National Cancer Institute

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

BRIDG 101

Smita Hastak and Wendy Ver Hoef
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Agenda

- BRIDG Overview
- Navigating the BRIDG Model
- Walking the Model
- Avenues of Learning
- BRIDG Implementation

BRIDG Overview

BRIDG Overview

- The **B**iomedical **R**esearch **I**ntegrated **D**omain **G**roup (BRIDG) Model is a collaborative effort to represent the semantics of clinical and translational research

- The stakeholders of BRIDG are – CDISC, FDA, HL7, ISO and NCI

- The objective of the BRIDG effort is to have a shared understanding of the concepts/semantics in this space and to represent it in a domain or information model.

- This common domain model (represented as a UML class diagram) can be leveraged to develop software solutions, such as database designs, APIs, data exchange formats, etc. The common semantics across the various solutions can provide the framework to enable semantic interoperability.

- BRIDG is an ISO Standard – ISO 14199

BRIDG Overview (continued)

- BRIDG Project started approximately 15 years ago by CDISC and NCI joined shortly after
- Started with clinical trials focus
- Inclusion of some high level life sciences concepts expanded the scope to translational research about 5 years ago
- Expansion to Imaging about 3 years ago
- Balloted periodically by 3 different standards development organizations (SDOs: HL7, CDISC, ISO)

BRIDG Content

- BRIDG is a metadata model that includes concepts from a variety of sub-domains of clinical and translational research
- Built from data sharing use cases by a process of harmonizing concepts with the BRIDG model and updating and adding model elements as necessary
- Includes vetted definitions and relevant metadata
- BRIDG 5.3.1* contains 326 classes, 927 attributes, and 612 associations

* BRIDG 5.3.1 is the latest official version at the time this slide deck was developed.

Topic/Areas covered in BRIDG

- Protocol Representation *(Trial Design, Study objectives, Amendments, etc.)*
- Study Subjects & Associated Persons *(Identifiers, Demographics, Relationships, etc.)*
- Research Organizations and Staff *(Sponsors, Healthcare Providers, Labs, PIs, Site PIs, etc.)*
- Products *(Drugs, Biologics, Devices, etc.)*
- Experiment *(Bench Research)*
- Study Conduct/Execution *(Study Sites, Study Resources, Oversight Authorities, Recruitment Status, etc.)*
- Findings (Observations, Diagnoses, Assessments, etc.)
- Interventions *(Substance Administration, Procedures, etc.)*

Topic/Areas covered in BRIDG (continued)

- Administrative Events *(CT Registration, Informed Consent, etc.)*
- Biospecimen *(Specimen, Specimen Collection Protocol, Specimen Processing, Specimen Storage, etc.)*
- Molecular Biology *(high level concepts of Gene, Protein, Biomarker, Genetic Variation, etc.)*
- Imaging *(Imaging Study, Measurements & Annotations, Devices, CT/MR/PET specifics, etc.)*
- Oncology *(Tumor identification, Lesion Evaluation, Disease Response, etc.)*
- Adverse Event *(AE, Causal Assessment, AE Outcome Result, AE Seriousness, etc.)*
- CDISC SDTM *(covers all domains/variables of SDTM 3.2)*

Navigating the BRIDG Model

Navigating BRIDG UML Model – 4 Mechanisms

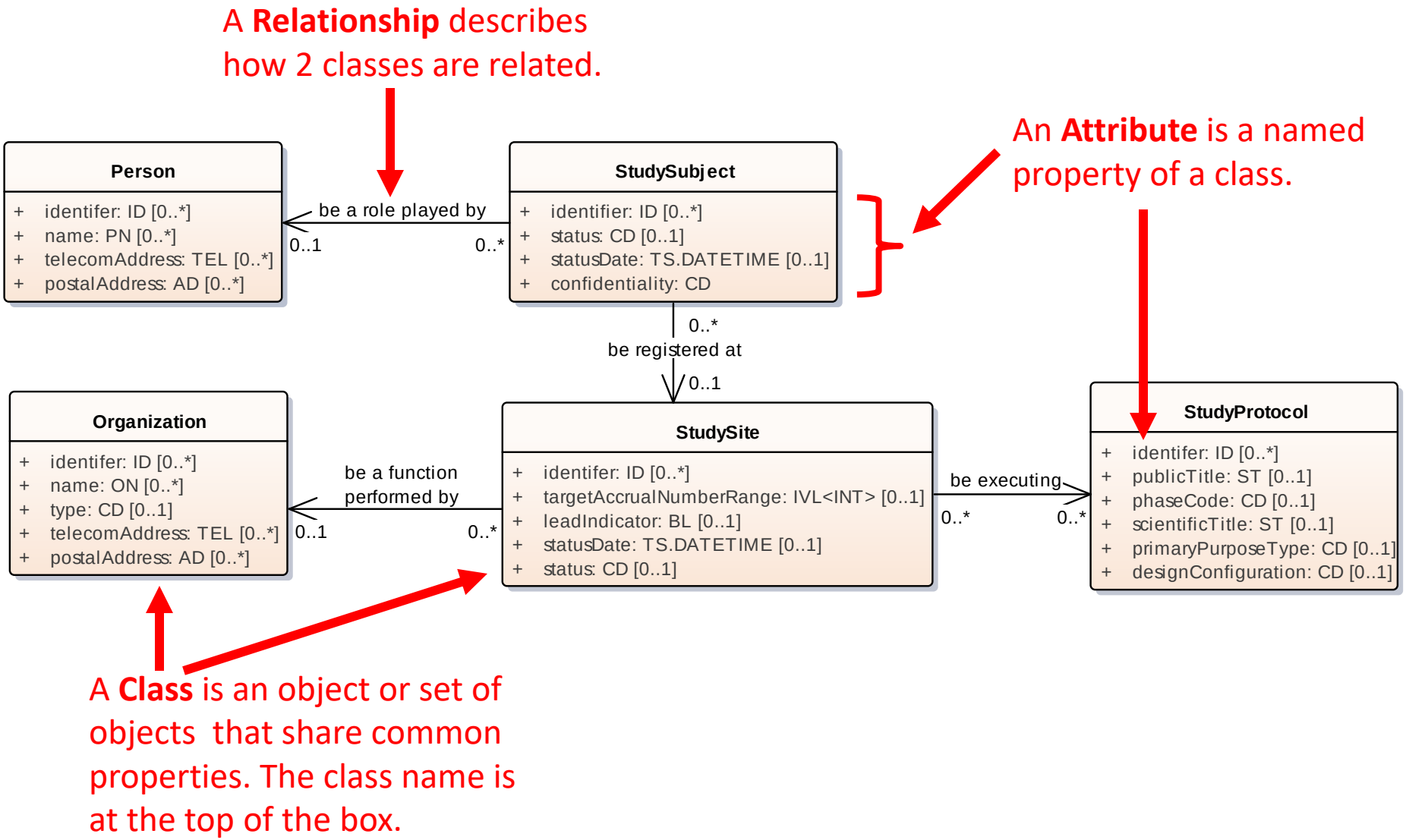
1. Maintained in Sparx Systems' Enterprise Architect (EA)

2. Free, read-only edition, Enterprise Architect Lite
   - http://www.sparxsystems.com/products/ea/downloads.html

3. HTML version of BRIDG model available on BRIDG Website home page
   - https://bridgmodel.nci.nih.gov

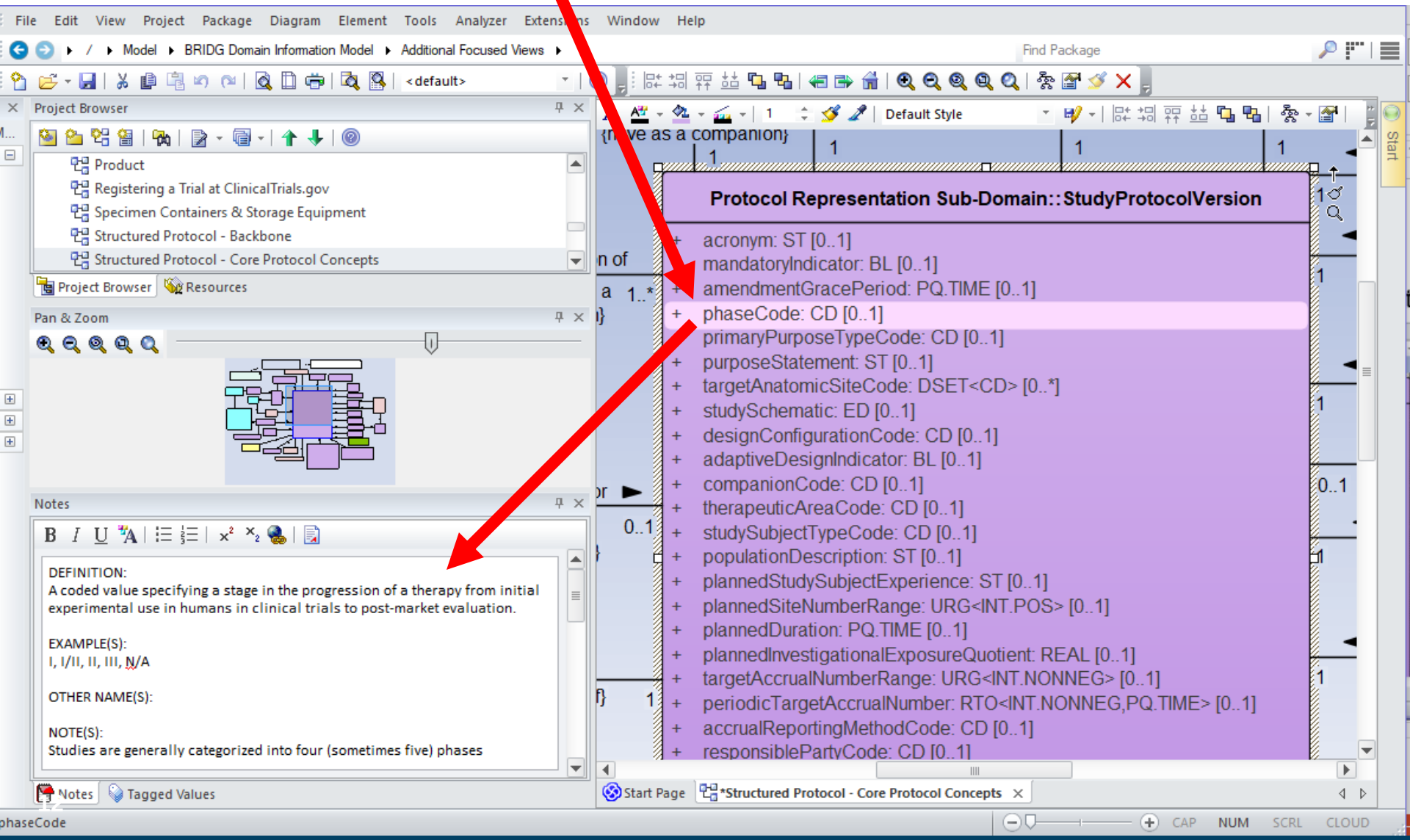
4. XMI export published with each BRIDG release
   - Can be imported into other tools if desired

BRIDG Example of UML Model Elements



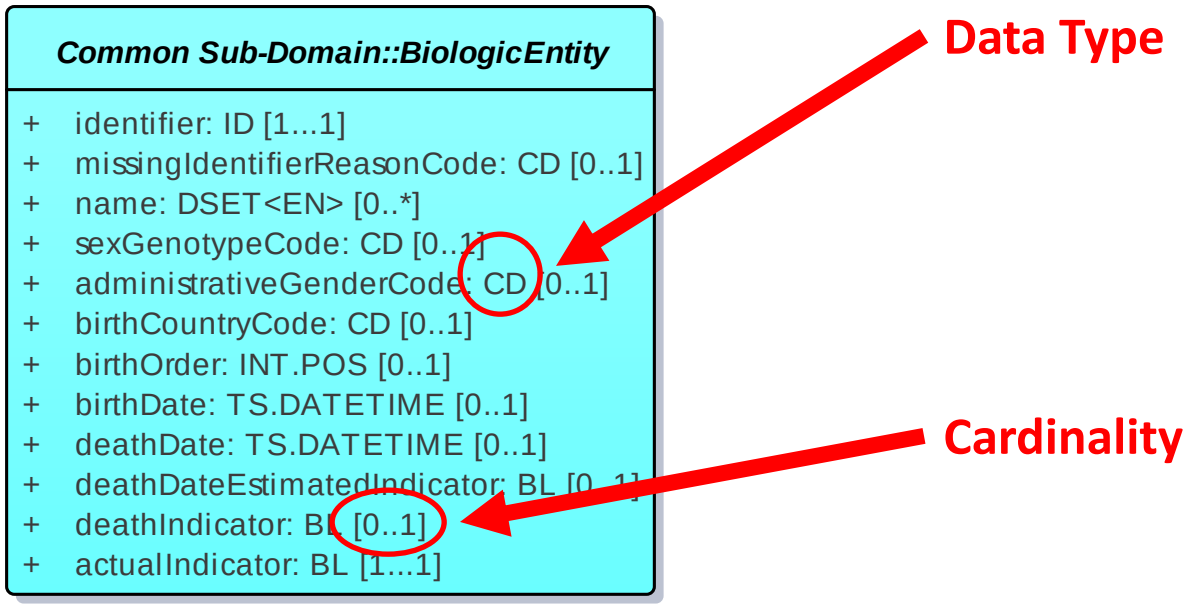
Details of UML Model Elements

Click any class, attribute or association to see the definition, examples, other names and notes that describe that element



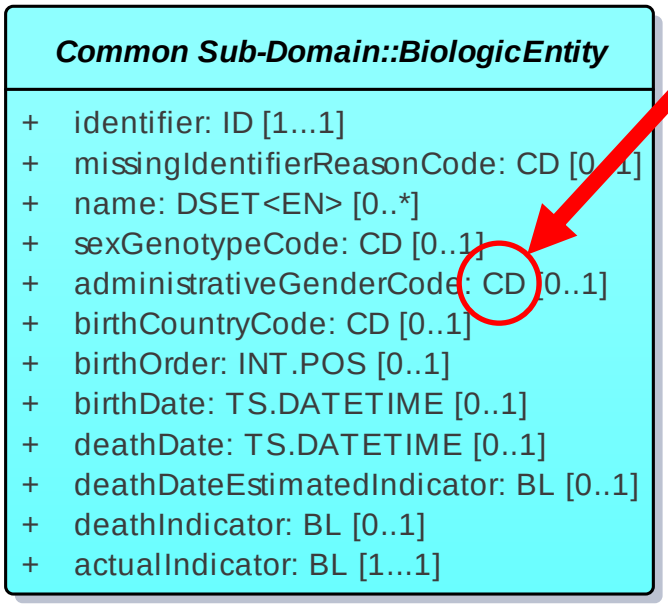
Details of UML Model Elements – Attributes

- Attributes are further defined by:
  - Data format (aka Data Type) – BRIDG uses the HL7 v3 Abstract Data Types
  - Multiplicity (aka Cardinality) – specifies how many values of a particular attribute can be present



Details of UML Model Elements – Data Types

- Complex Data Types – formal, structured data formats used when the value has more than one part or qualifier
  - Details out the parts needed to completely convey data
  - Example: coded values need more than just the code, so Concept Descriptor (CD) has other parts as well…



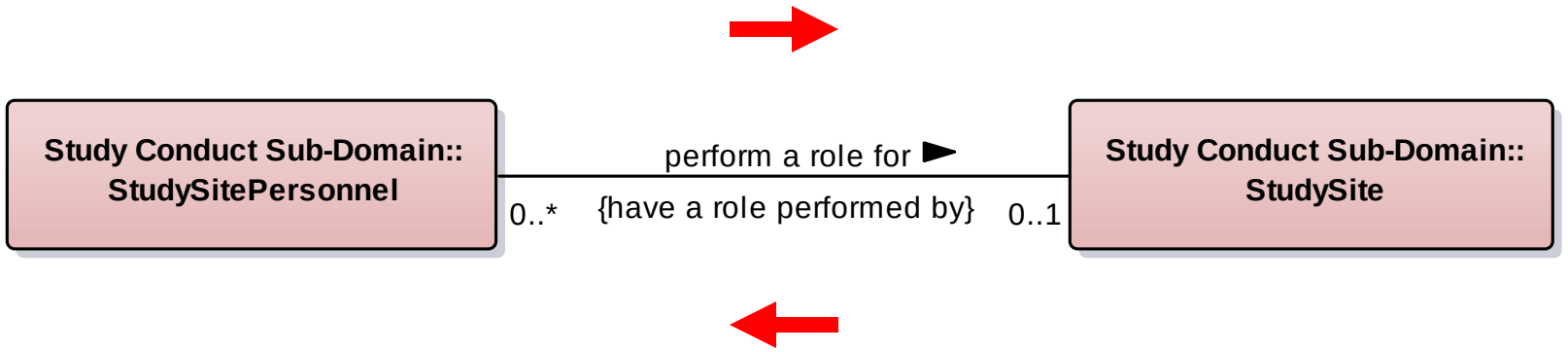
CD = Concept Descriptor

Data Type Attributes	Values
code	M
codeSystem	http://hl7.org/fhir/administrative-gender
codeSystemName	AdministrativeGender
codeSystemVersion	4.0.1
displayName	Male
originalText	m
…	

Details of UML Model Elements – Relationships

- Relationships (aka Associations) are defined by:
  - The ability to read the relationship in both directions
  - Cardinality and labels help provide meaning to the relationship

StudySitePersonnel may perform a role for one StudySite

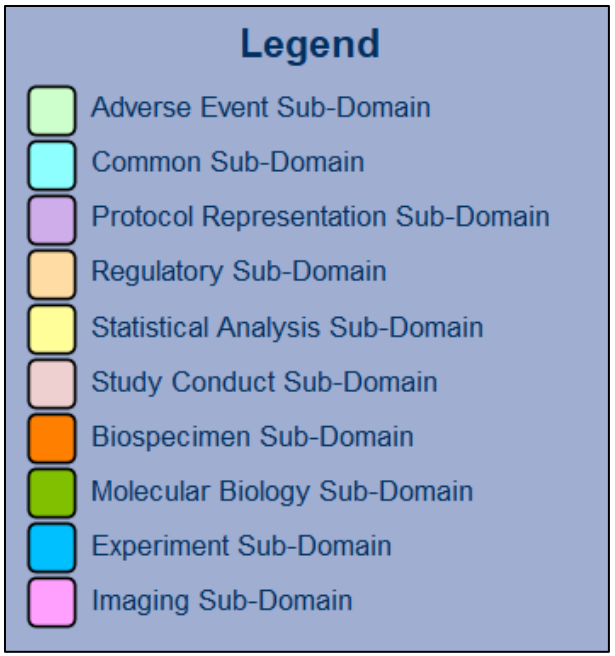


StudySite might have a role performed by one or more StudySitePersonnel

Model Organization in EA

- Package – a folder-like collection that is a user-friendly grouping of UML classes
  - In BRIDG, packages are used to logically group related classes

This legend shows the colors that designate which package a given class comes from

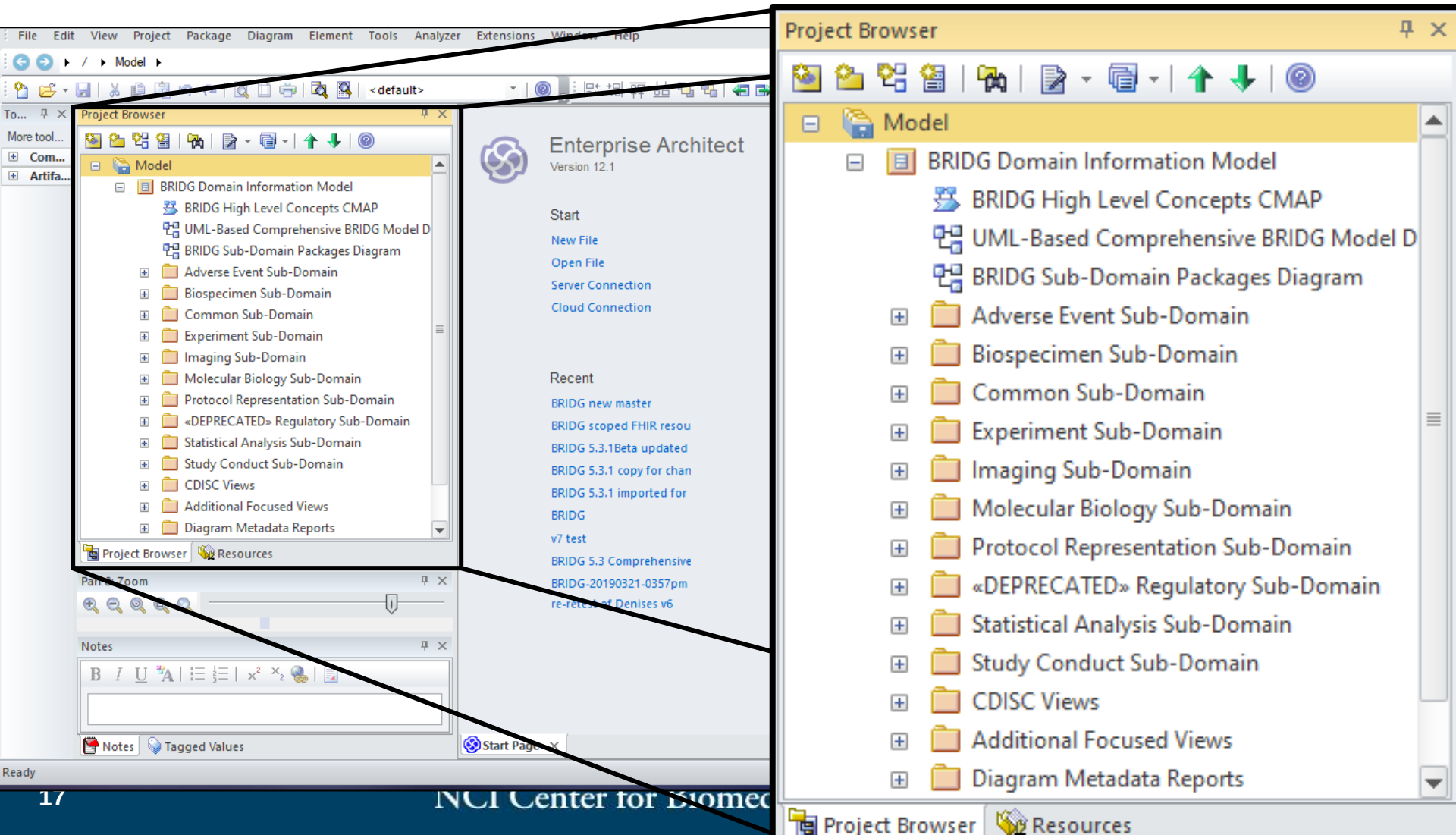


- Class Diagram – graphical representation of classes and relationships in a UML model

- A full tutorial on UML is outside the scope of this presentation, but more info on UML is available at http://www.UML.org

BRIDG Model Organization in EA

- Model content is grouped into packages containing groups of classes, diagrams or reports

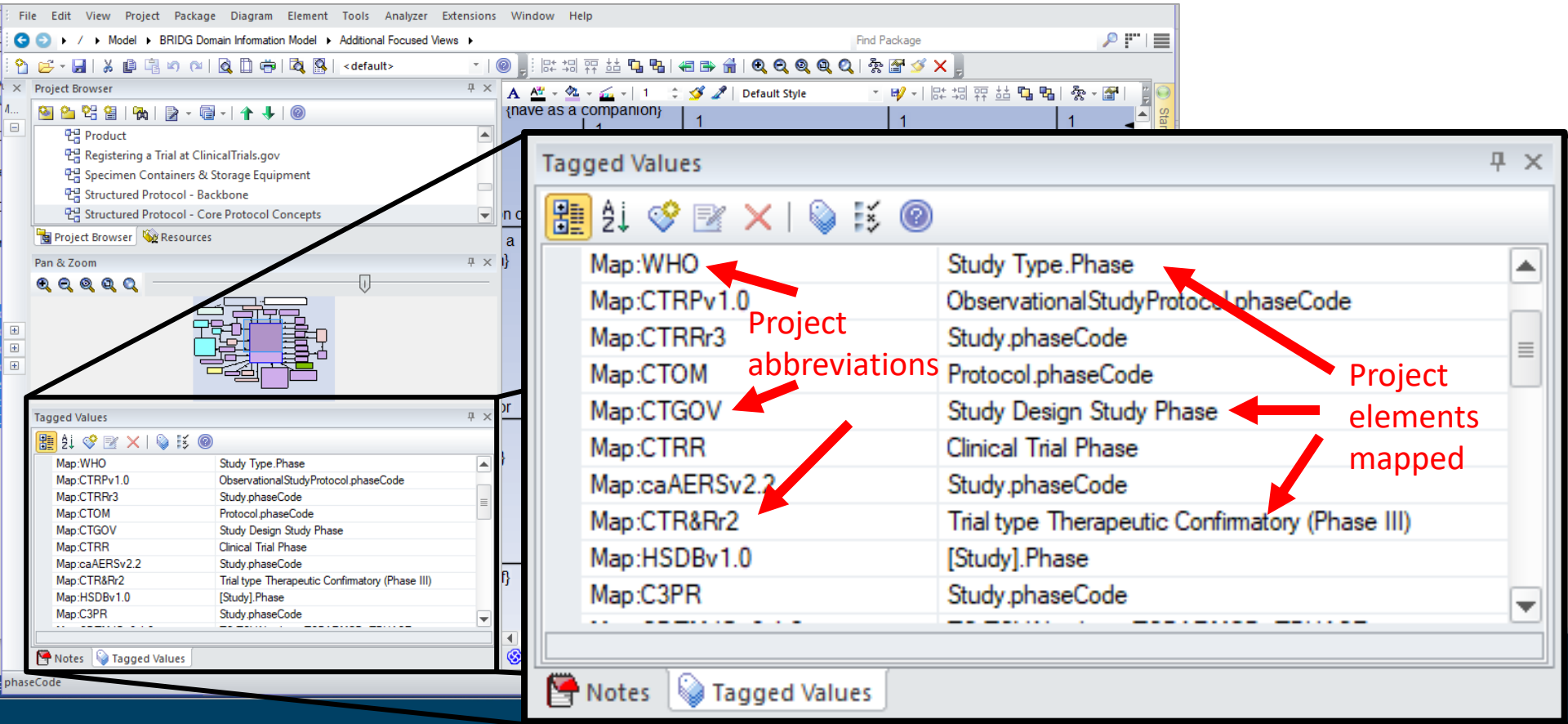


BRIDG Packages

- Packages containing classes:
  - Adverse Events
  - Biospecimen
  - Common
  - Experiment
  - Imaging
  - Molecular Biology
  - Protocol Representation
  - Regulatory
  - Statistical Analysis
  - Study Conduct
- Packages containing diagrams:
  - There are several different packages for diagrams and they change periodically, so check the latest BRIDG release for a current list

BRIDG Mapping Tags

- Every element in BRIDG has project semantics that were mapped to that element
- For each mapping, a Mapping Tag is added to the BRIDG model element with the project element name
- Serves as the provenance of each BRIDG element



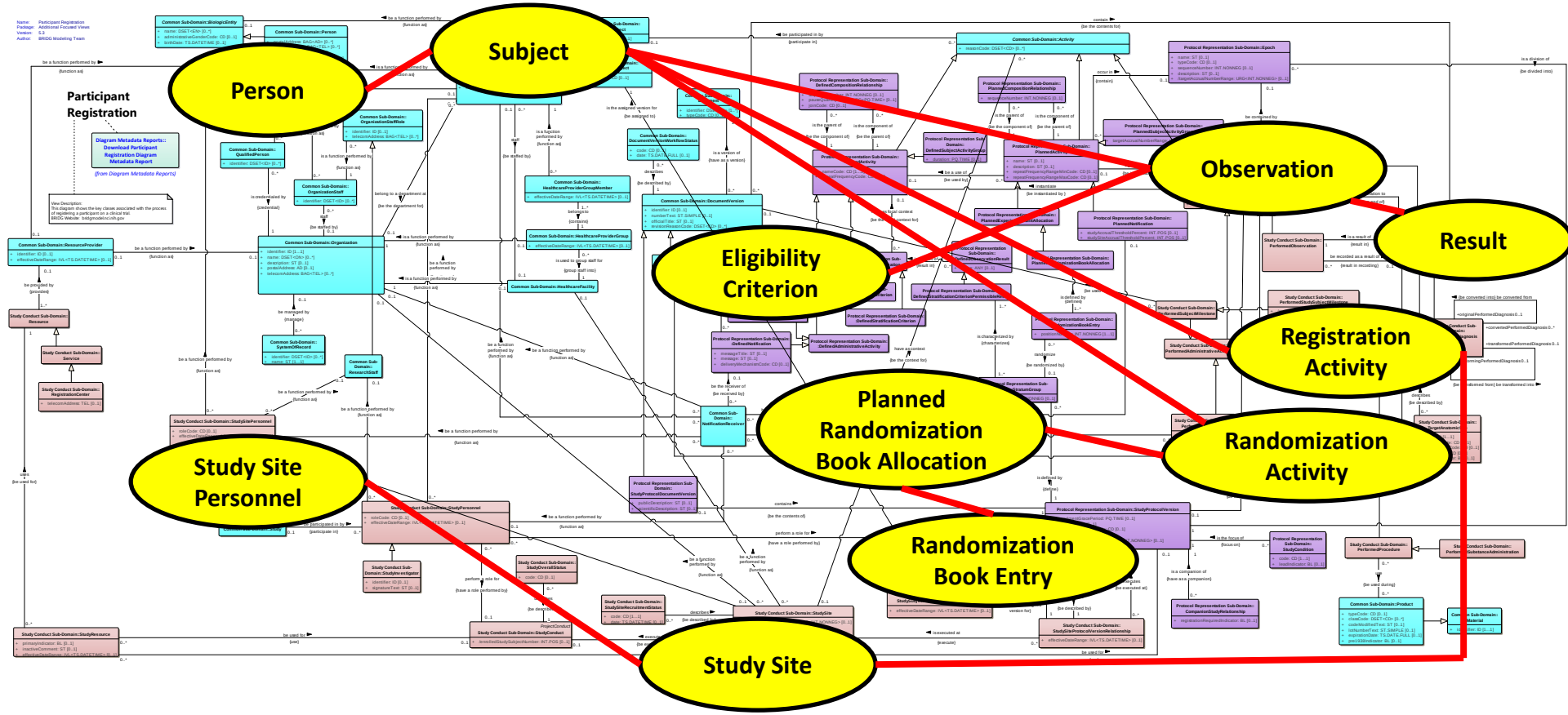
Walking the Model

Walking the Model – Overview

- Class diagrams allow the user to “tell the story” of a scenario, transaction or data exchange

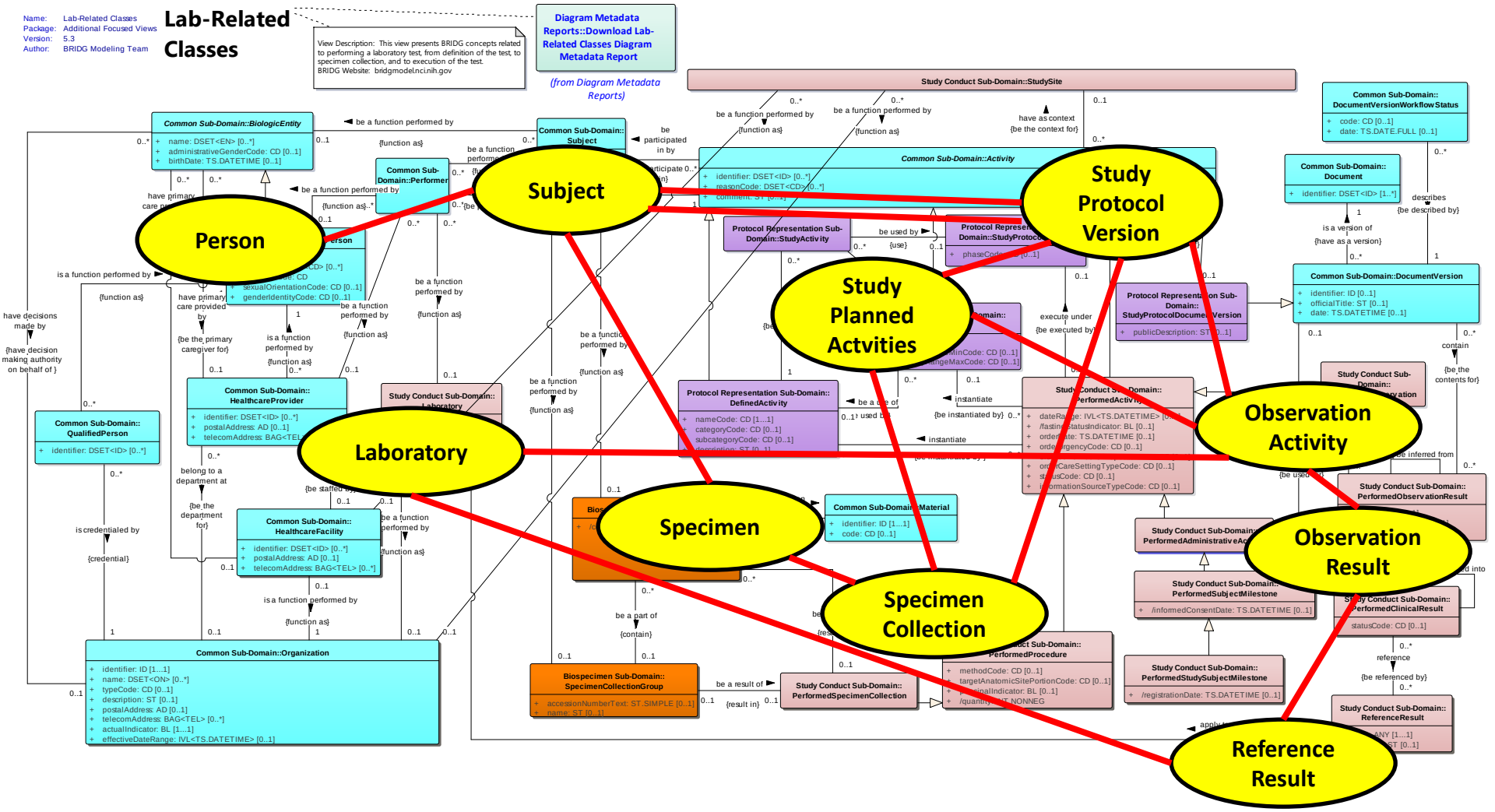
- Stringing together a sequence of classes shows the interrelationships in the model that support a scenario

Walking the Model – Participant Registration

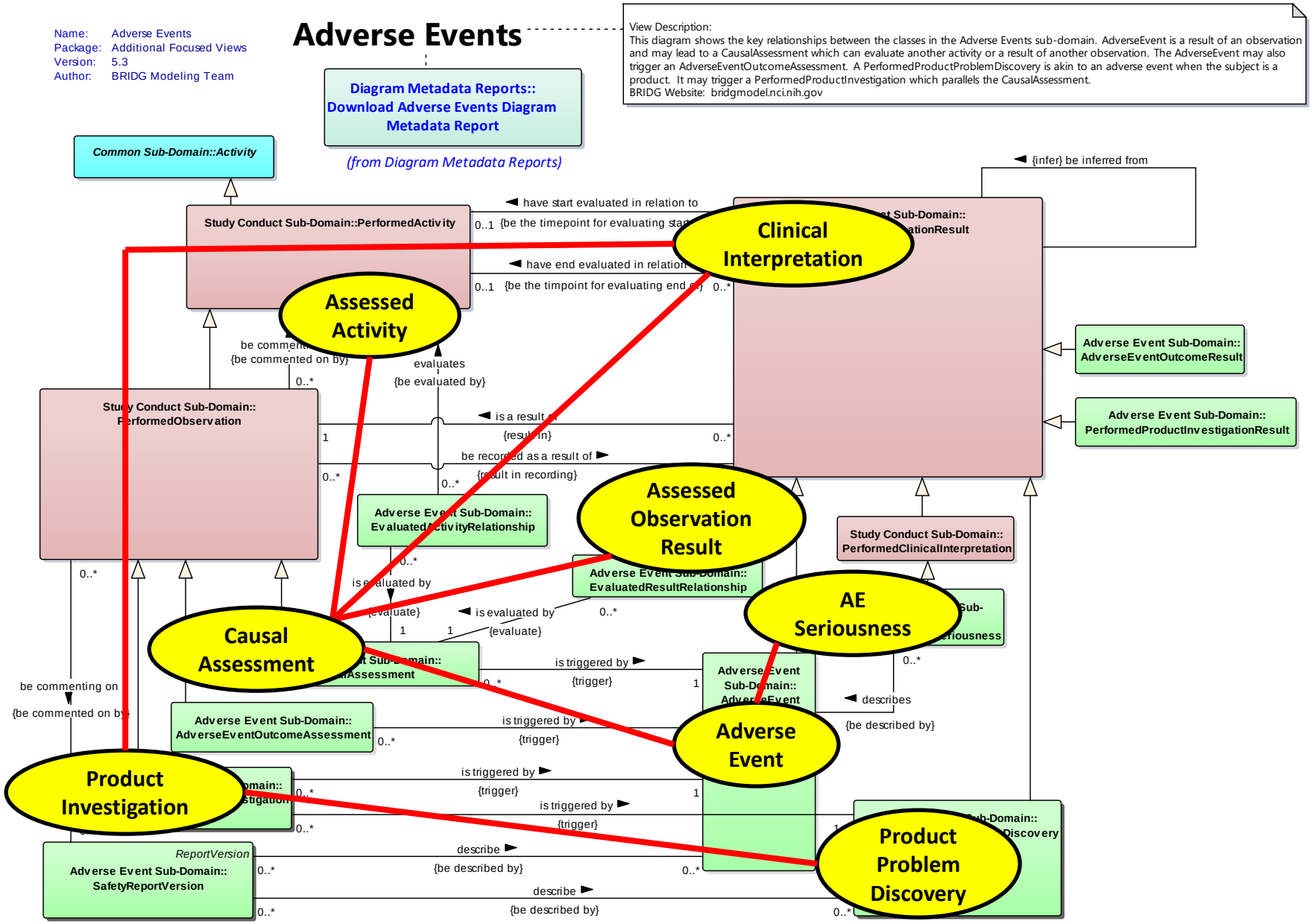


Note: The labels in the yellow bubbles on this slide and following are not necessarily the exact names of the BRIDG classes.

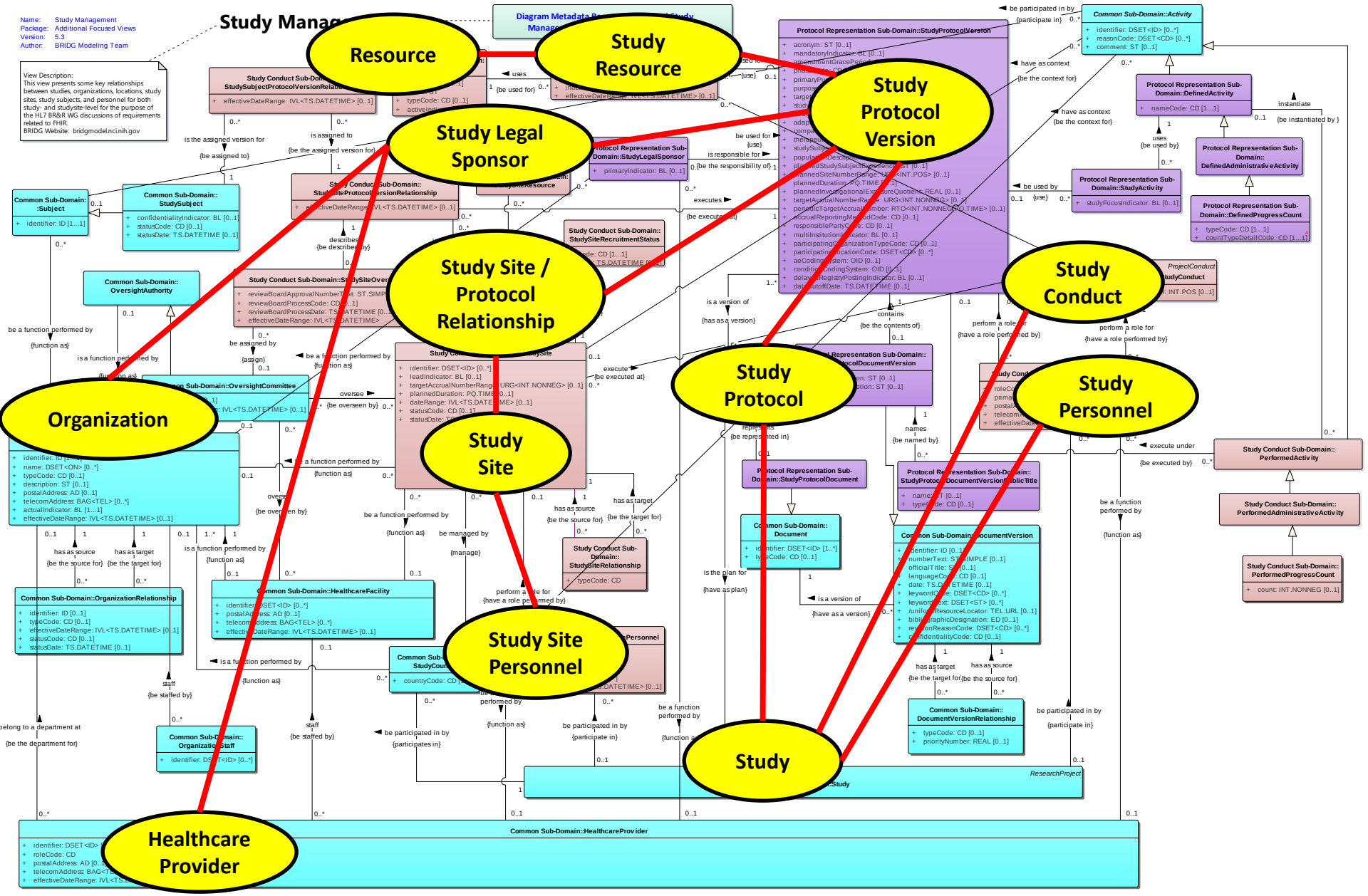
Walking the Model – Lab-Related Classes



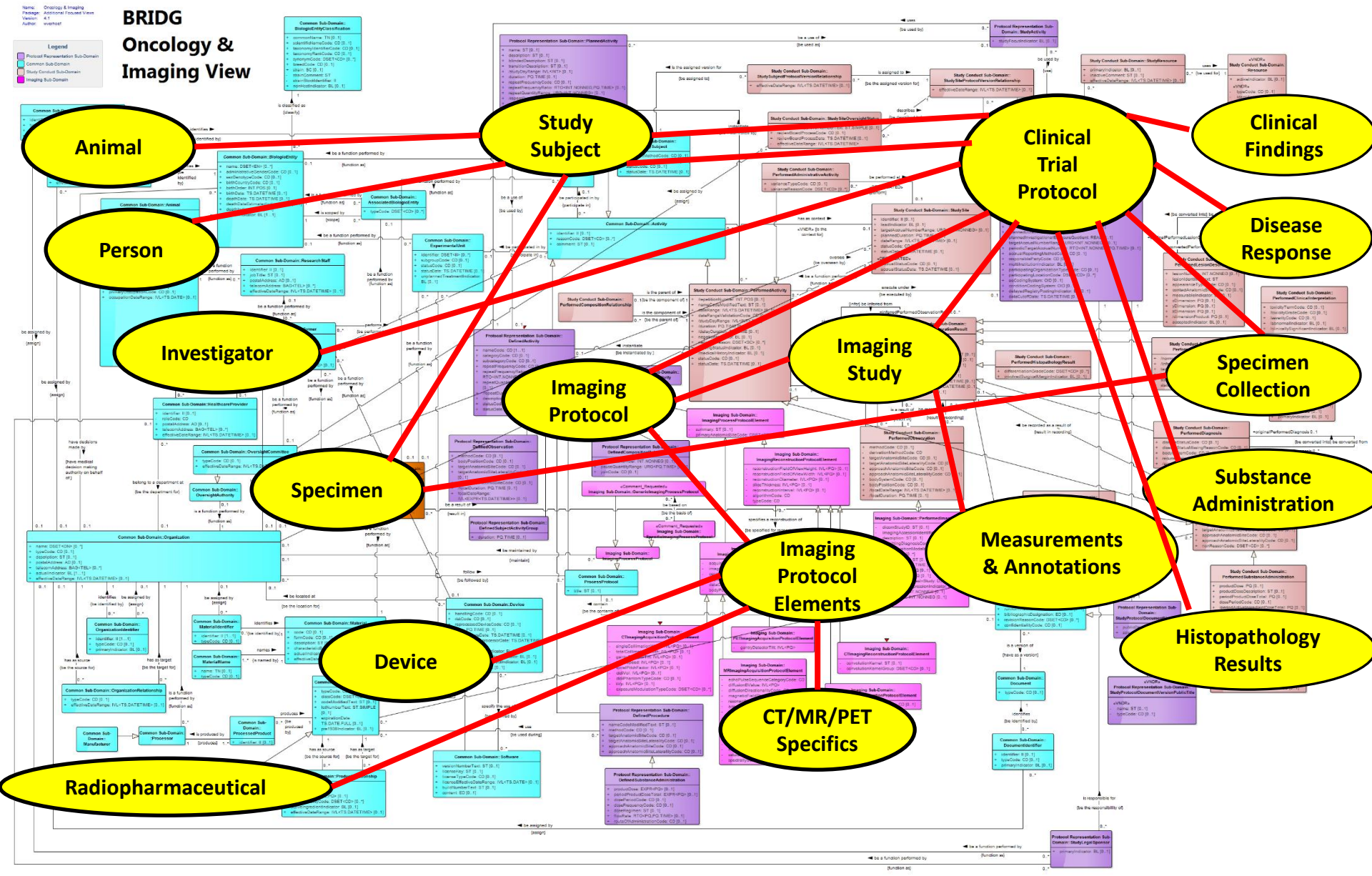
Walking the Model – Adverse Event



Walking the Model – Study Management



Walking the Model – Oncology & Imaging



BRIDG Avenues for Learning

Overview of Avenues of Learning

- Diagrams or views
- Review official BRIDG Mapping Spreadsheet
- Make your own BRIDG mapping spreadsheet & diagram
- Take BRIDG Training

Avenues for Learning - Diagrams

- BRIDG has a variety of class diagrams in the model and on the website
  - For example, click any of the following links to open that diagram in a browser window:

Computable Representation of Study Design:

Structured Protocol - Core Protocol Concepts

Structured Protocol - Schedule of Activities

CDISC Diagrams:

CDISC Lab Data Model v1.0.1

SDTM IG v3.2

Project-Based Diagrams:

Anatomic Pathology Structured Report (APSR)

National Marrow Donor Program (NMDP)

Topic-Based Diagrams:

Adverse Events

Diagnosis

Validate Paths

Avenues for Learning – Mapping Spreadsheet

- BRIDG Mapping Spreadsheet – captures the mapping of project elements that have been harmonized with BRIDG
  - Contains…
    - Project model semantics
    - BRIDG model semantics
    - Mapping path – shows the connections between the corresponding mapped BRIDG element and other relevant classes, for example:
      - PerformedObservation > Subject > Specimen > Material.identifier
- The BRIDG Mapping Spreadsheet can be found in the Documentation folder of the BRIDG release file
  - Download the BRIDG release file to see the spreadsheet on the next slide…

Validate Paths

Avenues for Learning – Mapping Spreadsheet Columns

Source Model Semantics

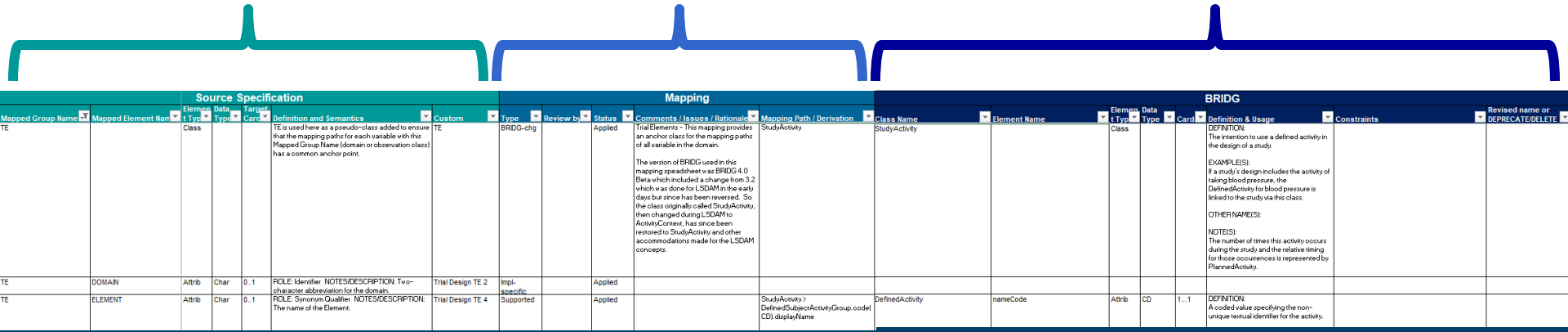
- Group & Element Name
- Cardinality
- Data Type
- Definition & other info

Mapping Support

- Mapping type
- Review by
- Status,
- Rationale/Comments
- Mapping Path & Derivation

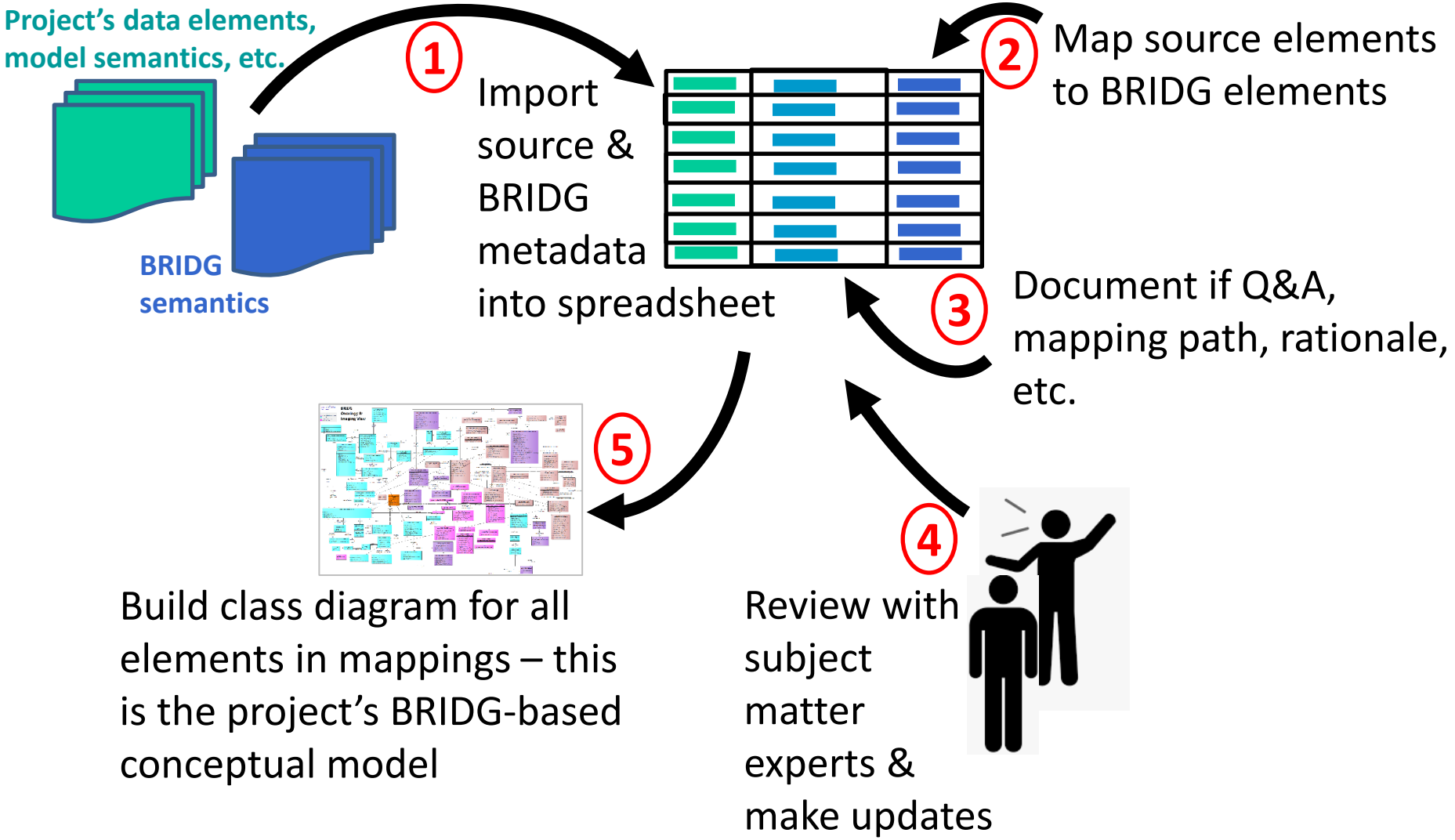
BRIDG Model Semantics

- Class, attribute & association name
- Cardinality
- Data Type
- Definition & other info



Source Specification							Mapping					BRIDG						
Mapped Group Name	Mapped Element Name	Element Type	Data Type	Target Card	Definition and Semantics	Custom	Type	Review by	Status	Comments / Issues / Rationale	Mapping Path / Derivation	Class Name	Element Name	Element Type	Data Type	Card	Definition & Usage	Constraints	Revised name or DEPRECATE/DELETE
TE		Class			TE is used here as a pseudo-class added to ensure that the mapping paths for each variable with this Mapped Group Name (domain or observation class) has a common anchor point.	TE	BRIDG-chg		Applied	Trial Elements - This mapping provides an anchor class for the mapping paths of all variable in the domain. The version of BRIDG used in this mapping spreadsheet was BRIDG 4.0 Beta which included a change from 3.2 which was done for LSDAM in the early days but since has been reversed. So the class originally called StudyActivity, then changed during LSDAM to ActivityContext, has since been restored to StudyActivity and other accommodations made for the LSDAM concepts.	StudyActivity	StudyActivity		Class			DEFINITION: The intention to use a defined activity in the design of a study. EXAMPLE(S): If a study's design includes the activity of taking blood pressure, the DefinedActivity for blood pressure is linked to the study via this class. OTHER NAME(S): NOTE(S): The number of times this activity occurs during the study and the relative timing for those occurrences is represented by PlannedActivity.		
TE	DOMAIN	Attrib	Char	0..1	ROLE: Identifier. NOTES/DESCRIPTION: Two-character abbreviation for the domain.	Trial Design TE 2	Impl-specific		Applied										
TE	ELEMENT	Attrib	Char	0..1	ROLE: Synonym Qualifier. NOTES/DESCRIPTION: The name of the Element.	Trial Design TE 4	Supported		Applied		StudyActivity>DefinedSubjectActivityGroup.code(CD).displayName	DefinedActivity	nameCode	Attrib	CD	1...1	DEFINITION: A coded value specifying the non-unique textual identifier for the activity.		

Avenues for Learning – Create Your Own Mapping



Avenues for Learning - Training

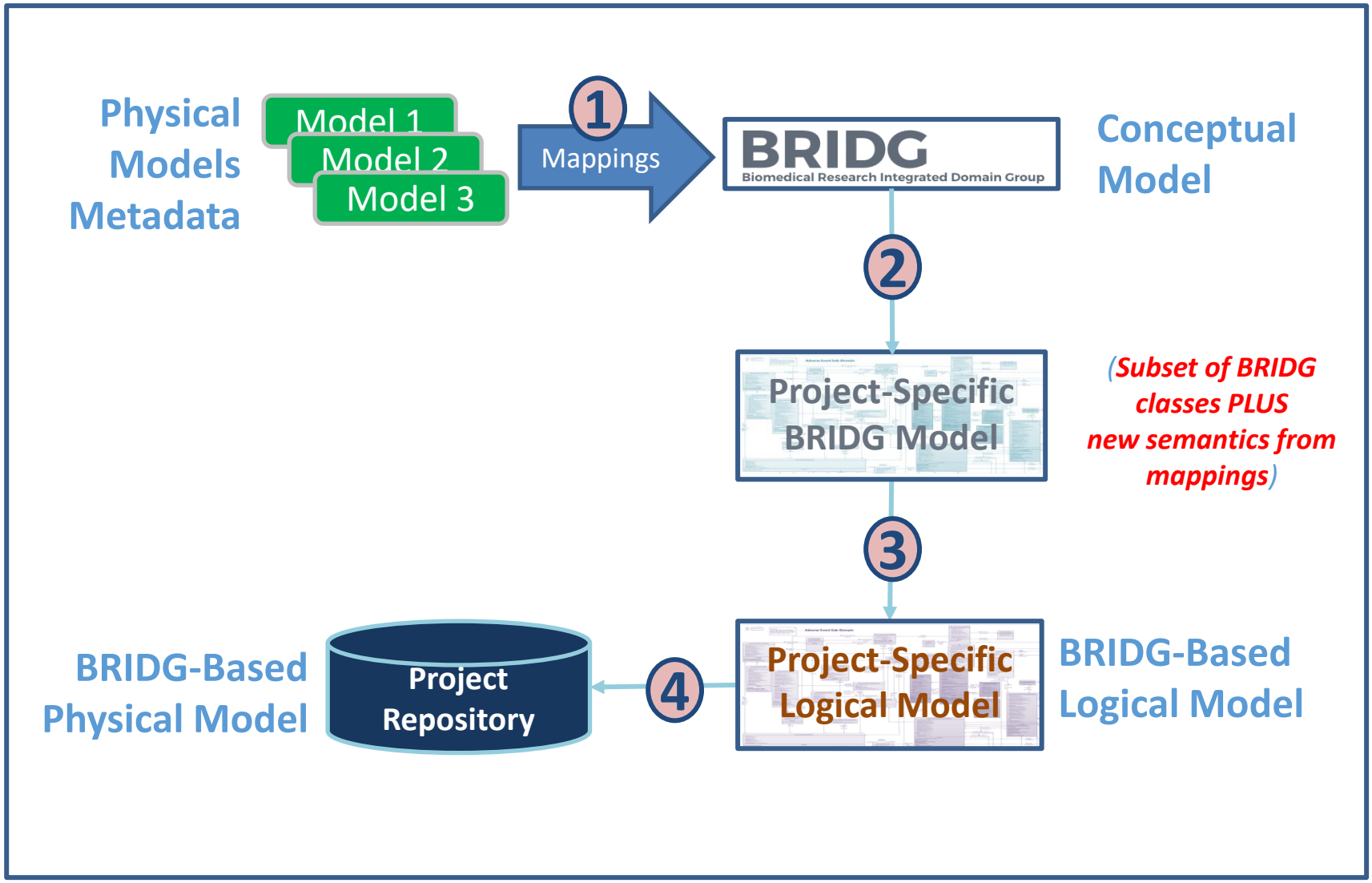
- BRIDG Training: https://www.cdisc.org/education
  - CDISC offers BRIDG Deep Dive classes
  - Custom, On-Site classes can be arranged

BRIDG Implementation

BRIDG Implementation Approaches

- Reference Model
  - Source for clinical research data semantics & foundation model
- Data Integration/Mapping Solutions
  - One mapping to a standard (BRIDG) rather than multiple point to point mappings
- Exchange Format
  - Subsets of BRIDG classes represented in XSD/XML
- Physical Database
  - Create logical and physical database models in support of clinical research software solutions
    - NMDP, Thomas Jefferson University, Large CRO, FDA, etc.
- Ontology
  - To develop clinical research ontology

Database Example – Mapping and Model Development Steps



For more information

- Read the BRIDG User's Guide and Release Notes that accompany each release of BRIDG

- See the BRIDG Website:
  - bridgmodel.nci.nih.gov

- Contact the BRIDG Modelers at the following email:
  - bridgTHC-L@list.nih.gov