

BRIDG Model Introduction

BRIDG Model

- BRIDG – Biomedical Research Integrated Domain Group Model - <https://bridgmodel.nci.nih.gov>
 - A UML class diagram – provides a visual representation of concepts of a domain and the relationships between the concepts
- Scope is Protocol-driven research and translational sciences research
- Provides rigorous definitions for concepts in clinical research and their relationship to each other
 - Covers Protocol representation, trial design, adverse event, etc.
- Collaborative standard developed by

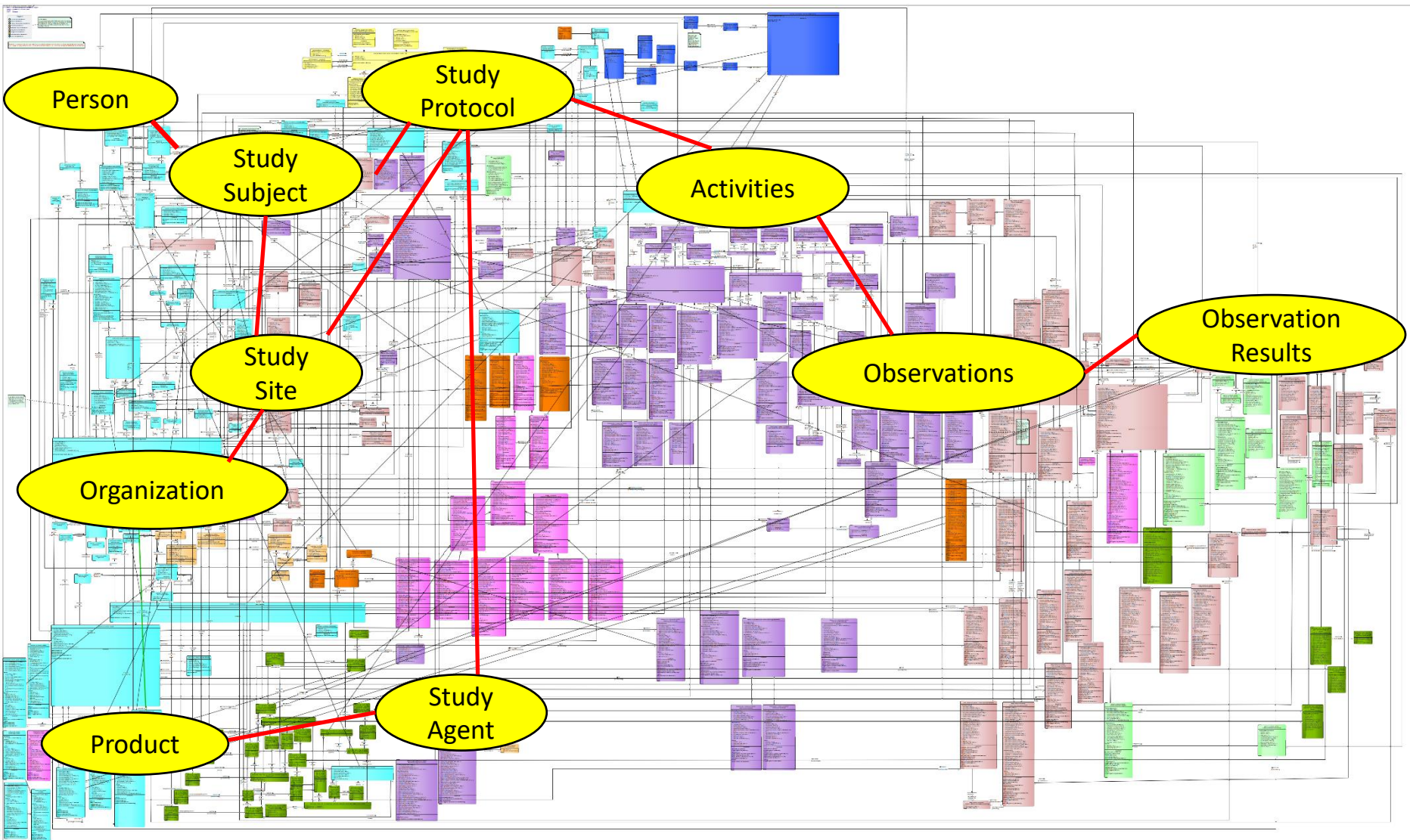


BRIDG Scope & Purpose

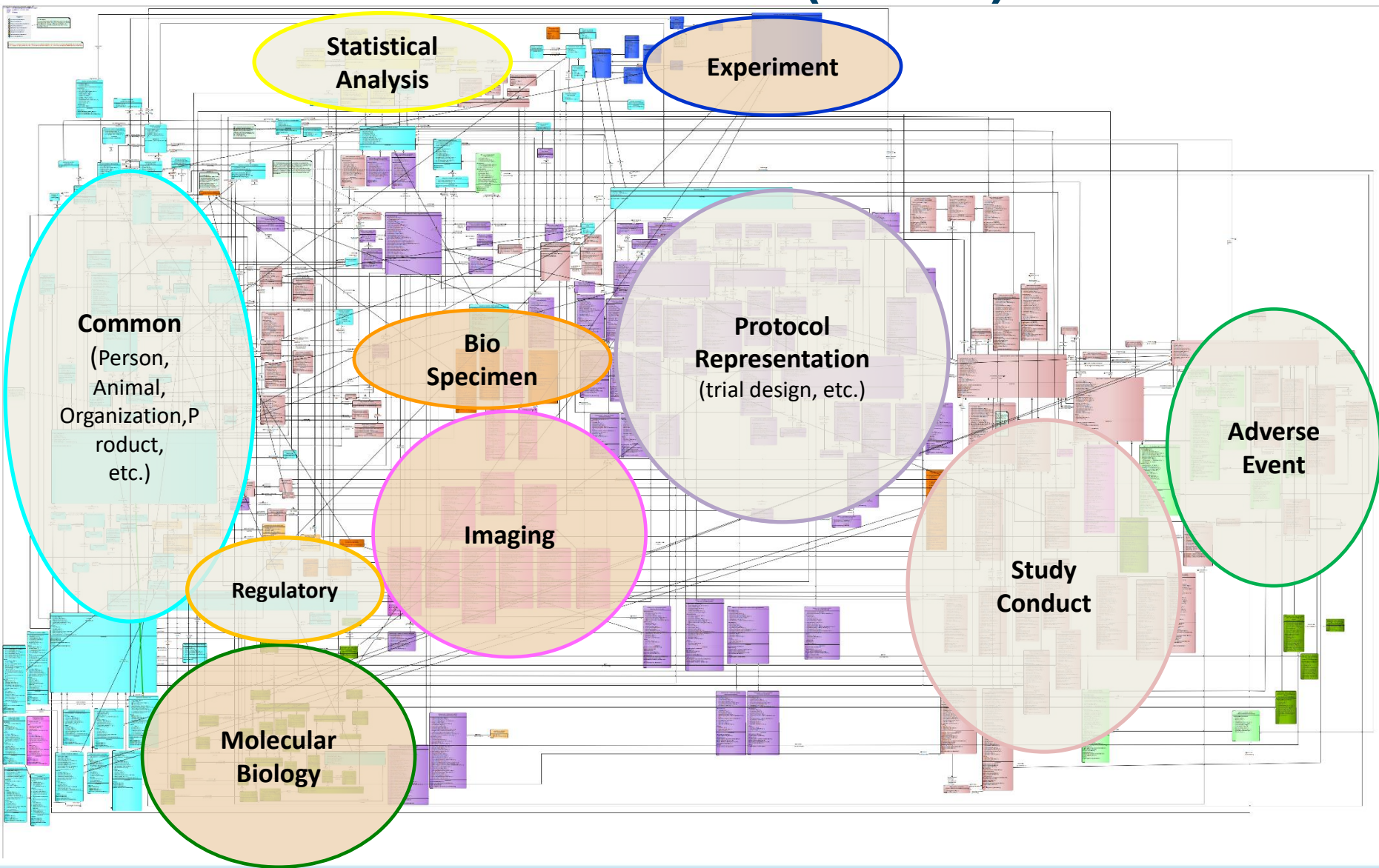
The goal of the BRIDG Model is to produce a shared view of the dynamic and static semantics for the domain of basic, pre-clinical, clinical, and translational research and its associated regulatory artifacts. This domain of interest is further defined as:

- The data, 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, subject characteristic, biologic, cosmetic, food or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with postmarket surveillance and adverse event reporting.
- Purpose is to enable semantic-based interoperability across the translational domain as well among the various stakeholders

BRIDG Model backbone (v 4.1.1)



BRIDG Model Subdomains (v 4.1.1)



BRIDG Sub-domains (*cont'd*)

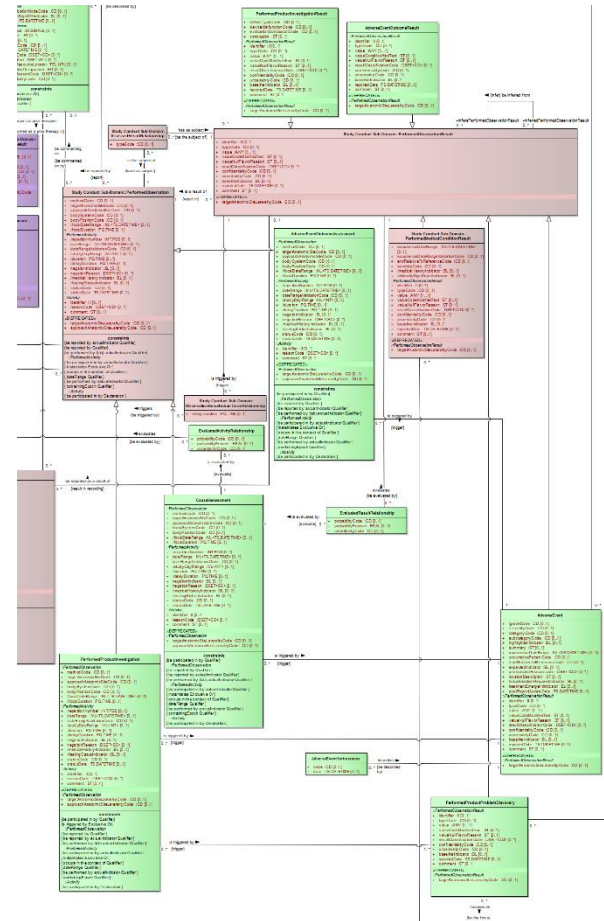
- **Adverse Event:** The Adverse Event sub-domain is intended for those involved in safety related activities; such as detection, evaluation, follow-up and reporting. This includes safety issues involving people or products. It also includes activities during or after a research protocol.
- **Biospecimen:** The Biospecimen sub-domain includes concepts related to a biologic specimen, including collection and processing.
- **Common:** The Common sub-domain represents the semantics that are common to all (or most) of the other sub-domains. For example, it includes semantics for such things as people, organizations, places and materials.
- **Experiment:** The Experiment sub-domain includes concepts related to the design, planning, resourcing and execution of experiments, which are intended to test hypotheses or lead to discoveries.
- **Molecular Biology:** The Molecular Biology sub-domain represents the core concepts related to this domain, including gene, protein, molecular sequence, chromosome, genome, and numerous other related concepts. Also includes the representation of these concepts in bioinformatics resources, such as public databases.

BRIDG Sub-domains

- **Protocol Representation:** The Protocol Representation sub-domain is intended for those involved in the planning and design of a research protocol. The majority of business requirements have come from those involved in clinical trial protocols. It focuses on the characteristics of a study and the definition and association of activities within the protocols, including "arms" and "epochs". It also includes the definitions of the roles that participate in those activities.
- **Regulatory:** The Regulatory sub-domain is intended for those involved in the creation and review of submissions to regulatory authorities. The majority of business requirements come from the regulated product submission (RPS) message specification. It focuses on the documentation required for a product submission to the Food and Drug Administration (FDA).
- **Statistical Analysis:** The Statistical Analysis Sub-Domain includes concepts describing the planning and performance of the statistical analysis of data collected during clinical trial research and their relationships.
- **Study Conduct:** The Study Conduct sub-domain is intended for those involved in the execution of a research study. The majority of business requirements have come from those involved in clinical trials. It focuses on the activities of conducting the study as well as the results from those activities.
- **Imaging (in v 5.0):** The Imaging sub-domain is intended for those involved in interfacing between a clinical trials management system (CTMS) and an imaging system such as a DICOM-based system. The majority of business requirements have come from DICOM and NCI's Annotation and Image Markup (AIM) project. It doesn't intend to replicate all the semantics of imaging studies, series, images, annotations and reports, but rather contains a summary level of key concepts which could serve as search criteria for interfacing between a CTMS and a DICOM-based system.

Concepts in some subdomains

- **Adverse Event:** The Adverse Event sub-domain is intended for those involved in safety related activities; such as detection, evaluation, follow-up and reporting. This includes safety issues involving people or products. It also includes activities during or after a research protocol.
- Key classes:
 - AdverseEvent
 - AdverseEventActionTaken
 - AdverseEventOutcome-Assessment
 - AdverseEventOutcome-Result
 - CausalAssessment
 - EvaluatedActivity
 - EvaluatedResult



Other Information about the Model

- BRIDG is maintained in a Sparx System's Enterprise Architect UML tool
- BRIDG 4.1.1 is the latest BRIDG release -- composed of 296 classes; 796 attributes which are fully annotated with comprehensive definitions and examples
 - Released in July 2016
- Primarily built with a bottom-up approach, i.e. – new semantics are added to the BRIDG model by a process of harmonization. Projects bring their models to the BRIDG Modeling team and the teams work together to harmonize the new semantics into the BRIDG model
- Finally, the BRIDG model is only as rich as the semantics that were/are brought to it by the larger clinical research community.

BRIDG Model and other Standards

- BRIDG is a foundational semantic model that links all the SDTM domains/variables
- BRIDG has the potential to enable an imaging submission package hyperlinked to SDTM results.
 - Review of the BRIDG Imaging concepts can help drive clearer semantics in data submissions
- Mapped to various existing standards
 - CDISC - SDTM, CDASH, SDTM PGx
 - Mapping in progress of various Therapeutic Area (TA) SDTM domains/variables
 - Clinical trials registry semantics (ClinicalTrials.gov, EUDRACT, etc.)
 - HL7 Individual Case Safety Reporting (ICSR) message (Adverse event)
 - DICOM (scoped to CT, MR, PET; Imaging Study and related concepts)
 - Other projects, e.g., Bone marrow trials, etc.

BRIDG and CDISC Standards

- The following CDISC Standards have been harmonized with BRIDG model
 - SDTM IG 3.1.2, 3.1.3
 - CDASH v1.1
 - Protocol Representation Model
 - SDTM IG PGx v1.0
 - Oncology TA domains/variable
- The mappings have been captured as tags in the BRIDG model file

BRIDG as a DIM

- Purpose is to enable semantic-based interoperability across the translational domain as well among the various stakeholders
- BRIDG is referred to as a Domain Analysis Model (DAM) or a Domain Information Model (DIM)
 - A DIM is used as reference material in development of information system interoperability specifications.
 - The DIM is a requirement specification and therefore rich in domain semantics.
 - It is the primary artifact from which information system design specifications are derived.
 - Logical and Physical models can be built from BRIDG. These design models are built by constraining the needed BRIDG classes/attributes/associations that are scoped to a particular set of use cases/business scenarios.
 - The preferred language for expression of a domain analysis model is UML

BRIDG Implementation Approaches

- Reference Model
 - Source for clinical research data semantics & foundation model
- Data Integration/Mapping Solutions
 - One mapping to a standard rather than multiple point to point mappings
- Exchange Format
 - Subsets of BRIDG classes represented in XSD/XML
- Physical Database
 - Generate logical and physical database models in support of clinical research software solutions
- Ontology
 - To develop clinical research ontology

BRIDG Model Website

(<https://bridgmodel.nci.nih.gov>)

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BRIDG

Biomedical Research Integrated Domain Group



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Download BRIDG Releases

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All the BRIDG model release packages can be downloaded by selecting from the Navigation panel at left. You can also view each of these releases in HTML format.

BRIDG Release Packages consists of some or all of the following files under various folders:

- **BRIDG Change List** (mandatory)
 - BRIDG Change List.xls
- **BRIDG Comprehensive Domain Information Model** (mandatory)
 - BRIDG Comprehensive Domain Information Model.eap
 - BRIDG Comprehensive Domain Information Model.pdf
 - BRIDG Comprehensive Domain Information Model.xml
- **BRIDG Documentation** (mandatory)
 - BRIDG Mapping Spreadsheet.xls
 - BRIDG Release Notes.doc
 - BRIDG User's Guide.doc
- **BRIDG OWL Model** (optional, not necessarily updated for every release)
 - BRIDG Comprehensive Domain Analysis Model.owl
- **BRIDG RIM Models** (optional, not necessarily updated for every release)
 - Excel View
 - Graphical View

BRIDG Model html version

- BRIDG 4.1.1
 - <https://bridgmodel.nci.nih.gov/download-model/bridg-releases/release-4-1-1/view-html-version>
- BRIDG 5.0
 - <https://bridgmodel.nci.nih.gov/download-model/bridg-releases/release-50/view-html-version>

HL7 BRIDG Work Group

- BRIDG related issues and items are discussed on the HL7 BRIDG wg
 - bridgwg@lists.hl7.org
- Open items are posted on the BRIDG wiki at
 - <http://wiki.hl7.org/index.php?title=BRIDG>
- Note: In HL7 BRIDG and RCRIM WG are going to be merged by May 2017. The new work group will be called Biomedical Research & Regulation (BR&R)

Thank you!