



Setting the
Global Standard
for Clinical Data

CDISC Standards, Present & Future

**CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM**

**French User Group Meeting
4 December 2009**

**Pierre-Yves Lastic
Sanofi-aventis & CDISC Board
Dave Ibersen-Hurst
CDISC, VP Technical Strategy**

Overview

- Standards Overview
 - Current CDISC Portfolio
 - Next Steps
- Regulatory Requirements driving CDISC developments
 - PDUFA IV, the FDA IT plan
- The Evolution of CDISC Standards
 - SDTM (& SEND) vs. CDISC-HL7 Messages
 - CSHARE: CDISC Shared Health And Clinical Research Electronic Library

Team	Current Product(s)	Project(s)	Notes
ADaM	ADaM V2.0	ADaM V2.1 ADaM IG V1.0	
BRIDG	BRIDG R3.0	SDTM into BRIDG ADaM into BRIDG	
CDASH	CDASH V1.0	CDASH V1.1 CDASH UG V1.0 CDASH ODM CDASH Devices	
CDISC SHARE	-	Inception Phase – SHARE Pilot plus Scope & Vision document	
eSDI	eSDI V1.0	-	Small amount of work performed in 2009 in support of healthcare link and liaison with FDA
CORE	-	US Interchange scenario(s)	
Glossary	Glossary V7.0	Glossary V8.0 Glossary alignment with external parties	
Healthcare Link	IHE Profiles HITSP Specifications	IHE RFD, CRD, Redaction HITSP	
HL7 CDISC	3 x HL7 Standards	HL7 CDISC RCRIM project	
ISD Pilot	-	ISD Pilot with Pilot Report V1.0	
LAB	LAB V1.0.1	-	
Protocol	-	Protocol V1.0	
TDM	-	ODM TDM V1.0 TDM into BRIDG	

Team	Current Product(s)	Project(s)	Notes
Terminology	EVS Terminology	Additional terminology for ADaM, LAB, SDTM, SEND plus Governance/Implementation	
Therapeutic Area Standards	-	Tuberculosis Cardiovascular (CRNFA & FDA) Diabetes Polycystic Kidney Parkinson & Alzheimer	
SDTM	SDTM V1.2 SDTM IG V3.1.2	SDTM Devices SDTM Oncology SDTM Questionnaires Metadata Implementation Guide	
SEND	SEND V3.0 draft A	SEND V3.0 SEND Pilot	
XML Technology	ODM V1.3 CRT-DDS V1.0	ODM V1.4 ODM TDM V1.0 CRT-DDS V2.0 ODM TDM V1.0	

Next Steps

◆ BRIDG V3.0

◆ PR V1.0

◆ ADaM V2.1

◆ CDASH V1.1
CDASH UG V1.0

and the miracle occurs here ...

 SHARE

◆ NCI caDSR++
initial SW release

Q4 09

Q1 10

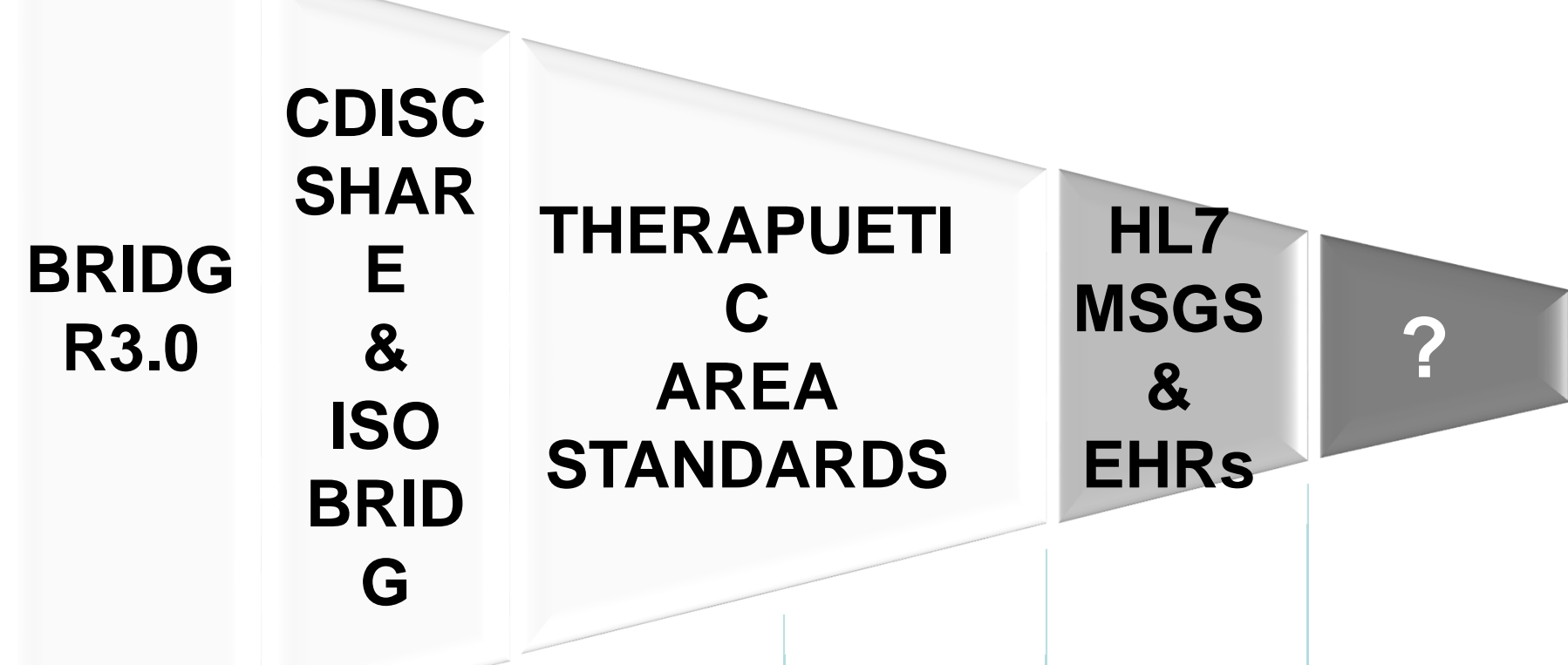
Q2 10

Q3 10

Q4 10

Q1 11

High Level View



SDTM, ADaM
...
CV, TB ...

SDTM, ADaM, CDASH, Protocol, CV, TB, any many more
delivered via SHARE with EHR integration...

2009 2010 2011 2012 2013 2014

Today

Level View

**BRIDGE
R3.0**

CDISC

HL7 CDISC and SDTM come together

HL7 CDISC, SHARE and SDTM come together

THERAPUETIC

**HL7
MCC9**

**&
ISO**

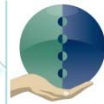
Further TA content

Start adding TA content such as TB, CV, Kidney, Oncology ...
Also incorporate ADaM, SEND etc.

DS

EHRs

SHARE incl. SDTM & CDASH plus ? (may be Devices, Protocol, Glossary)



SHARE & EHR integration

SDTM, AI

SDTM, ADaM, CDASH, Protocol, CV, TB, any many more delivered via SHARE with EHR integration...

2009

2010

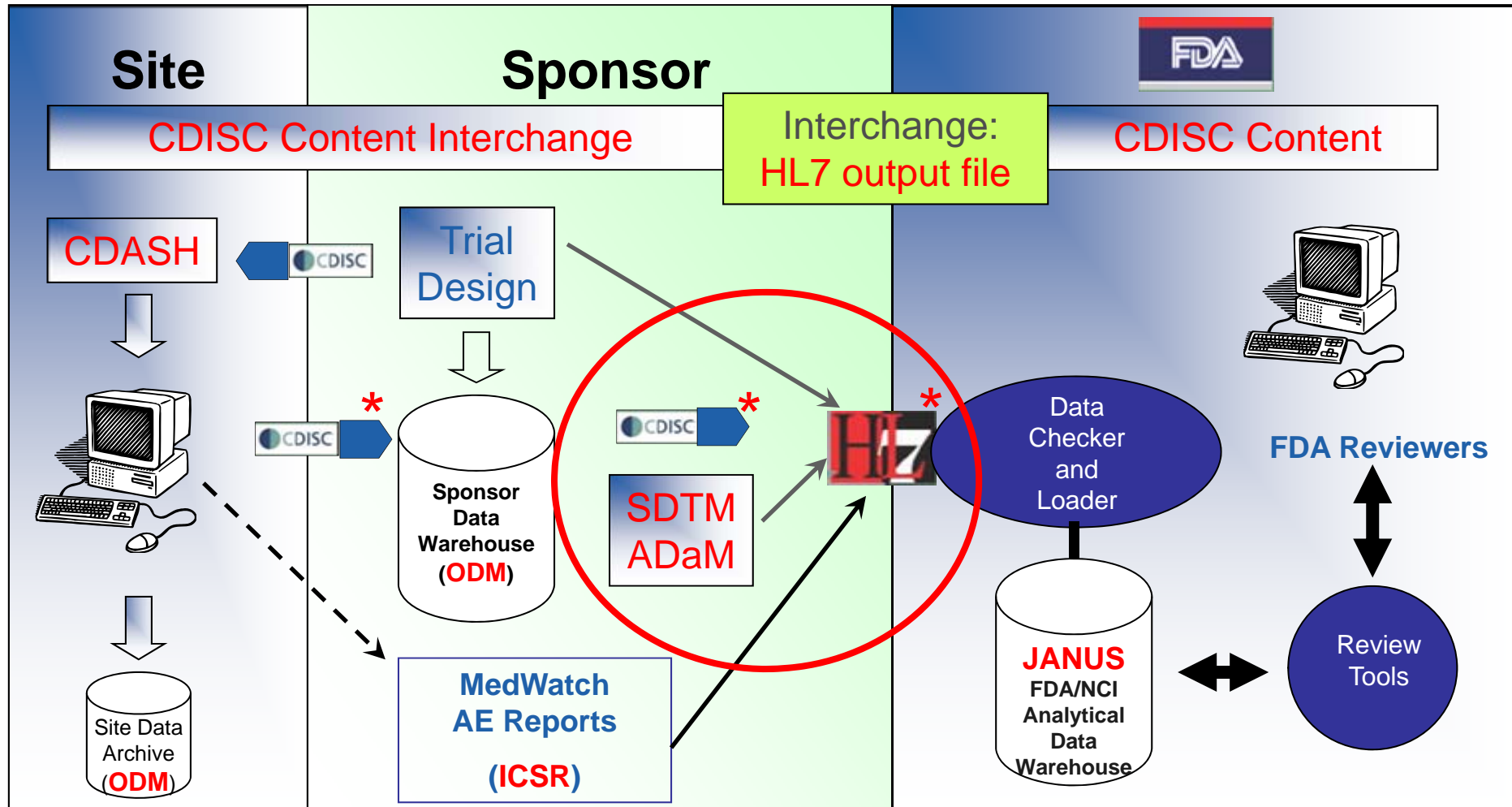
2011

2012

2013

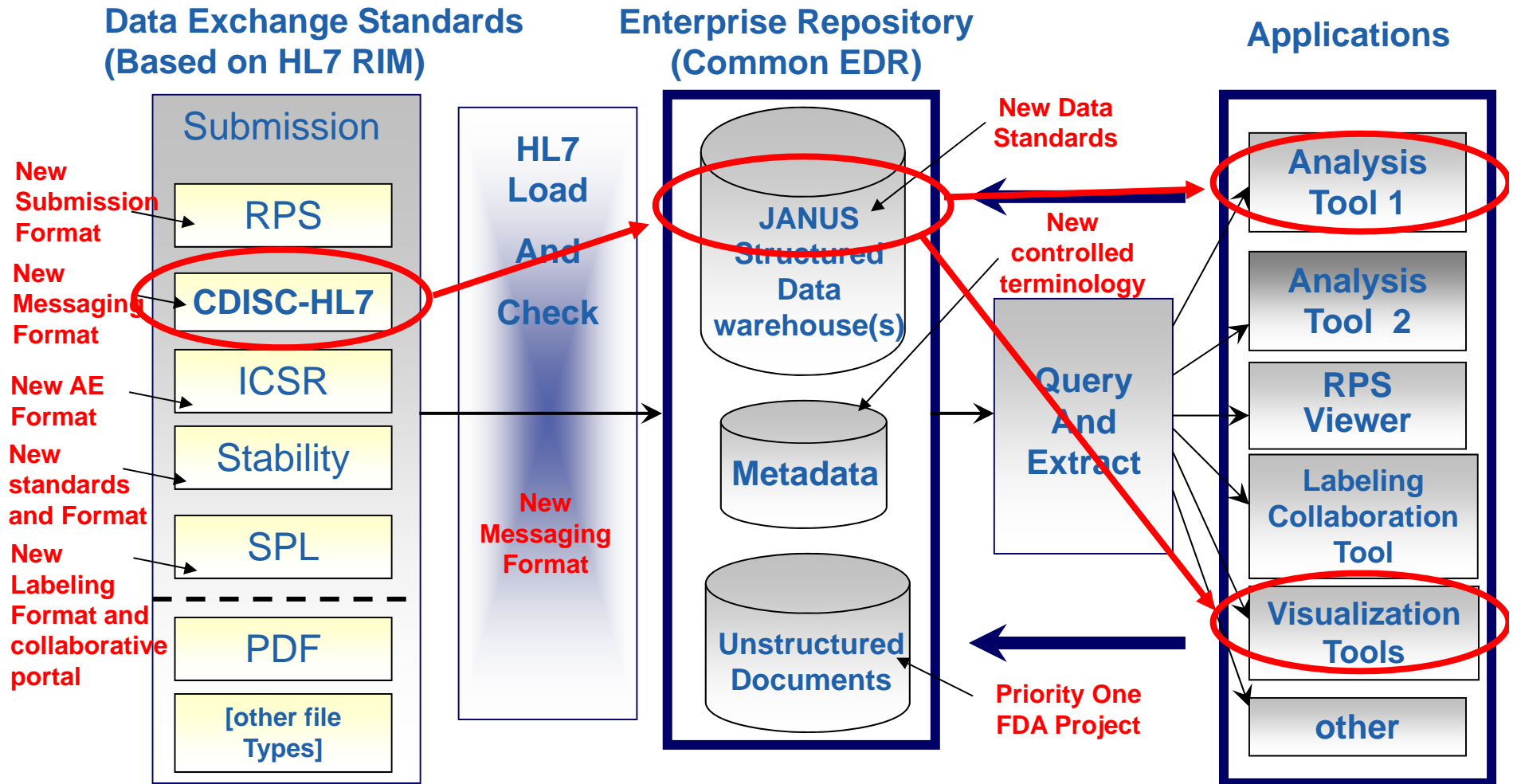
2014

FDA view of the future landscape for clinical data flow from the published plan



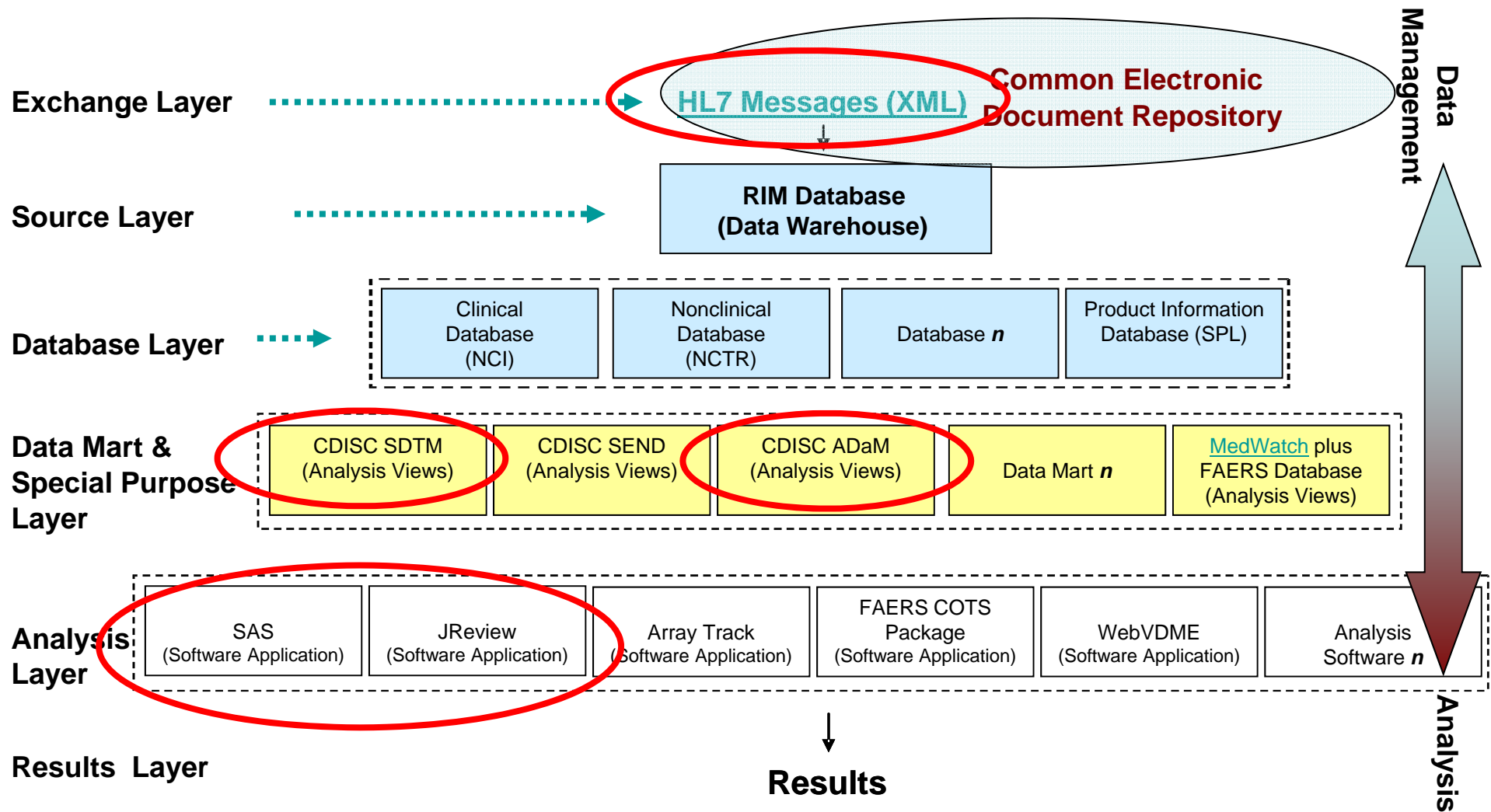
Red = new, modified, or to be implemented

Conceptual target data flow for regulated product information



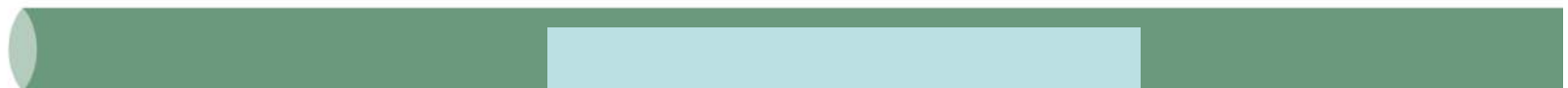


Janus Architecture (Q109 Update)

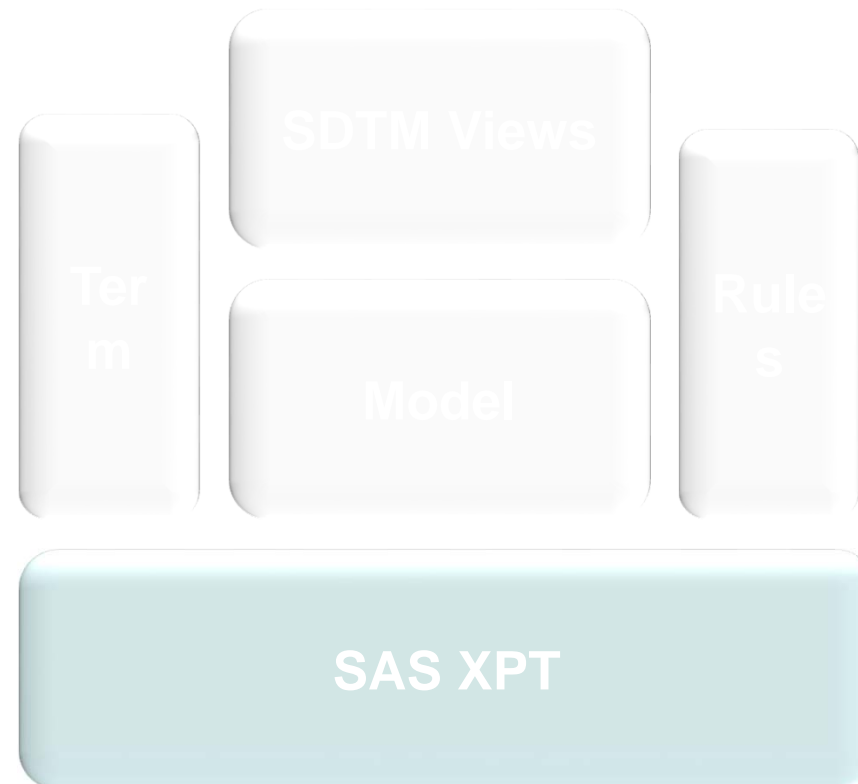


Impact on CDISC Standards: SDTM vs. HL7 Messages

- Look at the changes
- Explain what the impact is
- Put the changes in context
- Three Messages
 - Study Participation
 - Study Design
 - Subject Data (the focus of the talk)

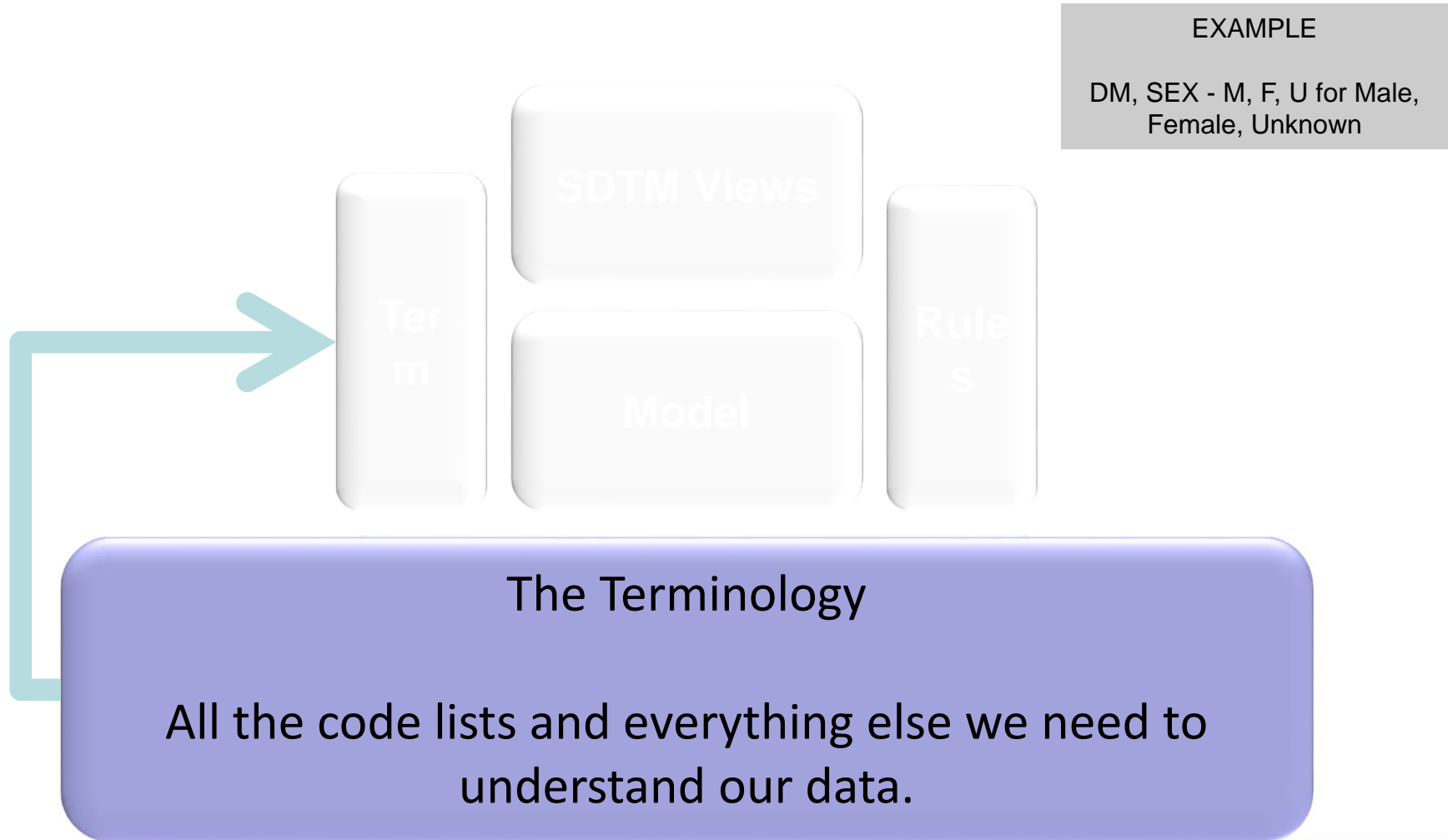


SDTM Today



SDTM today can be thought of as having a number of components

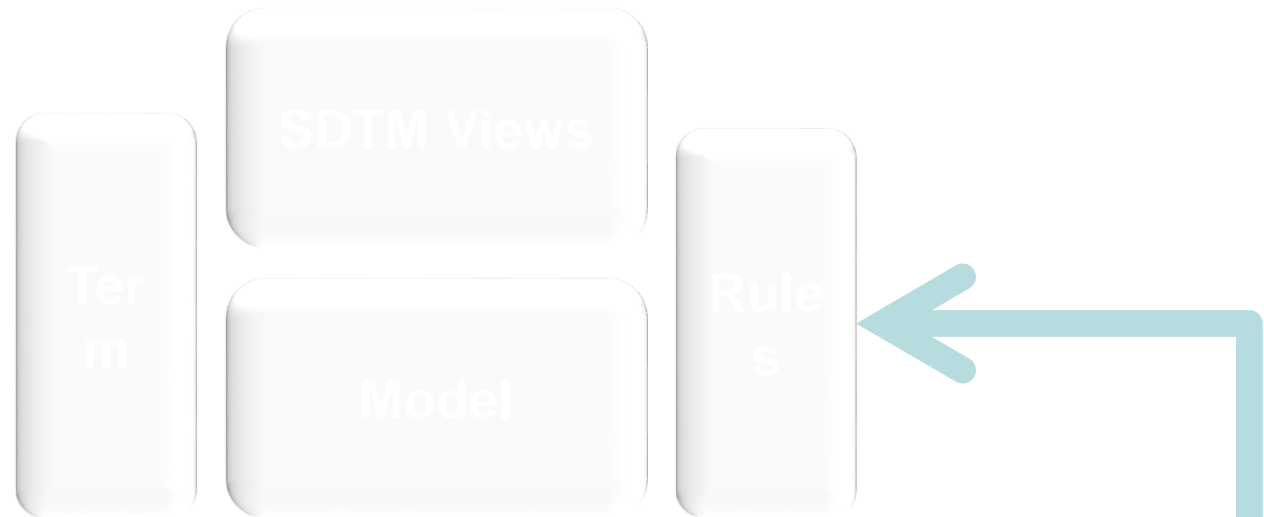
The Parts of SDTM



The Parts

EXAMPLE

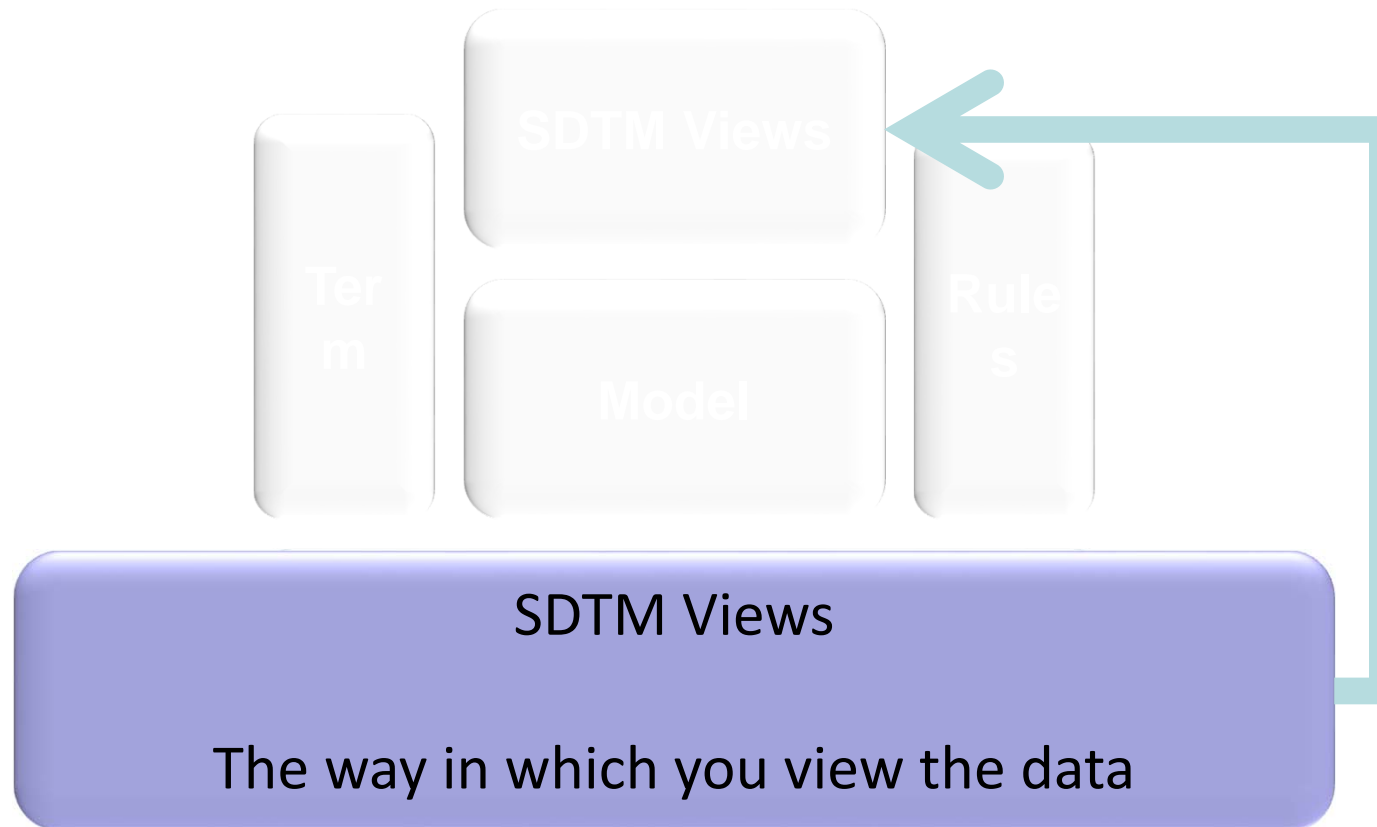
Subject identification: It is presumed that every subject in a study will have a subject identifier (SUBJID) and that in some cases a subject may be included in more than one study within a submission. To identify a subject uniquely across a submission, a unique identifier (USUBJID) should be assigned and included in all datasets within the submission.



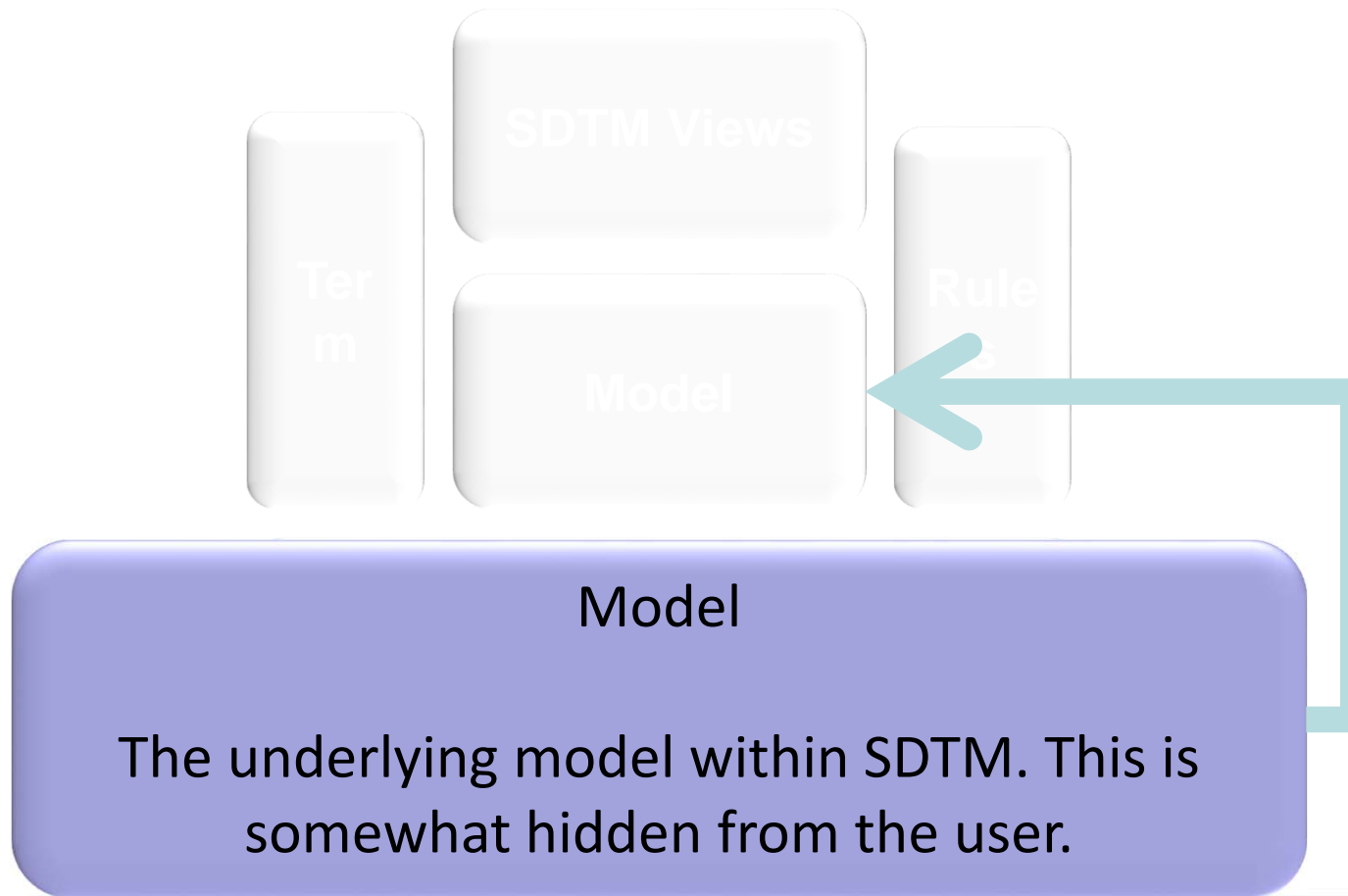
The Rules

Rules on the content and what needs to be provided to the FDA as part of a submission

The Parts



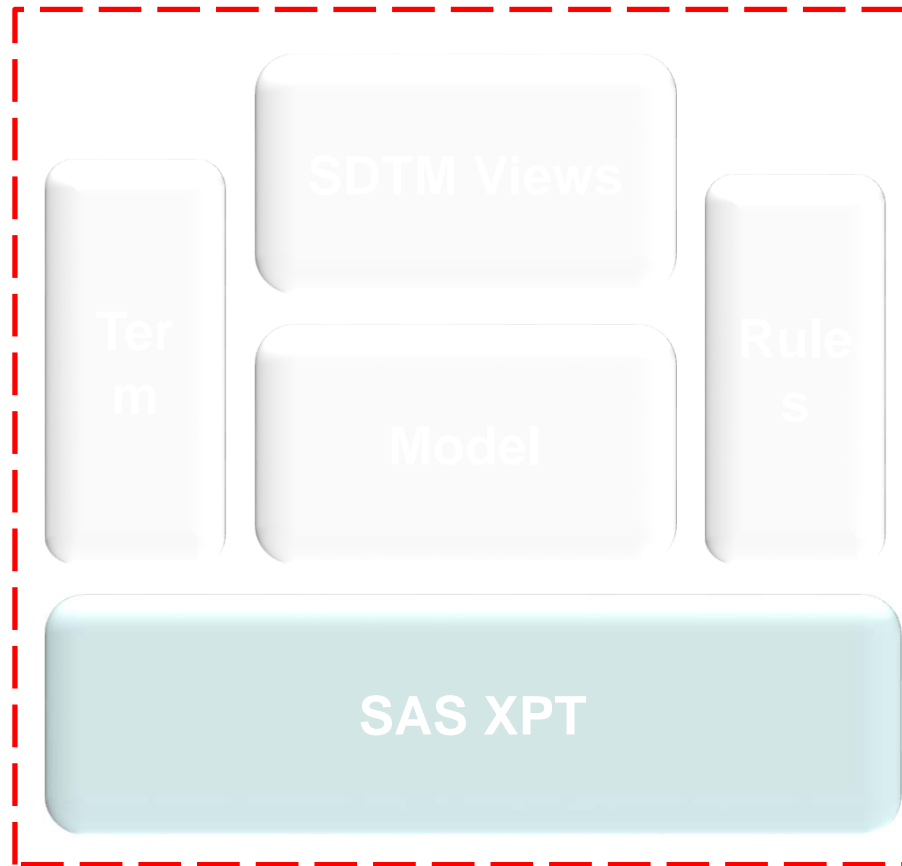
The Parts



Is this SDTM?



Or is that SDTM?



This is SDTM



This is SDTM



Remember that in fact SAS XPT is not really a standard. It is a format developed by SAS. It is a defacto standard.

Two Standards Involved



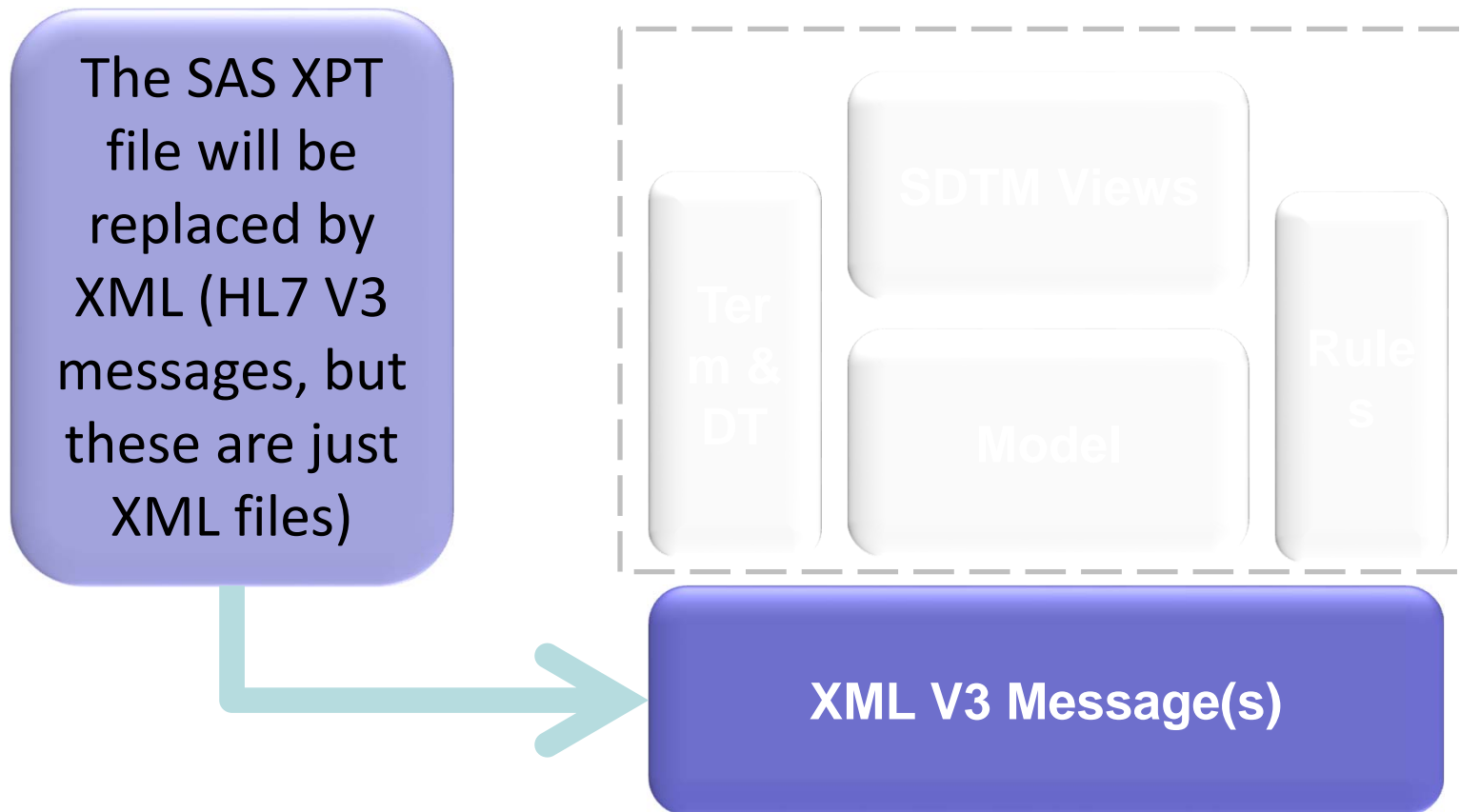
So when we send data to the FDA we are using two standards: a) SDTM the content standard; and b) the SAS XPT file

The Move to HL7

So are we just replacing the SAS XPT file?

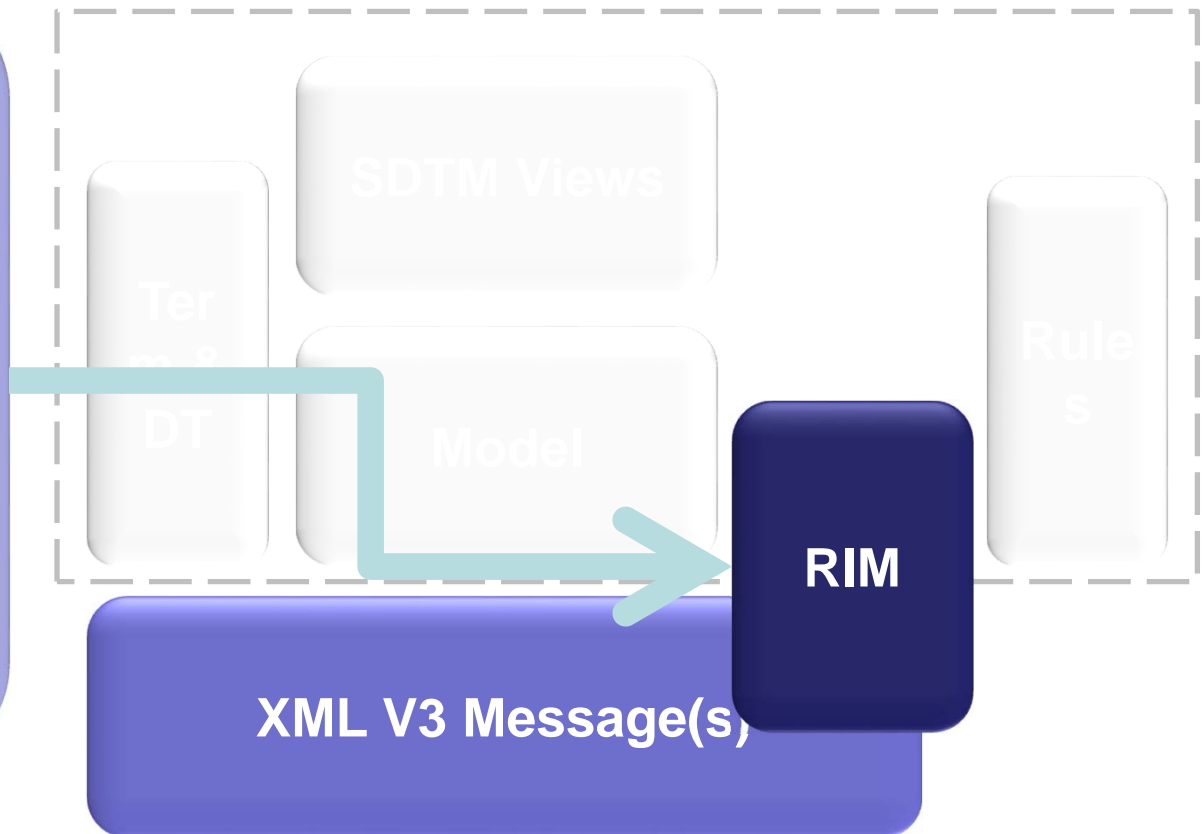


The Changes



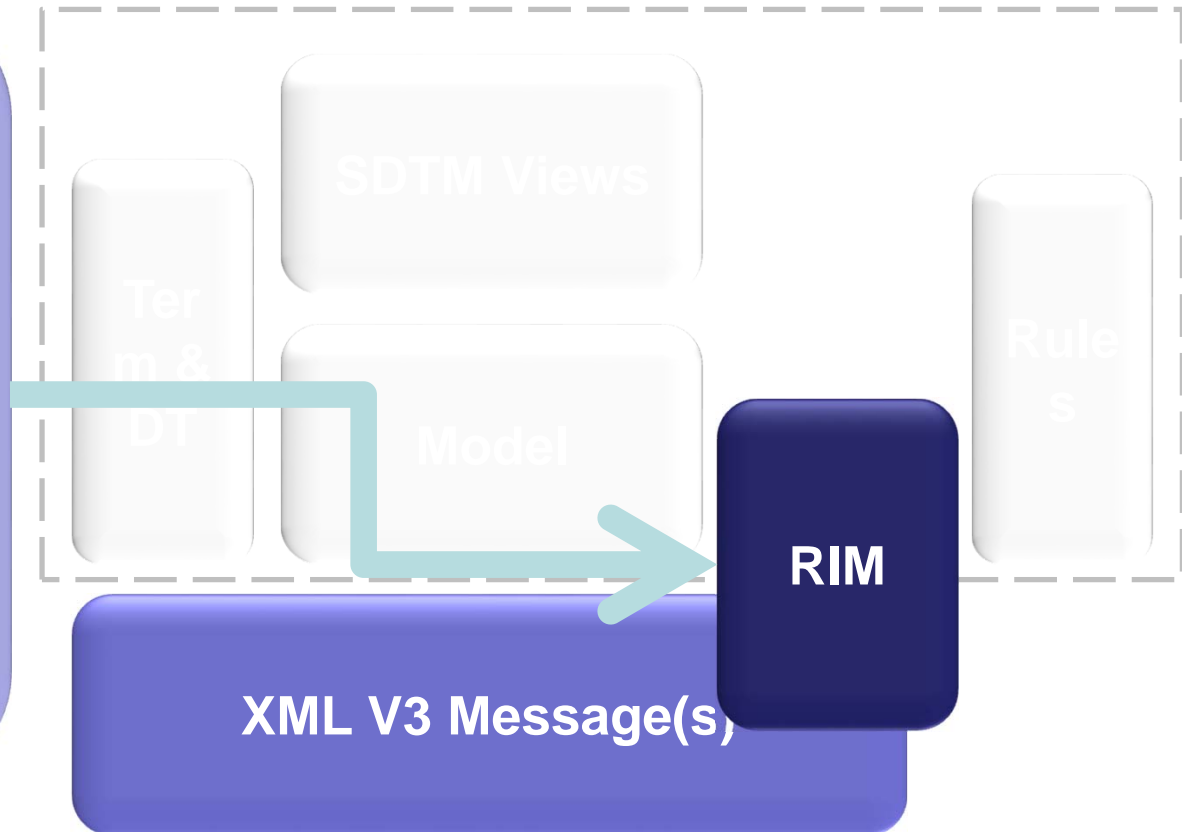
The Benefit

However, the benefit comes from the use by all HL7 messages of a common information model, the HL7 Reference Information Model (RIM)

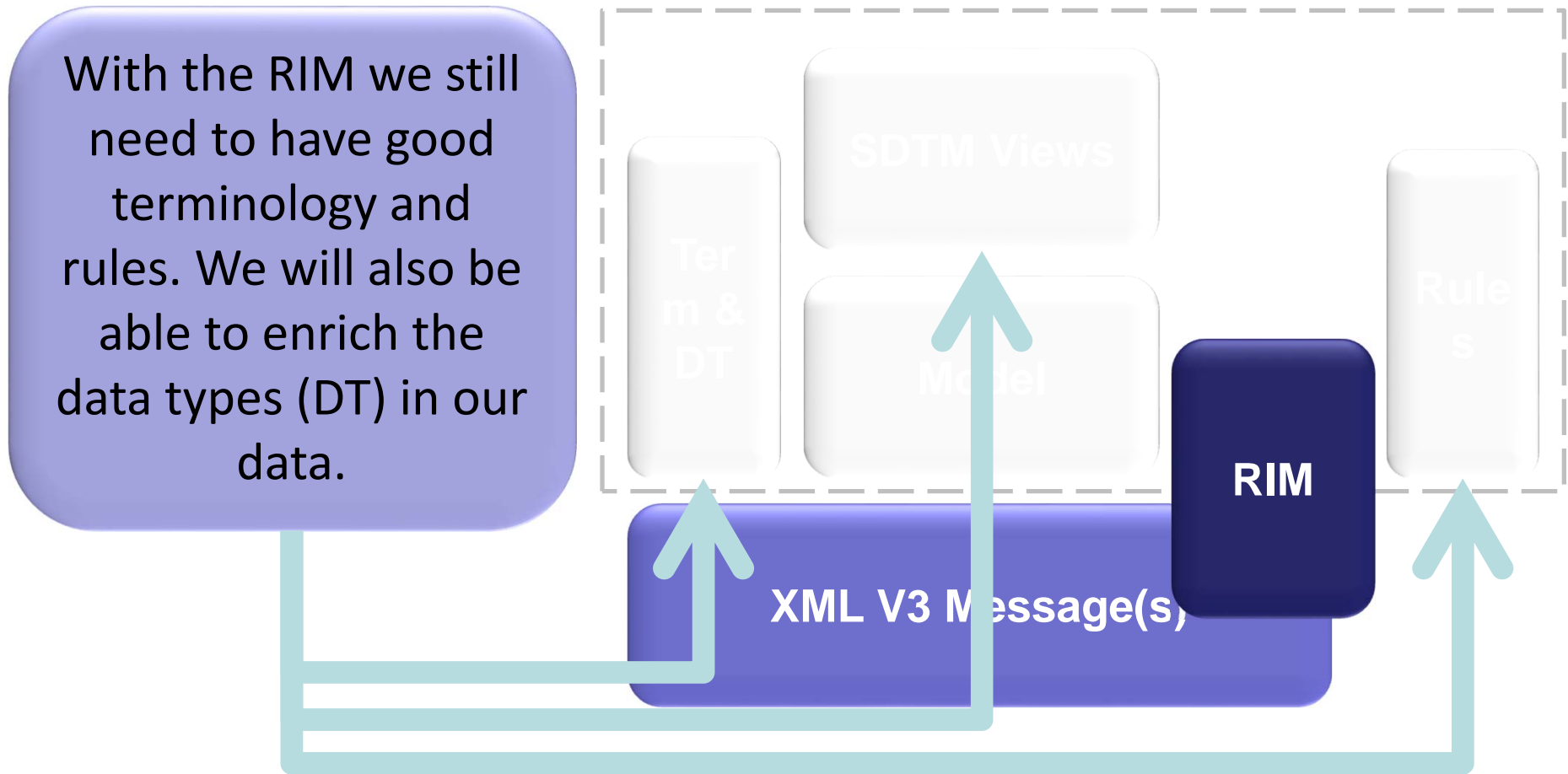


The Benefit

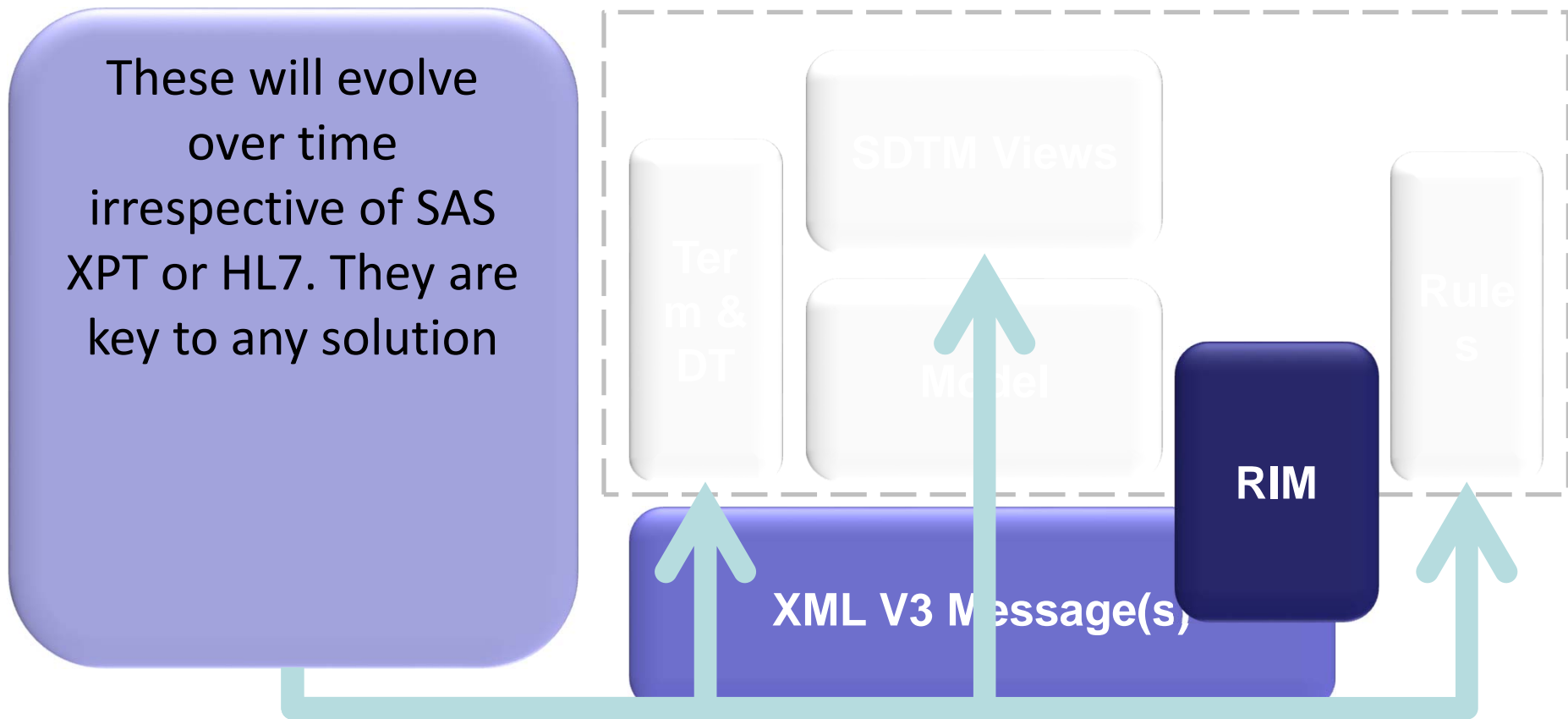
The RIM allows for the combination of content from any source as long as the content conforms to the RIM. Other FDA messages such as SPL and ICSR conform to the RIM



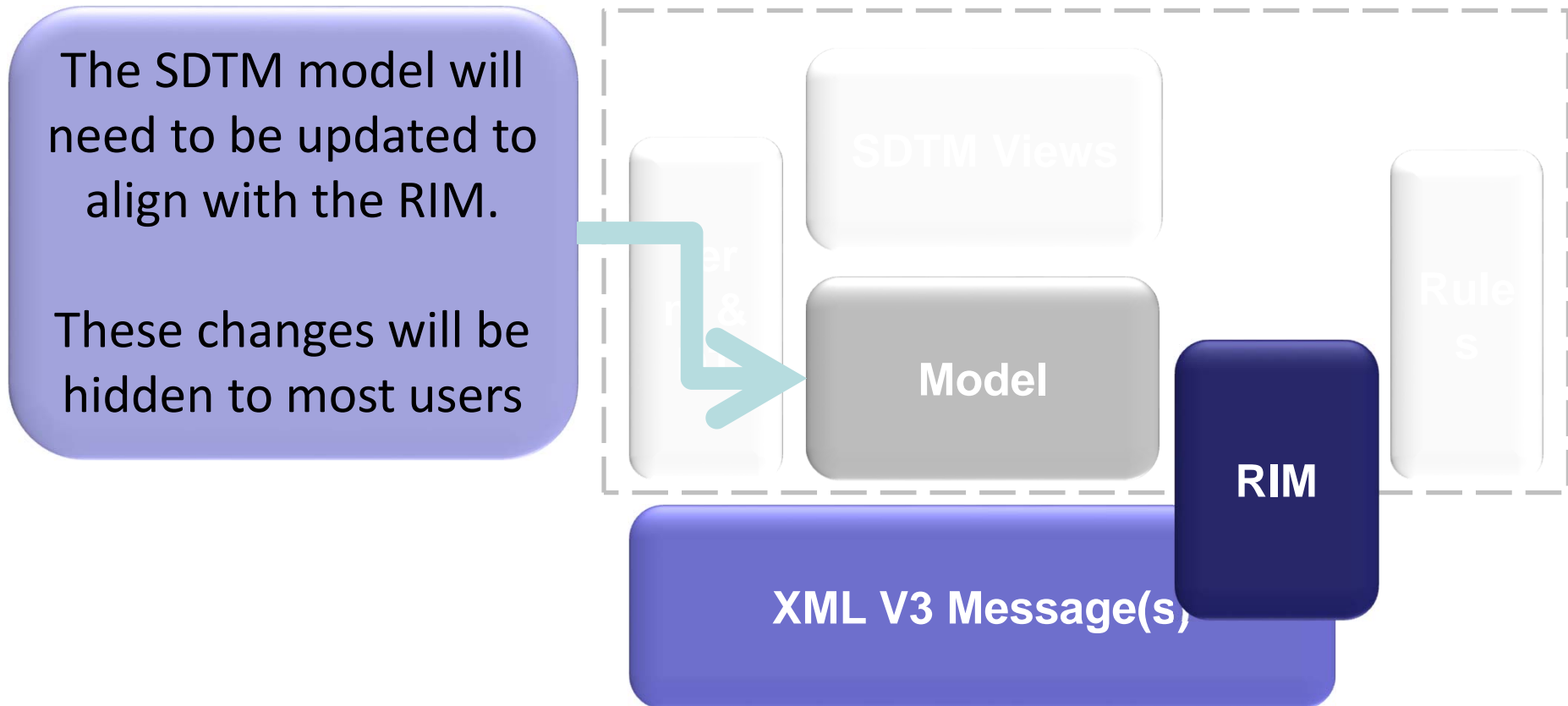
Some Things Won't Change



They will Evolve

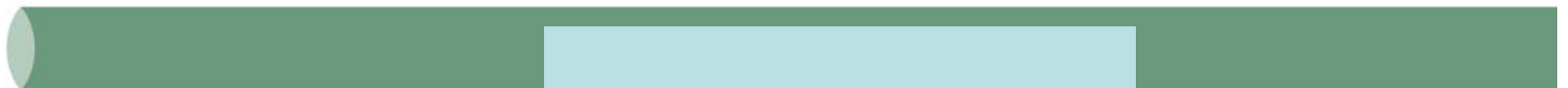


SDTM Model will be Updated



OK, But ...

- Why not just replace the SAS XPT file with XML?




Think about the meta data and data...

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



In the same way we cannot divide the lego brick, consider each cell as the lowest level building block

Looking at the meta data ...



USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg

Each cell is a building block.
Each coloured brick represents
the metadata for a column

Looking at the meta data ...



USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



Possible Values:
SYSBP or DIABP

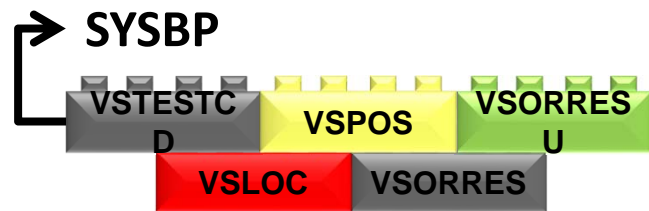


Possible Values:
LEFT ARM or RIGHT ARM

Each brick is a small piece of simple meta data


Looking at the meta data ...

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg

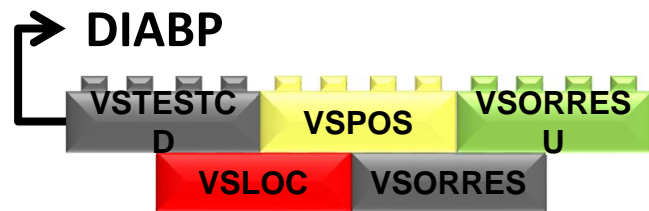


In the same way as with lego we can plug the bricks together, so systolic blood pressure can be described by a collection of meta data bricks

Looking at the meta data ...



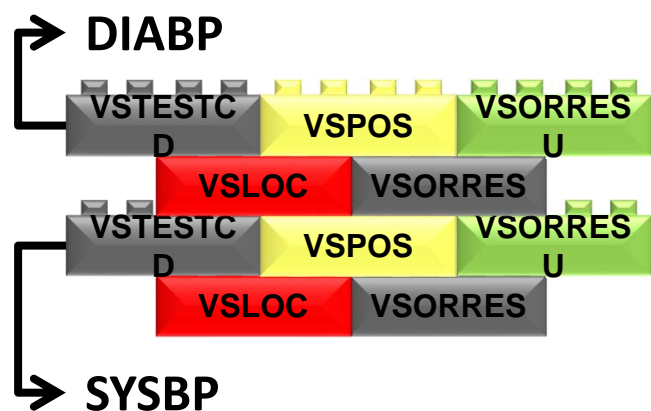
USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



And diastolic blood pressure is the same

Looking at the meta data ...

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg

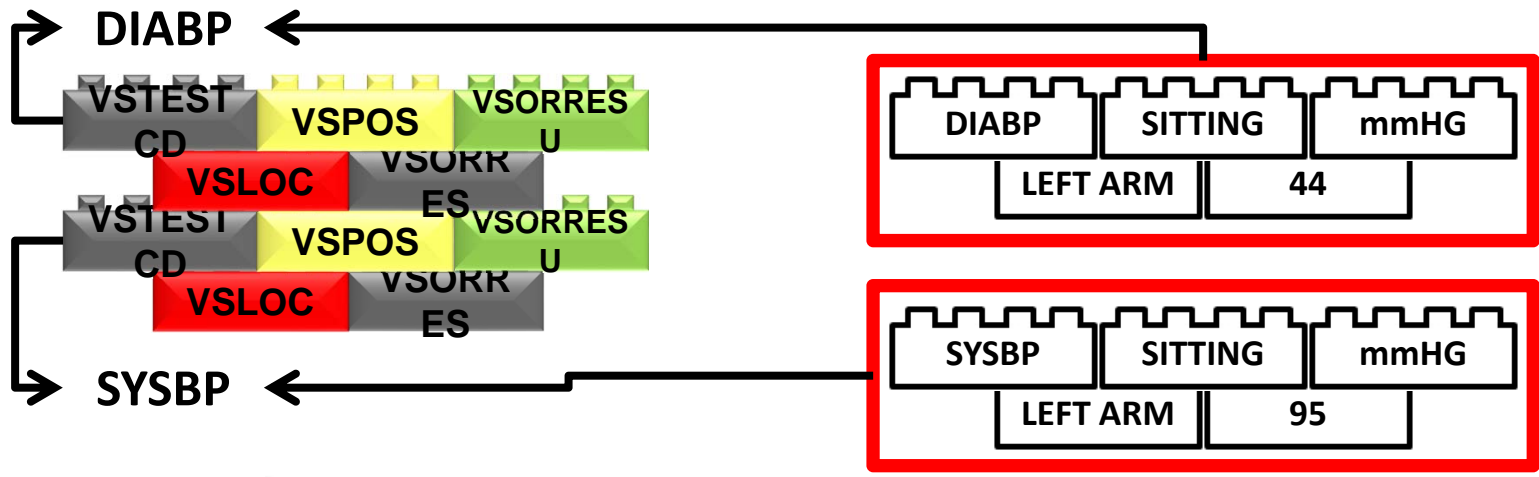


and blood pressure is the two together

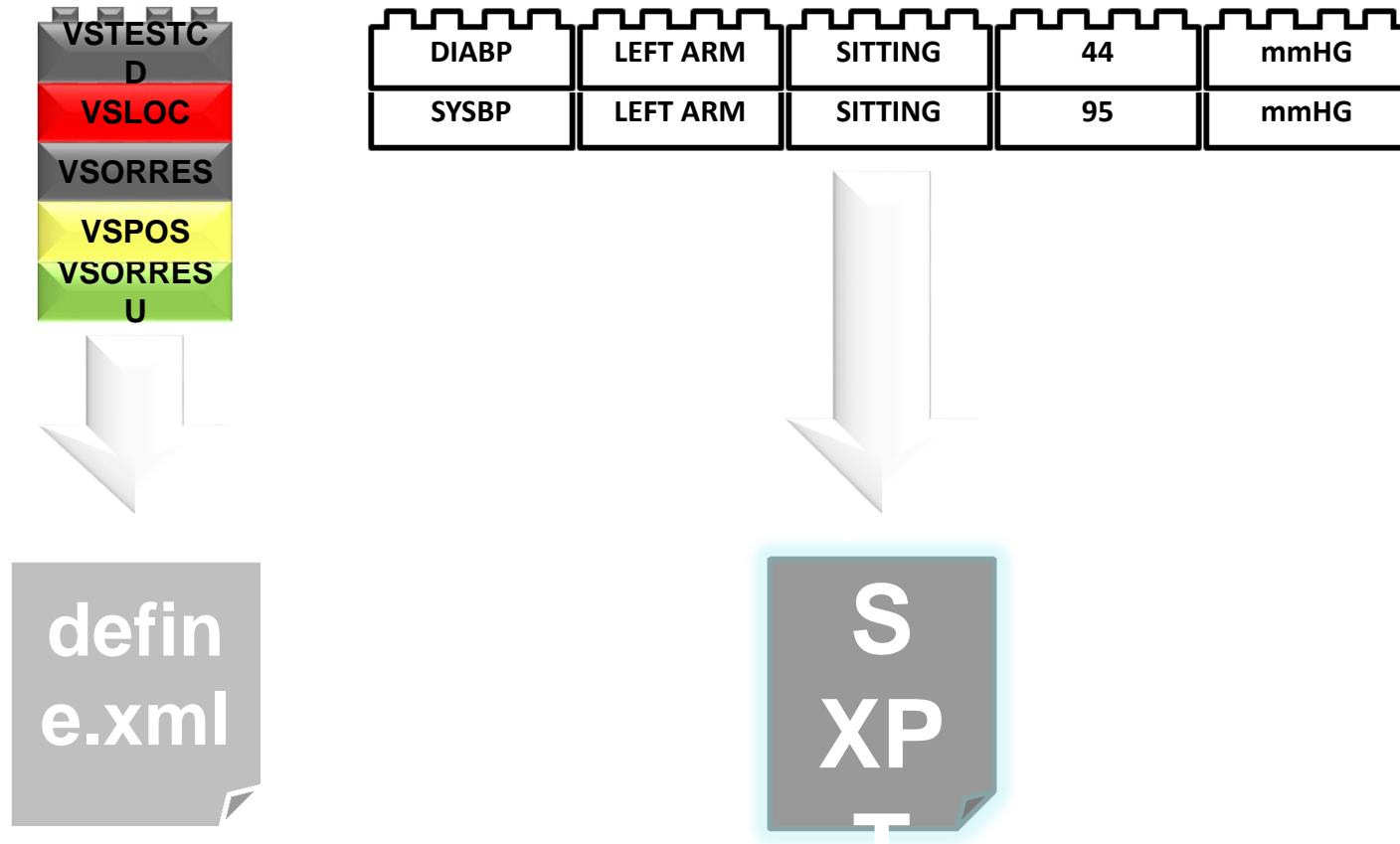
... and the data ...

The data only make sense when we link it to the meta data

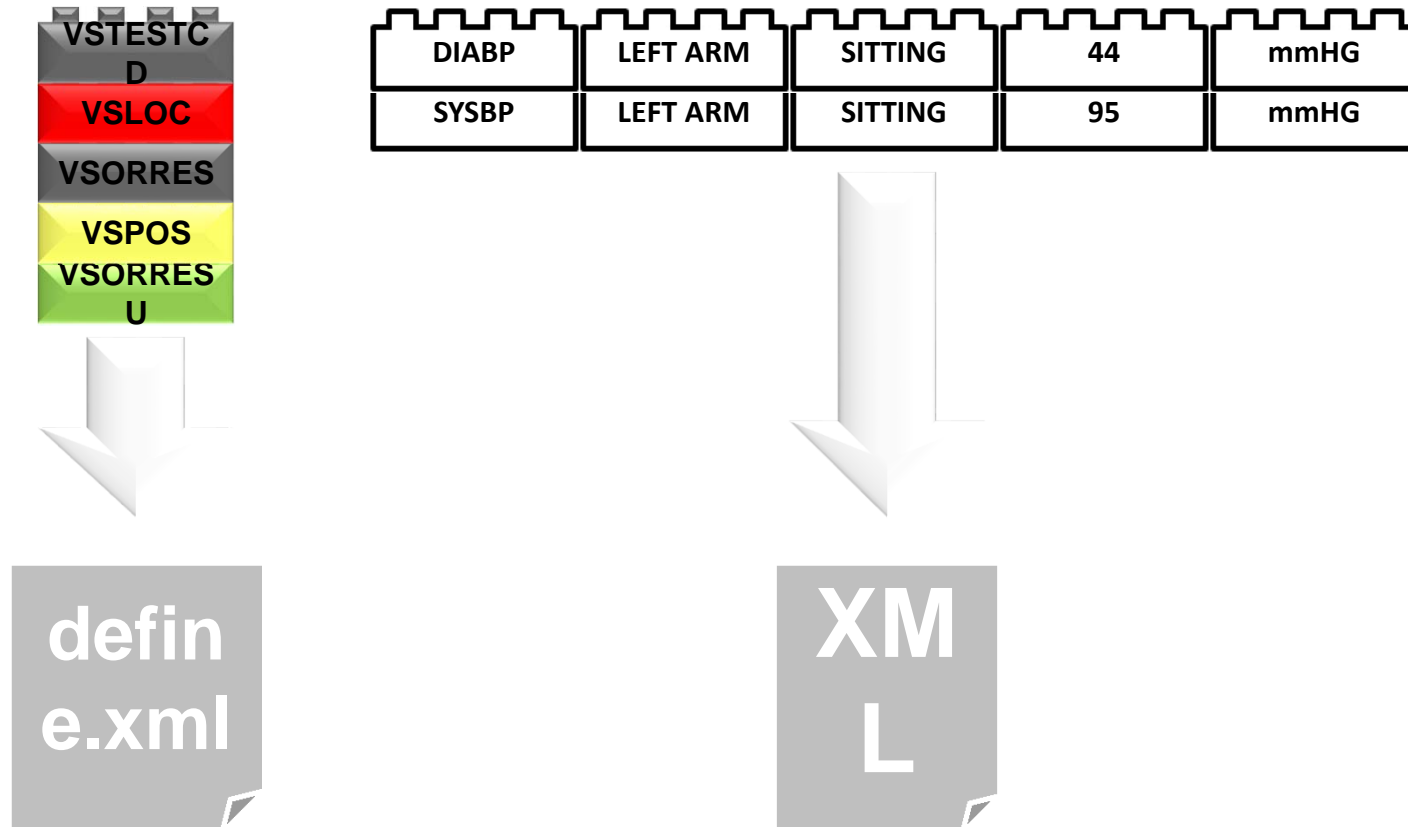
USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



... but when we send



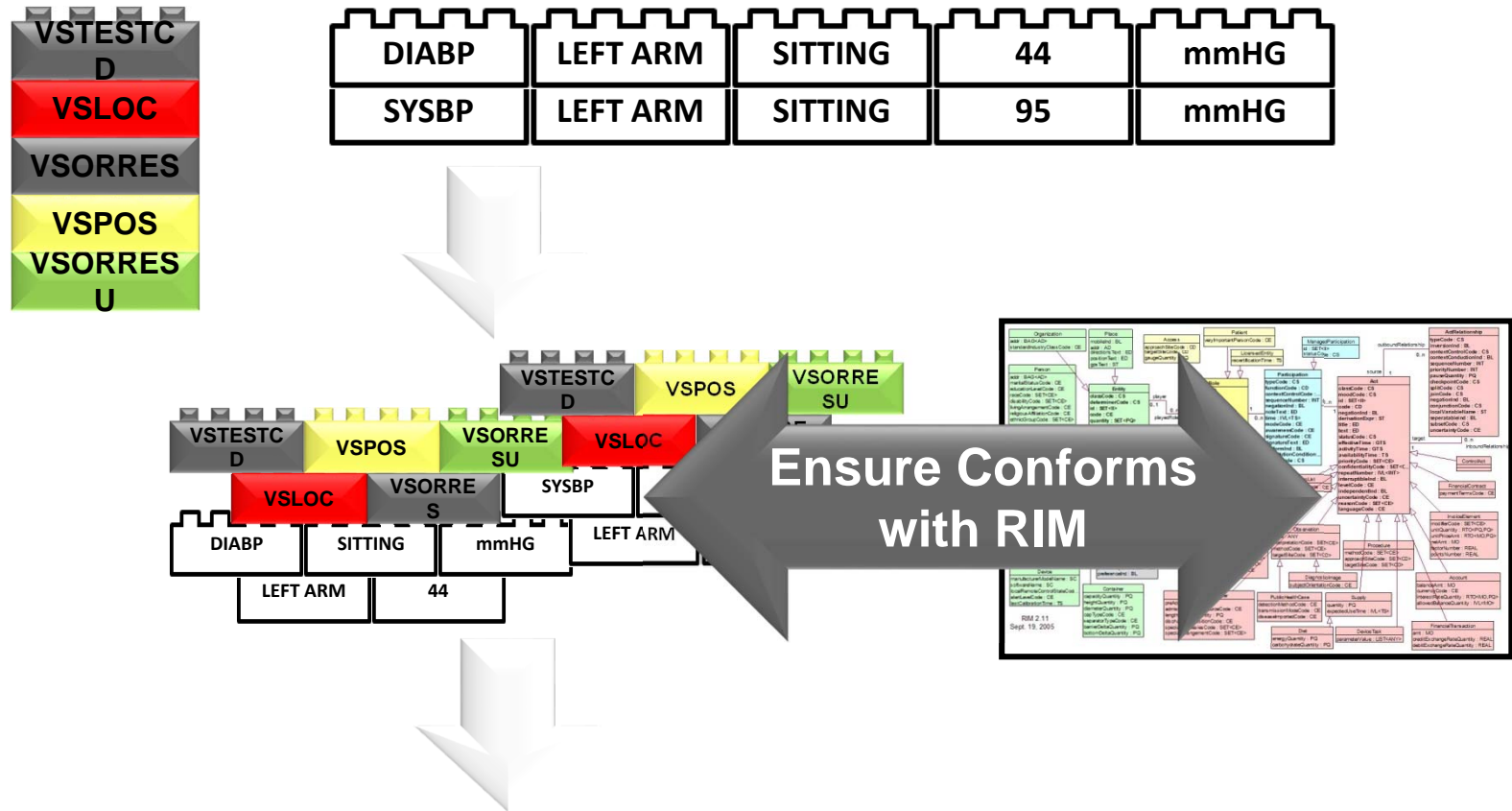
Just Replace SAS XPT with XML?



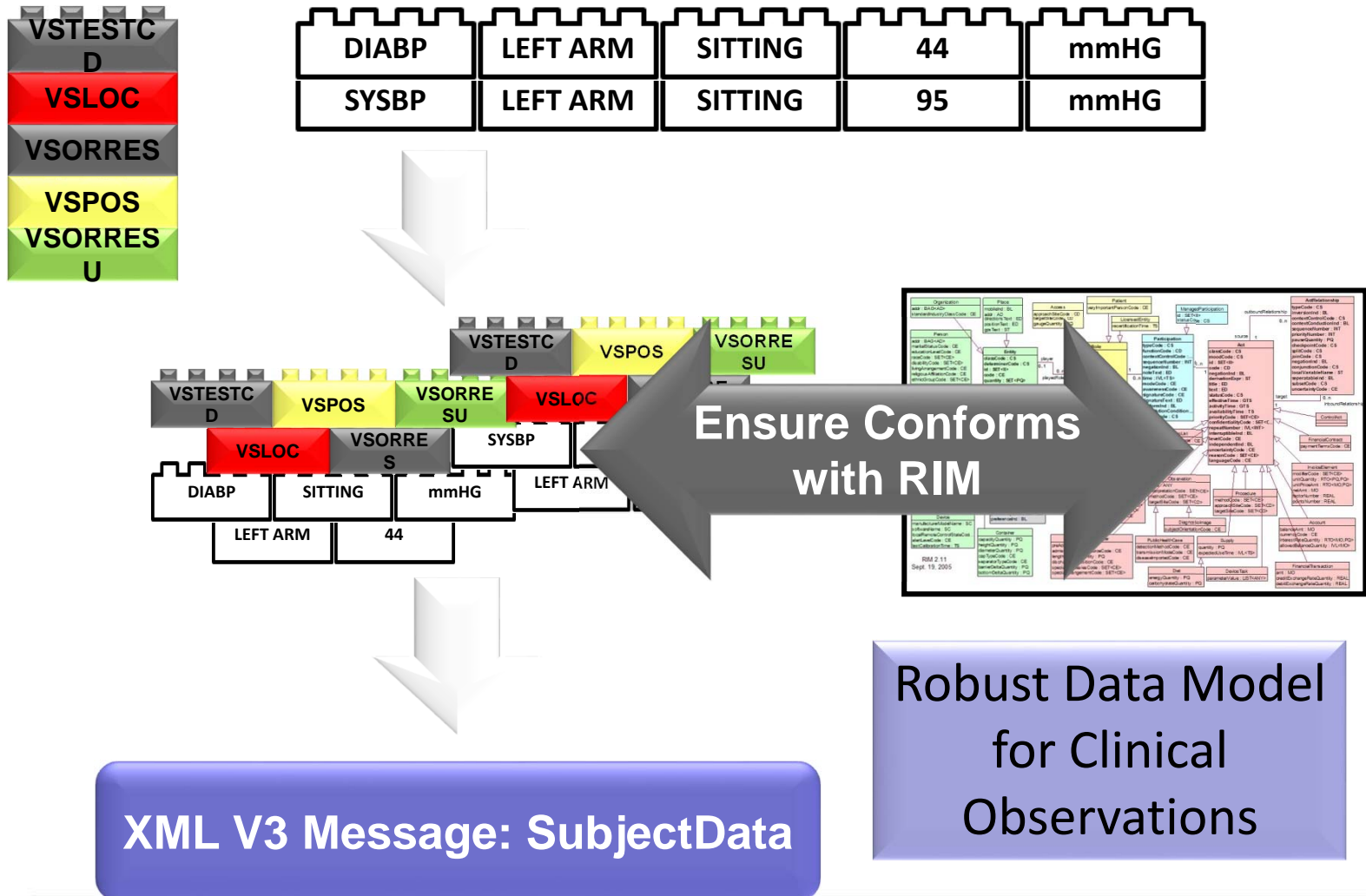
Just Replace SAS XPT with XML?

- This helps, e.g. removes restriction of SAS XPT format
- The collections are not carried in the exchange
- Still only allows SDTM data to be merged with SDTM data
- To merge non SDTM data we would need to expand our SDTM model to include the new area
- BUT, we already have a model and CDISC is not here to reinvent the wheel

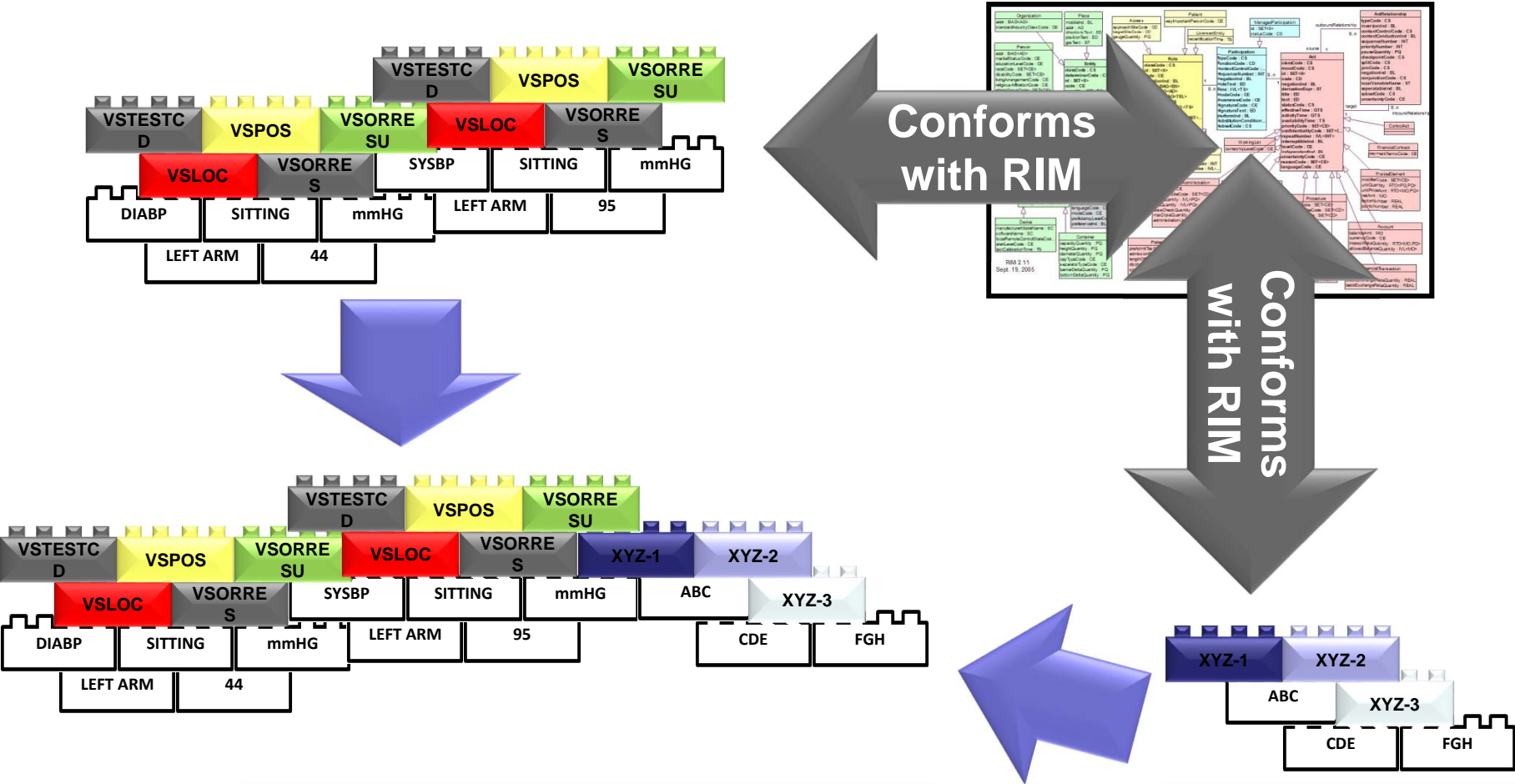
Bring SDTM together with the RIM



Adding rather than change

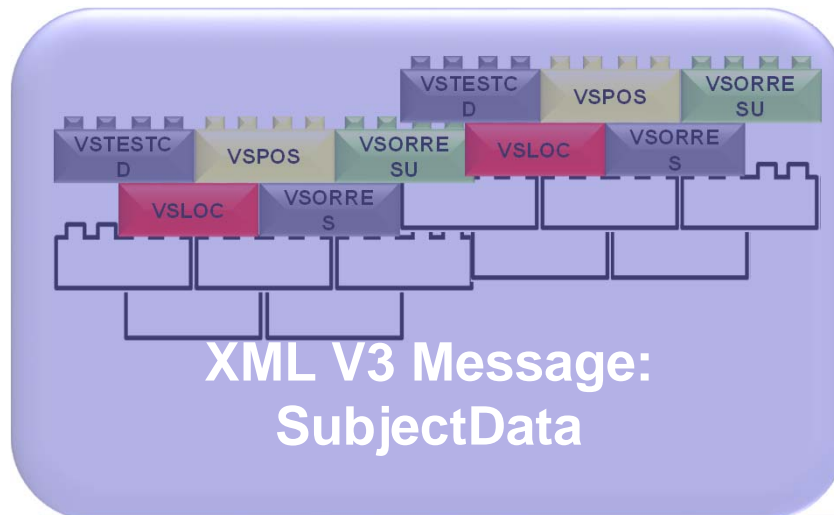
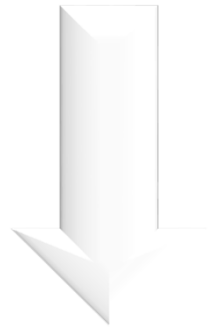


Merge with other RIM Content

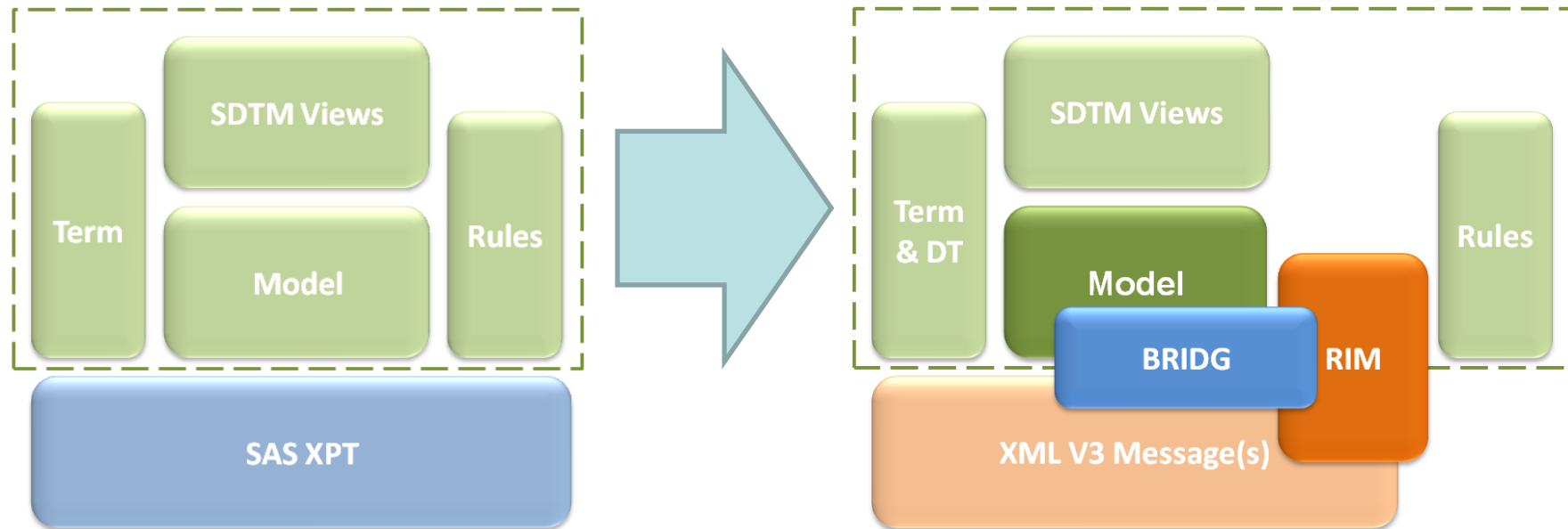


SDTM View

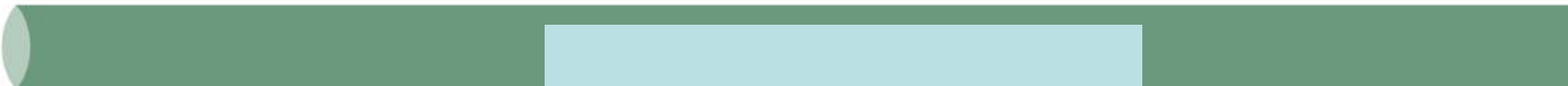
VSTESTC D	DIABP	LEFT ARM	SITTING	44	mmHG
VSLOC	SYSBP	LEFT ARM	SITTING	95	mmHG
VSORRES					
VSPOS					
VSORRES U					



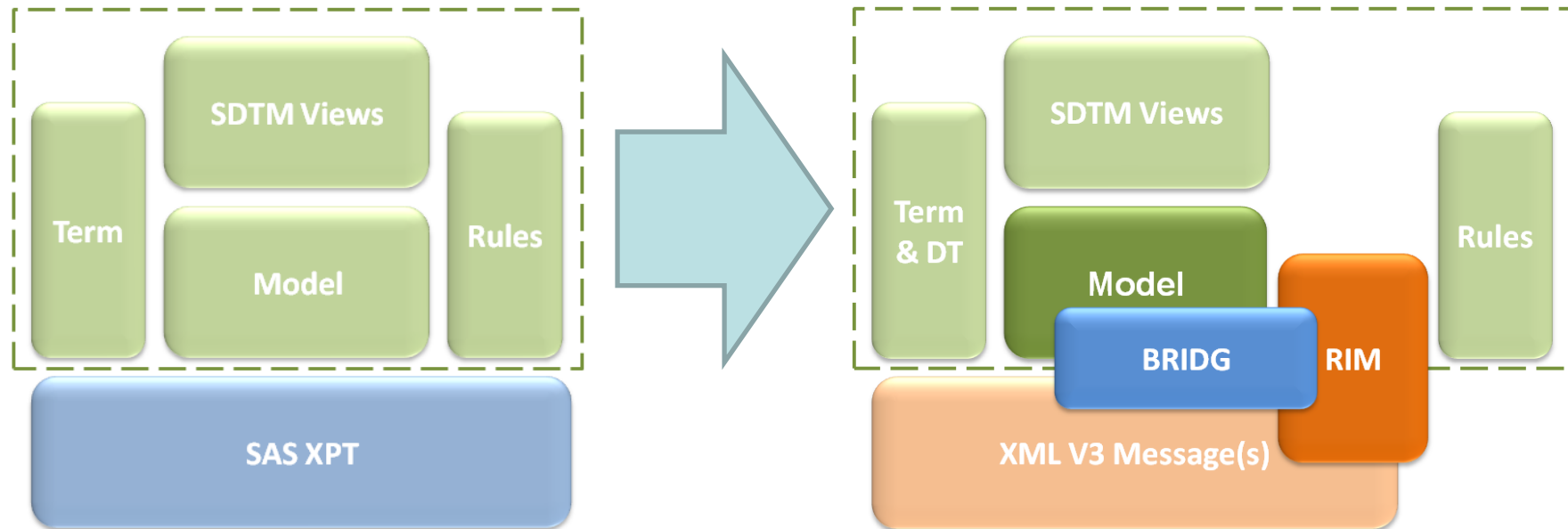
So, In Conclusion



The SAS XPT files will be replaced by XML files. We will align the SDTM model with RIM to allow SDTM data to integrate with other RIM compliant data sources.



So, In Conclusion



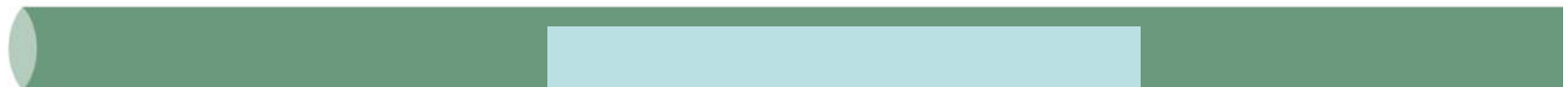
As stated clearly by the FDA, SDTM is not going away, this is the way they will view the data. RIM, BRIDG, the SDTM Model, the terminology and the rules are all crucial to the solution

Take Home Messages

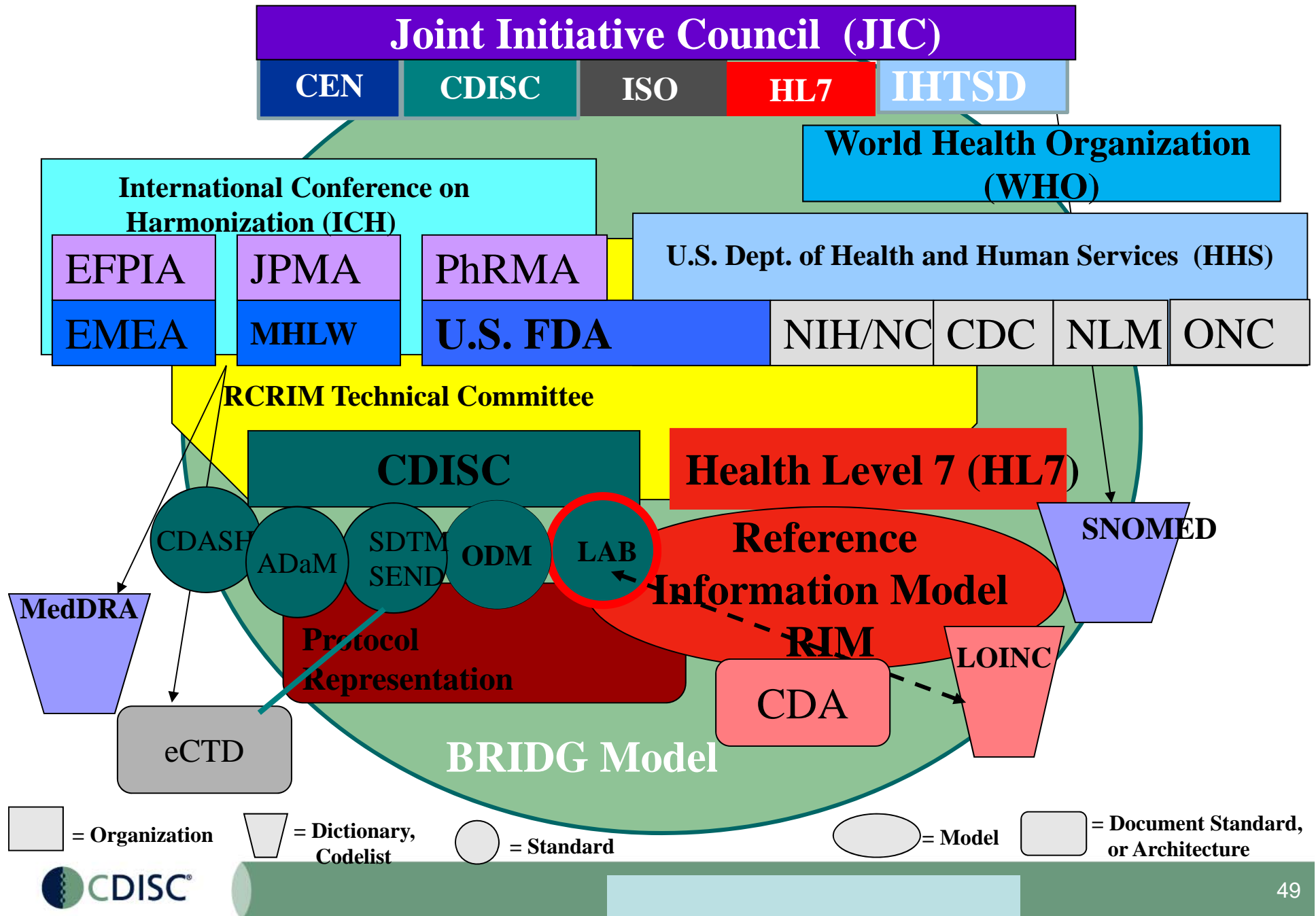
- SDTM remains a key view of the data
- The project brings greater flexibility while building on, and learning from, the success of SDTM
- There will be an impact, but CDISC are working to ensure a smooth transition

CSHARE

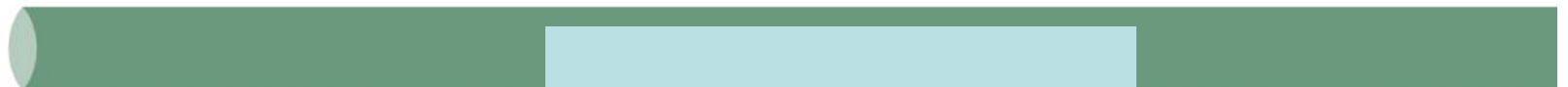
- **CDISC Shared Health And Research Electronic library**
- **Why?**
 - Growing complexity of CDISC standards
 - Need for better interoperability with the Healthcare World



CDISC in the "World of Standards" 2009



The Foundation Stone



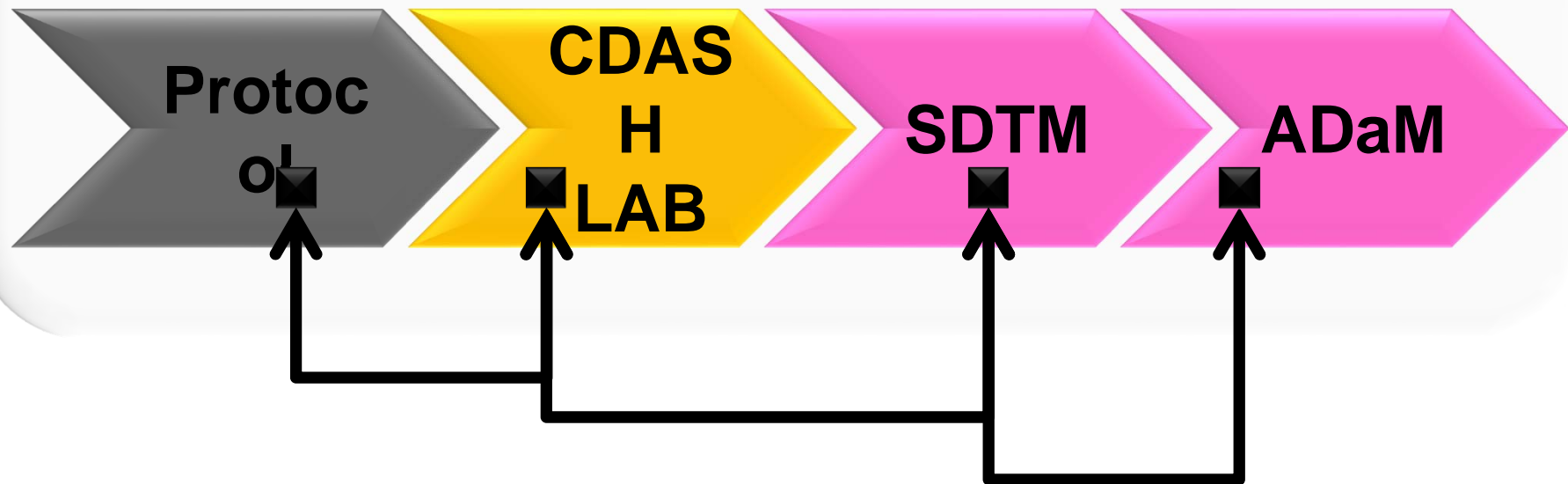
Aligned With and By BRIDG

Biomedical Research Integrated Domain Model (BRIDG)



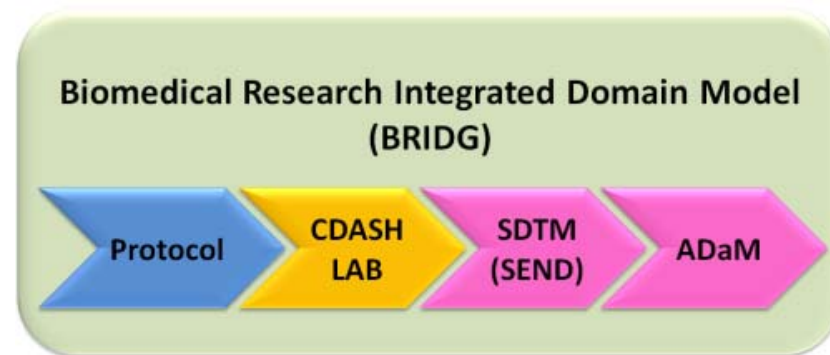
Same Concept, Same Meaning

Biomedical Research Integrated Domain Model (BRIDG)



During 2009

- CDASH User Guide
- Establishing ADaM
- Expanding Protocol
- SDTM 3.1.2
- Management of Metadata



Metadata Management

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



- **Link the HL7 CDISC project to the repository project**

Manage the Bricks

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg



- Consistent approach
- Improved access
- Facilitate data integration and aggregation
- Improved lifecycle management
- CDISC Shared Health And Clinical Research Electronic Library – **CDISC SHARE**

Consistent Approach

- Every definition to be consistently defined
 - No missing pieces
 - No assumptions
- Improves the quality of definition
 - Don't repeat mistakes of the past with “partial” definitions and implied context
- Brings consistency across **ALL** of our standards (and into healthcare)

Improved Access

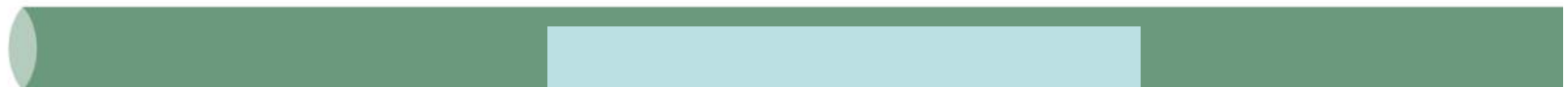
- Improve access to the standards for our users
- Machine-readable access will allow
 - Users to populate their own Metadata Repositories
 - Provide global access
 - Easier access
 - Always available

Data Integration & Aggregation

- We want to be able to (for datasets)
 - Combine
 - Compare
- Machine readable metadata allows for discovery by machines to determine if datasets can be combined/compared
- Provides a target for mapping legacy data if they cannot be combined/compared
- Provides “the” target for new data

Lifecycle Management

- Intended to improve
 - Speed of initial development
 - In particular new areas, e.g. efficacy
 - Speed of approval
 - Ease of update and maintenance
 - Governance



Why - Pharma

- It will support cost reduction in drug development (decreases cost for standards maintenance & data mapping) while improving data quality and re-use, critical for effective scientific decision making.
 - Company data dictionaries – up to 25.000 variables
 - Major problem with data re-use, outside their primary purpose

Why - CDISC

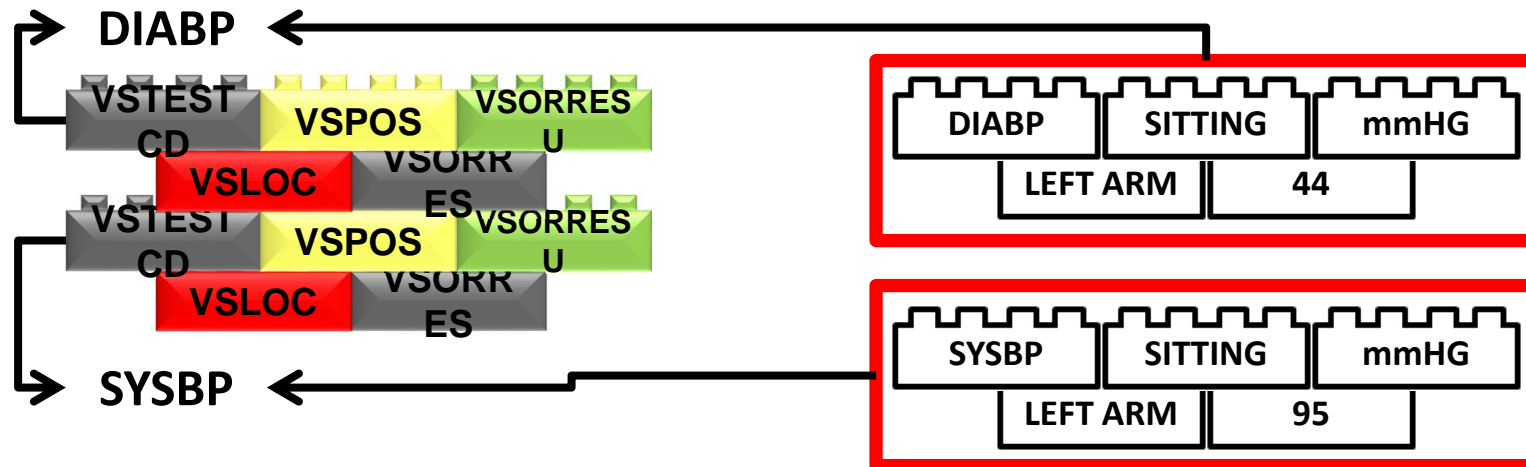
- Standards Development
 - Originally developed with little coordination across standards.
 - Implemented in subtly different ways
- Electronic Delivery
- Faster Development

Why - Regulator

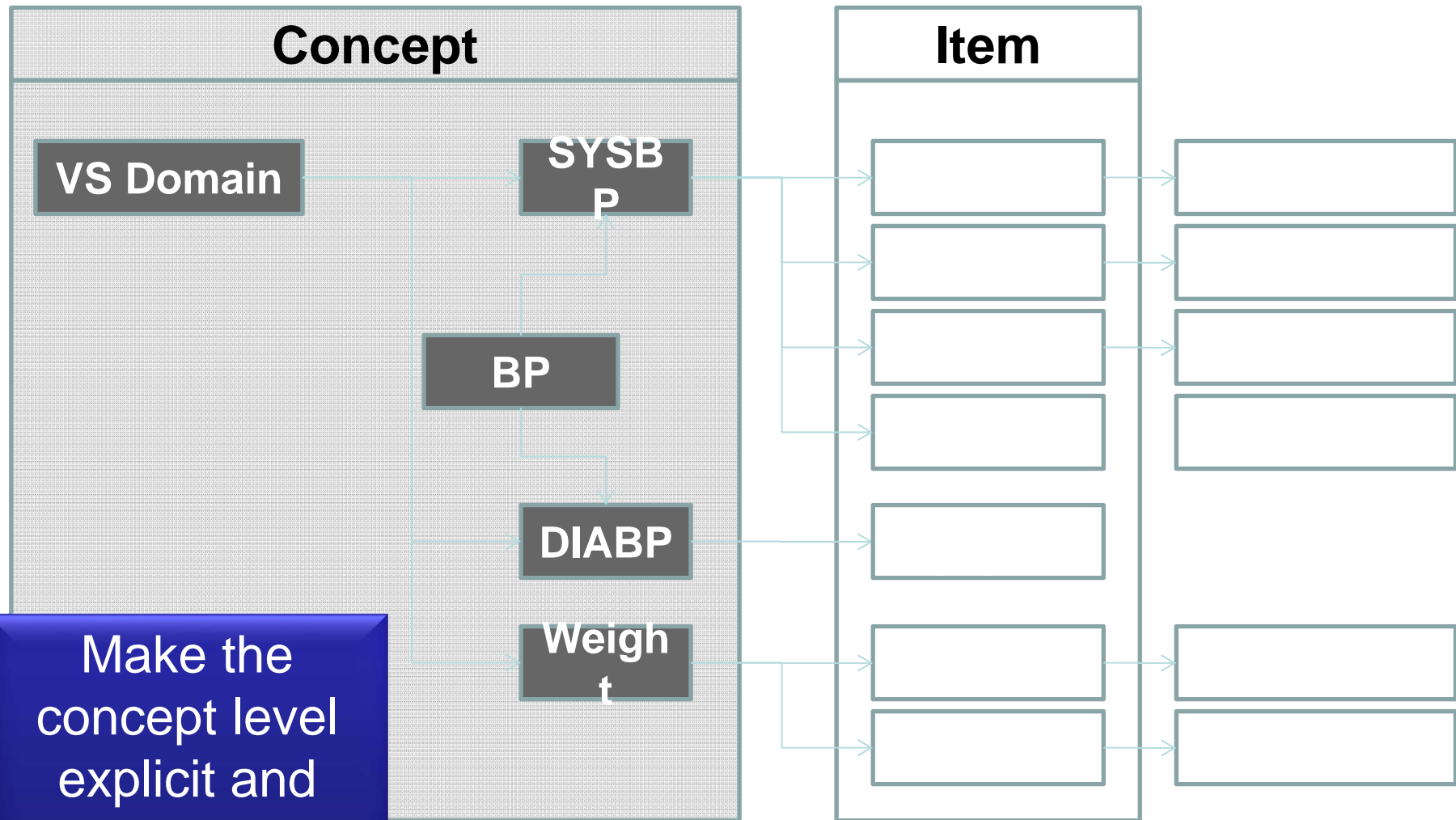
- It will enable new capabilities required by authorities – such as comparative profiles for safety and cost-efficacy on clinical research data – and will support EHR integration and re-use of clinical care data for medical research.

Make Explicit

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSLOC	VSORRES	VSORRESU
ABC-001-001	12	SYSBP	Systolic Blood Pressure	SITTING	LEFT ARM	95	mmHg
ABC-001-001	13	DIABP	Diastolic Blood Pressure	SITTING	LEFT ARM	44	mmHg

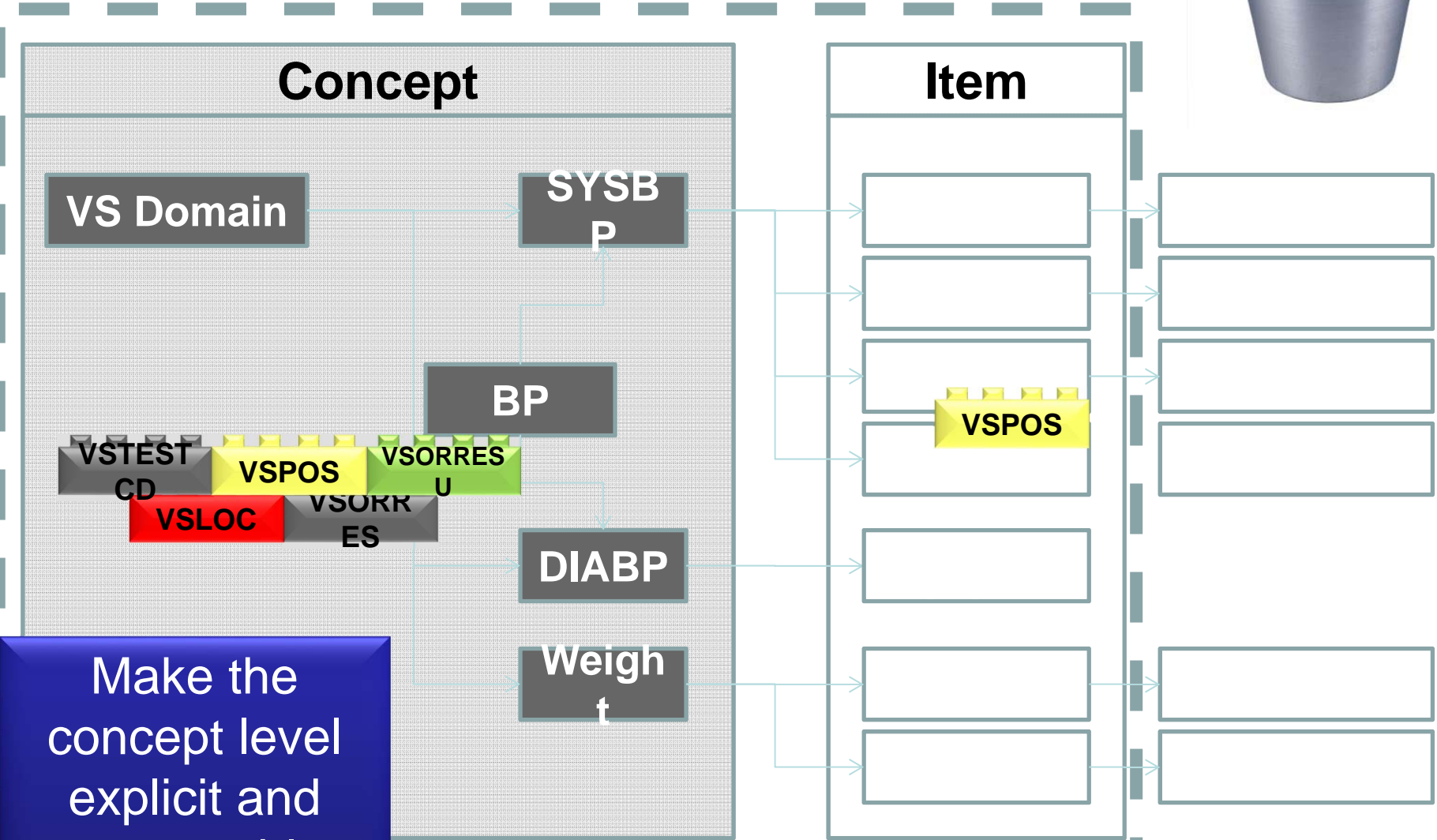


Simplistic View



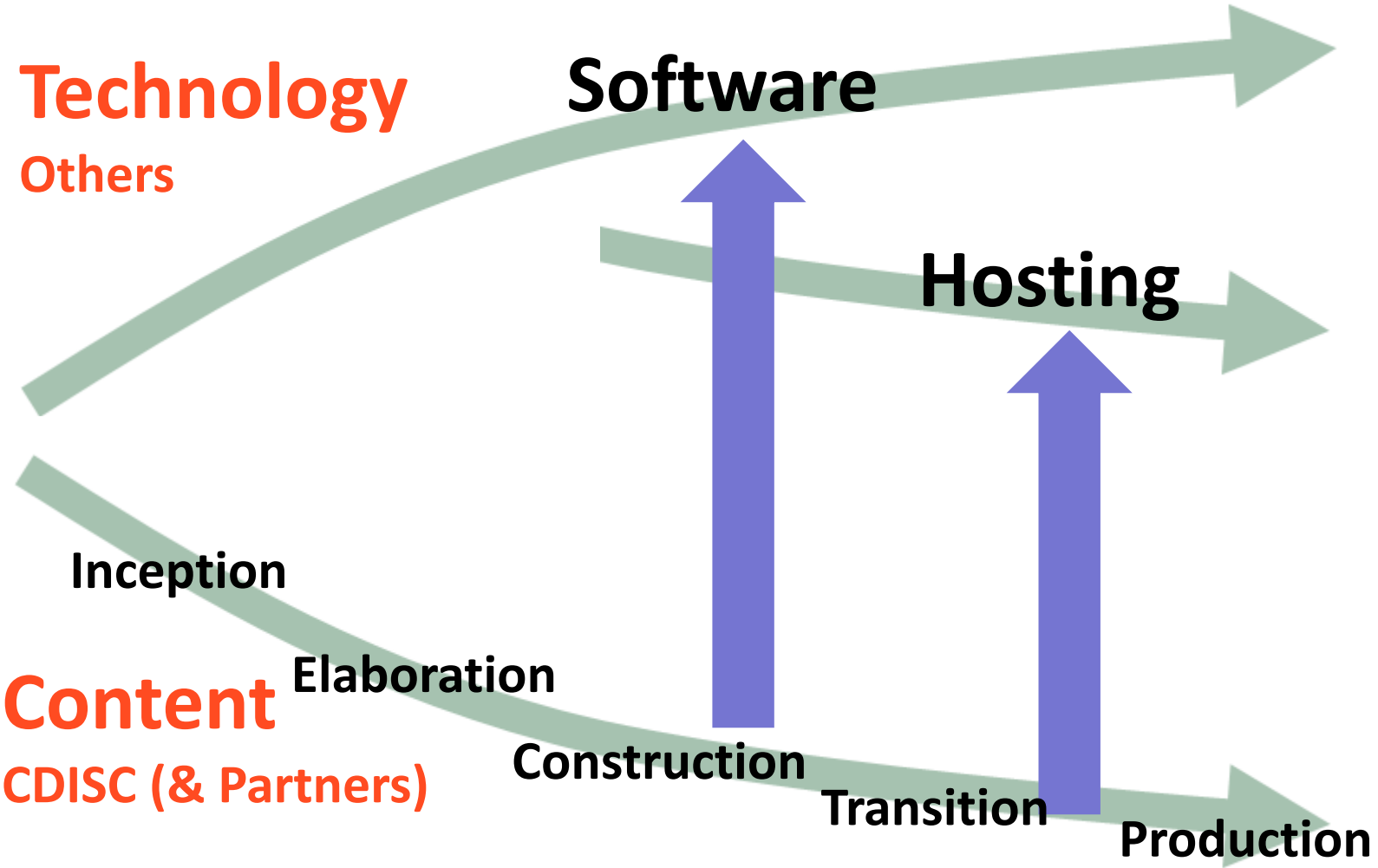
Make the concept level explicit and computable

Simplistic View

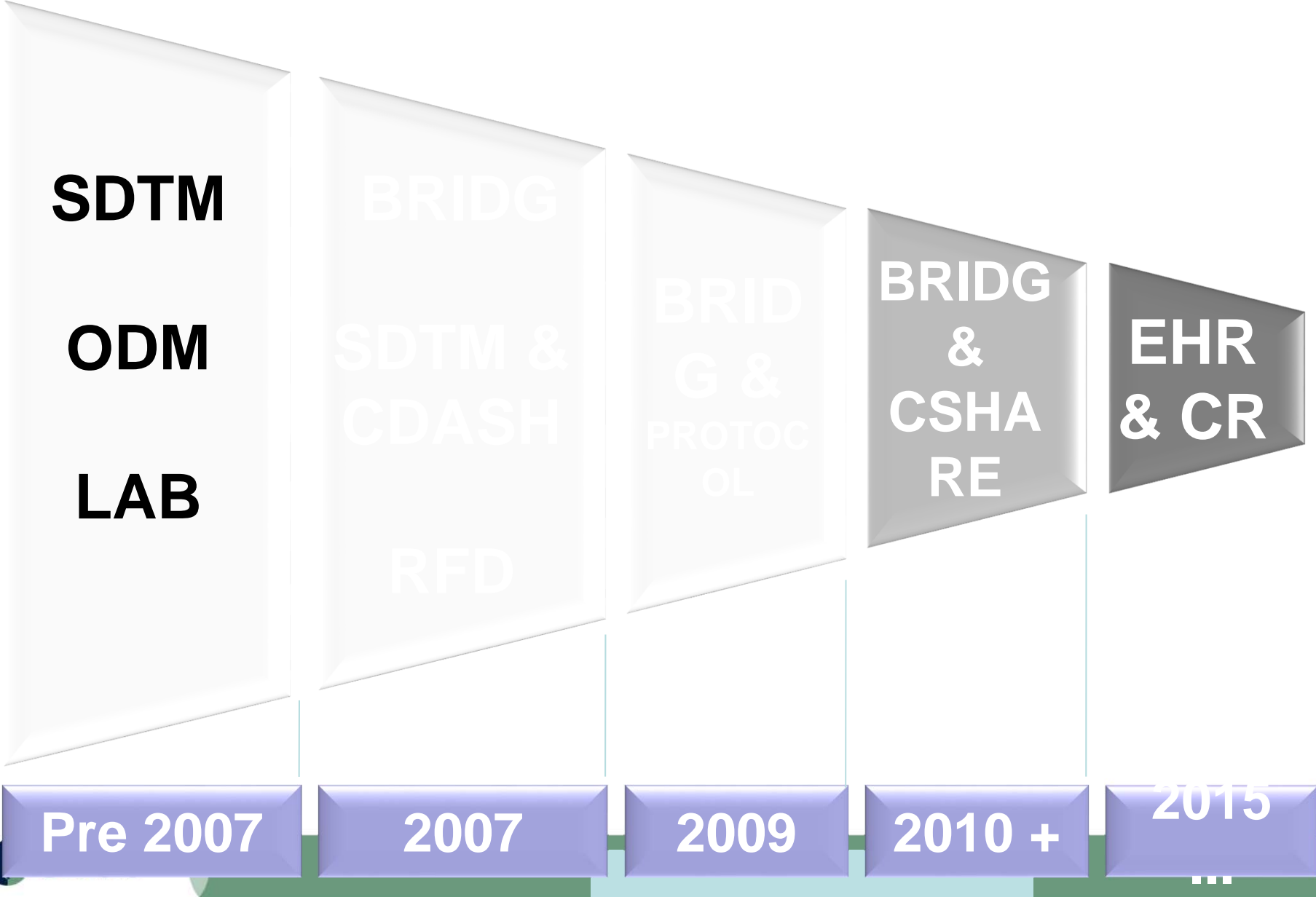


Make the concept level explicit and computable

CDISC Focus



Constant Improvement



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