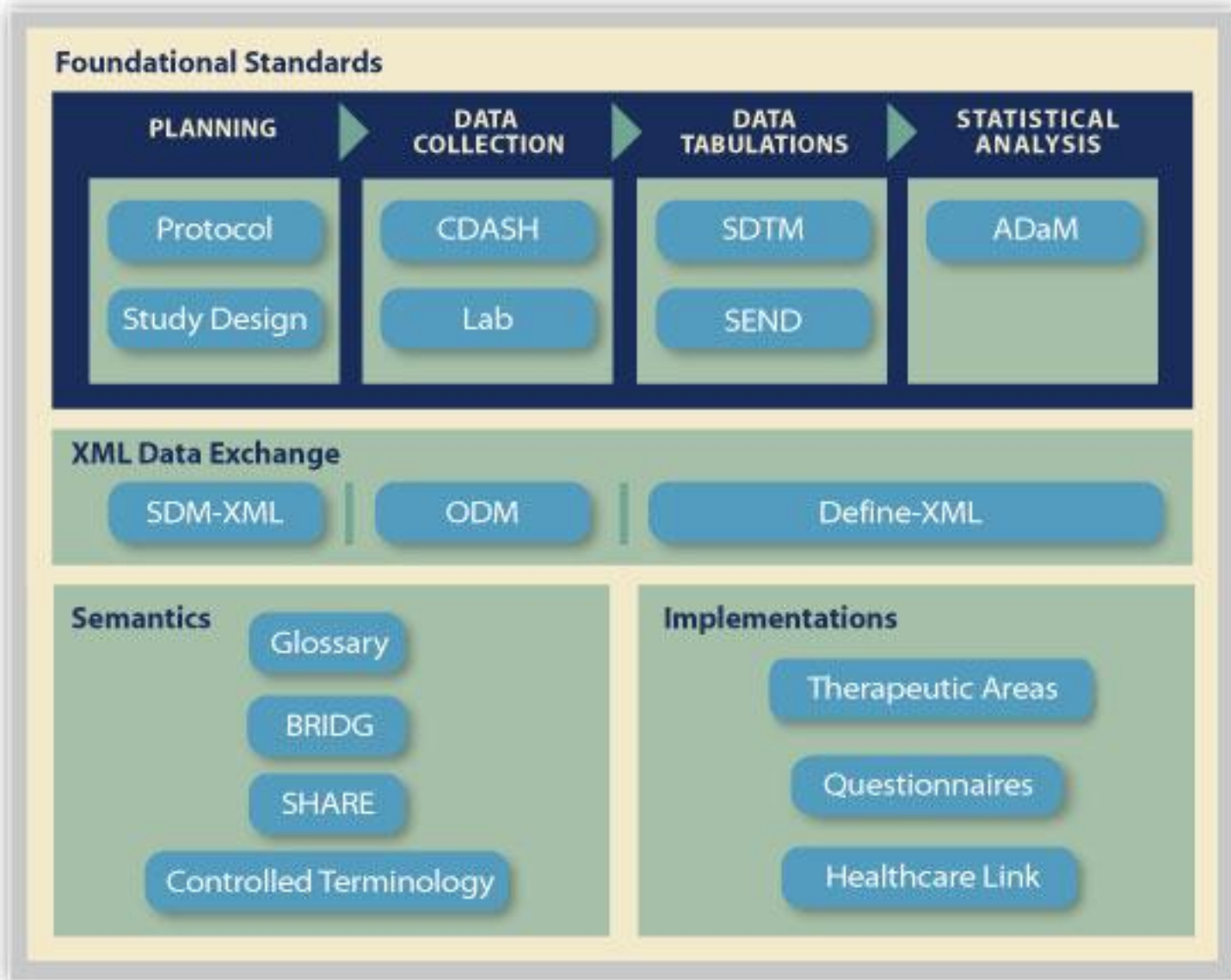# CDISC SHARE: A BRIDG-based Metadata Repository Environment

Wayne R. Kubick

CDISC

Strength *through Collaboration*

CDISC

The CDISC Standards Guide

BRIDG – Part of the SHARE Foundation

- **BRIDG Purpose:**
  A collaborative effort to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest.
  - The semantic foundation for HL7/CDISC-based application and message development

- **Domain-of-interest/scope:** Protocol-driven research
  - A Unified Modeling Language (UML) Model of the data (using ISO 21090 datatypes), organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.

- **Stakeholders:** CDISC NATIONAL CANCER INSTITUTE HL7 FDA

- **Governance Process:**
  Board of Directors prioritizes projects and committee consults with projects and harmonizes project models into main model with help of project analysts/SMEs

BRIDG Biomedical Research Integrated Domain Group

Domain-Friendly, Subdomain-Specific Business Models

SME View

Layer 1

- Adverse Event
- Study Conduct
- Common
- Protocol Representation
- Regulatory

Separate EA/XMI file for each subdomain

Transformer

BRIDG Domain Analysis Model (DAM)

Canonical View

Layer 2

Single Enterprise Comprehensive View
Contains subdomain level tags on classes and attributes to support subdomain-specific names for Layer 1 models

- Adverse Event
- Study Conduct
- Common
- Protocol Representation
- Regulatory

Single EA file with comprehensive and subdomain Views

BRIDG OWL-DL File (semantics)

OWL View

Manual Mapping

RIM-Based BRIDG Model

HL7 RIM View

Layer 3

Class and attribute level mappings to the Enterprise Comprehensive View will be captured in the Visio tool. The Visio tool generates mapping reports for documentation.
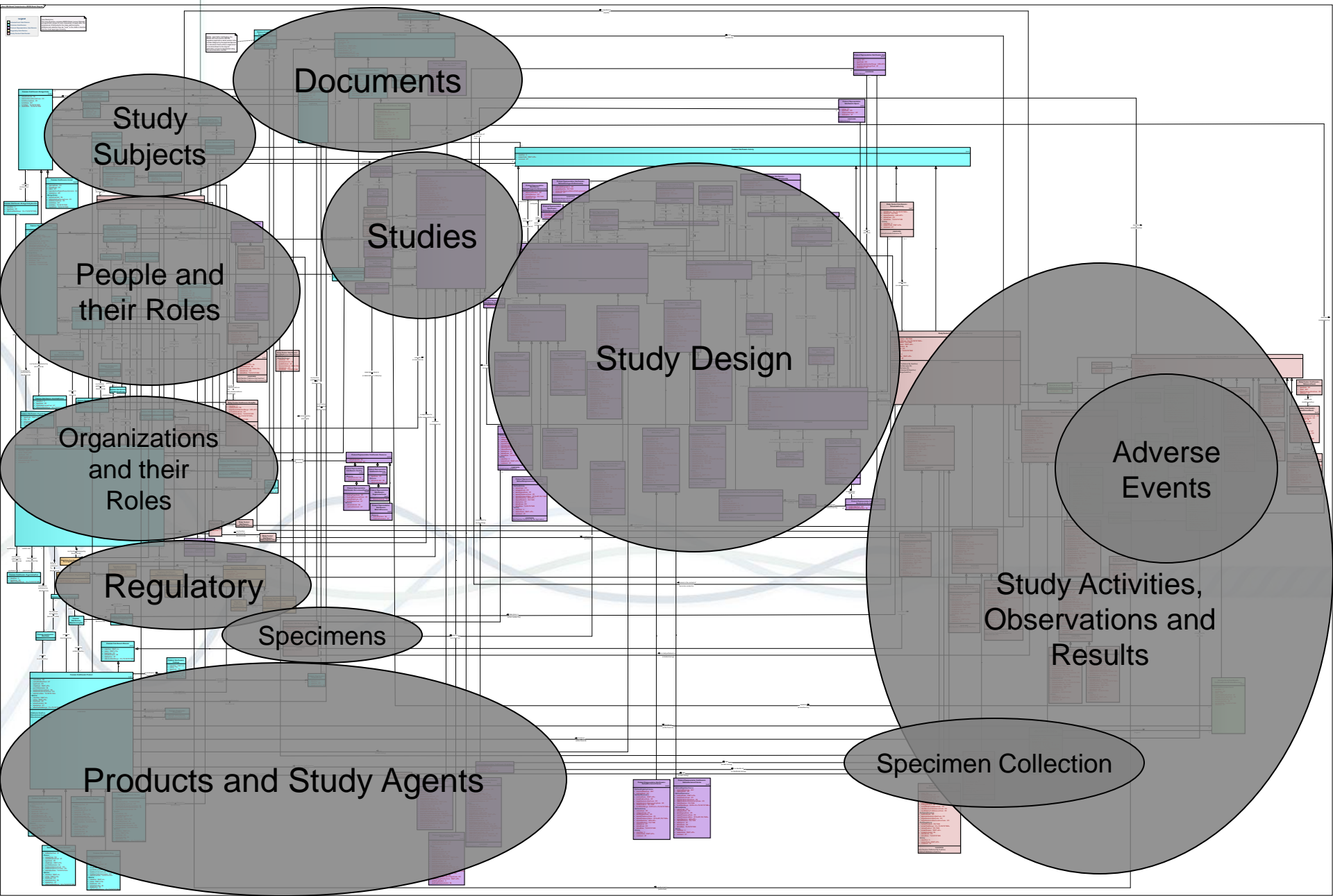
Equivalent to an HL7 DMIM (HL7 Visio)

BRIDG Model Content (Layer 2)

CDISC SHARE VISION

A global, accessible electronic metadata library, which through advanced technology, enables precise and standardized data element definitions **and richer metadata** that can be used in applications and studies to improve biomedical research and its link with healthcare.

http://www.cdisc.org/cdisc-share

CDISC SHARE
SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY
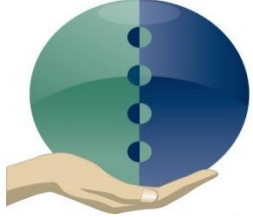
- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
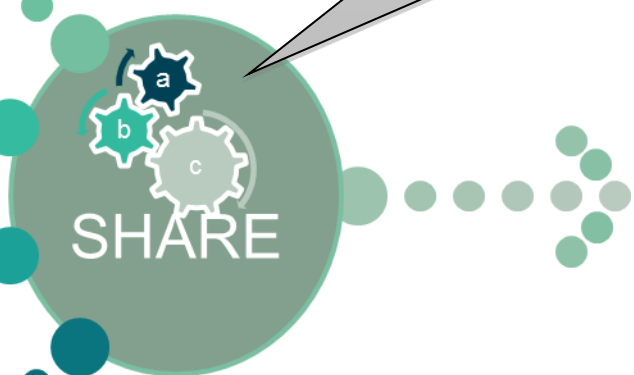- Aligned with NCI Semantic Systems

a. Change control

b. Gov'c work-flows

c. Impact Analysis & Inheritance
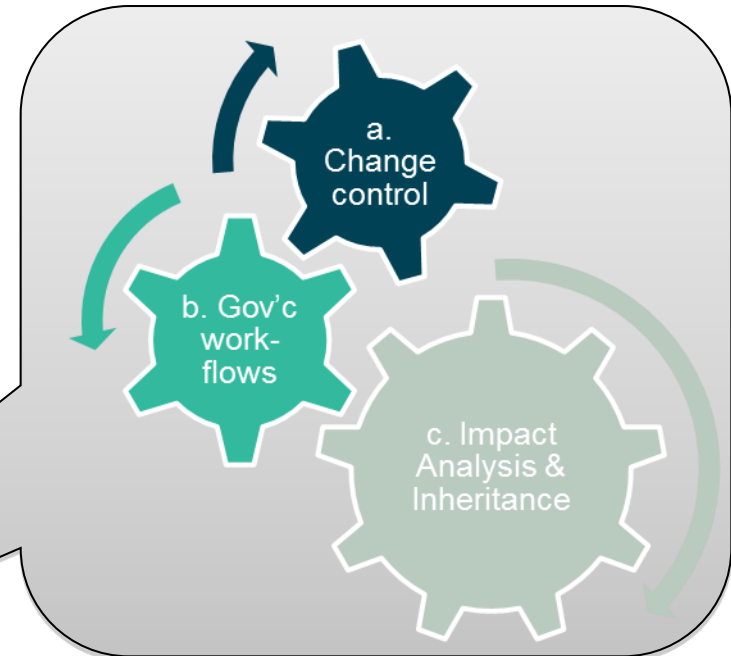
BRIDG, ISO21090

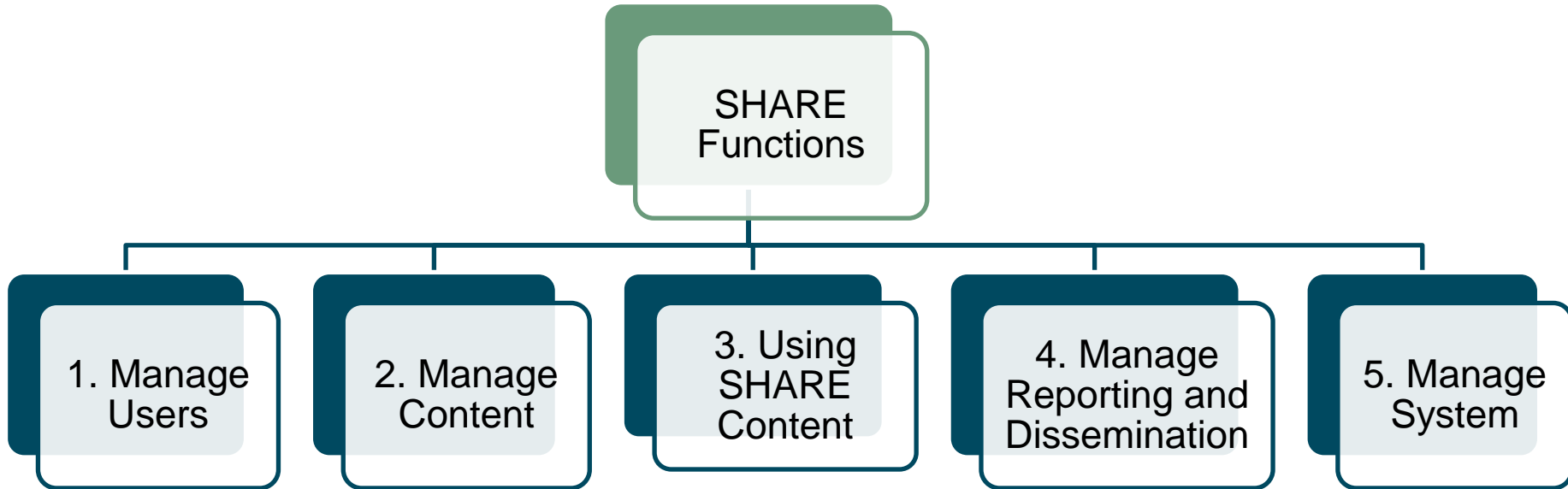Protocol, CDASH

SDTM, ADaM

Terminologies

SHARE

Facilitates Data Exchange

- Access to data standards
- Source to target mapping & traceability
- Transformation logic

bridg inside

Graphics adapted from Source by Sue Dubman, Sanofi-Aventis

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SHARE Top-Level Functions

```
                    SHARE
                    Functions
                       |
   ┌───────────┬───────────┼───────────┬───────────┐
```

1. Manage Users	2. Manage Content	3. Using SHARE Content	4. Manage Reporting and Dissemination	5. Manage System

- Manage User Roles
- Manage User Profiles
- Manage Password
- Manage User Dashboard

- Manage Work Items
- Manage Standard Objects
- Manage Audit Trail

- Search and Browse
- Import
- Export
- Print

- Send Notifications to users re object changes
- Manage listserv

- Manage SHARE MDR Framework Components
- Monitor User Activity
- Maintain Metrics
- Manage System Availability

CDISC SHARE Library Contents

- Metadata (including BRIDG, SDTM and CDASH)
  - Trial Design Metadata
  - Definitions
  - Datatypes (ISO 21090)
- Links to controlled terminology (CT) dictionaries via the NCIt (which links to CDISC CT, SNOMED, ICD9, ICD10, UMLS, etc.)
- Implementation instructions
- Links to analysis concepts.

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SHARE MDR Framework

Other External Resources (e.g. value Sets)
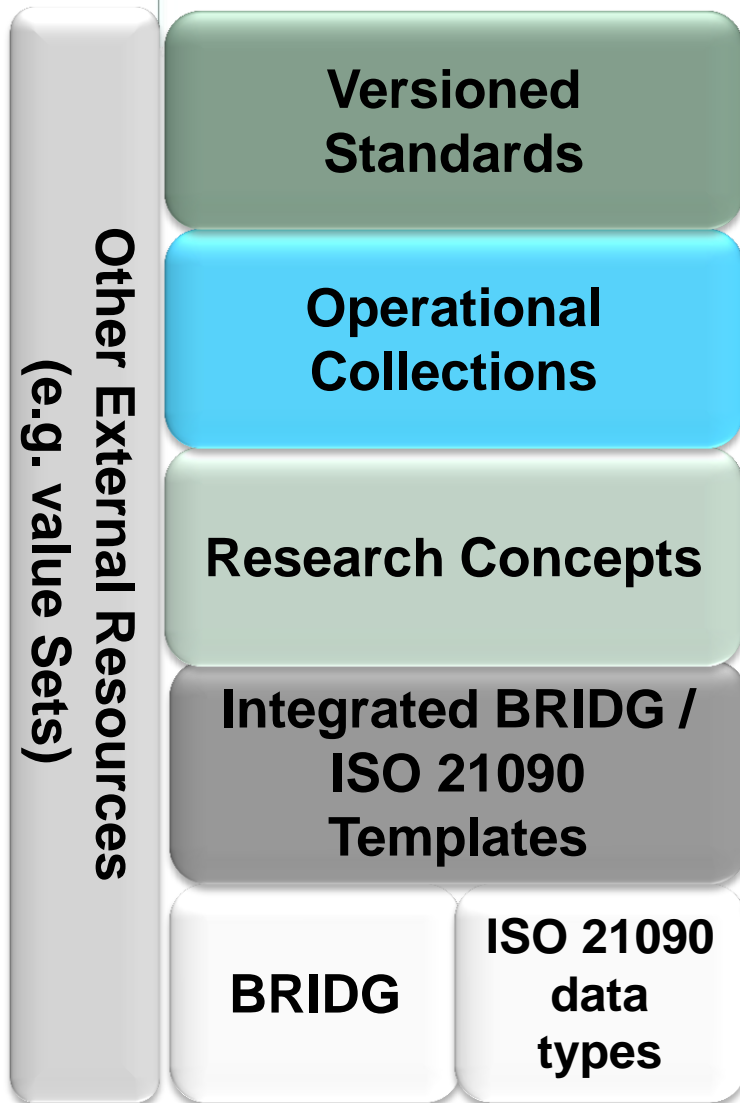
Versioned Standards	A Versioned Standard is comprised of a set of Operational Collections and associated variables and rules for a specific use case (e.g., SDTM, CDASH)
Operational Collections	An Operational Collection is a grouping of Research Concepts. There may be additional rules between objects within the Operational Collection. An Operational Collection may be analogous with a SDTM Domain, a CRF, an ADaM data set, or a similar level of operational structure.
Research Concepts	Basic elements that are the foundation for the content described in the SHARE repository. A Research Concept defines one or more related pieces of clinical data, which is developed using an Integrated BRIDG / ISO 21090 Template.
Integrated BRIDG / ISO 21090 Templates	Integrated BRIDG / ISO 21090 Templates use BRIDG classes and relationships to fashion small re-usable patterns that are commonly needed in clinical research
BRIDG / **ISO 21090 data types**	BRIDG is the foundation model for SHARE that provides classes, attributes and associations use to creates core building blocks.

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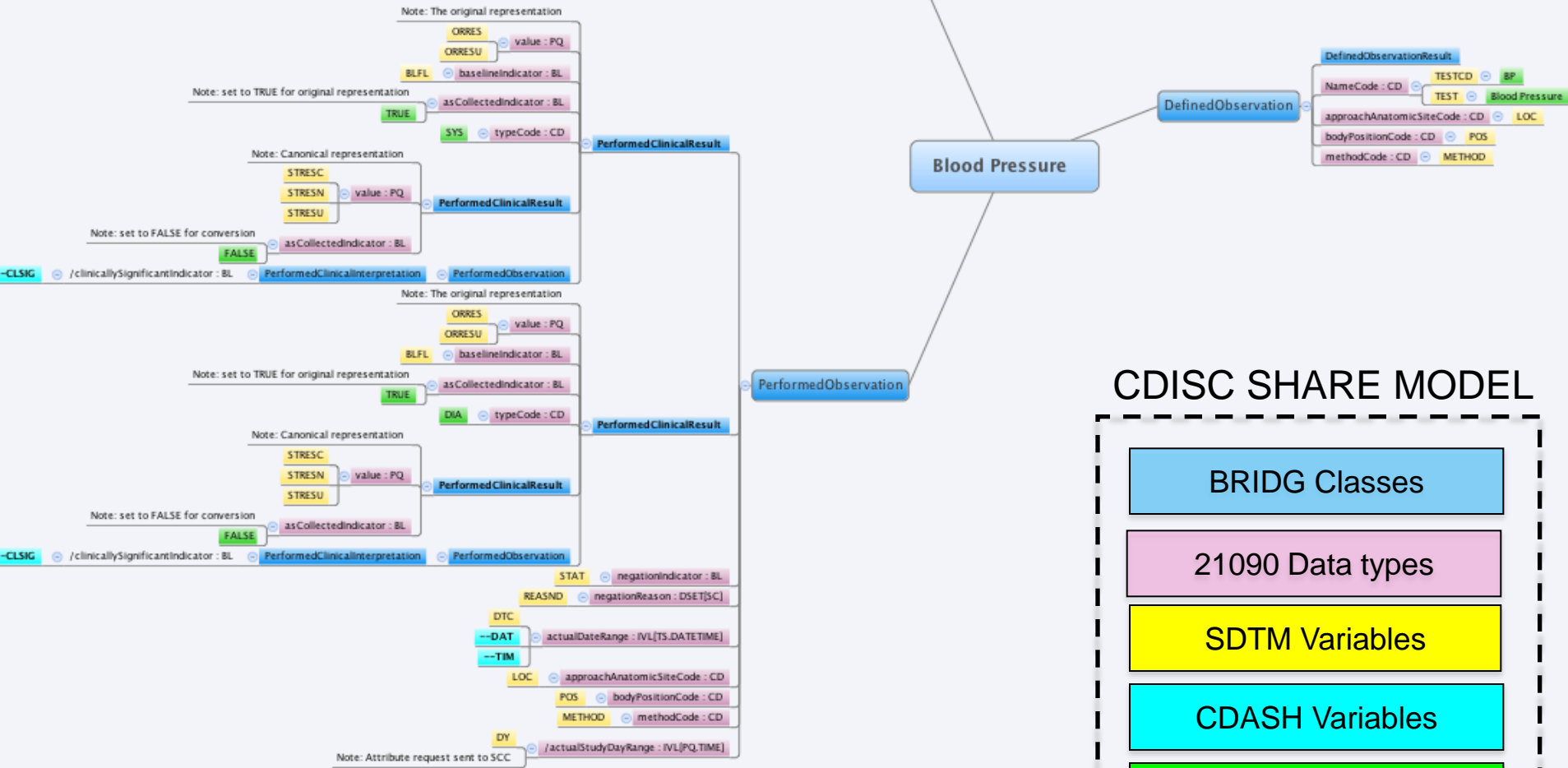
SHARE - Describes the Links between the Metadata
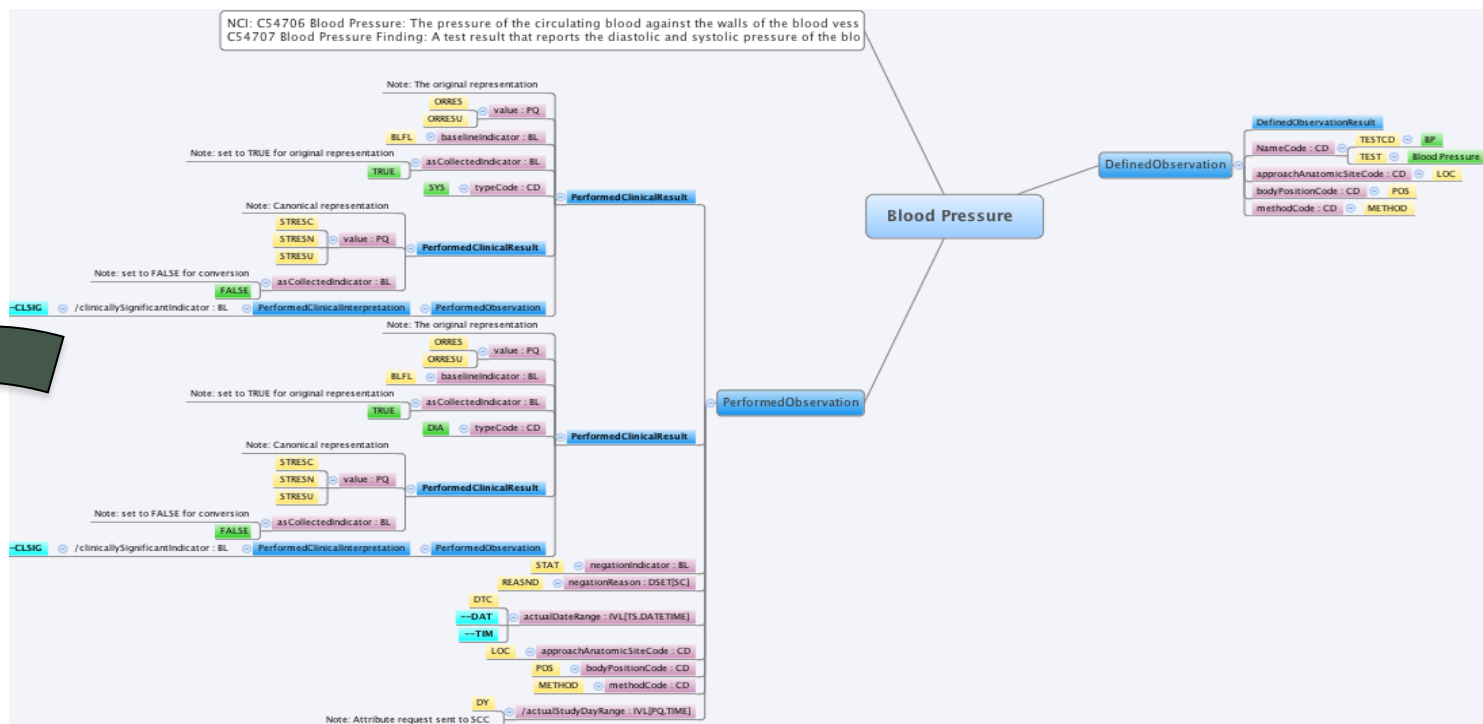

Relationship

Relationship

Relationship

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

Diagram – Dave Iberson-Hurst

The CDISC SHARE MODEL

CDISC SHARE MODEL

- BRIDG Classes
- 21090 Data types
- SDTM Variables
- CDASH Variables
- Controlled Terminology

Content Mapping

SHARE Concept-Based View

CONTROLLED TERMINOLOGY

DEFINITIONS

BRIDG

21090 DATA TYPES

SHARE FOUNDATION

SHARE CONCEPTS

(E.G. BLOOD PRESSURE)

VIEWS

Protocol/TDM

CRFs/CDASH

Analysis/ADaM

TFLs/SDTM

Define. XML

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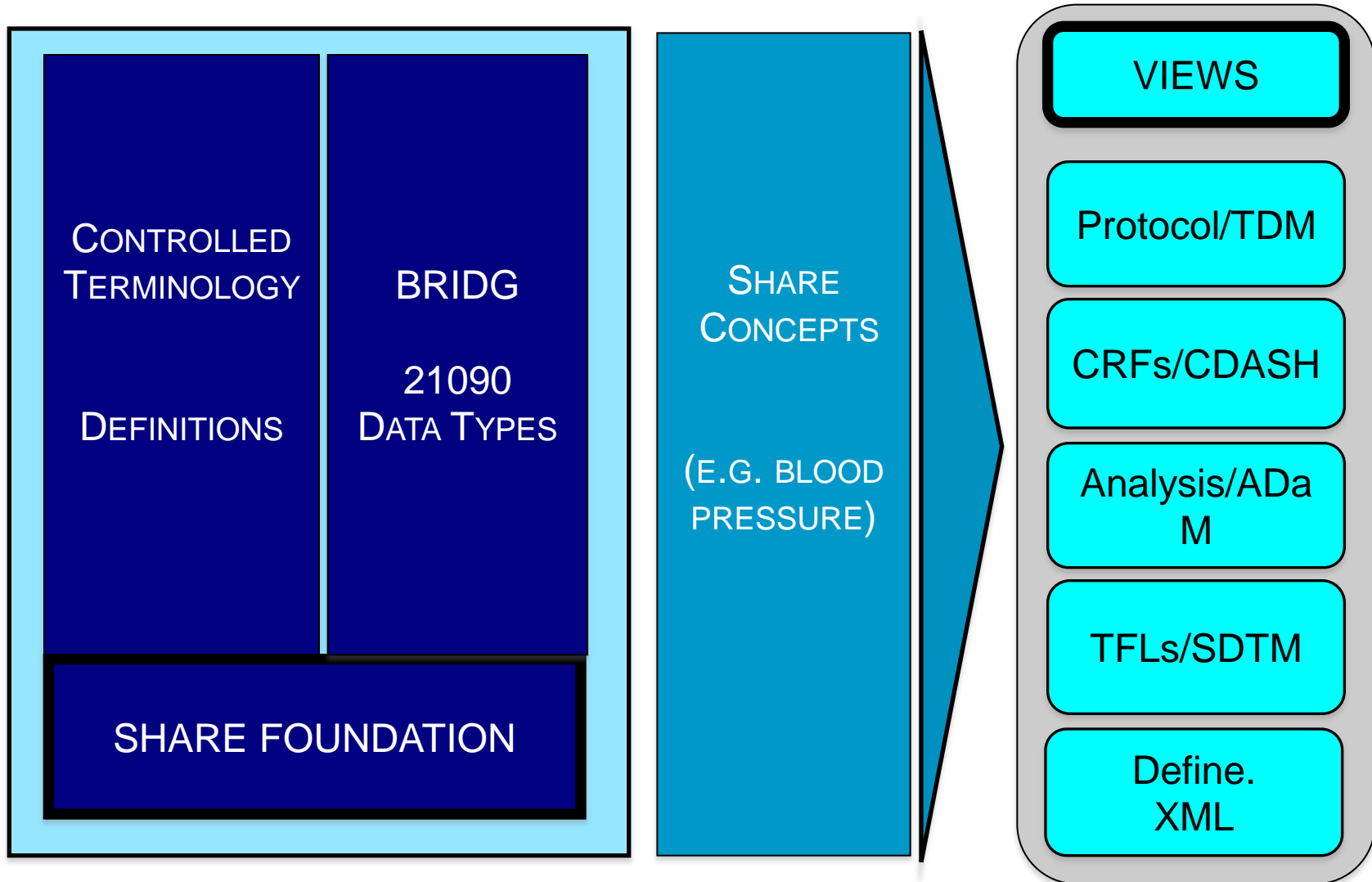
SHARE Status Update

- RFI issued in August – 24 responses; 10 short-listed
  - Software vendors, academics, system integrators
- Draft RFP due to be released in December - targeting a decision by Q1 2013
- Updated business requirements will soon be posted on CDISC website
- Currently exploring additional partnership and funding options.
- Goal is to have a release 1 prototype environment in initial use by end of 2013.

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