

BRIDG 101

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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*)

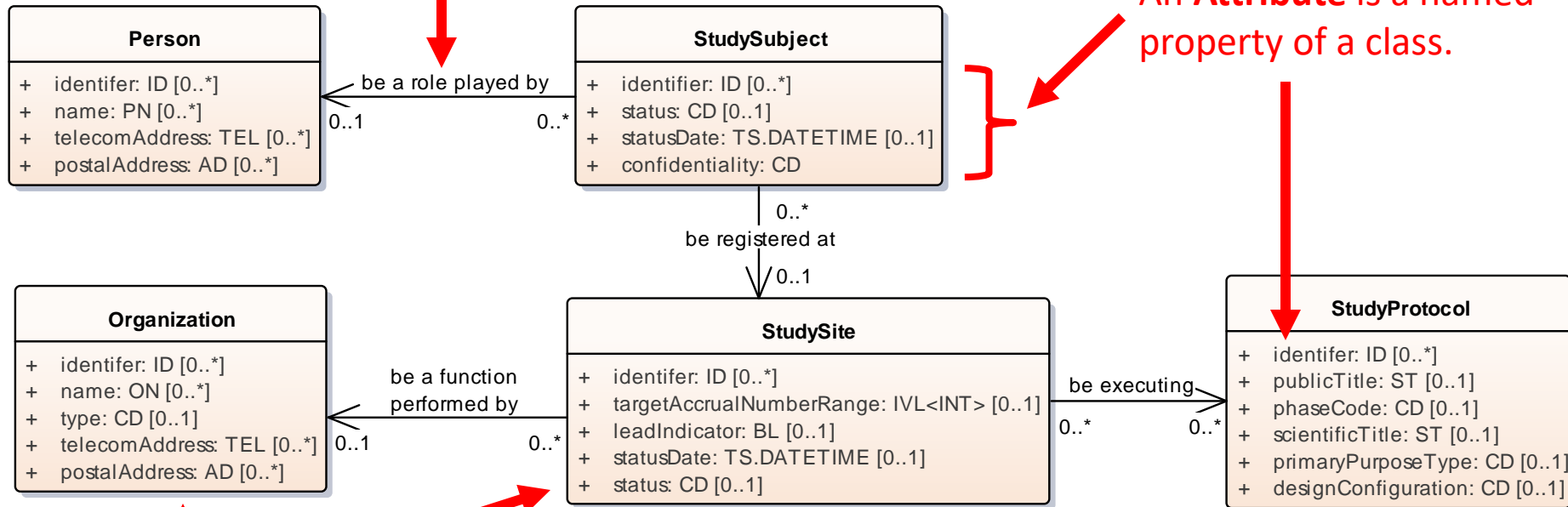
Navigating the BRIDG Model

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

A **Relationship** describes how 2 classes are related.



An **Attribute** is a named property of a class.

A **Class** is an object or set of objects that share common properties. The class name is at the top of the box.

Details of UML Model Elements

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

The screenshot displays a UML modeling software interface. The main window shows a class diagram with a class named "Protocol Representation Sub-Domain::StudyProtocolVersion". The class is highlighted in purple. The interface includes a Project Browser on the left, a Pan & Zoom window, and a Notes window at the bottom. The Notes window is open, showing the definition, examples, other names, and notes for the selected class.

Protocol Representation Sub-Domain::StudyProtocolVersion

- + acronym: ST [0..1]
- + mandatoryIndicator: BL [0..1]
- + amendmentGracePeriod: PQ.TIME [0..1]
- + phaseCode: CD [0..1]
- + primaryPurposeTypeCode: CD [0..1]
- + purposeStatement: ST [0..1]
- + targetAnatomicSiteCode: DSET<CD> [0..*]
- + studySchematic: ED [0..1]
- + designConfigurationCode: CD [0..1]
- + adaptiveDesignIndicator: BL [0..1]
- + companionCode: CD [0..1]
- + therapeuticAreaCode: CD [0..1]
- + studySubjectTypeCode: CD [0..1]
- + populationDescription: ST [0..1]
- + plannedStudySubjectExperience: ST [0..1]
- + plannedSiteNumberRange: URG<INT.POS> [0..1]
- + plannedDuration: PQ.TIME [0..1]
- + plannedInvestigationalExposureQuotient: REAL [0..1]
- + targetAccrualNumberRange: URG<INT.NONNEG> [0..1]
- + periodicTargetAccrualNumber: RTO<INT.NONNEG,PQ.TIME> [0..1]
- + accrualReportingMethodCode: CD [0..1]
- + responsiblePartyCode: CD [0..1]

DEFINITION:
A coded value specifying a stage in the progression of a therapy from initial experimental use in humans in clinical trials to post-market evaluation.

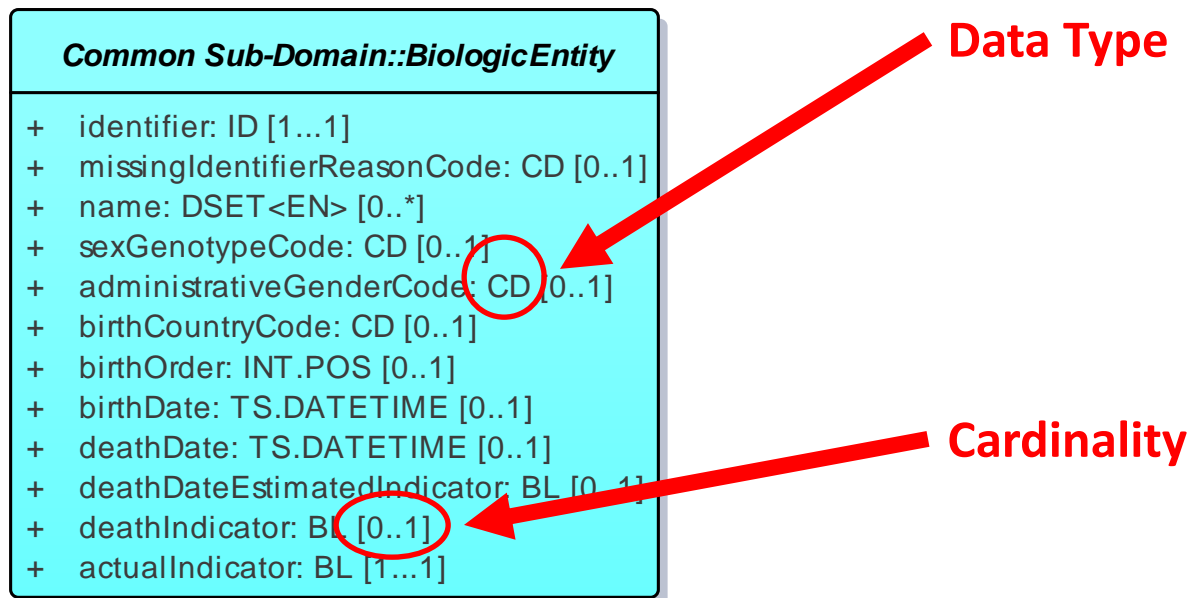
EXAMPLE(S):
I, I/II, II, III, N/A

OTHER NAME(S):

NOTE(S):
Studies are generally categorized into four (sometimes five) phases

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...

Common Sub-Domain::BiologicEntity

```
+ identifier: ID [1...1]
+ missingIdentifierReasonCode: CD [0..1]
+ name: DSET<EN> [0..*]
+ sexGenotypeCode: CD [0..1]
+ administrativeGenderCode: CD [0..1]
+ birthCountryCode: CD [0..1]
+ birthOrder: INT.POS [0..1]
+ birthDate: TS.DATETIME [0..1]
+ deathDate: TS.DATETIME [0..1]
+ deathDateEstimatedIndicator: BL [0..1]
+ deathIndicator: BL [0..1]
+ actualIndicator: BL [1...1]
```

CD = Concept Descriptor

Data Type Attributes

code

codeSystem

codeSystemName

codeSystemVersion

displayName

originalText

...

Values

M

<http://hl7.org/fhir/administrative-gender>

AdministrativeGender

4.0.1

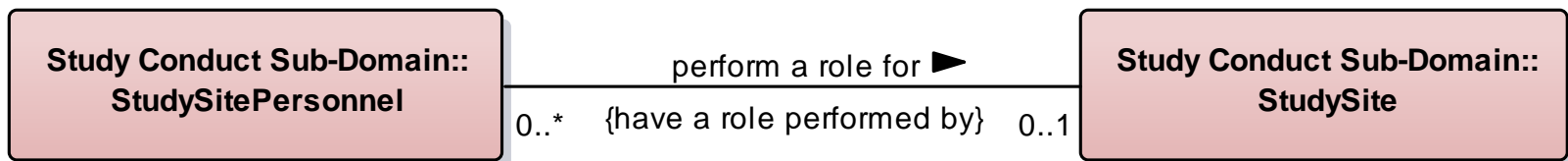
Male

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

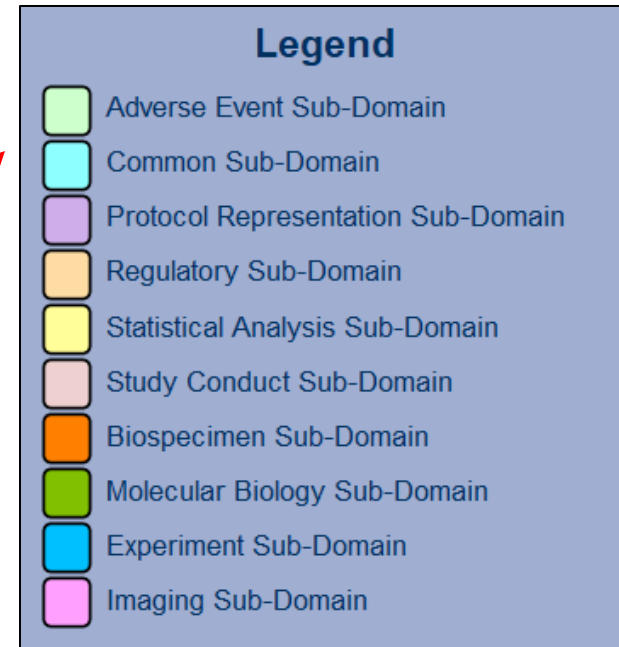


StudySite might have a role performed by one or more StudySitePersonnel

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

The screenshot displays the Enterprise Architect (EA) software interface, showing the organization of the BRIDG Model. The main window is titled "Enterprise Architect Version 12.1". The interface is divided into several panes:

- Project Browser (Left):** Shows a hierarchical tree structure of the model. The root is "Model", which contains "BRIDG Domain Information Model". Under this, there are several sub-domains: "BRIDG High Level Concepts CMAP", "UML-Based Comprehensive BRIDG Model D", "BRIDG Sub-Domain Packages Diagram", "Adverse Event Sub-Domain", "Biospecimen Sub-Domain", "Common Sub-Domain", "Experiment Sub-Domain", "Imaging Sub-Domain", "Molecular Biology Sub-Domain", "Protocol Representation Sub-Domain", "«DEPRECATED» Regulatory Sub-Domain", "Statistical Analysis Sub-Domain", "Study Conduct Sub-Domain", "CDISC Views", "Additional Focused Views", and "Diagram Metadata Reports".
- Central Workspace:** Displays the EA logo and version information. It includes options to "Start", "New File", "Open File", "Server Connection", and "Cloud Connection". Below these are "Recent" items, including "BRIDG new master", "BRIDG scoped FHIR resou", "BRIDG 5.3.1Beta updated", "BRIDG 5.3.1 copy for chan", "BRIDG 5.3.1 imported for BRIDG", "v7 test", "BRIDG 5.3 Comprehensive", "BRIDG-20190321-0357pm", and "re-release of Denises v6".
- Project Browser (Right):** Provides a detailed view of the "BRIDG Domain Information Model" structure, listing all sub-domains and their associated content, such as "BRIDG High Level Concepts CMAP", "UML-Based Comprehensive BRIDG Model D", "BRIDG Sub-Domain Packages Diagram", and various sub-domains like "Adverse Event Sub-Domain", "Biospecimen Sub-Domain", "Common Sub-Domain", "Experiment Sub-Domain", "Imaging Sub-Domain", "Molecular Biology Sub-Domain", "Protocol Representation Sub-Domain", "«DEPRECATED» Regulatory Sub-Domain", "Statistical Analysis Sub-Domain", "Study Conduct Sub-Domain", "CDISC Views", "Additional Focused Views", and "Diagram Metadata 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

The screenshot displays a software interface with a 'Project Browser' on the left and a 'Tagged Values' table on the right. The 'Project Browser' shows a hierarchy of project elements, including 'Product', 'Registering a Trial at ClinicalTrials.gov', 'Specimen Containers & Storage Equipment', 'Structured Protocol - Backbone', and 'Structured Protocol - Core Protocol Concepts'. The 'Tagged Values' table lists mappings between project abbreviations and BRIDG elements.

Map	Study
Map:WHO	Study Type.Phase
Map:CTRPv1.0	ObservationalStudyProtocol.phaseCode
Map:CTRRr3	Study.phaseCode
Map:CTOM	Protocol.phaseCode
Map:CTGOV	Study Design Study Phase
Map:CTRR	Clinical Trial Phase
Map:caAERSv2.2	Study.phaseCode
Map:CTR&Rr2	Trial type Therapeutic Confirmatory (Phase III)
Map:HSDbV1.0	[Study].Phase
Map:C3PR	Study.phaseCode

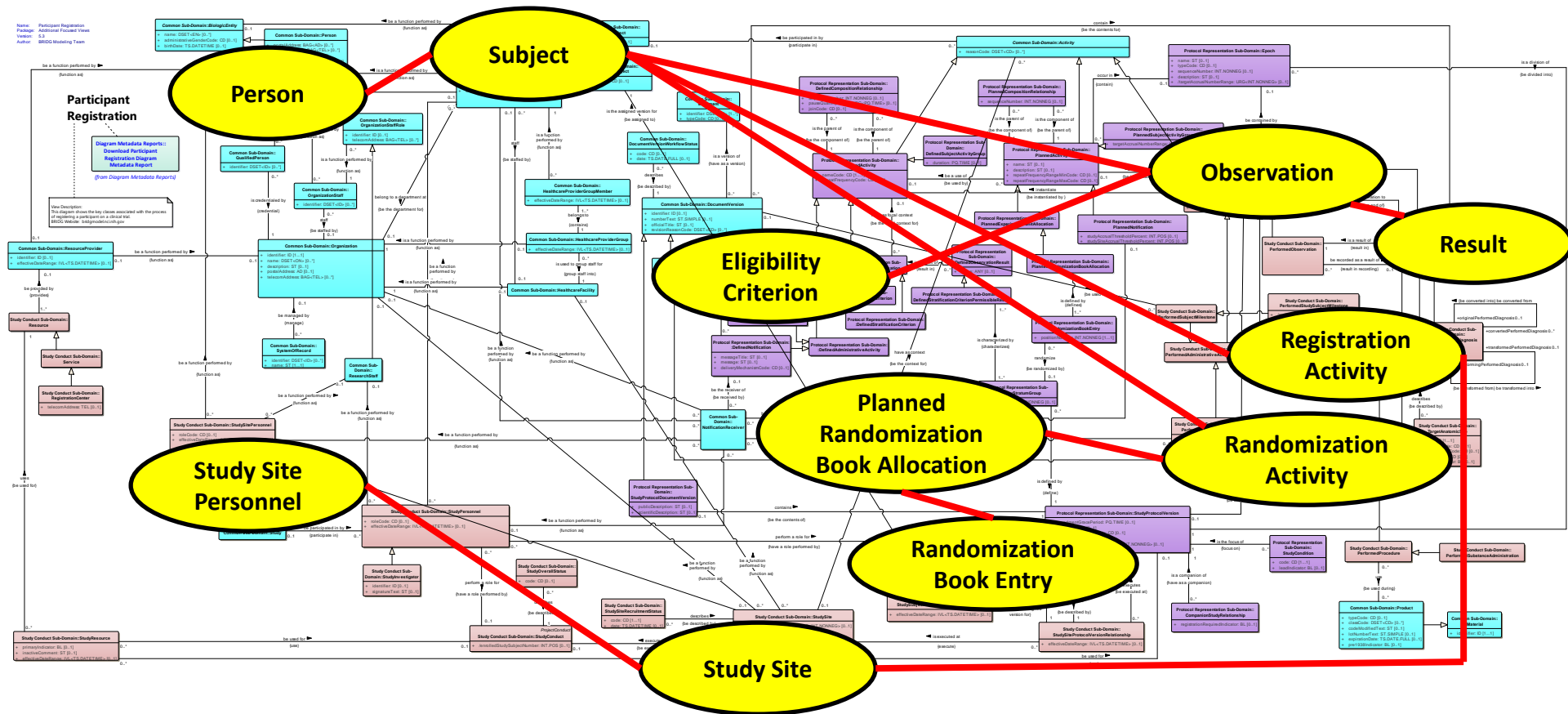
Red arrows point from the text 'Project abbreviations' to the 'Map' column and from 'Project elements mapped' to the 'Study' column.

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.

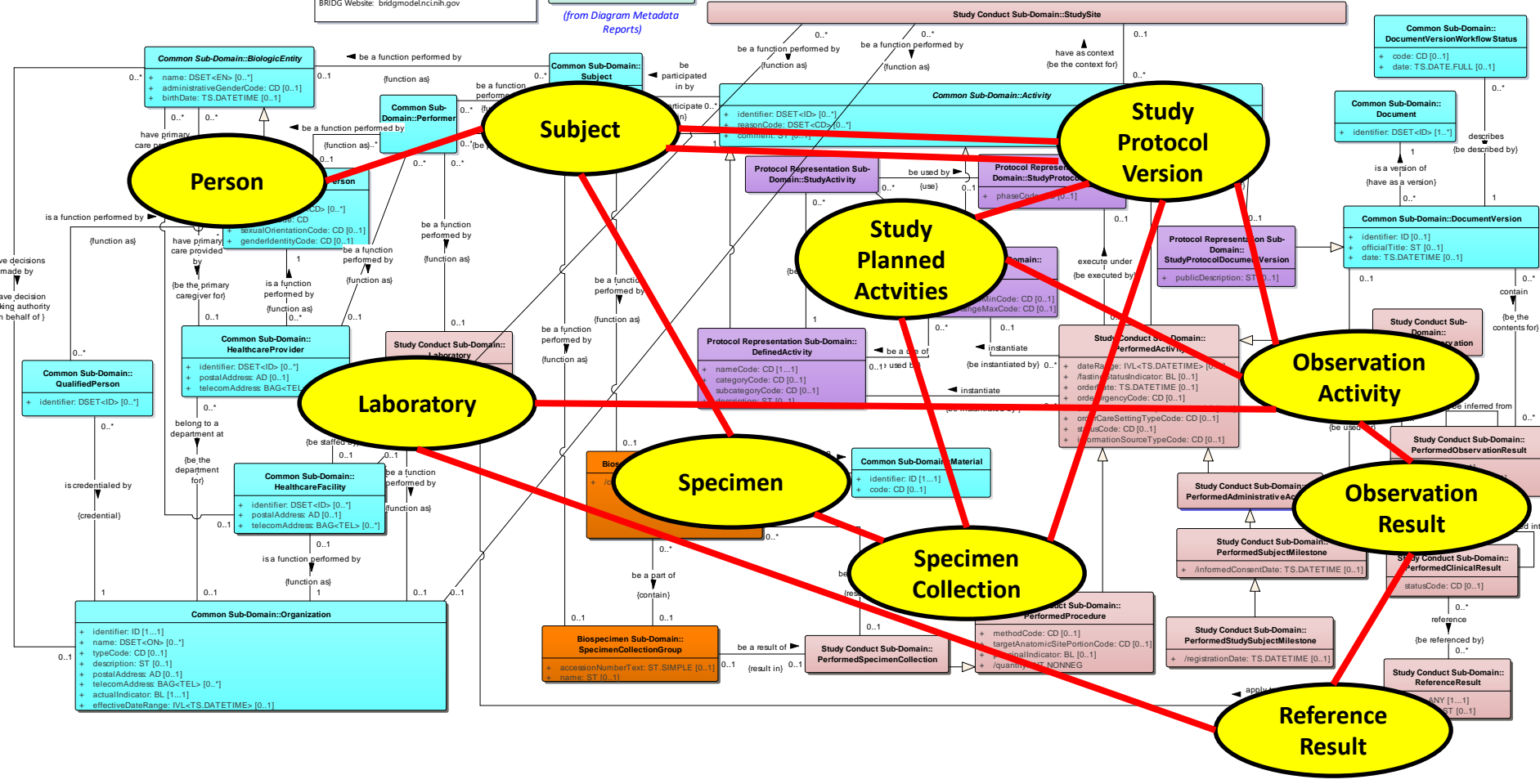
Walking the Model – Lab-Related Classes

Name: Lab-Related Classes
Package: Additional Focused Views
Version: 5.3
Author: BRIDG Modeling Team

Lab-Related Classes

Diagram Metadata Reports: Download Lab-Related Classes Diagram Metadata Report
(from Diagram Metadata Reports)

View Description: This view presents BRIDG concepts related to performing a laboratory test, from definition of the test to specimen collection, and to execution of the test.
BRIDG Website: bridgmodelinc.nih.gov



Walking the Model – Adverse Event

Name: Adverse Events
 Package: Additional Focused Views
 Version: 5.3
 Author: BRIDG Modeling Team

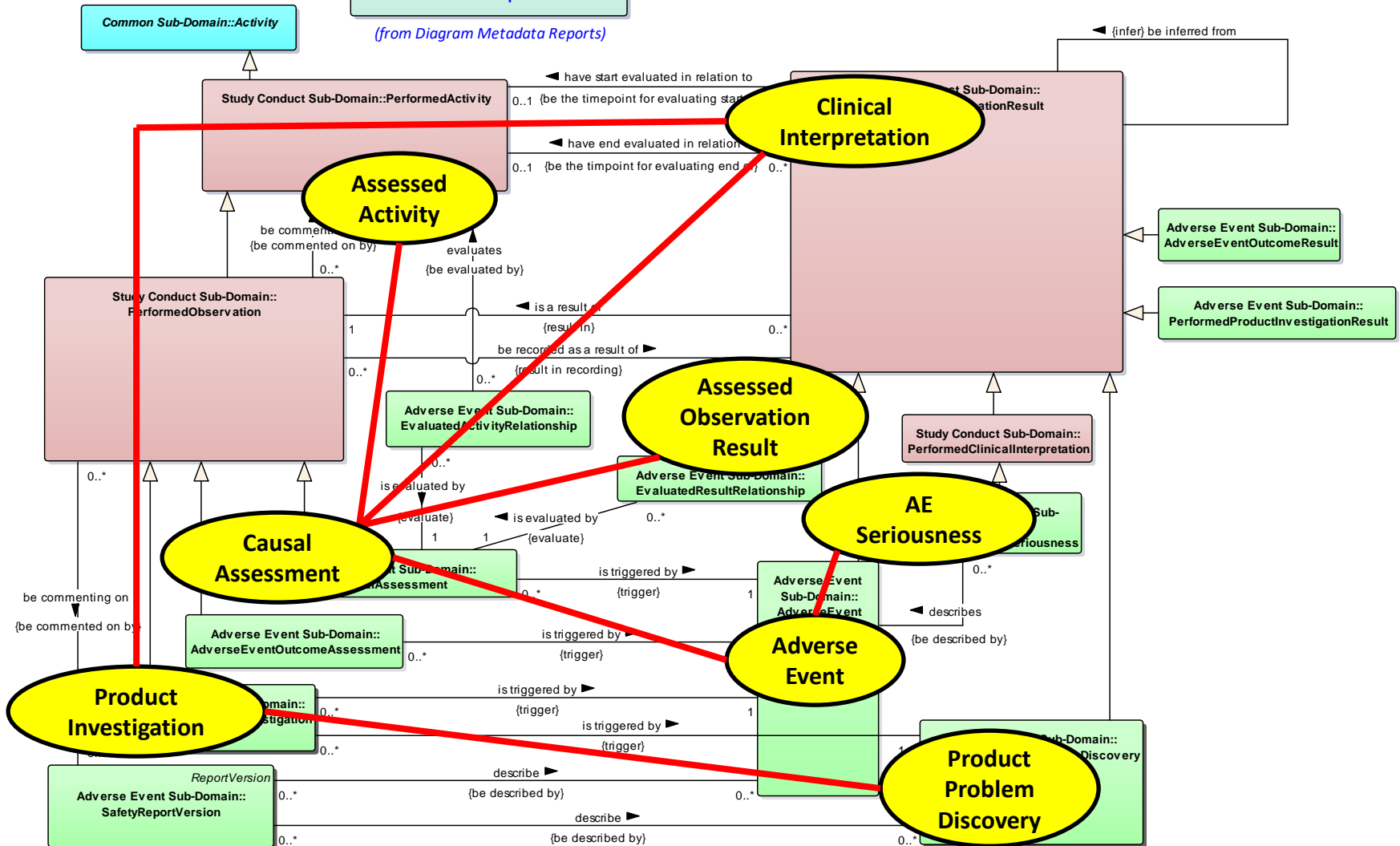
Adverse Events

Diagram Metadata Reports:
[Download Adverse Events Diagram](#)
[Metadata Report](#)

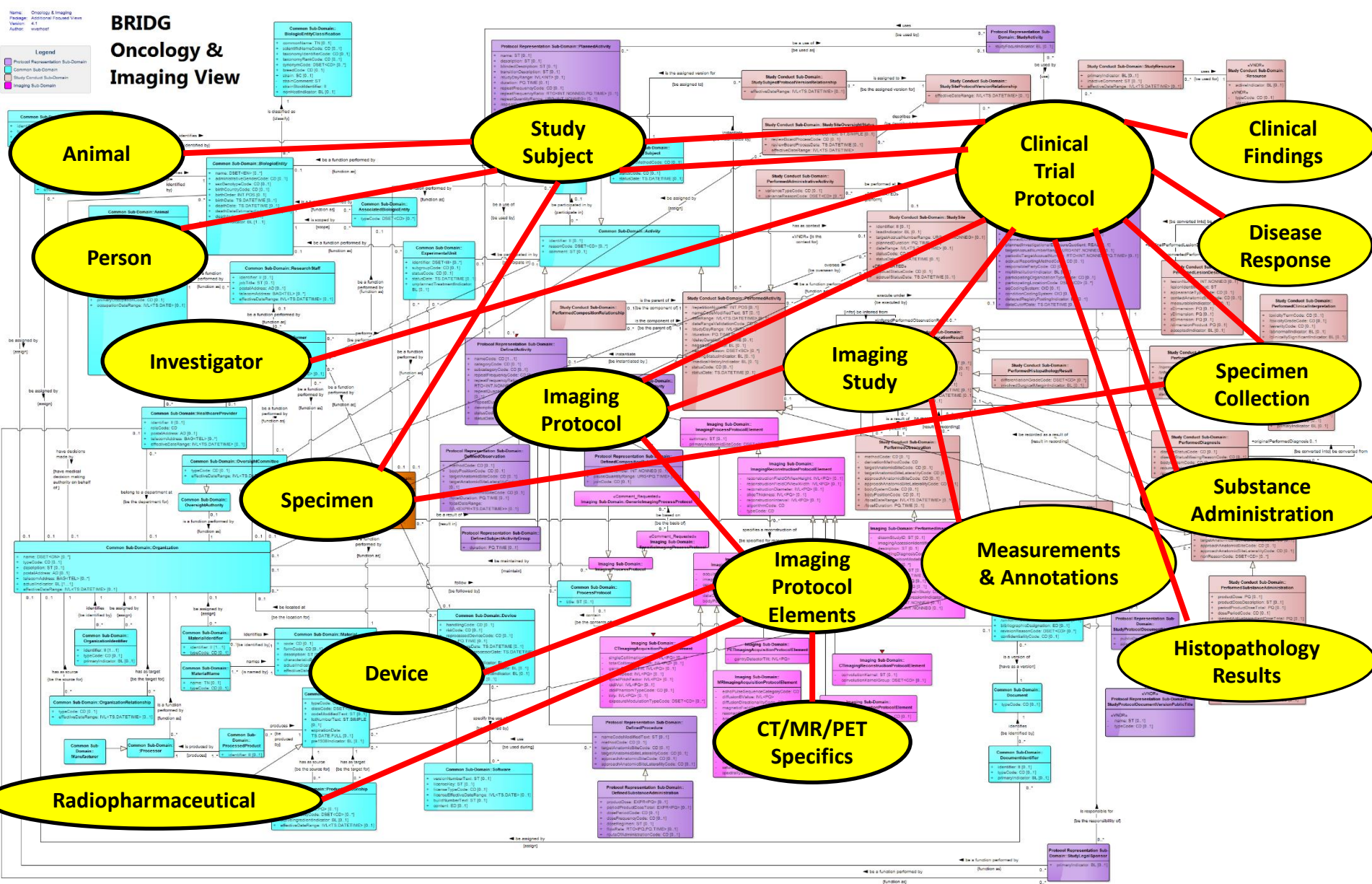
(from Diagram Metadata Reports)

View Description:

This diagram shows the key relationships between the classes in the Adverse Events sub-domain. AdverseEvent is a result of an observation and may lead to a CausalAssessment which can evaluate another activity or a result of another observation. The AdverseEvent may also trigger an AdverseEventOutcomeAssessment. A PerformedProductProblemDiscovery is akin to an adverse event when the subject is a product. It may trigger a PerformedProductInvestigation which parallels the CausalAssessment. BRIDG Website: bridgmodel.nci.nih.gov



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](#)

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...

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

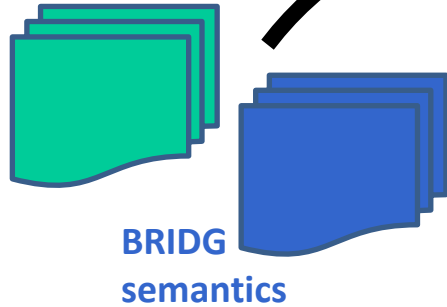
BRIDG Model Semantics

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

Source Specification					Mapping					BRIDG											
Mapped Group Name	Mapped Element Name	Element Type	Data Type	Cardinality	Target	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	TE 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.		BRIDG-Obj		Applied	Trial Elements - This mapping provides an anchor class for the mapping paths of all variables 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 renamed 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. EXAMPLES: 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): NOTES: 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 > (defined:StudyActivityGroup_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

Project's data elements,
model semantics, etc.



①

Import
source &
BRIDG
metadata
into spreadsheet

Green	Blue	Blue
Green	Blue	Blue
Green	Blue	Blue
Green	Blue	Blue
Green	Blue	Blue
Green	Blue	Blue
Green	Blue	Blue

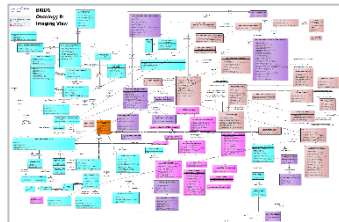
②

Map source elements
to BRIDG elements

③

Document if Q&A,
mapping path, rationale,
etc.

⑤



Build class diagram for all
elements in mappings – this
is the project's BRIDG-based
conceptual model

④

Review with
subject
matter
experts &
make updates



Avenues for Learning - Training

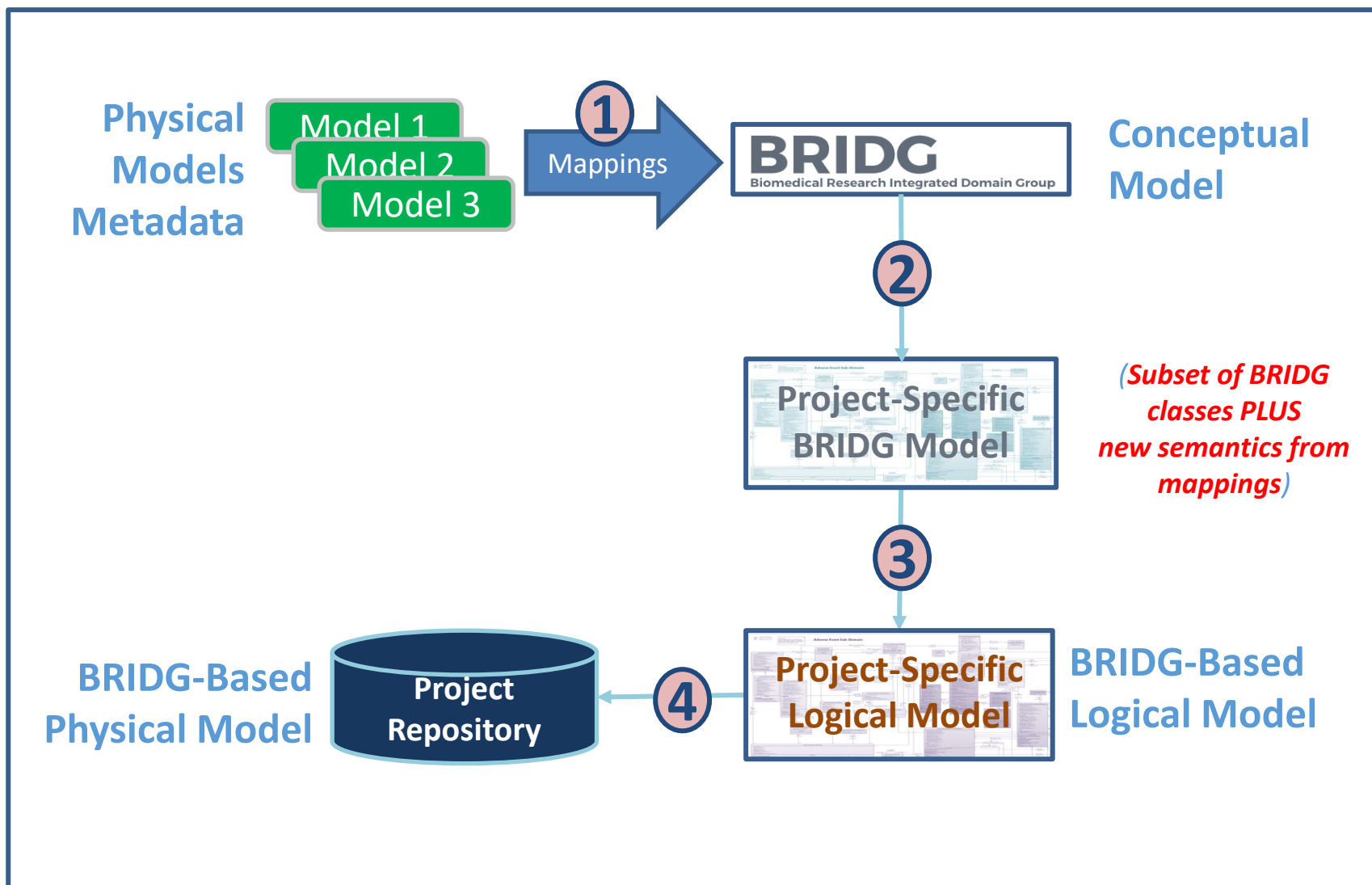
- BRIDG Training: <https://www.cdisc.org/education>
 - CDISC offers BRIDG Deep Dive classes
 - Custom, On-Site classes can be arranged

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