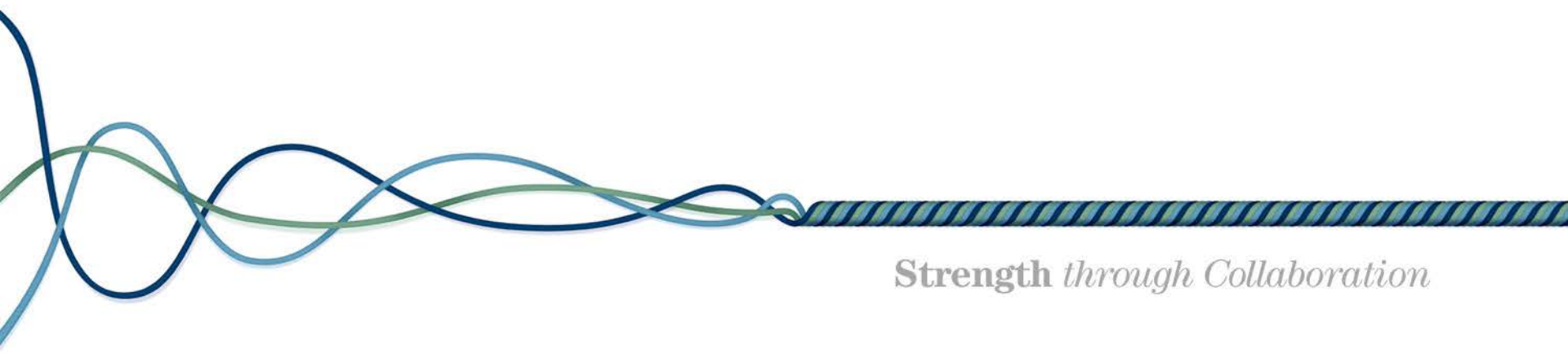
CDISC Public Webinar – Standards Updates and Additions

29 MAR 2017



Agenda

- BRIDG 5.0 Public Review
  - Michael Glickman, President, Computer Network Architects
  - Edward Helton, Associate Director of Clinical Trails Programs and Products, NIH, NCI/CBIIT
  - Wendy VerHoef, Senior Systems Analyst, Samvit Solutions
- CDISC Online Education & Event Updates
  - John Ezzell, Education Manager, CDISC

Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

1) What should be supported by ADaM datasets?
2) Is there a limit to the number of variables that can be in ADSL?

National Cancer Institute

BRIDG Model Status Update to CDISC

Wendy Ver Hoef, Julie Evans, Smita Hastak, Edward Helton

March 29, 2017

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

BRIDG 5.0 Timeline

- Dec. 09, 2016 - Model Freeze
  - No new semantics after 12/9
- Jan.01, 2016 – Complete Model QA/ Validation Scripts
- Jan 20, 2016 – Complete updates to all documentation
- Jan 20, 2016 – BRIDG 5.0 Internal release
- Jan 23, 2016 – Send to web master and all website changes
- Jan. 31, 2016 – BRIDG 5.0 Released
- Feb 01, 2016 – ISO ballot opens ?? (NWIP Status?)
- Feb 20, 2016 – HL7 NIB
- Mar 01, 2016 – CDISC Ballot opens
- April 01, 2016 – HL7 ballot opens
- May 01, 2016 – Joint ballot reconciliation begins

BRIDG 5.0 Scope

- **New Semantics**
  - Imaging
    - relevant parts of DICOM + NCI Annotated Imaging Markup (AIM)
  - Study Management
    - Vendor project
  - NCI Surveillance, Epidemiology, and End Results Program (SEER)

- **New Views**
  - Oncology (NCI + CDISC Oncology domains)
  - CDISC SDTM 3.1.3 (plus VS, RS, EX domains)

- **Controlled Vocabulary**
  - Compilation of Controlled Vocabulary for Imaging

National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

BRIDG Imaging

BRIDG Imaging Project Scope

- Harmonized with key concepts in DICOM to support interoperability between clinical research semantics and Imaging concepts in DICOM
  - NCI initiative to align BRIDG and DICOM in support of interoperability between clinical research data and imaging data
  - Under discussions with FDA to review the imaging concepts

- Harmonized key overlapping concepts from:
  - DICOM core modules (key concepts, series and image concepts summarized)
  - DICOM Supplement 121 (protocol specification, defined and performed, acquisition and reconstruction)
  - NCI AIM (annotations and measurements)
  - DICOM SR TID 1500 (structured reporting concepts)

Imaging Use Cases

1. Identification of entities – person, animal, specimen, image
   - DICOM has specimen identification
2. Image acquisition
3. Image Type (modalities) – could include WSI
4. Annotation & Structured Reporting
5. Anatomic Pathology (Selected fields and WSI)
6. Archiving (building a single archive for radiology, WSI and proteogenomic)
7. Support gene panels

Iteration 1

Iteration 2

Imaging Focus

- Focus of the DICOM to BRIDG mapping was to support the first 4 use cases of NCI (from previous slides)
  - Scoped to Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET)
  - Key concepts of Series and Image level of data were summarized

- Identify the touch points between BRIDG and DICOM to support an implementable interoperability scenario
  - Scoped to interfaces only

Summary of BRIDG–DICOM Harmonization

- Majority of the elements from identified DICOM Modules already existed in BRIDG

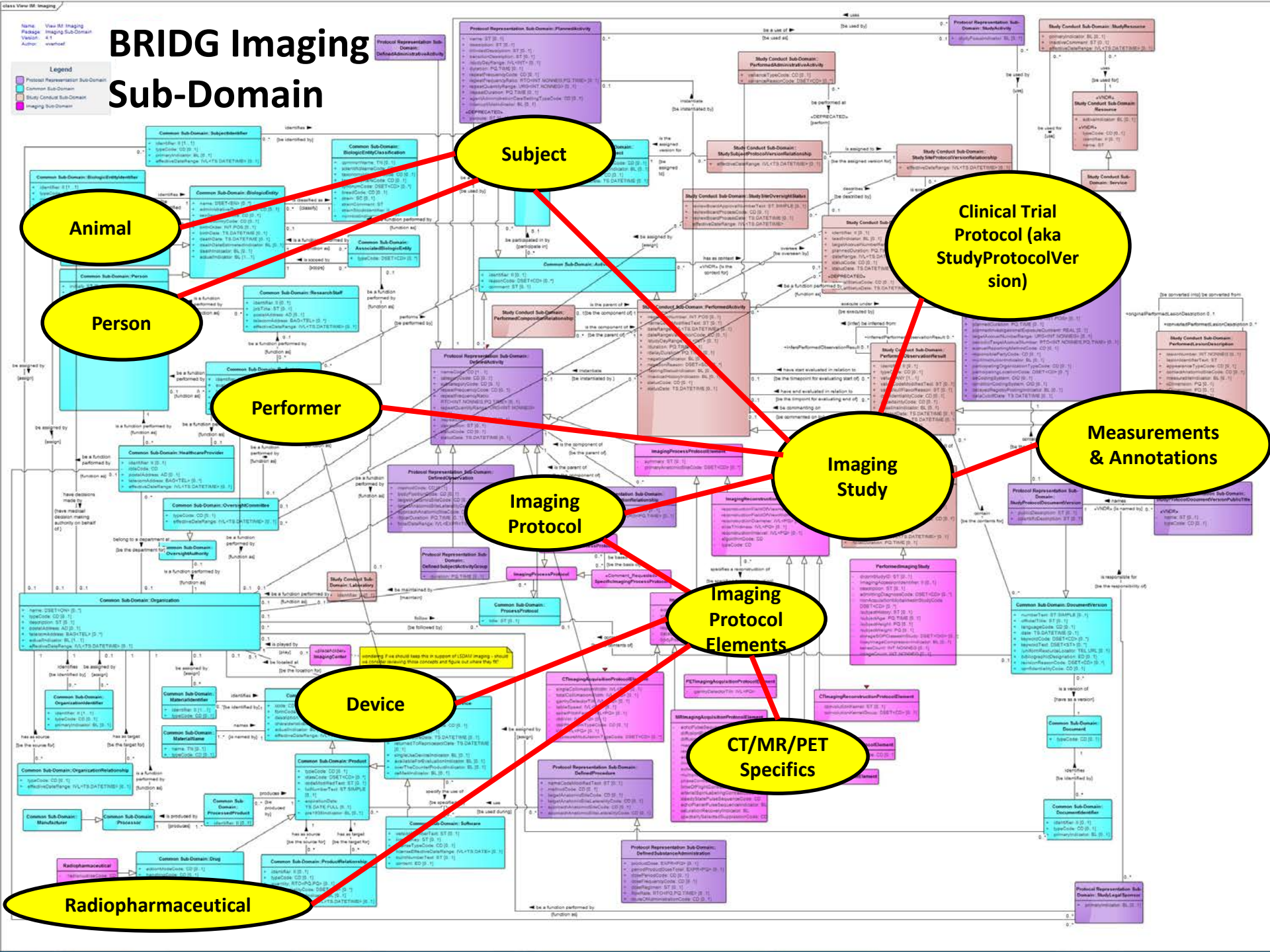
- A few new semantics (14 classes) were added to BRIDG as a result of harmonization that was focused on *modeling-by-reference*
  - i.e., harmonize on touch points and common semantics only

- Identified clinical trials related elements in DICOM that could point to BRIDG in the future
  - Two way modeling-by-reference

Principles used in DICOM Modeling-by-Reference

- If a standard exists, leverage and re-use the standard rather than represent it again in BRIDG. Align with existing overlapping BRIDG concepts

- In DICOM Harmonization, “modeling-by-reference” meant that not all DICOM semantics were added to BRIDG
  - Instead we reviewed what DICOM, FHIR, AIM and NBIA, etc. have & adopted portions that supported BRIDG use cases
  - Focused on key concepts and query/summary-level data, i.e.:
    - What data elements would you want to query on to find relevant clinical/imaging data and when found to build links to a DICOM-based system to access the detailed Imaging data
  - Omitted many concepts that are too detailed for a CTMS and best handled by DICOM-based systems, e.g. series & images


BRIDG Imaging Sub-Domain
Subject
Animal
Person
Performer
Clinical Trial Protocol (aka StudyProtocolVersion)
Imaging Study
Measurements & Annotations
Imaging Protocol
Imaging Protocol Elements
Device
CT/MR/PET Specifics
Radiopharmaceutical

BRIDG/DICOM Project Team Members

- Wendy Ver Hoef
- David Clunie
- Smita Hastak
- Ulli Wagner
- Ed Helton
- Boris Brodsky

National Cancer Institute

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Study Management

NCI Center for Biomedical Informatics and Information Technology

Harmonization Team

- Hugh Glover
- Julie James
- Jean Duteau
- Wendy Ver Hoef
- Julie Evans

Vendor Scope

- Business context for new semantics: Trial management and monitoring
  - harmonization scoped to tracking resources, countries, and subjects in a Study, etc.

- Vendor has implemented BRIDG so the semantics brought to harmonization are the ones that the vendor needed that were not part of the BRIDG model
  - Makes the BRIDG model richer to get implementable real use cases
  - On-going process. Additional semantics will be brought by the vendor for BRIDG harmonization in near future.

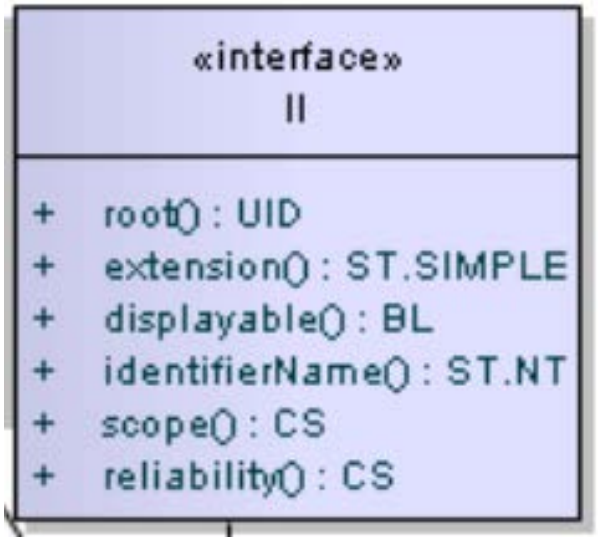
Key additions

- **Modification to the way Identifiers are represented in BRIDG model**
  - Prior to this change, BRIDG model represented Identifiers using the “II” HL7 R2 ADT datatype, which didn’t include all the semantics we needed. We used the vendor’s approach for identifiers, which is an extended datatype called ID, which contains all the semantics needed for identifiers, and allowed us to delete 11 identifier classes and move the identifiers to their “home” class.

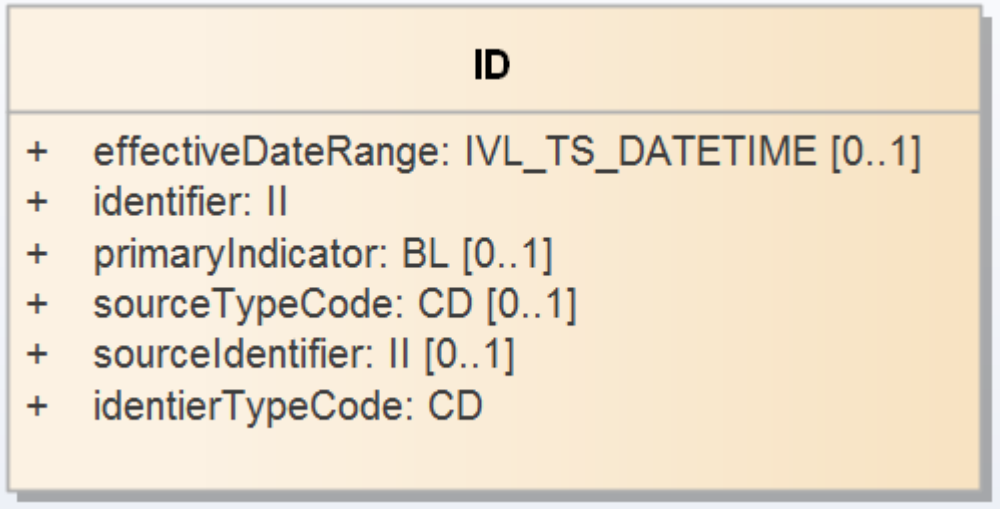
- **Addition of following New semantics (Vendor class names)**
  - ClinicalDevelopmentPlan
  - Activity – associations from StudyCountry, StudySite, Study
  - ProgressCount – new class and attributes
  - Resource – new attribute
  - StaffInterest – new class and attributes
  - StaffMember – new class and attributes
  - Study – new association to StudyProtocolVersion
  - StudyOverallStatus – 3 new attributes added – sitesActual, etc.
  - StudySitePersonnel – new association to StudyCountry

Identifier Data Types

OLD



NEW



Identifier Classes Deleted

- BiologicEntityGroupIdentifier
- BiologicEntityIdentifier
- DocumentIdentifier
- GeneIdentifier
- GeneticVariationIdentifier
- MaterialIdentifier
- MessengerRNAIdentifier
- OrganizationIdentifier
- PathwayIdentifier
- ProteinIdentifier
- SubjectIdentifier

National Cancer Institute

NCI Surveillance, Epidemiology, and End Results Reporting (SEER)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

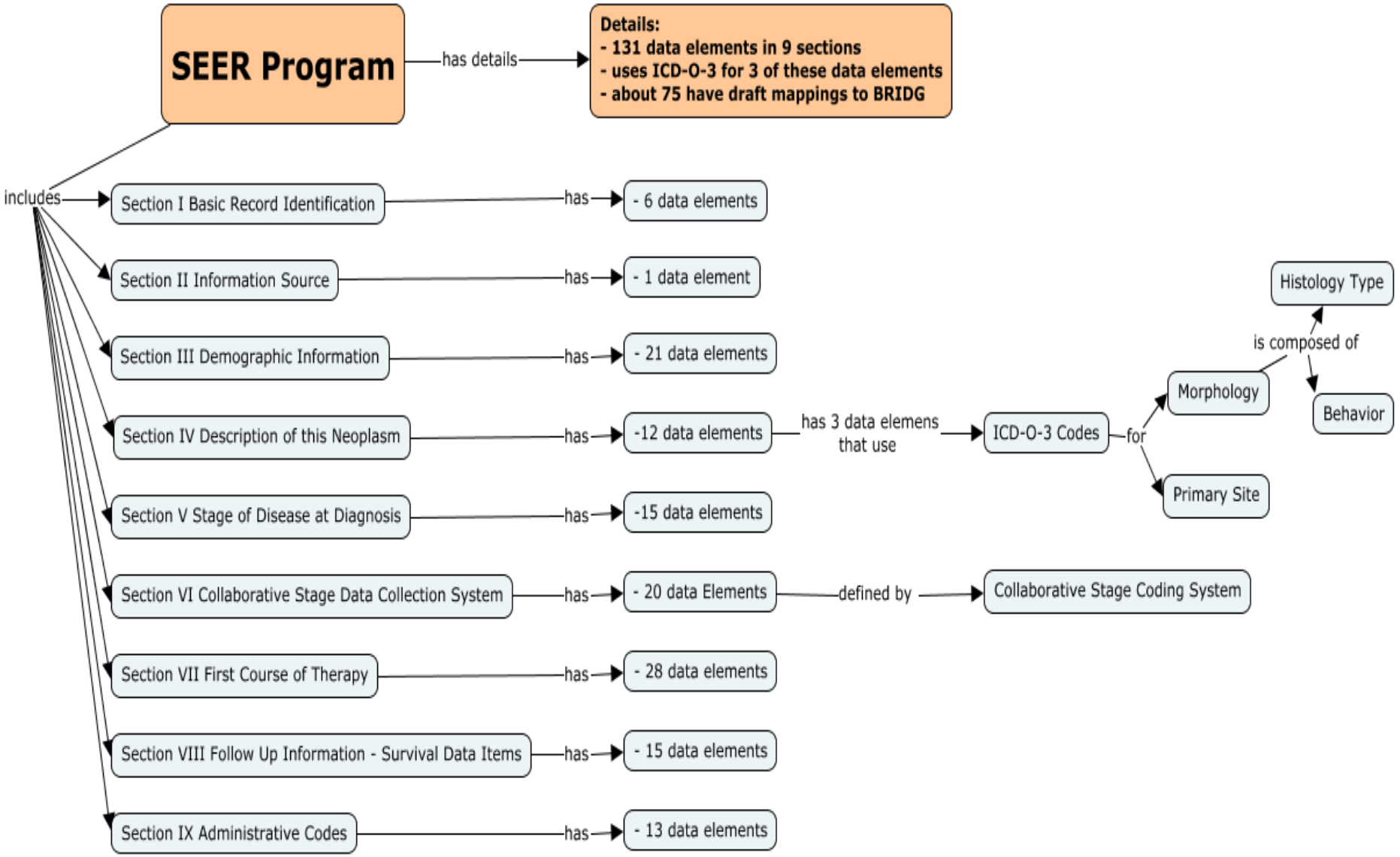
NCI SEER

- The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI) is an authoritative source of information on cancer incidence and survival in the United States.

- The SEER Program registries routinely collect data on patient demographics, primary tumor site, tumor morphology and stage at diagnosis, first course of treatment, and follow-up for vital status.

SEER Components

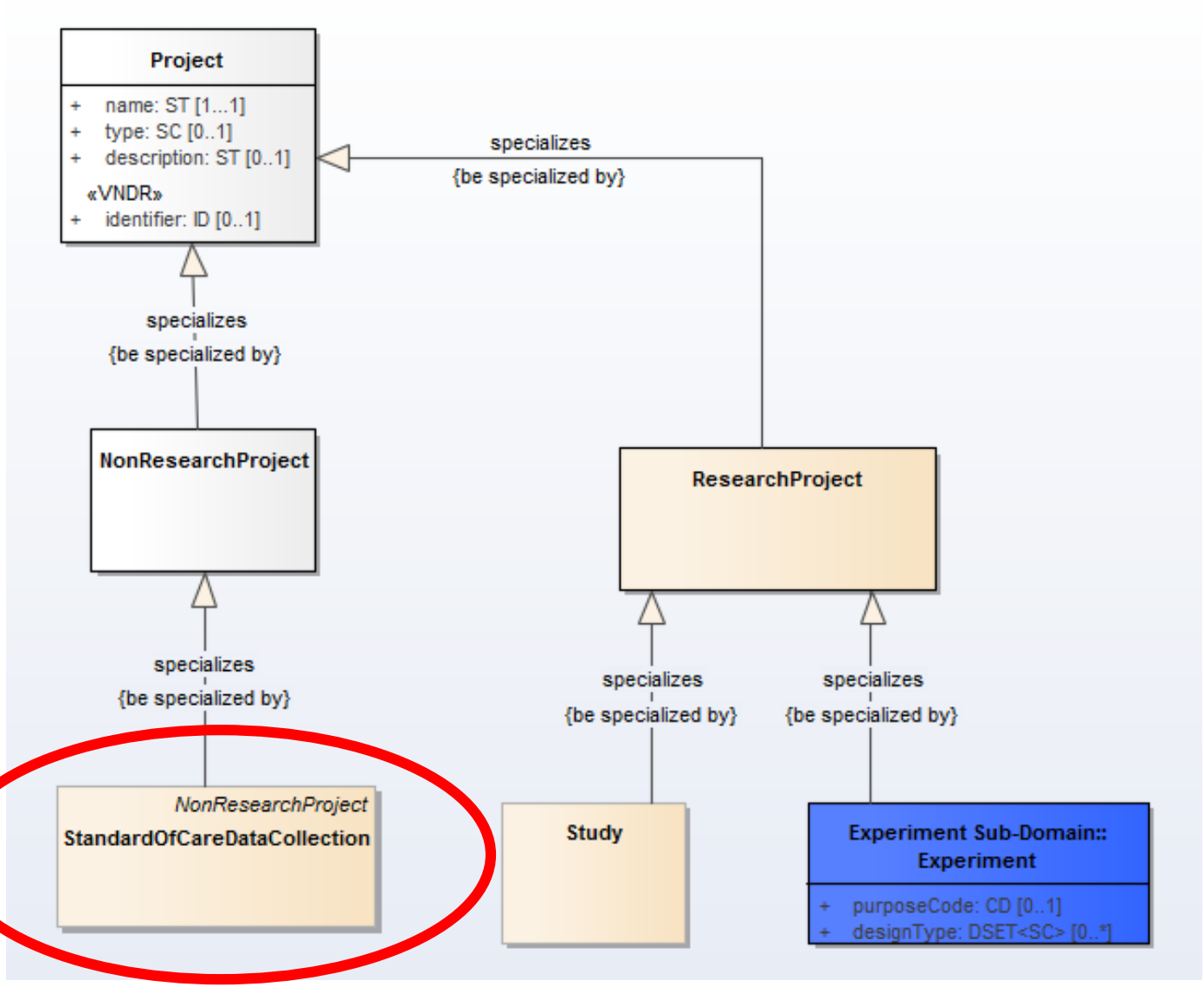
(Surveillance, Epidemiology, and End Results Program)



Summary of SEER Harmonization

- Key Aspects
  - Key point to make regarding SEER harmonization was the addition of the “Standard of Care” class in BRIDG which has now allowed BRIDG to support patient’s clinical data without being connected to a clinical trial
  - SEER has a defined and published a controlled vocabulary document
    - SEER Coding Manual - https://seer.cancer.gov/manuals/2016/SPCSM_2016_maindoc.pdf
    - Modeling team planning to compare these value sets to CDISC Oncology terminology, when available

New Core Class in BRIDG Backbone



National Cancer Institute

New Views in BRIDG 5.0

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Why BRIDG Views

- Addresses some of the concerns raised during previous HL7 ballot cycles
  - Makes BRIDG more accessible by presenting it in smaller sets
  - Makes BRIDG more consumable and usable
  - Less overwhelming
  - Easier to see the domain in smaller and controlled fashion
  - Started development of smaller views in release 4.1
    - Product, Organization, ..
  - Continuing on this plan and also looking at developing use case/activity based views in future

National Cancer Institute

BRIDG Controlled Vocabulary Analysis

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

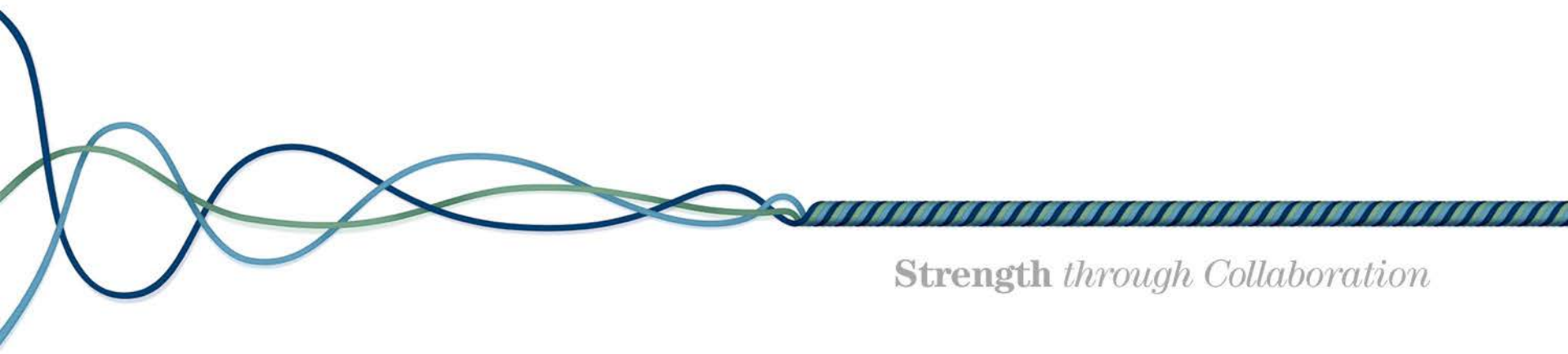
BRIDG Vocabulary Status

- BRIDG does not currently recommend value set binding for the coded attributes
  - This has been a long standing “to do “ for BRIDG model effort
  - Has been identified as something that needs to be done to truly support semantic interoperability at implementation level
  - Starting with BRIDG 5.0, the modeling team published a BRIDG vocabulary document that is a compilation of various value sets from different sources for given BRIDG coded attributes
    - In BRIDG 5.0, the value sets for DICOM and NCI AIM concepts of BRIDG will be published
  - Currently working on compiling the value sets for Oncology concepts from CDISC TA, NCI EVS, SEER, etc.

Q&A

CDISC Online Education & Event Updates

John Ezzell, CDISC



Upcoming Webinars

Topics	Presenters	Webinar Date
CDISC Members Only Mini-Training - Considerations in Submitting Data not Modeled in the SDTMIG	Fred Wood, Accenture Jerry Salyers, Accenture	06 APR 2017, 11:00 AM EST
CDISC Members Only Mini-Training - Demystifying Biomarkers	Jonathan Neville, Critical Path Institute Bess LeRoy, CDISC	11 MAY 2017, 11:00 AM EST

Webinar details and registration at www.cdisc.org/webinars

Standard currently out for review

- Vaccines TA User Guide v1
  - Comments Due by: 21 Apr 2017
- BRIDG v5.0
  - Comments Due by: 1 May 2017
- Define XML v2.1
  - Comments Due by: 5 May 2017

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Audubon, PA	3-7 Apr 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, CT, Define-XML	3 Jan 2017	3 Mar 2017	
South San Francisco, CA	15-19 May 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, Controlled Terminology	13 Feb 2017	15 Apr 2017	
Toronto, ON	5-9 Jun 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	6 Mar 2017	5 May 2017	

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
London, UK	24-28 Apr 2017	See web.	24 Feb 2017	24 Mar 2017	CDISC
Frankfurt, Germany	19-23 Jun 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	20 Mar 2017	20 May 2017	CLINIPACE WORLDWIDE
Leiden, Netherlands	11-15 Sep 2017	SDTM, CDASH, Define-XML, ADaM Primer, ADaM T&A	12 Jun 2017	13 Aug 2017	OCS Consulting
Copenhagen, Denmark	2-10 Nov 2017	SEND, SDTM, ADaM Primer, ADaM T&A, Define-XML	2 Aug 2017	3 Oct 2017	SCUBED

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Tokyo, Japan	5-9 Jun 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, ODM	TBD	TBD	Croit

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

Any more questions?

Thank you for attending this webinar.

CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research

CDISC Members Drive Global Standards

Thank you for your support!

Learn CDISC from CDISC!

Authoritative. Global. Vendor neutral.