The Protocol Representation Model
Version 1.0

Prepared by:

The CDISC Protocol Representation Group (PRG)

Revision History

Document Number	Release Date	Updates
Version 1.0	16/April/2009	First version for public comment.
Version 1.01	29/April/2009	Updated model diagram and List of Classes, Attributes, and Their Definitions to include additional classes left out of original document.
Version 1.0 Final	27/January/2010	Updated model and document based on CDISC review and comment process.

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1.0 List of Acronyms and Abbreviations

ASPIRE	Agreement on Standardized Protocol Inclusion Requirements for Eligibility
BRIDG	Biomedical Research Integrated Domain Group
caBIG®	cancer Biomedical Informatics Grid
CDA	Clinical Document Architecture
CDISC	Clinical Data Interchange Standards Consortium
CRA	Clinical Research Associate
CRF	Case Report Form
CTEP	Clinical Trial Evaluation Program (NCI)
E2B	ICH Guideline on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
EMA	European Medicines Agency
EudraCT	European Union Drug Regulating Authorities Clinical Trials
FAET	Federal Adverse Event Task Force (US)
FDA	U.S. Food and Drug Administration
HL7	Health Level 7
ICH	International Conference on Harmonisation
IHE	Integrating the Healthcare Enterprise
IRB	Institutional Review Board
NCI	National Cancer Institute
ODM	CDISC's Operational Data Model
PR	Protocol Representation
PRG	Protocol Representation Group
PRM	Protocol Representation Model
PSC	Patient Study Calendar
RCRIM	Regulated Clinical Research Information Management
SAP	Statistical Analysis Plan
SCTP	Structured Clinical Trial Protocol
SDTM	Study Data Tabulation Model
TDM	Trial Design Model
UML	Unified Modeling Language
WHO	World Health Organization

2.0 Organization of This Document

Section 3 provides an introduction to the Protocol Representation Model (PRM), places it in context, and explains why the PRM was developed as a domain analysis model expressed in the Unified Modeling Language (UML). The introduction explains what the model is and provides context by describing

- Intended uses of the model and their benefits
- The relationship of PRM to regulatory requirements
- The relationship of PRM to other standards, particularly the Biomedical Research Integrated Domain Group (BRIDG)

The reasons for developing PRM in UML are explained by summarizing the history of the project and describing the pros and cons of a domain analysis model in UML compared to the spreadsheet used in early stages of the project.

Sections 4 and 5 provide information about UML for users unfamiliar with this language. Section 4 explains UML notation using examples drawn from the PRM. Section 5 describes the organization and conventions used in the detailed specification.

Section 6 of this document is the detailed specification of the Protocol Representation Model (PRM).

3.0 Introduction to the Protocol Representation Model (PRM) v1.0

The PRM v1.0 is a clinical data standard that identifies, defines, and describes a set of over 100 common protocol elements and the relationships between them. The elements of the PRM are mapped to elements within the BRIDG model, a comprehensive domain analysis model representing the domain of protocol-driven research and its associated artifacts and processes. More information on the BRIDG model is at www.bridgmodel.org. The concept of a domain analysis model is described in Section 3.6 and the relationship between the PRM and BRIDG is further explained below in Section 3.5.1.

3.1 The Protocol Representation Group

The PRM was initiated as a project by leaders from CDISC and FDA within the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee. Medical communication specialists, statisticians, project managers, and other domain experts were recruited from CDISC member companies to augment the initial group and to provide domain expertise, including direct experience with protocol development for regulated clinical research. The resulting group, the PRG, is both an HL7 RCRIM project team and a CDISC team. Additionally, it now includes representatives from the NCI, caBIG®, the World Health Organization (WHO), and 'observers' from FDA and EMEA. It is therefore a multidisciplinary effort, representing the major types of stakeholders in clinical studies. The following organizations have contributed active participants/resources to the PRG since 2002:

Bayer Healthcare	J&J PRD	Sanofi-Aventis
Beardsworth Consulting	Medidata (Fast Track)	Sanofi-Synthelabo
Boehringer-Ingelheim	Memorial Sloan Kettering	SAS
Booz Allen Hamilton	Merck	Seattle Children's
CDISC	NIH, NCI, caBIG	TAP Pharmaceutical Products
City of Hope	Novartis	UCB Group
Digital Infuzion	Novo Nordisk	UCSF Med Ctr
Eli Lilly and Company	Octagon Research	University of Pittsburgh
EMEA	Omnicare	USF
FDA	Oracle	WHO

GlaxoSmithKline	Pfizer	Wyeth
HP	PHT	Zurich Biostatistics
IBM	Quintiles	Sanofi-Aventis
Intrasphere	SAIC	

3.2 Uses of the Protocol Representation Model

The PRM elements were developed so that protocol information could be reused and repurposed across multiple documents, databases, and systems from study start-up through reporting and regulatory submissions. The PRM is NOT a specific protocol template; rather, when a template is designed to meet the purposes of a given organization or study type, the use of the PRM common elements will enable and facilitate information re-use without constraining the design of the study or the style of the document. The PRM elements have been found to be typical across study protocols, but they do not reflect either a minimum or a maximum set of elements.

There are four major components of the PRM v1.0—that is, four major areas of a protocol that the elements are related to:

- **Clinical Trial/Study Registry**: Elements related to the background information of a study, based on the requirements from WHO and Clintrials.gov. Examples of elements in this area include Study Type, Registration ID, Sponsors, and Date of First Enrollment.
- **Eligibility**: Elements related to eligibility criteria such as minimum age, maximum age, and subject ethnicity.
- **Study Design Part 1**: Elements related to a study's experimental design, such as Arms and Epochs.
- **Study Design Part 2**: Elements related to a study's Schedule of Events and Activities.

Additional components of the PRM are under development and planned for future development. Statistical aspects of the protocol are being developed as part of the modeling of a Statistics Domain Analysis Model. The PRG will announce updated versions of the PRM as they become available.

3.3 Expected benefits of the Protocol Representation Model

The primary motivation for developing the PRM grew from the recognition that the protocol is the core to every clinical research study. The protocol is used in designing the study, selecting investigative sites, developing the data collection tools, and describing the study procedures and the analysis plan. Institutional Review Boards (IRBs) use the protocol as the basis for approving study initiation. A well-constructed protocol should ensure common understanding of the study objectives and procedures to be implemented, thereby improving quality and saving time and effort for those using it. Clearly, it is one of the most important documents used in clinical research.

However, the development of a protocol can consume significant company resources and time; particularly when the review group is large or the review process is complex. Leveraging technology can streamline aspects of this process and/or be used to evaluate the internal integrity of a protocol before it is finalized. However, to develop such an application requires that at least certain portions of the protocol are "machine-readable" as well as "human-readable," and implies some commonality among elements across all protocols.

The PRM provides such commonality. Specifically, it provides a common structure for protocols that can be used to streamline the creation, maintenance, sharing, and reuse of a protocol by breaking them down into standard, machine-readable "chunks" or components that can be electronically stored (e.g., in a database). These components can then be updated, shared across disparate systems, and maintained independently of each other. The practical benefit is that developing and maintaining protocols becomes

less time consuming and expensive, and that downstream systems, like those for CRF creation, SAP creation and supply ordering, can be supported with consistent and accurate information.

Furthermore, the PRM helps address the sheer volume of information generated within the biopharmaceutical industry in the form of documents such as protocols, investigator brochures, and statistical and data management plans. As these documents become more numerous and complex, it grows increasingly difficult to search for and find information within and across them, let alone reuse information within them effectively. Transcribing such documents into other documents or databases remains a highly manual, time-consuming process, even though organizations use templates to promote consistency. This is because the key information within most documents is buried in paragraphs of text.

However, by defining the elements of a protocol and the relationships between them, the PRM brings structure to a protocol, and makes it much easier to find key elements that are usually hidden within lengthy textual descriptions. Essentially, the PRM extracts and labels these key elements so they can be searched and read by a computer. Once this is done, protocol information can be readily entered into an information system or online registry that allows key protocol information to be searched, shared, analyzed, reported on, and reused. This would support a range of important clinical research goals, such as increasing transparency in clinical research, providing patients with the ability to find studies in which they are eligible to participate, adhering to study registry requirements, populating study management/tracking systems, sending information to IRBs or Ethics Committees, providing FDA with Study Summary and Study Design information, and writing post-study clinical reports.

Implementations of the model itself have already occurred in the areas listed below. A double star (**) indicates a partial implementation and does not include all of the PRM elements. Some of these may be still under development.

- CDISC SDTM standard** (www.cdisc.org)
- CDISC ODM Study Design extension (www.cdisc.org)
- HL7 Clinical Trial Registration and Results message (www.hl7.org)
- HL7 Study Design message (www.hl7.org)
- caBIG® Patient Study Calendar (PSC) application
  (https://cabig.nci.nih.gov/tools/PatientStudyCalendar)
- ASPIRE (Agreement on Standardized Protocol Inclusion Requirements for Eligibility)
- IHE Retrieve Protocol for Execution profile
  (http://wiki.ihe.net/index.php?title=Retrieve_Form_for_Data_Capture)

3.4 Relationship of the PRM to regulatory requirements

The identification of protocol elements began with examination of the International Conference on Harmonization (ICH) guidances E6, E3, and E9 and the requirements for registration of studies in EudraCT. The ICH E6 guidance on good clinical practice provided an outline of information that should be contained in a protocol, and the E3 guidance on clinical study reports and the E9 guidance on statistical considerations provided further detail. The specifications for registering trials on EudraCT provided protocol elements and terminology. Later work on protocol elements required for clinical trial registration considered the requirements of WHO and clinicaltrials.gov, in addition to those of EudraCT.

Links between PRM elements and requirements were initially documented in the spreadsheet described in Section 3.6.3.

3.5 Relationship of PRM to other standards

3.5.1 The PRM's relationship to BRIDG

The BRIDG model is a model representing the shared semantics of protocol-driven research and its associated regulatory artifacts. Since PRM is a representation of elements of the protocol, it became clear early in the development of BRIDG that the two models would have a great deal in common. In fact, the PRM is now embedded within the BRIDG model, and can be considered a subset of the BRIDG model.

Some background information on the BRIDG is provided here for readers who are unfamiliar with it. The BRIDG model is distinct from the other CDISC models in that it is a formal analysis model of the shared semantics of regulated bio-medical research, and as such requires additional steps to create an implementable standard. The other CDISC standards are implementations, i.e., you use the standard to format your data and exchange it with others. The BRIDG is developed and maintained by an open community of stakeholders who include CDISC, HL7 Regulated Clinical Research Information Management (RCRIM) Workgroup, the National Cancer Institute (NCI), cancer Biomedical Informatics Grid (caBIG®), and the U.S. Food and Drug Administration (FDA).

The aim of the BRIDG Project is to have a shared view of the data, relationships, and processes which collectively define the domain of clinical and pre-clinical protocol-driven research and its regulatory artifacts. In other words, BRIDG is a communication tool for bringing together a variety of stakeholders, and for bridging medical research experts from standards development organizations, government organizations, academia, and the biopharmaceutical industry.

Starting in 2004, CDISC initiated the BRIDG model activity based upon recommendations from an HL7 expert asked to evaluate the best strategy for ensuring a link between CDISC standards for clinical research and the healthcare standards of HL7. The purpose of the BRIDG model was to create a domain analysis model for clinical research—one that domain experts could comprehend, not just those who had technical expertise in HL7.

Not long after the BRIDG modeling was begun by CDISC, with the protocol at its center, the NCI expressed interest in collaborating on this model development. The BRIDG model was actually transformed by focusing specifically on incorporating elements from the PR Elements Spreadsheet and representing them in the BRIDG. As of 2009, most of the elements of the PR Elements Spreadsheet—along with their attributes and appropriate relationships—have been represented in the BRIDG model.

3.5.2 The PRM's relationship to CDISC SDTM

The CDISC Study Data Tabulation Model (SDTM) includes datasets that describe aspects of study plans that are part of the protocol. These datasets, called the Trial Design Model (TDM) datasets, were used as a source of elements for the PRM and BRIDG. Elements from the vocabulary for the Trial Summary SDTM dataset were referenced in the Clinical Trial Registry portion of the PRM.

3.5.3 The PRM's relationship to the HL7 Study Design Message

The Study Design component of the PRM provides much of the standard content for the HL7 Study Design message, a transport standard which is currently under development.

3.6 Rationale for representing PRM in UML

Most users of the protocol are unfamiliar with the idea of a domain analysis model and have no experience of UML, since these were created by software developers. This section explains what a domain analysis model is and its purpose. It also describes the course that led to PRM being developed as a domain analysis model expressed in UML

3.6.1 Domain Analysis Models

To software developers, a domain is a subject matter area for which they will be developing software. Since they may not have any prior knowledge of the domain, they must learn about it from subject matter experts, and then structure what they learn in a form that will support the requirements for the software they will be developing. A domain analysis model is a way to write that knowledge down. It can be used to facilitate discussions with subject matter experts to check that the developer's understanding of the domain is complete and accurate.

In technical terms, a Domain Analysis Model (DAM) is defined as a conceptual set of structured requirements that describe and document a particular domain. The DAM provides a model of objects or entities within the given domain along with their respective descriptive types, attributes and relationships. Collectively they describe the domain. Although founded in software development methodologies, the definition and creation of a DAM can effectively be applied to any domain ontology, or part of the world. For example, we can create a DAM of a home which defines the entities of the home such as the exterior, the interior rooms, electrical system, and appliances found in the kitchen.

The domain analysis model is the first and least technical step in software development. For a particular piece of software, a System Implementation Model (SIM) will be developed from the domain model. A SIM is concerned with the production and automation of abstract use cases, activities, and classifiers specified in the DAM. It utilizes all or some of the entities and relationships as defined in a DAM and applies those to an implementable design. The primary consumers of a DAM are humans, while the primary consumer of a SIM is the technical infrastructure component responsible for transforming the SIM into executable machine code. To continue with the example of the home DAM above, the Implementation Model would be the architectural blueprints and specifications used by the builder to construct the home.

The PRM is a domain analysis model. It represents knowledge about a protocol gathered from subject matter experts. Although the format in which that knowledge is presented will be unfamiliar to many users, the content should be familiar. The content will be found in the definitions of the objects (classes, attributes, and relationships) in the model. For the most part, those definitions are expressed in familiar text form, although parts of the definitions of relationships are expressed in special symbols, which are explained in Section 4.

3.6.2 Summary of PRG history

The PRM has undergone a series of phases to arrive at its current version. The following summary describes in broad strokes what was involved in the model's evolution, and why the PRM is in its current form.

1. The Protocol Representation project was launched in 2002 as an HL7 and CDISC joint project. A group of experts and representatives from various organizations and CDISC member companies was formed (i.e., the Protocol Representation Group, or PRG) to develop the model. See Section 3.6.3 for a list of the organizations who have contributed active participants/resources to the PRG since 2002.
2. Over the years, through a series of meetings, discussions, conferences, and strategic planning efforts, the PRG first created a spreadsheet of common protocol elements, later called the PR Elements Spreadsheet. The section headers in the spreadsheet reflect those from the ICH E6. Sub-sections and then elements were added. The elements were derived from other regulatory authorities worldwide such as EudraCT (European Union Drug Regulating Authorities Clinical Trials).

3. The PRG further elucidated each element with a glossary definition, source of the element (e.g., ICH, EudraCT), suggested code lists and attributes, cardinality, use case application, and other relevant information.
4. Using this hierarchical structure, the PRG was able to develop an extensive protocol glossary and create a structured clinical trial protocol. In this way, the PRM moves a protocol's "unstructured" information from a Word document or PDF and formats it into a series of data fields with attributes and relevant relationships, thereby making it "structured" information. "Structured," in this context, means that the data elements, and the relationships between them, are defined consistently and unambiguously, and are thus computable (i.e., amenable to automated processing) and will enable semantic interoperability (i.e., exchange of content and meaning).
5. The spreadsheet was also used for an initial modeling attempt to develop an HL7 Clinical Document Architecture (CDA) for a Structured Clinical Trial Protocol (SCTP), but the need for an approach that allowed for more complex structuring of data was acknowledged. At this juncture, it was decided that the UML modeling was the better method for developing a PRM.
6. The PRG mapped elements from the PRM to appropriate parts of the BRIDG model. As of the first quarter of 2009, the PRG successfully completed a version of the PRM ready for review, which is a subset of the BRIDG Model.

3.6.3 Relative merits of spreadsheet and UML modeling

This spreadsheet was found to be extremely valuable for capturing information from subject matter experts. It was a tool that used a familiar format and did not require particular technical expertise. Not only did it ensure that the team was including elements required by appropriate sources (e.g. EudraCT, WHO and clinicaltrials.gov for the Trial Registration elements), it also drove the development of the PRM over time. At certain points, PR team members were able to confirm the elements by comparing them to sample protocols. The spreadsheet forced harmonization and collection of definitions for the Glossary.

However, the spreadsheet also had limitations. The most critical of these limitations was that the headers and sub-headers of the spreadsheet provided only *hierarchical* structure. The PRM needed to represent other aspects of relationships between elements and objects such as *multiplicity*, *inheritance*, and *directionality*.

When BRIDG was initiated by CDISC in 2004, it was clear that the protocol was the pivot point for all clinical research studies, whether they are done for regulatory product approval, basic research, observational research, epidemiological studies or other biomedical research purposes. Work on BRIDG thus started with the protocol, and the PRM spreadsheet provided a key source for this UML modeling activity. As the PRM and BRIDG models evolved in parallel, people involved in both efforts decided it would be best to represent the PRM elements within the BRIDG model, which was being developed in UML. It had become clear that UML modeling provided the capability for modeling relationships that the PR spreadsheet lacked.

4.0 Introduction to Basic UML Concepts and Terms

4.1 UML and its use in PRM

The Unified Modeling Language (UML) is an industry-standard language for specifying, visualizing, constructing, and documenting the requirements of software systems. Through UML, developers can visually describe and represent the components and activities of a system they are creating. This is done by using standard lines, arrows, connectors, shapes, and colors to draw diagrams. Generally speaking, there are two major categories of UML diagrams: structure diagrams and behavior diagrams. Within these

categories, there are a variety of diagram types developers can choose from in order to represent the activities of a system.

For the PRM v1.0 modeling effort, the class diagram, in the *structure* diagram category, was selected. Class diagrams are intended to describe the structure, relationships, and characteristics of objects within a system, and these are the aspects of the protocol that were of primary interest.

4.2 How to read UML Class diagrams

A class diagram describes the structure of a system by depicting classes, class attributes, and relationships. A "class" is usually an entity that represents a person, place, or thing. **See Figure 1** below for an example.

In this diagram, classes are represented by yellow boxes or rectangles. The diagram shows a class called Employee and that an Employee has certain attributes (e.g., a "name"). The name of the class and its attribute are represented by dividing the box for a class into two compartments: the top compartment contains the class name, the lower compartment contains one or more attributes. The diagram shows another class named Company, and that a Company has certain attributes, including a name. Classes are often related to each other in some way. Such relationships or associations are depicted by different types of lines connecting the classes. The ends of the lines are labeled with multiplicity values; these tell you about the numeric aspects of that relationship.

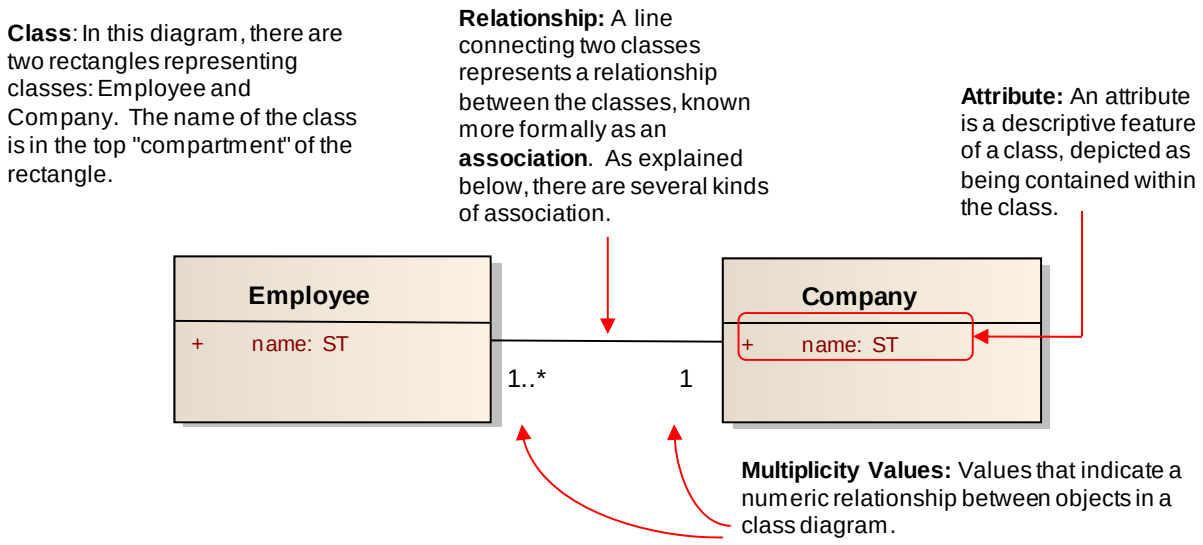


Figure 1: High-level overview of the parts of a class diagram

This diagram communicates, in a succinct form, that there are classes called Employee and Company, and that each of these classes has the attribute "name." Furthermore, the diagram says there is certain kind of relationship between Employee and Company. The details of how that relationship is described, as well as the meaning of the letters "ST" are described in more detail below.

The diagram does not show the definitions of the classes and their attributes. This essential information is part of PRM, although it is not shown in the UML diagrams. When the UML model is viewed with a software tool, the definitions can be displayed in a subsidiary window. In this document, the definitions are in the detailed specification in Section 6.

4.2.1 Attribute names and data types

This section explains the contents of the lower compartment, which describes class attributes, in more detail, using **Figure 2**, below. Most attribute descriptions have at least three parts: an **attribute name**, an **attribute type**, and a **visibility** mark.

In PRM, the visibility mark, which appears in front of the attribute name, is always a plus (+) sign, indicating that the attribute is "public."

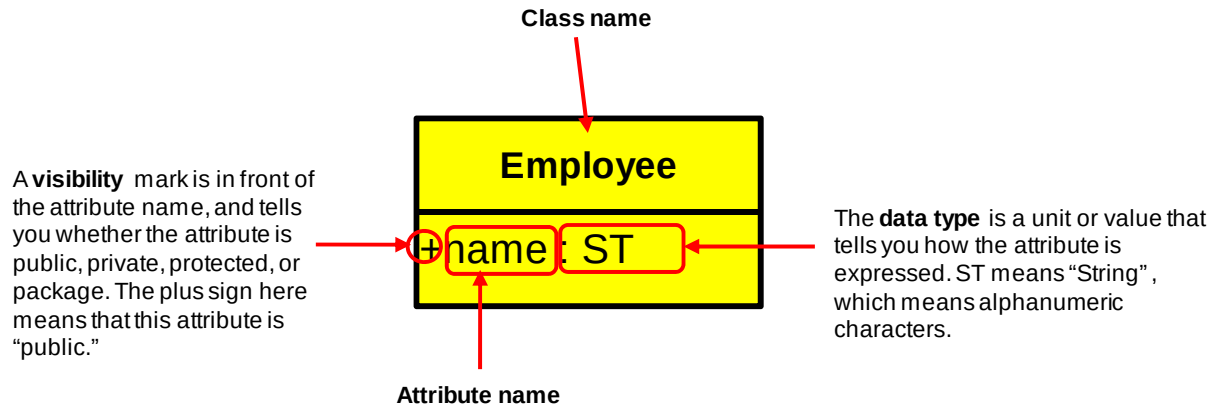


Figure 2: Anatomy of a UML class and its parts

The data type is placed after the name of the attribute. ST, which stands for "String", in particular means that the name attribute must be represented as a set of alphanumeric characters. Other attributes would have other data types, such as "integer" (i.e., numbers only) or "Boolean" (i.e., true or false), as shown in the next example.

4.2.2 Example of an attribute list of a class from the PRM

The InterventionalStudyProtocol class, shown on the next page in **Figure 3**, is one of the most important classes in the PR model. The lower compartment of the class lists the attributes of the class. (See next page.)

Most of these attribute names, such as *accrualReportingMethodCode* and *studySubjectTypeCode*, are relatively self-explanatory to people working in clinical research. The former is a coded value used to represent format on how subject accrual data should be reported back to the study sponsor (e.g., as "complete" or "abbreviated"). The latter is a coded value used to represent the target entity of the study of investigation. For example, in a clinical study, the study subject type would be "human," but in other studies it could be animals such as "rats" or "mice."

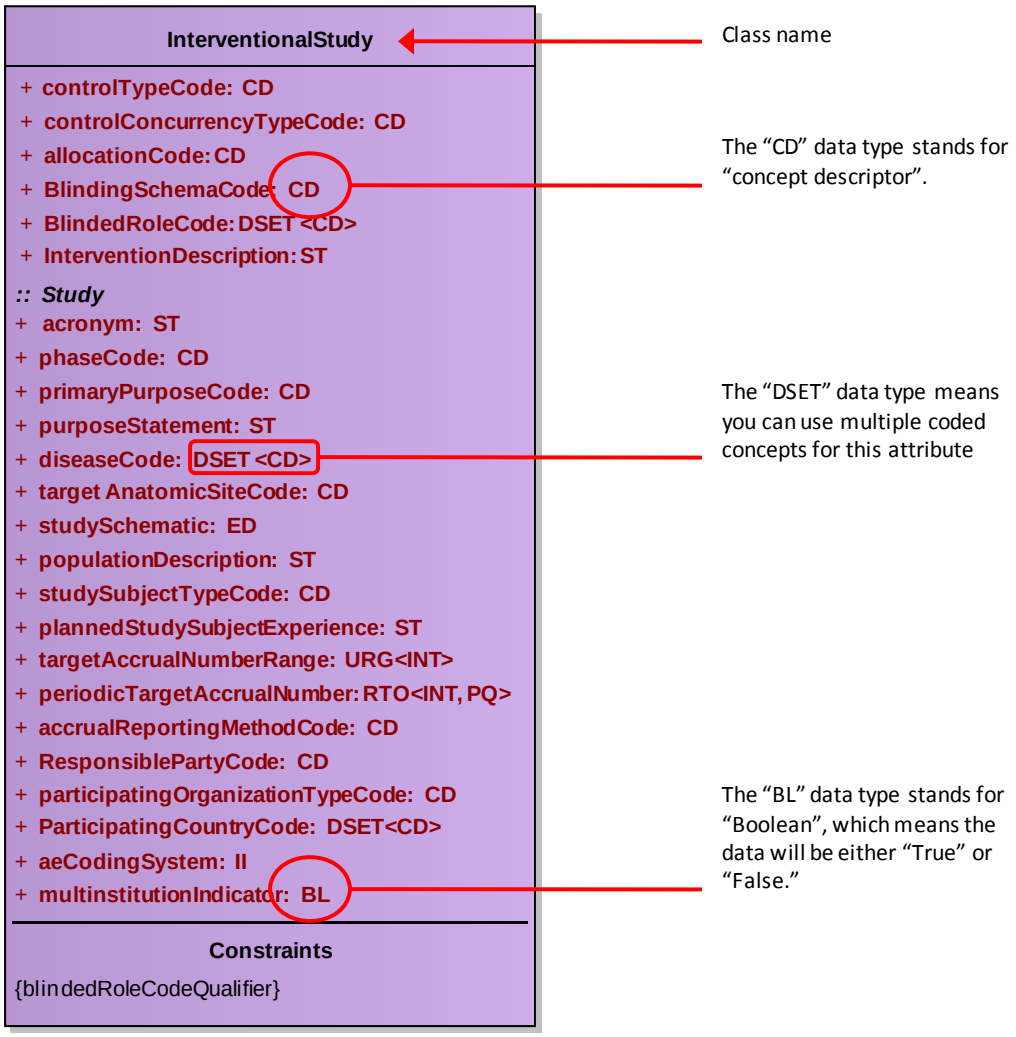


Figure 3: Example attribute list of the InterventialStudy class

Attribute names are written in a style known as camel case, which has no spaces between words and starts each word after the first with an upper case letter. Each attribute has a corresponding data type. These types are all based on the HL7 version 2 Data Types Specification, which can be found on the HL7 web site,
http://www.hl7.org/v3ballot/html/welcome/environment/index.htm. (Use the navigation tree to go to Foundation, then Data Types). Each type indicates what kind of data is used to represent the attribute. For example, look at the attribute, *acceptsHealthyVolunteersIndicator*. You can imagine that this attribute is designed to answer the question, "Does this protocol accept healthy volunteers?" The answer must be

either yes or no. Hence, it makes sense that its data type is BL, or Boolean, which means the data can be expressed as either "true" or "false."

4.2.3 Types of relationships between classes in a UML diagram

The concept of relationships or associations was introduced in the first example above. There are multiple types of associations between classes, including basic and specialization. While the names sound technical, these are relatively simple ideas.

Basic Relationships

A basic relationship means that both classes are aware of each other and their relationship. That is, both class are "known" to each other. A basic relationship is indicated by a solid line between the classes. At either end of the class is a multiplicity value. For example, in the **Figure 4** below, the multiplicity value of 0..* next to StudySubject class means that when an instance of StudySite exists, it can have *zero or more* instances of a StudySubject associated with it. Taken in the context of clinical research, this makes sense. When a study site is activated, it will have no study subjects until the first study subject is enrolled. Moreover, the number of study subjects associated with a study site should be left open-ended in order since the number of study subjects at a study site will vary by protocol.

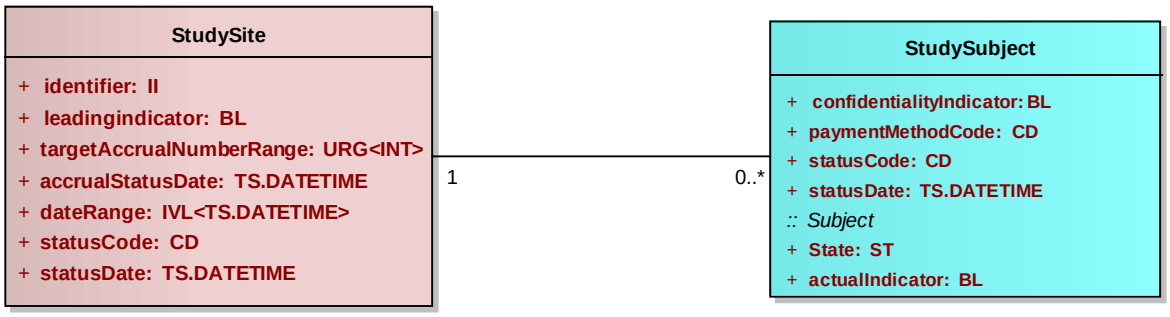


Figure 4: Example of a basic relationship between two classes from the PRM

Conversely, the multiplicity value of 1 next to the StudySite class means that when an instance of StudySubject exists, it can only have one *StudySite* associated with it. This also makes sense in context, because in a particular study, a study subject is not assigned to more than one treatment location. Subjects occasionally change sites during the course of a clinical trial. According to CDISC SDTMIGv3.1.2, the sponsor must decide how to populate the value of SITEID based on their operational and analysis needs. Some sponsors chose the value of SITEID based on where the subject's informed consent was signed.

There are a variety of ways you can designate multiplicity values. A few examples are shown in **Figure 5** below.

Multiplicity Value	Meaning
0..1	Zero or one
1	One only
0..*	Zero or more
*	Zero or more

1..*	One or more
2	Two only
0..6	Zero to six
5..15	Five to fifteen

Figure 5: Example of a basic relationship between two classes from the PRM

Specialization Relationship and Inheritance

Inheritance is the ability of a class to receive or acquire the same exact attributes and functionality of another class, plus its own set of unique attributes and functionalities. This relationship is expressed in terms of "parent" and "child." This terminology is drawn from real world inheritance. A child may inherit a parent's brown hair. However, that same child may be the only one in the family to have blue eyes. Likewise in UML, a class may inherit attributes from a parent class but have additional unique attributes of its own.

In the context of UML, inheritance is shown by drawing a solid line from the child to the parent class. At the end of the solid line is a closed, unfilled triangle (or arrowhead) pointing to the parent class. The child class also includes a listing of the parent class's elements under an italicized heading.

As an example from the BRIDG model, in **Figure 6** below, the InterventionalStudyProtocol class is a "child" to the Study class. This means that, in addition to the full set of attributes inherited from the Study class, the InterventionalStudyProtocol class has additional unique attributes.

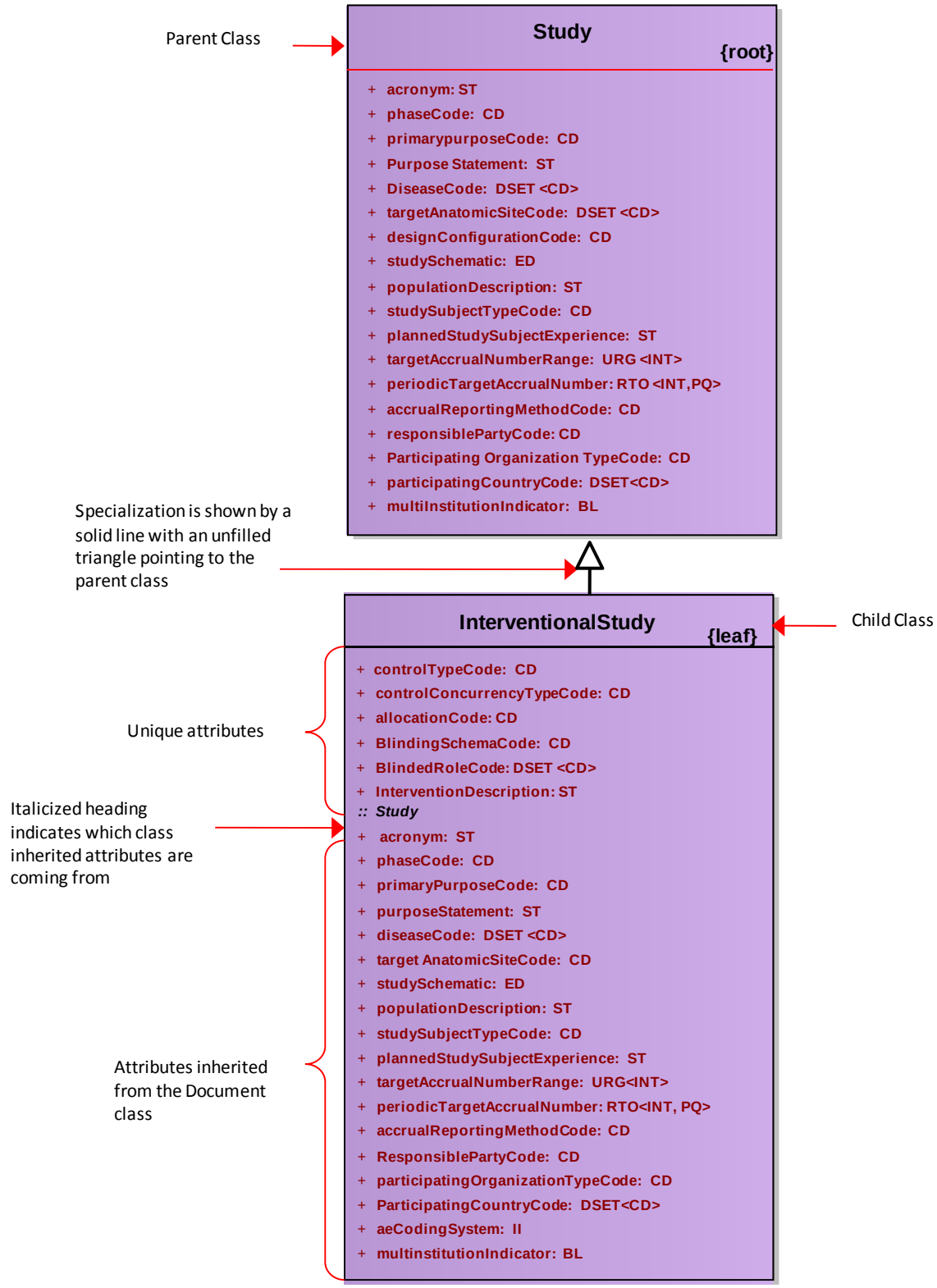


Figure 6: Example of specialization and inheritance within the PRM

Now consider this relationship in context. “Study” is a generic term that could *encompass many kinds* of studies, including studies which do not involve any intervention, such as observational studies like the Framingham heart study. All studies, interventional or not, will have certain attributes, such as a purposeStatement and a targetAccrualNumberRange. An Interventional Study is a *specific type of study* that falls under the broader category of Study. It thus makes sense for the InterventionalStudy class to inherit attributes from the Study class.

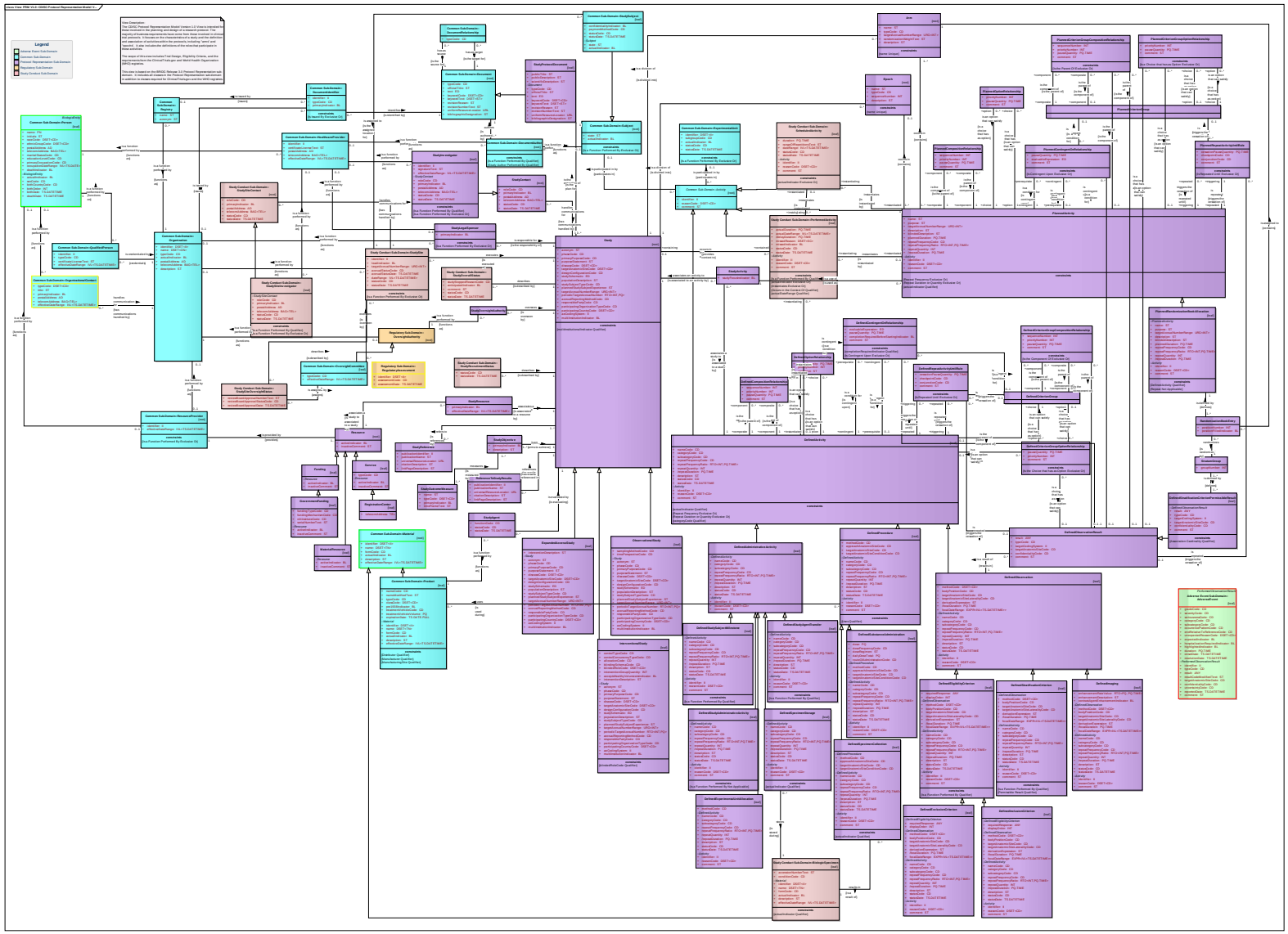
In the list of attributes for a class, those which it does not inherit are presented first. Inherited attributes are listed under the name of the class from which the attributes are inherited. It is possible for a class to have several levels of inherited attributes, i.e., those inherited from the parent class, from the parent class’s parent class, and so on.

5.0 The Complete Protocol Representation Model in UML

The UML diagram below provides a holistic view of the classes, attributes, and relationships of the PRM and its components as represented in the BRIDG model. The diagram is followed by several explanations of how to read and interpret its contents. You can also refer to Section 4.0 for an introduction to UML concepts, which explains some basic UML concepts that will help in deciphering the model.

Please note that a larger version of this diagram is available in an Excel file in the PRM V1.0 posting package on the CDISC website. You can also view the diagram in the modeling tool, Enterprise Architect, which allows resizing and scrolling of the diagram. Sparx Systems (http://www.sparxsystems.com.au/products/ea/index.html) offers a free Enterprise Architect viewer called "EA Lite".

Holistic Overview of the Protocol Representation Model



5.1 The PRM and its representation in the BRIDG model

The group responsible for developing the PRM, the Protocol Representation Group (PRG), harmonized the elements of the PR Elements Spreadsheet with the BRIDG model—i.e., they mapped the elements from this spreadsheet to appropriate elements within the BRIDG model. A sample view of some PR elements and their counterparts in the BRIDG UML model is given below in **Figure 7**.

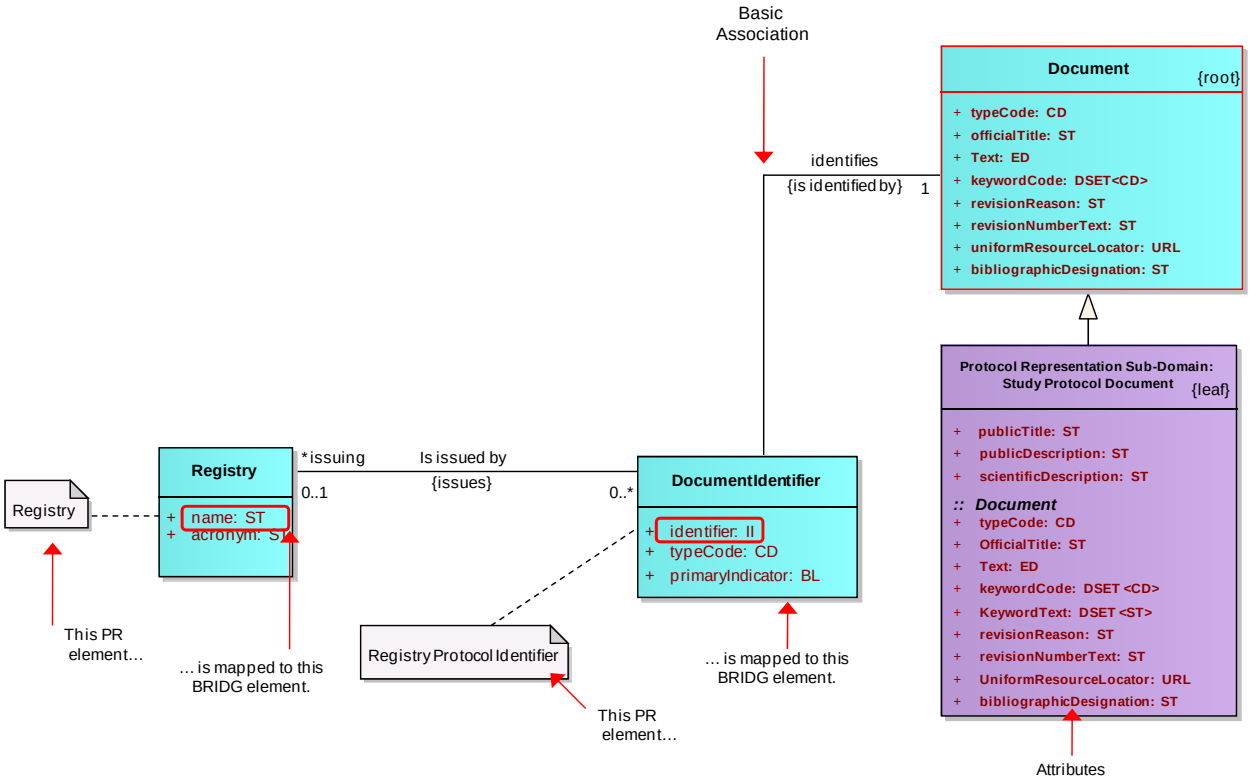


Figure 7: Sample view of how the PRM is actually a subset of the BRIDG model. Note that the white tags are not actual part of the model, but are used to show the mapping between the elements of the PRM and the elements of BRIDG.

If the PRG did not find a corresponding element in BRIDG, they created a new one. This resulted in representing the elements of the PRM in a UML diagram, because the BRIDG model is currently represented as UML class diagram. Although the UML diagram may *look* complex, it is relatively easy to read once you have a working knowledge of UML basics. (An overview of UML basics is provided in Section 4.0 and information on the historical development of the PRM is in Section 3.6.2.) In the sections that follow, more information is provided on the historical development of the PRM, as well as how to read and interpret the PRM as represented in UML.

5.2 Reading the model

5.2.1 Help on reading the diagrams

For an introduction to the UML concepts you will need in order to read and understand the diagram, see Section 4.0 above. In short, there are three important things to know: (1) Each rectangle in the diagram is

a “class” that has “attributes.” (2) Classes are commonly used in UML diagrams to represent “entities,” i.e., a unit that is either a person, place, or thing. (3) The lines between the rectangles represent a variety of “associations” or relationships between the classes, and these lines define how the classes interact or relate to each other. For guidance on how to interpret the different types of associations between classes in the PRM, see Section 4.2.3.

5.2.2 Help on reading the detailed specifications

The definitions of classes and attributes in the detailed specification in Section 6.0 are generated automatically by the software in which the model is maintained. The following notes will hellp in finding information about objects in the diagram in the detailed specification.

- Classes are listed in alphabetical order. For each class, a definition, a table of connectors, a table of attributes and a list of mappings are included.
- The table of connectors between a class and other classes includes the connector type in the column labelled “Connector”.
    - A connector type of “Generalization” indicates an inheritance relationship, as described in section 4.2.3. Information in the “Source” and “Target” columns will tell you which class is the parent, and which is the child.
    - A connector type of “Association” indicates a basic association relationship as described in Section 4.2.3. The name of the association is beneath the connector type. The “Source” and “Target” columns tell you the source and target class names, the class role, the multiplicity, whether the class role is an ordered list (all in PRM V1.0 are “unordered”), and whether the role is subject to change (all PRM V1.0 roles are “none”, which means the changeability is not specified).
- The table of attributes for a class lists only those unique to the class. Attributes inherited from other classes will be listed under those classes. Each attribute also includes a list of mappings that indicates the source project(s) and project attribute that provided the semantics for that attribute.
- The list of mappings includes the source projects that provided the semantics for that class. The legend for the source mapping project is below:
    - CTOM – NCI’s Clinical Trial Object Model
    - SDTM IG – CDISC’s Study Data Tabulation Model Implementation Guide 3.1.1
    - HL7SP – FDA’s HL7 Study Participation Message
    - HL7SD – FDA’s HL7 Study Design Message
    - Lab – CDISC’s and NCI’s Lab Models
    - AE – Adverse Events (CDISC, NCI, FAET, FDA)
    - C3PR – NCI’s Cancer Central Clinical Patient Registry
    - PSC – NCI’s Patient Study Calendar
    - COPPA – NCI’s Correlations, Organizations, People and Protocol Abstraction
    - CTGOV – United States Government’s clinicaltrials.gov
    - WHO – World Health Organization’s protocol registry

5.2.3 Study Lifecycle and the Temporal Grouping of Activities into "Pillars"

The CDISC Protocol Representation Model Version 1.0 View is intended for those involved in the planning and design of a research protocol. Consequently, the model represents several temporal stages of study activities. As a domain analysis model, the BRIDG SCC tries to represent each concept in a domain friendly way, but also in an analytically rigorous way. Thus the team has attempted to represent each concept once, in the temporal context in which it originates and link to it in other temporal contexts as needed. So for instance, most activities included in a study are not completely brand new, rather they are usually common tests or procedures, or they may be composite activities that are composed of several component activities that form a treatment strategy. These activities can be defined once and referenced in many different studies to save the time and effort of re-entering data and, more importantly, to make the semantic connection between an activity being used in two different studies or at two different points in the same study. This notion of activities being defined once and referenced in many studies is the core idea of the DefinedActivity class and its subclasses. These are reusable concepts that essentially form a global library of activities that can be referenced in studies being planned, implemented, executed and evaluated. This part of the model is what the BRIDG SCC calls the "Defined Pillar".

When these defined activities are used in the context of a particular study plan, they are associated to the PlannedActivity class. Any new semantics that are needed for the context of a particular study plan appear as subclasses of or associations to PlannedActivity. For instance, the notion of allocating subjects to arms on a study is a DefinedActivity, but when in the context of a particular study, the method chosen is Randomization, there is a study-specific association to the Randomization positions or slots and the stratum groups with which they are associated. This part of the model is called the "Planned Pillar" and forms what is commonly called the study calendar.

Similarly, when the plan of activities is applied to a particular subject to generate a schedule of activities, the PlannedActivities are referenced by the ScheduledActivities. The "Scheduled Pillar" consists of a single class that references the planned activity that has been scheduled and captures the intended timing of the activities for a specific subject, forming the subject-specific study calendar.

The "Performed Pillar" represents the execution of activities for actual subjects and the results that come out of those activities. The details of these activities may be different than planned so this set of classes captures the actual values for a substance administration, for instance, and the actual date of activities which may differ from what was originally scheduled if an adverse event occurs. The PerformedActivities reference the ScheduledActivities that they fulfill, the PlannedActivities in cases where the activities wasn't actually scheduled such as for contingent activities only performed if there is an adverse event, and DefinedActivities in cases of totally unplanned activities such as when a subjects breaks a leg and has to have a surgery that is considered study-relevant due to possible drug interactions.

From the above descriptions, it should be clear that the "pillars" are essentially related areas of the model and that naming them helps provide language to discuss issues that occur during the lifecycle of the study.

5.2.4 Rectangle colors

BRIDG 3.0 is divided into into several sub-domains, and uses colors to represent the primary sub-domain to which a class primarily belongs. Most of the classes in the PRM are purple, the color of the BRIDG Protocol Representation domain. A few classes are blue, indicating they are from the Common sub-domain, a set of classes which are used in multiple sub-domains. A few classes are gold, indicating its primary location is the Regulatory sub-domain, and a few are pink, from the Study Conduct sub-domain. **Figure 8** below shows the meaning of each class color.

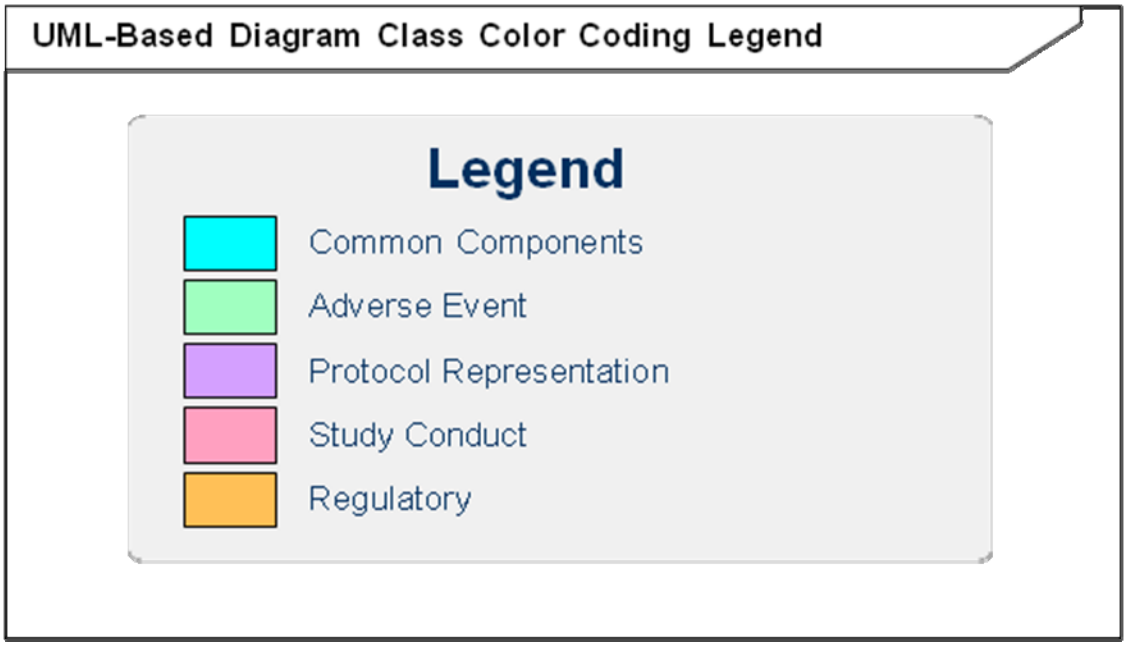


Figure 8: BRIDG Sub-domain Class Color Coding Legend

6.0 Protocol Representation Model V1.0

The CDISC Protocol Representation Model Version 1.0 View 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.

The scope of this view includes Trial Design, Eligibility Criteria, and the requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries.

This view is based on the BRIDG Release 3.0 Protocol Representation sub-domain. It includes all classes in the BRIDG Protocol Representation sub-domain plus some classes from other BRIDG sub-domians, generally classes required for ClinicalTrials.gov and the WHO registries.

Please note that a larger version of this diagram is available in an Excel file in the PRM V1.0 posting package on the CDISC website. You can also view the diagram in the modeling tool, Enterprise Architect, which allows resizing and scrolling of the diagram. Sparx Systems (http://www.sparxsystems.com.au/products/ea/index.html) offers a free Enterprise Architect viewer called "EA Lite".

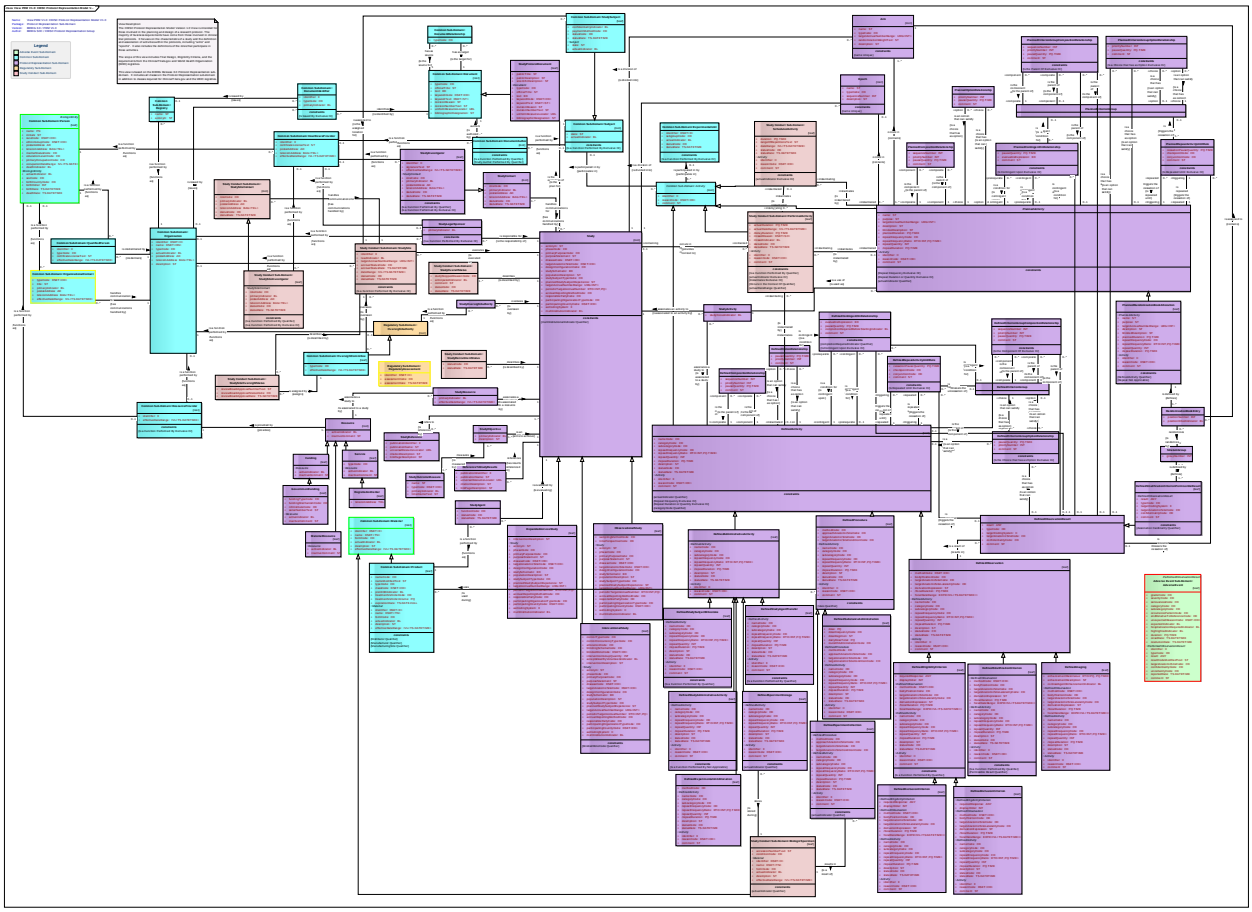


Figure 8 : View PRM V1.0: CDISC Protocol Representation Model V1.0

6.1 Adverse Event Sub-Domain::AdverseEvent

public Class {leaf}

Extends: PerformedObservationResult. :

Any unfavorable and unintended sign, symptom, disease, or other medical occurrence with a temporal association with the use of a medical product, procedure or other therapy, or in conjunction with a research study, regardless of causal relationship.

For example, death, back pain, headache, pulmonary embolism, heart attack.

Adverse Event Sub-Domain::AdverseEvent Connections

Connector	Source	Target	Notes
Association is triggered by	AdverseEventOutcomeAssessment +triggered 0..*, unordered, none	AdverseEvent +triggering 1, unordered, none	Each AdverseEventOutcomeAssessment always is triggered by one AdverseEvent. Each AdverseEvent sometimes triggers one or more AdverseEventOutcomeAssessment. *Constraints* Inverse Relation: triggers
Association is triggered by	AdverseEventActionTaken +triggered 0..*, unordered, none	AdverseEvent +triggering 1, unordered, none	Each AdverseEventActionTaken always is triggered by one AdverseEvent. Each AdverseEvent sometimes triggers one or more AdverseEventActionTaken. *Constraints* Inverse Relation: triggers
Association is triggered by	CausalAssessment +triggered 0..*, unordered, none	AdverseEvent +triggering 1, unordered, none	Each CausalAssessment always is triggered by one AdverseEvent. Each AdverseEvent sometimes triggers one or more CausalAssessment. *Constraints* Inverse Relation: triggers
Association is triggered by	PerformedProductInvestigation +triggered 0..*, unordered, none	AdverseEvent +triggering 1, unordered, none	Each PerformedProductInvestigation always is triggered by one AdverseEvent. Each AdverseEvent sometimes triggers one or more PerformedProductInvestigation. NOTE: The investigation may also involve either a subject, a study subject or an experimental unit as a focus of activity. *Constraints* Inverse Relation: triggers

Connector	Source	Target	Notes
Association describes	SafetyReport +describing 1..*, unordered, none	AdverseEvent +described 0..1, unordered, none	Each SafetyReport sometimes describes one AdverseEvent. Each AdverseEvent always is described by one or more SafetyReport. *Constraints* Inverse Relation: is described by
Generalization source > target	AdverseEvent Child	PerformedObservationResult Parent	

Adverse Event Sub-Domain::AdverseEvent Attributes

Attribute	Type	Notes
gradeCode	public : *CD*	A coded value specifying the level of injury suffered by the subject for whom the event is reported. For example, the gradeCode could be 3 if the CTCAE coding system is being used. Map:AE = 'AdverseEvent.gradeOrSeverity' Map:CTOM = 'AdverseEvent.ctcGradeCode' Map:CTOM = 'AdverseEvent.ctcGradeCodeSystem' Map:SDTM IG = 'AE.AETOXGR'
severityCode	public : *CD*	A coded value specifying the intensity of the event.For example, moderate could be used to describe acne. Map:AE = 'AdverseEvent.gradeOrSeverity' Map:SDTM IG = 'AE.AESEV'
seriousnessCode	public : *CD*	A coded value specifying the degree or extent of the consequence suffered by the subject. For example, resulted in death, required hospitalization, was life threatening. Map:AE = 'AdverseEvent.seriousnessCode' Map:AE = 'AdverseEvent.hospitalizationRequiredIndicator' Map:CTOM = 'AdverseEvent.seriousReasonCode' Map:SDTM IG = 'AE.AESHOSP' Map:SDTM IG = 'AE.AESER'
categoryCode	public : *CD*	A coded value specifying a classification of the adverse event.For example, bleeding, hypoglycemia.NOTE: Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model. Map:COPPA = 'InterventionalStudyProtocol.interventionTypeCode' Map:COPPA = 'SubstanceAdministration.categoryCode' Map:COPPA = 'PlannedActivity.categoryCode' Map:COPPA = 'PlannedObservation.categoryCode' Map:COPPA = 'PlannedEligibilityCriterion.categoryCode' Map:COPPA = 'Activity.categoryCode' Map:CTOM = 'Activity.type' Map:CTOM = 'Surgery.name' Map:CTOM = 'SpecimenAcquisition.type'

Attribute	Type	Notes
		Map:CTOM = 'Surgery.startDate' Map:CTOM = 'Radiation.type' Map:CTOM = 'Surgery.anatomicSiteCodeSystem' Map:CTOM = 'Surgery.reasonCode' Map:CTOM = 'SubstanceAdministration.name' Map:CTOM = 'Surgery.durationUnitOfMeasureCode' Map:CTOM = 'Surgery.durationValue' Map:CTOM = 'SubstanceAdministration.type' Map:CTOM = 'Procedure.type' Map:CTOM = 'Imaging.type' Map:CTOM = 'Surgery.stopDate' Map:CTOM = 'Surgery.type' Map:CTOM = 'Surgery.anatomicSiteCode' Map:CTOM = 'Surgery.descriptionText' Map:Lab = 'Activity.typeModifier' Map:Lab = 'SubjectAssignment.type ' Map:PSC = 'ActivityType.name' Map:SDTM IG = 'DS.DSCAT' Map:SDTM IG = 'QS.QSCAT' Map:SDTM IG = 'DA.DACAT' Map:SDTM IG = 'LB.LBCAT' Map:SDTM IG = 'CM.CMCAT' Map:SDTM IG = 'PE.PECAT' Map:SDTM IG = 'VS.VSCAT' Map:SDTM IG = 'EG.EGCAT' Map:SDTM IG = 'MH.MHCAT' Map:SDTM IG = 'EX.EXCAT' Map:SDTM IG = 'TI.IECAT' Map:SDTM IG = 'SC.SCCAT' Map:SDTM IG = 'SU.SUCAT' Map:SDTM IG = 'IE.IECAT'
subcategoryCode	public : *CD*	A coded value specifying a subdivision within a larger category of an adverse event.For example, neurologic.NOTE: Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model. Map:COPPA = 'Activity.subcategoryCode' Map:COPPA = 'PlannedActivity.subcategoryCode' Map:COPPA = 'SubstanceAdministration.subcategoryCode' Map:COPPA = 'PlannedObservation.subcategoryCode' Map:COPPA = 'PlannedEligibilityCriterion.subcategoryCode' Map:CTOM = 'Surgery.type' Map:Lab = 'Activity.typeModifier' Map:SDTM IG = 'VS.VSSCAT' Map:SDTM IG = 'MH.MHSCAT' Map:SDTM IG = 'IE.IESCAT' Map:SDTM IG = 'CM.CMSCAT' Map:SDTM IG = 'LB.LBSCAT' Map:SDTM IG = 'QS.QSSCAT' Map:SDTM IG = 'EX.EXSCAT' Map:SDTM IG = 'SU.SUSCAT' Map:SDTM IG = 'EG.EGSCAT' Map:SDTM IG = 'PE.PESCAT'

Attribute	Type	Notes
		Map:SDTM IG = 'DA.DASCAT' Map:SDTM IG = 'SC.SCSCAT' Map:SDTM IG = 'DS.DSSCAT' Map:WHO = 'Intervention(s)'
occurrencePatternCode	public : *CD*	A coded value specifying the time recurrence by which an adverse event occurs. For example, intermittent. Map:AE = 'AdverseEvent.patternCode' Map:CTOM = 'AdverseEvent.conditionPatternCode' Map:SDTM IG = 'AE.AEPATT'
endRelativeToReferenceCode	public : *CD*	A coded value specifying when this adverse event ended with respect to the sponsor-defined reference period. For example, before, during, during/after, after, etc.NOTE: If the reference period is computably represented, AdverseEvent.endRelativeToReferenceCode is conceptually derivable based on the reference period and the resolution date of the adverse event.NOTE: Sponsors should define the reference period in the study metadata.NOTE: This may be populated when a start date is not. Map:SDTM IG = 'AE.ENRF'
unexpectedReasonCode	public : *DSET<CD>*	A coded value specifying the representation of the criteria for determining whether an adverse event (experience or reaction) is considered unanticipated. For example, severity, frequency, or specificity from what has been previously documented. Map:AE = 'AdverseEvent.unexpectedReason'
expectedIndicator	public : *BL*	Specifies whether the specificity (nature), frequency, or severity of an adverse event is consistent with the applicable study documentation (e.g., investigator's brochure, protocol document, or consent document) or product labeling (package insert). Map:COPPA = 'AdverseEvent.expectedIndicator'
hospitalizationRequiredIndicator	public : *BL*	Specifies whether the subject requires hospitalization as a result of the adverse event. Map:AE = 'AdverseEvent.hospitalizationRequiredIndicator' Map:SDTM IG = 'AE.AESHOSP'
highlightedIndicator	public : *BL*	Specifies whether the adverse event or reaction term is a major concern or reason for reporting the adverse event. Map: AE = 'AdverseEvent.highlightedIndicator'
duration	public : *PQ.TIME*	The length of time of an adverse event. For example, 1 day, 2 hours.NOTE: This is used only when duration is collected on the CRF and not derived from start and end date/times. Map:SDTM IG = 'AE.DUR'

Attribute	Type	Notes
onsetDate	public : *TS.DATETIME*	The date (and time) on which an adverse event began. NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:AE = 'AdverseEvent.onsetDate' Map:CTOM = 'AdverseEvent.onsetDate' Map:SDTM IG = 'AE.AESTDTC'
resolutionDate	public : *TS.DATETIME*	The date (and time) when the adverse event ends or returns to baseline.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:AE = 'AdverseEvent.resolutionDate' Map:CTOM = 'AdverseEvent.resolvedDate' Map:SDTM IG = 'AE.AEENDTC'

Tagged Values

- Map:AE = AdverseEvent.adverseEventTermCode.
- Map:AE = AdverseEvent.baselineDate.
- Map:AE = AdverseEvent.
- Map:AE = AdverseEvent.reactionText.
- Map:AE = AdverseEvent.bodyLocation.
- Map:CTOM = AdverseEvent.descriptionText.
- Map:CTOM = AdverseEvent.outcomeCode.
- Map:SDTM IG = AE.AEDECOD.
- Map:SDTM IG = AE.AETERM.
- Map:SDTM IG = AE.AEMODIFY.
- Map:TDM = Incidents.

6.2 Common Sub-Domain::Activity

public abstract Class {root}:

Any action that can, in the context of a study, be planned, scheduled or performed.

For example, a surgical procedure, a laboratory test, or the administration of the drug.

Common Sub-Domain::Activity Connections

Connector	Source	Target	Notes
Association is participated in by	Activity +involving 0..*, unordered, none	Subject +involved 0..1, unordered, none	Each Activity sometimes is participated in by one Subject. Each Subject sometimes participates in one or more Activity. *Constraints* Inverse Relation: participates in *Tagged Values* Map:C3PR: StudySubject.identifier Map:C3PR: StudySubject.state

Connector	Source	Target	Notes
			Map:CTOM: Participant.employmentStatusCode Map:C3PR: StudySubject.statusDateRange Map:C3PR: StudySubject.status Map:CTOM: Participant.householdIncomeCode Map:C3PR: StudySubject.actualSubjectIndicator Map:AE: InvestigativeSubject.gestationPeriod Map:CTOM: StudyParticipantAssignment.enrollmentAge Map:CTOM: Participant.employmentStatusOtherText Map:CTOM: StudyParticipantAssignment.eligibilityWaiverReasonText Map:AE: Person.numberOfSiblings
Association is participated in by	Activity +involving 0..*, unordered, none	ExperimentalUnit +involved 0..1, unordered, none	Each Activity sometimes is participated in by one ExperimentalUnit. Each ExperimentalUnit sometimes participates in one or more Activity. *Constraints* Inverse Relation: participates in *Tagged Values* Map:C3PR: StudySubject.subgroup
Association performs	Performer +performing 0..*, unordered, none	Activity +performed 1..*, unordered, none	Each Performer always performs one or more Activity. Each Activity sometimes is performed by one or more Performer. *Constraints* Inverse Relation: is performed by
Generalization source > target	ScheduledActivity Child	Activity Parent	
Generalization source > target	DefinedActivity Child	Activity Parent	
Generalization source > target	PerformedActivity Child	Activity Parent	*Tagged Values* Map:HL7SP: Study.evaluation

Connector	Source	Target	Notes
Generalization source > target	PlannedActivity Child	Activity Parent	

Common Sub-Domain::Activity Attributes

Attribute	Type	Notes
identifier	public : *II*	A unique symbol that establishes identity of an activity.For example, 12345 is the identifier for a substance administration. Map:COPPA = 'PlannedEligibilityCriterion.identifier' Map:COPPA = 'Activity.identifier' Map:COPPA = 'PlannedObservation.identifier' Map:COPPA = 'PlannedActivity.identifier' Map:COPPA = 'SubstanceAdministration.identifier' Map:Lab = 'Activity.identifier'
reasonCode	public : *DSET<CD>*	A coded value specifying the motivation, cause, or rationale of an activity. For example, routine requirement, drug reaction, infectious disease reporting requirement, on patient request, etc. Map:AE = 'ProductInvestigation.reasonCode' Map:AE = 'Indication' Map:COPPA = 'Activity.reasonCode' Map:COPPA = 'PlannedActivity.reasonCode' Map:COPPA = 'PlannedEligibilityCriterion.reasonCode' Map:COPPA = 'PlannedObservation.reasonCode' Map:COPPA = 'SubstanceAdministration.reasonCode' Map:CTOM = 'SubstanceAdministration.reasonCode' Map:CTOM = 'Procedure.reasonCode' Map:CTOM = 'StudyParticipantAssignment.offStudyReasonCode' Map:CTOM = 'Activity.reasonCode' Map:CTOM = 'SpecimenAcquisition.reasonCode' Map:CTOM = 'Imaging.reasonCode' Map:CTOM = 'Surgery.reasonCode' Map:CTOM = 'FemaleReproductiveCharacteristic.menopauseReasonCode' Map:CTOM = 'Radiation.reasonCode' Map:CTOM = 'FemaleReproductiveCharacteristic.menopauseReasonOtherText' Map:CTOM = 'StudyParticipantAssignment.offStudyReasonOtherText' Map:Lab = 'Activity.reason' Map:PSC = 'Scheduled.reason' Map:PSC = 'ScheduledEventState.reason' Map:PSC = 'Occurred.reason' Map:SDTM IG = 'CM.CMINDC' Map:SDTM IG = 'DS.DSTERM' Map:TDM = 'ContactActivityPurpose.purposeType'
comment	public : *ST*	Additional description of the activity. AE:Exclude = 'True'

		Map:COPPA = 'PlannedActivity.comment' Map:COPPA = 'SubstanceAdministration.comment' Map:COPPA = 'PlannedObservation.comment' Map:COPPA = 'Activity.comment' Map:COPPA = 'PlannedEligibilityCriterion.comment' Map:CTOM = 'HistopathologyGrade.commentText' Map:Lab = 'Specimen.commentsFromLaboratory' Map:Lab = 'Specimen.commentsFromInvestigator' Map:Lab = 'LabTest.comments' Map:PSC = 'ScheduledEvent.notes'

Tagged Values

- Map:AE = Activity.
- Map:COPPA = Activity.
- Map:CTOM = Participant.householdIncomeCode.
- Map:CTOM = Participant.employmentStatusOtherText.
- Map:CTOM = Participant.employmentStatusCode.
- Map:HL7SP = Study.Evaluation.
- Map:Lab = LabResult.referenceRangeComments.
- Map:SDTM IG = MH.MHSCAT.
- Map:SDTM IG = DM.RFSTDTC.
- Map:SDTM IG = MH.CAT.

6.3 Common Sub-Domain::Document

public Class {root}:
A collection (physical or logical) of data with the following characteristics:
1) Stewardship, 2) Potential for authentication, 3) Wholeness, 4) Human readability, 5) Persistence, 6) Global vs local context (the person that signs it is the author of all sections unless otherwise noted).

For example, regulatory processes require the submission of documents from the Applicant to the Regulatory Authority. These documents are varied in focus and are often defined by the field of study or by the regulatory application requirements of the region or Regulatory Authority (e.g., Integrated Summary of Safety, Pharmacokinetics Written Summary).

For example, Adverse Event Report, Expedited Adverse Event Report, IRB Report, X-Ray Report, Lab Summary Report, Autopsy Report, etc.

Common Sub-Domain::Document Connections

Connector	Source	Target	Notes
Association identifies	DocumentIdentifier +identifying 0..*, unordered, none	Document +identified 1, unordered, none	Each DocumentIdentifier always identifies one Document. Each Document sometimes is identified by one or more DocumentIdentifier. *Constraints* Inverse Relation: is identified by *Tagged Values* Map:SDTM IG: LB.STUDYID Map:HL7SP: Study.id Map:AE: SafetyReport.identifier Map:COPPA: Document.identifier Map:COPPA:

Connector	Source	Target	Notes
			ObservationalStudyProtocol.identifier Map:Lab: Study.identifier Map:AE: SafetyReport.initialReportIndicator Map:SDTM IG: TI.STUDYID Map:AE: SafetyReport.narrativeText Map:SDTM IG: PE.STUDYID Map:HL7SP: PlannedStudy.id Map:SDTM IG: VS.STUDYID Map:SDTM IG: AE.STUDYID Map:SDTM IG: SU.STUDYID Map:AE: Study.additionalIdentifier Map:SDTM IG: QS.STUDYID Map:AE: Study.name Map:SDTM IG: DA.STUDYID Map:COPPA: InterventionalStudyProtocol.identifier Map:AE: SafetyReport.amendmentReportInd Map:SDTM IG: DV.STUDYID Map:SDTM IG: IE.STUDYID Map:SDTM IG: SV.STUDYID Map:SDTM IG: DM.STUDYID Map:AE: SafetyReport.alternateIdentifier Map:SDTM IG: DS.STUDYID Map:SDTM IG: EX.STUDYID Map:SDTM IG: MH.STUDYID Map:SDTM IG: CM.STUDYID Map:C3PR: StudyProtocol.identifier Map:SDTM IG: SC.STUDYID Map:SDTM IG: CO.STUDYID Map:CTOM: Protocol.navyNCIIdentifier Map:SDTM IG: TA.STUDYID Map:SDTM IG: TS.STUDYID Map:SDTM IG: SE.STUDYID Map:AE: SafetyReport.mostRecentInformationDate Map:SDTM IG: EG.STUDYID Map:AE: Study.primaryIdentifier Map:SDTM IG: TV.STUDYID Map:HL7SD: PlannedStudy.setID Map:CTOM: Protocol.nciIdentifier

Connector	Source	Target	Notes
Association includes	SubmissionUnit +including 0..*, unordered, none	Document +included 1..*, unordered, none	Each SubmissionUnit always includes one or more Document. Each Document sometimes is included in one or more SubmissionUnit. *Constraints* Inverse Relation: is included in
Association describes	DocumentWorkflowStatus +describing 0..*, unordered, none	Document +described 1, unordered, none	Each DocumentWorkflowStatus always describes one Document. Each Document sometimes is described by one or more DocumentWorkflowStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:CTOM: ProtocolStatus.statusCode Map:AE: SafetyReport.statusCode Map:CTOM: ProtocolStatus.statusDate Map:CTOM: Protocol.amendmentDate
Association authors	DocumentAuthor +authoring 1..*, unordered, none	Document +authored 1, unordered, none	Each DocumentAuthor always authors one Document. Each Document always is authored by one or more DocumentAuthor. *Constraints* Inverse Relation: is authored by
Association has as source	DocumentRelationship +target 0..*, unordered, none	Document +source 1, unordered, none	Each DocumentRelationship always has as source one Document. Each Document sometimes is the source for one or more DocumentRelationship. *Constraints* Inverse Relation: is the source for
Association uses	PerformedStudySubjectMilestone +using 0..*, unordered, none	Document +used 0..1, unordered, none	Each PerformedStudySubjectMilestone sometimes uses one Document. Each Document sometimes is used for one or more PerformedStudySubjectMilestone. *Constraints* Inverse Relation: is used for
Association has as target	DocumentRelationship +source 0..*, unordered, none	Document +target 1, unordered, none	Each DocumentRelationship always has as target one Document. Each Document sometimes is the target for one or more

Connector	Source	Target	Notes
			DocumentRelationship. *Constraints* Inverse Relation: is the target for
Generalization source > target	Report Child	Document Parent	
Generalization source > target	StudyProtocolDocument Child	Document Parent	

Common Sub-Domain::Document Attributes

Attribute	Type	Notes
typeCode	public : *CD*	A coded value specifying the kind of document.For example, amendment, background material, guide, etc.For example, in RPS, this is the code that specifies how the file is to be used within the submission process (e.g. Protocol, Summary Introduction). Also known as context of use.For example, a RegulatoryRecord - A document that meets a record requirement of a regulatory authority and must be retained in accordance with that agency's records retention requirements. Example: Data Clarification Form (DCF) Map:AE = 'AmendmentFollowUpReport.reportAmendedIdentifier' Map:AE = 'AmendmentFollowUpReport' Map:COPPA = 'Document.typeCode' Map:CTOM = 'Protocol.amendmentIdentifier' Map:CTOM = 'Protocol.nciIdentifier' Map:CTOM = 'Protocol.documentUri' Map:CTOM = 'Protocol.amendmentDate' Map:CTOM = 'Protocol.descriptionText' Map:CTOM = 'ProtocolStatus.statusDate' Map:CTOM = 'Protocol.navyNCIIdentifier' Map:CTOM = 'ProtocolStatus.statusCode' Map:CTOM = 'Protocol.precisText' Map:CTOM = 'Protocol.longTitleText' Map:HL7SD = 'ReplacementOf1.typeCode' Map:RPS1 = 'Documentation.context'
officialTitle	public : *ST*	The formal title of the document. NOTE: If there is only one title, use this attribute. AE:Exclude = 'True' Map:C3PR = 'Study.longTitleText' Map:COPPA = 'InterventionalStudyProtocol.officialTitle' Map:COPPA = 'ObservationalStudyProtocol.officialTitle' Map:CTGOV = 'Official Title' Map:CTOM = 'Protocol.longTitleText' Map:HL7SD = 'PlannedStudy.title' Map:Lab = 'Study.name' Map:PSC = 'Study.name' Map:RPS1 = 'Documentation.title' Map:WHO = 'Scientific Title'
text	public : *ED*	A character string that is the full or comprehensive narrative or content of the document.

Attribute	Type	Notes
		Map:AE = 'Document.text' Map:AE = 'SafetyReport.narrativeText' Map:COPPA = 'InterventionalStudyProtocol.text' Map:COPPA = 'StudyProtocol.text' Map:COPPA = 'ObservationalStudyProtocol.text' Map:CTOM = 'Protocol.descriptionText' Map:HL7SD = 'PlannedStudy.text'
keywordCode	public : *DSET<CD>*	A coded value specifying the words or phrases that best describe the document and/or its context. Keywords help users find documents of interest. For example, species, indication, biocompatibility, drug substance, drug product. AE:Exclude = 'True' Map:COPPA = 'InterventionalStudyProtocol.keywordCode' Map:COPPA = 'StudyProtocol.keywordCode' Map:COPPA = 'ObservationalStudyProtocol.keywordCode' Map:CTGOV = 'Keywords' Map:RPS1 = 'Keyword.code' Map:WHO = 'Keyword'
keywordText	public : *DSET<ST>*	A character string of ad hoc words or phrases that best describe the document and/or its context. Keywords help users find documents of interest. For example, species, indication, biocompatibility, drug substance, drug product. AE:Exclude = 'True' Map:COPPA = 'StudyProtocol.keywordText' Map:COPPA = 'ObservationalStudyProtocol.keywordText' Map:COPPA = 'InterventionalStudyProtocol.keywordText' Map:CTGOV = 'Keywords' Map:RPS1 = 'Keyword.textValue'
revisionReason	public : *ST*	The reason why the document is revised. Map:HL7SD = 'PlannedStudy.reasonCode'
revisionNumberText	public : *ST*	A character string that identifies a given collection of content of a document at a point in time.For example, over time, there may be multiple changes to a document, and the revision allows an individual to capture relationships between changes in the instances of a document over time. There can be a new revision every time the content changes. For example, in RPS this could be implemented as follows: The version number would be an integer starting at '1' and incrementing by 1. The first instance or original report should always be valued as '1'. The version number value must be incremented by one when a report is replaced, but can also be incremented more often to meet local requirements. Different versions of the same document belong to the same document group. Map:AE = 'SafetyReport.initialReportIndicator' Map:C3PR = 'Study.consentVersion' Map:COPPA = 'ObservationalStudyProtocol.revision'

Attribute	Type	Notes
		Map:COPPA = 'StudyProtocol.revision' Map:COPPA = 'InterventionalStudyProtocol.revision' Map:COPPA = 'Document.revision' Map:CTOM = 'Protocol.amendmentIdentifier' Map:HL7SD = 'PlannedStudy.versionNumber' Map:RPS1 = 'Documentation.version'
uniformResourceLocator	public : *URL*	A complete reference to a website (including http://) from which the document contents can be retrieved. Map:AE = 'Document.universalResourceLocator' Map:COPPA = 'Document.universalResourceLocator' Map:CTOM = 'Protocol.documentUri' Map:RPS1 = 'Documentation.fileID'
bibliographicDesignation	public : *ST*	A text block containing publishing and authoring information that allows receivers to refer appropriately to the cited document.For example, IRB Minutes, 18-Jan-2008; Charles Darwin, The Origin of the Species, London 1863, Oxford Press. AE:Exclude = 'True' Map:C3PR = 'Study.precisText' Map:COPPA = 'InterventionalStudyProtocol.bibliographicDesignation' Map:COPPA = 'ObservationalStudyProtocol.bibliographicDesignation' Map:COPPA = 'StudyProtocol.bibliographicDesignation'

Tagged Values

- Map:AE = Document.
- Map:AE = Study.primaryIdentifier.
- Map:AE = Study.name.
- Map:AE = Study.additionalIdentifier.
- Map:COPPA = Document.
- Map:COPPA = InterventionalStudyProtocol.publicTitle.
- Map:COPPA = InterventionalStudyProtocol.officialTitle.
- Map:COPPA = InterventionalStudyProtocol.identifier.
- Map:CTOM = ProtocolStatus.statusDate.
- Map:CTOM = ProtocolStatus.statusCode.
- Map:HL7SP = PlannedStudy.id.
- Map:HL7SP = Study.id.
- Map:Lab = Study.identifier.
- Map:RPS1 = DA.STUDYID.
- Map:RPS1 = Documentation.
- Map:SDTM IG = AE.STUDYID.
- Map:SDTM IG = DV.STUDYID.
- Map:SDTM IG = MH.STUDYID.
- Map:SDTM IG = SU.STUDYID.
- Map:SDTM IG = TE.STUDYID.
- Map:SDTM IG = PE.STUDYID.
- Map:SDTM IG = QS.STUDYID.
- Map:SDTM IG = SC.STUDYID.
- Map:SDTM IG = VS.STUDYID.

- Map:SDTM IG = TS.STUDYID.
- Map:SDTM IG = TA.STUDYID.
- Map:SDTM IG = SV.STUDYID.
- Map:SDTM IG = DS.STUDYID.
- Map:SDTM IG = TI.STUDYID.
- Map:SDTM IG = LB.STUDYID.
- Map:SDTM IG = SE.STUDYID.
- Map:SDTM IG = CM.STUDYID.
- Map:SDTM IG = DM.STUDYID.
- Map:SDTM IG = EG.STUDYID.
- Map:SDTM IG = CO.STUDYID.
- Map:SDTM IG = TV.STUDYID.
- Map:SDTM IG = EX.STUDYID.
- Map:SDTM IG = IE.STUDYID.

6.4 Common Sub-Domain::DocumentAuthor

public Class {root}:
The individual who is responsible for the content of a document.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  The DocumentAuthor must be a function performed by a Subject who is a Person and not an Animal or Product.
- *Approved Invariant* . Study Author Performed By Qualifier.
  When the DocumentAuthor is an author for a Study, the DocumentAuthor must be a function performed by a HealthcareProvider or ResearchStaff only.

Common Sub-Domain::DocumentAuthor Connections

Connector	Source	Target	Notes
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	AssociatedBiologicEntity +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one AssociatedBiologicEntity. Each AssociatedBiologicEntity sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	ResearchStaff +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one ResearchStaff. Each ResearchStaff sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an

Connector	Source	Target	Notes
			AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as
Association authors	DocumentAuthor +authoring 1..*, unordered, none	Document +authored 1, unordered, none	Each DocumentAuthor always authors one Document. Each Document always is authored by one or more DocumentAuthor. *Constraints* Inverse Relation: is authored by
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	Subject +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one Subject. Each Subject sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as

Tagged Values

- Map:AE = Reporter.

6.5 Common Sub-Domain::DocumentIdentifier

public Class:
The unique identification of a document in a specified context.

NOTE: This class is a resolution of the requirement for noting the type of an identifier which is not handled by the purely technical HL7 II data type. It is the result of applying a pattern provided by HL7 data type expert, Grahame Grieve.

Constraints

- *Approved Invariant* . Is Issued By Exclusive Or.
  A DocumentIdentifier is issued by an Organization or Registry, but not both.

Common Sub-Domain::DocumentIdentifier Connections

Connector	Source	Target	Notes
Association identifies	DocumentIdentifier +identifying 0..*, unordered, none	Document +identified 1, unordered, none	Each DocumentIdentifier always identifies one Document. Each Document sometimes is identified by one or more DocumentIdentifier. *Constraints* Inverse Relation: is identified by *Tagged Values* Map:SDTM IG: LB.STUDYID Map:HL7SP: Study.id Map:AE: SafetyReport.identifier Map:COPPA: Document.identifier Map:COPPA: ObservationalStudyProtocol.identifier Map:Lab: Study.identifier Map:AE: SafetyReport.initialReportIndicator Map:SDTM IG: TI.STUDYID Map:AE: SafetyReport.narrativeText Map:SDTM IG: PE.STUDYID Map:HL7SP: PlannedStudy.id Map:SDTM IG: VS.STUDYID Map:SDTM IG: AE.STUDYID Map:SDTM IG: SU.STUDYID Map:AE: Study.additionalIdentifier Map:SDTM IG: QS.STUDYID Map:AE: Study.name Map:SDTM IG: DA.STUDYID Map:COPPA: InterventionalStudyProtocol.identifier Map:AE: SafetyReport.amendmentReportInd Map:SDTM IG: DV.STUDYID Map:SDTM IG: IE.STUDYID Map:SDTM IG: SV.STUDYID Map:SDTM IG: DM.STUDYID Map:AE: SafetyReport.alternateIdentifier Map:SDTM IG: DS.STUDYID Map:SDTM IG: EX.STUDYID Map:SDTM IG: MH.STUDYID

Connector	Source	Target	Notes
			Map:SDTM IG: CM.STUDYID Map:C3PR: StudyProtocol.identifier Map:SDTM IG: SC.STUDYID Map:SDTM IG: CO.STUDYID Map:CTOM: Protocol.navyNCIIdentifier Map:SDTM IG: TA.STUDYID Map:SDTM IG: TS.STUDYID Map:SDTM IG: SE.STUDYID Map:AE: SafetyReport.mostRecentInformationDate Map:SDTM IG: EG.STUDYID Map:AE: Study.primaryIdentifier Map:SDTM IG: TV.STUDYID Map:HL7SD: PlannedStudy.setID Map:CTOM: Protocol.nciIdentifier
Association is issued by	DocumentIdentifier +issued 0..*, unordered, none	Organization +issuing 0..1, unordered, none	Each DocumentIdentifier sometimes is issued by one Organization. Each Organization sometimes issues one or more DocumentIdentifier. *Constraints* Inverse Relation: issues *Tagged Values* Map:HL7SP: LicenseIssuer Map:Lab: Study.assigningAuthority
Association is issued by	DocumentIdentifier +issued 0..*, unordered, none	Registry +issuing 0..1, unordered, none	Each DocumentIdentifier sometimes is issued by one Registry. Each Registry sometimes issues one or more DocumentIdentifier. *Constraints* Inverse Relation: issues

Common Sub-Domain::DocumentIdentifier Attributes

Attribute	Type	Notes
identifier	public : *II*	The unique symbol that establishes identity of the document.For example, an identifier assigned by some organization in the context of a study.For example, in a Regulatory Product Submission (RPS) message, this identifies the file (with a Uniform Resource Identifier (URI)), which is part of the documentation. A URI is a compact string of characters used to identify or name a resource. The main purpose of this identification is to enable interaction with representations of the resource over a network, typically the World Wide Web, using specific protocols. URIs are defined in schemes defining a specific syntax and associated

Attribute	Type	Notes
		protocols.NOTE: A particular document can have one or more ID. Map:AE = 'SafetyReport.alternateIdentifier' Map:AE = 'Study.primaryIdentifier' Map:AE = 'Study.additionalIdentifier' Map:AE = 'SafetyReport.identifier' Map:AE = 'AmendmentFollowUpReport.reportAmendedIdentifier' Map:C3PR = 'Identifier.value' Map:COPPA = 'StudyProtocol.identifier' Map:COPPA = 'Document.identifier' Map:COPPA = 'ObservationalStudyProtocol.identifier' Map:COPPA = 'InterventionalStudyProtocol.identifier' Map:COPPA = 'StudyParticipation.localStudyProtocolIdentifier' Map:CTGOV = 'Secondary IDs' Map:CTGOV = 'Organization's Unique Protocol ID' Map:CTGOV = 'IND/IDE Serial Number' Map:CTOM = 'Protocol.navyNCIIdentifier' Map:CTOM = 'Protocol.nciIdentifier' Map:CTOM = 'PartcipantEligibilityAnswer.checklistNumber' Map:CTOM = 'StudySite.localProtocolIdentifier' Map:HL7SD = 'PlannedStudy.setID' Map:HL7SP = 'PlannedStudy.id' Map:HL7SP = 'Study.id' Map:Lab = 'Study.identifier' Map:SDTM IG = 'DS.STUDYID' Map:SDTM IG = 'DM.STUDYID' Map:SDTM IG = 'DV.STUDYID' Map:SDTM IG = 'MH.STUDYID' Map:SDTM IG = 'EG.STUDYID' Map:SDTM IG = 'CM.STUDYID' Map:SDTM IG = 'TI.STUDYID' Map:SDTM IG = 'LB.STUDYID' Map:SDTM IG = 'TA.STUDYID' Map:SDTM IG = 'CO.STUDYID' Map:SDTM IG = 'QS.STUDYID' Map:SDTM IG = 'TE.STUDYID' Map:SDTM IG = 'PE.STUDYID' Map:SDTM IG = 'SV.STUDYID' Map:SDTM IG = 'SE.STUDYID' Map:SDTM IG = 'AE.STUDYID' Map:SDTM IG = 'EX.STUDYID' Map:SDTM IG = 'TS.STUDYID' Map:SDTM IG = 'IE.STUDYID' Map:SDTM IG = 'TV.STUDYID' Map:SDTM IG = 'SU.STUDYID' Map:SDTM IG = 'SC.STUDYID' Map:SDTM IG = 'DA.STUDYID' Map:SDTM IG = 'VS.STUDYID' Map:WHO = 'Secondary Identifying Numbers' Map:WHO = 'Primary Registry and Trial Identifying Number'
typeCode	public : *CD*	A coded value specifying the kind of document identifier.For example, sponsor protocol number, national number, cooperative group protocol number, CDISC protocol identifying number, registry identifier.

Attribute	Type	Notes
		Map:C3PR = 'Identifier.type'
primaryIndicator	public : *BL*	Specifies whether this is the main or principal document identifier. NOTE: primaryIndicator may only apply for a given typeCode. Map:AE = 'Study.primaryIdentifier' Map:C3PR = 'Identifier.isPrimary'

Tagged Values

- Map:AE = SafetyReport.initialReportIndicator.
- Map:AE = SafetyReport.identifier.
- Map:AE = SafetyReport.alternateIdentifier.
- Map:AE = Study.primaryIdentifier.
- Map:AE = Study.additionalIdentifier.
- Map:AE = Study.name.
- Map:AE = SafetyReport.narrativeText.
- Map:AE = SafetyReport.amendmentReportInd.
- Map:AE = SafetyReport.mostRecentInformationDate.
- Map:COPPA = ObservationalStudyProtocol.identifier.
- Map:COPPA = StudyProtocol.identifier.
- Map:COPPA = Document.identifier.
- Map:HL7SD = PlannedStudy.setID.
- Map:HL7SP = Study.id.
- Map:HL7SP = PlannedStudy.id.
- Map:HL7SP = LicenseIssuer.
- Map:HL7SP = DocumentIdentifier.
- Map:SDTM IG = EX.STUDYID.
- Map:SDTM IG = LB.STUDYID.
- Map:SDTM IG = SC.STUDYID.
- Map:SDTM IG = IE.STUDYID.
- Map:SDTM IG = CO.STUDYID.
- Map:SDTM IG = EG.STUDYID.
- Map:SDTM IG = DM.STUDYID.
- Map:SDTM IG = TV.STUDYID.
- Map:SDTM IG = AE.STUDYID.
- Map:SDTM IG = VS.STUDYID.
- Map:SDTM IG = SU.STUDYID.
- Map:SDTM IG = CM.STUDYID.
- Map:SDTM IG = QS.STUDYID.
- Map:SDTM IG = PE.STUDYID.
- Map:SDTM IG = DS.STUDYID.
- Map:SDTM IG = TI.STUDYID.
- Map:SDTM IG = MH.STUDYID.
- Map:SDTM IG = SE.STUDYID.
- Map:SDTM IG = TS.STUDYID.
- Map:SDTM IG = TA.STUDYID.
- Map:SDTM IG = DA.STUDYID.
- Map:SDTM IG = DV.STUDYID.
- Map:SDTM IG = SV.STUDYID.

6.6 Common Sub-Domain::DocumentRelationship

public Class:
Specifies the meaning (or semantics) of the relationship of one document to another.

For example, in a Regulated Product Submission (RPS), relationships of interest include "replaces" or "amends" (among others). For example, support of versioning could be accomplished by having two different revisions of a document related through a "replaces" relationship.

Common Sub-Domain::DocumentRelationship Connections

Connector	Source	Target	Notes
Association has as source	DocumentRelationship +target 0..*, unordered, none	Document +source 1, unordered, none	Each DocumentRelationship always has as source one Document. Each Document sometimes is the source for one or more DocumentRelationship. *Constraints* Inverse Relation: is the source for
Association has as target	DocumentRelationship +source 0..*, unordered, none	Document +target 1, unordered, none	Each DocumentRelationship always has as target one Document. Each Document sometimes is the target for one or more DocumentRelationship. *Constraints* Inverse Relation: is the target for

Common Sub-Domain::DocumentRelationship Attributes

Attribute	Type	Notes
typeCode	public : *CD*	A coded value specifying the kind of document relationship. Each value implies specific constraints to what kinds of objects can be related and in which way.For example, decomposition (component), pre-condition, post-condition, sequel (replaces, modifies), attribution (cause and effect) would be types of relationships that could be coded. Neutrophil count is a component of complete blood count. The IV bag is weighed before and after the infusion. (sequel) Injection site swelling and redness are attributed to the injection. (attribution) Map:AE = 'SafetyReport.amendmentReportInd' Map:RPS1 = 'RelatedDocumentation.relationship'

Tagged Values

- Map:HL7SD = ReplacementOf1.
- Map:RPS1 = RelatedDocumentation.

6.7 Common Sub-Domain::ExperimentalUnit

public Class:
A physical entity which is the primary unit of interest in a specific research objective. In an interventional study, the experimental unit is assigned to an intervention. The experimental unit is also the unit of primary statistical analysis. Commonly the individual StudySubject (animal, person or product) is the experimental unit. Different experimental units must be capable of receiving different experimental interventions.

For example, if all pigs in a pen receive the same intervention in their feed, and the primary observations and analyses of interest are associated with the entire pen (e.g. total feed consumed, total weight of all pigs combined), then the pen of pigs rather than the individual animal is the experimental unit. [CDISC/HL7 Study Participation RMIM, PORT_RM100001UV]

For example, a human StudySubject may have 10 patches of skin each considered an ExperimentalUnit, or a Product StudySubject may have 10 bearings in it, each considered an ExperimentalUnit. Alternatively, each StudySubject may be an ExperimentalUnit.

NOTE: Depending on the research objectives, a single study may have multiple levels of experimental units, such as whole people and patches of skin.

Constraints

- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  An ExperimentalUnit is a funciton performed by only one of the following: BiologicEntityPart, BiologicEntity, BiologicEntityGroup, Product or ProductGroup.

Common Sub-Domain::ExperimentalUnit Connections

Connector	Source	Target	Notes
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	Product +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one Product. Each Product sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	BiologicEntityGroup +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one BiologicEntityGroup. Each BiologicEntityGroup sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as

Connector	Source	Target	Notes
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	ProductGroup +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one ProductGroup. Each ProductGroup sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	BiologicEntity +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one BiologicEntity. Each BiologicEntity sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as
Association is participated in by	Activity +involving 0..*, unordered, none	ExperimentalUnit +involved 0..1, unordered, none	Each Activity sometimes is participated in by one ExperimentalUnit. Each ExperimentalUnit sometimes participates in one or more Activity. *Constraints* Inverse Relation: participates in *Tagged Values* Map:C3PR: StudySubject.subgroup
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	BiologicSpecimen +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one BiologicSpecimen. Each BiologicSpecimen sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as

Connector	Source	Target	Notes
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	BiologicEntityPart +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one BiologicEntityPart. Each BiologicEntityPart sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as

Common Sub-Domain::ExperimentalUnit Attributes

Attribute	Type	Notes
identifier	public : *DSET<II>*	A unique symbol that establishes identity of the experimental unit.For example, patient number 7 on a study. Map:HL7SP = 'ExperimentalUnit.id'
subgroupCode	public : *CD*	A coded value specifying the identification of uniform groups of subjects for separate analysis or treatment.For example, in National Cancer Institute (NCI) this is the Clinical Data Update System (CDUS) Reporting. Map:C3PR = 'StudySubject.subgroup' Map:CTOM = 'StudyParticipantAssignment.subgroupCode'
actualIndicator	public : *BL*	Specifies whether the experimental unit is real (actual) vs. placeholder (kind of). Map:HL7SD = 'ExperimentalUnit>ExperimentalUnit2(choice box).determinerCode'
statusCode	public : *CD*	A coded value specifying the state of the experimental unit.For example, active, cancelled, pending, suspended, terminated, nullified. Map:HL7SP = 'ExperimentalUnit.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the experimental unit. Map:HL7SP = 'ExperimentalUnit.effectiveTime'

Tagged Values

- Map:HL7SP = ExperimentalUnit.

6.8 Common Sub-Domain::HealthcareProvider

public Class:
A person who directly or indirectly administers interventions that are designed to improve the physical or emotional status of another person. A person licensed, certified or otherwise authorized or permitted by law to administer health care in the ordinary course of business or practice of a profession, including a healthcare facility.

Common Sub-Domain::HealthcareProvider Connections

Connector	Source	Target	Notes
Association is a function performed by	HealthcareProvider +performed 0..*, unordered, none	Person +performing 1, unordered, none	Each HealthcareProvider always is a function performed by one Person. Each Person sometimes functions as one or more HealthcareProvider. *Constraints* Inverse Relation: functions as *Tagged Values* Map:Lab: Investigator.name Map:Lab: Investigator.dateOfBirth Map:SDTM IG: DM.INVNAM Map:Lab: Investigator.initials
Association is a function performed by	HealthcareProviderGroupMember +performed 0..*, unordered, none	HealthcareProvider +performing 1, unordered, none	Each HealthcareProviderGroupMember always is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more HealthcareProviderGroupMember. *Constraints* Inverse Relation: functions as
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as

Connector	Source	Target	Notes
Association is a function performed by	StudyLegalSponsor +performed 0..1, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudyLegalSponsor sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one StudyLegalSponsor. *Constraints* Inverse Relation: functions as
Association is a function performed by	RegulatoryApplication Sponsor +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each RegulatoryApplicationSponsor always is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more RegulatoryApplicationSponsor. *Constraints* Inverse Relation: functions as
Association staffs	HealthcareProvider +staffing 0..*, unordered, none	HealthcareFacility +staffed 1, unordered, none	Each HealthcareProvider always staffs one HealthcareFacility. Each HealthcareFacility sometimes is staffed by one or more HealthcareProvider. *Constraints* Inverse Relation: is staffed by
Association is a function performed by	StudyInvestigator +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudyInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudyInvestigator. *Constraints* Inverse Relation: functions as *Tagged Values* Map:HL7SP: Investigator
Association is a function performed by	Assessor +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each Assessor sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more Assessor. NOTE: an Assessor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider or an OversightCommittee or a Laboratory or a Device. *Constraints* Inverse Relation: functions as

Connector	Source	Target	Notes
Association is a function performed by	StudySiteInvestigator +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudySiteInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudySiteInvestigator. *Constraints* Inverse Relation: functions as

Common Sub-Domain::HealthcareProvider Attributes

Attribute	Type	Notes
identifier	public : *II*	A unique symbol that establishes identity of the healthcare provider.For example, the identifier assigned in the NCI investigator registry (National Cancer Institute Principal Investigator Identifier Number) to a physician approved for conducting a clinical trial. Map:COPPA = 'HealthCareProvider.identifier' Map:CTOM = 'Investigator.nciIdentifier' Map:Lab = 'Investigator.identifier'
certificateLicenseText	public : *ST*	A character string that describes the credentials of the healthcare provider.For example, board certified, etc. Map:AE = 'Reporter.qualificationForReporting' Map:COPPA = 'HealthCareProvider.certificateLicenseText'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the healthcare provider. Map:COPPA = 'HealthCareProvider.postalAddress'
telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of the healthcare provider. Map:COPPA = 'HealthCareProvider.telecomAddress'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the healthcare provider is active. Map:C3PR = 'HealthcareSiteInvestigator.statusDate' Map:C3PR = 'HealthcareSiteInvestigator.statusCode' Map:COPPA = 'HealthCareProvider.statusCode' Map:COPPA = 'HealthCareProvider.statusDateRange'

Tagged Values

- Map:COPPA = HealthCareProvider.
- Map:CTOM = Investigator.streetAddress.

- Map:CTOM = Investigator.telecomAddress.
- Map:CTOM = Investigator.ethnicGroupCode.
- Map:CTOM = Investigator.lastName.
- Map:CTOM = Investigator.zipCode.
- Map:CTOM = Investigator.birthDate.
- Map:CTOM = Investigator.administrativeGenderCode.
- Map:CTOM = Investigator.raceCode.
- Map:CTOM = Investigator.countryCode.
- Map:CTOM = Investigator.state.
- Map:CTOM = Investigator.middleName.
- Map:CTOM = Investigator.city.
- Map:CTOM = Investigator.educationLevelCode.
- Map:CTOM = Investigator.maritalStatusCode.
- Map:CTOM = Investigator.phone.
- Map:CTOM = Investigator.firstName .
- Map:HL7SP = LicensedEntity.
- Map:HL7SP = Investigator.
- Map:Lab = Investigator.dateOfBirth.
- Map:Lab = Investigator.initials.
- Map:Lab = Investigator.name.
- Map:SDTM IG = DM.INVNAM.

6.9 Common Sub-Domain::Material

public abstract Class {root}:
A physical substance.

For example, drug, device, specimen.

Common Sub-Domain::Material Connections

Connector	Source	Target	Notes
Generalization source > target	BiologicSpecimen Child	Material Parent	
Generalization source > target	Product Child	Material Parent	

Common Sub-Domain::Material Attributes

Attribute	Type	Notes
identifier	public : *DSET<II>*	A unique symbol that establishes identity of the material.For example, serial number, product number, model number. Map:AE = 'Device.catalogNumber' Map:AE = 'Component.batchNumber' Map:AE = 'Device.otherNumber' Map:AE = 'Device.serialNumber' Map:AE = 'Device.modelNumber' Map:AE = 'Ingredient.batchnumber' Map:COPPA = 'Product.identifier' Map:COPPA = 'Device.identifier' Map:COPPA = 'Drug.identifier' Map:COPPA = 'Biologic.identifier' Map:COPPA = 'Cosmetic.identifier' Map:COPPA = 'Material.identifier'

Attribute	Type	Notes
		Map:COPPA = 'FoodProduct.identifier' Map:CTOM = 'Specimen.sampleIdentifier' Map:Lab = 'Specimen.identifier'
name	public : *DSET<TN>*	A non-unique textual identifier for the material. For example, the therapeutic agent used in a chemotherapy clinical trial. Map:AE = 'Ingredient.name' Map:AE = 'Product.name' Map:AE = 'Component.name' Map:COPPA = 'Device.name' Map:COPPA = 'Product.name' Map:COPPA = 'Device.alternateName' Map:COPPA = 'Biologic.name' Map:COPPA = 'FoodProduct.alternateName' Map:COPPA = 'Drug.name' Map:COPPA = 'Cosmetic.name' Map:COPPA = 'Drug.nameCode' Map:COPPA = 'Biologic.alternateName' Map:COPPA = 'FoodProduct.name' Map:COPPA = 'Cosmetic.alternateName' Map:COPPA = 'Material.name' Map:COPPA = 'Drug.alternateName' Map:CTGOV = 'Other Names' Map:CTOM = 'Agent.name' Map:HL7SD = 'Product.name' Map:SDTM IG = 'CM.CMDECOD' Map:SDTM IG = 'SU.SUDECOD' Map:SDTM IG = 'EX.EXTRT' Map:SDTM IG = 'CM.CMTRT' Map:SDTM IG = 'SU.SUTRT'
formCode	public : *CD*	A coded value specifying the state and nature of the material.For example, solid, liquid, gas, tablet, ointment, gel, etc. Map:AE = 'Component.formCode' Map:AE = 'Product.formCode' Map:COPPA = 'Cosmetic.formCode' Map:COPPA = 'Device.formCode' Map:COPPA = 'Material.formCode' Map:COPPA = 'Biologic.formCode' Map:COPPA = 'Product.formCode' Map:COPPA = 'FoodProduct.formCode' Map:COPPA = 'Drug.formCode' Map:CTOM = 'AgentOccurrence.formCode' Map:HL7SD = 'Product.formCode' Map:SDTM IG = 'EX.EXDOSFRM' Map:SDTM IG = 'CM.CMDOSFRM' Map:SDTM IG = 'SU.SUDOSFRM' Map:SDTM IG = 'LB.LBSPEC'
actualIndicator	public : *BL*	Specifies whether the material is real (actual) vs. placeholder (kind of). Map:Unknown = 'Defer to BRIDGv3.1'

Attribute	Type	Notes
description	public : *ST*	The textual representation of the material. Map:COPPA = 'ObservationalStudyProtocol.biospecimenDescription' Map:COPPA = 'Material.description' Map:COPPA = 'Drug.description' Map:COPPA = 'Biologic.description' Map:COPPA = 'Product.description' Map:COPPA = 'FoodProduct.description' Map:COPPA = 'Cosmetic.description' Map:COPPA = 'Device.description' Map:CTGOV = 'Biospecimen Description' Map:CTOM = 'Agent.descriptionText'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the material is active. Map:COPPA = 'FoodProduct.statusCode' Map:COPPA = 'Drug.statusDateRange' Map:COPPA = 'Material.statusCode' Map:COPPA = 'Product.statusCode' Map:COPPA = 'Drug.statusCode' Map:COPPA = 'Product.statusDateRange' Map:COPPA = 'Biologic.statusDateRange' Map:COPPA = 'TherapeuticAgent.StatusCode' Map:COPPA = 'Device.statusDateRange' Map:COPPA = 'Cosmetic.statusCode' Map:COPPA = 'FoodProduct.statusDateRange' Map:COPPA = 'TherapeuticProduct.statusDateRange' Map:COPPA = 'Cosmetic.statusDateRange' Map:COPPA = 'Biologic.statusCode' Map:COPPA = 'Material.statusDateRange' Map:COPPA = 'Device.statusCode' Map:CTOM = 'StudyAgent.statusCode' Map:CTOM = 'Agent.statusCode' Map:CTOM = 'StudyAgent.statusDate'

Tagged Values

- Map:COPPA = Material.

6.10 Common Sub-Domain::Organization

public Class:
A formalized group of persons or other organizations collected together for a common purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose.

Common Sub-Domain::Organization Connections

Connector	Source	Target	Notes
Association is a function performed by	Registry +performed 0..*, unordered, none	Organization +performing 1, unordered, none	Each Registry always is a function performed by one Organization. Each Organization sometimes

Connector	Source	Target	Notes
			functions as one or more Registry. *Constraints* Inverse Relation: functions as
Association is a function performed by	Performer +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each Performer sometimes is a function performed by one Organization. Each Organization sometimes functions as one or more Performer. *Constraints* Inverse Relation: functions as
Association is a function performed by	MemberInstitution +performed 0..*, unordered, none	Organization +performing 1, unordered, none	Each MemberInstitution always is a function performed by one Organization. Each Organization sometimes functions as one or more MemberInstitution. *Constraints* Inverse Relation: functions as
Association handles communication for	OrganizationalContact +supporting 0..*, unordered, none	Organization +supported 1, unordered, none	Each OrganizationalContact always handles communication for one Organization. Each Organization sometimes has communications handled by one or more OrganizationalContact. *Constraints* Inverse Relation: has communications handled by
Association is a function performed by	Laboratory +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each Laboratory always is a function performed by one Organization. Each Organization sometimes functions as one Laboratory. *Constraints* Inverse Relation: functions as *Tagged Values* Map:Lab: CentralLaboratory.name Map:Lab: PerformingLaboratory.identifier Map:Lab: PerformingLaboratory.name
Association is a function performed by	CooperativeGroup +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each CooperativeGroup always is a function performed by one Organization. Each Organization sometimes functions as one CooperativeGroup. *Constraints* Inverse Relation: functions as

Connector	Source	Target	Notes
Association is credentialed by	CooperativeGroup +credentialed 0..*, unordered, none	Organization +credentialing 1, unordered, none	Each CooperativeGroup always is credentialed by one Organization. Each Organization sometimes credentials one or more CooperativeGroup. *Constraints* Inverse Relation: credentials
Association is a function performed by	OversightAuthority +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each OversightAuthority always is a function performed by one Organization. Each Organization sometimes functions as one OversightAuthority. *Constraints* Inverse Relation: functions as *Tagged Values* Map:AE: Authorization.responsibleAuthority Map:CTOM: Protocol.monitorCode Map:AE: Authorization.authorizationHolder
Association is assigned by	StudySubjectIdentifier +assigned 0..*, unordered, none	Organization +assigning 0..1, unordered, none	Each StudySubjectIdentifier sometimes is assigned by one Organization. Each Organization sometimes assigns one or more StudySubjectIdentifier. *Constraints* Inverse Relation: assigns
Association is a function performed by	StudySite +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each StudySite sometimes is a function performed by one Organization. Each Organization sometimes functions as one or more StudySite. NOTE: A StudySite may be related to either a HealthcareFacility or an Organization (serving as a StudySite but is not a HealthcareFacility) *Constraints* Inverse Relation: functions as *Tagged Values* Map:SDTM IG: DM.COUNTRY
Association is a function performed by	Distributor +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each Distributor always is a function performed by one Organization. Each Organization sometimes functions as one Distributor.

Connector	Source	Target	Notes
			Constraints Inverse Relation: functions as
Association is a function performed by	OrganizationPart +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each OrganizationPart always is a function performed by one Organization. Each Organization sometimes functions as one OrganizationPart. *Constraints* Inverse Relation: functions as *Tagged Values* Map:AE: Receiver.organizationDepartment
Association is a function performed by	ResearchOrganization +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each ResearchOrganization always is a function performed by one Organization. Each Organization sometimes functions as one ResearchOrganization. *Constraints* Inverse Relation: functions as
Association has as parent	OrganizationPart +subdividing 0..*, unordered, none	Organization +subdivided 1, unordered, none	Each OrganizationPart always has as parent one Organization. Each Organization sometimes is the parent for one or more OrganizationPart. *Constraints* Inverse Relation: is the parent for
Association is a function performed by	RegulatoryApplicationSponsor +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each RegulatoryApplicationSponsor always is a function performed by one Organization. Each Organization always functions as one or more RegulatoryApplicationSponsor. *Constraints* Inverse Relation: functions as
Association is a function performed by	Manufacturer +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each Manufacturer always is a function performed by one Organization. Each Organization sometimes functions as one Manufacturer. *Constraints* Inverse Relation: functions as
Association is a function performed by	StudyLegalSponsor +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each StudyLegalSponsor sometimes is a function performed by one Organization. Each Organization sometimes functions

Connector	Source	Target	Notes
			as one or more StudyLegalSponsor. *Constraints* Inverse Relation: functions as
Association is a function performed by	HealthcareFacility +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each HealthcareFacility always is a function performed by one Organization. Each Organization sometimes functions as one HealthcareFacility. *Constraints* Inverse Relation: functions as *Tagged Values* Map:HL7SP: EthicalCommittee.addr Map:C3PR: HealthCareSite.name Map:HL7SP: EthicalCommittee.name Map:HL7SP: EthicalCommittee.telecom Map:Lab: HealthCareSite.name Map:PSC: Site.name Map:HL7SP: EthicalCommittee.id
Association is credentialed by	QualifiedPerson +credentialed 0..*, unordered, none	Organization +credentialing 1, unordered, none	Each QualifiedPerson always is credentialed by one Organization. Each Organization sometimes credentials one or more QualifiedPerson. *Constraints* Inverse Relation: credentials
Association is issued by	DocumentIdentifier +issued 0..*, unordered, none	Organization +issuing 0..1, unordered, none	Each DocumentIdentifier sometimes is issued by one Organization. Each Organization sometimes issues one or more DocumentIdentifier. *Constraints* Inverse Relation: issues *Tagged Values* Map:HL7SP: LicenseIssuer Map:Lab: Study.assigningAuthority
Association is a function performed by	ResourceProvider +performed 0..1, unordered, none	Organization +performing 0..1, unordered, none	Each ResourceProvider sometimes is a function performed by one Organization. Each Organization sometimes functions as one ResourceProvider.

Connector	Source	Target	Notes
			NOTE: A resource provider may be played by either an organization or a healthcare provider. *Constraints* Inverse Relation: functions as *Tagged Values* Map:CTOM: Protocol.sponsorCode
Association is a function performed by	HealthcareProviderGroup +performed 0..1, unordered, none	Organization +performing 1, unordered, none	Each HealthcareProviderGroup always is a function performed by one Organization. Each Organization sometimes functions as one HealthcareProviderGroup. *Constraints* Inverse Relation: functions as
Association is assigned by	BiologicEntityIdentifier +assigned 0..*, unordered, none	Organization +assigning 1, unordered, none	Each BiologicEntityIdentifier always is assigned by one Organization. Each Organization sometimes assigns one or more BiologicEntityIdentifier. *Constraints* Inverse Relation: assigns *Tagged Values* Map:C3PR: ResearchStaff.nciIdentifier Map:C3PR: Participant.identifiers
Association is a function performed by	DocumentReceiver +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each DocumentReceiver always is a function performed by one Organization. Each Organization sometimes functions as one or more DocumentReceiver. *Constraints* Inverse Relation: functions as

Common Sub-Domain::Organization Attributes

Attribute	Type	Notes
identifier	public : *DSET<II>*	A unique symbol that establishes identity of the organization.For example, in cases of laboratories this is the Clinical Laboratory Improvement Act/Amendment (CLIA) ID. Map:C3PR = 'OrganizationAssignedIdentifier' Map:C3PR = 'Organization.nciInstituteCode' Map:COPPA = 'Organization.identifier'

		Map:CTOM = 'Protocol.monitorCode ' Map:HL7SP = 'Organization.id' Map:HL7SP = 'EthicalCommittee.id' Map:Lab = 'Organization.identifier'
name	public : *DSET<ON>*	A non-unique textual identifier for the organization. Map:AE = 'Authorization.authorizationHolder' Map:AE = 'Authorization.responsibleAuthority' Map:C3PR = 'InvestigatorGroup.name' Map:C3PR = 'HealthCareSite.name' Map:C3PR = 'Study.SponsorCode' Map:C3PR = 'Organization.name' Map:COPPA = 'Organization.abbreviatedName' Map:COPPA = 'Organization.name' Map:CTGOV = 'IND/IDE Grantor' Map:CTGOV = 'Overall Study Officials - Organizational Affiliation' Map:CTGOV = 'Sponsor' Map:CTGOV = 'Responsible Party - Organization' Map:CTGOV = 'Facility - Name' Map:CTGOV = 'Board Name' Map:CTGOV = 'Board Affiliation' Map:CTGOV = 'Collaborators' Map:CTGOV = 'Oversight Authorities' Map:CTOM = 'Organization.name' Map:CTOM = 'Protocol.sponsorCode' Map:CTOM = 'HealthcareSite.name' Map:HL7SP = 'EthicalCommittee.name' Map:HL7SP = 'Organization.name' Map:Lab = 'Organization.name' Map:Lab = 'PerformingLaboratory.name' Map:Lab = 'CentralLaboratory.name' Map:Lab = 'HealthCareSite.name' Map:PSC = 'Site.name' Map:SDTM IG = 'EG.EGNAM' Map:SDTM IG = 'LB.LBNAM' Map:WHO = 'Contact for Public Queries - affiliation' Map:WHO = 'Primary Sponsor' Map:WHO = 'Secondary Sponsor(s)' Map:WHO = 'Source(s) of Monetary or Material Support'
typeCode	public : *CD*	A coded value specifying the kind of organization.For example, academic, pharmaceutical industry, government, other. EudraCT example: commercial, non-commercial. Map:PRM = 'Sponsor Organization Type'
actualIndicator	public : *BL*	Specifies whether the organization is real (actual) vs. placeholder (kind of).For example, a placeholder organization is the KIND OF organization that can play some role on a study during study design, whereas Good Health Hospital is an INSTANCE OF an organization that plays a role on a study conduct, such as StudySite. Map:HL7SP =

		'R_AssignedEntity(Universal)_COCT_RM_090000UV'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the organization. Map:COPPA = 'Organization.postalAddress' Map:CTGOV = 'Facility - Country' Map:CTGOV = 'Facility - State/Province' Map:CTGOV = 'Facility - Postal Code' Map:CTGOV = 'Facility - City' Map:CTOM = 'Organization.postalCode' Map:CTOM = 'Organization.countryCode' Map:CTOM = 'Organization.stateCode' Map:CTOM = 'Organization.city' Map:HL7SP = 'Organization.addr' Map:HL7SP = 'EthicalCommittee.addr' Map:SDTM IG = 'DM.COUNTRY'
telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of the organization.For example, the set of digits that serves as the address for a telephone device. Included in the phone number are country, city, and area codes needed to uniquely address the telephone. A URL or e-mail would be similarly described. Map:COPPA = 'Organization.telecomAddress' Map:CTOM = 'Organization.telecomAddress' Map:CTOM = 'HealthcareSite.telecomAddress' Map:HL7SP = 'EthicalCommittee.telecom'
description	public : *ST*	The textual representation of the organization. Map:C3PR = 'Organization.descriptionText' Map:C3PR = 'InvestigatorGroup.descriptionText' Map:COPPA = 'Organization.description' Map:CTOM = 'Organization.descriptionText' Map:CTOM = 'HealthcareSite.descriptionText'

Tagged Values

- Map:AE = Receiver.organizationDepartment.
- Map:C3PR = Participant.identifiers.
- Map:C3PR = ResearchStaff.nciIdentifier.
- Map:COPPA = Organization.
- Map:HL7SP = EthicalCommittee.name.
- Map:HL7SP = Study.performer2.
- Map:HL7SP = LicenseIssuer.
- Map:HL7SP = EthicalCommittee.addr.
- Map:HL7SP = EthicalCommittee.id.
- Map:HL7SP = Organization.
- Map:HL7SP = EthicalCommittee.telecom.
- Map:HL7SP = Service Provider.
- Map:Lab = PerformingLaboratory.identifier.
- Map:Lab = PerformingLaboratory.name.
- Map:SDTM IG = DM.COUNTRY.

6.11 Common Sub-Domain::OrganizationalContact

public Class:
A person who provides or receives information on behalf of an organization.

Common Sub-Domain::OrganizationalContact Connections

Connector	Source	Target	Notes
Association handles communication for	OrganizationalContact +supporting 0..*, unordered, none	Organization +supported 1, unordered, none	Each OrganizationalContact always handles communication for one Organization. Each Organization sometimes has communications handled by one or more OrganizationalContact. *Constraints* Inverse Relation: has communications handled by
Association is a function performed by	OrganizationalContact +performed 0..*, unordered, none	Person +performing 0..1, unordered, none	Each OrganizationalContact sometimes is a function performed by one Person. Each Person sometimes functions as one or more OrganizationalContact. *Constraints* Inverse Relation: functions as

Common Sub-Domain::OrganizationalContact Attributes

Attribute	Type	Notes
typeCode	public : *DSET<CD>*	A coded value specifying the kind of organizational contact.For example, safety, sales, financial, manufacturing, Review Board contact, etc. Map:COPPA = 'OrganizationalContact.typeCode' Map:CTGOV = 'Board Contact'
title	public : *ST*	A descriptive or distinctive appellation, especially one belonging to a person by right of rank, office, attainment, etc. Map:COPPA = 'OraganizationalContact.title'
primaryIndicator	public : *BL*	Specifies whether this is the main or principal organizational contact. Map:COPPA = 'OrganizationalContact.primaryIndicator'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the organizational contact. Map:AE = 'ContactPerson.address' Map:COPPA = 'OrganizationalContact.postalAddress' Map:CTGOV = 'Board Contact mailing address'

telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of the organizational contact. Map:AE = 'ContactPerson.phoneNumber' Map:C3PR = 'ContactMechanism.type' Map:C3PR = 'ContactMechanism.value' Map:CTGOV = 'Board Contact Phone' Map:CTGOV = 'Board Contact Ext' Map:CTGOV = 'Board Contact Email'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the organizational contact is active. Map:COPPA = 'OrganizationalContact.statusDateRange'

Tagged Values

- Map:AE = ContactPerson.name.
- Map:AE = ContactPerson.
- Map:COPPA = OrganizationalContact.

6.12 Common Sub-Domain::OversightCommittee

public Class {leaf}

Extends: OversightAuthority. :

An organization that approves, monitors and reviews biomedical research to protect the rights, safety and welfare of the StudySubjects. This committee performs critical oversight functions for research conducted on human StudySubjects that are scientific, ethical, and regulatory.

For example, Institutional Review Board (IRB), ethics committee, research ethics board, etc.

Common Sub-Domain::OversightCommittee Connections

Connector	Source	Target	Notes
Association is a function performed by	Assessor +performed 0..*, unordered, none	OversightCommittee +performing 0..1, unordered, none	Each Assessor sometimes is a function performed by one OversightCommittee. Each OversightCommittee sometimes functions as one or more Assessor. NOTE: an Assessor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider or an OversightCommittee or a Laboratory or a Device. *Constraints* Inverse Relation: functions as

Association oversees	OversightCommittee +overseeing 0..*, unordered, none	StudySite +overseen 0..*, unordered, none	Each OversightCommittee sometimes oversees one or more StudySite. Each StudySite sometimes is overseen by one or more OversightCommittee. *Constraints* Inverse Relation: is overseen by
Association is assigned by	StudySiteOversightStatus +assigned 0..*, unordered, none	OversightCommittee +assigning 1, unordered, none	Each StudySiteOversightStatus always is assigned by one OversightCommittee. Each OversightCommittee sometimes assigns one or more StudySiteOversightStatus. *Constraints* Invariant: assigns
Association oversees	OversightCommittee +overseeing 0..*, unordered, none	HealthcareFacility +overseen 1..*, unordered, none	Each OversightCommittee always oversees one or more HealthcareFacility. Each HealthcareFacility sometimes is overseen by one or more OversightCommittee. *Constraints* Inverse Relation: is overseen by *Tagged Values* Map:HL7SP: EthicalCommittee.addr Map:HL7SP: EthicalCommittee.name Map:HL7SP: EthicalCommittee.id Map:HL7SP: EthicalCommittee.telecom
Generalization source > target	OversightCommittee Child	OversightAuthority Parent	

Common Sub-Domain::OversightCommittee Attributes

Attribute	Type	Notes
typeCode	public : *CD*	A coded value specifying the kind of oversight committee.For example, Adjudication Committee, IRB, Data Safety Monitoring Board. Map:COPPA = 'OversightCommittee.typeCode'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the oversight committee is active. Map:COPPA = 'OversightCommittee.statusCode' Map:COPPA = 'OversightCommittee.statusDateRange'

Tagged Values

- Map:COPPA = OversightCommittee.
- Map:HL7SP = Verifier.
- Map:HL7SP = ServiceProvider.
- Map:HL7SP = EthicalCommittee.
- Map:HL7SP = EthicalCommittee.telecom.
- Map:HL7SP = EthicalCommittee.addr.
- Map:HL7SP = EthicalCommittee.name.
- Map:HL7SP = EthicalCommittee.id.

6.13 Common Sub-Domain::Person

public Class {leaf}

Extends: BiologicEntity. :

A human being.

Common Sub-Domain::Person Connections

Connector	Source	Target	Notes
Association is a function performed by	Performer +performed 0..*, unordered, none	Person +performing 0..1, unordered, none	Each Performer sometimes is a function performed by one Person. Each Person sometimes functions as one or more Performer. NOTE: A Performer may be played by either a Person, Organization or Device. *Constraints* Inverse Relation: functions as
Association is a function performed by	QualifiedPerson +performed 0..*, unordered, none	Person +performing 1, unordered, none	Each QualifiedPerson always is a function performed by one Person. Each Person sometimes functions as one or more QualifiedPerson. *Constraints* Inverse Relation: functions as
Association is a function performed by	HealthcareProvider +performed 0..*, unordered, none	Person +performing 1, unordered, none	Each HealthcareProvider always is a function performed by one Person. Each Person sometimes functions as one or more HealthcareProvider. *Constraints* Inverse Relation: functions as *Tagged Values* Map:Lab: Investigator.name Map:Lab: Investigator.dateOfBirth Map:SDTM IG: DM.INVNAM Map:Lab: Investigator.initials

Association is a function performed by	ResourceProvider +performed 0..1, unordered, none	Person +performing 0..1, unordered, none	Each ResourceProvider sometimes is a function performed by one Person. Each Person sometimes functions as one ResourceProvider. *Constraints* Inverse Relation: functions as
Association is a function performed by	DocumentReceiver +performed 0..*, unordered, none	Person +performing 0..1, unordered, none	Each DocumentReceivingPerson always is a function performed by one Person. Each Person sometimes functions as one or more DocumentReceivingPerson. *Constraints* Inverse Relation: functions as *Tagged Values* Map:AE: Receiver.personName
Association is a function performed by	ResearchStaff +performed 0..1, unordered, none	Person +performing 1, unordered, none	Each ResearchStaff always is a function performed by one Person. Each Person sometimes functions as one ResearchStaff. *Constraints* Inverse Relation: functions as *Tagged Values* Map:C3PR: ResearchStaff.nciIdentifier
Association is a function performed by	OrganizationalContact +performed 0..*, unordered, none	Person +performing 0..1, unordered, none	Each OrganizationalContact sometimes is a function performed by one Person. Each Person sometimes functions as one or more OrganizationalContact. *Constraints* Inverse Relation: functions as
Generalization source > target	Person Child	BiologicEntity Parent	

Common Sub-Domain::Person Attributes

Attribute	Type	Notes
name	public : *PN*	A non-unique textual identifier for the person.For example, proper name, nickname, legal name, etc. Map:AE = 'ContactPerson.name' Map:AE = 'Reporter.personName' Map:AE = 'Receiver.personName' Map:C3PR = 'Person.lastName'

		Map:C3PR = 'Person.middleName' Map:C3PR = 'Person.maidenName' Map:C3PR = 'Person.firstName' Map:COPPA = 'Person.name' Map:CTGOV = 'Overall Study Officials - Last Name' Map:CTGOV = 'Central Contact - First Name' Map:CTGOV = 'Responsible Party - Name/Official Title' Map:CTGOV = 'Facility Contact - Last Name' Map:CTGOV = 'Investigators - First Name' Map:CTGOV = 'Facility Contact - First Name' Map:CTGOV = 'Investigators - Last Name' Map:CTGOV = 'Central Contact - Middle Initial' Map:CTGOV = 'Investigators - Middle Initial' Map:CTGOV = 'Central Contact - Last Name' Map:CTGOV = 'Facility Contact - Middle Initial' Map:CTGOV = 'Overall Study Officials - Middle Initial' Map:CTGOV = 'Overall Study Officials - First Name' Map:CTOM = 'Investigator.firstName ' Map:CTOM = 'Participant.lastName' Map:CTOM = 'Person.lastName' Map:CTOM = 'Investigator.lastName' Map:CTOM = 'Participant.firstName' Map:CTOM = 'Person.firstName' Map:CTOM = 'Investigator.middleName' Map:CTOM = 'Person.middleName' Map:CTOM = 'Participant.middleName' Map:Lab = 'Investigator.name' Map:PSC = 'Participant.lastName' Map:PSC = 'Participant.firstName' Map:SDTM IG = 'DM.INVNAM' Map:WHO = 'Contact for Public Queries - firstname' Map:WHO = 'Primary Sponsor' Map:WHO = 'Contact for Scientific Queries - middlename' Map:WHO = 'Secondary Sponsor(s)' Map:WHO = 'Contact for Scientific Queries - lastname' Map:WHO = 'Source(s) of Monetary or Material Support' Map:WHO = 'Contact for Scientific Queries - firstname' Map:WHO = 'Contact for Public Queries - middlename' Map:WHO = 'Contact for Public Queries - lastname'
initials	public : *ST*	The first letters of the person's first name, middle name, and last name. NOTE: If the person does not have a middle initial, the initials will only be two characters. Map:CTOM = 'Participant.initials' Map:Lab = 'Person.initials' Map:Lab = 'Participant.initials' Map:Lab = 'Investigator.initials'
raceCode	public : *DSET<CD>*	A coded value specifying a self-declared racial origination, independent of ethnic origination.For example, for the National Cancer Institute, this code is based on Office of Management & Budget (OMB) approved categories. Map:C3PR = 'Participant.raceCode' Map:COPPA = 'Person.raceCode'

		Map:CTOM = 'Person.raceCode' Map:CTOM = 'Investigator.raceCode' Map:CTOM = 'Participant.raceCode' Map:SDTM IG = 'DM.RACE'
ethnicGroupCode	public : *DSET<CD>*	A coded value specifying the self-declared ethnic origination, independent of racial origination. For example, for the NCI, these ethnic groups are based on OMB approved categories. Map:C3PR = 'Participant.ethnicGroup' Map:CTOM = 'Investigator.ethnicGroupCode' Map:CTOM = 'Person.ethnicGroupCode' Map:CTOM = 'Participant.ethnicGroupCode' Map:SDTM IG = 'DM.ETHNIC'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the person. Map:C3PR = 'Address.postalCode' Map:C3PR = 'Address.stateCode' Map:C3PR = 'Address.cityCode' Map:C3PR = 'Address.countryCode' Map:C3PR = 'Address.streetAddress' Map:COPPA = 'Person.postalAddress' Map:CTOM = 'Participant.countryCode' Map:CTOM = 'Person.state' Map:CTOM = 'Participant.streetAddress' Map:CTOM = 'Investigator.zipCode' Map:CTOM = 'Investigator.streetAddress' Map:CTOM = 'Participant.state' Map:CTOM = 'Investigator.state' Map:CTOM = 'Person.streetAddress' Map:CTOM = 'Person.city' Map:CTOM = 'Participant.zipCode' Map:CTOM = 'Person.countryCode' Map:CTOM = 'Investigator.city' Map:CTOM = 'Investigator.countryCode' Map:CTOM = 'Participant.city' Map:CTOM = 'Person.zipCode'
telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of the person.For example, the set of digits that serves as the address for a telephone device. Included in the phone number are country, city, and area codes needed to uniquely address the telephone. A URL or e-mail would be similarly described. Map:COPPA = 'Person.telecomAddress' Map:CTOM = 'Investigator.telecomAddress' Map:CTOM = 'Participant.telecomAddress' Map:CTOM = 'Person.phone' Map:CTOM = 'Investigator.phone' Map:CTOM = 'Person.telecomAddress' Map:CTOM = 'Participant.phone'
maritalStatusCode	public :	A coded value specifying the domestic partnership status of a

	CD	person. For example, Married, Widowed, Single, Separated, etc. Map:C3PR = 'Participant.maritalStatusCode' Map:CTOM = 'Person.maritalStatusCode' Map:CTOM = 'Investigator.maritalStatusCode' Map:CTOM = 'Participant.maritalStatusCode'
educationLevelCode	public : *CD*	A coded value specifying the highest level of education completed.For example, Less than High School Diploma, High School Diploma, Some College, etc. Map:CTOM = 'Investigator.educationLevelCode' Map:CTOM = 'Person.educationLevelCode' Map:CTOM = 'Participant.educationLevelCode'
primaryOccupationCode	public : *CD*	A coded value specifying the principal activity that a person does to earn money. Map:CTOM = 'PersonOccupation.primaryTypeCodeSystem' Map:CTOM = 'PersonOccupation.primaryTypeCode'
occupationDateRange	public : *IVL<TS.DATE>*	The date and time span specifying the start and end of a person's occupation.NOTE: The occupation is determined by the Person.primaryOccupationCode. Map:CTOM = 'PersonOccupation.startDate' Map:CTOM = 'PersonOccupation.stopDate'
deathIndicator	public : *BL*	Specifies whether the person is dead. Map:CTOM = 'DeathSummary.deathDate (when date is not known but death is known)'

Tagged Values

- Map:AE = Person.
- Map:AE = Person.numberOfSiblings.
- Map:C3PR = ResearchStaff.nciIdentifier.
- Map:COPPA = Person.sexCode.
- Map:COPPA = Person.
- Map:CTOM = Person.administrativeGenderCode.
- Map:CTOM = Person.birthDate.
- Map:HL7SD = Person.
- Map:HL7SP = Person.
- Map:HL7SP = InvestigativePerson.
- Map:Lab = Investigator.dateOfBirth.
- Map:Lab = Person.dateOfBirth.
- Map:SDTM IG = DM.RACE.
- Map:SDTM IG = DM.INVNAM.
- Map:SDTM IG = DM.ETHNIC.

6.14 Common Sub-Domain::Product

public Class {leaf}

Extends: Material. :

A thing produced by or resulting from a process.

For example, a drug or device.

For example, the FDA list of regulated products: animal and human drugs; therapeutic biologics; allergenics; cell, tissue and gene therapy products; blood components; blood derivative products; devices; and animal (pets and livestock) and human food/feed (medicated and un-medicated); cosmetics; pet treats; and dietary supplements.

Constraints

- *Approved Invariant* . Distributor Qualifier.
  If Product.actualIndicator = True, then the upper limit is 1 on the Distributor association.
- *Approved Invariant* . Manufacturer Qualifier.
  If Product.actualIndicator = True, then the upper limit is 1 on the Manufacturer association.
- *Approved Invariant* . ManufacturingSite Qualifier.
  If Product.actualIndicator = True, then the upper limit is 1 on the ManufacturingSite association.

Common Sub-Domain::Product Connections

Connector	Source	Target	Notes
Aggregation is grouped by source > target	Product +grouped 1..*, unordered, none	ProductGroup +grouping 0..*, unordered, none	Each Product sometimes is grouped by one or more ProductGroup. Each ProductGroup always groups one or more Product. *Constraints* Inverse Relation: groups
Association is contained in	Product +contained 1..*, unordered, none	Package +containing 0..1, unordered, none	Each Product sometimes is contained in one Package. Each Package always contains one or more Product. *Constraints* Inverse Relation: contains
Association is a function performed by	Subject +performed 0..*, unordered, none	Product +performing 0..1, unordered, none	Each Subject sometimes is a function performed by one Product. Each Product sometimes functions as one or more Subject. *Constraints* Inverse Relation: functions as
Association produces	Manufacturer +produced 0..*, unordered, none	Product +producing 1..*, unordered, none	Each Manufacturer always produces one or more Product. Each Product sometimes is produced by one or more Manufacturer. *Constraints* Inverse Relation: is produced by

Association is a function performed by	StudyAgent +performed 0..*, unordered, none	Product +performing 1, unordered, none	Each StudyAgent always is a function performed by one Product. Each Product sometimes functions as one or more StudyAgent. *Constraints* Inverse Relation: functions as
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	Product +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one Product. Each Product sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as
Association focuses on	PerformedProductInvestigation +investigating 0..*, unordered, none	Product +investigated 1, unordered, none	Each PerformedProductInvestigation always focuses on one Product. Each Product sometimes is the focus of one or more PerformedProductInvestigation. *Constraints* Inverse Relation: is the focus of
Association has as subject	Submission +describing 0..*, unordered, none	Product +described 1, unordered, none	Each Submission always has as subject one Product. Each Product sometimes is the subject of one or more Submission. *Constraints* Inverse Relation: is the subject for
Association is a function performed by	ConcomitantAgent +performed 0..1, unordered, none	Product +performing 1, unordered, none	Each ConcomitantAgent always is a function performed by one Product. Each Product sometimes functions as one ConcomitantAgent. *Constraints* Inverse Relation: functions as
Association focuses on	PerformedProductProblemDiscovery +involving 0..*, unordered, none	Product +involved 1, unordered, none	Each PerformedProductProblemDiscovery always focuses on one Product. Each Product sometimes is the focus of one or more

			PerformedProductProblemDiscovery. *Constraints* Inverse Relation: is the focus of
Association is a function performed by	ProductPart +performed 0..*, unordered, none	Product +performing 1, unordered, none	Each ProductPart always is a function performed by one Product. Each Product sometimes functions as one or more ProductPart. *Constraints* Inverse Relation: functions as
Association uses	DefinedProcedure +using 0..*, unordered, none	Product +used 0..*, unordered, none	Each DefinedProcedure sometimes uses one or more Product. Each Product sometimes is used during one or more DefinedProcedure. *Constraints* Inverse Relation: is used during
Association provides	Distributor +provided 0..*, unordered, none	Product +providing 1..*, unordered, none	Each Distributor always provides one or more Product. Each Product sometimes is provided by one or more Distributor. *Constraints* Inverse Relation: is provided by
Association fabricates	ManufacturingSite +fabricated 0..*, unordered, none	Product +fabricating 1..*, unordered, none	Each ManufacturingSite always fabricates one or more Product. Each Product sometimes is fabricated by one or more ManufacturingSite. *Constraints* Inverse Relation: is fabricated by
Association uses	PerformedProcedure +using 0..*, unordered, none	Product +used 0..*, unordered, none	Each PerformedProcedure sometimes uses one or more Product. Each Product sometimes is used during one or more PerformedProcedure. *Constraints* Inverse Relation: is used during
Association is part of	ProductPart +component 0..*, unordered, none	Product +composite 1, unordered, none	Each ProductPart always is a part of one Product. Each Product sometimes has as part one or more ProductPart. *Constraints* Inverse Relation: has as part

Generalization source > target	FoodProduct Child	Product Parent	
Generalization source > target	Biologic Child	Product Parent	
Generalization source > target	Drug Child	Product Parent	
Generalization source > target	Cosmetic Child	Product Parent	
Generalization source > target	Product Child	Material Parent	
Generalization source > target	Device Child	Product Parent	

Common Sub-Domain::Product Attributes

Attribute	Type	Notes
nameCode	public : *CD*	A coded value specifying the non-unique textual identifier for the product.For example, aspirin, tobacco, caffeine.NOTE: The granularity of the code may vary depending on the specificity of the product. For example, acetaminophen, Tylenol, Tylenol 250 mg gel cap. Map:SDTM IG = 'CM.CMTRT'
nameModifiedText	public : *ST*	A character string that is a revision of the original text of the product to enable the coding of the text.For example, if the original text is "aspriin", the nameModifiedText could be set to "aspirin", so that the text can be successfully coded.NOTE: In the context of BRIDG, text modification occurs a single time for a given instance of OriginalText. Map:SDTM IG = 'SU.SUMODIFY' Map:SDTM IG = 'CM.CMMODIFY'
typeCode	public : *CD*	A coded value specifying the kind of product. For example, veterinary medicine, diagnostic device, etc. NOTE: All members of a type share similar functions and general characteristics, especially the purpose for which they are used. Map:AE = 'Product.typeCode' Map:AE = 'Component.typeCode' Map:AE = 'Ingredient.typeCode' Map:COPPA = 'Product.typeCode' Map:COPPA = 'Biologic.typeCode' Map:COPPA = 'Cosmetic.typeCode' Map:COPPA = 'Device.typeCode' Map:COPPA = 'FoodProduct.typeCode' Map:COPPA = 'Drug.typeCode' Map:HL7SD = 'Product.code'
classCode	public : *DSET<CD>*	A coded value specifying a group of products that are homogeneous or generally considered as substitutes for each other. The class is considered as narrow or broad depending on how substitutable the various products are. For example, stents, breakfast cereals, cox-2 inhibitors.

		Map:AE = 'ProductClass' Map:AE = 'ProductClass.typeCode' Map:AE = 'ProductClass.name' Map:COPPA = 'Cosmetic.classCode' Map:COPPA = 'Biologic.classCode' Map:COPPA = 'FoodProduct.classCode' Map:COPPA = 'Device.classCode' Map:COPPA = 'Drug.classCode' Map:COPPA = 'Product.classCode' Map:HL7SD = 'Product.classCode' Map:SDTM IG = 'SU.SUCLAS' Map:SDTM IG = 'CM.CMCLAS' Map:SDTM IG = 'CM.CMCLASCD' Map:SDTM IG = 'SU.SUCLASCD'
pre1938Indicator	public : *BL*	Specifies whether the product qualifies under the 1938 Grandfather Clause, contained in section 20l(p)(l) of the U.S. Federal Food, Drug and Cosmetic Act. Map:AE = 'Product.pre1938Indicator' Map:COPPA = 'Biologic.pre1938Indicator' Map:COPPA = 'FoodProduct.pre1938Indicator' Map:COPPA = 'Drug.pre1938Indicator' Map:COPPA = 'Device.pre1938Indicator' Map:COPPA = 'Cosmetic.pre1938Indicator' Map:COPPA = 'Product.pre1938Indicator'
treatmentVehicleCode	public : *CD*	A coded value specifying the material in which the product is dissolved or suspended for administration. For example, saline. Map:SDTM IG = 'EX.EXTRTV'
treatmentVehicleVolume	public : *PQ*	The quantity and units of treatmentVehicle used.For example, 10 milligrams, 2 milliliters, etc. Map:COPPA = 'SubstanceAdministration.treatmentVehicleVolume'
expirationDate	public : *TS.DATE.FULL*	The date (and time), assigned by the manufacturer, on which the product should not be used. Map:AE = 'Product.expirationDate' Map:COPPA = 'Cosmetic.expirationDate' Map:COPPA = 'FoodProduct.expirationDate' Map:COPPA = 'Device.expirationDate' Map:COPPA = 'Biologic.expirationDate' Map:COPPA = 'Product.expirationDate' Map:COPPA = 'Drug.expirationDate' Map:CTOM = 'AgentOccurrence.expirationDate'

Tagged Values

- Map:AE = Component.
- Map:AE = Product.
- Map:AE = Ingredient.

- Map:COPPA = Product.
- Map:CTOM = Agent.statusCode.
- Map:CTOM = AgentOccurrence.lotNumber.
- Map:CTOM = Agent.descriptionText.
- Map:CTOM = Agent.name.
- Map:HL7SD = Product.
- Map:HL7SP = Product.

6.15 Common Sub-Domain::QualifiedPerson

public Class:
A person that has been recognized as having certain training/experience or other characteristics that would make that person an appropriate performer for a certain activity.
For example, board certification, academic degree, medical license, etc.

Common Sub-Domain::QualifiedPerson Connections

Connector	Source	Target	Notes
Association is a function performed by	QualifiedPerson +performed 0..*, unordered, none	Person +performing 1, unordered, none	Each QualifiedPerson always is a function performed by one Person. Each Person sometimes functions as one or more QualifiedPerson. *Constraints* Inverse Relation: functions as
Association is credentialed by	QualifiedPerson +credentialed 0..*, unordered, none	Organization +credentialing 1, unordered, none	Each QualifiedPerson always is credentialed by one Organization. Each Organization sometimes credentials one or more QualifiedPerson. *Constraints* Inverse Relation: credentials

Common Sub-Domain::QualifiedPerson Attributes

Attribute	Type	Notes
identifier	public : *II*	A unique symbol that establishes identity of the qualified person. Map:CTGOV = 'Facility Contact - Degree' Map:CTGOV = 'Investigators - Degrees' Map:CTGOV = 'Central Contact - Degrees' Map:CTGOV = 'Overall State Officials - Degree'
typeCode	public : *CD*	A coded value specifying the kind of the qualified person.For example, license, academic degree, etc. Map:CTGOV = 'Overall State Officials - Degree' Map:CTGOV = 'Central Contact - Degrees' Map:CTGOV = 'Investigators - Degrees' Map:CTGOV = 'Facility Contact - Degree'
certificateLicenseText	public : *ST*	A character string that describes the credentials of the qualified person.For example, board certification, academic degree, medical

		license, etc. Map:CTGOV = 'Overall State Officials - Degree' Map:CTGOV = 'Central Contact - Degrees' Map:CTGOV = 'Investigators - Degrees' Map:CTGOV = 'Facility Contact - Degree'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the qualified person is active. Map:CTGOV = 'Facility Contact - Degree' Map:CTGOV = 'Investigators - Degrees' Map:CTGOV = 'Central Contact - Degrees' Map:CTGOV = 'Overall State Officials - Degree'

Tagged Values

- Map:CTGOV = Facility Contact - Degree.
- Map:CTGOV = Overall State Officials - Degree.
- Map:CTGOV = Investigators - Degrees.
- Map:CTGOV = Central Contact - Degrees.

6.16 Common Sub-Domain::Registry

public Class:
An organization (typically a government agency) that administers the registration of studies for products.

For example, ClinicalTrials.gov, The Netherlands National Trial Register (NTR)

NOTE: The registry should contain basic information about each trial sufficient to inform potential StudySubjects (and their healthcare practitioners) how to enroll in the study.

Common Sub-Domain::Registry Connections

Connector	Source	Target	Notes
Association is a function performed by	Registry +performed 0..*, unordered, none	Organization +performing 1, unordered, none	Each Registry always is a function performed by one Organization. Each Organization sometimes functions as one or more Registry. *Constraints* Inverse Relation: functions as
Association is issued by	DocumentIdentifier +issued 0..*, unordered, none	Registry +issuing 0..1, unordered, none	Each DocumentIdentifier sometimes is issued by one Registry. Each Registry sometimes issues one or more DocumentIdentifier. *Constraints* Inverse Relation: issues

Common Sub-Domain::Registry Attributes

Attribute	Type	Notes

name	public : *ST*	A non-unique textual identifier for the registry.For example, ClinicalTrials.gov Map:WHO = 'Primary Registry'
acronym	public : *ST*	The non-unique initials or abbreviated name used for identification of the registry.For example, NTR (Netherlands National Trial Register) Map:WHO = 'Primary Registry'

6.17 Common Sub-Domain::ResourceProvider

public Class {root}:
An organization or person that typically provides financial or other resources for the conduct of research.

For example, federal agencies (National Cancer Institute, National Institutes of Health) and private industry (pharmaceutical companies)

Constraints

- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A ResourceProvider can be a function performed by only a Organization or HealthcareProvider, not both.

Common Sub-Domain::ResourceProvider Connections

Connector	Source	Target	Notes
Association is a function performed by	ResourceProvider +performed 0..1, unordered, none	Person +performing 0..1, unordered, none	Each ResourceProvider sometimes is a function performed by one Person. Each Person sometimes functions as one ResourceProvider. *Constraints* Inverse Relation: functions as
Association is provided by	Resource +provided 1.., unordered, none	ResourceProvider +providing 1, unordered, none	Each Resource always is provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource. *Constraints* Inverse Relation: provides *Tagged Values* Map:CTOM: Protocol.sponsorCode Map:C3PR: StudyOrganization
Association is a function performed by	ResourceProvider +performed 0..1, unordered, none	Organization +performing 0..1, unordered, none	Each ResourceProvider sometimes is a function performed by one Organization. Each Organization sometimes functions as one ResourceProvider. NOTE: A resource provider may

			be played by either an organization or a healthcare provider. *Constraints* Inverse Relation: functions as *Tagged Values* Map:CTOM: Protocol.sponsorCode

Common Sub-Domain::ResourceProvider Attributes

Attribute	Type	Notes
identifier	public : *II*	A unique symbol that establishes identity of the resource provider. Map:C3PR = 'ResourceProvider.id' Map:COPPA = 'ResourceProvider.identifier' Map:CTOM = 'Protocol.sponsorCode' Map:HL7SP = 'StudyParticipation RMIM'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the resource provider is active. Map:COPPA = 'ResourceProvider.statusCode' Map:COPPA = 'ResourceProvider.statusDateRange' Map:HL7SP = 'StudyParticipation RMIM'

Tagged Values

- Map:C3PR = Study.SponsorCode.
- Map:C3PR = StudyOrganization.
- Map:COPPA = ResourceProvider.
- Map:CTOM = Protocol.sponsorCode.
- Map:HL7SP = Service Provider.
- Map:HL7SP = Study.performer2.

6.18 Common Sub-Domain::StudySubject

public Class {leaf}

Extends: Subject. :

A physical entity which is the primary unit of operational and/or administrative interest in a study.

For example, a person who is registered in a study as a recipient of an investigational product or as a control. May also include individuals who are being screened for studies, or individuals participating in observational or other studies. Other examples may include a pacemaker, a fuse that can be used in medical devices, a cow, a farm, a pen of pigs, a tissue sample from a tissue bank, etc.

NOTE: StudySubjects within a study are all of the same type. An entity registered in a study is not part of another entity registered in the same study.

Common Sub-Domain::StudySubject Connections

Connector	Source	Target	Notes

Association identifies	StudySubjectIdentifier +identifying 0..*, unordered, none	StudySubject +identified 1, unordered, none	Each StudySubjectIdentifier always identifies one StudySubject. Each StudySubject sometimes is identified by one or more StudySubjectIdentifier. *Constraints* Inverse Relation: is identified by *Tagged Values* Map:Lab: SubjectAssignment.studySubjectIdentifier
Association is assigned to	StudySubject +assigned 0..*, unordered, none	StudySite +assigning 1, unordered, none	Each StudySubject always is assigned to one StudySite. Each StudySite sometimes is the assigned location for one or more StudySubject. *Constraints* Inverse Relation: is the assigned location for *Tagged Values* Map:C3PR: StudySubject.informedConsentSignedDate Map:Lab: SubjectAssignment.studySubjectIdentifier Map:SDTM IG: DM.RFENDTC Map:SDTM IG: DM.RFSTDTC Map:HL7SP: Study.subject Map:CTOM: StudyParticipantAssignment.armIdentifier
Generalization source > target	StudySubject Child	Subject Parent	

Common Sub-Domain::StudySubject Attributes

Attribute	Type	Notes
confidentialityIndicator	public : *BL*	Specifies whether the subject, or their legally acceptable representative, has not authorized the use and disclosure of their protected health information (i.e., the subject's data is private and confidential). Map:CTOM = 'Participant.confidentialityIndicator'
paymentMethodCode	public : *CD*	A coded value specifying the primary payer/insurance carrier information at the time of treatment on a study. For example, Private Insurance, Medicare, Medicare And Private Insurance, Medicaid, etc.

		Map:CTOM = 'Participant.paymentMethodCode'
statusCode	public : *CD*	A coded value specifying the state of the study subject.For example, new, active, inactive, nullified, normal, completed, suspended, draft, retired, terminated, pending approval, held, cancelled, aborted) of a study subject.For example, the status change of a study protocol to 'suspended', requiring that subject accrual be halted until the study protocol is restored to fully active status. This refers to codes to represent the status of a study protocol in relation to the ability to enroll participants/subjects. Map:C3PR = 'StudySubject.status' Map:C3PR = 'StudyPersonnel.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the study subject. Map:C3PR = 'StudyPersonnel.startDate' Map:C3PR = 'StudyPersonnel.endDate' Map:C3PR = 'StudySubject.statusDateRange'

Tagged Values

- Map:AE = InvestigativeSubject.gestationPeriod.
- Map:AE = Person.numberOfSiblings.
- Map:AE = Animal.overallStateOfHealthCode.
- Map:C3PR = Participant.identifiers.
- Map:C3PR = Participant.administrativeGenderCode.
- Map:C3PR = Participant.maritalStatusCode.
- Map:C3PR = StudySubject.state.
- Map:C3PR = Participant.raceCode.
- Map:C3PR = Participant.birthDate.
- Map:C3PR = Participant.ethnicGroup.
- Map:C3PR = StudySubject.statusDateRange.
- Map:C3PR = StudySubject.actualSubjectIndicator.
- Map:C3PR = StudySubject.identifier.
- Map:C3PR = StudySubject.status.
- Map:C3PR = StudySubject.informedConsentSignedDate.
- Map:CTOM = StudyParticipantAssignment.enrollmentAge.
- Map:CTOM = StudyParticipantAssignment.eligibilityWaiverReasonText.
- Map:CTOM = StudyParticipantAssignment.armIdentifier.
- Map:HL7SP = Study.subject.
- Map:Lab = Study.identifier.
- Map:SDTM IG = DM.RFENDTC.
- Map:SDTM IG = DM.SEX.
- Map:SDTM IG = DM.BRTHDTC.
- Map:SDTM IG = DM.RFSTDTC.
- Map:SDTM IG = DM.ETHNIC.
- Map:SDTM IG = DM.RACE.

6.19 Common Sub-Domain::Subject

public Class {root}:

An entity of interest, either biological or otherwise.

For example, a human being who might be of interest because they are on a study, a sheep who might have experienced an adverse event, or a pacemaker that failed.

Constraints

- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A Subject is a function performed by either a BiologicEntity or Product but not both.

Common Sub-Domain::Subject Connections

Connector	Source	Target	Notes
Association is a function performed by	Subject +performed 0..*, unordered, none	Product +performing 0..1, unordered, none	Each Subject sometimes is a function performed by one Product. Each Product sometimes functions as one or more Subject. *Constraints* Inverse Relation: functions as
Association is a function performed by	Subject +performed 0..*, unordered, none	BiologicEntity +performing 0..1, unordered, none	Each Subject sometimes is a function performed by one BiologicEntity. Each BiologicEntity sometimes functions as one or more Subject. *Constraints* Inverse Relation: functions as *Tagged Values* Map:CTOM: Participant.middleName Map:AE: Animal.overallStateOfHealthCode Map:CTOM: Participant.birthDate Map:CTOM: Participant.paymentMethodCode Map:PSC: Participant.lastName Map:SDTM IG: DM.RACE Map:CTOM: Participant.educationLevelCode Map:CTOM: Participant.firstName Map:SDTM IG: DM.ETHNIC Map:SDTM IG: DM.SEX Map:C3PR: Participant.ethnicGroup Map:PSC: Participant.birthDate Map:C3PR: Participant.raceCode Map:CTOM: Participant.administrativeGenderCode Map:AE: numberOfSiblings Map:CTOM: Participant.raceCode Map:PSC: Participant.gender

			Map:CTOM: Participant.streetAddress Map:CTOM: Participant.lastName Map:PSC: Participant.firstName Map:CTOM: Participant.initials Map:Lab: Participant.dateOfBirth Map:CTOM: Participant.telecomAddress Map:Lab: Participant.initials Map:CTOM: Participant.zipCode Map:C3PR: Participant.identifiers Map:PSC: Participant.personId Map:C3PR: Participant.birthDate Map:CTOM: Participant.maritalStatusCode Map:CTOM: Participant.phone Map:C3PR: Participant.administrativeGenderCode Map:CTOM: Participant.ethnicGroupCode Map:CTOM: Participant.city Map:CTOM: Participant.state Map:CTOM: Participant.countryCode Map:C3PR: Participant.maritalStatusCode Map:SDTM IG: DM.BRTHDTC
Association is a function performed by	DocumentAuthor +performed 0..*, unordered, none	Subject +performing 0..1, unordered, none	Each DocumentAuthor sometimes is a function performed by one Subject. Each Subject sometimes functions as one or more DocumentAuthor. NOTE: a DocumentAuthor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider. *Constraints* Inverse Relation: functions as
Association is participated in by	Activity +involving 0..*, unordered, none	Subject +involved 0..1, unordered, none	Each Activity sometimes is participated in by one Subject. Each Subject sometimes participates in one or more Activity. *Constraints* Inverse Relation: participates in

			Tagged Values Map:C3PR: StudySubject.identifier Map:C3PR: StudySubject.state Map:CTOM: Participant.employmentStatusCode Map:C3PR: StudySubject.statusDateRange Map:C3PR: StudySubject.status Map:CTOM: Participant.householdIncomeCode Map:C3PR: StudySubject.actualSubjectIndicator Map:AE: InvestigativeSubject.gestationPeriod Map:CTOM: StudyParticipantAssignment.enrollmentAge Map:CTOM: Participant.employmentStatusOtherText Map:CTOM: StudyParticipantAssignment.eligibilityWaiverReasonText Map:AE: Person.numberOfSiblings
Association is a function performed by	Assessor +performed 0..*, unordered, none	Subject +performing 0..1, unordered, none	Each Assessor sometimes is a function performed by one Subject. Each Subject sometimes functions as one or more Assessor. NOTE: an Assessor can be represented by one and only one of the following: a ResearchStaff or a Subject or an AssociatedBiologicEntity or a HealthcareProvider or an OversightCommittee or a Laboratory or a Device. *Constraints* Inverse Relation: functions as
Generalization source > target	StudySubject Child	Subject Parent	

Common Sub-Domain::Subject Attributes

Attribute	Type	Notes
state	public : *ST*	A value specifying the state of participation of a person in the given investigation.

		Map:C3PR = 'StudySubject.state'
actualIndicator	public : *BL*	Specifies whether the subject is real (actual) vs. placeholder (kind of). Invariant: DefinedActivity Qualifier - For DefinedActivity the Subject.actualIndicator = N (kind of) or may not be used. Invariant: PerformedActivity Qualifier - For PerformedActivity the Subject.actualIndicator = N (kind of) or may not be used. Invariant: PlannedActivity Qualifier - For PlannedActivity the Subject.actualIndicator = Y (instance of) or may not be used. Invariant: ScheduledActivity Qualifier - for ScheduledActivity the Subject.actualIndicator = Y (instance of) or may not be used. Map:C3PR = 'StudySubject.actualSubjectIndicator' Map:CTOM = 'StudyParticipantAssignment.studyParticipantIdentifier'

Tagged Values

- AE:Alias = InvestigativeSubject.
- Map:AE = InvestigativeSubject.
- Map:CTOM = Participant.phone.
- Map:CTOM = Participant.ethnicGroupCode.
- Map:CTOM = Participant.city.
- Map:CTOM = Participant.zipCode.
- Map:CTOM = Participant.employmentStatusCode.
- Map:CTOM = Participant.countryCode.
- Map:CTOM = Participant.administrativeGenderCode.
- Map:CTOM = Participant.birthDate.
- Map:CTOM = Participant.educationLevelCode.
- Map:CTOM = Participant.lastName.
- Map:CTOM = Participant.employmentStatusOtherText.
- Map:CTOM = Participant.firstName.
- Map:CTOM = Participant.initials.
- Map:CTOM = Participant.raceCode.
- Map:CTOM = Participant.state.
- Map:CTOM = Participant.streetAddress.
- Map:CTOM = Participant.telecomAddress.
- Map:CTOM = Participant.householdIncomeCode.
- Map:CTOM = Participant.maritalStatusCode.
- Map:CTOM = Participant.middleName.
- Map:Lab = Participant.initials.
- Map:Lab = Participant.dateOfBirth.
- Map:PSC = Participant.personId.
- Map:PSC = Participant.gender.
- Map:PSC = Participant.lastName.
- Map:PSC = Participant.firstName.
- Map:PSC = Participant.birthDate.

6.20 Protocol Representation Sub-Domain::Arm

public Class {root}:

A path through the study which describes what activities the StudySubject or ExperimentalUnit will be involved in as they pass through the study, and is typically equivalent to a treatment group in a parallel design trial. Generally, each subject is assigned to an Arm, and the design of the study is reflected in the number and composition of the individual arms. This intended path the subject progresses in a trial is composed of time point events (study cell) for each Epoch of the study. Each time point event, in turn, has a pattern of child time points through which the subject would pass. This planned path thus describes how subjects assigned to the Arm will be treated.

For example, a study could have 2 arms named IV-Oral and Oral-IV. The name IV-Oral reflects a path that passes through IV treatment, then Oral treatment.

Constraints

- *Approved Invariant* . name Unique.
  An Arm name must be unique within the context of the study that contains it.

Protocol Representation Sub-Domain::Arm Connections

Connector	Source	Target	Notes
Association occurs in	PlannedActivity +contained 1..*, unordered, none	Arm +containing 1..*, unordered, none	Each PlannedActivity always occurs in one or more Arm. Each Arm always contains one or more PlannedActivity. *Constraints* Inverse Relation: contains
Association is a division of	Arm +subdividing 0..*, unordered, none	Study +subdivided 1, unordered, none	Each Arm always is a division of one Study. Each Study sometimes is divided into one or more Arm. *Constraints* Inverse Relation: is divided into *Tagged Values* Map:COPPA: ObservationalStudyProtocol.groupNumber Map:CTOM: StudyParticipantAssignment.armIdentifier
Association is assigned to	RandomizationBookEntry +assigned 0..*, unordered, none	Arm +containing 1, unordered, none	Each RandomizationBookEntry always is assigned to one Arm. Each Arm sometimes has assigned one or more RandomizationBookEntry. *Constraints* Inverse Relation: contains

Protocol Representation Sub-Domain::Arm Attributes

Attribute	Type	Notes
name	public : *ST*	A non-unique textual identifier for the arm.For example, Treatment A. Map:C3PR = 'ScheduledArm.name' Map:C3PR = 'PlannedArm.name'

		Map:C3PR = 'Arm.name' Map:COPPA = 'Arm.name' Map:CTGOV = 'Arm Number or Label' Map:CTGOV = 'Arms/Groups' Map:CTGOV = 'Group/Cohort Number or Label' Map:CTOM = 'StudyParticipantAssignment.armIdentifier' Map:HL7SD = 'Arm.title' Map:SDTM IG = 'TV.ARMCD' Map:SDTM IG = 'TA.ARMCD' Map:SDTM IG = 'DM.ARMCD' Map:TDM = 'StudyDesignArm.name'
typeCode	public : *CD*	A coded value specifying the kind of arm.For example, Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No intervention, Other Map:COPPA = 'Arm.typeCode' Map:CTGOV = 'Arm Type'
targetAccrualNumberRange	public : *URG<INT>*	A range of integers specifying the minimum and maximum number of subjects to be accrued for the arm.NOTE: This may represent the minimum number of subjects needed to support data analysis and/or the maximum number of subjects that may be accrued to this arm. Map:C3PR = 'PlannedArm.targetAccrual' Map:C3PR = 'Arm.targetAccrualNumber' Map:CTGOV = 'Number of Subjects per Treatment Arm' Map:TDM = 'StudyDesignArm.plannedArmAccrual'
randomizationWeightText	public : *ST*	The relative proportion of subjects to be randomized to the arm. For example, if 1/3 of subjects are to be randomized to Arm A and 2/3 to Arm B, then the values of randomizationWeight for Arms A and B, respectively, could be expressed as 1 and 2 or as 1/3 and 2/3. Map:C3PR = 'PlannedArm.randomizationWeight' Map:C3PR = 'ScheduledArm.randomizationWeight' Map:COPPA = 'Arm.randomizationWeight' Map:TDM = 'StudyDesignArm.randomizationWeightForArn'
description	public : *ST*	The textual representation of the arm.For example, in a particular treatment regimen, this is a description of the pathway followed by all subjects. For example, "Subjects receive Drug X" or "Subjects receive Placebo." or, "Subjects receive IV in the first arm, Oral in second arm."NOTE: This description should point out what is different between the Arms, if there is more than one Arm. Map:C3PR = 'Arm.descriptionText' Map:C3PR = 'ScheduledArm.description' Map:C3PR = 'PlannedArm.description' Map:COPPA = 'Arm.description' Map:CTGOV = 'Arm Description' Map:SDTM IG = 'DM.ARM' Map:SDTM IG = 'TV.ARM' Map:SDTM IG = 'TA.ARM'

		Map:TDM = 'StudyDesignArm.description'

Tagged Values

- Map:COPPA = Arm.
- Map:HL7SD = Arm.

6.21 Protocol Representation Sub-Domain::DefinedActivity

public Class {leaf}

Extends: Activity. :

An activity that frequently occurs in studies (e.g. more than one time in more than one arm) and therefore is called out as a reusable template and may be used in the composition of a defined study segment. A defined activity is a "kind of" activity rather than an "instance of" an activity.

For example, standard blood chemistries are frequently included in studies - also activities that are study-specific and recur more than one time in more than one arm may be defined, such as a SubstanceAdministration activity involving X amount of drug Y.

NOTE: A defined activity is represented here as a subtype of Activity, but could also be thought of as an activity at a particular stage in the business process in which the activities occur, i.e., in the "defined" stage rather than the "planned" stage, the "scheduled" stage or the "performed" stage.

Constraints

- *Approved Invariant* . actualIndicator Qualifier.
  Only Subjects and ExperiementalUnits with actualIndicator = N are valid for DefinedActivities.
- *Approved Invariant* . Repeat Frequency Exclusive Or.
  A DefinedActivity may have a value for repeatFrequencyCode or repeatFrequencyRatio, but not both.
- *Approved Invariant* . Repeat Duration or Quantity Exclusive Or.
  A DefinedActivity may have a value for repeatDuration or repeatQuantity, but not both.
- *Approved Invariant* . categoryCode Qualifier.
  The type of activity determines what the value set should be for category.

Protocol Representation Sub-Domain::DefinedActivity Connections

Connector	Source	Target	Notes
Association associates a study to	StudyActivity +associating 0..*, unordered, none	DefinedActivity +associated 1, unordered, none	Each StudyActivity always associates a study to one DefinedActivity. Each DefinedActivity sometimes is associated to a study by one or more StudyActivity. *Constraints* Inverse Relation: is associated to a study by *Tagged Values* Map:Lab: SubjectAssignment.studySubject Identifier
Association is repeated until	DefinedRepeatActivity UntilRule	DefinedActivity +triggering	Each DefinedRepeatActivityUntilRule

	+repeated 0..*, unordered, none	1, unordered, none	always is repeated until one DefinedActivity. Each DefinedActivity sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is a condition for	DefinedContingentOnRelationship +prerequisite 0..*, unordered, none	DefinedActivity +contingent 1, unordered, none	Each DefinedContingentOnRelationship always is a condition for one DefinedActivity. Each DefinedActivity sometimes is contingent upon one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is contingent upon
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	DefinedActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one DefinedActivity. Each DefinedActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by *Tagged Values* Map:CTOM: QualitativeEvaluation.anamResultAccuracyPercent Map:CTOM: QualitativeEvaluation.painIndexCodeSystem Map:CTOM: Participant.employmentStatusOtherText Map:CTOM: QualitativeEvaluation.painIndexCode Map:CTOM: QualitativeEvaluation.performanceStatusCode Map:CTOM: Radiation.doseUnitOfMeasureCode Map:Lab: LabResult.referenceRangeComments Map:CTOM: Procedure.descriptionText Map:Lab:

			LabResult.referenceTextList Map:CTOM: Participant.householdIncomeCode Map:CTOM: Radiation.durationUnitOfMeasureCode Map:CTOM: QualitativeEvaluation.menstrualPatternTypeCode Map:CTOM: SubstanceAdministration.type Map:CTOM: Procedure.type Map:CTOM: Radiation.anatomicSiteCode Map:CTOM: Radiation.descriptionText Map:CTOM: Participant.employmentStatusCode Map:CTOM: Assessment.evaluationDate Map:CTOM: Radiation.dose Map:Lab: SubjectAssignment.type Map:CTOM: CancerStage.stageCodeSystem Map:Lab: LabResult.numericResult Map:CTOM: Radiation.startDate Map:CTOM: Radiation.type Map:CTOM: Procedure.name Map:CTOM: Radiation.stopDate Map:CTOM: QualitativeEvaluation.performanceStatusCodeSystem Map:CTOM: CancerStage.stageCode Map:CTOM: Radiation.anatomicSiteCodeSystem Map:Lab: LabResult.textResult Map:Lab: LabResult.numericPrecision Map:Lab: LabResult.testPerformedDateTime Map:CTOM: Radiation.durationValue Map:CTOM: QualitativeEvaluation.menstrualIndicator Map:Lab: SubjectAssignment.studySubjectIdentifier Map:CTOM:

			Radiation.reasonCode Map:CTOM: LesionEvaluation.evaluationDate Map:CTOM: LesionEvaluation.evaluationCode Map:Lab: LabResult.reportedResultStatus Map:CTOM: SubstanceAdministration.name Map:PSC: StudyParticipantAssignment.startDate Map:CTOM: Radiation.name Map:CTOM: Diagnosis.name Map:CTOM: QualitativeEvaluation.survivalStatusCode Map:CTOM: Radiation.scheduleText Map:CTOM: QualitativeEvaluation.survivalStatusDescriptionText
Association is the parent of	DefinedCompositionRelationship +composite 0..*, unordered, none	DefinedActivity +component 1, unordered, none	Each DefinedCompositionRelationship always is the parent of one DefinedActivity. Each DefinedActivity sometimes is the component of one or more DefinedCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is a choice that has as option	DefinedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedActivity +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedActivity. Each DefinedActivity sometimes is an option that can satisfy one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Association is the parent of	DefinedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedActivity +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedActivity. Each DefinedActivity sometimes is

			the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the component of	DefinedCompositionRelationship +component 0..*, unordered, none	DefinedActivity +composite 1, unordered, none	Each DefinedCompositionRelationship always is the component of one DefinedActivity. Each DefinedActivity sometimes is the parent of one or more DefinedCompositionRelationship. *Constraints* Inverse Relation: is the parent of
Association is an option that can satisfy	DefinedOptionRelationship +option 0..*, unordered, none	DefinedActivity +choice 1, unordered, none	Each DefinedOptionRelationship always is an option that can satisfy one DefinedActivity. Each DefinedActivity sometimes is a choice that has as option one or more DefinedOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option
Association triggers the cessation of	DefinedRepeatActivityUntilRule +triggering 0..*, unordered, none	DefinedActivity +repeated 1, unordered, none	Each DefinedRepeatActivityUntilRule always triggers the cessation of one DefinedActivity. Each DefinedActivity sometimes is repeated until one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: is repeated until
Association is a choice that has as option	DefinedOptionRelationship +choice 0..*, unordered, none	DefinedActivity +option 1, unordered, none	Each DefinedOptionRelationship always is a choice that has as option one DefinedActivity. Each DefinedActivity sometimes is an option that can satisfy one or more DefinedOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Association is contingent upon	DefinedContingentOnRelationship +contingent	DefinedActivity +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one

	0..*, unordered, none		DefinedActivity. Each DefinedActivity sometimes is a condition for one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Generalization source > target	DefinedObservation Child	DefinedActivity Parent	
Generalization source > target	DefinedProcedure Child	DefinedActivity Parent	
Generalization source > target	DefinedActivity Child	Activity Parent	
Generalization source > target	DefinedAdministrativeActivity Child	DefinedActivity Parent	

Protocol Representation Sub-Domain::DefinedActivity Attributes

Attribute	Type	Notes
nameCode	public : *CD*	A coded value specifying the non-unique textual identifier for the activity.For example, a surgical procedure might be described with CPT4 or SNOMED term.For example, in a lab test, this coded value would be associated with a single analytic procedure (and the property of the results). The textual description of the analytic test is captured in the complex data type CD. For example, the code and text of an individual question on the eligibility checklist of a protocol. Map:AE = 'ProductObservation.typeCode' Map:AE = 'Animal.overallStateOfHealthCode' Map:AE = 'SafetyReport.timeReportCompleted' Map:C3PR = 'StratificationCriterion.questionText' Map:COPPA = 'PlannedEligibilityCriterion.alternateName' Map:COPPA = 'SubstanceAdministration.nameCode' Map:COPPA = 'PlannedObservation.alternateName' Map:COPPA = 'PlannedActivity.alternateName' Map:CTOM = 'DiseaseResponse.responseCode' Map:CTOM = 'Radiation.dose' Map:CTOM = 'QualitativeEvaluation.survivalStatusCode' Map:CTOM = 'Radiation.anatomicSiteCodeSystem' Map:CTOM = 'Radiation.reasonCode' Map:CTOM = 'FemaleReproductiveCharacteristic.abortionIndicator' Map:CTOM = 'QualitativeEvaluation.anamResultAccuracyPercent' Map:CTOM = 'CancerStage.stageCode' Map:CTOM = 'DiseaseResponse.doseChangeIndicatorCode' Map:CTOM = 'FemaleReproductiveCharacteristic.firstLiveBirthAge' Map:CTOM = 'Person.employmentStatusOtherText' Map:CTOM = 'Person.employmentStatusCode ' Map:CTOM = 'Radiation.stopDate' Map:CTOM = 'StudyParticipantAssignment.offStudyDate'

		Map:CTOM = 'FemaleReproductiveCharacteristic.stillBirthCount' Map:CTOM = 'QualitativeEvaluation.performanceStatusCode' Map:CTOM = 'Radiation.name' Map:CTOM = 'Radiation.startDate' Map:CTOM = 'Radiation.durationUnitOfMeasureCode' Map:CTOM = 'Imaging.name' Map:CTOM = 'Participant.householdIncomeCode' Map:CTOM = 'DiseaseResponse.courseDispositionCode' Map:CTOM = 'Radiation.type' Map:CTOM = 'DiseaseResponse.progressionDate' Map:CTOM = 'StudyParticipantAssignment.offStudyReasonCode' Map:CTOM = 'StudyParticipantAssignment.enrollmentAge' Map:CTOM = 'DiseaseResponse.progressionPeriod' Map:CTOM = 'FemaleReproductiveCharacteristic.menopauseAge' Map:CTOM = 'Participant.employmentStatusOtherText' Map:CTOM = 'Radiation.descriptionText' Map:CTOM = 'FemaleReproductiveCharacteristic.liveBirthCount' Map:CTOM = 'Diagnosis.name' Map:CTOM = 'DiseaseResponse.commentText' Map:CTOM = 'ClinicalResult.panelName' Map:CTOM = 'DiseaseResponse.evaluationDate' Map:CTOM = 'Procedure.name' Map:CTOM = 'QualitativeEvaluation.menstrualIndicator' Map:CTOM = 'QualitativeEvaluation.survivalStatusDescriptionText' Map:CTOM = 'Radiation.scheduleText' Map:CTOM = 'CancerStage.stageCodeSystem' Map:CTOM = 'SpecimenAcquisition.name' Map:CTOM = 'AdverseEventTherapy.id' Map:CTOM = 'QualitativeEvaluation.performanceStatusCodeSystem' Map:CTOM = 'DiseaseResponse.responseCodeSystem' Map:CTOM = 'Radiation.durationValue' Map:CTOM = 'QualitativeEvaluation.painIndexCodeSystem' Map:CTOM = 'Person.householdIncomeCode' Map:CTOM = 'Specimen.volumeUnitOfMeasureCode' Map:CTOM = 'Radiation.anatomicSiteCode' Map:CTOM = 'Participant.employmentStatusCode ' Map:CTOM = 'StudyParticipantAssignment.informedConsentFormSignedDate' Map:CTOM = 'FemaleReproductiveCharacteristic.menopauseStartDate' Map:CTOM = 'Activity.name' Map:CTOM = 'QualitativeEvaluation.menstrualPatternTypeCode' Map:CTOM = 'Surgery.name' Map:CTOM = 'DiseaseResponse.progressionPeriodUnitOfMeasureCode' Map:CTOM = 'Radiation.doseUnitOfMeasureCode' Map:CTOM = 'QualitativeEvaluation.painIndexCode' Map:HL7SP = 'VerificationEvent' Map:HL7SP = 'Study.evaluation' Map:HL7SP = 'VerificationEvent.availabilityTime' Map:HL7SP = 'RegistrationEvent' Map:Lab = 'LabResult.referenceTextList' Map:Lab = 'LabTest.additionalTestDescription' Map:Lab = 'LabResult.textResult'

		Map:Lab = 'LabResult.testPerformedDateTime' Map:Lab = 'LabTest.comments' Map:Lab = 'LabTest.status' Map:Lab = 'LabResult.numericPrecision' Map:Lab = 'LabResult.reportedResultStatus' Map:Lab = 'LabResult.numericResult' Map:Lab = 'LabResult.referenceRangeComments' Map:PSC = 'Activity.name' Map:PSC = 'StudyParticipantAssignment.startDate' Map:PSC = 'VitalSign.measureTime' Map:SDTM IG = 'IE.IETEST' Map:SDTM IG = 'AE.AEACNOTH' Map:SDTM IG = 'SC.SCTESTCD' Map:SDTM IG = 'EG.EGTESTCD' Map:SDTM IG = 'PE.PETESTCD' Map:SDTM IG = 'DS.DSTERM' Map:SDTM IG = 'DM.DMDTC' Map:SDTM IG = 'QS.QSTESTCD' Map:SDTM IG = 'DS.DSSCAT' Map:SDTM IG = 'VS.VSTEST' Map:SDTM IG = 'EG.EGTEST' Map:SDTM IG = 'TI.TITEST' Map:SDTM IG = 'SC.SCTEST' Map:SDTM IG = 'VS.VSTESTCD' Map:SDTM IG = 'PE.PETEST' Map:SDTM IG = 'CO.CODTC' Map:SDTM IG = 'LB.TESTCD' Map:SDTM IG = 'DS.DSCAT' Map:SDTM IG = 'DA.DATEST' Map:SDTM IG = 'DS.DSSTDTC' Map:SDTM IG = 'LB.TEST' Map:SDTM IG = 'AE.AEACN' Map:SDTM IG = 'DA.DATESTCD' Map:SDTM IG = 'AE.AECONTRT' Map:SDTM IG = 'EX.EXTPTREF' Map:SDTM IG = 'DS.DSDECOD' Map:SDTM IG = 'IE.IETESTCD' Map:SDTM IG = 'QS.QSTEST ' Map:TDM = 'TDMPlannedActivity.codedDescription'
categoryCode	public : *CD*	A coded value specifying a classification of activities.For example, in the case where the category is "anti-cancer treatment", the subcategory may be "radiotherapy" and the nameCode may be "external beam radiotherapy".For example, in Procedure, a category might be "abdominal surgery".For example, in AdministrativeActivity, the category might be "Disposition" (off study, epoch completion), "Milestone" (informed consent, enrollment, registry, randomization) or "Other" (unblinding) activities. For example, for lab procedures, category might be "hematology", "urinalysis", "chemistry".NOTE: Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model. Map:COPPA = 'PlannedActivity.categoryCode' Map:COPPA = 'Activity.categoryCode'

		Map:COPPA = 'PlannedEligibilityCriterion.categoryCode' Map:COPPA = 'SubstanceAdministration.categoryCode' Map:COPPA = 'PlannedObservation.categoryCode' Map:COPPA = 'InterventionalStudyProtocol.interventionTypeCode' Map:CTOM = 'Imaging.type' Map:CTOM = 'Surgery.durationValue' Map:CTOM = 'Surgery.stopDate' Map:CTOM = 'SpecimenAcquisition.type' Map:CTOM = 'SubstanceAdministration.type' Map:CTOM = 'Radiation.type' Map:CTOM = 'Surgery.startDate' Map:CTOM = 'Surgery.anatomicSiteCode' Map:CTOM = 'Surgery.durationUnitOfMeasureCode' Map:CTOM = 'Surgery.name' Map:CTOM = 'Activity.type' Map:CTOM = 'Surgery.type' Map:CTOM = 'Surgery.anatomicSiteCodeSystem' Map:CTOM = 'Surgery.descriptionText' Map:CTOM = 'Surgery.reasonCode' Map:CTOM = 'Procedure.type' Map:CTOM = 'SubstanceAdministration.name' Map:Lab = 'Activity.typeModifier' Map:Lab = 'SubjectAssignment.type ' Map:PSC = 'ActivityType.name' Map:SDTM IG = 'PE.PECAT' Map:SDTM IG = 'DA.DACAT' Map:SDTM IG = 'EX.EXCAT' Map:SDTM IG = 'SU.SUCAT' Map:SDTM IG = 'VS.VSCAT' Map:SDTM IG = 'SC.SCCAT' Map:SDTM IG = 'TI.IECAT' Map:SDTM IG = 'IE.IECAT' Map:SDTM IG = 'CM.CMCAT' Map:SDTM IG = 'QS.QSCAT' Map:SDTM IG = 'EG.EGCAT' Map:SDTM IG = 'LB.LBCAT' Map:SDTM IG = 'DS.DSCAT' Map:SDTM IG = 'MH.MHCAT'
subcategoryCode	public : *CD*	A coded value specifying a subdivision within a larger category of activities.For example, "chemotherapy", "radiotherapy", "hormonal therapy", "alternative therapy". In the case where category is "anti-cancer treatment", the subcategory may be "radiotherapy" and the nameCode may be "external beam radiotherapy". For example, if categoryCode is "Intervention", subcategoryCode may be "Drug" (including placebo), "Device" (including sham), "Biological/Vaccine", "Procedure/Surgery", "Radiation", "Behavioral" (e.g., Psychotherapy, Lifestyle Counseling), "Genetic" (including gene transfer, stem cell and recombinant DNA), Dietary Supplement, etc.NOTE: Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model. Map:COPPA = 'SubstanceAdministration.subcategoryCode'

		Map:COPPA = 'PlannedObservation.subcategoryCode' Map:COPPA = 'Activity.subcategoryCode' Map:COPPA = 'PlannedEligibilityCriterion.subcategoryCode' Map:COPPA = 'PlannedActivity.subcategoryCode' Map:CTOM = 'Surgery.type' Map:Lab = 'Activity.typeModifier' Map:SDTM IG = 'EX.EXSCAT' Map:SDTM IG = 'SC.SCSCAT' Map:SDTM IG = 'EG.EGSCAT' Map:SDTM IG = 'MH.MHSCAT' Map:SDTM IG = 'SU.SUSCAT' Map:SDTM IG = 'QS.QSSCAT' Map:SDTM IG = 'IE.IESCAT' Map:SDTM IG = 'DS.DSSCAT' Map:SDTM IG = 'DA.DASCAT' Map:SDTM IG = 'LB.LBSCAT' Map:SDTM IG = 'CM.CMSCAT' Map:SDTM IG = 'PE.PESCAT' Map:SDTM IG = 'VS.VSSCAT' Map:WHO = 'Intervention(s)'
repeatFrequencyCode	public : *CD*	A coded value specifying the number of occurrences of an activity within a given time period.For example, BID = Two times per day, at unspecified times (does not necessarily imply that these are 12 hours apart) or Q12H = Every twelve hours. (examples from NCI) Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'
repeatFrequencyRatio	public : *RTO<INT,PQ.TIME>*	A ratio representing the number of occurrences of an activity within a given time period.For example, once per 12 hours or 2 times per day. Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'
repeatQuantity	public : *INT*	The number of times the activity occurs.NOTE: If the frequency is more than once a day, this is still interpreted per time, e.g. BID for 5 days is 10 repeats. Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions'

		Map:TDM = 'CyclingRule.repeatCount'
repeatDuration	public : *PQ.TIME*	The period of time over which the activity is repeated.NOTE: repeatDuration is considered derivable from repeatQuantity and frequency. In any given implementation, if quantity is not provided, duration may be provided instead, however the BRIDG team determined that quantity is considered more fundamental. Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'
description	public : *ST*	The textual representation of the activity.NOTE: This may contain more detail than the description present in the text part of a coded concept. Map:AE = 'ProductInvestigation.description' Map:BRIDGv2.2 = 'ExperimentalUnitAllocationMethod.description' Map:COPPA = 'PlannedActivity.textDescription' Map:COPPA = 'PlannedEligibilityCriterion.textDescription' Map:COPPA = 'SubstanceAdministration.textDescription' Map:COPPA = 'PlannedObservation.textDescription' Map:COPPA = 'Activity.textDescription' Map:CTOM = 'Imaging.descriptionText' Map:CTOM = 'Surgery.descriptionText' Map:CTOM = 'Radiation.descriptionText' Map:CTOM = 'Histopathology.reportDescriptiveText' Map:CTOM = 'SpecimenAcquisition.descriptionText' Map:CTOM = 'Procedure.descriptionText' Map:CTOM = 'Activity.descriptionText' Map:HL7SD = 'EligibilityCriterion.text' Map:Lab = 'LabTest.additionalTestDescription' Map:PSC = 'Activity.description' Map:SDTM IG = 'SV.SVUPDES' Map:TDM = 'TDMPlannedActivity.description'
statusCode	public : *CD*	A coded value specifying the state of the activity as part of a global library.For example, "Draft New", "Released", "Retired Archived", etc.NOTE: A state is a named phase (or potential phase) of an instance of a concept in its lifecycle. Map:COPPA = 'PlannedActivity.statusCode' Map:COPPA = 'PlannedObservation.statusCode' Map:COPPA = 'PlannedEligibilityCriterion.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the activity. Map:COPPA = 'PlannedEligibilityCriterion.statusDateRange' Map:COPPA = 'PlannedActivity.statusDateRange' Map:COPPA = 'PlannedObservation.statusDateRange'

6.22 Protocol Representation Sub-Domain::DefinedAdministrativeActivity

public Class {leaf}

Extends: DefinedActivity. :

The defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is not directly related to hypothesis evaluation or testing, but is typically essential to the efficient and/or effective coordination and execution of a study.

For example, assignment to a treatment arm, registration to a study, start of on-study period, end of on-study period, obtain informed consent, verify eligibility criteria, enroll, randomize, complete study visits, exit trial, break treatment blind, protocol violation, premature withdrawal, etc.

Protocol Representation Sub-Domain::DefinedAdministrativeActivity Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedStudySubjectMilestone Child	DefinedAdministrativeActivity Parent	
Generalization source > target	DefinedStudyAdministrativeActivity Child	DefinedAdministrativeActivity Parent	
Generalization source > target	DefinedSpecimenStorage Child	DefinedAdministrativeActivity Parent	
Generalization source > target	DefinedAdministrativeActivity Child	DefinedActivity Parent	
Generalization source > target	DefinedExperimentalUnitAllocation Child	DefinedAdministrativeActivity Parent	
Generalization source > target	DefinedStudyAgentTransfer Child	DefinedAdministrativeActivity Parent	

6.23 Protocol Representation Sub-Domain::DefinedCompositionRelationship

public Class:

A relationship between a composite activity and the component activities that comprise it, i.e. parent and child activities, where all these activities are part of a global library of activities.

For example, a battery of tests may be composed of multiple routine labs that are always ordered together as a group. Another example is a glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose.

NOTE: This class helps represent an AND relationship between siblings with the same parent activity.

Protocol Representation Sub-Domain::DefinedCompositionRelationship Connections

Connector	Source	Target	Notes
Association is the parent of	DefinedCompositionRelationship +composite 0..*, unordered, none	DefinedActivity +component 1, unordered, none	Each DefinedCompositionRelationship always is the parent of one DefinedActivity. Each DefinedActivity sometimes is the

			component of one or more DefinedCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the component of	DefinedCompositionRelationship +component 0..*, unordered, none	DefinedActivity +composite 1, unordered, none	Each DefinedCompositionRelationship always is the component of one DefinedActivity. Each DefinedActivity sometimes is the parent of one or more DefinedCompositionRelationship. *Constraints* Inverse Relation: is the parent of

Protocol Representation Sub-Domain::DefinedCompositionRelationship Attributes

Attribute	Type	Notes
sequenceNumber	public : *INT*	An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.For example, in a course of treatment (a composite activity) that is composed of a chemotherapy activity and a radiotherapy activity, the sequence number indicates which component activity precedes the other. Map:CTOM = 'ActivityRelationship.sequenceNumber'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference. NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution.For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:TDMv2 = '(New content)'
comment	public : *ST*	Additional description of the composition relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.
- Map:Lab = Activity.plannedTimeElapsed.

6.24 Protocol Representation Sub-Domain::DefinedContingentOnRelationship

public Class:
A relationship between an activity and one of the following:

- the outcome of another activity where the source activity does not occur unless the target activity outcome has occurred and all activities are part of the global library of activities;
- another activity where the source activity does not occur unless the target activity has occurred and all these activities are part of a global library of activities;
- a group of other criteria that may be composed of a mix of other activities, observation results and/or other groups.

For example, only perform a certain lab test if drug X was administered. (target = another activity)

For example, only perform a substance administration of drug X if the blood pressure was over some threshold number. (target = observation result from another activity that is an observation)

For example, only perform a substance administration of drug Y if the blood pressure was over some threshold number and either the result of a certain lab test was positive or the subjects temperature was elevated, i.e. "(A and (B or C))".

Constraints

- *Approved Invariant* . completionRequiredIndicator Qualifier.
  The completionRequiredBeforeStartingIndicator may only be used if the target of this relationship is an activity, not if the target is an observation result or a criterion group.
- *Approved Invariant* . Is Contingent Upon Exclusive Or.
  A DefinedContingentOnRelationship must only be associated to only one of the following: a DefinedActivity, a DefinedObservationResult, or a DefinedCriterionGroup.

Protocol Representation Sub-Domain::DefinedContingentOnRelationship Connections

Connector	Source	Target	Notes
Association is a condition for	DefinedContingentOnRelationship +prerequisite 0..*, unordered, none	DefinedActivity +contingent 1, unordered, none	Each DefinedContingentOnRelationship always is a condition for one DefinedActivity. Each DefinedActivity sometimes is contingent upon one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is contingent upon
Association is contingent upon	DefinedContingentOnRelationship +contingent 0..*, unordered, none	DefinedObservationResult +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each DefinedObservationResult sometimes is a condition for one or

			more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is contingent upon	DefinedContingentOnRelationship +contingent 0..*, unordered, none	DefinedCriterionGroup +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is a condition for one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is contingent upon	DefinedContingentOnRelationship +contingent 0..*, unordered, none	DefinedActivity +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one DefinedActivity. Each DefinedActivity sometimes is a condition for one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for

Protocol Representation Sub-Domain::DefinedContingentOnRelationship Attributes

Attribute	Type	Notes
evaluableExpression	public : *ED*	A computable logical expression that can involve temporal, clinical, and other operands. It can be composed of sub expressions to create arbitrarily complex and recursive statements.For example, (<2 weeks> since <last dose >) and (SysBP[now] > 140 and DiaBP [now]> 90)NOTE: The data type of this attribute is ED, reflecting the ability of the attribute to support the semantics of one of several grammars for building evaluable expressions via ED.mediaType. An assumption here is that a system defining such an expression must identify the source grammar in the mediaType to ensure that any consuming system parses the expression with the proper parser. For example, an evaluable expression in the 'TDM Markup Language' (TDML) with the form "IF X > 12 THEN ~ EPOCH --TO +3 D ``PREVIOUS EPOCH" would be carried in the ED data type properties as follows:ED.value: IF X > 12 THEN ~ EPOCH --TO +3 D ``PREVIOUS EPOCHED.mediaType: text/bridg-tdm+xml (this is an invented expression language used for this example)Example values for known expression languages and the related ED.mediatype include but are not limited to:Language: OCL; MediaType: text/plain+oclLanguage: Factor; MediaType: application/hl7-factor+xmlLanguage: MathML; MediaType: application/mathml+xml

		Map:TDM = 'TriggeringRule'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed'
completionRequiredBeforeStartingIndicator	public : *BL*	Indicates whether or not the target activity must have completed prior to starting the source activity.NOTE: This attribute may only be used if the target is an activity, not if the target is an observation result or a criterion group. Map:TDM = 'TriggeringRule'
comment	public : *ST*	Additional description of the contingent on relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.25 Protocol Representation Sub-Domain::DefinedCriterionGroup

public Class:
A collection of conditions joined together via composition (ANDed) and/or optionality (ORed) to form a logical expression upon which the execution of an activity is based or upon which the cessation of a repeated activity is based, where components of the group may include other activities, observation results and/or other criterion groups, and where both the criterion group and it's components are defined as part of the global library and as such are not necessarily part of any particular study.

For example, (A and (B or C)), where A might be an activity, B and C might be 2 different observation results, and the two sets of parentheses are 2 criterion groups, one inside (a component of) the other.

NOTE: A criterion group represents the parentheses around a set of criteria in a logical expression.

Protocol Representation Sub-Domain::DefinedCriterionGroup Connections

Connector	Source	Target	Notes
Association is the parent of	DefinedCriterionGroup CompositionRelationship +composite 0..*, unordered, none	DefinedCriterionGroup +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of

Association is repeated until	DefinedRepeatActivityUntilRule +repeated 0..*, unordered, none	DefinedCriterionGroup +triggering 0..1, unordered, none	Each DefinedRepeatActivityUntilRule sometimes is repeated until one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is a choice that has as option	DefinedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedCriterionGroup +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is an option that can satisfy one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Association is an option that can satisfy	DefinedCriterionGroupOptionRelationship +option 0..*, unordered, none	DefinedCriterionGroup +choice 1, unordered, none	Each DefinedCriterionGroupOptionRelationship always is an option that can satisfy one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is a choice that has as option one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option
Association is contingent upon	DefinedContingentOnRelationship +contingent 0..*, unordered, none	DefinedCriterionGroup +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is a condition for one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for

Association is the component of	DefinedCriterionGroup CompositionRelationship +component 0..*, unordered, none	DefinedCriterionGroup +composite 1, unordered, none	Each DefinedCriterionGroupCompositionRelationship always is the component of one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is the parent of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the parent of

6.26 Protocol Representation Sub-Domain::DefinedCriterionGroupCompositionRelationship

public Class:
A relationship between a criterion group and an activity, observation result or other criterion group that is a component, i.e. a relationship between a logical set of parenthesis and one of the items inside the parentheses, where the criterion group and its components are both part of a global library of activities.

For example, a battery of tests may be composed of multiple routine labs that are always ordered together as a group.

Another example is a glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose.

NOTE: This class helps represent an AND relationship between siblings in the same criterion group.

Constraints

- *Approved Invariant* . Is the Component Of Exclusive Or.
  A DefinedCriterionGroupCompositionRelationship must be associated to only one of the following targets: a DefinedActivity, a DefinedObservationResult, or another DefinedCriterionGroup.

Protocol Representation Sub-Domain::DefinedCriterionGroupCompositionRelationship Connections

Connector	Source	Target	Notes
Association is the parent of	DefinedCriterionGroup CompositionRelationship +composite 0..*, unordered, none	DefinedCriterionGroup +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of

Association is the parent of	DefinedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedActivity +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedActivity. Each DefinedActivity sometimes is the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the parent of	DefinedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedObservationResult +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedObservationResult. Each DefinedObservationResult sometimes is the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the component of	DefinedCriterionGroupCompositionRelationship +component 0..*, unordered, none	DefinedCriterionGroup +composite 1, unordered, none	Each DefinedCriterionGroupCompositionRelationship always is the component of one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is the parent of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the parent of

Protocol Representation Sub-Domain::DefinedCriterionGroupCompositionRelationship Attributes

Attribute	Type	Notes
sequenceNumber	public : *INT*	An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.For example, in a criterion group that is composed of a substance administration activity and a lab test activity, the sequence number indicates which activity precedes the other. Map:CTOM = 'ActivityRelationship.sequenceNumber'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with

		the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference. NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an Activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:TDMv2 = '(New content)'
comment	public : *ST*	Additional description of the criterion group composition relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.27 Protocol Representation Sub-Domain::DefinedCriterionGroupOptionRelationship

public Class:

A relationship between a criterion group and an option that can satisfy it, either an activity, observation result or other criterion group, i.e. a relationship between a logical set of parenthesis and one of the options inside the parentheses, where the criterion group and its option are both part of a global library of activities.

For example, a pain management criterion group may be comprised of three options, one for substance administration of Tylenol, another for substance administration of aspirin, and a third for substance administration of ibuprofen. The pain management criterion would be satisfied/accomplished with any one of these activities and would be associated to each of the three via a different DefinedCriterionGroupOptionRelationship.

NOTE: This class helps represent an OR relationship between siblings in the same criterion group.

Constraints

- *Approved Invariant* . Is the Choice that has as Option Exclusive Or.
  A DefinedCriterionGroupOptionRelationship must be associated to only one of the following targets: a DefinedActivity, a DefinedObservationResult, or another DefinedCriterionGroup.

Protocol Representation Sub-Domain::DefinedCriterionGroupOptionRelationship Connections

Connector	Source	Target	Notes
Association is a choice that has as option	DefinedCriterionGroup OptionRelationship +choice 0..*, unordered, none	DefinedActivity +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedActivity. Each DefinedActivity sometimes is an option that can satisfy one or

			more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Association is a choice that has as option	DefinedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedCriterionGroup +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is an option that can satisfy one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Association is an option that can satisfy	DefinedCriterionGroupOptionRelationship +option 0..*, unordered, none	DefinedCriterionGroup +choice 1, unordered, none	Each DefinedCriterionGroupOptionRelationship always is an option that can satisfy one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes is a choice that has as option one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option
Association is a choice that has as option	DefinedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedObservationResult +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedObservationResult. Each DefinedObservationResult sometimes is an option that can satisfy one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy

Protocol Representation Sub-Domain::DefinedCriterionGroupOptionRelationship Attributes

Attribute	Type	Notes
pauseQuantity	public :	A quantity of time that should elapse between when an activity is

	PQ.TIME	ready for execution and the actual beginning of the execution.For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference. NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
comment	public : *ST*	Additional description of the criterion group option relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.28 Protocol Representation Sub-Domain::DefinedEligibilityCriterion

public Class {leaf}

Extends: DefinedObservation. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, identifies one of a set of conditions that a Subject must meet in order to participate in a study, or that a StudySubject must meet into order to participate in a certain part of the study.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  A DefinedEligibilityCriterion may only be associated with a Subject or StudySubject, not an ExperimentalUnit.

Protocol Representation Sub-Domain::DefinedEligibilityCriterion Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedEligibilityCriterion Child	DefinedObservation Parent	
Generalization source > target	DefinedExclusionCriterion Child	DefinedEligibilityCriterion Parent	
Generalization source > target	DefinedInclusionCriterion Child	DefinedEligibilityCriterion Parent	

Protocol Representation Sub-Domain::DefinedEligibilityCriterion Attributes

Attribute	Type	Notes
requiredResponse	public : *ANY*	The reply necessary to include/exclude a potential subject on a study. Map:COPPA = 'PlannedEligibilityCriterion.requiredResponse'
displayOrder	public : *INT*	The sequence or position of a component in a list of question or data items. Map:COPPA = 'PlannedEligibilityCriterion.displayOrder'

Tagged Values

- Map:HL7SD = EligibilityCriterion.

6.29 Protocol Representation Sub-Domain::DefinedExclusionCriterion

public Class {leaf}

Extends: DefinedEligibilityCriterion. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, identifies a characteristic or requirement intended to be applied to a potential StudySubject to determine whether they may participate in a study.

For example, must be over the age of 18.

Protocol Representation Sub-Domain::DefinedExclusionCriterion Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedExclusionCriterion Child	DefinedEligibilityCriterion Parent	

6.30 Protocol Representation Sub-Domain::DefinedExperimentalUnitAllocation

public Class {leaf}

Extends: DefinedAdministrativeActivity. :

The defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is not directly related to hypothesis evaluation or testing, but is the assignment of an experimental unit to a portion of the study, such as an Arm or a portion of an Arm (when secondary allocations may occur).

For example, randomization, direct assignment based on eligibility criteria, etc.

Protocol Representation Sub-Domain::DefinedExperimentalUnitAllocation Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedExperimentalUnitAllocation Child	DefinedAdministrativeActivity Parent	

Protocol Representation Sub-Domain::DefinedExperimentalUnitAllocation Attributes

Attribute	Type	Notes
methodCode	public : *CD*	A coded value specifying the technique that is used for allocating experimental units.For example, adaptive, blocked, stratified,

		allocation based on past response. Map:BRIDGv2.2 = 'ExperimentalUnitAllocationMethod.typeCode'

6.31 Protocol Representation Sub-Domain::DefinedImaging

public Class {leaf}

Extends: DefinedObservation. :

A reusable, "template" description of an activity whose intention is to obtain pictures of the interior of the body usually for diagnostic reasons.

For example, X-ray, MRI, etc.

Protocol Representation Sub-Domain::DefinedImaging Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedImaging Child	DefinedObservation Parent	

Protocol Representation Sub-Domain::DefinedImaging Attributes

Attribute	Type	Notes
enhancementRateValue	public : *RTO<PQ, PQ.TIME>*	Numeric value to indicate an increase in voxel signal over time for an MRI, expressed as signal intensity units per second. Map:CTOM = 'Imaging.enhancementRateValue'
enhancementDescription	public : *ST*	The textual representation for how an image is enhanced either physically or electronically. Map:CTOM = 'Imaging.enhancementDescriptionText'
contrastAgentEnhancementIndicator	public : *BL*	Specifies whether the image is enhanced by the use of a contrast agent. Map:CTOM = 'Imaging.contrastAgentEnhancementIndicator'

6.32 Protocol Representation Sub-Domain::DefinedInclusionCriterion

public Class {leaf}

Extends: DefinedEligibilityCriterion. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, identifies a characteristic or requirement intended to be applied to a potential StudySubject to determine whether they may not participate in a study.

For example, pregnancy.

Protocol Representation Sub-Domain::DefinedInclusionCriterion Connections

Connector	Source	Target	Notes

Generalization source > target	DefinedInclusionCriterion Child	DefinedEligibilityCriterion Parent	

6.33 Protocol Representation Sub-Domain::DefinedObservation

public Class {leaf}

Extends: DefinedActivity. :

A reusable, "template" description of an activity whose intention is to obtain a result by observing, monitoring, measuring or otherwise qualitatively or quantitatively gathering data or information about one or more aspects of a StudySubject's or ExperimentalUnit's physiologic or psychologic state.

For example, a blood chemistry panel, a body mass index calculation, a blood pressure measurement, etc.

Protocol Representation Sub-Domain::DefinedObservation Connections

Connector	Source	Target	Notes
Association is a result of	DefinedObservationResult +produced 0..*, unordered, none	DefinedObservation +producing 1, unordered, none	Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation sometimes results in one or more DefinedObservationResult. *Constraints* Inverse Relation: results in
Generalization source > target	DefinedEligibilityCriterion Child	DefinedObservation Parent	
Generalization source > target	DefinedObservation Child	DefinedActivity Parent	
Generalization source > target	DefinedStratificationCriterion Child	DefinedObservation Parent	
Generalization source > target	DefinedImaging Child	DefinedObservation Parent	

Protocol Representation Sub-Domain::DefinedObservation Attributes

Attribute	Type	Notes
methodCode	public : *DSET<CD>*	A coded value specifying the technique that is used for the observation.For example, blood pressure measurement method could be arterial puncture or sphygmomanometry.For example, global introspection, algorithm, bayesian to assess AE causality.For example for a clinical result assay method, values could include: Estrogen Receptor Assay, Progesterone Receptor Assay, p53 Assay, etc. Map:AE = 'CausalAssessment.methodCode' Map:AE = 'PerformedProductInvestigation.evaluationMethodCode' Map:CTOM = 'LesionDescription.methodCode' Map:CTOM = 'ClinicalResult.meansVitalStatusObtainedCode' Map:CTOM = 'ClinicalResult.assayMethodCode' Map:CTOM = 'ClinicalResult.labTechniqueCode'

bodyPositionCode	public : *CD*	A coded value specifying the 3-dimensional spatial orientation of a subject during a particular observation.For example, supine, trendelenburg, standing, etc. AE:Exclude = 'True' Map:CTOM = 'ClinicalResult.bodyPositionCode' Map:PSC = 'VS.VSPOS' Map:SDTM IG = 'EG.EGPOS'
targetAnatomicSiteCode	public : *CD*	A coded value specifying the anatomic location that is the focus of the observation.For example, gastrointestinal, cardiovascular. Map:AE = 'AdverseEvent.bodyLocation' Map:CTOM = 'LesionDescription.anatomicSiteCode' Map:CTOM = 'Diagnosis.primaryAnatomicSiteCode' Map:CTOM = 'LesionDescription.anatomicSiteCodeSystem' Map:CTOM = 'Diagnosis.primaryAnatomicSiteCodeSystem'
targetAnatomicSiteLaterality Code	public : *CD*	A coded value specifying the side of the body (or a paired organ) where the target anatomic site is. For example, Bilateral, Left, Right. Map:AE = 'AdverseEvent.bodyLocation' Map:CTOM = 'Diagnosis.primaryAnatomicSiteLateralityCode'
derivationExpression	public : *ST*	A character string containing a formal language expression that specifies how the observation's attributes are, should be, or have been derived from input parameters associated with activity. Map:TDMv2 = '(New content)'
focalDuration	public : *PQ.TIME*	A quantity of time in which the observation result is held to be true.For example, 2 months is the evaluation interval for a question such as "Have you smoked in the last 2 months".NOTE: The focalDuration can be derived from the expression captured in the focalDateRange.EXPR<IVL<TS.DATETIME>>. AE:Exclude = 'True' Map:CTOM = 'DiseaseResponse.progressionPeriodUnitOfMeasureCode' Map:CTOM = 'DiseaseResponse.progressionPeriod' Map:SDTM IG = 'QS.QSEVLINT'
focalDateRange	public : *EXPR<IVL<TS.DATETIME>>*	The time period in which the observation result is held to be true, expressed either as a simple date range or as an evaluable expression that references a study-defined date or milestone.For example, for a survey question, "Have you traveled to Europe between 1990 and 1999?", the focalDateRange would be "January 1, 1990 to December 31, 1999", or for the question, "Have you smoked in the last 2 months", the focalDateRange would be an expression referencing a variable that represents the PerformedObservation.actualDateRange (a value yet to be defined) and a formula for the date range between when the question is asked (PerformedObservation.actualDateRange.low) and 2 months prior (PerformedObservation.actualDateRange.low -

		2 months).NOTE: As an attribute with data type EXPR<IVL<TS.DATETIME>>, focalDateRange can be used to express a simple date range such as "January 1, 1990 to December 31, 1999" or a relative time expression that includes a variable that represents another date in the model that is a study-defined anchor point. The other date may or may not be known at the time the DefinedObservation is created, but will be known by the time the PerformedObservation is created. AE:Exclude = 'True' Map:CTOM = 'Diagnosis.confirmationDate' Map:CTOM = 'Histopathology.reportingDate' Map:CTOM = 'DiseaseResponse.evaluationDate' Map:CTOM = 'DiseaseResponse.progressionDate'

6.34 Protocol Representation Sub-Domain::DefinedObservationResult

public Class:
A reusable, "template" description of a possible outcome of an observation.

For example, a blood pressure measurement may result in a diastolic number and a systolic number.

NOTE: The DefinedObservationResult class can be used to represent defined ranges for contingencies by constraining the result attribute from ANY to IVL<PQ>, for instance, or any other range value. Such DefinedObservationResults may be used as criteria for conditional activities or repeated activities.

Protocol Representation Sub-Domain::DefinedObservationResult Connections

Connector	Source	Target	Notes
Association is contingent upon	DefinedContingentOnRelationship +contingent 0..*, unordered, none	DefinedObservationResult +prerequisite 0..1, unordered, none	Each DefinedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each DefinedObservationResult sometimes is a condition for one or more DefinedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is repeated until	DefinedRepeatActivityUntilRule +repeated 0..*, unordered, none	DefinedObservationResult +triggering 0..1, unordered, none	Each DefinedRepeatActivityUntilRule sometimes is repeated until one DefinedObservationResult. Each DefinedObservationResult sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of

Association is the parent of	PlannedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedObservationResult +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedObservationResult. Each DefinedObservationResult sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is a result of	DefinedObservationResult +produced 0..*, unordered, none	DefinedObservation +producing 1, unordered, none	Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation sometimes results in one or more DefinedObservationResult. *Constraints* Inverse Relation: results in
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	DefinedObservationResult +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each DefinedObservationResult sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is a choice that has as option	PlannedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedObservationResult +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedObservationResult. Each DefinedObservationResult sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy

Association is the parent of	DefinedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedObservationResult +component 0..1, unordered, none	Each DefinedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedObservationResult. Each DefinedObservationResult sometimes is the component of one or more DefinedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is repeated until	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	DefinedObservationResult +triggering 0..1, unordered, none	Each PlannedRepeatActivityUntilRule sometimes is repeated until one DefinedObservationResult. Each DefinedObservationResult sometimes triggers the cessation of one or more PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is a choice that has as option	DefinedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedObservationResult +option 0..1, unordered, none	Each DefinedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedObservationResult. Each DefinedObservationResult sometimes is an option that can satisfy one or more DefinedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy
Generalization source > target	DefinedStratificationCriterionPermissibleResult Child	DefinedObservationResult Parent	

Protocol Representation Sub-Domain::DefinedObservationResult Attributes

Attribute	Type	Notes
result	public : *ANY*	Data or information that is determined by an act of observation.For example, the result of a lab test, physical finding, self-reported symptom.For example, the adverse event term code.NOTE: The DefinedObservationResult class can be used to represent defined ranges for contingencies by constraining the result attribute from ANY to IVL<PQ>, for instance, or any other range value. Such

		DefinedObservationResults may be used as criteria for conditional activities or repeated activities. Map:AE = 'AdverseEvent.reactionText' Map:AE = 'Assessment.textInterpretation' Map:AE = 'ProductInvestigation.evaluationResultCode' Map:AE = 'Assessment.codedInterpretation' Map:AE = 'Animal.overallStateOfHealthCode' Map:AE = 'InvestigativeSubject.gestationPeriod' Map:AE = 'AdverseEvent.adverseEventTermCode' Map:AE = 'Person.numberOfSiblings' Map:AE = 'ProductObservation.value' Map:C3PR = 'StratificationCriterionPermissbleAnswer.permissibleAnswer' Map:CTOM = 'QualitativeEvaluation.performanceStatusCodeSystem' Map:CTOM = 'DeathSummary.deathCauseText' Map:CTOM = 'QualitativeEvaluation.painIndexCodeSystem' Map:CTOM = 'AdverseEvent.descriptionText' Map:CTOM = 'QualitativeEvaluation.survivalStatusDescriptionText' Map:CTOM = 'FemaleReproductiveCharacteristic.stillBirthCount' Map:CTOM = 'Diagnosis.diseaseDiagnosisCode' Map:CTOM = 'DeathSummary.deathCauseCode' Map:CTOM = 'ClinicalResult.valueUnitOfMeasureCode' Map:CTOM = 'ClinicalResult.value' Map:CTOM = 'FemaleReproductiveCharacteristic.menopauseAge' Map:CTOM = 'FemaleReproductiveCharacteristic.abortionIndicator' Map:CTOM = 'CancerStage.stageCode' Map:CTOM = 'PartcipantEligibilityAnswer.answerText' Map:CTOM = 'QualitativeEvaluation.menstrualPatternTypeCode' Map:CTOM = 'Diagnosis.diseaseDiagnosisCodeSystem' Map:CTOM = 'QualitativeEvaluation.menstrualIndicator' Map:CTOM = 'Participant.householdIncomeCode' Map:CTOM = 'QualitativeEvaluation.performanceStatusCode' Map:CTOM = 'Diagnosis.diseaseStatusCode' Map:CTOM = 'FemaleReproductiveCharacteristic.firstLiveBirthAge' Map:CTOM = 'QualitativeEvaluation.anamResultAccuracyPercent' Map:CTOM = 'Specimen.volume' Map:CTOM = 'AdverseEvent.outcomeCode' Map:CTOM = 'LesionEvaluation.evaluationCode' Map:CTOM = 'Specimen.volumeUnitOfMeasureCode' Map:CTOM = 'DiseaseResponse.courseDispositionCode' Map:CTOM = 'Diagnosis.recurrenceIndicator' Map:CTOM = 'QualitativeEvaluation.survivalStatusCode' Map:CTOM = 'CancerStage.stageCodeSystem' Map:CTOM = 'QualitativeEvaluation.painIndexCode' Map:CTOM = 'Histopathology.grossExamResultCode' Map:CTOM = 'FemaleReproductiveCharacteristic.liveBirthCount' Map:CTOM = 'DiseaseResponse.responseCodeSystem' Map:CTOM = 'DiseaseResponse.responseCode' Map:HL7SP = 'VerificationEvent.value' Map:Lab = 'LabResult.referenceTextList'

		Map:Lab = 'LabResult.numericResult' Map:Lab = 'LabResult.numericPrecision' Map:Lab = 'LabResult.textResult' Map:SDTM IG = 'EG.EGSTRESC' Map:SDTM IG = 'EG.EGORRESU' Map:SDTM IG = 'LB.LBLOINC' Map:SDTM IG = 'VS.VSORRES' Map:SDTM IG = 'QS.QSORRES' Map:SDTM IG = 'TS.TSVAL' Map:SDTM IG = 'AE.AETERM' Map:SDTM IG = 'DV.DVDECOD' Map:SDTM IG = 'IE.IESTRESC' Map:SDTM IG = 'SC.SCORRES' Map:SDTM IG = 'LB.LBORRES' Map:SDTM IG = 'PE.PESTRESN' Map:SDTM IG = 'PE.PEORRESU' Map:SDTM IG = 'MH.MHTERM' Map:SDTM IG = 'PE.PESTRESU ' Map:SDTM IG = 'QS.QSORRESU' Map:SDTM IG = 'LB.LBSTRESU' Map:SDTM IG = 'VS.VSSTRESN' Map:SDTM IG = 'LB.LBSTRESC' Map:SDTM IG = 'LB.LBORRESU' Map:SDTM IG = 'SC.SCSTRESC' Map:SDTM IG = 'EG.EGSTRESN' Map:SDTM IG = 'PE.PESTRESC' Map:SDTM IG = 'VS.VSSTRESC' Map:SDTM IG = 'QS.QSSTRESC' Map:SDTM IG = 'SC.SCSTRESU' Map:SDTM IG = 'QS.QSSTRESU' Map:SDTM IG = 'EG.EGLOINC' Map:SDTM IG = 'SC.SCSTRESN' Map:SDTM IG = 'MH.MHDECOD' Map:SDTM IG = 'EG.EGORRES' Map:SDTM IG = 'SC.SCORRESU' Map:SDTM IG = 'VS.VSLOINC' Map:SDTM IG = 'EG.EGSTRESU' Map:SDTM IG = 'VS.VSSTRESU' Map:SDTM IG = 'MH.MHOCCUR' Map:SDTM IG = 'VS.VSORRESU' Map:SDTM IG = 'LB.LBSTRESN' Map:SDTM IG = 'CM.CMOCCUR' Map:SDTM IG = 'AE.AEDECOD' Map:SDTM IG = 'PE.PEORRES' Map:SDTM IG = 'QS.QSSTRESN' Map:SDTM IG = 'DS.DSTERM' Map:SDTM IG = 'IE.IEORRES'
typeCode	public : *CD*	A coded value specifying the kind of observation result.For example, for blood pressure, the results might be 120 for systolic and 80 for diastolic, where systolic and diastolic are the typeCode distinguishing the two numbers. Map:CTOM = 'ClinicalResult.value'
targetCodingSystem	public :	The coding system to use for recording results for the associated

	II	activity or evaluation. Map:BRIDGv2.2 = 'PlannedObservationResult.targetCodingSystem'
targetAnatomicSiteCode	public : *CD*	A coded value specifying the anatomic location that is the focus of an observation result.For example, left arm for skin rash. NOTE: The target site of the result may be different than the target site of the activity (PerformedObservation) that generated it. Map:CTOM = 'LesionDescription.contactAnatomicSiteCodeSystem' Map:CTOM = 'LesionDescription.contactAnatomicSiteCode'
confidentialityCode	public : *CD*	A coded value specifying the degree of privacy applicable for the observation result. Map:CTOM = 'Histopathology.confidentialityCode' Map:CTOM = 'LesionDescription.confidentialityCode' Map:CTOM = 'Observation.confidentialityCode' Map:CTOM = 'ClinicalResult.confidentialityCode'
comment	public : *ST*	Additional description of the observation result.For example, comments from the investigator regarding the condition of the specimen or any other observation.For example, comments in addition to the specimen condition from the central or performing laboratory describing the specimen. Map:CTOM = 'DiseaseResponse.commentText' Map:Lab = 'LabResult.referenceRangeComments' Map:SDTM IG = 'CO.COVAL'

6.35 Protocol Representation Sub-Domain::DefinedOptionRelationship

public Class:
A relationship between a composite activity and an option that can satisfy it, i.e. choice and option activities, where all these activities are part of a global library of activities.

For example, a pain management activity may be comprised of three options, one for substance administration of Tylenol, another for substance administration of aspirin, and a third for substance administration of ibuprofen. The pain management activity would be satisfied/accomplished with any one of these activities and would be associated to each of the three via a different DefinedOptionRelationship.

NOTE: This class helps represent an OR relationship between siblings with the same parent activity.

Protocol Representation Sub-Domain::DefinedOptionRelationship Connections

Connector	Source	Target	Notes
Association is an option that can satisfy	DefinedOptionRelationship +option 0..*, unordered, none	DefinedActivity +choice 1, unordered, none	Each DefinedOptionRelationship always is an option that can satisfy one DefinedActivity. Each DefinedActivity sometimes is a choice that has as option one or more DefinedOptionRelationship.

			Constraints Inverse Relation: is a choice that has as option
Association is a choice that has as option	DefinedOptionRelationship +choice 0..*, unordered, none	DefinedActivity +option 1, unordered, none	Each DefinedOptionRelationship always is a choice that has as option one DefinedActivity. Each DefinedActivity sometimes is an option that can satisfy one or more DefinedOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy

Protocol Representation Sub-Domain::DefinedOptionRelationship Attributes

Attribute	Type	Notes
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference. NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
comment	public : *ST*	Additional description of the option relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.36 Protocol Representation Sub-Domain::DefinedProcedure

public Class {leaf}

Extends: DefinedActivity. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is an action whose immediate and primary intention is the alteration of the physical condition of the StudySubject or ExperimentalUnit.

For example, procedures may involve the disruption of some body surface (e.g. an incision in a surgical procedure), conservative procedures such as reduction of a luxated joint, including physiotherapy such as chiropractic treatment, massage, balneotherapy, acupuncture, shiatsu, etc.

Constraints

- *Approved Invariant* . Uses Qualifier.
  A DefinedProcedure can only use Product where actualIndicator = False.

Protocol Representation Sub-Domain::DefinedProcedure Connections

Connector	Source	Target	Notes
Association uses	DefinedProcedure +using 0..*, unordered, none	Product +used 0..*, unordered, none	Each DefinedProcedure sometimes uses one or more Product. Each Product sometimes is used during one or more DefinedProcedure. *Constraints* Inverse Relation: is used during
Generalization source > target	DefinedSubstanceAdministration Child	DefinedProcedure Parent	
Generalization source > target	DefinedProcedure Child	DefinedActivity Parent	
Generalization source > target	DefinedSpecimenCollection Child	DefinedProcedure Parent	

Protocol Representation Sub-Domain::DefinedProcedure Attributes

Attribute	Type	Notes
methodCode	public : *CD*	A coded value specifying the technique that is used for the procedure.For example, for a specimen collection the methodCode could represent finger stick, veni puncture, Abdominal/ ascites effusion, Biopsy, Bronchial alveolar lavage (BAL), etc.For example, if procedure is cholecystectomy the methodCode could represent "open" or "laproscopic". Map:BRIDGv2.2 = 'PlannedProcedure.methodCode'
approachAnatomicSiteCode	public : *CD*	A coded value specifying the anatomic location or access point for a procedure.For example, right arm for an injection, trans-abdominal for a nephrectomy. Map:BRIDGv2.2 = 'PlannedProcedure.approachSiteCode'
targetAnatomicSiteCode	public : *CD*	A coded value specifying the anatomic location that is the focus of a procedure.For example, for a nephrectomy, the target site could be left kidney. NOTE: multiple contiguous sites within the same organ system may be referenced. Map:BRIDGv2.2 = 'PlannedProcedure.targetSiteCode'
targetAnatomicSiteConditionCode	public : *CD*	A coded value specifying the state of the target anatomic site.For example, the subject's left arm was bruised where the IV was inserted.

		Map:BRIDGv2.2 = 'PlannedProcedure.targetSiteConditionCode'

6.37 Protocol Representation Sub-Domain::DefinedRepeatActivityUntilRule

public Class:
A relationship between two activities where the source activity continues repeating until the target activity occurs and all activities are part of a global library.

For example, continue repeating kidney dialysis until kidney transplant surgery.

A relationship between a defined repeating activity and one of the following that may trigger the repeating activity to stop:

- another defined activity where the source activity does not occur unless the target activity has occurred and both activities are part of a global library of activities;
- the outcome of another defined activity where the source activity does not occur unless the target activity outcome has occurred and all activities are part of the global library of activities;
- a defined group of other criteria that may be composed of a mix of other activities, observation results and/or other groups.

For example, continue performing a certain lab test weekly until the three-month checkup occurs. (target = another activity)

For example, continue substance administration of drug X until the blood pressure is over some minimum threshold number. (target = observation result from another activity that is an observation)

For example, continue substance administration of drug Y until the blood pressure is over some minimum threshold number and either the result of a certain lab test is positive or the subjects temperature is elevated, i.e. "(A and (B or C))".

Constraints

- *Approved Invariant* . Is Repeated Until Exclusive Or.
  A DefinedRepeatActivityUntilRule must only be associated to only one of the following: a DefinedActivity, a DefinedObservationResult, or a DefinedCriterionGroup.

Protocol Representation Sub-Domain::DefinedRepeatActivityUntilRule Connections

Connector	Source	Target	Notes
Association is repeated until	DefinedRepeatActivity UntilRule +repeated 0..*, unordered, none	DefinedActivity +triggering 1, unordered, none	Each DefinedRepeatActivityUntilRule always is repeated until one DefinedActivity. Each DefinedActivity sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is repeated until	DefinedRepeatActivity UntilRule	DefinedCriterionGroup +triggering	Each DefinedRepeatActivityUntilRule

	+repeated 0..*, unordered, none	0..1, unordered, none	sometimes is repeated until one DefinedCriterionGroup. Each DefinedCriterionGroup sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is repeated until	DefinedRepeatActivityUntilRule +repeated 0..*, unordered, none	DefinedObservationResult +triggering 0..1, unordered, none	Each DefinedRepeatActivityUntilRule sometimes is repeated until one DefinedObservationResult. Each DefinedObservationResult sometimes triggers the cessation of one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association triggers the cessation of	DefinedRepeatActivityUntilRule +triggering 0..*, unordered, none	DefinedActivity +repeated 1, unordered, none	Each DefinedRepeatActivityUntilRule always triggers the cessation of one DefinedActivity. Each DefinedActivity sometimes is repeated until one or more DefinedRepeatActivityUntilRule. *Constraints* Inverse Relation: is repeated until

Protocol Representation Sub-Domain::DefinedRepeatActivityUntilRule Attributes

Attribute	Type	Notes
cessationPauseQuantity	public : *PQ.TIME*	The length of time that should elapse after the observed result occurs and before the cessation of repeating the activity.For example, stop 20 days after the observed event occurs. Map:Lab = 'Activity.plannedTimeElapsed'
checkpointCode	public : *CD*	A coded value specifying when in the course of an activity a precondition for the activity is evaluated (e.g., before the activity starts for the first time, before every repetition, after each repetition but not before the first, or throughout the entire time of the activity).For example, at the end of the cycle, evaluate disease response, and decide whether to administer another cycle. Before administering the daily dose, check the conditions for continuing treatment, and continue only if those conditions are met. Map:TDM = 'CyclingRule'

conjunctionCode	public : *CD*	A coded value specifying the logical conjunction of the criteria among all the condition-links of activities (e.g., and, or, exclusive-or).For example, fill out the "Liver event" report if the subject has an ALT value > 3 times the upper limit of normal and a bilirubin value > 1.5 times the upper limit of normal. Map:TDM = 'CyclingRule'
comment	public : *ST*	Additional description of the repeat activity until rule. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.38 Protocol Representation Sub-Domain::DefinedSpecimenCollection

public Class {leaf}

Extends: DefinedProcedure. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is an action of gathering samples that may be used for subsequent analysis.

For example, a blood draw.

SCC NOTE: PlannedSpecimenCollection was added only to support PlannedSpecimenStorage, but at that time BRIDG had not encountered a specific use case for the addition of that class. This class is based on that class.

Constraints

- *Approved Invariant* . actualIndicator Qualifier.
  For a DefinedSpecimenCollection, BiologicSpeciment.actualIndicator = "N".

Protocol Representation Sub-Domain::DefinedSpecimenCollection Connections

Connector	Source	Target	Notes
Association results in	DefinedSpecimenCollection +producing 0..*, unordered, none	BiologicSpecimen +produced 1, unordered, none	Each DefinedSpecimenCollection always results in one BiologicSpecimen. Each BiologicSpecimen sometimes is a result of one or more DefinedSpecimenCollection. *Constraints* Inverse Relation: is a result of
Generalization source > target	DefinedSpecimenCollection Child	DefinedProcedure Parent	

6.39 Protocol Representation Sub-Domain::DefinedSpecimenStorage

public Class {leaf}

Extends: DefinedAdministrativeActivity. :

A defined administrative activity at a global library level, outside the context of any particular study, that is an action of storing samples.

Constraints

- *Approved Invariant* . actualIndicator Qualifier.
  For a DefinedSpecimentStorage, BiologicSpecimen.actualIndicator = "N".

Protocol Representation Sub-Domain::DefinedSpecimenStorage Connections

Connector	Source	Target	Notes
Association stores	DefinedSpecimenStorage +storing 0..*, unordered, none	BiologicSpecimen +stored 1, unordered, none	Each DefinedSpecimenStorage always stores one BiologicSpecimen. Each BiologicSpecimen sometimes is stored during one or more DefinedSpecimenStorage. *Constraints* Inverse Relation: is stored during
Generalization source > target	DefinedSpecimenStorage Child	DefinedAdministrativeActivity Parent	

6.40 Protocol Representation Sub-Domain::DefinedStratificationCriterion

public Class {leaf}

Extends: DefinedObservation. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, identifies pre-treatment factors by which StudySubjects are segregated to assure balance of these factors before randomization to a study arm or some smaller segment of a study. The decisive factor used to help segregate the study subject into a stratum group.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  A DefinedStratificationCriterion may only be associated with a StudySubject, not a Subject or an ExperiementalUnit.
- *Approved Invariant* . Permissible Result Qualifier.
  A DefinedStratificationCriterion must be associated with 2 or more DefinedStratificationCriterionPermissibleResults.

Protocol Representation Sub-Domain::DefinedStratificationCriterion Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedStratificationCriterion Child	DefinedObservation Parent	

6.41 Protocol Representation Sub-Domain::DefinedStratificationCriterionPermissibleResult

public Class {leaf}

Extends: DefinedObservationResult. :

A reusable, "template" description of an allowable response to a stratification criterion.

For example, the stratification criterion for gender can have permissible answers of male and female.

Constraints

- *Approved Invariant* . Association Cardinality Qualifier.
  For associations between DefinedStratificationCriterion and DefinedStratificationCriterionPermissibleResult, the cardinality should be 2..* on the DefinedStratificationCriterionPermissibleResult.

Protocol Representation Sub-Domain::DefinedStratificationCriterionPermissibleResult Connections

Connector	Source	Target	Notes
Association is defined by	StratumGroup +defined 1..*, unordered, none	DefinedStratificationCriterionPermissibleResult +defining 1..*, unordered, none	Each StratumGroup always is defined by one or more DefinedStratificationCriterionPermissibleResult. Each DefinedStratificationCriterionPermissibleResult always defines one or more StratumGroup. *Constraints* Inverse Relation: defines
Generalization source > target	DefinedStratificationCriterionPermissibleResult Child	DefinedObservationResult Parent	

6.42 Protocol Representation Sub-Domain::DefinedStudyAdministrativeActivity

public Class {leaf}

Extends: DefinedAdministrativeActivity. :

The defined activity at a global library level, outside the context of any particular study, that, as a reusable template, represents a common non-study-subject-specific administrative landmark that a study goes through.

For example, IRB Approval, site enrollment, FDA audit, etc.

Constraints

- *Approved Invariant* . Is a Function Performed By Not Applicable.
  A DefinedStudyAdministrativeActivity must not be associated with a Subject, StudySubject or ExperiementalUnit.

Protocol Representation Sub-Domain::DefinedStudyAdministrativeActivity Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedStudyAdministrativeActivity Child	DefinedAdministrativeActivity Parent	

6.43 Protocol Representation Sub-Domain::DefinedStudyAgentTransfer

public Class {leaf}

Extends: DefinedAdministrativeActivity. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is an action in which an authorized party at a designated study site dispenses or receives a study agent to/from a study

subject, though as a defined activity, no actual study subject is identified.

For example, dispensing a bottle of pills.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  A DefinedStudyAgentTransfer can only be associated with a StudySubject, not a Subject not an ExperiementalUnit.

Protocol Representation Sub-Domain::DefinedStudyAgentTransfer Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedStudyAgentTransfer Child	DefinedAdministrativeActivity Parent	

6.44 Protocol Representation Sub-Domain::DefinedStudySubjectMilestone

public Class {leaf}

Extends: DefinedAdministrativeActivity. :

The defined activity at a global library level, outside the context of any particular study, that, as a reusable template, represents a common administrative landmark for a study subject in the course of a study.

For example, obtain informed consent, verify eligibility criteria, enroll, registration to a study, randomize, assignment to a treatment arm, start of on-study period, complete study visits, end of on-study period, exit trial, break treatment blind, protocol violation, premature withdrawal, etc.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  A Defined StudySubjectMilestone may only be associated to a StudySubject, not a Subject or an ExperiementalUnit.

Protocol Representation Sub-Domain::DefinedStudySubjectMilestone Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedStudySubjectMilestone Child	DefinedAdministrativeActivity Parent	

6.45 Protocol Representation Sub-Domain::DefinedSubstanceAdministration

public Class {leaf}

Extends: DefinedProcedure. :

A defined activity at a global library level, outside the context of any particular study, that, as a reusable template, is an action of applying, dispensing or otherwise giving medications or other substances.

For example, administration of methotrexate as part of chemotherapy.

Protocol Representation Sub-Domain::DefinedSubstanceAdministration Connections

Connector	Source	Target	Notes
Generalization source > target	DefinedSubstanceAdministration Child	DefinedProcedure Parent	

Protocol Representation Sub-Domain::DefinedSubstanceAdministration Attributes

Attribute	Type	Notes

dose	public : *PQ*	The quantity of a substance or medication to be administered.For example, 5 mg, 20 mg/kg. Map:COPPA = 'SubstanceAdministration.dose'
doseFrequencyCode	public : *CD*	A coded value specifying how often doses are administered. For example, BID, TID, QID. Map:COPPA = 'SubstanceAdministration.doseFrequencyCode'
doseRegimen	public : *ST*	Text description of the intended schedule for administering a substance. For example, 2 weeks on, 2 weeks off. NOTE: This represents the dosing calendar in a text format. This is a non-computational description that may need to be expanded as additional use cases arise. Map:COPPA = 'SubstanceAdministration.doseRegimen'
dailyDoseTotal	public : *PQ*	Total daily dose of treatment.NOTE: This is needed because the dose may not always be derivable, e.g., if it is a string. Map:COPPA = 'SubstanceAdministration.doseTotal'
routeOfAdministrationCode	public : *CD*	A coded value specifying the physiological path or method of introducing the substance into or onto the subject.For example, oral, intravenous, nasal, intradermal, intracardial, etc. Map:COPPA = 'SubstanceAdministration.routeOfAdministrationCode'

6.46 Protocol Representation Sub-Domain::Epoch

public Class {root}:
One of a set of ordered partitions of an experimental unit's planned time in a study.

Each Epoch serves a purpose in the trial as a whole, typically exposing the subject to a treatment or preparing them for a treatment, or gathering post-treatment data. Epoch-specific (state) transition rules control the subject's movement from one Epoch to another.

For example, a study designed to assess the effects of treatments might have 3 epochs, a Screening epoch in which subjects' eligibility is determined and baseline measurements are made, a Treatment epoch during which treatments are given and effects of treatment are assessed, and a Follow-up epoch during which post-treatment assessments are conducted.

NOTE: A subject moves from one Epoch to another and can only be in one epoch at a time. The subject can only move to an Epoch with a greater sequenceNumber. The main purpose of the Epoch is to organize the Arms for comparison purposes. Activities in the same Epoch but a different Arm need not be similar in time and pattern.

Constraints

- *Approved Invariant* . name Unique.
  An Epoch name must be unique within the context of the study that contains it.

Protocol Representation Sub-Domain::Epoch Connections

Connector	Source	Target	Notes
Association occurs in	PlannedActivity +contained 1..*, unordered, none	Epoch +containing 0..1, unordered, none	Each PlannedActivity sometimes occurs in one Epoch. Each Epoch always contains one or more PlannedActivity. *Constraints* Inverse Relation: contains *Tagged Values* Map:PSC: Period.repetitions
Association is a division of	Epoch +subdividing 0..*, unordered, none	Study +subdivided 1, unordered, none	Each Epoch always is a division of one Study. Each Study sometimes is divided into one or more Epoch. *Constraints* Inverse Relation: is divided into

Protocol Representation Sub-Domain::Epoch Attributes

Attribute	Type	Notes
name	public : *ST*	A non-unique textual identifier for the epoch.For example, first treatment epoch, second treatment epoch, first wash-out epoch, second wash-out epoch.NOTE: When multiple Epochs have the same purpose (e.g., treatment), then the titles will probably include order numbers to distinguish them. Map:C3PR = 'Epoch.name' Map:C3PR = 'PlannedEpoch.name' Map:CTOM = 'StudyTimePoint.epochName' Map:HL7SD = 'Epoch.title' Map:PSC = 'Period.name' Map:PSC = 'Epoch.name' Map:SDTM IG = 'DS.EPOCH' Map:SDTM IG = 'TA.EPOCH' Map:TDM = 'StudyDesignEpoch.name'
typeCode	public : *CD*	A coded value specifying the kind of epoch.For example, screening, treatment, follow-up, etc. Map:C3PR = 'PlannedEpoch.type'
sequenceNumber	public : *INT*	An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.For example, in a Study that has Screening, Treatment and Follow-Up epochs, the sequence number indicates which Epoch precedes the other. Map:C3PR = 'Epoch.epochOrder' Map:C3PR = 'PlannedEpoch.firstEpochIndicator' Map:HL7SD = 'Component2.sequenceNumber' Map:TDM = 'StudyDesignEpoch.epochSequenceNumber'
description	public :	The textual representation of the epoch.For example, the

	ST	description for Screening Epoch could be "A 2-week period during which eligibility is determined and baseline measurements are taken".For example, the description for Treatment Epoch could be, "The first treatment epoch is a one-week period during which a single dose of one of the three investigational treatments is administered". Map:C3PR = 'PlannedEpoch.description' Map:C3PR = 'Epoch.descriptionText' Map:HL7SD = 'Epoch.text' Map:TDM = 'StudyDesignEpoch.description'

6.47 Protocol Representation Sub-Domain::ExpandedAccessStudy

public Class {leaf}

Extends: Study. :

An action plan and execution of a pre-clinical or clinical study describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study.

NOTE: This type of study is used to register all types of non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.

Protocol Representation Sub-Domain::ExpandedAccessStudy Connections

Connector	Source	Target	Notes
Generalization source > target	ExpandedAccessStudy Child	Study Parent	

Protocol Representation Sub-Domain::ExpandedAccessStudy Attributes

Attribute	Type	Notes
interventionDescription	public : *ST*	A character string that provides the key details of the intervention. For example, the details may distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration. (50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.) Map:COPPA = 'InterventionalStudyProtocol.primaryPurposeCode' Map:CTGOV = 'Intervention Description'

Tagged Values

- Map:COPPA = InterventionalStudyProtocol.expandedAccessIndicator.
- Map:COPPA = ObservationalStudyProtocol.expandedAccessIndicator.
- Map:COPPA = StudyProtocol.expandedAccessIndicator.
- Map:CTGOV = Has Expanded Access.
- Map:CTGOV = Study Type - Expanded Access and Has Expanded Access?.
- Map:WHO = Study Type.

6.48 Protocol Representation Sub-Domain::Funding

public Class {leaf}

Extends: Resource. :

Fiscal support for research from industry, government, or non-commercial, non-governmental organizations.

For example, funding from pharmaceutical, device or biotechnology companies, the US NIH or the Gates Foundation.

Protocol Representation Sub-Domain::Funding Connections

Connector	Source	Target	Notes
Generalization source > target	Funding Child	Resource Parent	
Generalization source > target	GovernmentFunding Child	Funding Parent	

6.49 Protocol Representation Sub-Domain::GovernmentFunding

public Class {leaf}

Extends: Funding. :

Fiscal support from governmental organizations.

For example, US NIH.

Protocol Representation Sub-Domain::GovernmentFunding Connections

Connector	Source	Target	Notes
Generalization source > target	GovernmentFunding Child	Funding Parent	

Protocol Representation Sub-Domain::GovernmentFunding Attributes

Attribute	Type	Notes
fundingTypeCode	public : *CD*	A coded value specifying the single digit code identifying the kind of application received and processed. For example, Type 5 (Noncompeting Grant Progress Report), Type 1 (New), etc. Map:COPPA = 'StudyResourcing.fundingTypeCode' Map:COPPA = 'StudyResourcing.grantTypeCode'
fundingMechanismCode	public : *CD*	A coded value specifying the unique identifier for areas of extramural research activity applied to various funding mechanisms.For example, R01 (Research Project), U10 (Cooperative Clinical Research Cooperative Agreements), etc. Map:COPPA = 'ResearchOrganization.fundingMechanism' Map:COPPA = 'StudyResourcing.fundingMechanismCode'
nihInstituteCode	public : *CD*	A coded value specifying the administering organization code, A two-letter code identifying the first major-level subdivision, the organization that supports a grant, contract, or inter-agency agreement. The support may be financial or administrative.For example, CP2 Division of Cancer Epidemiology and Genetics

		(NCI), LM National Library of Medicine (NLM), etc. Map:COPPA = 'StudyResourcing.nihInstituteCode'
serialNumberText	public : *ST*	A character string that represents the six-digit number generally assigned sequentially to a series within an institute, center, or division. Map:COPPA = 'StudyResourcing.serialNumber'

6.50 Protocol Representation Sub-Domain::InterventionalStudy

public Class {leaf}

Extends: Study. :

An action plan and execution of a pre-clinical or clinical study in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. StudySubjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.

Constraints

- *Approved Invariant* . blindedRoleCode Qualifier.
  For blindedRoleCode, the roles identified map to StudySubject, StudyInvestigator, Assessor, and AssociatedPerson.

Protocol Representation Sub-Domain::InterventionalStudy Connections

Connector	Source	Target	Notes
Generalization source > target	InterventionalStudy Child	Study Parent	

Protocol Representation Sub-Domain::InterventionalStudy Attributes

Attribute	Type	Notes
controlTypeCode	public : *CD*	A coded value specifying the comparator against which the study treatment is evaluated.For example, placebo, active, historical, uncontrolled, dose comparison. Map:COPPA = 'InterventionalStudyProtocol.controlType'
controlConcurrencyTypeCode	public : *CD*	A coded value specifying the temporal relationships of the control to the study intervention.For example, concurrent, historical, pre/post (patient owned control). Map:COPPA = 'InterventionalStudyProtocol.controlConcurrencyType'
allocationCode	public : *CD*	A coded value specifying the method of assigning subjects to treatment or control groups.For example, n/a, randomized controlled trial, non-randomized trial. Map:COPPA = 'InterventionalStudyProtocol.allocationCode' Map:CTGOV = 'Study Design Allocation'
blindingSchemaCode	public :	A coded value specifying the type of masking used on a study

	CD	protocol to ensure that the results are not biased by the subjects or investigators.For example, double-blinded would indicate that both the investigator and the participant would not know whether the intervention was a placebo or an active therapeutic intervention. This will be drawn from a coded list of terms that define the blinding type. For example, Open Label, Double Blind, Single Blind, etc. Map:C3PR = 'Study.descriptionText' Map:C3PR = 'Study.blindedIndicator' Map:COPPA = 'InterventionalStudyProtocol.blindingSchemaCode' Map:CTGOV = 'Study Design Masking' Map:CTOM = 'Protocol.blindedIndicator' Map:WHO = 'Masking'
blindedRoleCode	public : *DSET<CD>*	A coded value specifying the roles of individuals who are masked for single or double blind studies.For example, subject, caregiver, investigator, or outcomes assessor. Map:COPPA = 'InterventionalStudyProtocol.blindedRoleCode' Map:CTGOV = 'Masking Role' Map:WHO = 'Study Type Masking Who is Blinded'
interventionGroupQuantity	public : *INT*	An integer specifying the number of intervention groups.For example, enter 1 for single-arm study.NOTE: This attribute should be derivable once arms have been defined for the study. Map:COPPA = 'InterventionalStudyProtocol.numberOfInterventionGroups' Map:CTGOV = 'Number of Arms'
acceptsHealthyVolunteersIndicator	public : *BL*	Specifies whether persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Map:COPPA = 'InterventionalStudyProtocol.acceptsHealthyVolunteersIndicator' Map:CTGOV = 'Accepts Healthy Volunteers?'
interventionDescription	public : *ST*	A character string that provides the key details of the intervention. For example, the details may distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration. (50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.) Map:COPPA = 'InterventionalStudyProtocol.primaryPurposeCode' Map:CTGOV = 'Intervention Description'

Tagged Values

- Map:COPPA = InterventionalStudyProtocol.keywordText.

- Map:COPPA = InterventionalStudyProtocol.AECodingSystem.
- Map:COPPA = InterventionalStudyProtocol.
- Map:COPPA = InterventionalStudyProtocol.publicDescription.
- Map:COPPA = InterventionalStudyProtocol.acronym.
- Map:COPPA = InterventionalStudyProtocol.officialTitle.
- Map:COPPA = InterventionalStudyProtocol.publicTitle.
- Map:COPPA = InterventionalStudyProtocol.keywordCode.
- Map:COPPA = InterventionalStudyProtocol.targetAccrualNumber.
- Map:COPPA = InterventionalStudyProtocol.responsiblePartyCode.
- Map:COPPA = InterventionalStudyProtocol.dataMonitoringCommitteeAppointedIndicator.
- Map:COPPA = InterventionalStudyProtocol..startDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.targetAnatomicSiteCode.
- Map:COPPA = InterventionalStudyProtocol.revision.
- Map:COPPA = InterventionalStudyProtocol.primaryCompletionDate.
- Map:COPPA = InterventionalStudyProtocol.primaryCompletionDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.identifier.
- Map:COPPA = InterventionalStudyProtocol.statusDate.
- Map:COPPA = InterventionalStudyProtocol.scientificDescription.
- Map:COPPA = InterventionalStudyProtocol.bibliographicDesignation.
- Map:COPPA = InterventionalStudyProtocol.text.
- Map:CTGOV = Study Type - Interventional.
- Map:WHO = Study Type.

6.51 Protocol Representation Sub-Domain::MaterialResource

public Class {leaf}

Extends: Resource. :

Physical supplies provided by an individual company, institution, or organization for the conduct of research.

For example, in kind contributions, donations of study drug, device, etc.

Protocol Representation Sub-Domain::MaterialResource Connections

Connector	Source	Target	Notes
Generalization source > target	MaterialResource Child	Resource Parent	

6.52 Protocol Representation Sub-Domain::ObservationalStudy

public Class {leaf}

Extends: Study. :

An action plan and execution of a pre-clinical or clinical study in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. StudySubjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the StudySubjects or ExperimentalUnits of the study.

Protocol Representation Sub-Domain::ObservationalStudy Connections

Connector	Source	Target	Notes
Generalization source > target	ObservationalStudy Child	Study Parent	

Protocol Representation Sub-Domain::ObservationalStudy Attributes

Attribute	Type	Notes

samplingMethodCode	public : *CD*	A coded value specifying the process used to define a representative set of a population for a study.For example, a Probability Sample: exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling.For example, a Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer. Map:COPPA = 'ObservationalStudyProtocol.samplingMethodCode' Map:CTGOV = 'Sampling Method'
timePerspectiveCode	public : *CD*	A coded value specifying the temporal relationship of observation period to time of subject enrollment. For example, prospective, retrospective, cross-sectional, other. Map:COPPA = 'ObservationalStudyProtocol.timePerspectiveCode' Map:CTGOV = 'Time Perspective'

Tagged Values

- Map:CTGOV = Study Type - Observational.
- Map:WHO = Study Type.

6.53 Protocol Representation Sub-Domain::PlannedActivity

public abstract Class

Extends: Activity. :

An activity that is intended to occur at some point in the course of a particular study.

For example, pregnancy tests are planned for StudySubjects who are females of childbearing potential. The pregnancy tests are part of the study and the test should be applied to StudySubjects with an actualIndicator of "N" and a sexCode of "F"..

NOTE: A PlannedActivity may be a container of other activities and have a complex structure involving components, options and contingencies using the associated relationship classes. This structure allows BRIDG 3.0 to represent concepts in previous versions of BRIDG such as StudyCells, StudySegments and StudySubjectEncounters.

NOTE: A planned activity could also be thought of as an activity at a particular stage in the business process in which the activities occur, i.e., in the "planned" stage rather than the "scheduled" stage or the "performed" stage. An instance of a planned activity is not assigned to a particular StudySubject, but to a "kind of" StudySubject.

Constraints

- *Approved Invariant* . Repeat Frequency Exclusive Or.
  A PlannedActivity may have a value for repeatFrequencyCode or repeatFrequencyRatio, but not both.
- *Approved Invariant* . Repeat Duration or Quantity Exclusive Or.
  A PlannedActivity may have a value for repeatDuration or repeatQuantity, but not both.
- *Approved Invariant* . actualIndicator Qualifier.
  Only Subjects and ExperiementalUnits with actualIndicator = N are valid for PlannedActivities.

Protocol Representation Sub-Domain::PlannedActivity Connections

Connector	Source	Target	Notes
Association instantiates	ScheduledActivity +instantiating 0..*, unordered, none	PlannedActivity +instantiated 1, unordered, none	Each ScheduledActivity always instantiates one PlannedActivity. Each PlannedActivity sometimes is instantiated by one or more ScheduledActivity. *Constraints* Inverse Relation: is instantiated by
Association is a choice that has as option	PlannedOptionRelationship +choice 0..*, unordered, none	PlannedActivity +option 1, unordered, none	Each PlannedOptionRelationship always is a choice that has as option one PlannedActivity. Each PlannedActivity sometimes is an option that can satisfy one or more PlannedOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2
Association triggers the cessation of	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	PlannedActivity +triggering 1, unordered, none	Each PlannedRepeatActivityUntilRule always triggers the cessation of one PlannedActivity. Each PlannedActivity sometimes is repeated until one or more PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: is repeated until
Association occurs in	PlannedActivity +contained 1..*, unordered, none	Epoch +containing 0..1, unordered, none	Each PlannedActivity sometimes occurs in one Epoch. Each Epoch always contains one or more PlannedActivity. *Constraints* Inverse Relation: contains *Tagged Values* Map:PSC: Period.repetitions
Association occurs in	PlannedActivity +contained 1..*, unordered, none	Arm +containing 1..*, unordered, none	Each PlannedActivity always occurs in one or more Arm. Each Arm always contains one or more PlannedActivity. *Constraints*

			Inverse Relation: contains
Association is an option that can satisfy	PlannedOptionRelationship +option 0..*, unordered, none	PlannedActivity +choice 1, unordered, none	Each PlannedOptionRelationship always is an option that can satisfy one PlannedActivity. Each PlannedActivity sometimes is a choice that has as option one or more PlannedOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2
Association is a condition for	PlannedContingentOnRelationship +prerequisite 0..*, unordered, none	PlannedActivity +contingent 1, unordered, none	Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity sometimes is contingent upon one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is contingent upon
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	PlannedActivity +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedActivity. Each PlannedActivity sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is a choice that has as option	PlannedCriterionGroupOptionRelationship +choice 0..*, unordered, none	PlannedActivity +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one PlannedActivity. Each PlannedActivity sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints* Invariant: is an option that can satisfy

Association is the parent of	PlannedCompositionRelationship +composite 0..*, unordered, none	PlannedActivity +component 1, unordered, none	Each PlannedCompositionRelationship always is the parent of one PlannedActivity. Each PlannedActivity sometimes is the component of one or more PlannedCompositionRelationship. *Constraints* Inverse Relation: is the component of *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2
Association is repeated until	PlannedRepeatActivityUntilRule +triggering 1, unordered, none	PlannedActivity +repeated 1, unordered, none	Each PlannedRepeatActivityUntilRule always is repeated until one PlannedActivity. Each PlannedActivity always triggers the cessation of one PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is the parent of	PlannedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	PlannedActivity +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one PlannedActivity. Each PlannedActivity sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the component of	PlannedCompositionRelationship +component 0..*, unordered, none	PlannedActivity +composite 1, unordered, none	Each PlannedCompositionRelationship always is the component of one PlannedActivity. Each PlannedActivity sometimes is the parent of one or more PlannedCompositionRelationship. *Constraints* Inverse Relation: is the parent of *Tagged Values*

			Map:HL7SD: EligibilityCriterion.Precondition 2
Association is a use of	PlannedActivity +using 0..*, unordered, none	StudyActivity +used 1, unordered, none	Each PlannedActivity always is a use of one StudyActivity. Each StudyActivity sometimes is used as one or more PlannedActivity. *Constraints* Inverse Relation: is used as *Tagged Values* Map:HL7SD: PlannedStudy.Component2 Map:HL7SD: PlannedStudy.Precondition1 Map:HL7SD: EligibilityCriterion
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	PlannedActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one PlannedActivity. Each PlannedActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by
Generalization source > target	PlannedActivity Child	Activity Parent	
Generalization source > target	PlannedRandomization BookAllocation Child	PlannedActivity Parent	

Protocol Representation Sub-Domain::PlannedActivity Attributes

Attribute	Type	Notes
name	public : *ST*	A non-unique textual identifier for the planned activity. Map:C3PR = 'PlannedStudyCell.name' Map:COPPA = 'PlannedActivity.name' Map:COPPA = 'PlannedObservation.name' Map:COPPA = 'SubstanceAdministration.name' Map:CTOM = 'StudyTimePoint.visitName' Map:CTOM = 'StudyTimePoint.courseNumber' Map:PSC = 'Arm.name' Map:SDTM IG = 'LB.VISIT' Map:SDTM IG = 'SE.ETCD' Map:SDTM IG = 'VS.VISIT' Map:SDTM IG = 'VS.VSTPTNUM' Map:SDTM IG = 'TV.VISIT' Map:SDTM IG = 'LB.LBTPTNUM' Map:SDTM IG = 'SU.VISIT' Map:SDTM IG = 'TE.ETCD'

		Map:SDTM IG = 'TA.ETCD' Map:SDTM IG = 'EG.EGTPTNUM' Map:SDTM IG = 'EG.VISIT' Map:SDTM IG = 'DA.VISIT' Map:SDTM IG = 'QS.QSTPTNUM' Map:SDTM IG = 'IE.VISIT' Map:SDTM IG = 'SV.VISIT' Map:SDTM IG = 'MH.VISIT' Map:SDTM IG = 'QS.VISIT' Map:SDTM IG = 'PE.VISIT' Map:TDM = 'SubjectTrialContact.eventAlias' Map:TDM = 'StudyDesignElement.name'
purpose	public : *ST*	The reason for the planned activity. For example, treating a disease (treatment), determining eligibility for a study (screening), etc. Map:TDMv2 = '(New content)'
targetAccrualNumberRange	public : *URG<INT>*	A range of integers specifying the minimum and maximum number of subjects to be accrued for the planned activity. Map:BRIDGv2.2 = 'PlannedStudyCell.targetAccrualNumber'
description	public : *ST*	The textual representation of the planned activity.For example, in a migraine trial, the Wait activity may have a description of "Wait until first grade 2 or 3 migraine". Map:SDTM IG = 'SE.ELEMENT' Map:SDTM IG = 'TE.ELEMENT' Map:SDTM IG = 'TA.ELEMENT' Map:TDM = 'StudyDesignElement.description'
blindedDescription	public : *ST*	The textual representation of the planned activity from the point of view of a blinded subject participant (study subject or study investigator). For example, during the second treatment epoch of a study, Arms A and B are still blinded and Arm C is no longer blinded. So, Arm A and B must have identical blindedDescriptions.For example, in a study with 3 arms, Arm 1: standard vaccine given in three shots at 2 months, 5 months, and 12 months of age; Arm 2: new vaccine given in three shots at 2 months, 5 months, and 12 months of age; Arm 3: new vaccine given in two shots at 2 months and 5 months of age. Subjects assigned to the third arm are unblinded at some point during 5 months and 12 months. By the time of the Third Shot Epoch, the "Arm 3/Third Shot" activity can be called by this, its unblinded name. However, the "Arm 1/Third Shot" and "Arm2/Third Shot" activities still need blinded names. Both these activities would have the blinded name (something like) "3-shot Arm/Third Shot". Map:C3PR = 'PlannedStudyCell.blindedDescription' Map:TDM = 'TrialCell.blindedDescription'
plannedDuration	public : *PQ.TIME*	The intended period of time for the planned activity as defined by the study.For example, 6 weeks may be the planned duration for a composite activity that represents the activities occurring during an epoch on arm A.

		Map:PSC = 'Duration.quantity' Map:PSC = 'Duration.units' Map:SDTM IG = 'TE.TEDUR'
repeatFrequencyCode	public : *CD*	A coded value specifying the number of occurrences of a planned activity within a given time period.For example, BID = Two times per day, at unspecified times (does not necessarily imply that these are 12 hours apart) or Q12H = Every twelve hours. (examples from NCI) Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'
repeatFrequencyRatio	public : *RTO<INT,PQ.TIME>*	A ratio representing the number of occurrences of a planned activity within a given time period.For example, once per 12 hours or 2 times per day. Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'
repeatQuantity	public : *INT*	The number of times the planned activity occurs.NOTE: If the frequency is more than once a day, this is still interpreted per time, e.g. BID for 5 days is 10 repeats. Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions' Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:PSC = 'Period.repetitions' Map:TDM = 'CyclingRule'
repeatDuration	public : *PQ.TIME*	The period of time over which the planned activity is repeated.NOTE: repeatDuration is considered derivable from repeatQuantity and frequency. In any given implementation, if quantity is not provided, duration may be provided instead, however the BRIDG team determined that quantity is considered more fundamental. Map:COPPA = 'PlannedEligibilityCriterion.plannedRangeOfRepetitions' Map:COPPA = 'SubstanceAdministration.plannedRangeOfRepetitions' Map:COPPA = 'PlannedObservation.plannedRangeOfRepetitions'

		Map:COPPA = 'PlannedActivity.plannedRangeOfRepetitions' Map:TDM = 'CyclingRule'

Tagged Values

- Map:HL7SD = EligibilityCriterion.

6.54 Protocol Representation Sub-Domain::PlannedCompositionRelationship

public Class:
A relationship between a composite activity and the component activities that comprise it, i.e. parent and child activities.

For example, a battery of tests may be composed of multiple routine labs that are always ordered together as a group. Another example is a glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose.

NOTE: This class helps represent an AND relationship between siblings with the same parent activity.

Protocol Representation Sub-Domain::PlannedCompositionRelationship Connections

Connector	Source	Target	Notes
Association is the parent of	PlannedCompositionRelationship +composite 0..*, unordered, none	PlannedActivity +component 1, unordered, none	Each PlannedCompositionRelationship always is the parent of one PlannedActivity. Each PlannedActivity sometimes is the component of one or more PlannedCompositionRelationship. *Constraints* Inverse Relation: is the component of *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2
Association is the component of	PlannedCompositionRelationship +component 0..*, unordered, none	PlannedActivity +composite 1, unordered, none	Each PlannedCompositionRelationship always is the component of one PlannedActivity. Each PlannedActivity sometimes is the parent of one or more PlannedCompositionRelationship. *Constraints* Inverse Relation: is the parent of *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2

Protocol Representation Sub-Domain::PlannedCompositionRelationship Attributes

Attribute	Type	Notes
sequenceNumber	public : *INT*	An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.For example, in a course of treatment (a composite activity) that is composed of a chemotherapy activity and a radiotherapy activity, the sequence number indicates which component activity precedes the other. Map:CTOM = 'ActivityRelationship.sequenceNumber' Map:HL7SD = 'PlannedStudy.Component2.sequenceNumber'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:HL7SD = 'PlannedStudy.Component2.pauseQuantity' Map:Lab = 'Activity.plannedTimeElapsed' Map:PSC = 'PlannedEvent.startDay' Map:PSC = 'PlannedEvent.units' Map:PSC = 'PlannedEvent.day' Map:SDTM IG = 'EX.EXELTM'
comment	public : *ST*	Additional description of the composition relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.
- Map:HL7SD = PlannedActivity.precondition1.conjunctionCode.
- Map:HL7SD = EligibilityCriterion.Precondition2.
- Map:HL7SD = EligibilityCriterion.Precondition2.conjunctionCode.

6.55 Protocol Representation Sub-Domain::PlannedContingentOnRelationship

public Class:
A relationship between a planned activity and one of the following:

- another planned activity where the source activity does not occur unless the target activity has occurred;
- the defined outcome of another planned activity where the source activity does not occur unless the target activity outcome has occurred;
- a planned group of other criteria that may be composed of a mix of other activities, observation results and/or other groups.

For example, only perform a certain lab test if drug X was administered. (target = another activity)

For example, only perform a substance administration of drug X if the blood pressure was over some threshold number. (target = observation result from another activity that is an observation)

For example, only perform a substance administration of drug Y if the blood pressure was over some threshold number and either the result of a certain lab test was positive or the subject's temperature was elevated, i.e. "(A and (B or C))".

Constraints

- *Approved Invariant* . Is Contingent Upon Exclusive Or.
  A PlannedContingentOnRelationship must be associated to only one of the following: a PlannedActivity, a DefinedObservationResult, or a PlannedCriterionGroup.

Protocol Representation Sub-Domain::PlannedContingentOnRelationship Connections

Connector	Source	Target	Notes
Association is a condition for	PlannedContingentOnRelationship +prerequisite 0..*, unordered, none	PlannedActivity +contingent 1, unordered, none	Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity sometimes is contingent upon one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is contingent upon
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	PlannedActivity +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedActivity. Each PlannedActivity sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	DefinedObservationResult +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each

			DefinedObservationResult sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	PlannedCriterionGroup +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for

Protocol Representation Sub-Domain::PlannedContingentOnRelationship Attributes

Attribute	Type	Notes
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed' Map:PSC = 'PlannedEvent.day' Map:PSC = 'PlannedEvent.units' Map:PSC = 'PlannedEvent.startDay' Map:SDTM IG = 'EX.EXELTM'
evaluableExpression	public : *ED*	A computable logical expression that can involve temporal, clinical, and other operands. It can be composed of sub expressions to create arbitrarily complex and recursive statements.For example, (<2 weeks> since <last dose >) and (SysBP[now] < 140 and DiaBP [now]> 90)NOTE: The data type of this attribute is ED, reflecting the ability of the attribute to support the semantics of one of several grammars for building evaluable expressions via ED.mediaType. An assumption here is that a system defining such an expression must identify the source grammar in the mediaType to ensure that any consuming system parses the expression with the proper parser. For example, an evaluable expression in the 'TDM Markup Language' (TDML) with the form "IF X > 12 THEN ~ EPOCH --TO +3 D ``PREVIOUS EPOCH" would be carried in the ED data type properties as follows:ED.value: IF X > 12 THEN ~ EPOCH --TO +3 D ``PREVIOUS EPOCHED.mediaType: text/bridg-tdm+xml (this is an invented expression language used for this example)Example values for known expression languages and the related ED.mediatype include but are not limited to:Language: OCL; MediaType: text/plain+oclLanguage: Factor; MediaType: application/hl7-factor+xmlLanguage: MathML; MediaType:

		application/mathml+xml Map:TDM = 'AbstractRule.evaluableExpression'
comment	public : *ST*	Additional description of the contingent on relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.56 Protocol Representation Sub-Domain::PlannedCriterionGroup

public Class:
A collection of conditions joined together via composition (ANDed) and/or optionality (ORed) to form a logical expression upon which the execution of an activity is based or upon which the cessation of a repeated activity is based, where components of the group may include other activities, observation results and/or other criterion groups, and where both the criterion group and its components are planned to be used at a particular point in a particular study.

For example, (A and (B or C)), where A might be an activity, B and C might be 2 different observation results, and the two sets of parentheses are 2 criterion groups, one inside (a component of) the other.

NOTE: A criterion group represents the parentheses around a set of criteria in a logical expression.

Protocol Representation Sub-Domain::PlannedCriterionGroup Connections

Connector	Source	Target	Notes
Association is the parent of	PlannedCriterionGroup CompositionRelationship +composite 0..*, unordered, none	PlannedCriterionGroup +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is a choice that has as option	PlannedCriterionGroup OptionRelationship +choice 0..*, unordered, none	PlannedCriterionGroup +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints*

			Inverse Relation: is an option that can satisfy
Association is an option that can satisfy	PlannedCriterionGroupOptionRelationship +option 0..*, unordered, none	PlannedCriterionGroup +choice 1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is an option that can satisfy one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is a choice that has as option one or more PlannedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option
Association is the component of	PlannedCriterionGroupCompositionRelationship +component 0..*, unordered, none	PlannedCriterionGroup +composite 1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the component of one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is the parent of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the parent of
Association is repeated until	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	PlannedCriterionGroup +triggering 0..1, unordered, none	Each PlannedRepeatActivityUntilRule sometimes is repeated until one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes triggers the cessation of one or more PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is contingent upon	PlannedContingentOnRelationship +contingent 0..*, unordered, none	PlannedCriterionGroup +prerequisite 0..1, unordered, none	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is a condition for one or more PlannedContingentOnRelationship. *Constraints* Inverse Relation: is a condition for

6.57 Protocol Representation Sub-Domain::PlannedCriterionGroupCompositionRelationship

public Class:
A relationship between a planned criterion group and a planned activity, planned observation result or other planned criterion group that is a component, i.e. a relationship between a logical set of parenthesis and one of the items inside the parentheses.

For example, a battery of tests may be composed of multiple routine labs that are always ordered together as a group.

Another example is a glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose.

NOTE: This class helps represent an AND relationship between siblings in the same criterion group.

Constraints

- *Approved Invariant* . Is the Parent Of Exclusive Or.
  A PlannedCriterionGroupCompositionRelationship must be associated to only one of the following targets: a PlannedActivity, a DefinedObservationResult, or another PlannedCriterionGroup.

Protocol Representation Sub-Domain::PlannedCriterionGroupCompositionRelationship Connections

Connector	Source	Target	Notes
Association is the parent of	PlannedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	PlannedCriterionGroup +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of
Association is the parent of	PlannedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	DefinedObservationResult +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one DefinedObservationResult. Each DefinedObservationResult sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of

Association is the component of	PlannedCriterionGroupCompositionRelationship +component 0..*, unordered, none	PlannedCriterionGroup +composite 1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the component of one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is the parent of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the parent of
Association is the parent of	PlannedCriterionGroupCompositionRelationship +composite 0..*, unordered, none	PlannedActivity +component 0..1, unordered, none	Each PlannedCriterionGroupCompositionRelationship sometimes is the parent of one PlannedActivity. Each PlannedActivity sometimes is the component of one or more PlannedCriterionGroupCompositionRelationship. *Constraints* Inverse Relation: is the component of

Protocol Representation Sub-Domain::PlannedCriterionGroupCompositionRelationship Attributes

Attribute	Type	Notes
sequenceNumber	public : *INT*	An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.For example, in a criterion group that is composed of a substance administration activity and a lab test activity, the sequence number indicates which activity precedes the other. Map:CTOM = 'ActivityRelationship.sequenceNumber'
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference. NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal.

		Map:Lab = 'Activity.plannedTimeElapsed' Map:PSC = 'PlannedEvent.startDay' Map:PSC = 'PlannedEvent.day' Map:PSC = 'PlannedEvent.units'
comment	public : *ST*	Additional description of the criterion group composition relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTGOV = ActivityRelationship.typeCode.

6.58 Protocol Representation Sub-Domain::PlannedCriterionGroupOptionRelationship

public Class:
A relationship between a planned criterion group and an option that can satisfy it, either a planned activity, a planned observation result or another planned criterion group, i.e. a relationship between a logical set of parenthesis and one of the options inside the parentheses.

For example, a pain management criterion group may be comprised of three options, one for substance administration of Tylenol, another for substance administration of aspirin, and a third for substance administration of ibuprofen. The pain management criterion would be satisfied/accomplished with any one of these activities and would be associated to each of the three via a different DefinedCriterionGroupOptionRelationship.

NOTE: This class helps represent an OR relationship between siblings in the same criterion group.

Constraints

- *Approved Invariant* . Is a Choice that has as Option Exclusive Or.
  A PlannedCriterionGroupOptionRelationship must be associated to only one of the following targets: a PlannedActivity, a DefinedObservationResult, or another PlannedCriterionGroup.

Protocol Representation Sub-Domain::PlannedCriterionGroupOptionRelationship Connections

Connector	Source	Target	Notes
Association is a choice that has as option	PlannedCriterionGroupOptionRelationship +choice 0..*, unordered, none	PlannedCriterionGroup +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy

Association is a choice that has as option	PlannedCriterionGroupOptionRelationship +choice 0..*, unordered, none	PlannedActivity +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one PlannedActivity. Each PlannedActivity sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints* Invariant: is an option that can satisfy
Association is an option that can satisfy	PlannedCriterionGroupOptionRelationship +option 0..*, unordered, none	PlannedCriterionGroup +choice 1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is an option that can satisfy one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes is a choice that has as option one or more PlannedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option
Association is a choice that has as option	PlannedCriterionGroupOptionRelationship +choice 0..*, unordered, none	DefinedObservationResult +option 0..1, unordered, none	Each PlannedCriterionGroupOptionRelationship sometimes is a choice that has as option one DefinedObservationResult. Each DefinedObservationResult sometimes is an option that can satisfy one or more PlannedCriterionGroupOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy

Protocol Representation Sub-Domain::PlannedCriterionGroupOptionRelationship Attributes

Attribute	Type	Notes
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values.

		Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed' Map:PSC = 'PlannedEvent.units' Map:PSC = 'PlannedEvent.day' Map:PSC = 'PlannedEvent.startDay'
comment	public : *ST*	Additional description of the criterion group option relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.59 Protocol Representation Sub-Domain::PlannedOptionRelationship

public Class:
A relationship between a composite activity and an option that can satisfy it, i.e. choice and option activities.

For example, a pain management activity may be comprised of three options, one for substance administration of Tylenol, another for substance administration of aspirin, and a third for substance administration of ibuprofen. The pain management activity would be satisfied/accomplished with any one of these activities and would be associated to each of the three via a different DefinedOptionRelationship.

NOTE: This class helps represent an OR relationship between siblings with the same parent activity.

Protocol Representation Sub-Domain::PlannedOptionRelationship Connections

Connector	Source	Target	Notes
Association is a choice that has as option	PlannedOptionRelationship +choice 0..*, unordered, none	PlannedActivity +option 1, unordered, none	Each PlannedOptionRelationship always is a choice that has as option one PlannedActivity. Each PlannedActivity sometimes is an option that can satisfy one or more PlannedOptionRelationship. *Constraints* Inverse Relation: is an option that can satisfy *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2

Association is an option that can satisfy	PlannedOptionRelationship +option 0..*, unordered, none	PlannedActivity +choice 1, unordered, none	Each PlannedOptionRelationship always is an option that can satisfy one PlannedActivity. Each PlannedActivity sometimes is a choice that has as option one or more PlannedOptionRelationship. *Constraints* Inverse Relation: is a choice that has as option *Tagged Values* Map:HL7SD: EligibilityCriterion.Precondition 2

Protocol Representation Sub-Domain::PlannedOptionRelationship Attributes

Attribute	Type	Notes
priorityNumber	public : *INT*	An integer specifying the relative preference for considering this relationship before other similar relationships having the same source activity.For example, for multiple criteria, this specifies which criteria are considered before others. For components with the same sequence number, it specifies which ones are considered before others. Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.NOTE: Relationships with lower priorityNumber values are considered before and above those with higher values. Map:TDM = 'AbstractRule.isExclusive'
pauseQuantity	public : *PQ.TIME*	A quantity of time that should elapse between when an activity is ready for execution and the actual beginning of the execution. For example, take a blood sample 15 minutes after administration of study drug or measure blood glucose 2 hours after each meal. Map:Lab = 'Activity.plannedTimeElapsed' Map:PSC = 'PlannedEvent.units' Map:PSC = 'PlannedEvent.startDay' Map:PSC = 'PlannedEvent.day' Map:SDTM IG = 'EX.EXELTM'
comment	public : *ST*	Additional description of the option relationship. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.
- Map:HL7SD = EligibilityCriterion.Precondition2.conjunctionCode.
- Map:HL7SD = PlannedActivity.precondition1.conjunctionCode.
- Map:HL7SD = EligibilityCriterion.Precondition2.

6.60 Protocol Representation Sub-Domain::PlannedRandomizationBookAllocation

public Class {leaf}

Extends: PlannedActivity. :

An activity that is intended to occur at some point in the course of a particular study and that is the assignment of an experimental unit to a portion of the study, such as an Arm or a portion of an Arm (when secondary allocations may occur) based on a randomization book.

Constraints

- *Approved Invariant* . DefinedActivity Qualifier.
  A PlannedRandomizationBookAllocation can only reference a StudyActivity that points to DefinedExperimentalUnitAllocation, no any other subclass of DefinedActivity.
- *Approved Invariant* . Repeat Not Applicable.
  The Repeat attributes should not be used for a PlannedRandomizationBookAllocation.

Protocol Representation Sub-Domain::PlannedRandomizationBookAllocation Connections

Connector	Source	Target	Notes
Association is defined by	RandomizationBookEntry +defined 1..*, unordered, none	PlannedRandomizationBookAllocation +defining 1, unordered, none	Each RandomizationBookEntry always is defined by one PlannedRandomizationBookAllocation. Each PlannedRandomizationBookAllocation always defines one or more RandomizationBookEntry. *Constraints* Inverse Relation: defines
Generalization source > target	PlannedRandomizationBookAllocation Child	PlannedActivity Parent	

6.61 Protocol Representation Sub-Domain::PlannedRepeatActivityUntilRule

public Class:

A relationship between two activities where the source activity continues repeating until the target activity has occurred.

For example, continue repeating kidney dialysis until kidney transplant surgery.

Constraints

- *Approved Invariant* . Is Repeated Until Exclusive Or.
  A PlannedRepeatActivityUntilRule must be associated to only one of the following: a PlannedActivity, a DefinedObservationResult, or a PlannedCriterionGroup.

Protocol Representation Sub-Domain::PlannedRepeatActivityUntilRule Connections

Connector	Source	Target	Notes
Association triggers the cessation of	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	PlannedActivity +triggering 1, unordered, none	Each PlannedRepeatActivityUntilRule always triggers the cessation of one PlannedActivity. Each PlannedActivity sometimes is repeated until one or more

			PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: is repeated until
Association is repeated until	PlannedRepeatActivityUntilRule +triggering 1, unordered, none	PlannedActivity +repeated 1, unordered, none	Each PlannedRepeatActivityUntilRule always is repeated until one PlannedActivity. Each PlannedActivity always triggers the cessation of one PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is repeated until	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	PlannedCriterionGroup +triggering 0..1, unordered, none	Each PlannedRepeatActivityUntilRule sometimes is repeated until one PlannedCriterionGroup. Each PlannedCriterionGroup sometimes triggers the cessation of one or more PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of
Association is repeated until	PlannedRepeatActivityUntilRule +repeated 0..*, unordered, none	DefinedObservationResult +triggering 0..1, unordered, none	Each PlannedRepeatActivityUntilRule sometimes is repeated until one DefinedObservationResult. Each DefinedObservationResult sometimes triggers the cessation of one or more PlannedRepeatActivityUntilRule. *Constraints* Inverse Relation: triggers the cessation of

Protocol Representation Sub-Domain::PlannedRepeatActivityUntilRule Attributes

Attribute	Type	Notes
cessationPauseQuantity	public : *PQ.TIME*	The length of time that should elapse after the observed result occurs and before the cessation of repeating the activity.For example, stop 20 days after the observed event occurs. Map:Lab = 'Activity.plannedTimeElapsed'
checkpointCode	public : *CD*	A coded value specifying when in the course of an activity a precondition for the activity is evaluated (e.g., before the activity

		starts for the first time, before every repetition, after each repetition but not before the first, or throughout the entire time of the activity).For example, at the end of the cycle, evaluate disease response, and decide whether to administer another cycle. Before administering the daily dose, check the conditions for continuing treatment, and continue only if those conditions are met. Map:TDM = 'CyclingRule'
conjunctionCode	public : *CD*	A coded value specifying the logical conjunction of the criteria among all the condition-links of activities (e.g., and, or, exclusive-or).For example, fill out the "Liver event" report if the subject has an ALT value > 3 times the upper limit of normal and a bilirubin value > 1.5 times the upper limit of normal. Map:TDM = 'CyclingRule'
comment	public : *ST*	Additional description of the repeat activity until rule. Map:CTOM = 'ActivityRelationship.commentText'

Tagged Values

- Map:CTOM = ActivityRelationship.typeCode.

6.62 Protocol Representation Sub-Domain::RandomizationBookEntry

public Class:
An item/element of a randomization book that can be used to assign a subject to a planned arm or portion of an arm in a study.

For example, an entry might be mapping Stratum Group to a Treatment Arm.

Protocol Representation Sub-Domain::RandomizationBookEntry Connections

Connector	Source	Target	Notes
Association randomizes	RandomizationBookEntry +randomizing 0..*, unordered, none	StratumGroup +randomized 1, unordered, none	Each RandomizationBookEntry always randomizes one StratumGroup. Each StratumGroup sometimes is randomized by one or more RandomizationBookEntry. *Constraints* Inverse Relation: is randomized by
Association is assigned to	RandomizationBookEntry +assigned 0..*, unordered, none	Arm +containing 1, unordered, none	Each RandomizationBookEntry always is assigned to one Arm. Each Arm sometimes has assigned one or more RandomizationBookEntry. *Constraints* Inverse Relation: contains

Association is defined by	RandomizationBookEntry +defined 1..*, unordered, none	PlannedRandomizationBookAllocation +defining 1, unordered, none	Each RandomizationBookEntry always is defined by one PlannedRandomizationBookAllocation. Each PlannedRandomizationBookAllocation always defines one or more RandomizationBookEntry. *Constraints* Inverse Relation: defines

Protocol Representation Sub-Domain::RandomizationBookEntry Attributes

Attribute	Type	Notes
positionNumber	public : *INT*	An integer specifying the value of a numerical sequence for a Stratum Group that should be used to assign a subject to an arm or a portion of an arm. An example would be:StratumGroup#: 0; Position: 0; Arm/Portion of Arm: AStratumGroup#: 0; Position: 1; Arm/Portion of Arm: BIf 2 patients fall in the same Stratum Group i.e. say 0 in the above example, the first patient will be assigned Arm A because the current position would be 0 and the 2nd patient would be assigned Arm B since the current position would be incremented by 1 each time an assignment happens. Map:C3PR = 'BookRandomizationEntry.position'
positionFilledIndicator	public : *BL*	Specifies whether the position is filled by a subject assignment. Map:C3PR = 'StratumGroup.currentPosition'

6.63 Protocol Representation Sub-Domain::ReferenceToStudyResults

public Class:
Citations to publications related to the study results.

NOTE: CT.gov instruction say to provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.

Protocol Representation Sub-Domain::ReferenceToStudyResults Connections

Connector	Source	Target	Notes
Association references the results of	ReferenceToStudyResults +referencing 0..*, unordered, none	Study +referenced 1, unordered, none	Each ReferenceToStudyResults always references the results of one Study. Each Study sometimes has results referenced in one or more ReferenceToStudyResults. *Constraints* Inverse Relation: has results referenced in

Protocol Representation Sub-Domain::ReferenceToStudyResults Attributes

Attribute	Type	Notes
publicationIdentifier	public : *II*	The unique symbol that establishes identity to a publication that cites this study's results.For example, 10987815 is the unique PubMed Identifier (PMID) for the citation in MEDLINE. Map:CTGOV = 'MEDLINE Identifier'
publicationName	public : *ST*	A non-unique textual identifier specifying the source of the publication identifier.For example, MEDLINE is the source for PMID 10987815 Map:PRM = 'PublishedResults.title'
universalResourceLocator	public : *URL*	A complete reference to a website (including http://) that is directly relevant to the study. For example, "http://www.alzheimers.org/". Map:CTGOV = 'Links URL'
citationDescription	public : *ST*	A bibliographic reference in NLM's MEDLINE format. Map:CTGOV = 'Citation'
linkPageDescription	public : *ST*	The textual representation of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. Map:CTGOV = 'Links Description'

6.64 Protocol Representation Sub-Domain::RegistrationCenter

public Class {leaf}

Extends: Service. :

The service of recording subject participation on a study and allocating them to an arm.

Protocol Representation Sub-Domain::RegistrationCenter Connections

Connector	Source	Target	Notes
Generalization source > target	RegistrationCenter Child	Service Parent	

Protocol Representation Sub-Domain::RegistrationCenter Attributes

Attribute	Type	Notes
telecomAddress	public : *TEL*	A sequence of digits or characters used to identify a particular telephone, fax, or email of a registration center.For example, the phone number to call to request that a subject be registered and randomized on a study. Map:C3PR = 'PhoneCallRandomization.phoneNumber'

6.65 Protocol Representation Sub-Domain::Resource

public Class {root}:
Fiscal, material or labor support for research.

Protocol Representation Sub-Domain::Resource Connections

Connector	Source	Target	Notes
Association is provided by	Resource +provided 1.., unordered, none	ResourceProvider +providing 1, unordered, none	Each Resource always is provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource. *Constraints* Inverse Relation: provides *Tagged Values* Map:CTOM: Protocol.sponsorCode Map:C3PR: StudyOrganization
Association associates a study to	StudyResource +associating 0..*, unordered, none	Resource +associated 1, unordered, none	Each StudyResource always associates a study to one Resource. Each Resource sometimes is associated to a study by one or more StudyResource. *Constraints* Inverse Relation: is associated to a study by *Tagged Values* Map:CTOM: Protocol.sponsorCode Map:C3PR: StudyOrganization
Generalization source > target	MaterialResource Child	Resource Parent	
Generalization source > target	Service Child	Resource Parent	
Generalization source > target	Funding Child	Resource Parent	

Protocol Representation Sub-Domain::Resource Attributes

Attribute	Type	Notes
activeIndicator	public : *BL*	Specifies whether the resource is active. Map:COPPA = 'StudyResourcing.activeIndicator'
inactiveComment	public : *ST*	Additional description why the resource is no longer active. Map:COPPA = 'StudyResourcing.inactiveCommentText '

Tagged Values

- Map:C3PR = Study.sponsorCode.
- Map:C3PR = StudyOrganization.
- Map:COPPA = StudyResourcing.
- Map:CTOM = Protocol.sponsorCode.
- Map:HL7SP = Study.performer2.
- Map:HL7SP = Service Provider.

6.66 Protocol Representation Sub-Domain::Service

public Class {leaf}
Extends: Resource. :
Labor support for research.

Protocol Representation Sub-Domain::Service Connections

Connector	Source	Target	Notes
Generalization source > target	Service Child	Resource Parent	
Generalization source > target	RegistrationCenter Child	Service Parent	

Protocol Representation Sub-Domain::Service Attributes

Attribute	Type	Notes
typeCode	public : *CD*	A coded value specifying the kind of service.For example, contract research organization, independent safety monitoring board, etc. Map:C3PR = 'BookRandomization' Map:C3PR = 'Randomization' Map:C3PR = 'StudyCoordinatingCenter' Map:HL7SP = 'Service Provider.code'

Tagged Values

- Map:HL7SP = Service Provider.

6.67 Protocol Representation Sub-Domain::StratumGroup

public Class:
A designation used to segregate StudySubjects into collections in order to balance the study for analysis. The stratum group is made up of a combination of stratification criterion answers, which ultimately is used to assign StudySubjects to arms on a study.

Protocol Representation Sub-Domain::StratumGroup Connections

Connector	Source	Target	Notes
Association randomizes	RandomizationBookEntry +randomizing 0..*, unordered, none	StratumGroup +randomized 1, unordered, none	Each RandomizationBookEntry always randomizes one StratumGroup. Each StratumGroup sometimes is

			randomized by one or more RandomizationBookEntry. *Constraints* Inverse Relation: is randomized by
Association is defined by	StratumGroup +defined 1..*, unordered, none	DefinedStratificationCriterionPermissibleResult +defining 1..*, unordered, none	Each StratumGroup always is defined by one or more DefinedStratificationCriterionPermissibleResult. Each DefinedStratificationCriterionPermissibleResult always defines one or more StratumGroup. *Constraints* Inverse Relation: defines

Protocol Representation Sub-Domain::StratumGroup Attributes

Attribute	Type	Notes
groupNumber	public : *INT*	An integer that identifies the stratum group to study personnel, such as the statistician and registrars. This index is used to cross-reference the stratum group and set of arms during registration. It is provided to perform a lookup in the randomization book or statistical algorithm when performing randomization. Map:C3PR = 'StratumGroup.stratumGroupNumber' Map:COPPA = 'StratumGroup.groupNumberText'

Tagged Values

- Map:COPPA = StratumGroup.

6.68 Protocol Representation Sub-Domain::Study

public Class {root}:
A formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic.

NOTE: The notion of a study includes (but is not limited to) the design, statistical considerations and activities to test a particular hypothesis or answer a particular question that is the basis of the study. The study may be of any type that involves subjects, including prevention, therapeutic, interventional or observational. Subjects may be biological entities (human, animal, specimen, tissue, organ, etc.) or products. The complete notion of the study is represented by the Study class and all its associations which make explicit the details identified in the StudyProtocolDocument.

Constraints

- *Approved Invariant* . mulitInstitutionalIndicator Qualifier.
  Study.multiInstitutionIndicator is derived when Study.participatingOrganizationTypeCode = Multi Center

Protocol Representation Sub-Domain::Study Connections

Connector	Source	Target	Notes
Association is responsible for	StudyLegalSponsor +sponsoring 0..*, unordered, none	Study +sponsored 1, unordered, none	Each StudyLegalSponsor always is responsible for one Study. Each Study sometimes is the responsibility of one or more StudyLegalSponsor. *Constraints* Inverse Relation: is the responsibility of
Association is the execution of	Study +instantiating 0..*, unordered, none	StudyProtocolDocument +instantiated 1, unordered, none	Each Study always is the execution of one StudyProtocolDocument. Each StudyProtocolDocument sometimes is the plan for one or more Study. *Constraints* Inverse Relation: is the plan for *Tagged Values* Map:SDTM IG: TV.STUDYID Map:CTOM: Protocol.blindedIndicator Map:SDTM IG: DM.STUDYID Map:CTOM: Protocol.multiInstitutionIndicator Map:CTOM: Protocol.targetAccrualNumber Map:SDTM IG: TA.STUDYID Map:SDTM IG: DS.STUDYID Map:SDTM IG: EX.STUDYID Map:CTOM: Protocol.phaseCode Map:SDTM IG: SC.STUDYID Map:SDTM IG: QS.STUDYID Map:SDTM IG: AE.STUDYID Map:SDTM IG: DV.STUDYID Map:SDTM IG: TE.STUDYID Map:SDTM IG: SV.STUDYID Map:CTOM: Protocol.intentCode Map:CTOM: Protocol.monitorCode Map:SDTM IG: SE.STUDYID Map:SDTM IG: SU.STUDYID Map:SDTM IG: TI.STUDYID Map:SDTM IG: CM.STUDYID Map:SDTM IG: MH.STUDYID Map:SDTM IG: VS.STUDYID Map:SDTM IG: CO.STUDYID Map:SDTM IG: PE.STUDYID Map:SDTM IG: DA.STUDYID Map:SDTM IG: TS.STUDYID Map:SDTM IG: IE.STUDYID Map:CTOM: Protocol.diseaseCode

			Map:SDTM IG: LB.STUDYID Map:SDTM IG: EG.STUDYID
Association associates an activity to	StudyActivity +associating 0..*, unordered, none	Study +associated 1, unordered, none	Each StudyActivity always associates an activity to one Study. Each Study sometimes is associated to an activity by one or more StudyActivity. *Constraints* Inverse Relation: is associated to an activity by *Tagged Values* Map:HL7SD: PlannedStudy.Component2 Map:HL7SD: PlannedStudy.Precondition1 Map:Lab: SubjectAssignment.studySubject Identifier
Association is evaluated by	StudyAgent +evaluated 0..*, unordered, none	Study +evaluating 1, unordered, none	Each StudyAgent always is evaluated by one Study. Each Study sometimes is evaluating one or more StudyAgent. *Constraints* Inverse Relation: is evaluating
Association handles communications for	StudyContact +communicating 1..*, unordered, none	Study +communicated 1, unordered, none	Each StudyContact always handles communications for one Study. Each Study always has communications handled by one or more StudyContact. *Constraints* Inverse Relation: has communications handled by
Association is an aim of	StudyObjective +involved 1..*, unordered, none	Study +involving 1, unordered, none	Each StudyObjective always is an aim of one Study. Each Study always aims to achieve one or more StudyObjective. *Constraints* Inverse Relation: aims to achieve
Association is a division of	Arm +subdividing 0..*, unordered, none	Study +subdivided 1, unordered, none	Each Arm always is a division of one Study. Each Study sometimes is divided into one or more Arm. *Constraints* Inverse Relation: is divided into *Tagged Values*

			Map:COPPA: ObservationalStudyProtocol.groupNumber Map:CTOM: StudyParticipantAssignment.armIdentifier
Association oversees	StudyOversightAuthority +overseeing 0..*, unordered, none	Study +overseen 1, unordered, none	Each StudyOversightAuthority always oversees one Study. Each Study sometimes is overseen by one or more StudyOversightAuthority. *Constraints* Inverse Relation: is overseen by *Tagged Values* Map:COPPA: InterventionalStudyProtocol.dataMonitoringCommitteeAppointedIndicator Map:CTOM: Protocol.monitorCode Map:COPPA: ObservationalStudyProtocol.dataMonitoringCommitteeAppointedIndicator Map:COPPA: StudyProtocol.dataMonitoringCommitteeAppointedIndicator
Association is a division of	Epoch +subdividing 0..*, unordered, none	Study +subdivided 1, unordered, none	Each Epoch always is a division of one Study. Each Study sometimes is divided into one or more Epoch. *Constraints* Inverse Relation: is divided into
Association associates a resource to	StudyResource +associating 0..*, unordered, none	Study +associated 1, unordered, none	Each StudyResource always associates a resource to one Study. Each Study sometimes is associated to a resource by one or more StudyResource. *Constraints* Inverse Relation: is associated to a resource by
Association describes	StudyRecruitmentStatus +describing 0..*, unordered, none	Study +described 1, unordered, none	Each StudyRecruitmentStatus always describes one Study. Each Study sometimes is described by one or more StudyRecruitmentStatus. *Constraints* Inverse Relation: is described by

			Tagged Values Map:HL7SP: Study.subjectOf2
Association describes	StudyOverallStatus +describing 1..*, unordered, none	Study +described 1, unordered, none	Each StudyOverallStatus always describes one Study. Each Study always is described by one or more StudyOverallStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:COPPA: ObservationalStudyProtocol.primaryCompletionDateTypeCode Map:COPPA: InterventionalStudyProtocol.primaryCompletionDate Map:COPPA: InterventionalStudyProtocol.primaryCompletionDateTypeCode Map:COPPA: StudyProtocol.startDateTypeCode Map:COPPA: InterventionalStudyProtocol.recordVerificationDate Map:COPPA: ObservationalStudyProtocol.startDate Map:HL7SP: Study.subjectOf1 Map:COPPA: StudyProtocol.primaryCompletionDateTypeCode Map:COPPA: ObservationalStudyProtocol.primaryCompletionDate Map:COPPA: InterventionalStudyProtocol.statusDate Map:COPPA: InterventionalStudyProtocol.startDateTypeCode Map:COPPA: StudyProtocol.primaryCompletionDate Map:COPPA: ObservationalStudyProtocol.startDateTypeCode Map:COPPA: StudyProtocol.startDate
Association occurs in the context of	PerformedActivity +contained	Study +containing	Each PerformedActivity sometimes occurs in the context of one Study.

	0..*, unordered, none	0..1, unordered, none	Each Study sometimes provides context to one or more PerformedActivity. *Constraints* Inverse Relation: provides context to
Association references the results of	ReferenceToStudyResults +referencing 0..*, unordered, none	Study +referenced 1, unordered, none	Each ReferenceToStudyResults always references the results of one Study. Each Study sometimes has results referenced in one or more ReferenceToStudyResults. *Constraints* Inverse Relation: has results referenced in
Association refers to	Study +referencing 1..*, unordered, none	StudyReference +referenced 0..*, unordered, none	Each Study sometimes refers to one or more StudyReference. Each StudyReference always is referenced by one or more Study. *Constraints* Inverse Relation: is referenced by
Association executes	StudySite +executing 0..*, unordered, none	Study +executes 1, unordered, none	Each StudySite always executes one Study. Each Study sometimes is executed at one or more StudySite. NOTE: a StudySite may be related to either a HealthcareFacility or an Organization (serving as a StudySite but is not a HealthcareFacility). *Constraints* Inverse Relation: is executed at *Tagged Values* Map:CTOM: StudyParticipantAssignment.armIdentifier Map:HL7SP: Study.subject Map:HL7SP: Study.performer1 Map:HL7SP: Study.performer3 Map:CTOM: StudySite.localProtocolIdentifier Map:Lab: SubjectAssignment.studySubjectIdentifier
Generalization source > target	ExpandedAccessStudy Child	Study Parent	

Generalization source > target	ObservationalStudy Child	Study Parent	
Generalization source > target	InterventionalStudy Child	Study Parent	

Protocol Representation Sub-Domain::Study Attributes

Attribute	Type	Notes
acronym	public : *ST*	The non-unique initials or abbreviated name for identification of the study. For example, WHI for Women's Health Initiative Map:COPPA = 'StudyProtocol.acronym' Map:COPPA = 'ObservationalStudyProtocol.acronym' Map:COPPA = 'InterventionalStudyProtocol.acronym' Map:CTGOV = 'Acronym' Map:WHO = 'Acronym'
phaseCode	public : *CD*	A coded value specifying the designation of approval phase for a study.For example, I, I/II, II, III, N/A.NOTE: Studies are generally categorized into four (sometimes five) phases described separately herein. An investigational medicine or product may be evaluated in two or more phases simultaneously in different studies, and some studies may overlap two different phases. Phase 1: The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. Phase 2: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 3: Studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3b: Phase 3b studies are a sub category of phase 3 trials near the time of approval to elicit additional findings. Phase 4: Concurrent with marketing approval, Food and Drug Administration (FDA) may seek agreement from the sponsor to conduct certain post-marketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. Phase 5: Post-marketing surveillance is sometimes referred to as Phase 5. Map:C3PR = 'Study.phaseCode' Map:COPPA = 'StudyProtocol.phaseCode' Map:COPPA = 'InterventionalStudyProtocol.phaseCode' Map:COPPA = 'ObservationalStudyProtocol.phaseCode' Map:CTGOV = 'Study Design Study Phase' Map:CTOM = 'Protocol.phaseCode' Map:WHO = 'Study Type.Phase'
primaryPurposeCode	public : *CD*	A coded value specifying the type of study based upon the intent of the study's activities.For example, treatment studies test new treatments, new combinations of drugs, or new approaches to

		surgery or radiation therapy. Prevention studies look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes. Diagnostic studies are conducted to find better tests or procedures for diagnosing a particular disease or condition. Screening studies test the best way to detect certain diseases or health conditions. Quality of Life studies (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness. Map:COPPA = 'StudyProtocol.primaryPurposeCode' Map:COPPA = 'ObservationalStudyProtocol.primaryPurposeCode' Map:COPPA = 'InterventionalStudyProtocol.primaryPurposeCode' Map:CTGOV = 'Study Design Primary Purpose' Map:CTGOV = 'Intervention Type' Map:CTOM = 'Protocol.intentCode'
purposeStatement	public : *ST*	A statement describing the overall rationale of the study. This field describes the contribution of this study to product development, i.e., what knowledge is being contributed from the conduct of this study.NOTE: This differs from StudyObjective which describes what the study hopes to accomplish whereas the purposeStatement is the reason why the study is being conducted. Map:PRM = 'Trial Purpose Summary'
diseaseCode	public : *DSET<CD>*	A coded value specifying the condition that is the focus of the study. For example, in a study to examine risk factors for Lupus, might have as an inclusion criterion "healthy volunteer", but the target condition code would be a Lupus SNOMED code. Map:COPPA = 'ObservationalStudyProtocol.diseaseCode' Map:COPPA = 'StudyProtocol.diseaseCode' Map:COPPA = 'InterventionalStudyProtocol.diseaseCode' Map:CTGOV = 'Conditions or Focus of Study' Map:CTOM = 'Protocol.diseaseCode'
targetAnatomicSiteCode	public : *DSET<CD>*	A coded value specifying the anatomic location that is the focus of a study.For example, breast, ovary. Map:COPPA = 'StudyProtocol.targetAnatomicSiteCode' Map:COPPA = 'ObservationalStudyProtocol.targetAnatomicSiteCode' Map:COPPA = 'InterventionalStudyProtocol.targetAnatomicSiteCode'
designConfigurationCode	public : *CD*	A coded value specifying a trial pattern developed to compare treatment groups in a clinical pre-clinical trial.For example, Parallel Group Design, Crossover Design, Factorial Designs, Cohort, Case-control, Case-only, Case-crossover, Ecologic or Community Studies, Family-based, etc.NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. Map:COPPA =

		'InterventionalStudyProtocol.designConfigurationCode' Map:COPPA = 'ObservationalStudyProtocol.studyModelCode' Map:CTGOV = 'Intervention Model' Map:CTGOV = 'Observational Study Model' Map:CTGOV = 'Study Design' Map:WHO = 'Study Type Study Design Assignment'
studySchematic	public : *ED*	Diagram which outlines all study epochs, timing of randomization and duration of treatments. Map:COPPA = 'StudyProtocol.studySchematic' Map:COPPA = 'InterventionalStudyProtocol.studySchematic' Map:COPPA = 'ObservationalStudyProtocol.studySchematic'
populationDescription	public : *ST*	The textual representation of the subject characteristics, including inclusion and exclusion criteria and describes the population for which the study may be generalized. NOTE: This would include all subgroups as well. Map:C3PR = 'Study.type' Map:COPPA = 'InterventionalStudyProtocol.populationDescription' Map:COPPA = 'ObservationalStudyProtocol.populationDescription' Map:COPPA = 'ObservationalStudyProtocol.studyPopulationDescription' Map:COPPA = 'StudyProtocol.populationDescription' Map:CTGOV = 'Study Population Description' Map:WHO = 'Health Condition(s) or Problem(s) Studied'
studySubjectTypeCode	public : *CD*	A coded value specifying the target entity of the study of investigation.For example, in a clinical trial, the subject type would be "human". Other studies could involve animals (rats, mice). Map:HL7SP = 'StudyParticipation RMIM'
plannedStudySubjectExperience	public : *ST*	Sequence and duration of study epochs, including pre-randomization and post-treatment epochs, therapy withdrawal epochs, and single- and double-blind treatment epochs. Map:PRM = 'Planned Subject Participation Experience (ICH)'
targetAccrualNumberRange	public : *URG<INT>*	A range of integers specifying the minimum and maximum number of subjects to be accrued for the study.NOTE: A typical target accrual number (always assumed to be a minimum target) would be targetAccrualRange.IVL<INT>.low, a maximum target accrual would be targetAccrualRange.IVL<INT>.high. Map:C3PR = 'Study.targetAccrualNumber' Map:COPPA = 'ObservationalStudyProtocol.maximumTargetAccrualNumber' Map:COPPA = 'InterventionalStudyProtocol.maximumTargetAccrualNumber' Map:COPPA = 'InterventionalStudyProtocol.targetAccrualNumber'

		Map:COPPA = 'StudyProtocol.targetAccrualNumber' Map:COPPA = 'ObservationalStudyProtocol.targetAnatomicSiteCode.targetAccrualNumber' Map:COPPA = 'StudyProtocol.maximumTargetAccrualNumber' Map:CTGOV = 'Enrollment' Map:CTOM = 'Protocol.targetAccrualNumber' Map:WHO = 'Target Sample Size'
periodicTargetAccrualNumber	public : *RTO<INT,PQ>*	A range of integers specifying the minimum and maximum number of subjects to be accrued per a specified amount of time.For example, for monthly target accrual, a given study may have a target accrual of 100 per 1 month meaning the numerator of the ratio is the integer 100 and the denominator is a PQ where the value is 1 and the unit is month. Map:COPPA = 'StudyProtocol.monthlyTargetAccrualNumber' Map:COPPA = 'ObservationalStudyProtocol.monthlyTargetAccrualNumber' Map:COPPA = 'InterventionalStudyProtocol.monthlyTargetAccrualNumber'
accrualReportingMethodCode	public : *CD*	A coded value specifying the technique that is used for reporting subject accrual data to the study sponsor.For example, complete, abbreviated. Map:COPPA = 'StudyProtocol.accrualReportingMethodCode' Map:COPPA = 'ObservationalStudyProtocol.accrualReportingMethodCode' Map:COPPA = 'InterventionalStudyProtocol.accrualReportingMethodCode'
responsiblePartyCode	public : *CD*	A coded value specifying the type of entity who is legally responsible for the execution of the study.For example, the PI or the sponsor. Map:COPPA = 'StudyProtocol.responsiblePartyCode' Map:COPPA = 'ObservationalStudyProtocol.responsiblePartyCode' Map:COPPA = 'InterventionalStudyProtocol.responsiblePartyCode' Map:CTGOV = 'Responsible Party'
participatingOrganizationTypeCode	public : *CD*	A coded value specifying the kind of organizational participation planned for this study.For example, Cancer Center, Clinical Center, Consortium, Group, Intergroup, Multi-Center, Network, or Single Institution. Map:COPPA = 'StudyProtocol.participatingOrganizationTypeCode' Map:COPPA = 'ObservationalStudyProtocol.participatingOrganizationTypeCode' Map:COPPA = 'InterventionalStudyProtocol.participatingOrganizationTypeCode'
participatingCountryCode	public :	A coded value specifying the countries from which participants

	DSET<CD>	will be, are intended to be, or have been recruited for the study. Map:WHO = 'Countries of Recruitment'
aeCodingSystem	public : *II*	The coding system used for recording adverse events for a study. Map:COPPA = 'StudyProtocol.AEcodingSystem' Map:COPPA = 'ObservationalStudyProtocol.AECodingSystem' Map:COPPA = 'InterventionalStudyProtocol.AECodingSystem'
multiInstitutionIndicator	public : *BL*	Specifies whether a study is designed to be conducted at more than one site concurrently.NOTE: This could be conceived as derivable, but since it needs to be defined before study sites are associated with a study, it is needed here. Map:C3PR = 'Study.multiInstitutionIndicator' Map:CTOM = 'Protocol.multiInstitutionIndicator'

Tagged Values

- Map:AE = Study.
- Map:AE = Study.name.
- Map:AE = Study.primaryIdentifier.
- Map:AE = Study.additionalIdentifier.
- Map:C3PR = Study.sponsorCode.
- Map:C3PR = StudySubject.informedConsentSignedDate.
- Map:COPPA = StudyProtocol.
- Map:COPPA = InterventionalStudyProtocol.primaryCompletionDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.dataMonitoringCommitteeAppointedIndicator.
- Map:CTGOV = Protocol.blindedIndicator.
- Map:CTOM = StudyParticipantAssignment.armIdentifier.
- Map:CTOM = Protocol.sponsorCode.
- Map:CTOM = Protocol.monitorCode .
- Map:HL7SD = PlannedStudy.
- Map:HL7SD = StudyCharacteristic.
- Map:HL7SP = Study.performer2.
- Map:HL7SP = Study.performer1.
- Map:HL7SP = Study.evaluation.
- Map:HL7SP = Study.subjectOf1.
- Map:HL7SP = PlannedStudy.id.
- Map:HL7SP = Study.
- Map:HL7SP = PlannedStudy.
- Map:HL7SP = Study.subject.
- Map:HL7SP = Study.id.
- Map:Lab = SubjectAssignment.studySubjectIdentifier.
- Map:SDTM IG = TA.STUDYID.
- Map:SDTM IG = TI.STUDYID.
- Map:SDTM IG = AE.STUDYID.
- Map:SDTM IG = CM.STUDYID.
- Map:SDTM IG = DS.STUDYID.
- Map:SDTM IG = EX.STUDYID.
- Map:SDTM IG = CO.STUDYID.
- Map:SDTM IG = DV.STUDYID.
- Map:SDTM IG = DM.STUDYID.
- Map:SDTM IG = MH.STUDYID.

- Map:SDTM IG = DA.STUDYID.
- Map:SDTM IG = TS.STUDYID.
- Map:SDTM IG = SU.STUDYID.
- Map:SDTM IG = SV.STUDYID.
- Map:SDTM IG = SE.STUDYID.
- Map:SDTM IG = TV.STUDYID.
- Map:SDTM IG = TE.STUDYID.
- Map:SDTM IG = VS.STUDYID.
- Map:SDTM IG = IE.STUDYID.
- Map:SDTM IG = QS.STUDYID.
- Map:SDTM IG = LB.STUDYID.
- Map:SDTM IG = EG.STUDYID.
- Map:SDTM IG = SC.STUDYID.
- Map:SDTM IG = PE.STUDYID.

6.69 Protocol Representation Sub-Domain::StudyActivity

public Class:
A DefinedActivity that is part of the design of a Study.

For example, 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.

NOTE: The number of times this activity occurs during the Study and the relative timing for those occurrences is represented by PlannedActivity.

Protocol Representation Sub-Domain::StudyActivity Connections

Connector	Source	Target	Notes
Association associates a study to	StudyActivity +associating 0..*, unordered, none	DefinedActivity +associated 1, unordered, none	Each StudyActivity always associates a study to one DefinedActivity. Each DefinedActivity sometimes is associated to a study by one or more StudyActivity. *Constraints* Inverse Relation: is associated to a study by *Tagged Values* Map:Lab: SubjectAssignment.studySubject Identifier
Association associates an activity to	StudyActivity +associating 0..*, unordered, none	Study +associated 1, unordered, none	Each StudyActivity always associates an activity to one Study. Each Study sometimes is associated to an activity by one or more StudyActivity. *Constraints* Inverse Relation: is associated to an activity by *Tagged Values*

			Map:HL7SD: PlannedStudy.Component2 Map:HL7SD: PlannedStudy.Precondition1 Map:Lab: SubjectAssignment.studySubject Identifier
Association is a use of	PlannedActivity +using 0..*, unordered, none	StudyActivity +used 1, unordered, none	Each PlannedActivity always is a use of one StudyActivity. Each StudyActivity sometimes is used as one or more PlannedActivity. *Constraints* Inverse Relation: is used as *Tagged Values* Map:HL7SD: PlannedStudy.Component2 Map:HL7SD: PlannedStudy.Precondition1 Map:HL7SD: EligibilityCriterion

Protocol Representation Sub-Domain::StudyActivity Attributes

Attribute	Type	Notes
studyFocusIndicator	public : *BL*	Specifies whether the activity is the focus of the investigation for a study.NOTE: If a study has study agents, one or more of the study focused activities will presumably use the agent. Map:COPPA = 'PlannedEligibilityCriterion.name'

Tagged Values

- Map:HL7SD = PlannedStudy.Component2.
- Map:HL7SD = PlannedStudy.Precondition1.
- Map:HL7SD = EligibilityCriterion.

6.70 Protocol Representation Sub-Domain::StudyAgent

public Class:
A product or a combination that is being used or tested as part of a study.

NOTE: If a study has study agents, presumably one or more of the StudyActivity will use the agent and have studyFocusedIndicator = Y.

Protocol Representation Sub-Domain::StudyAgent Connections

Connector	Source	Target	Notes
Association is evaluated by	StudyAgent +evaluated 0..*, unordered, none	Study +evaluating 1, unordered, none	Each StudyAgent always is evaluated by one Study. Each Study sometimes is evaluating one or more StudyAgent.

			Constraints Inverse Relation: is evaluating
Association is a function performed by	StudyAgent +performed 0..*, unordered, none	Product +performing 1, unordered, none	Each StudyAgent always is a function performed by one Product. Each Product sometimes functions as one or more StudyAgent. *Constraints* Inverse Relation: functions as
Association uses	PerformedProcedure +using 0..*, unordered, none	StudyAgent +used 0..*, unordered, none	Each PerformedProcedure sometimes uses one or more StudyAgent. Each StudyAgent sometimes is used during one or more PerformedProcedure. *Constraints* Inverse Relation: is used during
Association is a transfer of	PerformedStudyAgent Transfer +transferring 0..*, unordered, none	StudyAgent +transferred 1, unordered, none	Each PerformedStudyAgentTransfer always is a transfer of one StudyAgent. Each StudyAgent sometimes is transferred during one or more PerformedStudyAgentTransfer. *Constraints* Inverse Relation: is transferred during

Protocol Representation Sub-Domain::StudyAgent Attributes

Attribute	Type	Notes
functionCode	public : *CD*	A coded value specifying how this agent is used in the study.For example, Lead Agent, Comparator Agent, Placebo, Active Control, etc.NOTE: This is important to know in multi-agent studies. Map:COPPA = 'StudyProduct.leadProductIndicator' Map:CTOM = 'StudyAgent.investigationalIndicator'
statusCode	public : *CD*	A coded value specifying the state of the study agent.For example, pending, active, complete, or cancelled. Map:COPPA = 'StudyProduct.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the study agent. Map:COPPA = 'StudyProduct.statusDateRange' Map:CTOM = 'StudyAgent.statusDate'

Tagged Values

- Map:COPPA = StudyProduct.
- Map:CTOM = StudyAgent.statusDate.
- Map:CTOM = AgentOccurrence.lotNumber.
- Map:CTOM = AgentOccurrence.formCode.
- Map:CTOM = AgentOccurrence.expirationDate.
- Map:CTOM = StudyAgent.investigationalNewDrugIdentifier.

6.71 Protocol Representation Sub-Domain::StudyContact

public Class {root}:
A person who provides or receives information on behalf of a study.

Protocol Representation Sub-Domain::StudyContact Connections

Connector	Source	Target	Notes
Association is a function performed by	StudyContact +performed 0..*, unordered, none	ResearchStaff +performing 0..1, unordered, none	Each StudyContact sometimes is a function performed by one ResearchStaff. Each ResearchStaff sometimes functions as one or more StudyContact. NOTE: a StudyContact can be represented by either a ResearchStaff or a Person but not both. *Constraints* Inverse Relation: functions as
Association handles communications for	StudyContact +communicating 1..*, unordered, none	Study +communicated 1, unordered, none	Each StudyContact always handles communications for one Study. Each Study always has communications handled by one or more StudyContact. *Constraints* Inverse Relation: has communications handled by
Generalization source > target	StudyResearchCoordinator Child	StudyContact Parent	
Generalization source > target	StudyInvestigator Child	StudyContact Parent	

Protocol Representation Sub-Domain::StudyContact Attributes

Attribute	Type	Notes
roleCode	public : *CD*	A coded value specifying the type of responsibility of the study contact.For example, Study Principal Investigator, Coordinating Investigator, Study Director, Study Chair, Public Queries, Scientific Queries, Scientific Leadership.

		Map:C3PR = 'StudyInvestigator.roleCode' Map:C3PR = 'StudyPersonnel.roleCode' Map:COPPA = 'StudyContact.roleCode' Map:COPPA = 'StudyInvestigator.roleCode' Map:CTGOV = 'Overall Study Officials - Official's Role' Map:CTGOV = 'Central Contact' Map:CTGOV = 'Central Contact Backup' Map:CTGOV = 'Overall Study Officials' Map:CTOM = 'HealthcareSiteParticipantRole.roleCode' Map:CTOM = 'StudyInvestigator.responsibilityRoleCode' Map:HL7SP = 'Investigator.code' Map:WHO = 'Contact for Public Queries' Map:WHO = 'Contact for Scientific Queries - type' Map:WHO = 'Contact for Public Queries - type' Map:WHO = 'Contact for Scientific Queries'
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study contact. Map:COPPA = 'StudyInvestigator.primaryIndicator' Map:COPPA = 'StudyContact.primaryIndicator'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the study contact. Map:COPPA = 'StudyInvestigator.postalAddress' Map:COPPA = 'StudyContact.postalAddress' Map:CTGOV = 'Responsible Party - Contact Information' Map:WHO = 'Contact for Scientific Queries - zip' Map:WHO = 'Contact for Public Queries - country' Map:WHO = 'Contact for Public Queries - zip' Map:WHO = 'Contact for Public Queries - city' Map:WHO = 'Contact for Scientific Queries - country' Map:WHO = 'Contact for Scientific Queries - city' Map:WHO = 'Contact for Public Queries - address' Map:WHO = 'Contact for Scientific Queries - address'
telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of the study contact. Map:COPPA = 'StudyContact.telecomAddress' Map:COPPA = 'StudyInvestigator.telecomAddress' Map:CTGOV = 'Central Contact - Ext' Map:CTGOV = 'Responsible Party - Contact Information' Map:CTGOV = 'Central Contact - Email' Map:CTGOV = 'Central Contact - Phone' Map:WHO = 'Contact for Scientific Queries - telephone' Map:WHO = 'Contact for Public Queries - telephone' Map:WHO = 'Contact for Public Queries - email' Map:WHO = 'Contact for Scientific Queries - email'
statusCode	public : *CD*	A coded value specifying the state of the study contact.For example, pending, active, complete, or cancelled. Map:C3PR = 'StudyInvestigator.statusCode' Map:COPPA = 'StudyContact.statusCode' Map:COPPA = 'StudyInvestigator.statusCode'

		Map:CTOM = 'StudyInvestigator.statusCode' Map:HL7SP = 'Investigator.statusCode'
statusDate	public : *TS.DATETIME*	The date and time on which a status is assigned to the study contact. Map:COPPA = 'StudyInvestigator.statusDateRange' Map:COPPA = 'StudyContact.statusDateRange'

Tagged Values

- Map:COPPA = StudyContact.

6.72 Protocol Representation Sub-Domain::StudyInvestigator

public Class {leaf}

Extends: StudyContact. :

A researcher in a study who oversees all aspects of the study, such as concept development, protocol writing, protocol submission for IRB approval, participant recruitment, informed consent, data collection, analysis, interpretation and presentation.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  If the associated Study is an InterventionalStudy then the StudyInvestigator must be a function performed by a HealthcareProvider.
- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A StudyInvestigator can be a function performed by either a ResearchStaff or a HealthcareProvider but not both.

Protocol Representation Sub-Domain::StudyInvestigator Connections

Connector	Source	Target	Notes
Association is a function performed by	StudyInvestigator +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudyInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudyInvestigator. *Constraints* Inverse Relation: functions as *Tagged Values* Map:HL7SP: Investigator
Generalization source > target	StudyInvestigator Child	StudyContact Parent	

Protocol Representation Sub-Domain::StudyInvestigator Attributes

Attribute	Type	Notes
identifier	public : *II*	A unique symbol that establishes identity of the study investigator. Map:C3PR = 'Investigator.nciIdentifier'

		Map:COPPA = 'StudyInvestigator.id' Map:HL7SP = 'Investigator.id' Map:SDTM IG = 'DM.INVID'
signatureText	public : *ST*	The signed name of the investigator who is responsible for completing a form or report for a clinical trial.NOTE: A textual or multimedia depiction of the signature by which the participant endorses his or her participation in the Act as a specified role and that he or she agrees to assume the associated accountability. Map:C3PR = 'StudyInvestigator.signatureIndicator' Map:C3PR = 'StudyInvestigator.signatureText' Map:COPPA = 'StudyInvestigator.signatureText' Map:CTOM = 'StudyInvestigator.signatureText' Map:CTOM = 'StudyInvestigator.signatureIndicator'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the study investigator is active. Map:C3PR = 'StudyInvestigator.startDate' Map:C3PR = 'StudyInvestigator.endDate' Map:COPPA = 'StudyInvestigator.dateRange' Map:CTOM = 'StudyInvestigator.stopDate' Map:CTOM = 'StudyInvestigator.startDate' Map:HL7SP = 'Investigator.effectiveTime'

Tagged Values

- Map:C3PR = StudyInvestigator.roleCode.
- Map:C3PR = StudyInvestigator.statusCode.
- Map:COPPA = StudyInvestigator.
- Map:CTOM = StudyInvestigator.statusCode.
- Map:CTOM = StudyInvestigator.responsibilityRoleCode.
- Map:HL7SP = Investigator.statusCode.
- Map:HL7SP = Investigator.code.
- Map:HL7SP = Investigator.

6.73 Protocol Representation Sub-Domain::StudyLegalSponsor

public Class:
A sponsor that initiates the investigation and is legally responsible for the study.

For example, federal agencies (National Cancer Institute, National Institutes of Health) and private industry (pharmaceutical companies).

Constraints

- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A StudyLegalSponsor is a function performed by either a HealthcareProvider or Organization but not both.

Protocol Representation Sub-Domain::StudyLegalSponsor Connections

Connector	Source	Target	Notes
Association is responsible for	StudyLegalSponsor +sponsoring	Study +sponsored	Each StudyLegalSponsor always is responsible for one Study. Each

	0..*, unordered, none	1, unordered, none	Study sometimes is the responsibility of one or more StudyLegalSponsor. *Constraints* Inverse Relation: is the responsibility of
Association is authorized by	PerformedProtocolDeviation +authorized 0..*, unordered, none	StudyLegalSponsor +authorizing 1, unordered, none	Each PerformedProtocolDeviation always is authorized by one StudyLegalSponsor. Each StudyLegalSponsor sometimes authorizes one or more PerformedProtocolDeviation. *Constraints* Inverse Relation: authorizes
Association is a function performed by	StudyLegalSponsor +performed 0..1, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudyLegalSponsor sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one StudyLegalSponsor. *Constraints* Inverse Relation: functions as
Association is a function performed by	StudyLegalSponsor +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each StudyLegalSponsor sometimes is a function performed by one Organization. Each Organization sometimes functions as one or more StudyLegalSponsor. *Constraints* Inverse Relation: functions as

Protocol Representation Sub-Domain::StudyLegalSponsor Attributes

Attribute	Type	Notes
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study legal sponsor. Map:WHO = 'Primary Sponsor' Map:WHO = 'Secondary Sponsor'

Tagged Values

- Map:C3PR = StudySponsor.
- Map:HL7SP = Investigator .

6.74 Protocol Representation Sub-Domain::StudyObjective

public Class:

The reason for performing a study in terms of the scientific questions to be answered by the analysis of data collected during the study.

Protocol Representation Sub-Domain::StudyObjective Connections

Connector	Source	Target	Notes
Association is an aim of	StudyObjective +involved 1..*, unordered, none	Study +involving 1, unordered, none	Each StudyObjective always is an aim of one Study. Each Study always aims to achieve one or more StudyObjective. *Constraints* Inverse Relation: aims to achieve
Association measures	StudyOutcomeMeasure +measuring 1..*, unordered, none	StudyObjective +measured 1..*, unordered, none	Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is measured by one or more StudyOutcomeMeasure. *Constraints* Inverse Relation: is measured by

Protocol Representation Sub-Domain::StudyObjective Attributes

Attribute	Type	Notes
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study objective. Map:SDTM IG = 'TS.TSPARMCD'
description	public : *ST*	The textual representation of the study objective. Map:SDTM IG = 'TS.TSPARMCD'

Tagged Values

- Map:SDTM IG = TS.TSPARMCD.

6.75 Protocol Representation Sub-Domain::StudyOutcomeMeasure

public Class:

Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment. The specific measure that receives the most emphasis in assessment.

Protocol Representation Sub-Domain::StudyOutcomeMeasure Connections

Connector	Source	Target	Notes
Association measures	StudyOutcomeMeasure +measuring 1..*, unordered, none	StudyObjective +measured 1..*, unordered, none	Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is measured by one or more

			StudyOutcomeMeasure. *Constraints* Inverse Relation: is measured by

Protocol Representation Sub-Domain::StudyOutcomeMeasure Attributes

Attribute	Type	Notes
name	public : *ST*	A non-unique textual identifier for the study outcome measure.For example, all cause mortality. Map:COPPA = 'StudyOutcomeMeasure.name' Map:CTGOV = 'Secondary Outcome Measure' Map:CTGOV = 'Outcome Measure'
typeCode	public : *DSET<CD>*	A coded value specifying the type of study outcome measure.For example, n/a, safety, efficacy, bio-equivalence, bio-availability, pharmacokinetics, pharmacodynamics. Map:COPPA = 'StudyOutcomeMeasure.typeCode' Map:CTGOV = 'Study Classification' Map:CTGOV = 'Safety Issue?'
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study outcome measure. Map:COPPA = 'StudyOutcomeMeasure.primaryIndicator' Map:CTGOV = 'Primary Outcome Measure'
timeFrameText	public : *ST*	Time point(s) at which the study outcome measure is assessed.For example, one year. Map:COPPA = 'StudyOutcomeMeasure.timeframe' Map:CTGOV = 'Time Frame'

Tagged Values

- Map:COPPA = StudyOutcomeMeasure.

6.76 Protocol Representation Sub-Domain::StudyOversightAuthority

public Class:
A role of an organization with monitoring, regulatory, or supervisory authority over biomedical research at the local, regional, national, or international level for a particular study.

Protocol Representation Sub-Domain::StudyOversightAuthority Connections

Connector	Source	Target	Notes
Association oversees	StudyOversightAuthority +overseeing 0..*, unordered, none	Study +overseen 1, unordered, none	Each StudyOversightAuthority always oversees one Study. Each Study sometimes is overseen by one or more StudyOversightAuthority.

			Constraints Inverse Relation: is overseen by *Tagged Values* Map:COPPA: InterventionalStudyProtocol.dataMonitoringCommitteeAppointedIndicator Map:CTOM: Protocol.monitorCode Map:COPPA: ObservationalStudyProtocol.dataMonitoringCommitteeAppointedIndicator Map:COPPA: StudyProtocol.dataMonitoringCommitteeAppointedIndicator
Association is a function performed by	StudyOversightAuthority +performed 0..*, unordered, none	OversightAuthority +performing 1, unordered, none	Each StudyOversightAuthority always is a function performed by one OversightAuthority. Each OversightAuthority sometimes functions as one or more StudyOversightAuthority. *Constraints* Inverse Relation: functions as *Tagged Values* Map:CTOM: Protocol.monitorCode

Tagged Values

- Map:COPPA = InterventionalStudyProtocol.FDAregulatedIndicator.
- Map:CTGOV = Data Monitoring Committee?.
- Map:CTGOV = FDA Regulated Intervention?.
- Map:CTOM = Protocol.monitorCode .

6.77 Protocol Representation Sub-Domain::StudyProtocolDocument

public Class {leaf}

Extends: Document. :

A document containing an action plan for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic.

The study protocol document includes (but is not limited to) the definitions, specifications, objective(s), background, plan (including the design, methodology, statistical considerations, organization), and other supplemental materials. It should describe the pre-study, study, and post-study portions of the plan.

NOTE: The term "protocol" is somewhat overloaded and must be qualified to provide semantic context. Therefore the term "study protocol" was chosen to disambiguate it from other protocols. In previous versions of BRIDG, there

was one class for StudyProtocol. However this too represented two distinct aspects of the semantics of StudyProtocol; which have now been split into StudyProtocolDocument and Study.

NOTE: A StudyProtocolDocument is related to other supporting Documents involved in the study, including (but not limited to) informed consent documents, case report forms (CRFs), regulatory and approval documentation, correlative studies, etc. via the inherited association to DocumentRelationship. In previous versions of BRIDG, there was an aggregation relationship between StudyProtocol and Document. However that was somewhat redundant with DocumentRelationship and has now been removed.

NOTE: BRIDG does not yet have a business requirement for Correlative Studies, however these could be handled via a DocumentRelationship between a StudyProtocolDocument for the primary study and the StudyProtocolDocument for the correlative study.

Protocol Representation Sub-Domain::StudyProtocolDocument Connections

Connector	Source	Target	Notes
Association is the execution of	Study +instantiating 0..*, unordered, none	StudyProtocolDocument +instantiated 1, unordered, none	Each Study always is the execution of one StudyProtocolDocument. Each StudyProtocolDocument sometimes is the plan for one or more Study. *Constraints* Inverse Relation: is the plan for *Tagged Values* Map:SDTM IG: TV.STUDYID Map:CTOM: Protocol.blindedIndicator Map:SDTM IG: DM.STUDYID Map:CTOM: Protocol.multiInstitutionIndicator Map:CTOM: Protocol.targetAccrualNumber Map:SDTM IG: TA.STUDYID Map:SDTM IG: DS.STUDYID Map:SDTM IG: EX.STUDYID Map:CTOM: Protocol.phaseCode Map:SDTM IG: SC.STUDYID Map:SDTM IG: QS.STUDYID Map:SDTM IG: AE.STUDYID Map:SDTM IG: DV.STUDYID Map:SDTM IG: TE.STUDYID Map:SDTM IG: SV.STUDYID Map:CTOM: Protocol.intentCode Map:CTOM: Protocol.monitorCode Map:SDTM IG: SE.STUDYID Map:SDTM IG: SU.STUDYID Map:SDTM IG: TI.STUDYID Map:SDTM IG: CM.STUDYID Map:SDTM IG: MH.STUDYID Map:SDTM IG: VS.STUDYID Map:SDTM IG: CO.STUDYID Map:SDTM IG: PE.STUDYID Map:SDTM IG: DA.STUDYID

			Map:SDTM IG: TS.STUDYID Map:SDTM IG: IE.STUDYID Map:CTOM: Protocol.diseaseCode Map:SDTM IG: LB.STUDYID Map:SDTM IG: EG.STUDYID
Generalization source > target	StudyProtocolDocument Child	Document Parent	

Protocol Representation Sub-Domain::StudyProtocolDocument Attributes

Attribute	Type	Notes
publicTitle	public : *ST*	The title of the document intended for the general population. Map:AE = 'Study.name' Map:C3PR = 'Study.shortTitleText' Map:COPPA = 'StudyProtocol.publicTitle' Map:COPPA = 'ObservationalStudyProtocol.publicTitle' Map:COPPA = 'InterventionalStudyProtocol.publicTitle' Map:CTGOV = 'Brief Title' Map:CTOM = 'Protocol.shortTitleText' Map:WHO = 'Public Title'
publicDescription	public : *ST*	The textual representation of a document intended for the general population. Map:C3PR = 'Study.precisText' Map:COPPA = 'StudyProtocol.publicDescription' Map:COPPA = 'ObservationalStudyProtocol.publicDescription' Map:COPPA = 'InterventionalStudyProtocol.publicDescription' Map:CTGOV = 'Brief Summary' Map:CTOM = 'Protocol.precisText'
scientificDescription	public : *ST*	The textual representation including an extended description of the document including scientific or technical information if desired. Map:COPPA = 'ObservationalStudyProtocol.scientificDescription' Map:COPPA = 'InterventionalStudyProtocol.scientificDescription' Map:COPPA = 'StudyProtocol.scientificDescription' Map:CTGOV = 'Detailed Description'

Tagged Values

- Map:AE = Study.primaryIdentifier.
- Map:C3PR = Study.longTitleText.
- Map:C3PR = Study.consentVersion.
- Map:COPPA = InterventionalStudyProtocol.identifier.
- Map:CTOM = ProtocolStatus.statusDate.
- Map:CTOM = ProtocolStatus.statusCode.
- Map:CTOM = Protocol.descriptionText.
- Map:CTOM = Protocol.targetAccrualNumber.
- Map:CTOM = Protocol.diseaseCode.
- Map:CTOM = Protocol.monitorCode.

- Map:CTOM = Protocol.phaseCode.
- Map:CTOM = Protocol.multiInstitutionIndicator.
- Map:CTOM = Protocol.documentUri.
- Map:CTOM = Protocol.amendmentIdentifier.
- Map:CTOM = Protocol.amendmentDate.
- Map:CTOM = Protocol.navyNCIIdentifier.
- Map:CTOM = Protocol.nciIdentifier.
- Map:CTOM = Protocol.intentCode.
- Map:CTOM = Protocol.longTitleText.
- Map:CTOM = Protocol.blindedIndicator.
- Map:HL7SD = PlannedStudy.setID.
- Map:HL7SP = PlannedStudy.id.
- Map:Lab = Study.name.
- Map:Lab = Study.identifier.
- Map:PSC = Study.name.
- Map:SDTM IG = SC.STUDYID.
- Map:SDTM IG = TS.STUDYID.
- Map:SDTM IG = SV.STUDYID.
- Map:SDTM IG = AE.STUDYID.
- Map:SDTM IG = EG.STUDYID.
- Map:SDTM IG = CO.STUDYID.
- Map:SDTM IG = TA.STUDYID.
- Map:SDTM IG = CM.STUDYID.
- Map:SDTM IG = PE.STUDYID.
- Map:SDTM IG = EX.STUDYID.
- Map:SDTM IG = VS.STUDYID.
- Map:SDTM IG = SU.STUDYID.
- Map:SDTM IG = LB.STUDYID.
- Map:SDTM IG = QS.STUDYID.
- Map:SDTM IG = DS.STUDYID.
- Map:SDTM IG = SE.STUDYID.
- Map:SDTM IG = MH.STUDYID.
- Map:SDTM IG = DV.STUDYID.
- Map:SDTM IG = TE.STUDYID.
- Map:SDTM IG = TI.STUDYID.
- Map:SDTM IG = DA.STUDYID.
- Map:SDTM IG = TV.STUDYID.
- Map:SDTM IG = IE.STUDYID.

6.78 Protocol Representation Sub-Domain::StudyReference

public Class:
Citations to publications related to the protocol's background.

NOTE: CT.gov instruction say to provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.

Protocol Representation Sub-Domain::StudyReference Connections

Connector	Source	Target	Notes
Association refers to	Study +referencing 1..*, unordered, none	StudyReference +referenced 0..*, unordered, none	Each Study sometimes refers to one or more StudyReference. Each StudyReference always is referenced by one or more Study. *Constraints*

			Inverse Relation: is referenced by

Protocol Representation Sub-Domain::StudyReference Attributes

Attribute	Type	Notes
publicationIdentifier	public : *II*	The unique symbol that establishes identity to a publication related to the study protocol background.For example, 10987815 is the unique PubMed Identifier (PMID) for the citation in MEDLINE. Map:CTGOV = 'MEDLINE Identifier'
publicationName	public : *ST*	A non-unique textual identifier specifying the source of the publication identifier.For example, MEDLINE is the source for PMID 10987815 Map:PRM = 'PublishedResults.title'
universalResourceLocator	public : *URL*	A complete reference to a website (including http://) that is directly relevant to the study. For example, "http://www.alzheimers.org/". Map:CTGOV = 'Links URL'
citationDescription	public : *ST*	A bibliographic reference in NLM's MEDLINE format. Map:CTGOV = 'Citation'
linkPageDescription	public : *ST*	The textual representation of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. Map:CTGOV = 'Links Description'

Tagged Values

- Map:CTGOV = References.

6.79 Protocol Representation Sub-Domain::StudyResource

public Class:

The association between material, fiscal or labor support and the study on which it is used.

Protocol Representation Sub-Domain::StudyResource Connections

Connector	Source	Target	Notes
Association associates a study to	StudyResource +associating 0..*, unordered, none	Resource +associated 1, unordered, none	Each StudyResource always associates a study to one Resource. Each Resource sometimes is associated to a study by one or more StudyResource.

			Constraints Inverse Relation: is associated to a study by *Tagged Values* Map:CTOM: Protocol.sponsorCode Map:C3PR: StudyOrganization
Association associates a resource to	StudyResource +associating 0..*, unordered, none	Study +associated 1, unordered, none	Each StudyResource always associates a resource to one Study. Each Study sometimes is associated to a resource by one or more StudyResource. *Constraints* Inverse Relation: is associated to a resource by

Protocol Representation Sub-Domain::StudyResource Attributes

Attribute	Type	Notes
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study resource. Map:COPPA = 'StudyResourceProvider.primaryIndicator'
effectiveDateRange	public : *IVL<TS.DATETIME>*	The date and time span for when the study resource is active. Map:COPPA = 'StudyResourcing.activeIndicator'

Tagged Values

- Map:C3PR = StudyOrganization.
- Map:C3PR = Study.sponsorCode.
- Map:CTOM = Protocol.sponsorCode.
- Map:HL7SP = Study.performer2.

6.80 Regulatory Sub-Domain::OversightAuthority

public Class {root}:
A role of an organization with monitoring, regulatory, or supervisory authority over biomedical research at the local, regional, national, or international level.

For example, Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, the Food and Drug Administration (FDA) in the USA, World Health Organization (WHO), Institutional Review Board (IRB), ethics committee, research ethics board, etc.

Regulatory Sub-Domain::OversightAuthority Connections

Connector	Source	Target	Notes
Association is a function performed by	OversightAuthority +performed	Organization +performing	Each OversightAuthority always is a function performed by one

	0..1, unordered, none	1, unordered, none	Organization. Each Organization sometimes functions as one OversightAuthority. *Constraints* Inverse Relation: functions as *Tagged Values* Map:AE: Authorization.responsibleAuthority Map:CTOM: Protocol.monitorCode Map:AE: Authorization.authorizationHolder
Association is a function performed by	StudyOversightAuthority +performed 0..*, unordered, none	OversightAuthority +performing 1, unordered, none	Each StudyOversightAuthority always is a function performed by one OversightAuthority. Each OversightAuthority sometimes functions as one or more StudyOversightAuthority. *Constraints* Inverse Relation: functions as *Tagged Values* Map:CTOM: Protocol.monitorCode
Generalization source > target	RegulatoryAuthority Child	OversightAuthority Parent	
Generalization source > target	OversightCommittee Child	OversightAuthority Parent	

Tagged Values

- Map:AE = Authorization.responsibleAuthority.
- Map:AE = Authorization.authorizationHolder.
- Map:CTOM = Protocol.monitorCode.

6.81 Regulatory Sub-Domain::RegulatoryAssessment

public Class:
An evaluation of a submission by a regulatory body.

For example, an evaluation of a submission for a new drug or device that requires FDA approval.

Regulatory Sub-Domain::RegulatoryAssessment Connections

Connector	Source	Target	Notes
Association is performed by	RegulatoryAssessment +performed 0..*, unordered, none	RegulatoryAuthority +performing 1, unordered, none	Each RegulatoryAssessment always is performed by one RegulatoryAuthority. Each

			RegulatoryAuthority sometimes performs one or more RegulatoryAssessment. *Constraints* Inverse Relation: performs
Association is evaluated in	Submission +evaluated 1..*, unordered, none	RegulatoryAssessment +evaluating 0..1, unordered, none	Each Submission sometimes is evaluated in one RegulatoryAssessment. Each RegulatoryAssessment always evaluates one or more Submission. *Constraints* Inverse Relation: evaluates

Regulatory Sub-Domain::RegulatoryAssessment Attributes

Attribute	Type	Notes
identifier	public : *DSET<II>*	A unique symbol that establishes identity of the regulatory assessment.For example, NDA number, IND number, BLA, PMA, 510K, etc. Map:AE = 'Authorization.approvalId' Map:COPPA = 'TherapeuticProduct.identifier' Map:CTOM = 'StudyAgent.investigationalNewDrugIdentifier'
assessmentCode	public : *CD*	A coded value specifying the regulatory designation made by the regulatory authority.For example, for regular submissions the code can either be approved, not approvable, approvable, complete response or cleared.For example, for expanded access submissions the code can be Available, No longer available, Temporarily not available, or Approved for marketing.NOTE: For some submissions, there are business processes that will make "default" action based on timelines --i.e., if no action is taken, then the submission is "approved". NOTE: For a submission, there may be multiple regulatory assessments that correspond to the state transitions for a submission, but only one regulatory assessment is true at a given time. A submission can first be "approvable" and then when the data is complete, a new regulatory assessment can be made that is "approved". Map:CTGOV = 'Expanded Access Status'
assessmentDate	public : *TS.DATETIME*	The date (and time) on which this particular assessment is completed.Note: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:CTGOV = 'Expanded Access Status'

6.82 Study Conduct Sub-Domain::BiologicSpecimen

public Class {leaf}

Extends: Material. :

A substance or portion of material obtained for use in testing, examination, or study

For example, a serum sample from blood.

Constraints

- *Approved Invariant* . actualIndicator Qualifier.
  Material.actualIndicator must = "N" for planned activities and actualIndicator = "Y" for performed activities.

Study Conduct Sub-Domain::BiologicSpecimen Connections

Connector	Source	Target	Notes
Association stores	DefinedSpecimenStorage +storing 0..*, unordered, none	BiologicSpecimen +stored 1, unordered, none	Each DefinedSpecimenStorage always stores one BiologicSpecimen. Each BiologicSpecimen sometimes is stored during one or more DefinedSpecimenStorage. *Constraints* Inverse Relation: is stored during
Association is a function performed by	ExperimentalUnit +performed 0..*, unordered, none	BiologicSpecimen +performing 0..1, unordered, none	Each ExperimentalUnit sometimes is a function performed by one BiologicSpecimen. Each BiologicSpecimen sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup. *Constraints* Inverse Relation: functions as
Association is a test performed on	PerformedObservation +testing 0..*, unordered, none	BiologicSpecimen +tested 0..*, unordered, none	Each PerformedObservation sometimes is a test performed on one or more BiologicSpecimen. Each BiologicSpecimen sometimes is tested during one or more PerformedObservation. *Constraints* Inverse Relation: is tested during *Tagged Values* Map:CTOM: Specimen.volumeUnitOfMeasureCode Map:Lab: Specimen.commentsFromInvesti

			gator Map:Lab: Specimen.commentsFromLaboratory Map:COPPA: ObservationalStudyProtocol.biospecimenDescription
Association results in	DefinedSpecimenCollection +producing 0..*, unordered, none	BiologicSpecimen +produced 1, unordered, none	Each DefinedSpecimenCollection always results in one BiologicSpecimen. Each BiologicSpecimen sometimes is a result of one or more DefinedSpecimenCollection. *Constraints* Inverse Relation: is a result of
Association is a result of	BiologicSpecimen +produced 1..*, unordered, none	PerformedSpecimenCollection +producing 0..1, unordered, none	Each BiologicSpecimen sometimes is a result of one PerformedSpecimenCollection. Each PerformedSpecimenCollection always results in one or more BiologicSpecimen. *Constraints* Inverse Relation: results in
Generalization source > target	BiologicSpecimen Child	Material Parent	

Study Conduct Sub-Domain::BiologicSpecimen Attributes

Attribute	Type	Notes
accessionNumberText	public : *ST*	An alphanumeric identifier (not necessarily unique to the specimen) assigned by a receiving lab to specimens that are received together as a set. Map:Lab = 'Specimen.accessionNumber'
conditionCode	public : *CD*	A coded value specifying the discreet list of values describing the condition of the specimen at time of receipt at the lab. For example, Hemolyzed, Icteric, Lipemic, etc. Map:Lab = 'Specimen.condition' Map:SDTM IG = 'LB.LBSPCCND'

Tagged Values

- Map:COPPA = ObservationalStudyProtocol.biospecimenDescription.
- Map:COPPA = Material.
- Map:CTOM = Specimen.volume.
- Map:CTOM = Specimen.volumeUnitOfMeasureCode.

- Map:Lab = Specimen.identifier.
- Map:Lab = Specimen.commentsFromLaboratory.
- Map:Lab = Specimen.commentsFromInvestigator.

6.83 Study Conduct Sub-Domain::PerformedActivity

public Class {leaf}

Extends: Activity. :

An activity that is successfully or unsuccessfully completed.

For example, CBC performed on a specific StudySubject on a given day.

For example, a scheduled blood draw that is missed by a specific ExperimentalUnit on a given day.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  Associations from Subject, StudySubject and ExperimentalUnit are subclass specific
- *Approved Invariant* . actualIndicator Exclusive Or.
  The Subject.actualSubjectIndicator = Y (instance of) or may not be used.
- *Approved Invariant* . Instantiates Exclusive Or.
  A PerformedActivity can only instantiate only of the following: DefinedActivity, PlannedActivity, ScheduledActivity.
- *Approved Invariant* . Occurs in the Context Of Qualifier.
  A PerformedActivity is only directly related to a Study if it is instantiating a DefinedActivity (not a PlannedActivity or a ScheduledActivity).
- *Approved Invariant* . actualDateRange Qualifier.
  When PerformedObservation.focalDateRange is present, this must be a single date.

Study Conduct Sub-Domain::PerformedActivity Connections

Connector	Source	Target	Notes
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	DefinedActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one DefinedActivity. Each DefinedActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by *Tagged Values* Map:CTOM: QualitativeEvaluation.anamResultAccuracyPercent Map:CTOM: QualitativeEvaluation.painIndexCodeSystem Map:CTOM: Participant.employmentStatusOtherText Map:CTOM: QualitativeEvaluation.painIndexCode Map:CTOM: QualitativeEvaluation.performan

			ceStatusCode Map:CTOM: Radiation.doseUnitOfMeasureCode Map:Lab: LabResult.referenceRangeComments Map:CTOM: Procedure.descriptionText Map:Lab: LabResult.referenceTextList Map:CTOM: Participant.householdIncomeCode Map:CTOM: Radiation.durationUnitOfMeasureCode Map:CTOM: QualitativeEvaluation.menstrualPatternTypeCode Map:CTOM: SubstanceAdministration.type Map:CTOM: Procedure.type Map:CTOM: Radiation.anatomicSiteCode Map:CTOM: Radiation.descriptionText Map:CTOM: Participant.employmentStatusCode Map:CTOM: Assessment.evaluationDate Map:CTOM: Radiation.dose Map:Lab: SubjectAssignment.type Map:CTOM: CancerStage.stageCodeSystem Map:Lab: LabResult.numericResult Map:CTOM: Radiation.startDate Map:CTOM: Radiation.type Map:CTOM: Procedure.name Map:CTOM: Radiation.stopDate Map:CTOM: QualitativeEvaluation.performanceStatusCodeSystem Map:CTOM: CancerStage.stageCode Map:CTOM: Radiation.anatomicSiteCodeSystem Map:Lab: LabResult.textResult Map:Lab: LabResult.numericPrecision Map:Lab: LabResult.testPerformedDateTi

			me Map:CTOM: Radiation.durationValue Map:CTOM: QualitativeEvaluation.menstrualIndicator Map:Lab: SubjectAssignment.studySubjectIdentifier Map:CTOM: Radiation.reasonCode Map:CTOM: LesionEvaluation.evaluationDate Map:CTOM: LesionEvaluation.evaluationCode Map:Lab: LabResult.reportedResultStatus Map:CTOM: SubstanceAdministration.name Map:PSC: StudyParticipantAssignment.startDate Map:CTOM: Radiation.name Map:CTOM: Diagnosis.name Map:CTOM: QualitativeEvaluation.survivalStatusCode Map:CTOM: Radiation.scheduleText Map:CTOM: QualitativeEvaluation.survivalStatusDescriptionText
Association triggers	AdverseEventActionTaken +triggered 0..*, unordered, none	PerformedActivity +triggering 1, unordered, none	Each AdverseEventActionTaken always triggers one PerformedActivity. Each PerformedActivity sometimes is triggered by one or more AdverseEventActionTaken. *Constraints* Inverse Relation: is triggered by
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	ScheduledActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one ScheduledActivity. Each ScheduledActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by *Tagged Values* Map:PSC:

			ScheduledEventState.occurred
Association takes place in	PerformedActivity +located 0..*, unordered, none	Place +locating 0..1, unordered, none	Each PerformedActivity sometimes takes place in one Place. Each Place sometimes is the location for one or more PerformedActivity. *Constraints* Inverse Relation: is the location for
Association triggers	ProductActionTaken +triggering 0..*, unordered, none	PerformedActivity +triggered 1, unordered, none	Each ProductActionTaken always triggers one PerformedActivity. Each PerformedActivity sometimes is triggered by one or more ProductActionTaken. *Constraints* Inverse Relation: is triggered by
Association evaluates	EvaluatedActivity +evaluating 0..*, unordered, none	PerformedActivity +evaluated 1, unordered, none	Each EvaluatedActivity always evaluates one PerformedActivity. Each PerformedActivity sometimes is evaluated by one or more EvaluatedActivity. *Constraints* Inverse Relation: is evaluated by
Association occurs in the context of	PerformedActivity +contained 0..*, unordered, none	Study +containing 0..1, unordered, none	Each PerformedActivity sometimes occurs in the context of one Study. Each Study sometimes provides context to one or more PerformedActivity. *Constraints* Inverse Relation: provides context to
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	PlannedActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one PlannedActivity. Each PlannedActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by
Generalization source > target	PerformedObservation Child	PerformedActivity Parent	
Generalization source > target	PerformedActivity Child	Activity Parent	*Tagged Values* Map:HL7SP: Study.evaluation

Generalization source > target	PerformedAdministrativeActivity Child	PerformedActivity Parent	*Tagged Values* Map:HL7SP: Study.evaluation
Generalization source > target	PerformedProcedure Child	PerformedActivity Parent	

Study Conduct Sub-Domain::PerformedActivity Attributes

Attribute	Type	Notes
actualDuration	public : *PQ.TIME*	The period of time over which the activity is performed. AE:Exclude = 'True' Map:CTOM = 'SpecimenAcquisition.durationValue' Map:CTOM = 'Procedure.durationValue' Map:CTOM = 'Imaging.durationUnitOfMeasureCode' Map:CTOM = 'Surgery.durationValue' Map:CTOM = 'SubstanceAdministration.durationUnitOfMeasureCode' Map:CTOM = 'Procedure.durationUnitOfMeasureCode' Map:CTOM = 'Surgery.durationUnitOfMeasureCode' Map:CTOM = 'SubstanceAdministration.durationValue' Map:CTOM = 'Radiation.durationUnitOfMeasureCode' Map:CTOM = 'Imaging.durationValue' Map:CTOM = 'Radiation.durationValue' Map:CTOM = 'Activity.durationValue' Map:CTOM = 'SpecimenAcquisition.durationUnitOfMeasureCode' Map:CTOM = 'Activity.durationUnitOfMeasureCode' Map:SDTM IG = 'EX.EXDUR' Map:SDTM IG = 'SU.SUDUR' Map:SDTM IG = 'CM.CMDUR'
actualDateRange	public : *IVL<TS.DATETIME>*	The date and time span when this activity began and ended.For example, the date and time when a sample is taken from the subject. For example, a dose of chemotherapy is given on June 12th starting at 9am and finishing at 12pm.NOTE: Whether administrative or preparatory activities are included in this time frame is up to whoever is defining the activity - this time frame is all that matters when the activity occurred. Map:AE = 'AdverseEvent.baselineDate' Map:AE = 'ProductInvestigation.investigationDate' Map:AE = 'Device.dateDeviceReturnedToManufacturer' Map:COPPA = 'ObservationalStudyProtocol.recordVerificationDate' Map:COPPA = 'StudyProtocol.recordVerificationDate' Map:COPPA = 'InterventionalStudyProtocol.recordVerificationDate' Map:CTGOV = 'Record Verification Date' Map:CTOM = 'Activity.startDate' Map:CTOM = 'SubstanceAdministration.startDate' Map:CTOM = 'SpecimenAcquisition.startDate'

		Map:CTOM = 'Surgery.startDate' Map:CTOM = 'Radiation.stopDate' Map:CTOM = 'Activity.stopDate' Map:CTOM = 'Imaging.startDate' Map:CTOM = 'StudyParticipantAssignment.enrollmentAge' Map:CTOM = 'Procedure.startDate' Map:CTOM = 'Surgery.stopDate' Map:CTOM = 'DeathSummary.evaluationDate' Map:CTOM = 'SpecimenAcquisition.stopDate' Map:CTOM = 'StudyParticipantAssignment.offStudyDate' Map:CTOM = 'Procedure.stopDate' Map:CTOM = 'StudyParticipantAssignment.informedConsentFormSignedDate' Map:CTOM = 'Imaging.stopDate' Map:CTOM = 'QualitativeEvaluation.evaluationDate' Map:CTOM = 'AdverseEventTherapy.treatmentDate' Map:CTOM = 'SubstanceAdministration.stopDate' Map:CTOM = 'Assessment.evaluationDate' Map:Lab = 'Activity.actualStartDateTime' Map:Lab = 'LabResult.testPerformedDateTime' Map:Lab = 'Activity.actualEndDateTime' Map:PSC = 'StudyParticipantAssignment.startDate' Map:PSC = 'VitalSign.measureTime' Map:PSC = 'ScheduledEventState.occured' Map:PSC = 'Occurred.date ' Map:SDTM IG = 'SE.SESTDTC' Map:SDTM IG = 'DM.DMDTC' Map:SDTM IG = 'SC.SCDTC' Map:SDTM IG = 'DA.DADTC' Map:SDTM IG = 'QS.QSDTC' Map:SDTM IG = 'PE.PEDTC' Map:SDTM IG = 'CO.CODTC' Map:SDTM IG = 'SU.SUENDTC' Map:SDTM IG = 'VS.VSDTC' Map:SDTM IG = 'SU.SUSTDTC' Map:SDTM IG = 'SV.SVSTDTC' Map:SDTM IG = 'LB.LBDTC' Map:SDTM IG = 'SV.SVENDTC' Map:SDTM IG = 'EX.EXSTDTC' Map:SDTM IG = 'EG.EGDTC' Map:SDTM IG = 'EX.EXENDTC' Map:SDTM IG = 'SE.SEENDTC' Map:SDTM IG = 'DS.DSSTDTC' Map:SDTM IG = 'IE.IEDTC' Map:SDTM IG = 'DS.DSDTC' Map:SDTM IG = 'CM.CMENDTC' Map:SDTM IG = 'LB.LBENDTC' Map:SDTM IG = 'CM.CMSTDTC' Map:WHO = 'Date of Registration in Primary Registry' Map:WHO = 'Date of First Enrollment'
delayDuration	public : *PQ.TIME*	The period of time that an action is delayed relative to an original schedule. For example, if a substance administration is delayed 2 days as a result of an adverse event, then the delayDuration is 2 days.NOTE: This is derivable by comparing the dates of the scheduled activity with the corresponding performed activity.

		AE:Exclude = 'True'
missedReason	public : *DSET<SC>*	The text and/or code that describes the rationale behind why an activity is not done.NOTE: This captures Study Data Tabulation Model's (SDTM) REASND Variable. At present there is no coded set of values. In HL7, there is a list of permissible missing value types, and we need to ensure that HL7's list is a superset of what is needed by SDTM (tracker issue 23158). Map:AE = 'ProductInvestigation.notEvaluatedByManufacturerExplanation' Map:PSC = 'Canceled' Map:SDTM IG = 'LB.LBREASND' Map:SDTM IG = 'MH.MHREASND' Map:SDTM IG = 'CM.CMREASND' Map:SDTM IG = 'QS.QSREASND' Map:SDTM IG = 'SC.SCREASND' Map:SDTM IG = 'SU.SUREASND' Map:SDTM IG = 'PE.PEREASND' Map:SDTM IG = 'VS.VSREASND' Map:SDTM IG = 'EG.EGREASND' Map:SDTM IG = 'DA.DAREASND'
missedIndicator	public : *BL*	Specifies whether an activity did not occur.For example, Y designates that the PerformedActivity is missed. Map:AE = 'negationIndicator' Map:AE = 'ProductInvestigation.investigationPerformedIndicator' Map:SDTM IG = 'DA.DASTAT' Map:SDTM IG = 'QS.QSSTAT' Map:SDTM IG = 'VS.VSSTAT' Map:SDTM IG = 'SU.SUSTAT' Map:SDTM IG = 'EG.EGSTAT' Map:SDTM IG = 'LB.LBSTAT' Map:SDTM IG = 'PE.PESTAT' Map:SDTM IG = 'CM.CMSTAT' Map:SDTM IG = 'SC.SCSTAT' Map:SDTM IG = 'MH.MHSTAT'
statusCode	public : *CD*	A coded value specifying the state of a performed activity.For example, for a lab test, this would be the condition or stage in the lifecycle of the test (e.g., "completed", "canceled", etc.).NOTE: A state is a named phase (or potential phase) of an instance of a concept in its lifecycle. Map:AE = 'PerformedActivity.ongoingPerformanceIndicator' Map:AE = 'ProductInvestigation.manufacturerEvaluationStatus' Map:COPPA = 'Activity.statusCode' Map:COPPA = 'SubstanceAdministration.statusCode' Map:CTOM = 'Observation.statusCode' Map:CTOM = 'ClinicalResult.statusCode' Map:CTOM = 'Histopathology.statusCode' Map:HL7SD = 'EligibilityCriterion.statusCode' Map:Lab = 'LabTest.status'

statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the activity. Map:COPPA = 'Activity.statusDateRange' Map:COPPA = 'SubstanceAdministration.statusDateRange'

Tagged Values

- Map:AE = SafetyReport.timeReportCompleted.
- Map:AE = PerformedActivity.ongoingPerformanceIndicator.
- Map:AE = PerformedActivity.
- Map:CTOM = Radiation.anatomicSiteCodeSystem.
- Map:CTOM = QualitativeEvaluation.painIndexCode.
- Map:CTOM = QualitativeEvaluation.painIndexCodeSystem.
- Map:CTOM = QualitativeEvaluation.performanceStatusCode.
- Map:CTOM = QualitativeEvaluation.anamResultAccuracyPercent.
- Map:CTOM = QualitativeEvaluation.survivalStatusCode.
- Map:CTOM = Diagnosis.name.
- Map:CTOM = Radiation.anatomicSiteCode.
- Map:CTOM = Radiation.name.
- Map:CTOM = Radiation.descriptionText.
- Map:CTOM = Radiation.doseUnitOfMeasureCode.
- Map:CTOM = Radiation.durationUnitOfMeasureCode.
- Map:CTOM = Radiation.durationValue.
- Map:CTOM = QualitativeEvaluation.performanceStatusCodeSystem.
- Map:CTOM = QualitativeEvaluation.menstrualIndicator.
- Map:CTOM = Radiation.type.
- Map:CTOM = Radiation.scheduleText.
- Map:CTOM = QualitativeEvaluation.menstrualPatternTypeCode.
- Map:CTOM = Radiation.stopDate.
- Map:CTOM = Imaging.name.
- Map:CTOM = Radiation.reasonCode.
- Map:CTOM = Imaging.type.
- Map:CTOM = CancerStage.stageCodeSystem.
- Map:CTOM = CancerStage.stageCode.
- Map:CTOM = Imaging.reasonCode.
- Map:CTOM = QualitativeEvaluation.survivalStatusDescriptionText.
- Map:CTOM = Radiation.startDate.
- Map:Lab = Specimen.commentsFromLaboratory.
- Map:Lab = Specimen.commentsFromInvestigator.
- Map:Lab = SubjectAssignment.type .
- Map:Lab = SubjectAssignment.studySubjectIdentifier.
- Map:PSC = StudyParticipantAssignment.startDate.
- Map:SDTM IG = MH.MHREASND.

6.84 Study Conduct Sub-Domain::ScheduledActivity

public Class {leaf}

Extends: Activity. :

An activity that is anticipated to occur at some time in the future and has been assigned a time or date when that activity is to be performed.

For example, an X-Ray scheduled for February 15 is in state "Scheduled." If John is unable to have the X-Ray on that date, the X-Ray would either be rescheduled (remain in "Scheduled" state, but "date" attribute would change) or

moved to state "Canceled."

For example, anticipated study completion date.

Constraints

- *Approved Invariant* . actualIndicator Exclusive Or.
  Subject.actualSubjectIndicator = Y (instance of) or may not be used.

Study Conduct Sub-Domain::ScheduledActivity Connections

Connector	Source	Target	Notes
Association instantiates	ScheduledActivity +instantiating 0..*, unordered, none	PlannedActivity +instantiated 1, unordered, none	Each ScheduledActivity always instantiates one PlannedActivity. Each PlannedActivity sometimes is instantiated by one or more ScheduledActivity. *Constraints* Inverse Relation: is instantiated by
Association instantiates	PerformedActivity +instantiating 0..*, unordered, none	ScheduledActivity +instantiated 0..1, unordered, none	Each PerformedActivity sometimes instantiates one ScheduledActivity. Each ScheduledActivity sometimes is instantiated by one or more PerformedActivity. *Constraints* Inverse Relation: is instantiated by *Tagged Values* Map:PSC: ScheduledEventState.occurred
Generalization source > target	ScheduledActivity Child	Activity Parent	

Study Conduct Sub-Domain::ScheduledActivity Attributes

Attribute	Type	Notes
duration	public : *PQ.TIME*	The scheduled length of time of the activity to be performed. Map:PSC = 'Period.startDay'
rangeOfRepetitionsText	public : *ST*	A span of integers specifying the minimum and maximum number of repetitions of the scheduled activity. The number of repeats is additionally constrained by time. NOTE: The ScheduledActivity will repeat at least the minimum number of times and at most, the maximum number of times. Map:PSC = 'Period.repetitions'
dateRange	public : *IVL<TS.DATETIME >*	The date and time span when the activity is scheduled to begin and end. NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits).

		Map:CTGOV = 'Anticipated Study Completion Date' Map:PSC = 'ScheduledEventState.scheduled ' Map:PSC = 'Scheduled.date' Map:PSC = 'ScheduledEvent.date/idealDate'
statusCode	public : *CD*	A coded value specifying the state of a scheduled activity.For example, for a lab test, this would be the condition or stage in the lifecycle of the test (e.g., "scheduled", "canceled", "performed", etc.).NOTE: A state is a named phase (or potential phase) of an instance of a concept in its lifecycle. Map:PSC = 'ScheduledEventState'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the activity. Map:PSC = 'ScheduledEventState.cancelled'

Tagged Values

- Map:PSC = ScheduledEvent.notes.
- Map:PSC = ScheduledEventState.reason.
- Map:PSC = ScheduledEventState.canceled.
- Map:PSC = ScheduledEventState.

6.85 Study Conduct Sub-Domain::StudyOverallStatus

public Class:
Describes the comprehensive state of the study.

NOTE: The actual overall status of a study may be derived if it is possible to roll-up the site-specific status.

Study Conduct Sub-Domain::StudyOverallStatus Connections

Connector	Source	Target	Notes
Association describes	StudyOverallStatus +describing 1..*, unordered, none	Study +described 1, unordered, none	Each StudyOverallStatus always describes one Study. Each Study always is described by one or more StudyOverallStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:COPPA: ObservationalStudyProtocol.primaryCompletionDateTypeCode Map:COPPA: InterventionalStudyProtocol.primaryCompletionDate Map:COPPA: InterventionalStudyProtocol.primaryCompletionDateTypeCode Map:COPPA: StudyProtocol.startDateTypeCode

			Map:COPPA: InterventionalStudyProtocol.recordVerificationDate Map:COPPA: ObservationalStudyProtocol.startDate Map:HL7SP: Study.subjectOf1 Map:COPPA: StudyProtocol.primaryCompletionDateTypeCode Map:COPPA: ObservationalStudyProtocol.primaryCompletionDate Map:COPPA: InterventionalStudyProtocol.statusDate Map:COPPA: InterventionalStudyProtocol.startDateTypeCode Map:COPPA: StudyProtocol.primaryCompletionDate Map:COPPA: ObservationalStudyProtocol.startDateTypeCode Map:COPPA: StudyProtocol.startDate

Study Conduct Sub-Domain::StudyOverallStatus Attributes

Attribute	Type	Notes
studyStoppedReasonCode	public : *CD*	A coded value specifying why the study has been halted or terminated (for suspended, terminated or withdrawn studies). Map:COPPA = 'StudyOverallStatus.studyStoppedReasonCode' Map:CTGOV = 'Why Study Stopped'
anticipatedIndicator	public : *BL*	Specifies whether the overall status of the study is an estimate.NOTE: BRIDG SCC has made the decision to add an anticipatedIndicator until we learn the business rules of how the overall study status could be derived. Map:COPPA = 'InterventionalStudyProtocol.startDateTypeCode' Map:COPPA = 'StudyProtocol.primaryCompletionDateTypeCode' Map:COPPA = 'ObservationalStudyProtocol.primaryCompletionDateTypeCode' Map:COPPA = 'ObservationalStudyProtocol.startDateTypeCode' Map:COPPA = 'StudyProtocol.startDateTypeCode' Map:COPPA = 'InterventionalStudyProtocol.primaryCompletionDateTypeCode' Map:COPPA = 'StudyOverallStatus.anticipatedIndicator'
comment	public : *ST*	Additional description of the overall status of the study. Map:COPPA = 'StudyOverallStatus.commentText'

statusCode	public : *CD*	A coded value specifying the overall state of the study.For example, In Review, Approved, Active, Closed to Accrual, Closed to Accrual and Intervention, Temporary Closed to Accrual, Temporary Closed to Accrual and Intervention, Disapproved, Withdrawn, Administratively complete. Map:COPPA = 'StudyOverallStatus.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the overall status of the study is assigned.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:COPPA = 'InterventionalStudyProtocol.statusDate' Map:COPPA = 'ObservationalStudyProtocol.primaryCompletionDate' Map:COPPA = 'StudyProtocol.primaryCompletionDate' Map:COPPA = 'ObservationalStudyProtocol.startDate' Map:COPPA = 'StudyProtocol.startDate' Map:COPPA = 'StudyOverallStatus.statusDate' Map:COPPA = 'InterventionalStudyProtocol.primaryCompletionDate' Map:CTGOV = 'Anticipated Study Completion Date' Map:CTGOV = 'Actual Primary Completion Date' Map:CTGOV = 'Study Start Date' Map:CTGOV = 'Anticipated Primary Completion Date' Map:CTGOV = 'Actual Study Completion Date'

Tagged Values

- Map:COPPA = ObservationalStudyProtocol.startDate.
- Map:COPPA = ObservationalStudyProtocol.primaryCompletionDate.
- Map:COPPA = StudyOverallStatus.
- Map:COPPA = InterventionalStudyProtocol.recordVerificationDate.
- Map:COPPA = ObservationalStudyProtocol.startDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.statusDate.
- Map:COPPA = InterventionalStudyProtocol.startDateTypeCode.
- Map:COPPA = ObservationalStudyProtocol.primaryCompletionDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.primaryCompletionDateTypeCode.
- Map:COPPA = InterventionalStudyProtocol.primaryCompletionDate.
- Map:HL7SP = Study.subjectOf2.
- Map:HL7SP = Study.subjectOf1.

6.86 Study Conduct Sub-Domain::StudyRecruitmentStatus

public Class:
Status of finding and enrolling appropriate StudySubjects (those selected on the basis of the protocol's inclusion/exclusion criteria) into a study.

Study Conduct Sub-Domain::StudyRecruitmentStatus Connections

Connector	Source	Target	Notes
Association describes	StudyRecruitmentStatus	Study +described	Each StudyRecruitmentStatus always describes one Study. Each

	+describing 0..*, unordered, none	1, unordered, none	Study sometimes is described by one or more StudyRecruitmentStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:HL7SP: Study.subjectOf2

Study Conduct Sub-Domain::StudyRecruitmentStatus Attributes

Attribute	Type	Notes
statusCode	public : *CD*	A coded value specifying the state of the recruitment for the study.For example, Not yet recruiting; recruiting; enrolling by invitation; active, not recruiting; completed; suspended; terminated; withdrawn. Map:COPPA = 'StudyRecruitmentStatus.statusCode' Map:CTGOV = 'Recruitment Status' Map:CTGOV = 'Overall Recruitment Status' Map:WHO = 'Recruitment Status'
statusDate	public : *TS.DATETIME*	The date (and time) on which the recruitment status is assigned.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:COPPA = 'StudyRecruitmentStatus.statusDate'

Tagged Values

- Map:COPPA = StudyRecruitmentStatus.

6.87 Study Conduct Sub-Domain::StudySite

public Class:
A facility in which study activities are conducted.

For example, the site where the StudySubject encounter occurs, or the site of the Investigator.

NOTE: Account for hierarchy in sites and relation to Study ID (tracker issue 23154).

Constraints

- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A StudySite may be a function performed by either a HealthcareFacility or an Organization (serving as a StudySite but is not a HealthcareFacility) but not both.

Study Conduct Sub-Domain::StudySite Connections

Connector	Source	Target	Notes
Association handles communications for	StudySiteContact +communicating 0..*, unordered, none	StudySite +communicated 1, unordered, none	Each StudySiteContact always handles communications for one StudySite. Each StudySite sometimes has communications

			handled by one or more StudySiteContact. *Constraints* Invariant: has communications handled by *Tagged Values* Map:HL7SP: Study.performer3
Association is performed at	PerformedAdministrativeActivity +located 0..*, unordered, none	StudySite +locating 0..1, unordered, none	Each PerformedAdministrativeActivity sometimes is performed at one StudySite. Each StudySite sometimes performs one or more PerformedAdministrativeActivity. *Constraints* Inverse Relation: performs
Association oversees	OversightCommittee +overseeing 0..*, unordered, none	StudySite +overseen 0..*, unordered, none	Each OversightCommittee sometimes oversees one or more StudySite. Each StudySite sometimes is overseen by one or more OversightCommittee. *Constraints* Inverse Relation: is overseen by
Association is assigned to	StudySubject +assigned 0..*, unordered, none	StudySite +assigning 1, unordered, none	Each StudySubject always is assigned to one StudySite. Each StudySite sometimes is the assigned location for one or more StudySubject. *Constraints* Inverse Relation: is the assigned location for *Tagged Values* Map:C3PR: StudySubject.informedConsentSignedDate Map:Lab: SubjectAssignment.studySubjectIdentifier Map:SDTM IG: DM.RFENDTC Map:SDTM IG: DM.RFSTDTC Map:HL7SP: Study.subject Map:CTOM: StudyParticipantAssignment.armIdentifier
Association is a function performed by	StudySite +performed 0..*, unordered, none	Organization +performing 0..1, unordered, none	Each StudySite sometimes is a function performed by one Organization. Each Organization

			sometimes functions as one or more StudySite. NOTE: A StudySite may be related to either a HealthcareFacility or an Organization (serving as a StudySite but is not a HealthcareFacility) *Constraints* Inverse Relation: functions as *Tagged Values* Map:SDTM IG: DM.COUNTRY
Association describes	StudySiteOversightStatus +describing 0..*, unordered, none	StudySite +described 1, unordered, none	Each StudySiteOversightStatus always describes one StudySite. Each StudySite sometimes is described by one or more StudySiteOversightStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:C3PR: StudySite.irbApprovalDate
Association is a function performed by	StudySite +performed 0..*, unordered, none	HealthcareFacility +performing 0..1, unordered, none	Each StudySite sometimes is a function performed by one HealthcareFacility. Each HealthcareFacility sometimes functions as one or more StudySite. NOTE: a StudySite can be represented by either a HealthcareFacility or an Organization. *Constraints* Inverse Relation: functions as
Association executes	StudySite +executing 0..*, unordered, none	Study +executes 1, unordered, none	Each StudySite always executes one Study. Each Study sometimes is executed at one or more StudySite. NOTE: a StudySite may be related to either a HealthcareFacility or an Organization (serving as a StudySite but is not a HealthcareFacility). *Constraints* Inverse Relation: is executed at *Tagged Values* Map:CTOM: StudyParticipantAssignment.armIdentifier

			Map:HL7SP: Study.subject Map:HL7SP: Study.performer1 Map:HL7SP: Study.performer3 Map:CTOM: StudySite.localProtocolIdentifier Map:Lab: SubjectAssignment.studySubject Identifier

Study Conduct Sub-Domain::StudySite Attributes

Attribute	Type	Notes
identifier	public : *II*	The unique symbol that establishes identity of the study site. Map:HL7SP = 'StudySite.id' Map:SDTM IG = 'DM.SITEID'
leadIndicator	public : *BL*	Specifies whether this is the principal administrative organization responsible for the study. Exception: A multi-site trial with no single assigned coordination center; in this case, every participating organization can be named as lead organization. Map:C3PR = 'StudySite.roleCode' Map:CTOM = 'StudySite.roleCode'
targetAccrualNumberRange	public : *URG<INT>*	A range of integers specifying the minimum and maximum number of patients/subjects/participants needed for enrollment at this site. Map:C3PR = 'StudySite.targetAccrualNumber' Map:COPPA = 'StudyParticipation.targetAccrualNumber' Map:CTOM = 'StudySite.targetAccrualNumber'
accrualStatusCode	public : *CD*	A coded value specifying the state of a participating site in the given study relative to the enrollment of additional subjects.For example, open to accrual, closed to accrual, temporarily closed to accrual, and pending accrual. Map:COPPA = 'StudySiteAccrualStatus.statusCode'
accrualStatusDate	public : *TS.DATETIME*	The date (and time) on which the accrual status is established.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:COPPA = 'StudySiteAccrualStatus.statusCode'
dateRange	public : *IVL<TS.DATETIME>*	The date and time span specifying the start of the site's participation in the study and the end of the participation.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:C3PR = 'StudySite.endDate' Map:C3PR = 'StudySite.startDate' Map:COPPA = 'StudyParticipation.dateRange'

		Map:CTGOV = 'StudySite.startDate' Map:CTOM = 'StudySite.stopDate'
statusCode	public : *CD*	A coded value specifying the state of the study site.For example, pending, active, complete, or cancelled.For example, In Review, Approved, Active, Closed to Accrual, Closed to Accrual and Intervention, Temporary Closed to Accrual, Temporary Closed to Accrual and Intervention, Disapproved, Withdrawn, Administratively complete. Map:COPPA = 'StudyParticipation.statusCode' Map:CTOM = 'StudySite.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) on which the status is assigned to the study site.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:COPPA = 'StudyParticipation.statusDateRange' Map:CTOM = 'StudySite.irbApprovalDate'

Tagged Values

- Map:C3PR = StudySite.irbApprovalDate.
- Map:COPPA = StudyParticipation.
- Map:CTGOV = Facility.
- Map:CTOM = StudySite.localProtocolIdentifier.
- Map:CTOM = StudyParticipantAssignment.armIdentifier.
- Map:HL7SP = Study.subject.
- Map:HL7SP = SubjectProtectionApproval.
- Map:HL7SP = StudySite.
- Map:HL7SP = Study.performer3.
- Map:HL7SP = Study.performer1.
- Map:PSC = StudySite.
- Map:SDTM IG = DM.COUNTRY.
- Map:SDTM IG = DM.RFENDTC.
- Map:SDTM IG = DM.RFSTDTC.

6.88 Study Conduct Sub-Domain::StudySiteContact

public Class {root}:
A person who provides or receives information on behalf of a study site.

Study Conduct Sub-Domain::StudySiteContact Connections

Connector	Source	Target	Notes
Association handles communications for	StudySiteContact +communicating 0..*, unordered, none	StudySite +communicated 1, unordered, none	Each StudySiteContact always handles communications for one StudySite. Each StudySite sometimes has communications handled by one or more StudySiteContact. *Constraints* Invariant: has communications handled by

			Tagged Values Map:HL7SP: Study.performer3
Association is a function performed by	StudySiteContact +performed 0..1, unordered, none	ResearchStaff +performing 0..*, unordered, none	Each StudySiteContact sometimes is a function performed by one or more ResearchStaff. Each ResearchStaff sometimes functions as one StudySiteContact. *Constraints* Inverse Relation: functions as
Generalization source > target	StudySiteInvestigator Child	StudySiteContact Parent	*Tagged Values* Map:HL7SP: Study.performer3
Generalization source > target	StudySiteResearchCoordinator Child	StudySiteContact Parent	

Study Conduct Sub-Domain::StudySiteContact Attributes

Attribute	Type	Notes
roleCode	public : *CD*	The coded value specifying a type of responsibility for a study site contact.For example, Principal Investigator, Sub Investigator, Facility. Map:COPPA = 'StudySiteInvestigator.roleCode' Map:COPPA = 'StudyParticipationContact.roleCode' Map:CTGOV = 'Facility Contact Backup'
primaryIndicator	public : *BL*	Specifies whether this is the main or principal study site contact. Map:COPPA = 'StudySiteInvestigator.primaryIndicator' Map:COPPA = 'StudyParticipationContact.primaryIndicator'
postalAddress	public : *AD*	A contact point used to send physical forms of communication to the study site contact. Map:COPPA = 'StudySiteInvestigator.postalAddress' Map:COPPA = 'StudyParticipationContact.postalAddress'
telecomAddress	public : *BAG<TEL>*	A sequence of digits or characters used to identify a particular telephone, fax, or email of a study site contact. Map:COPPA = 'StudyParticipationContact.telecomAddress' Map:COPPA = 'StudySiteInvestigator.telecomAddress' Map:CTGOV = 'Facility Contact - Phone' Map:CTGOV = 'Facility Contact - Email' Map:CTGOV = 'Facility Contact - Ext'
statusCode	public : *CD*	A coded value specifying the state of the study site contact. For example, pending, active, complete, or cancelled.

		Map:COPPA = 'StudySiteInvestigator.statusCode' Map:COPPA = 'StudyParticipationContact.statusCode'
statusDate	public : *TS.DATETIME*	The date (and time) the status is assigned to the study site contact.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:COPPA = 'StudyParticipationContact.statusDateRange' Map:COPPA = 'StudySiteInvestigator.statusDateRange'

Tagged Values

- Map:COPPA = StudyParticipationContact.
- Map:CTGOV = Facility Contact.
- Map:HL7SP = Study.performer3.

6.89 Study Conduct Sub-Domain::StudySiteInvestigator

public Class {leaf}

Extends: StudySiteContact. :

A researcher at a study site who oversees all aspects of the study at a site, including protocol submission for IRB approval, participant recruitment, informed consent, data collection, and analysis.

Constraints

- *Approved Invariant* . Is a Function Performed By Qualifier.
  If the associated Study is an InterventionalStudy then the StudySiteInvestigator must be a function performed by a HealthcareProvider.
- *Approved Invariant* . Is a Function Performed By Exclusive Or.
  A StudySiteInvestigator can be a function performed by either a ResearchStaff or a HealthcareProvider but not both.

Study Conduct Sub-Domain::StudySiteInvestigator Connections

Connector	Source	Target	Notes
Association is a function performed by	StudySiteInvestigator +performed 0..*, unordered, none	HealthcareProvider +performing 0..1, unordered, none	Each StudySiteInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudySiteInvestigator. *Constraints* Inverse Relation: functions as
Generalization source > target	StudySiteInvestigator Child	StudySiteContact Parent	*Tagged Values* Map:HL7SP: Study.performer3

Tagged Values

- Map:C3PR = HealthcareSiteInvestigator.statusDate.
- Map:C3PR = HealthcareSiteInvestigator.statusCode.

- Map:COPPA = StudySiteInvestigator.statusCode.
- Map:COPPA = StudySiteInvestigator.primaryIndicator.
- Map:COPPA = StudySiteInvestigator.
- Map:COPPA = StudySiteInvestigator.telecomAddress.
- Map:COPPA = StudySiteInvestigator.statusDateRange.
- Map:COPPA = StudySiteInvestigator.roleCode.
- Map:COPPA = StudySiteInvestigator.postalAddress.
- Map:CTGOV = Investigators (at the protocol location).
- Map:HL7SP = Study.performer3.
- Map:SDTM IG = DM.INVNAM.

6.90 Study Conduct Sub-Domain::StudySiteOversightStatus

public Class:
Describes the state of a study at a particular site as assigned by an oversight committee.

For example, request not submitted; submitted, pending; submitted, approved; submitted, exempt; submitted, denied; submission not required.

Study Conduct Sub-Domain::StudySiteOversightStatus Connections

Connector	Source	Target	Notes
Association is assigned by	StudySiteOversightStatus +assigned 0..*, unordered, none	OversightCommittee +assigning 1, unordered, none	Each StudySiteOversightStatus always is assigned by one OversightCommittee. Each OversightCommittee sometimes assigns one or more StudySiteOversightStatus. *Constraints* Invariant: assigns
Association describes	StudySiteOversightStatus +describing 0..*, unordered, none	StudySite +described 1, unordered, none	Each StudySiteOversightStatus always describes one StudySite. Each StudySite sometimes is described by one or more StudySiteOversightStatus. *Constraints* Inverse Relation: is described by *Tagged Values* Map:C3PR: StudySite.irbApprovalDate

Study Conduct Sub-Domain::StudySiteOversightStatus Attributes

Attribute	Type	Notes
reviewBoardApprovalNumber Text	public : *ST*	A character string that is assigned by the review board upon approval of the protocol. Map:CTGOV = 'Board Approval Number'
reviewBoardApprovalStatusC	public : *CD*	A coded value specifying the state of submission and associated review board decision.For example, request not submitted;

ode		submitted, pending; submitted, approved; submitted, exempt; submitted, denied; submission not required. Map:CTGOV = 'Board Approval Status'
reviewBoardApprovalDate	public : *TS.DATETIME*	The date (and time) on which the Institutional Review Board (IRB) approved this study protocol for execution at this site.NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits). Map:C3PR = 'StudySite.irbApprovalDate'

7.0 Representations and Warranties, Limitations of Liability, and Disclaimers

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8.0 Appendix

Appendix A: References

CDISC Glossary. <http://cdisc.org/glossary/index.html>
BRIDG Overview. <http://cdisc.org/standards/bridg.html>
HL7 Data Types. <http://www.hl7.org/v3ballot/html/welcome/environment/index.htm>

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