

Time Travel for Librarians

PhUSE 2013
Brussels

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Clinical Data Standardization

2

Clinical Data Standards Platform

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Time Travel for Librarians

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Clinical Data Standardization

Business and Regulatory drivers

Variety of
Clinical Data
Standards
(CDS)

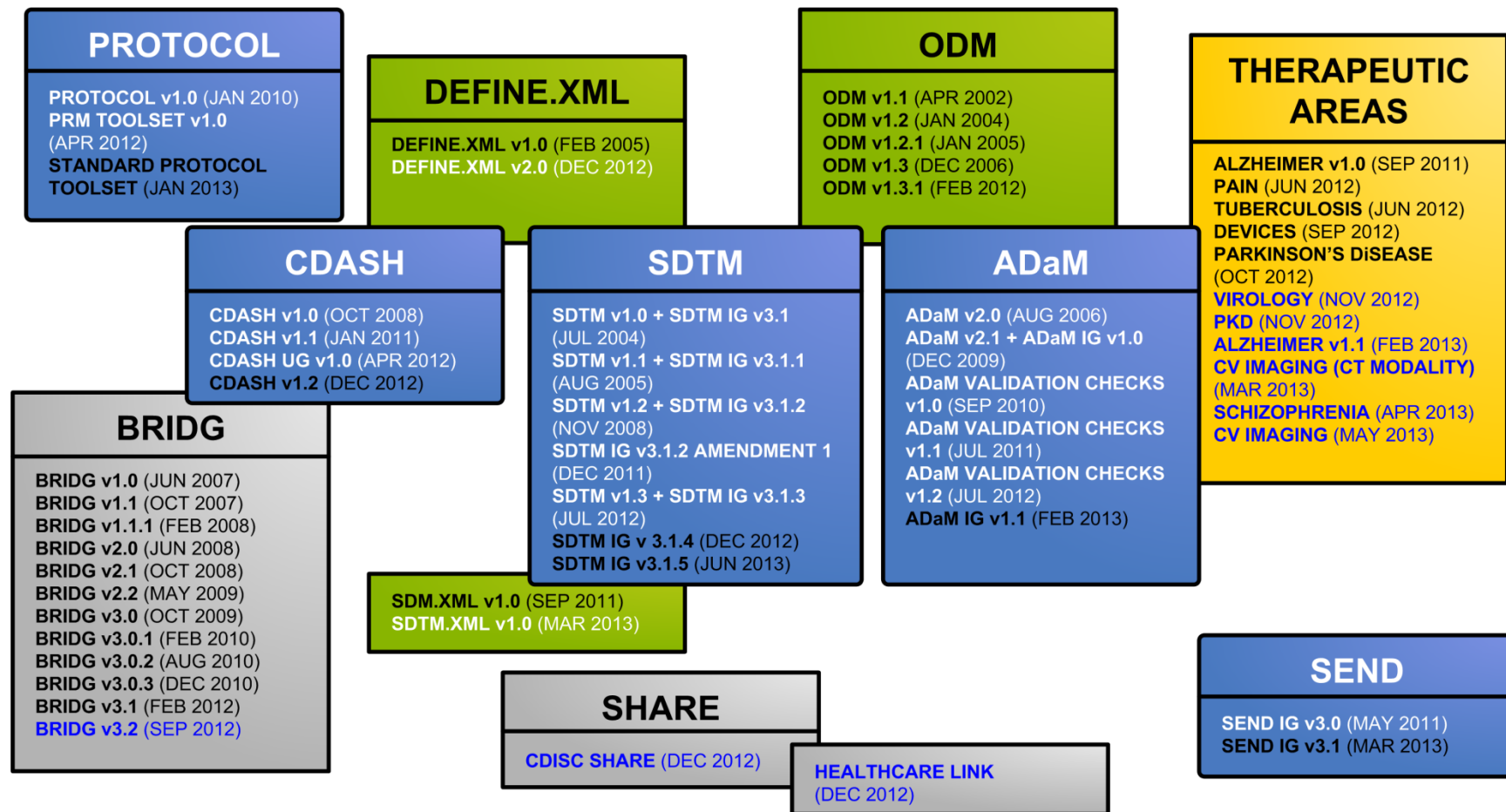
Intra-company
CDS

Increased
competition,
critical to achieve
Operational
Excellence

Inter-company
CDS

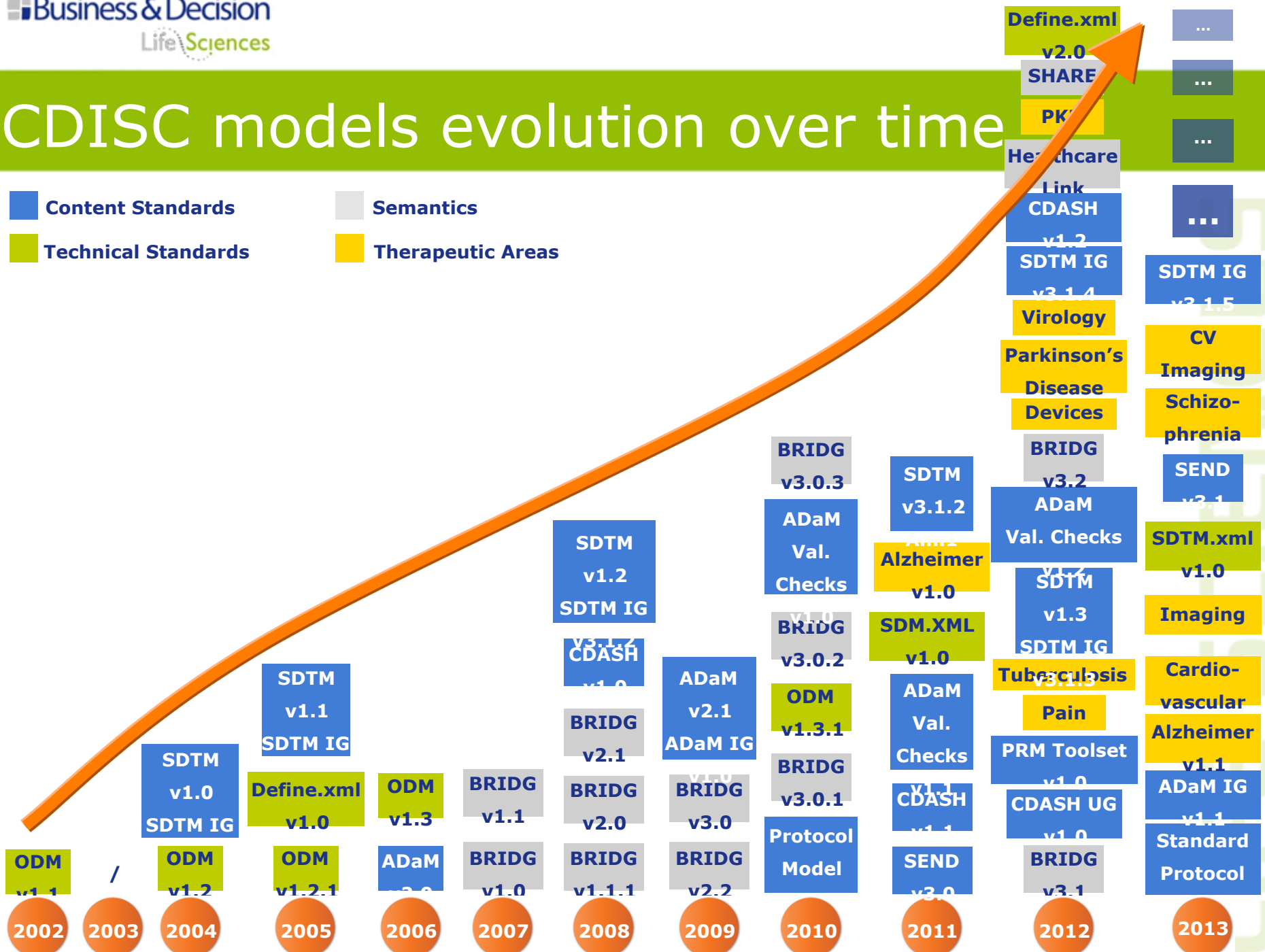
FDA requirement
for submitting
clinical data in a
CDISC format.
Is evolving
further ...

Overview of CDISC models

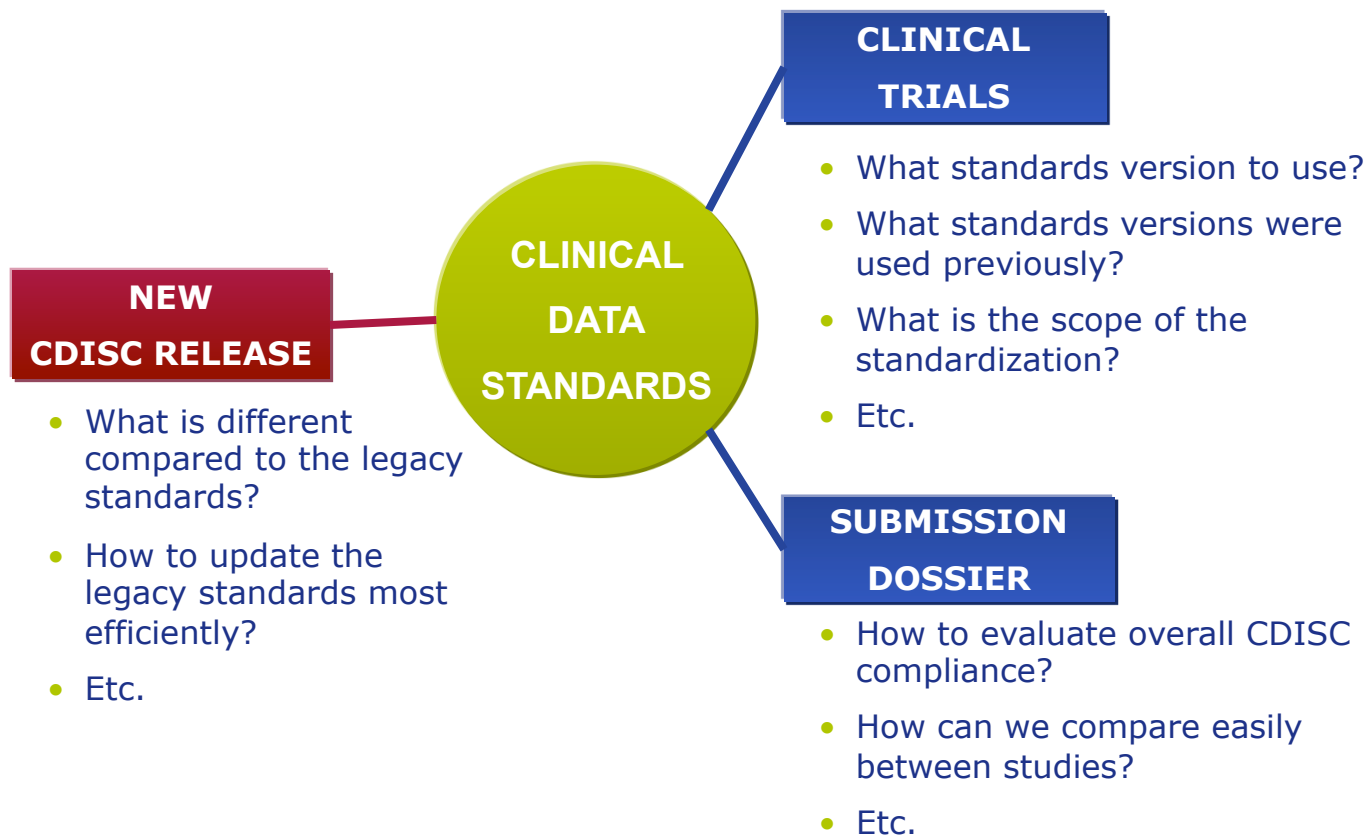


CDISC models evolution over time

■ Content Standards ■ Semantics
■ Technical Standards ■ Therapeutic Areas



More complex and increasing challenges



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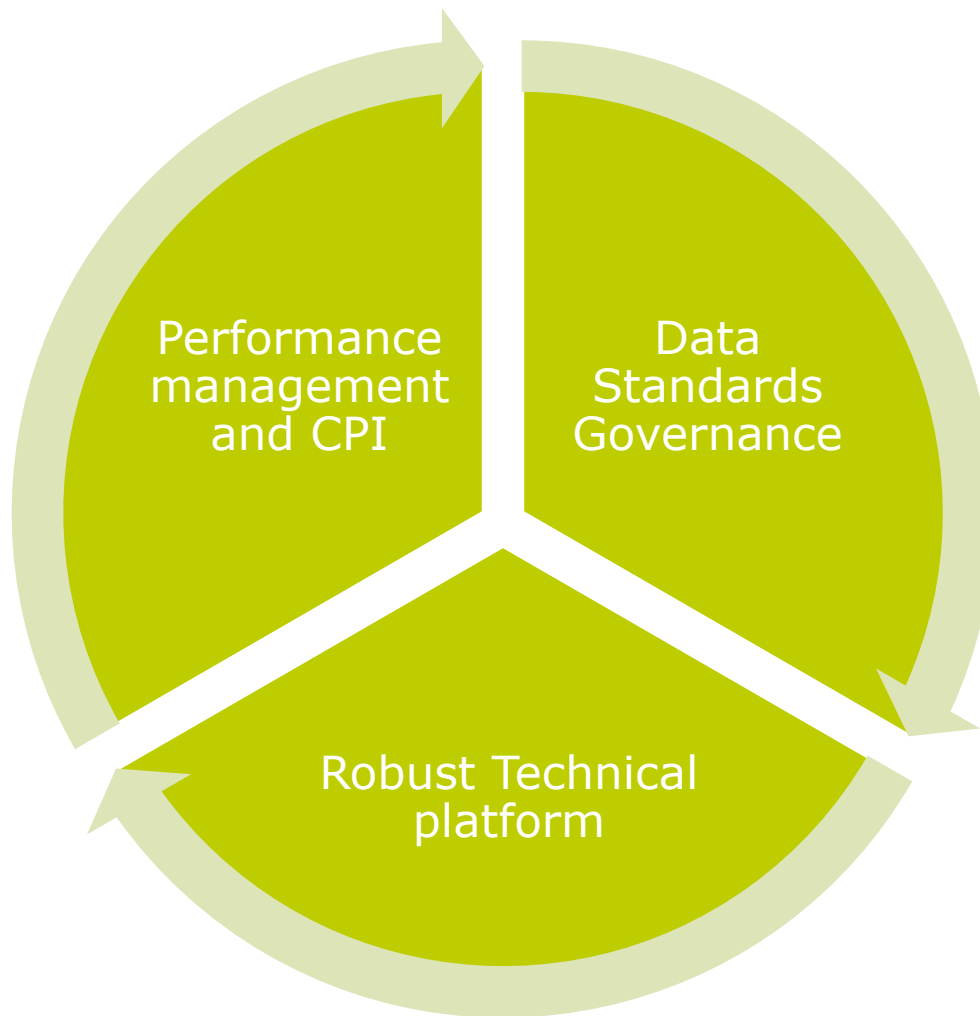
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Time Travel for Librarians

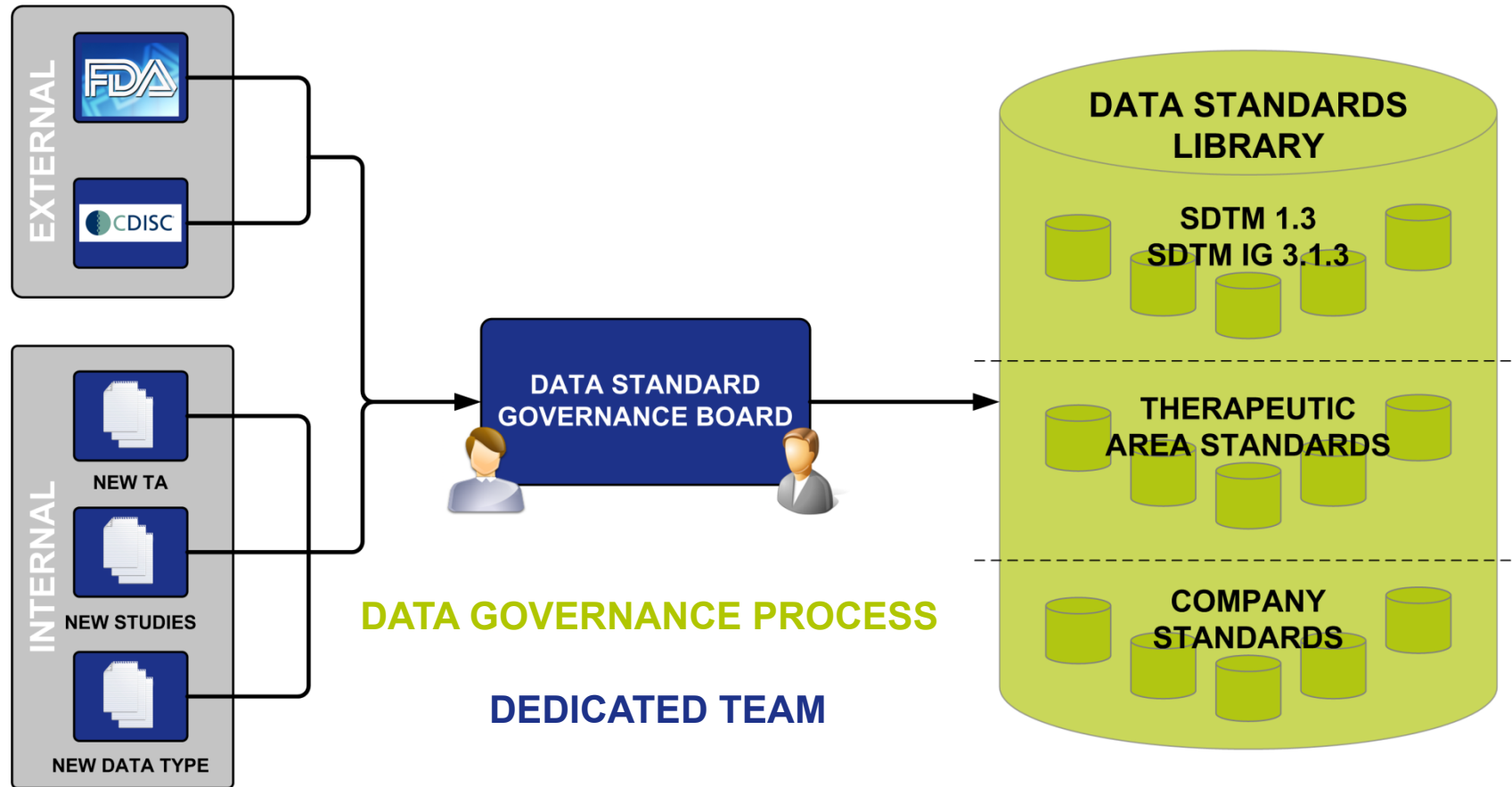
4

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Clinical Data Standards Platform

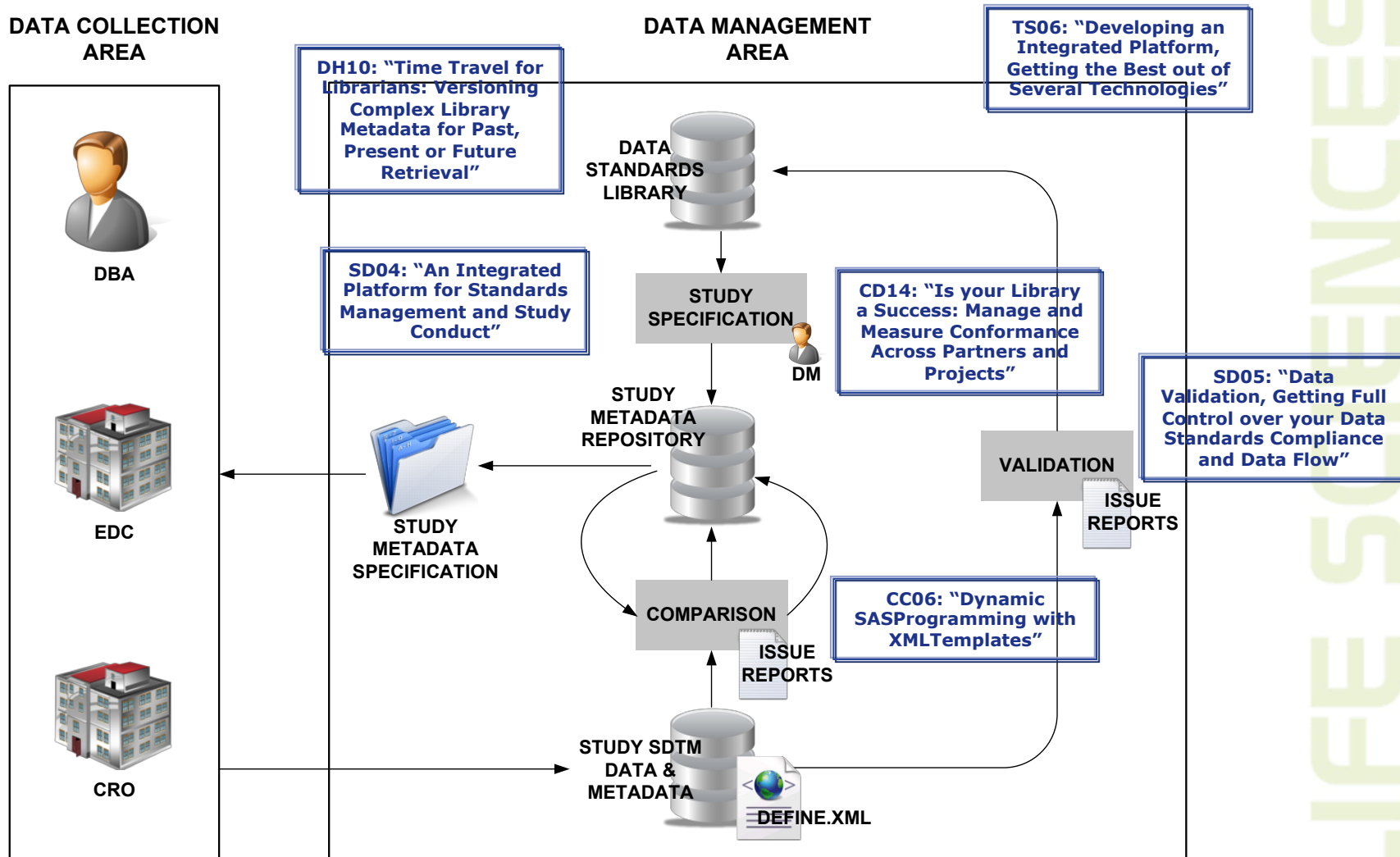


Data Standards Governance



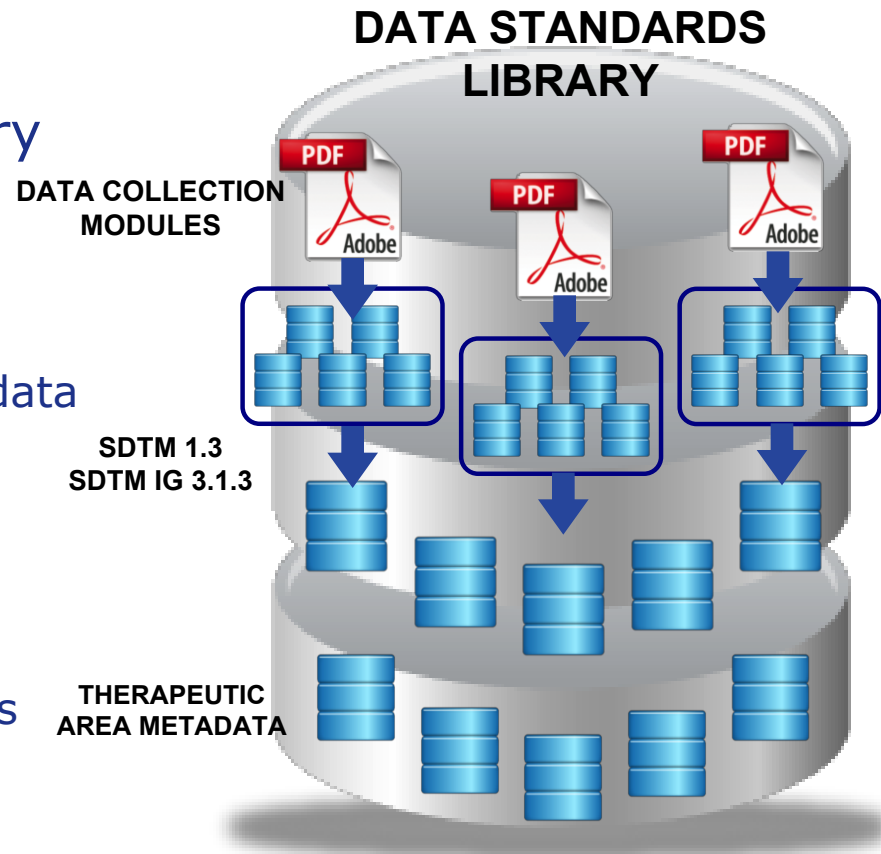
Define Strategic and Operational Objectives, KPIs, KPI targets and Initiatives for improving Clinical Data Standards management

Technical Platform - high level flow



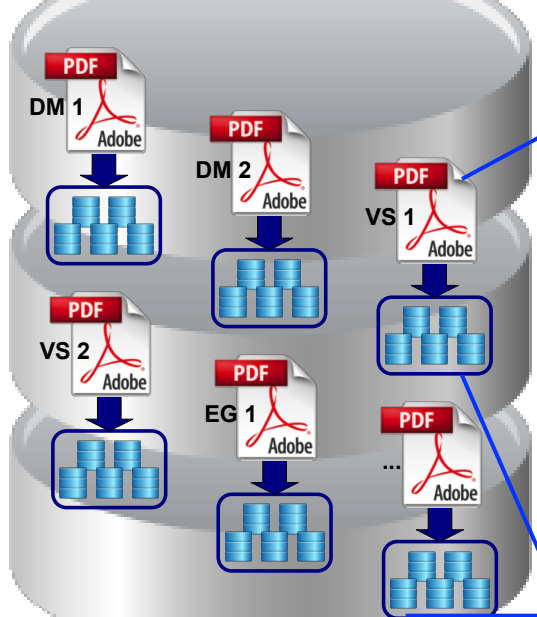
Data Standards Library

- 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

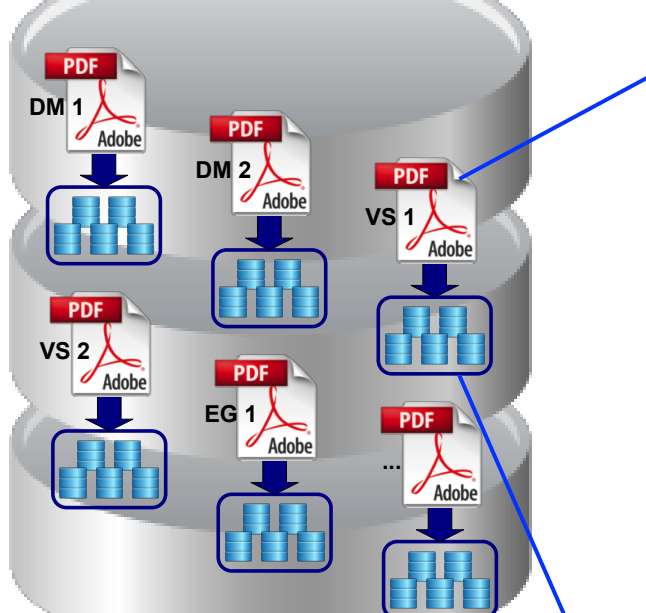
VSDAT		VSTIM	
Date and time performed		(24 h time clock)	
dd mmm yy		hh mm	
VSTEST	VSORRESU	VSTEST	VSORRES
Weight	kg	Height	cm
VSTEST	VSORRES	VSTEST	VSORRESU
Pulse	beats/min	VSTEST	VSORRESU
Supine*		Standing*	
VSTEST	VSORRES	VSTEST	VSORRESU
Blood pressure	systolic/diastolic (mmHg)	VSTEST	VSORRESU
Supine*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

DATA COLLECTION MODULES LIBRARY



Vital Signs

Vital signs

Date and time performed (24 h time clock)
dd mmm yy **VSDTC** hh mm

VSORRES where VSTESTCD = "WEIGHT"

Weight kg Height cm
VSORRES where VSTESTCD = "HEIGHT"

Pulse Supine* beats/min Standing* beats/min
VSPOS = "SUPINE", "STANDING" **VSORRES where VSTESTCD = "PULSE"**

Blood pressure Supine* / systolic/diastolic (mmHg) Standing* / systolic/diastolic (mmHg)
VSORRES where VSTESTCD = "SYSBP", "DIABP"

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

Value Level Metadata (ValueList.VS.VSTESTCD)

Source Variable	Value	Label	Type	Controlled Terminology	Origin	Role	Comment
VSTESTCD	DIABP	DIASTOLIC BLOOD PRESSURE	integer		CRF		
VSTESTCD	HEIGHT	HEIGHT	integer		CRF		
VSTESTCD	PULSE	PULSE RATE	integer		CRF		
VSTESTCD	SYSBP	SYSTOLIC BLOOD PRESSURE	integer		CRF		
VSTESTCD	WEIGHT	WEIGHT	integer		CRF		

Build within a controlled environment

- Version control
- Search for Library Objects
- Integrity and Consistency checks
- Groups, Roles & Privileges
- Change Request Reasons
- Audit Trails

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Library Objects, Types and Linking

DCM → CDASH metadata*

CDASH metadata → Domain*
CDASH metadata → SDTM metadata
CDASH metadata → VLM/Code List

SDTM metadata → Domain*
SDTM metadata → Computational Algorithms
SDTM metadata → VLM/Code List

VLM Name → VLM Value*

Code list → Code Value*

Versioning of Library Objects: principle

- **Versioning through date fields**
- Each record in the library contains an **“Active From”** and **“Active To”** field
- There can be no overlap of dates
- The “Active From” date
 - No date in the past permitted
 - > than today if the record is already created prior to release
- The “Active To” date can remain blank if expected to be used indefinitely
- There can never be more than one “version” of an object active at any point in time

Versioning through date fields

An example for a Code List record

Code List

Library version: SDTM 3.1.2

Name	NCI Code List ID	Data Type	Extensible	CodeList Type	Description	Change Request	Active from	Active to
YN		C	Yes	Sponsor defined	Code Values: Yes No	Creation of Code List: YN	2013-10-07	2013-10-08
YN						YN_1: added Code Value U-Unknown	2013-10-09	2013-10-14
YN						YN_2: added Code Value NA-Not Applicable	2013-10-15	

Library version: SDTM 3.1.2

Active from	Active to
2013-10-07	2013-10-08
2013-10-09	2013-10-14
2013-10-15	

Versioning of Library Objects: example

CV3a:

Active From

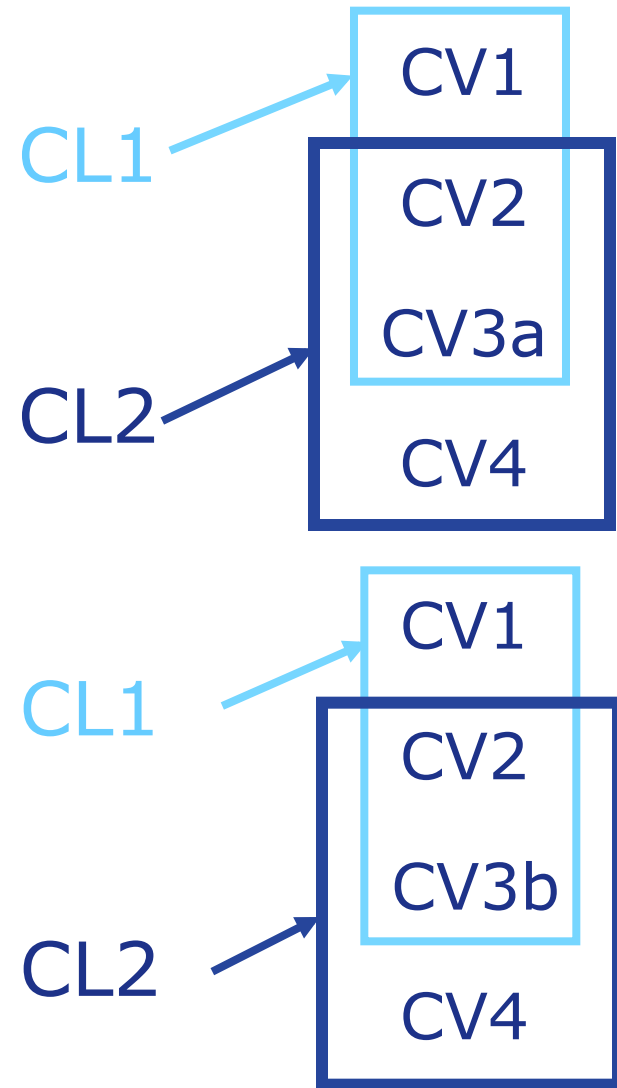
01 JAN 2013

Active To

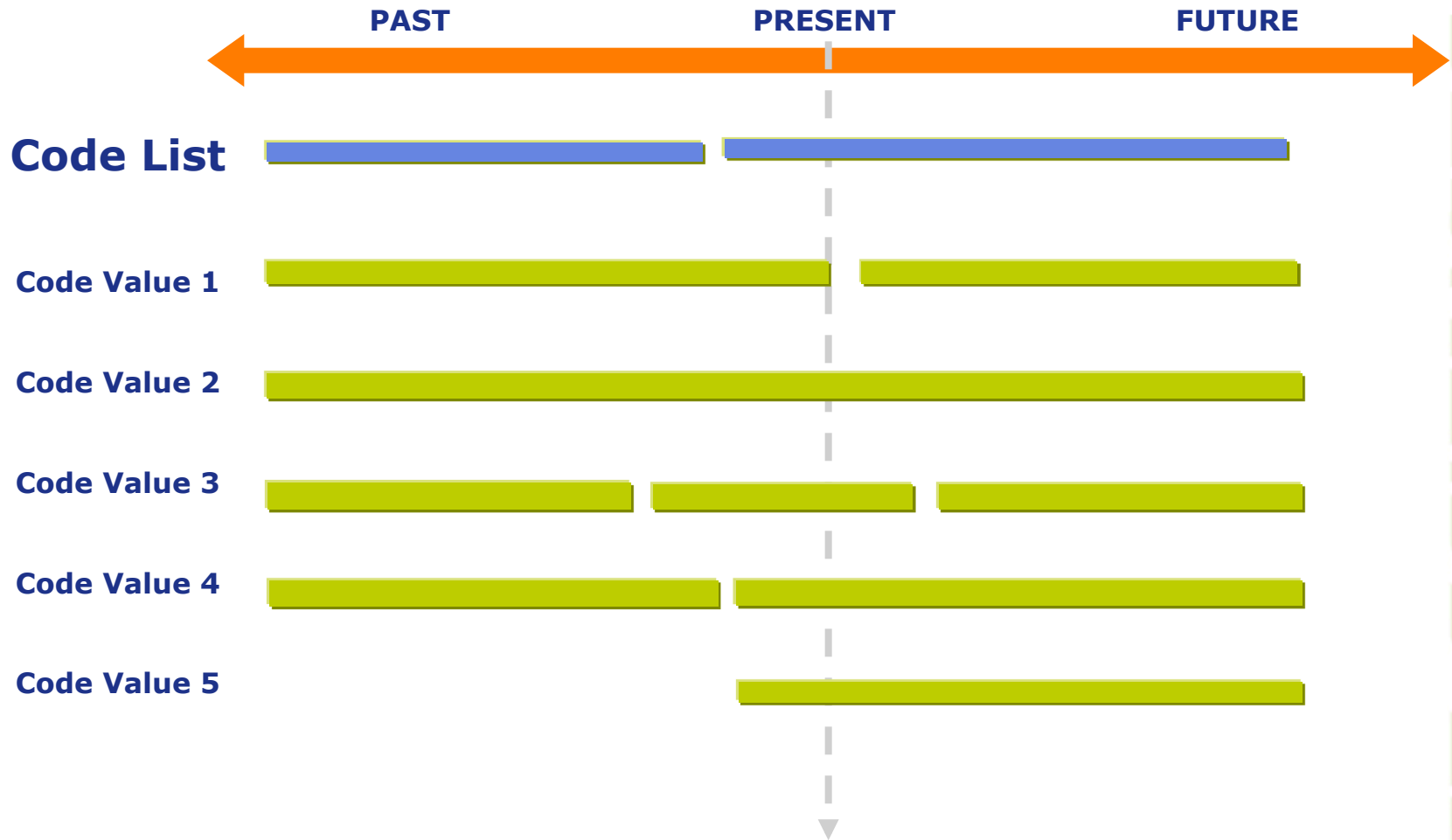
01 OCT 2013

CV3b:

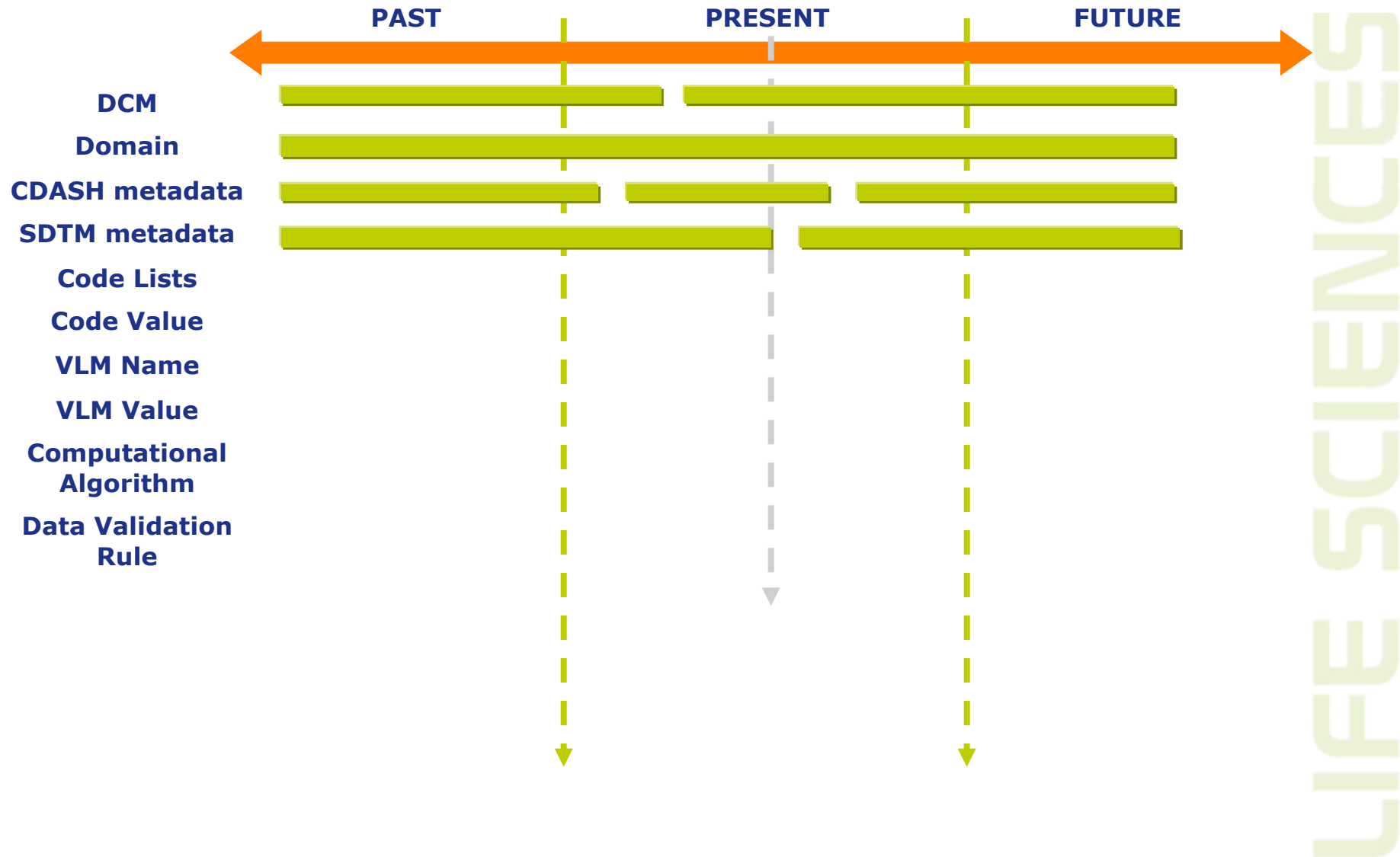
02 OCT 2013



Versioning of Library Objects: example



Allowing Time Travel for Librarians ...



Data Standards Library comparisons

SAS® Drug Development

View

Tools

Administration

Help

Log Off

Dashboard

Repository

Workspace

CompareOracle (1.0) [read-o...

General

SAS Programs

Parameters

Inputs

Outputs

Publish History

Variable Name	Label	Type	Default Value
START_PATH	Path of the programs	Character	/SAS/Files/Global Files/Programs/Comparison
REPORTPATH	Path of the report		
VERSION1	Date of version one		
VERSION2	Date of version two		
SOURCEWORD1	Name of source one		
SOURCEWORD2	Name of source two		
METADATA_LEVEL	Metadata Level (DOMAIN,VARIABLE,CODELIST,...		
LIBRARY_NAME	Name of the library		

CHECK	NAME	DESCRIPTION	DATASET	v22MAY2013	v30MAY2013
Ok	AE_101	testing AE 101d	DEMO	X	X
Ok	AE_900	AE_900	AE	X	X
Ok	AIMSV76_QS_001		QS	X	X
Ok	AVETST2	Field that can be used to describe the DCM content	CM	X	X
Ok	CM_900	CM_900	CM	X	X
Ok	CO_900	CO_900	CO	X	X
Ok	DM_900	DM_900	DM	X	X
Error	DS_900	DS_900	DS	X	
Error	DS_900	DS_900_A	DS		X
Error	DS_901	DS_901	DS	X	
Error	DS_901	DS_901_B	DS		X
Ok	EX_900	EX_900	EX	X	X
Ok	LB_900	LB_900	LB	X	X
Ok	LB_901	LB_901	LB	X	X
Ok	MH_900	MH_900	MH	X	X
Ok	MH_901	MH_901	MH	X	X
Ok	PR_807	PR_807	PR	X	X
Ok	PR_900	PR_900	PR	X	X
Ok	SU_900	SU_900	SU	X	X
Ok	SV_800	SV_800	SV	X	X
Ok	SV_900	SV_900	SV	X	X
Ok	SV_901	SV_901	SV	X	X
Ok	TEST_001	Description test 001	DM	X	X

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- Increased and complex Clinical Data Standards challenges
- Clinical Data Standards Platform requires:
 - Data Standards Governance,
 - Robust Technical platform,
 - Performance Management
- Version control with Active From an To dates allows **TIME TRAVEL** for librarians
- Ensures:
 - Increased CDISC clinical data standards adaptability
 - Better collaboration and easier regulatory submissions
 - Continuous Process Improvement
 - ...

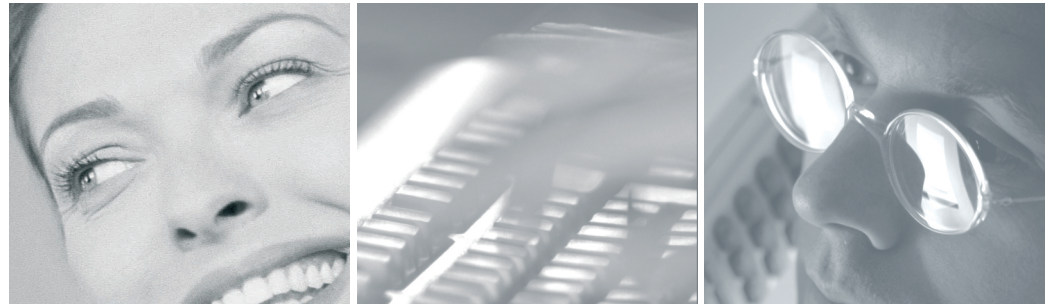


Thank you for your attention

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