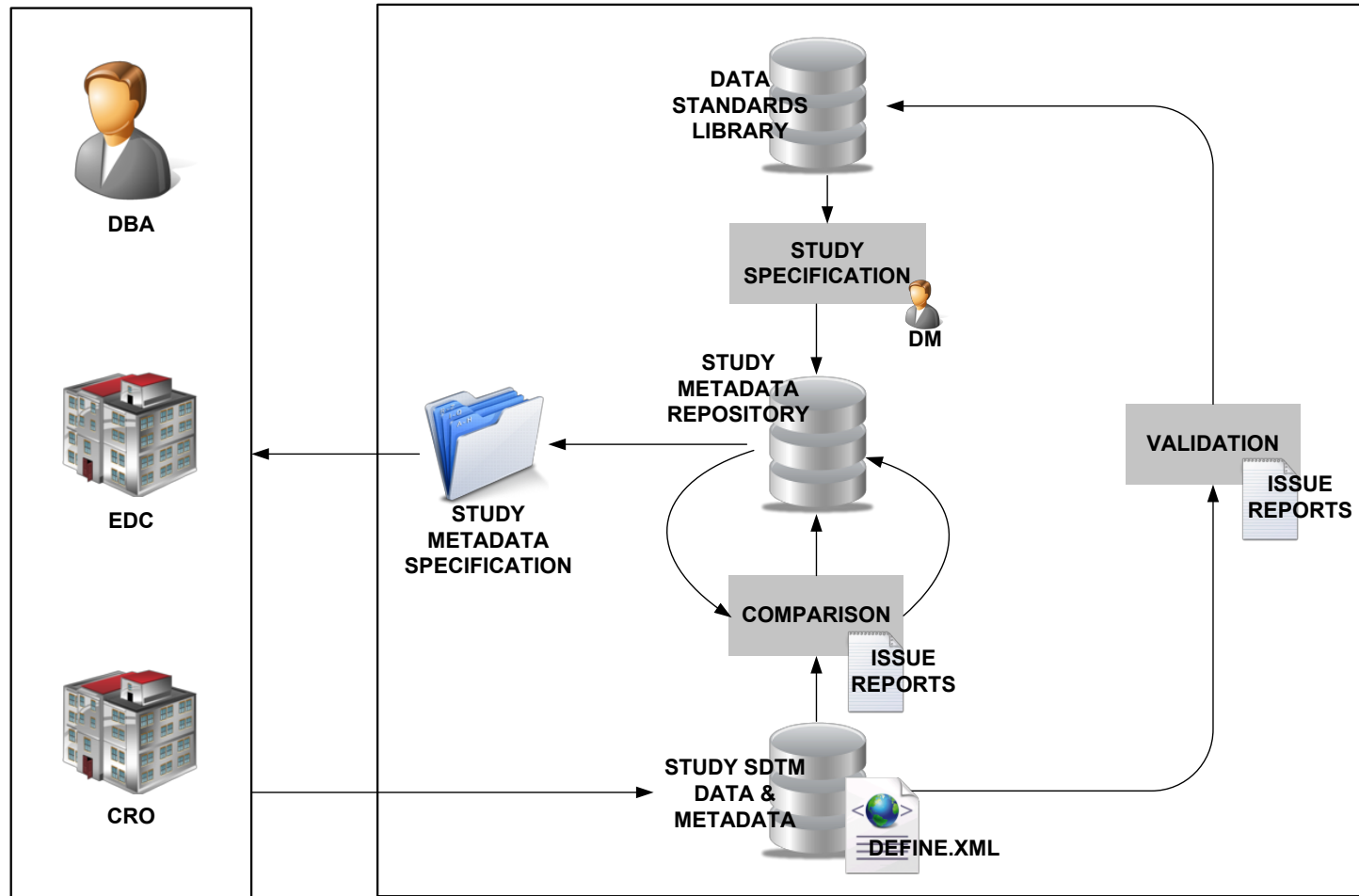
Case Study Overview

- The Data Standards Library enables to define **CDASH and SDTM metadata linked to your DCMs** available for easy selection to create study metadata
- A **flexible concept for linking metadata** across the 3-level CDASH and 5-level SDTM libraries
- An innovative concept of **metadata versioning based on active 'from' and 'to' dates** providing full control and flexibility over library changes
- **Reporting capability** to create Comparison Reports across library versions as well as other reporting

Case Study - high level flow

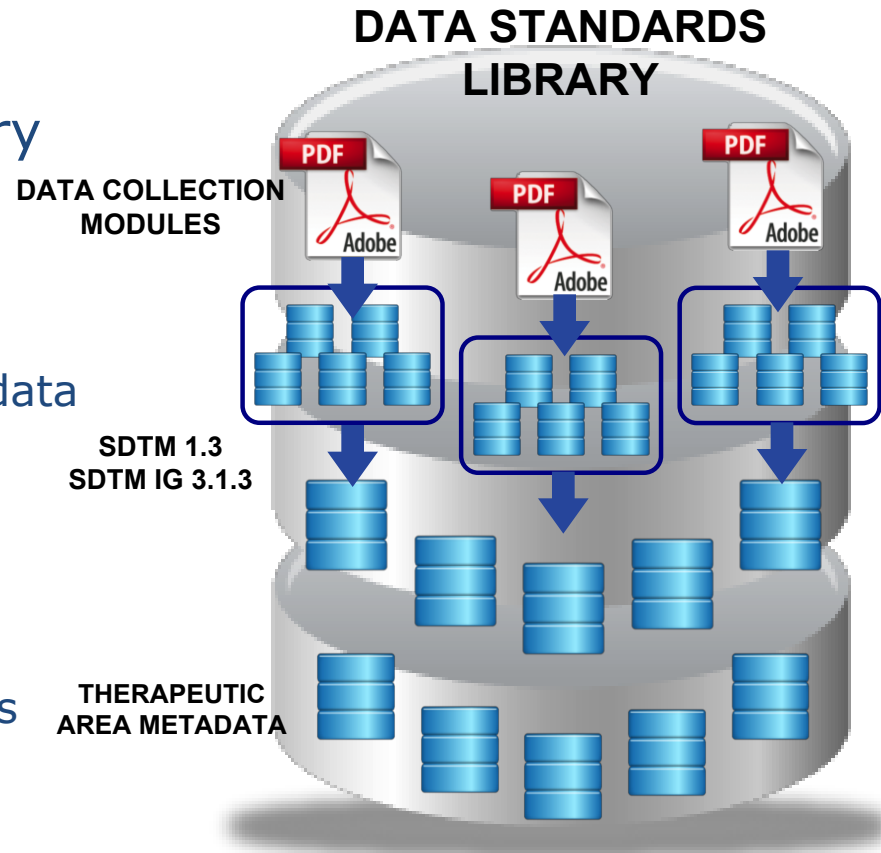
DATA COLLECTION
AREA

DATA MANAGEMENT
AREA



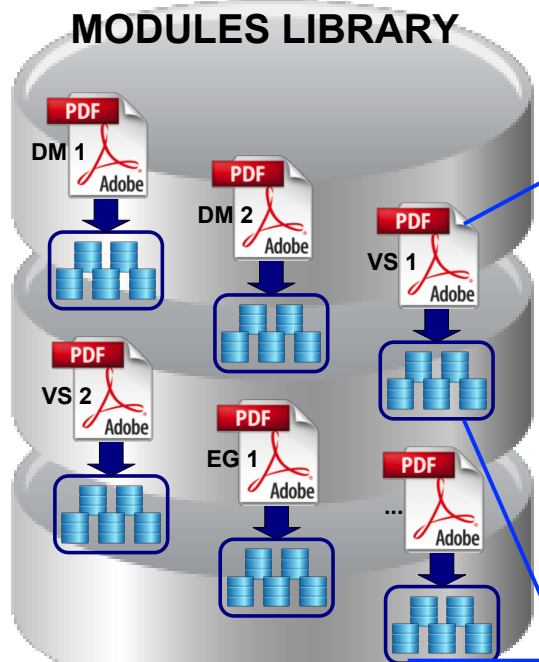
Data Standards Library

- The Data Standards Library contains :
 - Data Collection Modules:
 - using CDASH metadata
 - with clustered SDTM metadata
 - annotated for CDASH
 - annotated for SDTM
 - Metadata Definitions :
 - SDTM Standards
 - Therapeutic Area Standards



Data Collection Modules - CDASH

DATA COLLECTION MODULES LIBRARY



Vital Signs

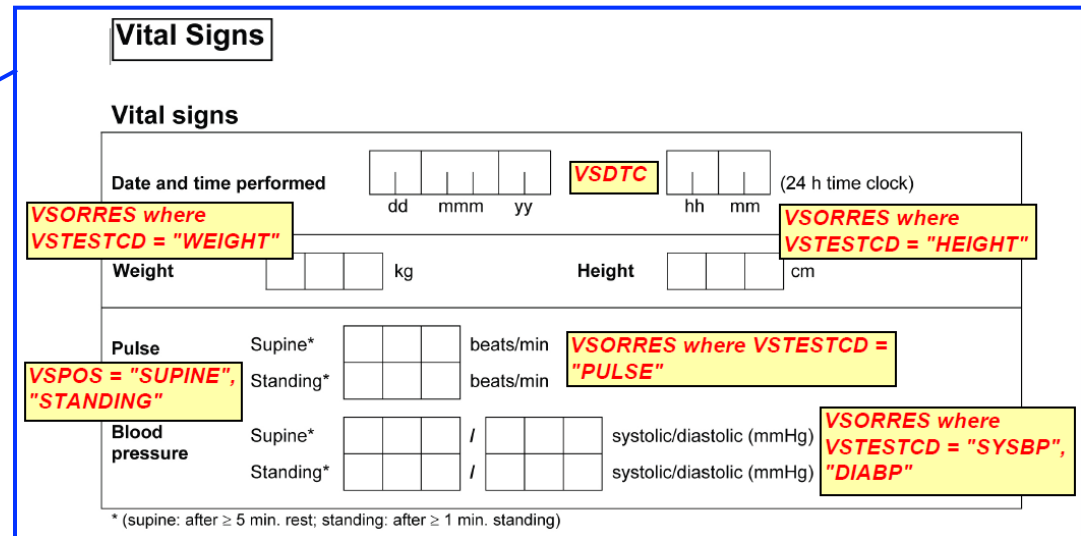
Vital signs

Date and time performed		VSDAT dd mmm yy	VSTIM hh mm (24 h time clock)				
Weight	VSORRESU	kg	VSTEST	Height	VSORRES	cm	VSORRESU
Pulse	VSTEST Supine* Standing*	VSORRES	beats/min	VSORRESU			
Blood pressure	VSTEST Supine* Standing*	VSORRES	systolic/diastolic (mmHg)	VSORRESU			

* (supine: after ≥ 5 min. rest; standing: after ≥ 1 min. standing)

Collected CDASH Variables	CRF Prompt	Codelist	Preprinted values
VSDAT	Date		
VSTIM	Time		
VSPOS	Position	POSITION	
VSTEST	Test	VLM VSTESTCD	Height
VSTEST	Test	VLM VSTESTCD	Weight
VSTEST	Test	VLM VSTESTCD	Pulse
VSTEST	Test	VLM VSTESTCD	Systolic Blood Pressure
VSTEST	Test	VLM VSTESTCD	Diastolic Blood Pressure
VSORRESU	Unit	VSRESU	cm
VSORRESU	Unit	VSRESU	kg
VSORRESU	Unit	VSRESU	beats/min
VSORRESU	Unit	VSRESU	mmHg

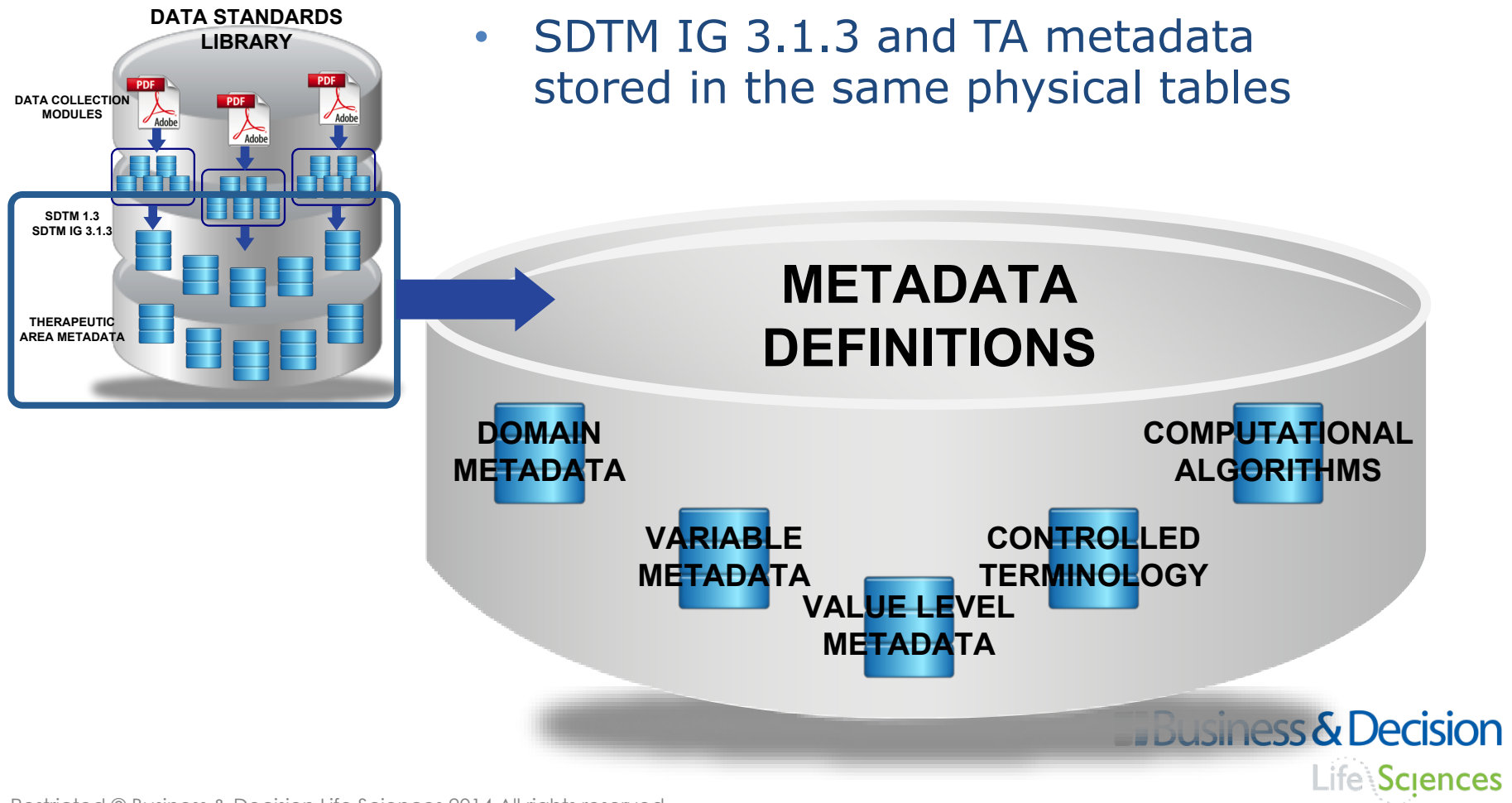
DATA COLLECTION MODULES LIBRARY



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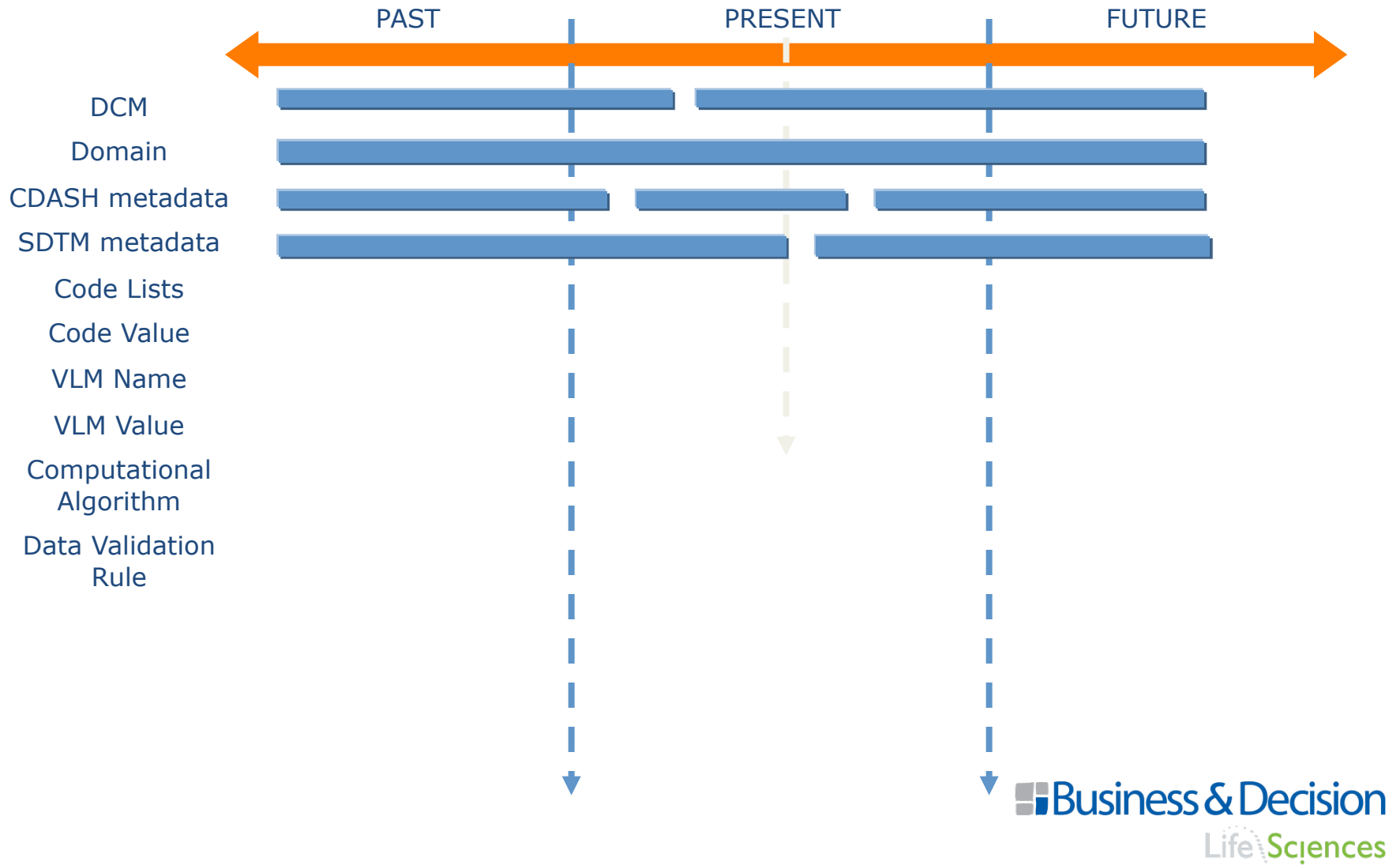
Metadata Definitions

- 5 levels of metadata
- SDTM IG 3.1.3 and TA metadata stored in the same physical tables



Allows Time Travel for Librarians

...



Comparison of library metadata against study build

- 4 different statuses :
 - *Ok* : no conflict in metadata
 - *Difference* : difference in the metadata value
 - *Missing* : metadata not in study data
 - *Addition* : metadata not in study specifications

Status	Dataset	Variable	Label	Specifications	Study
Difference	AE	AEACN	Action Taken with Study Trtment		X
Difference	AE	AEACN	Action Taken with Study Treatment	X	
Ok	AE	AEBODSYS	Body System or Organ Class	X	X
Missing	AE	AECAT	Category for Adverse Event	X	
Addition	AE	AECOM	Comment about Adverse Event		X
Ok	AE	AECONTRT	Concomitant or Additional Trtmnt Given	X	X

Case Study Summary

- Can manage links between CDASH and SDTM and accommodate differing version releases between the two
- Can easily run reports to compare metadata from study specifications against new version of standards
- Quickly identify if any studies are affected by the new standard
- Use this information along with the metrics on effort to up-version to make business decision for your submission



Thank you



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