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HL7 Version 3 Domain Analysis Model: Clinical Trials Registration and Results (CTR&R), Release 1

An informative specification representing the behavioral and information requirements of the Clinical Trial Registration and Results Reporting domain.

May, 2011

HL7 Informative Document

Sponsored by:
Regulated Clinical Research Information Management Work Group

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Clinical Trial Registration and Results Domain Analysis Model

This document is the domain analysis model for the Clinical Trial Registration and Results (CTR&R) project. The CTR&R project is an effort of the Health Level Seven (HL7) Regulated Clinical Research Information Management (RCRIM) workgroup.

The objective of the CTR&R project is develop information system interoperability specifications that facilitate the required exchange of information between parties involved in the registration of clinical trials and the reporting of results for registered trials.

This domain analysis model represents the behavioral and information requirements for the CTR&R domain. It serves as a tool for subject matter experts to examine, express, and evaluate their requirements for use in guiding development of technical interoperability specifications.

The model is expressed using Uniform Modeling Language (UML) constructs. These constructs were arrived at by conducting extensive interviews, work sessions, and collaborations with subject matter experts from sponsoring organizations, registration authorities, and other interest parities (regulatory, public, and private) from throughout the world.

The CTR&R Domain Analysis Model (DAM) is an interim deliverable of an ongoing requirements specification effort. When it is complete the CTR&R DAM will represent the universal requirements of clinical trial sponsor organizations and registration authorities world wide and will include clinical trial results reporting. This iteration of the CTR&R DAM focuses on the registration process and considers the behavioral and information requirements of the CT.gov. WHO.ctr. and EMEA registries.

Data Type Conventions

The datatypes specified in the DAM are taken from the HL7 V3 Data Types, Abstract specification. Due to the length and complexity of that document, a brief digest of those data types is provided. This table is condensed from the HL7 V3 Data Types, Abstract specification for convenience only: it is not normative.

Name	Symbol	Description
Boolean	BL	A binary value for use in boolean logic. A *BL* value can be either *true* or *false*, or, as any other value, MAY be NULL.
EncapsulatedData	ED	Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7.
CharacterString	ST	Text data, primarily intended for machine processing (e.g., sorting, querying, indexing, presentation, etc.).
ConceptDescriptor	CD	A reference to a concept defined in a code system
InstanceIdentifier	II	An identifier that uniquely identifies a thing or object. Examples are object identifier for HL7 RIM objects, medical record number, order id, service catalog item id, Vehicle Identification Number (VIN), etc.
TelecommunicationAddress	TEL	A locatable resource that is identified by a URI. The address is specified as a Universal Resource Identifier (URL) qualified by time specification and use codes that help in deciding which address to use for a given time and purpose. TEL may be used to designate a retrievable resource such as a web page, a telephone number (voice, fax or some other resource mediated by telecommunication equipment), an e-mail address, or any other locatable resource that can be specified by a URL.
PostalAddress	AD	Mailing and home or office addresses. A sequence of address parts, such as street or post office box, city, postal code, country, etc.

Name	Symbol	Description
EntityName	EN	A name for a person, organization, place or thing. A sequence of name parts, such as given name or family name, prefix, suffix, etc. Examples for entity name values are "Jim Bob Walton, Jr.", "Health Level Seven, Inc.", "Lake Tahoe", etc. An entity name may be as simple as a character string or may consist of several entity name parts, such as, "Jim", "Bob", "Walton", and "Jr.", "Health Level Seven" and "Inc.", "Lake" and "Tahoe".
IntegerNumber	INT	Integer numbers (-1,0,1,2, 100, 3398129, etc.) are precise numbers that are results of counting and enumerating. Integer numbers are discrete, the set of integers is infinite but countable. No arbitrary limit is imposed on the range of integer numbers. Two NULL flavors are defined for the positive and negative infinity.
RealNumber	REAL	A scalar magnitude. Typically used whenever quantities are measured, estimated, or computed from other real numbers. The typical representation is decimal, where the number of significant decimal digits is known as the precision.
PhysicalQuantity	PQ	A dimensioned quantity expressing the result of measuring.
MonetaryAmount	MO	A quantity expressing an amount of money in some currency. While the monetary amount is a single kind of quantity (money) the exchange rates between the different units are variable. This is the principle difference between PQ and *MO*, and the reason why currency units are not physical units.
PointInTime	TS	A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression.
Interval	IVL	A set of consecutive values of an ordered base data type.

In addition to these standard data types, several attributes are assigned enumerations, which can be found at the end of this document.

CTRR DAM Behavioural Requirements Specification

The behavioral requirements specification portion of the CTRR DAM depicts the major actors, activities, and flows of information in the domain of clinical trials registration and results reporting.

The behavioral requirements specification includes Use Case, Activity, and Interaction specifications.

CTRR DAM Use Case Specifications

The CTRR DAM use case specifications identify the major collections of activities and actors of interest in the regulated clinical trial registration and result reporting domain.

A use case is named collection of activities which result in discernable benefit to the actors involved. Use cases serve as a convenient mechanism for partitioning the domain into logical component sub-domains.

Use Cases

The use cases specified here define the scope of the CTRR DAM. Each use case represents a collection of activities within the domain.

Use Cases - *(Use Case diagram)*

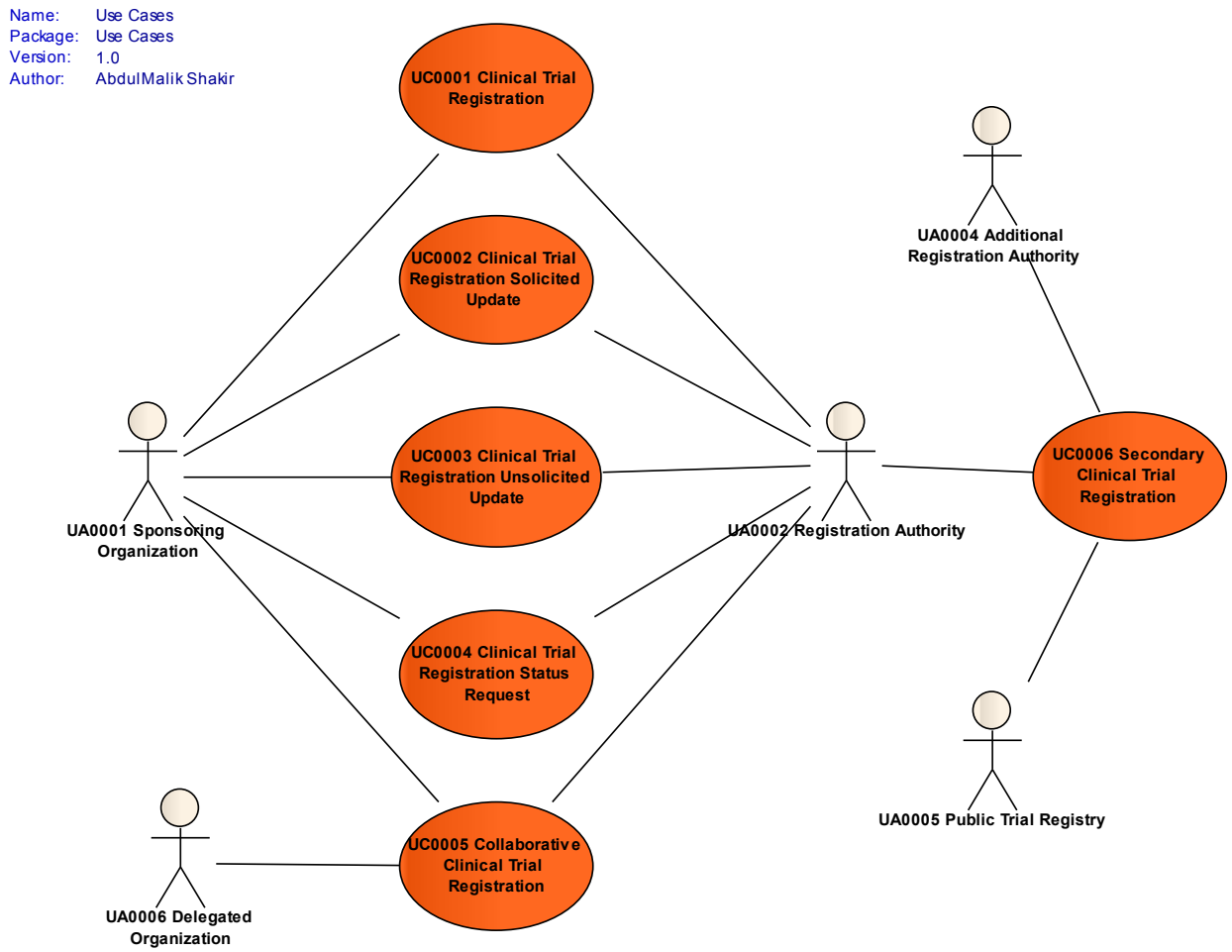

Figure: 1

UC0001 Clinical Trial Registration

This use case is the collection of activities associated with submission of a clinical trial by a sponsor organization to a registration authority for inclusion in a registry of clinical trial and the subsequent acceptance or rejection of the clinical trail by the registration authority.

Connections

Connector	Source	Target	Notes
Association	UA0001 Sponsoring Organization	UC0001 Clinical Trial Registration	
Association	UC0001 Clinical Trial Registration	UA0002 Registration Authority	
Realisation	Clinical Trial Registration Activities	UC0001 Clinical Trial Registration	

UC0002 Clinical Trial Registration Solicited Update

This use case is the set of activities related to the soliciting and provision of additional clinical trial registration information from the clinical trial sponsoring organization by the registration authority.

Connections

Connector	Source	Target	Notes
Association	UC0002 Clinical Trial Registration Solicited Update	UA0001 Sponsoring Organization	
Association	UA0002 Registration Authority	UC0002 Clinical Trial Registration Solicited Update	

UC0003 Clinical Trial Registration Unsolicited Update

This use case is the set of activities related to the unsolicited provisioning of additional clinical trial registration information by the clinical trial sponsor organization to the clinical trial registration authority.

Connections

Connector	Source	Target	Notes
Association	UA0001 Sponsoring Organization	UC0003 Clinical Trial Registration Unsolicited Update	
Association	UC0003 Clinical Trial Registration Unsolicited Update	UA0002 Registration Authority	

UC0004 Clinical Trial Registration Status Request

This use case is the set of activities related to a clinical trial sponsoring organization requesting registration status information from a clinical trial registration authority.

Connections

Connector	Source	Target	Notes
Association	UC0004 Clinical Trial Registration Status Request	UA0002 Registration Authority	
Association	UA0001 Sponsoring Organization	UC0004 Clinical Trial Registration Status Request	

UC0005 Collaborative Clinical Trial Registration

This use case is the collection of activities related to the collaborative submission of clinical trial registration information to a clinical trial registration authority by a sponsoring organization and one or more delegated organizations.

Connections

Connector	Source	Target	Notes
Association	UC0005 Collaborative Clinical Trial Registration	UA0002 Registration Authority	
Association	UA0001 Sponsoring Organization	UC0005 Collaborative Clinical Trial Registration	
Association	UA0006 Delegated Organization	UC0005 Collaborative Clinical Trial Registration	

UC0006 Secondary Clinical Trial Registration

This use case is the set of activities related to the secondary registration of a clinical trial initiated by an initial registration authority to an additional registration authority and / or public trial registry.

Connections

Connector	Source	Target	Notes
Association	UC0006 Secondary Clinical Trial Registration	UA0005 Public Trial Registry	
Association	UC0006 Secondary Clinical Trial Registration	UA0004 Additional Registration Authority	
Association	UA0002 Registration Authority	UC0006 Secondary Clinical Trial Registration	

Use Case Actors

Use case actors are the participants of activities represented by use cases. Each actor participates in one or more use cases. Some actors are a more general form of more specific actor types.

This specification defines each actor and provides a accounting of the use cases and interactions in which the actor is involved.

Use Case Actors - *(Use Case diagram)*

Name: Use Case Actors
Package: Use Case Actors
Version: 1.0
Author: AShakir

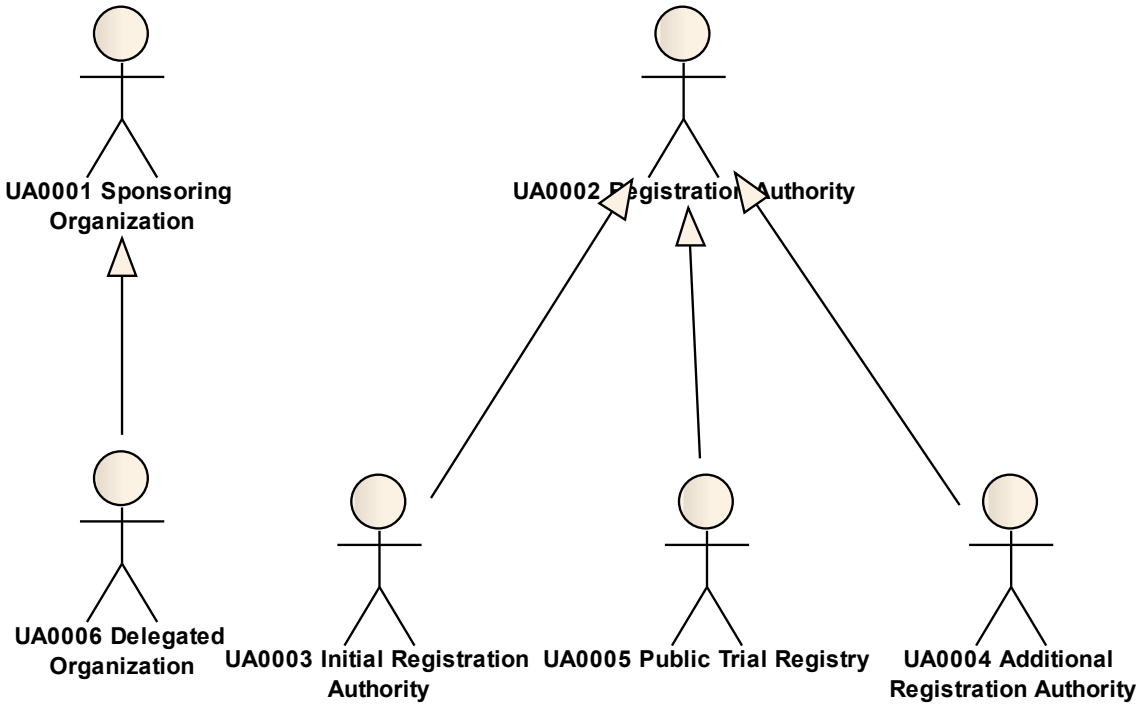

Figure: 2

UA0001 Sponsoring Organization

This actor represents the organization that prepares the clinical trial protocol specification and is responsible for the planning, execution, and results reporting of the trial.

Connections

Connector	Source	Target	Notes
Association	UA0001 Sponsoring Organization	UC0001 Clinical Trial Registration	
Generalization	UA0006 Delegated Organization	UA0001 Sponsoring Organization	
Association	UA0001 Sponsoring	UC0004 Clinical Trial	

Connector	Source	Target	Notes
	Organization	Registration Status Request	
Association	UA0001 Sponsoring Organization	UC0003 Clinical Trial Registration Unsolicited Update	
Association	UC0002 Clinical Trial Registration Solicited Update	UA0001 Sponsoring Organization	
Association	UA0001 Sponsoring Organization	UC0005 Collaborative Clinical Trial Registration	

UA0002 Registration Authority

This actor represents the organization that maintains a registry of clinical trials and establishes processes for submission, adjudication, retention, and distribution of clinical trial information.

Connections

Connector	Source	Target	Notes
Generalization	UA0004 Additional Registration Authority	UA0002 Registration Authority	
Association	UC0004 Clinical Trial Registration Status Request	UA0002 Registration Authority	
Association	UC0005 Collaborative Clinical Trial Registration	UA0002 Registration Authority	
Generalization	UA0003 Initial Registration Authority	UA0002 Registration Authority	
Association	UA0002 Registration Authority	UC0002 Clinical Trial Registration Solicited Update	
Association	UC0001 Clinical Trial Registration	UA0002 Registration Authority	

Connector	Source	Target	Notes
Association	UC0003 Clinical Trial Registration Unsolicited Update	UA0002 Registration Authority	
Association	UA0002 Registration Authority	UC0006 Secondary Clinical Trial Registration	
Generalization	UA0005 Public Trial Registry	UA0002 Registration Authority	

UA0003 Initial Registration Authority

This actor represents an organization which is the registration authority with which a clinical trial is first registered. This initial registration authority may pass the clinical trial information on to additional registration authorities.

Connections

Connector	Source	Target	Notes
Generalization	UA0003 Initial Registration Authority	UA0002 Registration Authority	

UA0004 Additional Registration Authority

This actor represent the organization which is not the initial registration authority for a clinical trial. This organization typically receive clinical trial information from an initial registration authority.

Connections

Connector	Source	Target	Notes
Generalization	UA0004 Additional Registration Authority	UA0002 Registration Authority	
Association	UC0006 Secondary Clinical Trial Registration	UA0004 Additional Registration Authority	

UA0005 Public Trial Registry

This actor represents a registration authority that makes information concerning registered clinical trial available for public access.

Connections

Connector	Source	Target	Notes
Association	UC0006 Secondary	UA0005 Public Trial	

Connector	Source	Target	Notes
	Clinical Trial Registration	Registry	
Generalization	UA0005 Public Trial Registry	UA0002 Registration Authority	

UA0006 Delegated Organization

This actor represents an organization that works in collaboration with a sponsoring organization in some or all aspects of planning, executing, and results reporting clinical trials. The delegated organization acts as a agent of the sponsoring organizations for aspects of the clinical trial delegated by the sponsor.

Connections

Connector	Source	Target	Notes
Generalization	UA0006 Delegated Organization	UA0001 Sponsoring Organization	
Association	UA0006 Delegated Organization	UC0005 Collaborative Clinical Trial Registration	

CTRR DAM Activity Specifications

The CTRR DAM activity specifications includes specifications for the activities which collectively realize the use cases depicted in the CTRR DAM use case specifications.

The activities have been organized into packages where each package of activities corresponds to a single use case. Each package of activities includes a diagram depicting the sequencing of activities - represented by control flows; the flow of information between activities - represented by information flows and information objects; and a allocation of primary accountability for an activity to an actor - represented by swim lanes. The swim lanes used in the activity diagrams are bound to actors used in the use case specifications.

CTRR DAM Activities - *(Package diagram)*

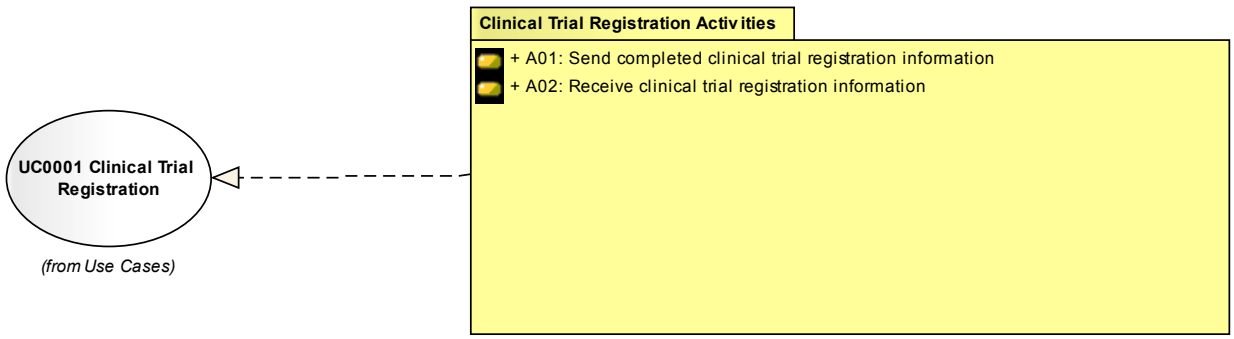

Figure: 3

Clinical Trial Registration Activities

This package of activities is the collection of activities associated with submission of a clinical trial by a sponsor organization to a registration authority for inclusion in a registry of clinical trials and the subsequent acceptance or rejection of the clinical trail by the registration authority.

This package is a realization of the UC0001 Clinical Trial Registration use case.

Clinical Trial Info Registration - *(Activity diagram)*

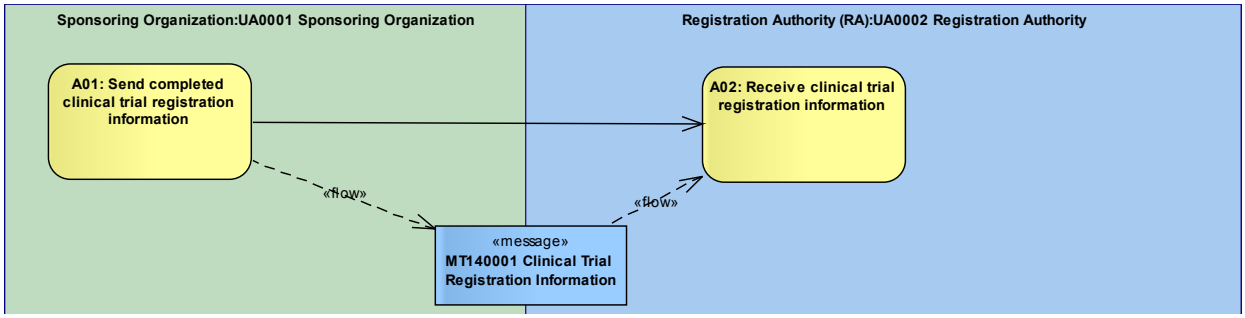

Figure: 4

A01: Send completed clinical trial registration information

The Sponsor / Clinical Research Organization submits clinical trial registration information (e.g. protocol ID, protocol I/E Criteria, administrative, recruitment status and enrollment information. Also included is the initial 25 unique investigators and their locations assigned to the trial

Connections

Connector	Source	Target	Notes
Information Flow	A01: Send completed clinical trial registration information	MT140001 Clinical Trial Registration Information	
ControlFlow	A01: Send completed clinical trial registration information	A02: Receive clinical trial registration information	

A02: Receive clinical trial registration information

A clinical trial registration authority receives clinical trial registration information from a clinical trial sponsoring organization.

Connections

Connector	Source	Target	Notes
Information Flow	MT140001 Clinical Trial Registration Information	A02: Receive clinical trial registration information	
ControlFlow			

Connector	Source	Target	Notes
	A01: Send completed clinical trial registration information	A02: Receive clinical trial registration information	

CTRR DAM Interaction Specifications

The CTRR DAM interaction specifications illustrate the flow of information between actors in the domain. The interactions are grouped into packages traced to a package of activities. The interactions included in the each package of interactions correspond to information flow depicted in corresponding activity diagrams.

CTRR DAM Interactions - *(Package diagram)*

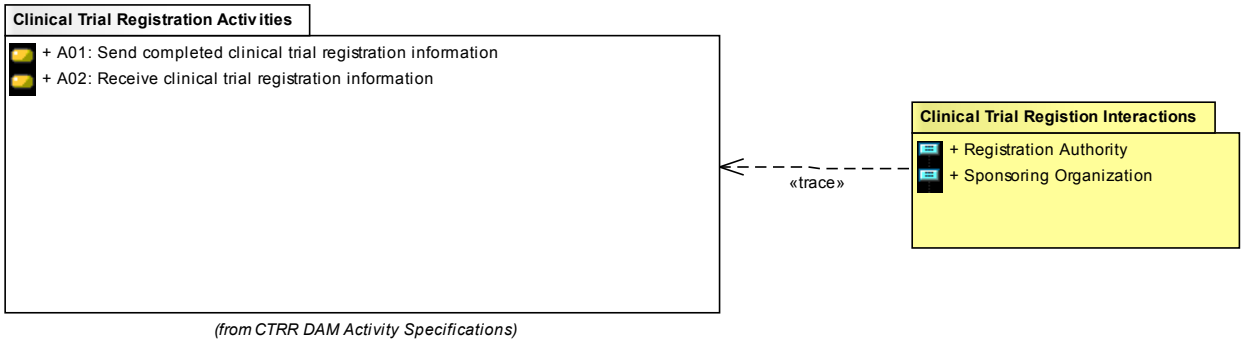

Figure: 5

Clinical Trial Registion Interactions

The clinical trial registration interactions are the set of information exchanges depicted in the clinical trial registration activities specification.

Clinical Trial Registion Interactions - *(Sequence diagram)*

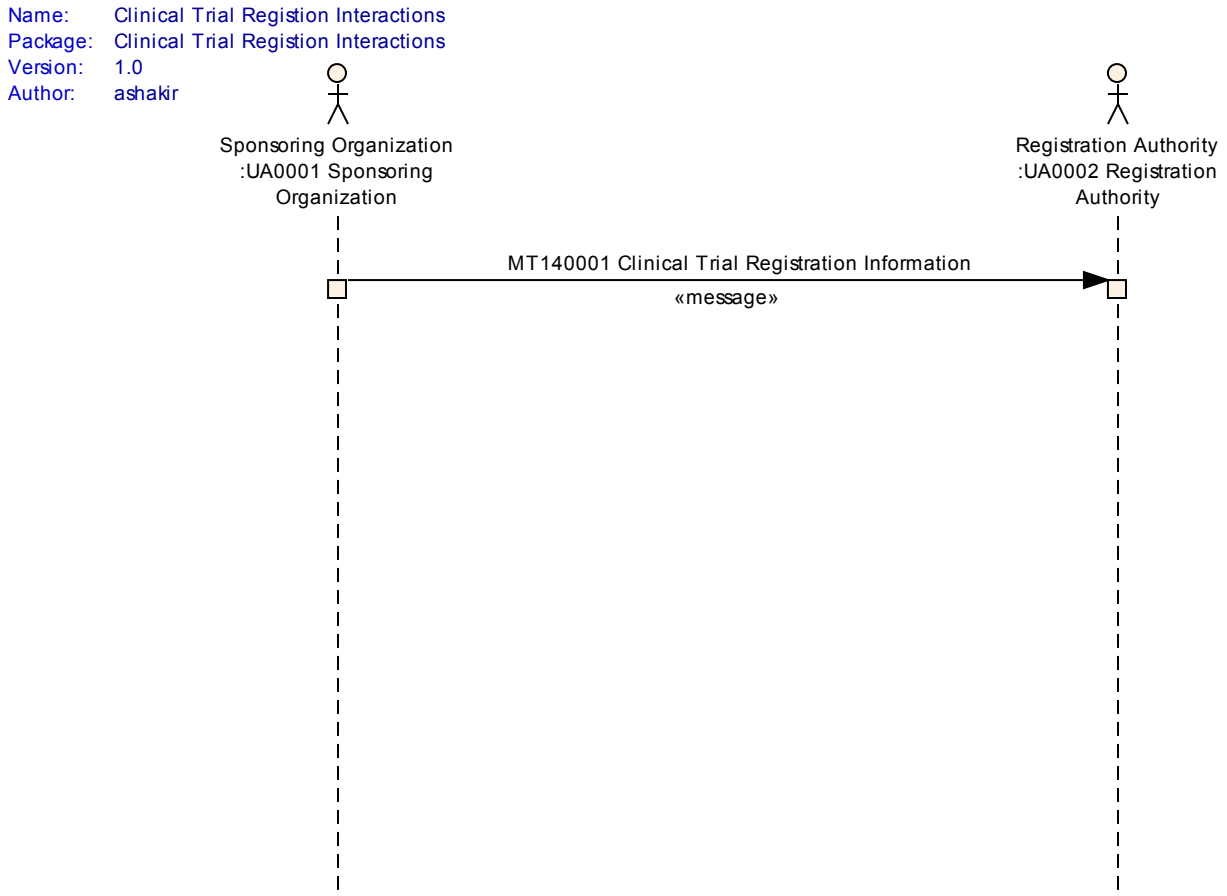

Figure: 6

Registration Authority

Connections

Connector	Source	Target	Notes
Sequence MT140001 Clinical Trial Registration Information	Sponsoring Organization	Registration Authority	

Sponsoring Organization

Connections

Connector	Source	Target	Notes
Sequence MT140001 Clinical Trial Registration Information	Sponsoring Organization	Registration Authority	

CTRR DAM Information Requirements Specification

The CTRR DAM information requirements specification declares the information requirements of the CTRR domain. The specification includes a declaration of the classes of data required and the data objects exchanged.

CTRR Information View

CTRR Information View - *(Package diagram)*

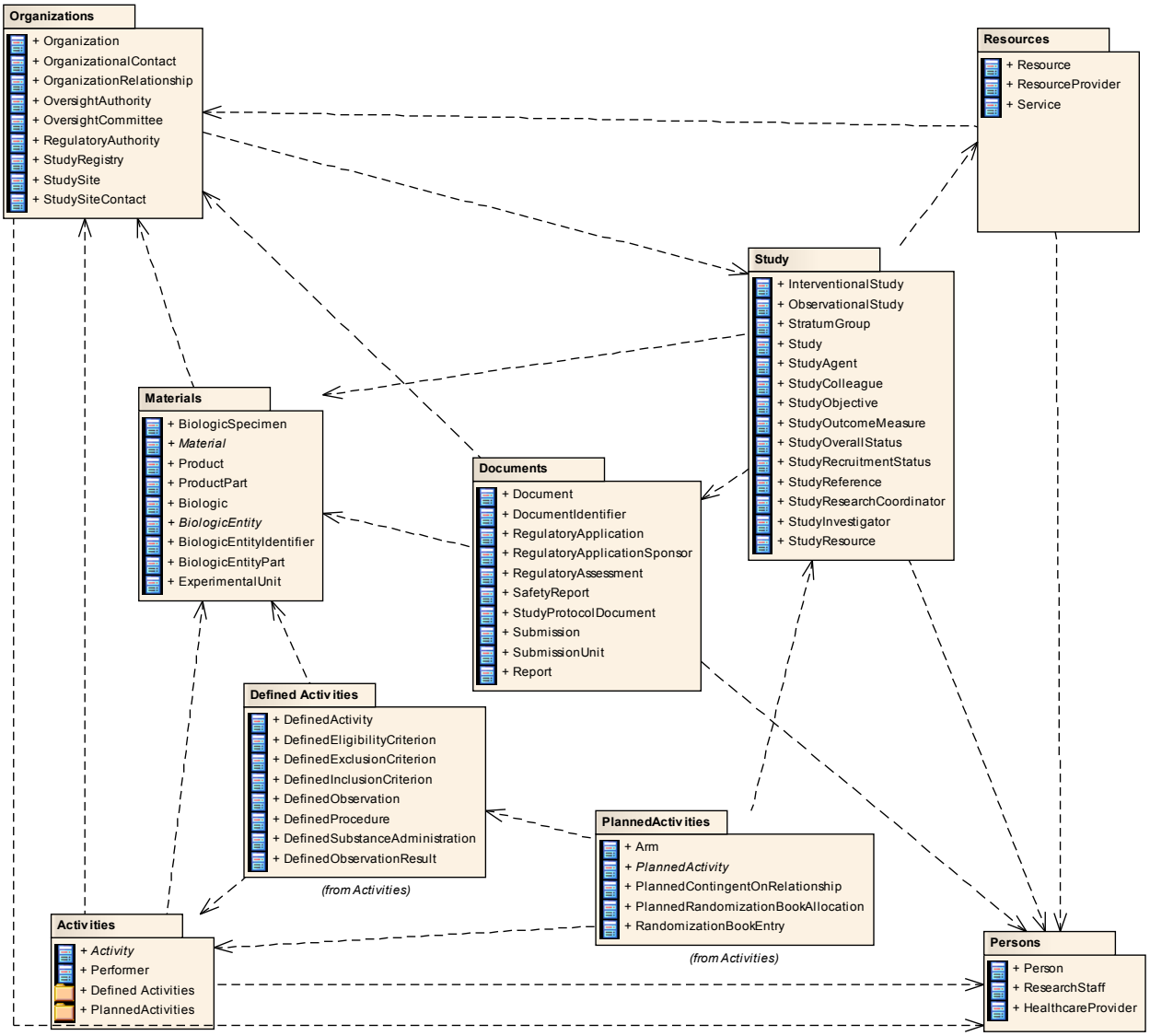

Figure: 7

Activities

Activities - *(Logical diagram)*

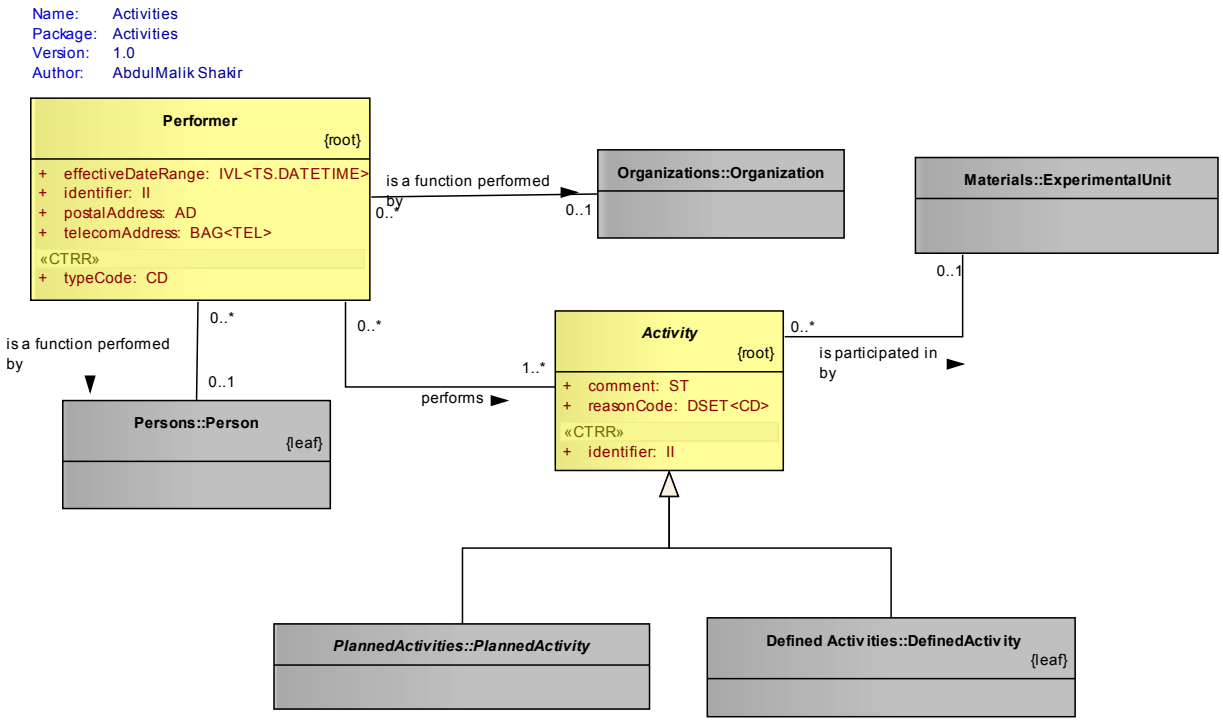

Figure: 8

Activity

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 a drug.

Connections

Connector	Source	Target	Notes
Association performs	performing Performer	performed Activity	Each Performer always performs one or more Activity. Each Activity sometimes is performed by one or more Performer.
Association is participated in by	involving Activity	involved ExperimentalUnit	Each Activity sometimes is participated in by one ExperimentalUnit. Each ExperimentalUnit sometimes participates in one or more Activity.
Generalization specializes	PlannedActivity	Activity	Each PlannedActivity always specializes one Activity. Each Activity sometimes is specialized by one PlannedActivity.
Generalization specializes	DefinedActivity	Activity	Each DefinedActivity always specializes one Activity. Each Activity sometimes is specialized by one DefinedActivity.

Connector	Source	Target	Notes

Attributes

Attribute	Notes	Constraints
comment ST	Additional description of the activity.	
identifier II «CTRR»	A unique symbol that establishes identity of an activity. For example, 12345 is the identifier for a substance administration.	
reasonCode 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.	

Performer

A person, organization or device that is participates in an activity.

For example, surgeon, monitoring device, performing laboratory.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed Performer	performing Organization	Each Performer sometimes is a function performed by one Organization. Each Organization sometimes functions as one or more Performer.
Association is a function performed by	performed Performer	performing Person	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.
Association performs	performing Performer	performed Activity	Each Performer always performs one or more Activity. Each

Connector	Source	Target	Notes
			Activity sometimes is performed by one or more Performer.

Attributes

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the performer is active.	
identifier II	A unique symbol that establishes identity of the performer.	
postalAddress AD	A contact point used to send physical forms of communication to the performer.	
telecomAddress BAG<TEL>	A sequence of digits or characters used to identify a particular telephone, fax, or email of the performer.	
typeCode CD «CTRR»	A coded value specifying the kind of performer. For example, surgeon, monitoring device, performing laboratory.	

Defined Activities

Defined Activities - *(Logical diagram)*

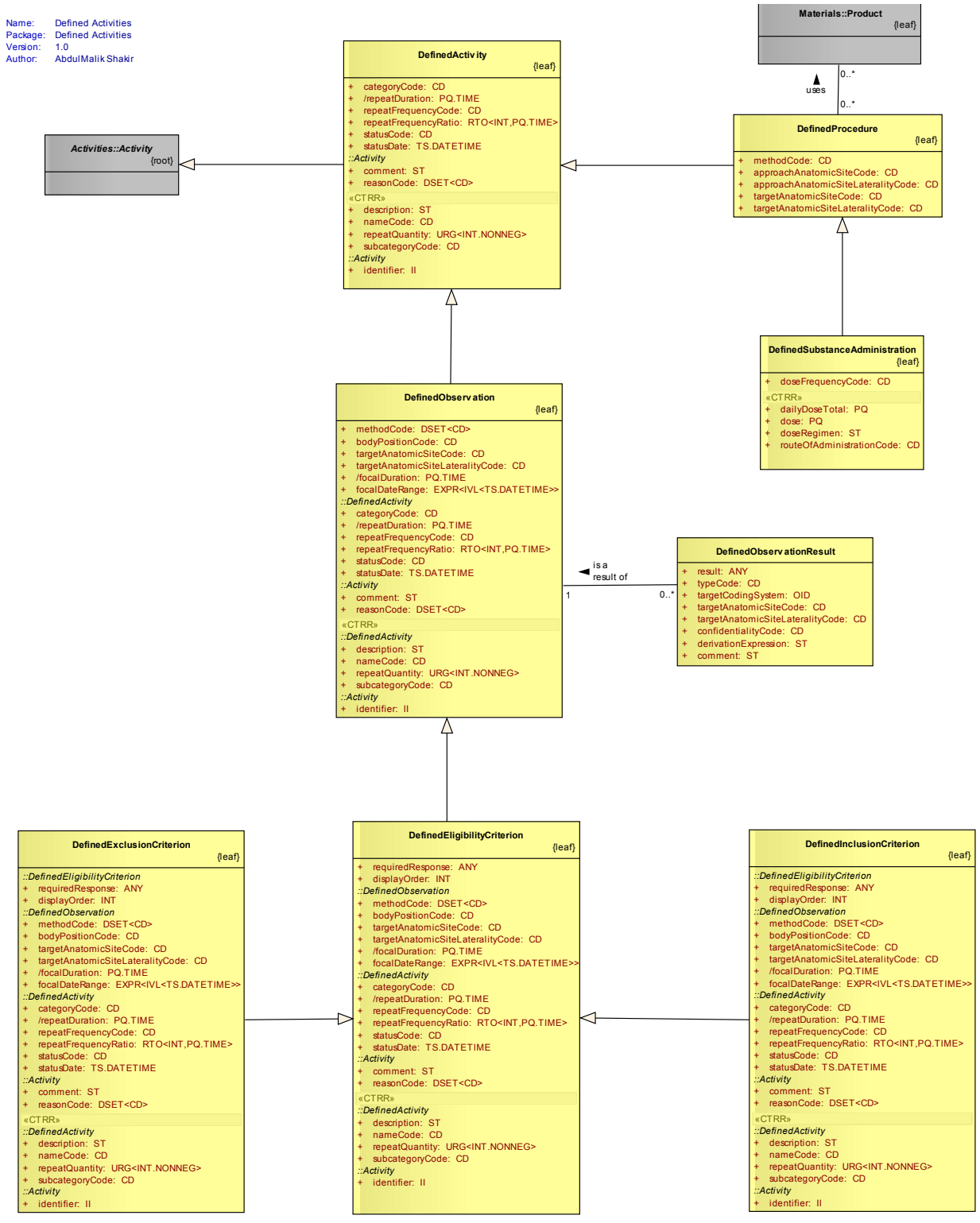

Figure: 9

DefinedActivity

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 substance administration 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.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedObservation	DefinedActivity	Each DefinedObservation always specializes one DefinedActivity. Each DefinedActivity sometimes is specialized by one DefinedObservation.
Generalization specializes	DefinedProcedure	DefinedActivity	Each DefinedProcedure always specializes one DefinedActivity. Each DefinedActivity sometimes is specialized by one DefinedProcedure.
Generalization specializes	DefinedActivity	Activity	Each DefinedActivity always specializes one Activity. Each Activity sometimes is specialized by one DefinedActivity.

Attributes

Attribute	Notes	Constraints
categoryCode 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	

Attribute	Notes	Constraints
	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.	
description ST «CTRR»	The textual representation of the activity. NOTE: This may contain more detail than the description present in the text part of a coded concept.	
nameCode CD «CTRR»	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.	
repeatDuration 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.	
repeatFrequencyCode 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)	

Attribute	Notes	Constraints
repeatFrequencyRatio 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.	
repeatQuantity URG<INT.NONNEG> «CTRR»	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.	
statusCode 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.	
statusDate TS.DATETIME	The date (and time) on which the status is assigned to the activity.	
subcategoryCode CD «CTRR»	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,	

Attribute	Notes	Constraints
	however if there may only be a category and not a subcategory, then both attributes must be present in the model.	

DefinedEligibilityCriterion

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 study subject must meet into order to participate in a certain part of the study.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedInclusionCriterion	DefinedEligibilityCriterion	Each DefinedInclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion sometimes is specialized by one DefinedInclusionCriterion.
Generalization specializes	DefinedExclusionCriterion	DefinedEligibilityCriterion	Each DefinedExclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion sometimes is specialized by one DefinedExclusionCriterion.
Generalization specializes	DefinedEligibilityCriterion	DefinedObservation	Each DefinedEligibilityCriterion always specializes one DefinedObservation. Each DefinedObservation sometimes is specialized by one DefinedEligibilityCriterion.

Attributes

Attribute	Notes	Constraints
requiredResponse ANY	The reply necessary to include/exclude a potential subject on a study.	

Attribute	Notes	Constraints
displayOrder INT	The sequence or position of a component in a list of question or data items.	

DefinedExclusionCriterion

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 study subject to determine whether they may participate in a study.

For example, must be over the age of 18.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedExclusionCriterion	DefinedEligibilityCriterion	Each DefinedExclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion sometimes is specialized by one DefinedExclusionCriterion.

DefinedInclusionCriterion

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 study subject to determine whether they may not participate in a study.

For example, pregnancy.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedInclusionCriterion	DefinedEligibilityCriterion	Each DefinedInclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion sometimes is specialized by one DefinedInclusionCriterion.

DefinedObservation

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 study subject's or experimental unit's physiologic or psychologic state.

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

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedObservation	DefinedActivity	Each DefinedObservation always specializes one DefinedActivity. Each DefinedActivity sometimes is specialized by one DefinedObservation.
Association is a result of	produced DefinedObservationResult	producing DefinedObservation	Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation sometimes results in one or more DefinedObservationResult.
Generalization specializes	DefinedEligibilityCriterion	DefinedObservation	Each DefinedEligibilityCriterion always specializes one DefinedObservation. Each DefinedObservation sometimes is specialized by one DefinedEligibilityCriterion.

Attributes

Attribute	Notes	Constraints
methodCode 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.	
bodyPositionCode CD	A coded value specifying the 3-dimensional spatial orientation of a subject during a particular observation. For example, supine, trendelenburg, standing, etc.	
targetAnatomicSiteCode CD	A coded value specifying the anatomic location that is the focus of the observation. For example, gastrointestinal, cardiovascular. NOTE: The target site of the observation result may be different than the target site of the observation that generated it. For instance, the	

Attribute	Notes	Constraints
	target site of the observation may be broad (e.g. skin) while the target site of the observation result is specific (e.g. skin on chest).	
targetAnatomicSiteLaterality Code 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.	
focalDuration 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>>.	
focalDateRange 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	

Attribute	Notes	Constraints
	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.	

DefinedProcedure

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 study subject or experimental unit.

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.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedProcedure	DefinedActivity	Each DefinedProcedure always specializes one DefinedActivity. Each DefinedActivity sometimes is specialized by one DefinedProcedure.
Association uses	using DefinedProcedure	used Product	Each DefinedProcedure sometimes uses one or more Product. Each Product sometimes is used during one or more DefinedProcedure.
Generalization specializes	DefinedSubstanceAdministration	DefinedProcedure	Each DefinedSubstanceAdministration always specializes one DefinedProcedure. Each DefinedProcedure sometimes is specialized by one DefinedSubstanceAdministration.

Attributes

Attribute	Notes	Constraints
methodCode 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".	

Attribute	Notes	Constraints
approachAnatomicSiteCode CD	A coded value specifying the anatomic location or access point for a procedure. For example, arm for an injection, trans-abdominal for a nephrectomy.	
approachAnatomicSiteLateralityCode CD	A coded value specifying the side of the body (or a paired organ) that is an access point for a procedure. For example, Bilateral, Left, Right.	
targetAnatomicSiteCode 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 kidney. NOTE: multiple contiguous sites within the same organ system may be referenced.	
targetAnatomicSiteLateralityCode CD	A coded value specifying the side of the body (or a paired organ) that is a target site for a procedure. For example, Bilateral, Left, Right.	

DefinedSubstanceAdministration

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.

Connections

Connector	Source	Target	Notes
Generalization specializes	DefinedSubstanceAdministration	DefinedProcedure	Each DefinedSubstanceAdministration always specializes one DefinedProcedure. Each DefinedProcedure sometimes is specialized by one DefinedSubstanceAdministration.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
dailyDoseTotal PQ «CTRR»	Total daily dose of treatment. NOTE: This is needed because the dose may not always be derivable, e.g., if it is a string.	
dose PQ «CTRR»	The quantity of a substance or medication to be administered. For example, 5 mg, 20 mg/kg.	
doseFrequencyCode CD	A coded value specifying how often doses are administered. For example, BID, TID, QID.	
doseRegimen ST «CTRR»	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.	
routeOfAdministrationCode CD «CTRR»	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.	

DefinedObservationResult

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.

Connections

Connector	Source	Target	Notes
Association is a result of	produced DefinedObservationResult	producing DefinedObservation	Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation sometimes results in one or more DefinedObservationResult.
Association is contingent upon	contingent PlannedContingentOnRelationship	prerequisite DefinedObservationResult	Each PlannedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each DefinedObservationResult sometimes is a condition for one or more PlannedContingentOnRelationship.

Attributes

Attribute	Notes	Constraints
result 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.	
typeCode 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.	
targetCodingSystem OID	The coding system to use for recording results for the associated activity or evaluation.	

Attribute	Notes	Constraints
targetAnatomicSiteCode CD	A coded value specifying the anatomic location that is the focus of an observation result. For example, arm for skin rash. NOTE: The target site of the observation result may be different than the target site of the observation that generated it. For instance, the target site of the observation may be broad (e.g. skin) while the target site of the observation result is specific (e.g. skin on chest).	
targetAnatomicSiteLaterality Code CD	A coded value specifying the side of the body (or a paired organ) that is a target site for a procedure. For example, Bilateral, Left, Right.	
confidentialityCode CD	A coded value specifying the degree of privacy applicable for the observation result.	
derivationExpression ST	A character string containing a formal language expression that specifies how the observation result's attributes are, should be, or have been derived from input parameters associated with activity.	
comment 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.	

PlannedActivities

PlannedActivities - *(Logical diagram)*

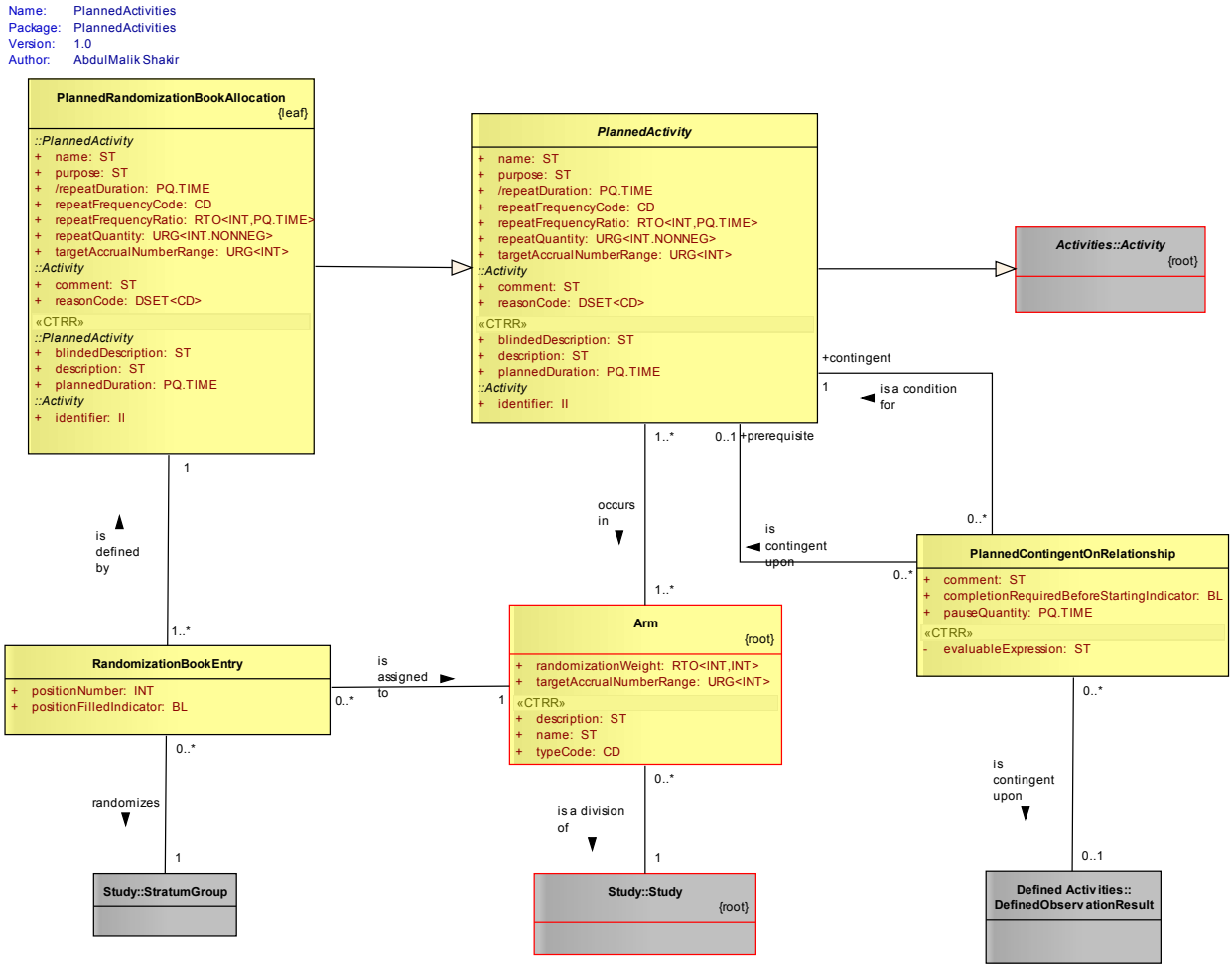

Figure: 10

Arm

A path through the study which describes what activities the study subject or experimental unit 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.

Connections

Connector	Source	Target	Notes
Association occurs in	contained PlannedActivity	containing Arm	Each PlannedActivity always occurs in one or more Arm. Each Arm always contains one or more PlannedActivity.
Association is a division of	subdividing Arm	subdivided Study	Each Arm always is a division of one Study. Each Study sometimes

Connector	Source	Target	Notes
			is divided into one or more Arm.
Association is assigned to	assigned RandomizationBookEntry	containing Arm	Each RandomizationBookEntry always is assigned to one Arm. Each Arm sometimes has assigned one or more RandomizationBookEntry.

Attributes

Attribute	Notes	Constraints
description ST «CTRR»	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.	
name ST «CTRR»	A non-unique textual identifier for the arm. For example, Treatment A.	
randomizationWeight RTO<INT,INT>	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.	
targetAccrualNumberRange 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.	

Attribute	Notes	Constraints
typeCode CD «CTRR»	A coded value specifying the kind of arm. For example, Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No intervention, Other	

PlannedActivity

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.

Connections

Connector	Source	Target	Notes
Association is contingent upon	contingent PlannedContingentOnRelationship	prerequisite PlannedActivity	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedActivity. Each PlannedActivity sometimes is a condition for one or more PlannedContingentOnRelationship.
Association occurs in	contained PlannedActivity	containing Arm	Each PlannedActivity always occurs in one or more Arm. Each Arm always contains one or more PlannedActivity.
Association is a condition for	prerequisite PlannedContingentOnRelationship	contingent PlannedActivity	Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity sometimes is contingent upon one or more PlannedContingentOnRelationship.
Generalization specializes	PlannedActivity	Activity	Each PlannedActivity always specializes one Activity. Each Activity sometimes is specialized by one PlannedActivity.

Connector	Source	Target	Notes
Generalization specializes	PlannedRandomizationBookAllocation	PlannedActivity	Each PlannedRandomizationBookAllocation always specializes one PlannedActivity. Each PlannedActivity sometimes is specialized by one PlannedRandomizationBookAllocation.

Attributes

Attribute	Notes	Constraints
blindedDescription ST «CTRR»	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".	
description ST «CTRR»	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".	

Attribute	Notes	Constraints
name ST	A non-unique textual identifier for the planned activity.	
plannedDuration PQ.TIME «CTRR»	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.	
purpose ST	The reason for the planned activity. For example, treating a disease (treatment), determining eligibility for a study (screening), etc.	
repeatDuration 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.	
repeatFrequencyCode 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)	
repeatFrequencyRatio 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.	

Attribute	Notes	Constraints
repeatQuantity URG<INT.NONNEG>	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.	
targetAccrualNumberRange URG<INT>	A range of integers specifying the minimum and maximum number of subjects to be accrued for the planned activity.	

PlannedContingentOnRelationship

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))".

Connections

Connector	Source	Target	Notes
Association is contingent upon	contingent PlannedContingentOnRelationship	prerequisite PlannedActivity	Each PlannedContingentOnRelationship sometimes is contingent upon one PlannedActivity. Each PlannedActivity sometimes is a condition for one or more PlannedContingentOnRelationship.
Association is a condition for	prerequisite PlannedContingentOnRelationship	contingent PlannedActivity	Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity sometimes is contingent upon one or more PlannedContingentOnRelationship.

Connector	Source	Target	Notes
Association is contingent upon	contingent PlannedContingentOnRelationship	prerequisite DefinedObservationResult	Each PlannedContingentOnRelationship sometimes is contingent upon one DefinedObservationResult. Each DefinedObservationResult sometimes is a condition for one or more PlannedContingentOnRelationship.

Attributes

Attribute	Notes	Constraints
comment ST	Additional description of the contingent on relationship.	
completionRequiredBeforeStartingIndicator 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.	
pauseQuantity 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, the pauseQuantity would be 15 minutes and 2 hours respectively. For the more complex examples of doing activity A 5 minutes after the start of B or 5 minutes after the end of B, use pauseQuantity in combination with completionRequiredBeforeStartingIndicator where the pauseQuantity in both cases would be 5 minutes and "after the start of" would be completionRequiredBeforeStartingIndicator = "N" and "after the end of" = "Y". NOTE: The pauseQuantity defines the amount of time between two points in time: (1) the point when all preceding steps (in sequence) and preconditions of an activity have been completed, and (2) the actual start of the activity. The completion of all pre-conditions and preceding steps (based on sequence number) indicates that an activity is "ready for	

Attribute	Notes	Constraints
	execution" according to the definition above. The pauseQuantity counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantity with a negative value means that the activity starts some amount of time prior to the estimated time that the activity is "ready for execution", i.e. prior to the estimated time that the pre-conditions and preceding steps will be completed.	
evaluableExpression ST «CTRR»		

PlannedRandomizationBookAllocation

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.

NOTE: A randomization book is a predefined set of assignments to portions of a study based on criteria, such as stratum group for example, that ensures a desired distribution of subjects across those portions of the study. For example, the book entries indicate which arm a given subject, Joe, is assigned to based on the fact that he's the 5th person in stratum group #2.

Connections

Connector	Source	Target	Notes
Association is defined by	defined RandomizationBookEntry	defining PlannedRandomizationBookAllocation	Each RandomizationBookEntry always is defined by one PlannedRandomizationBookAllocation. Each PlannedRandomizationBookAllocation always defines one or more RandomizationBookEntry.
Generalization specializes	PlannedRandomizationBookAllocation	PlannedActivity	Each PlannedRandomizationBookAllocation always specializes one PlannedActivity. Each PlannedActivity sometimes is specialized by one PlannedRandomizationBookAllocation.

RandomizationBookEntry

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.

NOTE: A randomization book is a predefined set of assignments to portions of a study based on criteria, such as stratum group for example, that ensures a desired distribution of subjects across those portions of the study. For example, the book entries indicate which arm a given subject, Joe, is assigned to based on the fact that he's the 5th person in stratum group #2.

Connections

Connector	Source	Target	Notes
Association randomizes	randomizing RandomizationBookEntry	randomized StratumGroup	Each RandomizationBookEntry always randomizes one StratumGroup. Each StratumGroup sometimes is randomized by one or more RandomizationBookEntry.
Association is assigned to	assigned RandomizationBookEntry	containing Arm	Each RandomizationBookEntry always is assigned to one Arm. Each Arm sometimes has assigned one or more RandomizationBookEntry.
Association is defined by	defined RandomizationBookEntry	defining PlannedRandomizationBookAllocation	Each RandomizationBookEntry always is defined by one PlannedRandomizationBookAllocation. Each PlannedRandomizationBookAllocation always defines one or more RandomizationBookEntry.

Attributes

Attribute	Notes	Constraints
positionNumber 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: A StratumGroup#: 0; Position: 1; Arm/Portion of Arm: B If 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.	

Attribute	Notes	Constraints
positionFilledIndicator BL	Specifies whether the position is filled by a subject assignment.	

Documents

Documents - *(Logical diagram)*

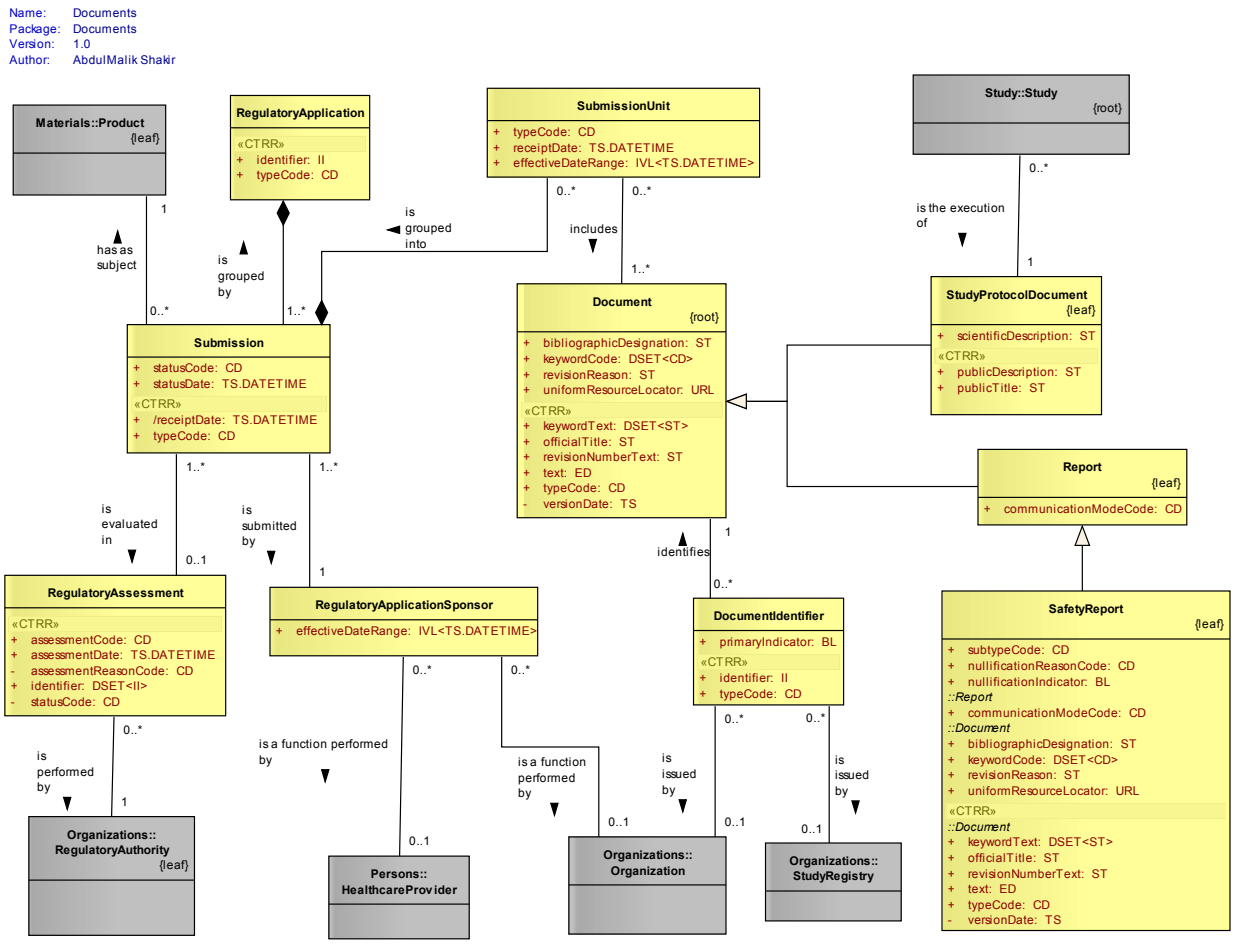

Figure: 11

Document

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, Institutional Review Board (IRB) Report, X-Ray Report, Lab Summary Report, Autopsy Report, etc.

Connections

Connector	Source	Target	Notes
Generalization specializes	StudyProtocolDocument	Document	Each StudyProtocolDocument always specializes one Document. Each Document sometimes is specialized by one StudyProtocolDocument.
Association includes	including SubmissionUnit	included Document	Each SubmissionUnit always includes one or more Document. Each Document sometimes is included in one or more SubmissionUnit.
Association identifies	identifying DocumentIdentifier	identified Document	Each DocumentIdentifier always identifies one Document. Each Document sometimes is identified by one or more DocumentIdentifier.
Generalization specializes	Report	Document	Each Report always specializes one Document. Each Document sometimes is specialized by one Report.

Attributes

Attribute	Notes	Constraints
bibliographicDesignation 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.	
keywordCode 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.	

Attribute	Notes	Constraints
keywordText DSET<ST> «CTRR»	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.	
officialTitle ST «CTRR»	The formal title of the document. NOTE: If there is only one title, use this attribute.	
revisionNumberText ST «CTRR»	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.	
revisionReason ST	The reason why the document is revised.	

Attribute	Notes	Constraints
text ED «CTRR»	A character string that is the full or comprehensive narrative or content of the document.	
typeCode CD «CTRR»	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)	
uniformResourceLocator URL	A complete reference to a website (including http://) from which the document contents can be retrieved.	
versionDate TS «CTRR»		

DocumentIdentifier

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.

Connections

Connector	Source	Target	Notes
Association is issued by	issued DocumentIdentifier	issuing StudyRegistry	Each DocumentIdentifier sometimes is issued by one

Connector	Source	Target	Notes
			Registry. Each Registry sometimes issues one or more DocumentIdentifier.
Association identifies	identifying DocumentIdentifier	identified Document	Each DocumentIdentifier always identifies one Document. Each Document sometimes is identified by one or more DocumentIdentifier.
Association is issued by	issued DocumentIdentifier	issuing Organization	Each DocumentIdentifier sometimes is issued by one Organization. Each Organization sometimes issues one or more DocumentIdentifier.

Attributes

Attribute	Notes	Constraints
identifier II Collection «CTRR»	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 protocols. NOTE: A particular document can have one or more ID.	
primaryIndicator BL	Specifies whether this is the main or principal document identifier. NOTE: primaryIndicator may only apply for a given typeCode.	

Attribute	Notes	Constraints
typeCode CD «CTRR»	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.	

RegulatoryApplication

A collection of submissions that are grouped together for regulatory purposes, and are usually specific to a particular device, food or feed additive or biopharmaceutical substance.

For example, the marketing application for a drug product can generate multiple regulatory decisions. The first decision may support the initial marketing approval of the product for a specific indication. Subsequent regulatory decisions may approve or deny additional indications for the drug product. The application thus contains multiple submissions, each with their own regulatory action.

NOTE: Over time, an application will typically consist of multiple submissions and regulatory assessments

Connections

Connector	Source	Target	Notes
Aggregation is grouped by	grouped Submission	grouping RegulatoryApplication	Each Submission always is grouped by one RegulatoryApplication. Each RegulatoryApplication always groups one or more Submission.

Attributes

Attribute	Notes	Constraints
identifier II «CTRR»	A unique symbol that establishes identity of the regulatory application.	
typeCode CD «CTRR»	A coded value specifying the kind of regulatory application. For example, New Drug Application, 510k, Veterinary New Drug Submission, etc. NOTE: Each product type will be supported by a different application type.	

RegulatoryApplicationSponsor

An organization that assumes responsibility for producing and submitting documentation to a regulatory authority to seek approval for testing, marketing and the continuation of marketing of new drugs or devices.

For example, a pharmaceutical company.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed RegulatoryApplicationSponsor	performing HealthcareProvider	Each RegulatoryApplicationSponsor always is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more RegulatoryApplicationSponsor.
Association is a function performed by	performed RegulatoryApplicationSponsor	performing Organization	Each RegulatoryApplicationSponsor always is a function performed by one Organization. Each Organization always functions as one or more RegulatoryApplicationSponsor.
Association is submitted by	submitted Submission	submitting RegulatoryApplicationSponsor	Each Submission always is submitted by one RegulatoryApplicationSponsor. Each RegulatoryApplicationSponsor always submits one or more Submission.

Attributes

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the regulatory application sponsor is active. NOTE: Must be at least a full Date (8 digits) but could contain a time (14 digits).	

RegulatoryAssessment

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.

Connections

Connector	Source	Target	Notes
Association is performed by	performed RegulatoryAssessment	performing RegulatoryAuthority	Each RegulatoryAssessment always is performed by one RegulatoryAuthority. Each RegulatoryAuthority sometimes performs one or more RegulatoryAssessment.

Connector	Source	Target	Notes
Association is evaluated in	evaluated Submission	evaluating RegulatoryAssessment	Each Submission sometimes is evaluated in one RegulatoryAssessment. Each RegulatoryAssessment always evaluates one or more Submission.

Attributes

Attribute	Notes	Constraints
assessmentCode CD «CTRR»	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".	
assessmentDate TS.DATETIME «CTRR»	The date (and time) on which this particular assessment is completed.	
assessmentReasonCode CD «CTRR»		

Attribute	Notes	Constraints
identifier DSET<II> «CTRR»	A unique symbol that establishes identity of the regulatory assessment. For example, NDA number, IND number, BLA, PMA, 510K, etc.	
statusCode CD «CTRR»		

SafetyReport

A report that provides notification of an adverse event, product problem, and/or information that is relevant to either. A report typically includes causal association, management strategies, authorship, sender/receiver organizations, subject of adverse event, or name of product.

For example, an Expedited AE report - a report of a serious and unexpected adverse event that must be submitted within specific timeframes to the sponsor and regulatory agencies.

Connections

Connector	Source	Target	Notes
Generalization specializes	SafetyReport	Report	Each SafetyReport always specializes one Report. Each Report sometimes is specialized by one SafetyReport.

Attributes

Attribute	Notes	Constraints
subtypeCode CD	A coded value specifying a further classification of type. For example, an Adverse Event Report would map to Document.typeCode and the Document.subtypeCode would map to a 7-day AE Report.	
nullificationReasonCode CD	A coded value specifying the reason why the adverse event report is nullified.	

Attribute	Notes	Constraints
nullificationIndicator BL	Specifies whether the report cancels a previously sent adverse event.	

StudyProtocolDocument

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.

Connections

Connector	Source	Target	Notes
Generalization specializes	StudyProtocolDocument	Document	Each StudyProtocolDocument always specializes one Document. Each Document sometimes is specialized by one StudyProtocolDocument.
Association is the execution of	instantiating Study	instantiated StudyProtocolDocument	Each Study always is the execution of one StudyProtocolDocument. Each StudyProtocolDocument sometimes is the plan for one or more Study.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
publicDescription ST «CTRR»	The textual summary of a document intended for the general population.	
publicTitle ST «CTRR»	The title of the document intended for the general population.	
scientificDescription ST	The textual summary of a document that includes extended scientific or technical information.	

Submission

A compilation of the contents of one or more submission units that supports a specific regulatory purpose or decision.

For example, a request for approval to either market a product or to allow the applicant to start testing of a proposed product.

NOTE: In most cases, the compilation of the submission units is used to assess a product's quality, safety and effectiveness.

NOTE: Submissions are always associated with some regulatory action (or inaction). Each submission contains their own regulatory action. Submissions (e.g., initial marketing application, supplemental marketing application) would generally be comprised of multiple submissions units.

NOTE: Most typically the submission will be used to organize information based on a review clock. Receipt date from the regulatory authority is important for a submission.

Connections

Connector	Source	Target	Notes
Aggregation is grouped into	grouped SubmissionUnit	grouping Submission	Each SubmissionUnit sometimes is grouped into one Submission. Each Submission sometimes groups one or more SubmissionUnit.
Aggregation is grouped by	grouped Submission	grouping RegulatoryApplication	Each Submission always is grouped by one

Connector	Source	Target	Notes
			RegulatoryApplication. Each RegulatoryApplication always groups one or more Submission.
Association has as subject	describing Submission	described Product	Each Submission always has as subject one Product. Each Product sometimes is the subject of one or more Submission.
Association is submitted by	submitted Submission	submitting RegulatoryApplicationSponsor	Each Submission always is submitted by one RegulatoryApplicationSponsor. Each RegulatoryApplicationSponsor always submits one or more Submission.
Association is evaluated in	evaluated Submission	evaluating RegulatoryAssessment	Each Submission sometimes is evaluated in one RegulatoryAssessment. Each RegulatoryAssessment always evaluates one or more Submission.

Attributes

Attribute	Notes	Constraints
receiptDate TS.DATETIME «CTRR»	The date (and time) on which the first submission unit is received by the regulatory authority.	
statusCode CD	A coded value specifying the state of the submission. For example, active or withdrawn.	
statusDate TS.DATETIME	The date (and time) on which the status is assigned to the submission.	

Attribute	Notes	Constraints
typeCode CD «CTRR»	A coded value specifying the kind of submission. For example, original, supplement, or annual report.	

SubmissionUnit

The collection of documents provided to the regulatory authority at one time.

NOTE: A submission unit is made up of one to many documents. Properly defined, the submission unit concept enables companies to create new submission units from any combination of new and previously submitted document.

NOTE: In the dynamic aspects of the model, a submission unit is one message that may have a collection of many documents. There are rules for how submission units are evaluated are described in a state diagram, and the receipt date of the submission unit "starts the clock" for the review of the contents of the submission unit.

Connections

Connector	Source	Target	Notes
Association includes	including SubmissionUnit	included Document	Each SubmissionUnit always includes one or more Document. Each Document sometimes is included in one or more SubmissionUnit.
Aggregation is grouped into	grouped SubmissionUnit	grouping Submission	Each SubmissionUnit sometimes is grouped into one Submission. Each Submission sometimes groups one or more SubmissionUnit.

Attributes

Attribute	Notes	Constraints
typeCode CD	A coded value specifying the kind of submission unit. For example, original, amendment, or supplement. NOTE: Typically each submission unit type would cause a different regulatory request.	

Attribute	Notes	Constraints
receiptDate TS.DATETIME	The date (and time) on which the submission unit is received by the regulatory authority. NOTE: Typically, this date will start a review clock, if applicable. The combination of the code and where the submission unit was received will determine the deadline for the submission unit to be reviewed.	
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the submission unit is active.	

Report

A document characterized by information or other content which is tailored to the context of a given situation and audience.

For example, Safety Report, Study Report, etc.

Connections

Connector	Source	Target	Notes
Generalization specializes	Report	Document	Each Report always specializes one Document. Each Document sometimes is specialized by one Report.
Generalization specializes	SafetyReport	Report	Each SafetyReport always specializes one Report. Each Report sometimes is specialized by one SafetyReport.

Attributes

Attribute	Notes	Constraints
communicationModeCode CD	A coded value specifying the form in which the report is transmitted. For example, physically present, over the telephone, written communication, electronic.	

Materials

Materials - *(Logical diagram)*

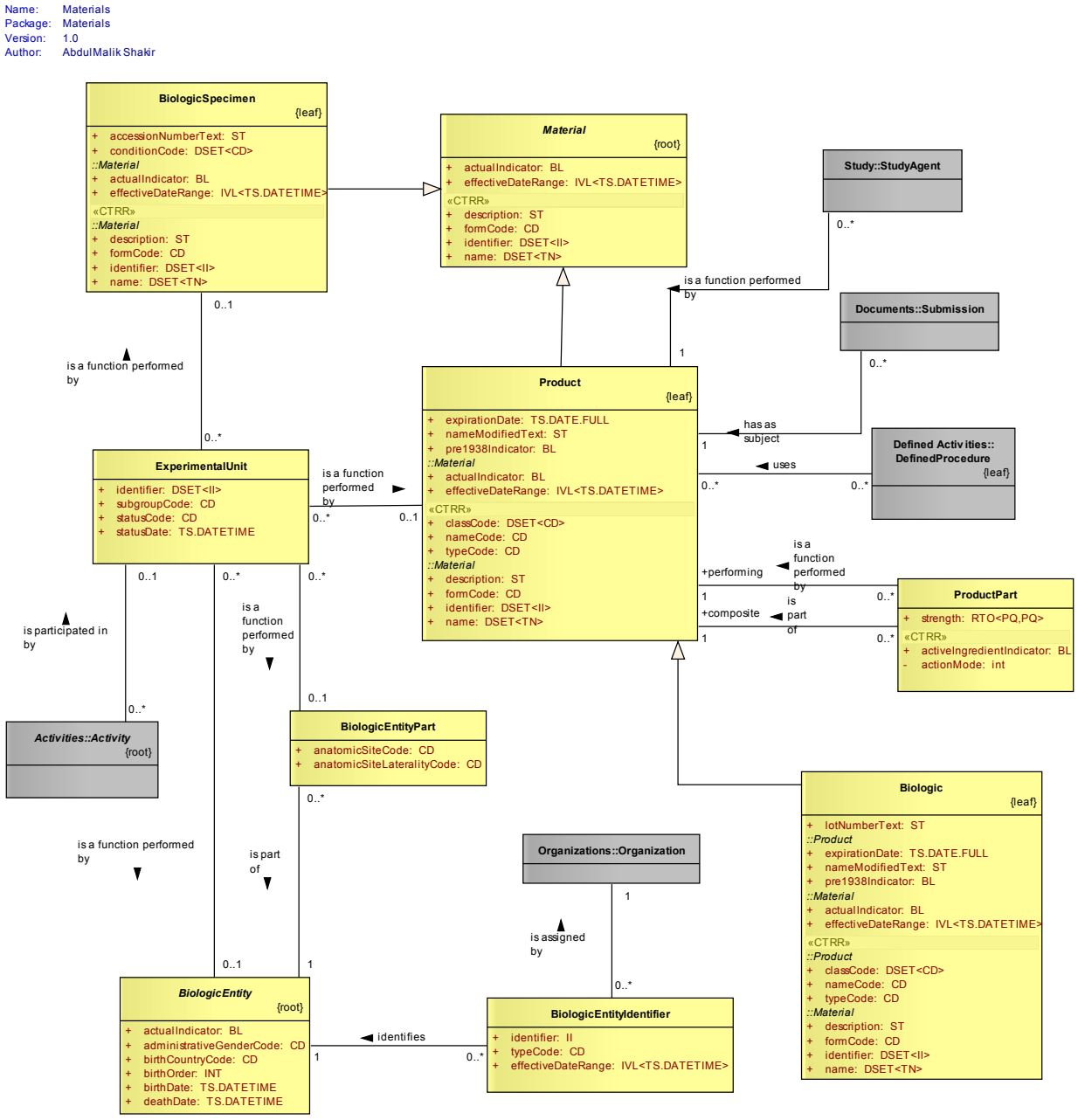

Figure: 12

BiologicSpecimen

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

For example, a serum sample from blood.

Connections

Connector	Source	Target	Notes
Generalization specializes	BiologicSpecimen	Material	Each BiologicSpecimen always specializes one Material. Each Material sometimes is specialized

Connector	Source	Target	Notes
			by one BiologicSpecimen.
Association is a function performed by	performed ExperimentalUnit	performing BiologicSpecimen	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.

Attributes

Attribute	Notes	Constraints
accessionNumberText ST	An alphanumeric identifier (not necessarily unique to the specimen) assigned by a receiving lab to specimens that are received together as a set.	
conditionCode DSET<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.	

Material

A physical substance.

For example, drug, device, specimen.

Connections

Connector	Source	Target	Notes
Generalization specializes	BiologicSpecimen	Material	Each BiologicSpecimen always specializes one Material. Each Material sometimes is specialized by one BiologicSpecimen.
Generalization specializes	Product	Material	Each Product always specializes one Material. Each Material sometimes is specialized by one Product.

Attributes

Attribute	Notes	Constraints
actualIndicator BL	Specifies whether the material is real (actual) vs. placeholder (kind of).	
description ST «CTRR»	The textual representation of the material.	
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the material is active.	
formCode CD «CTRR»	A coded value specifying the state and nature of the material. For example, solid, liquid, gas, tablet, ointment, gel, etc.	
identifier DSET<II> «CTRR»	A unique symbol that establishes identity of the material. For example, serial number, product number, model number.	
name DSET<TN> «CTRR»	A non-unique textual identifier for the material. For example, the therapeutic agent used in a chemotherapy clinical trial.	

Product

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.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed StudyAgent	performing Product	Each StudyAgent always is a function performed by one Product. Each Product sometimes functions as one or more StudyAgent.
Generalization specializes	Product	Material	Each Product always specializes one Material. Each Material sometimes is specialized by one Product.
Association has as subject	describing Submission	described Product	Each Submission always has as subject one Product. Each Product sometimes is the subject of one or more Submission.
Association uses	using DefinedProcedure	used Product	Each DefinedProcedure sometimes uses one or more Product. Each Product sometimes is used during one or more DefinedProcedure.
Association is part of	component ProductPart	composite Product	Each ProductPart always is a part of one Product. Each Product sometimes has as part one or more ProductPart.
Generalization specializes	Biologic	Product	Each Biologic always specializes one Product. Each Product sometimes is specialized by one Biologic.
Association is a function performed by	performed ProductPart	performing Product	Each ProductPart always is a function performed by one Product. Each Product sometimes functions as one or more ProductPart.
Association is a function performed by	performed ExperimentalUnit	performing Product	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

Connector	Source	Target	Notes
			ProductGroup.

Attributes

Attribute	Notes	Constraints
classCode DSET<CD> «CTRR»	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.	
expirationDate TS.DATE.FULL	The date (and time), assigned by the manufacturer, on which the product should not be used.	
nameCode CD «CTRR»	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.	
nameModifiedText 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.	
pre1938Indicator 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.	

Attribute	Notes	Constraints
typeCode CD «CTRR»	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.	

ProductPart

A subdivision of a product

Connections

Connector	Source	Target	Notes
Association is part of	component ProductPart	composite Product	Each ProductPart always is a part of one Product. Each Product sometimes has as part one or more ProductPart.
Association is a function performed by	performed ProductPart	performing Product	Each ProductPart always is a function performed by one Product. Each Product sometimes functions as one or more ProductPart.

Attributes

Attribute	Notes	Constraints
activeIngredientIndicator BL «CTRR»	Specifies whether the ingredient is an active ingredient.	
strength RTO<PQ,PQ>	An indication of the amount of the ingredient contained in a reference amount of the product. For example, 50 mg per tablet, or 300 ml / liter.	
actionMode int «CTRR»		

Biologic

A substance made from living organisms or things they produce.

For example, virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product.

Connections

Connector	Source	Target	Notes
Generalization specializes	Biologic	Product	Each Biologic always specializes one Product. Each Product sometimes is specialized by one Biologic.

Attributes

Attribute	Notes	Constraints
lotNumberText ST	An alphanumeric string used to identify a particular batch of biologic.	

BiologicEntity

Any individual living (or previously living) being.

For example, animal, human being.

Connections

Connector	Source	Target	Notes
Association identifies	identifying BiologicEntityIdentifier	identified BiologicEntity	Each BiologicEntityIdentifier always identifies one BiologicEntity. Each BiologicEntity sometimes is identified by one or more BiologicEntityIdentifier.
Generalization specializes	Person	BiologicEntity	Each Person always specializes one BiologicEntity. Each BiologicEntity sometimes is specialized by one Person.
Association is part of	contained BiologicEntityPart	containing BiologicEntity	Each BiologicEntityPart always is a part of one BiologicEntity. Each BiologicEntity sometimes has one or more BiologicEntityPart.
Association is a function performed by	performed ExperimentalUnit	performing BiologicEntity	Each ExperimentalUnit sometimes is a function performed by one BiologicEntity. Each BiologicEntity sometimes

Connector	Source	Target	Notes
			functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup.

Attributes

Attribute	Notes	Constraints
actualIndicator BL	Specifies whether the biologic entity is real (actual) vs. placeholder (kind of).	
administrativeGenderCode CD	A coded value specifying the physical or societal properties by which male is distinguished from female. NOTE: For humans, identification of sex is usually based upon self-report and may come from a form, questionnaire, interview, etc.	
birthCountryCode CD	A coded value specifying the name of the country in which the biologic entity is born.	
birthOrder INT	Indicates the sequence of a biologic entity's birth in the family group.	
birthDate TS.DATETIME	The date (and time) on which the biologic entity is born.	

Attribute	Notes	Constraints
deathDate TS.DATETIME	The date (and time) on which the biologic entity died.	

BiologicEntityIdentifier

The unique identification of a biologic entity 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.

Connections

Connector	Source	Target	Notes
Association identifies	identifying BiologicEntityIdentifier	identified BiologicEntity	Each BiologicEntityIdentifier always identifies one BiologicEntity. Each BiologicEntity sometimes is identified by one or more BiologicEntityIdentifier.
Association is assigned by	assigned BiologicEntityIdentifier	assigning Organization	Each BiologicEntityIdentifier always is assigned by one Organization. Each Organization sometimes assigns one or more BiologicEntityIdentifier.

Attributes

Attribute	Notes	Constraints
identifier II	The unique symbol that establishes identity of the biologic entity. For example, medical record number. NOTE: This is different from the StudySubject.identifier.	
typeCode CD	A coded value specifying the kind of biologic entity identifier. For example, hospital record number, medical record number.	

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the biologic entity identifier is active.	

BiologicEntityPart

A limb, organ, or other portion of a biologic entity.

For example, the left kidney of a person, a dog's right from paw, a patch of skin on a person's left forearm, etc.

Connections

Connector	Source	Target	Notes
Association is part of	contained BiologicEntityPart	containing BiologicEntity	Each BiologicEntityPart always is a part of one BiologicEntity. Each BiologicEntity sometimes has one or more BiologicEntityPart.
Association is a function performed by	performed ExperimentalUnit	performing BiologicEntityPart	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.

Attributes

Attribute	Notes	Constraints
anatomicSiteCode CD	A coded value specifying the anatomic site(s) or system of the biologic entity part. For example, eye, skin, kidney, etc.	
anatomicSiteLateralityCode CD	A coded value specifying the side of the body (or a paired organ) where the anatomic site is in a biologic entity part. For example, left, right, both, etc.	

ExperimentalUnit

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 study subject (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.

Connections

Connector	Source	Target	Notes
Association is participated in by	involving Activity	involved ExperimentalUnit	Each Activity sometimes is participated in by one ExperimentalUnit. Each ExperimentalUnit sometimes participates in one or more Activity.
Association is a function performed by	performed ExperimentalUnit	performing Product	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.
Association is a function performed by	performed ExperimentalUnit	performing BiologicEntity	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.
Association is a function performed by	performed ExperimentalUnit	performing BiologicSpecimen	Each ExperimentalUnit sometimes is a function performed by one BiologicSpecimen. Each

Connector	Source	Target	Notes
			BiologicSpecimen sometimes functions as one or more ExperimentalUnit. NOTE: An ExperimentalUnit can be represented by a BiologicEntity, BiologicEntityGroup, BiologicEntityPart, BiologicSpecimen, Product, or ProductGroup.
Association is a function performed by	performed ExperimentalUnit	performing BiologicEntityPart	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.

Attributes

Attribute	Notes	Constraints
identifier DSET<II>	A unique symbol that establishes identity of the experimental unit. For example, patient number 7 on a study.	
subgroupCode 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.	
statusCode CD	A coded value specifying the state of the experimental unit. For example, active, cancelled, pending, suspended, terminated, nullified.	

Attribute	Notes	Constraints
statusDate TS.DATETIME	The date (and time) on which the status is assigned to the experimental unit.	

Organizations

Organizations - *(Logical diagram)*

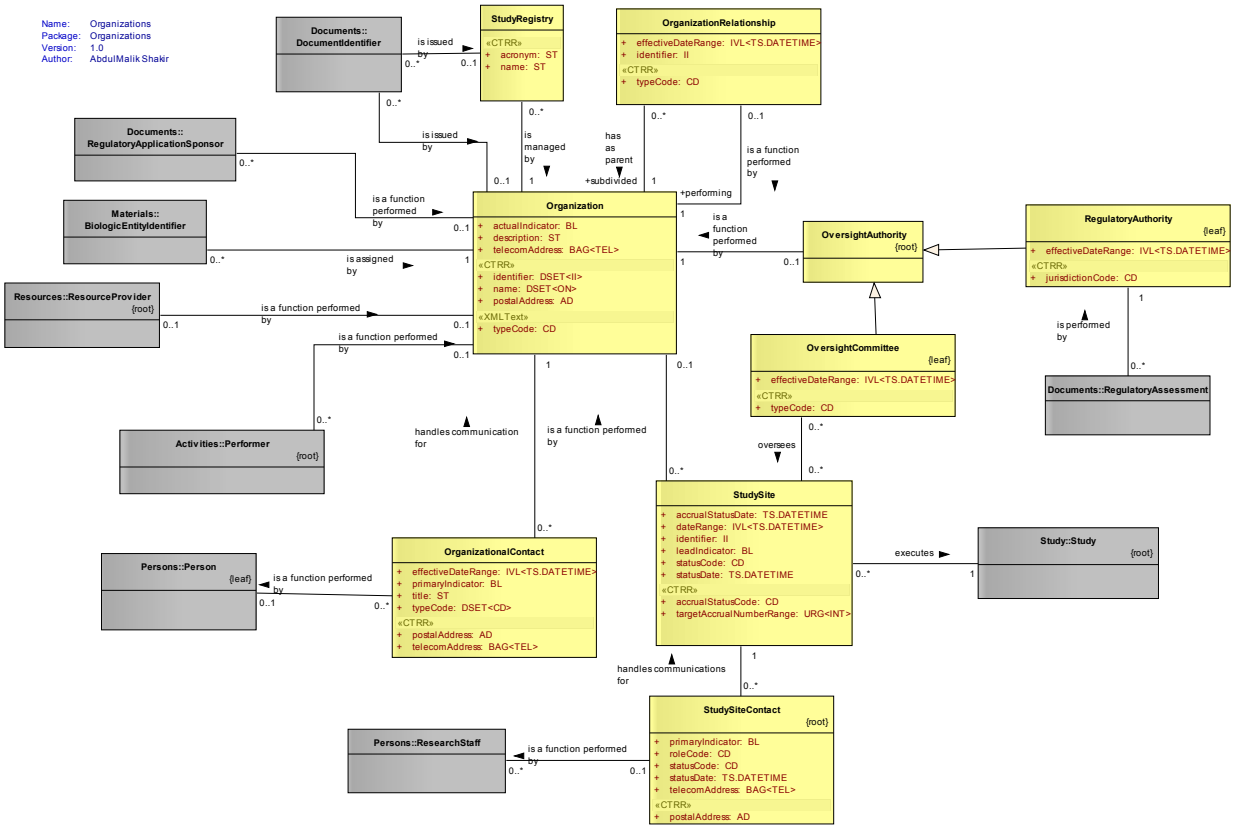

Figure: 13

Organization

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.

Connections

Connector	Source	Target	Notes
Association is managed by	managed StudyRegistry	managing Organization	Each StudyRegistry always is managed by one Organization.

Connector	Source	Target	Notes
			Each Organization sometimes manages one or more StudyRegistry.
Association is a function performed by	performed StudySite	performing Organization	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)
Association is a function performed by	performed ResourceProvider	performing Organization	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.
Association is issued by	issued DocumentIdentifier	issuing Organization	Each DocumentIdentifier sometimes is issued by one Organization. Each Organization sometimes issues one or more DocumentIdentifier.
Association is a function performed by	performed OversightAuthority	performing Organization	Each OversightAuthority always is a function performed by one Organization. Each Organization sometimes functions as one OversightAuthority.
Association is a function performed by	performed Performer	performing Organization	Each Performer sometimes is a function performed by one Organization. Each Organization sometimes functions as one or more Performer.
Association has as parent	subdividing OrganizationRelationship	subdivided Organization	Each OrganizationPart always has as parent one Organization. Each Organization sometimes is the parent for one or more OrganizationPart.
Association is assigned by	assigned BiologicEntityIdentifier	assigning Organization	Each BiologicEntityIdentifier always is assigned by one Organization. Each Organization sometimes assigns one or more BiologicEntityIdentifier.
Association is a function	performed	performing	Each OrganizationPart always is a

Connector	Source	Target	Notes
performed by	OrganizationRelationship	Organization	function performed by one Organization. Each Organization sometimes functions as one OrganizationPart.
Association handles communication for	supporting OrganizationalContact	supported Organization	Each OrganizationalContact always handles communication for one Organization. Each Organization sometimes has communications handled by one or more OrganizationalContact.
Association is a function performed by	performed RegulatoryApplicationSponsor	performing Organization	Each RegulatoryApplicationSponsor always is a function performed by one Organization. Each Organization always functions as one or more RegulatoryApplicationSponsor.

Attributes

Attribute	Notes	Constraints
actualIndicator 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.	
description ST	The textual representation of the organization.	
identifier DSET<II> «CTRR»	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.	

Attribute	Notes	Constraints
name DSET<ON> «CTRR»	A non-unique textual identifier for the organization.	
postalAddress AD «CTRR»	A contact point used to send physical forms of communication to the organization.	
telecomAddress 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.	
typeCode CD «XMLText»	A coded value specifying the kind of organization. For example, academic, pharmaceutical industry, government, other. EudraCT example: commercial, non-commercial.	

OrganizationRelationship

A subdivision within an organization.

Connections

Connector	Source	Target	Notes
Association has as parent	subdividing OrganizationRelationship	subdivided Organization	Each OrganizationPart always has as parent one Organization. Each Organization sometimes is the parent for one or more OrganizationPart.
Association is a function performed by	performed OrganizationRelationship	performing Organization	Each OrganizationPart always is a function performed by one Organization. Each Organization sometimes functions as one OrganizationPart.

Attributes

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the organization part is active.	
identifier II	A unique symbol that establishes identity of the organization part.	
typeCode CD «CTRR»	A coded value specifying the kind of organization part. For example, department, center, etc.	

OrganizationalContact

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

Connections

Connector	Source	Target	Notes
Association handles communication for	supporting OrganizationalContact	supported Organization	Each OrganizationalContact always handles communication for one Organization. Each Organization sometimes has communications handled by one or more OrganizationalContact.
Association is a function performed by	performed OrganizationalContact	performing Person	Each OrganizationalContact sometimes is a function performed by one Person. Each Person sometimes functions as one or more OrganizationalContact.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the organizational contact is active.	
postalAddress AD «CTRR»	A contact point used to send physical forms of communication to the organizational contact.	
primaryIndicator BL	Specifies whether this is the main or principal organizational contact.	
telecomAddress BAG<TEL> «CTRR»	A sequence of digits or characters used to identify a particular telephone, fax, or email of the organizational contact.	
title ST	A descriptive or distinctive appellation, especially one belonging to a person by right of rank, office, attainment, etc.	
typeCode DSET<CD>	A coded value specifying the kind of organizational contact. For example, safety, sales, financial, manufacturing, Review Board contact, etc.	

OversightAuthority

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.

Connections

Connector	Source	Target	Notes
Generalization specializes	RegulatoryAuthority	OversightAuthority	Each RegulatoryAuthority always specializes one OversightAuthority. Each OversightAuthority sometimes is specialized by one RegulatoryAuthority.
Generalization specializes	OversightCommittee	OversightAuthority	Each OversightCommittee always specializes one OversightAuthority. Each OversightAuthority sometimes is specialized by one OversightCommittee.
Association is a function performed by	performed OversightAuthority	performing Organization	Each OversightAuthority always is a function performed by one Organization. Each Organization sometimes functions as one OversightAuthority.

OversightCommittee

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

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

Connections

Connector	Source	Target	Notes
Association oversees	overseeing OversightCommittee	overseen StudySite	Each OversightCommittee sometimes oversees one or more StudySite. Each StudySite sometimes is overseen by one or more OversightCommittee.
Generalization specializes	OversightCommittee	OversightAuthority	Each OversightCommittee always specializes one OversightAuthority. Each OversightAuthority sometimes is specialized by one OversightCommittee.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the oversight committee is active.	
typeCode CD «CTRR»	A coded value specifying the kind of oversight committee. For example, Adjudication Committee, IRB, Data Safety Monitoring Board.	

RegulatoryAuthority

Governmental bodies that have the power to pass and enforce laws.

For example, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, the Food and Drug Administration (FDA) in the USA.

Connections

Connector	Source	Target	Notes
Generalization specializes	RegulatoryAuthority	OversightAuthority	Each RegulatoryAuthority always specializes one OversightAuthority. Each OversightAuthority sometimes is specialized by one RegulatoryAuthority.
Association is performed by	performed RegulatoryAssessment	performing RegulatoryAuthority	Each RegulatoryAssessment always is performed by one RegulatoryAuthority. Each RegulatoryAuthority sometimes performs one or more RegulatoryAssessment.

Attributes

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the regulatory authority is active.	

Attribute	Notes	Constraints
jurisdictionCode CD «CTRR»	A coded value specifying the area or limits an authority has to make laws and enforce them. For example, the FDA exercises responsibility for pharmacovigilance in the US.	

StudyRegistry

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 providers) how to enroll in the study.

Connections

Connector	Source	Target	Notes
Association is managed by	managed StudyRegistry	managing Organization	Each StudyRegistry always is managed by one Organization. Each Organization sometimes manages one or more StudyRegistry.
Association is issued by	issued DocumentIdentifier	issuing StudyRegistry	Each DocumentIdentifier sometimes is issued by one Registry. Each Registry sometimes issues one or more DocumentIdentifier.

Attributes

Attribute	Notes	Constraints
acronym ST «CTRR»	The non-unique initials or abbreviated name used for identification of the registry. For example, NTR (Netherlands National Trial Register)	
name ST «CTRR»	A non-unique textual identifier for the registry. For example, ClinicalTrials.gov	

StudySite

A facility in which study activities are conducted.

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

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

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed StudySite	performing Organization	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)
Association executes	executing StudySite	executes Study	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).
Association oversees	overseeing OversightCommittee	overseen StudySite	Each OversightCommittee sometimes oversees one or more StudySite. Each StudySite sometimes is overseen by one or more OversightCommittee.
Association handles communications for	communicating StudySiteContact	communicated StudySite	Each StudySiteContact always handles communications for one StudySite. Each StudySite sometimes has communications handled by one or more StudySiteContact.

Attributes

Attribute	Notes	Constraints
accrualStatusCode CD «CTRR»	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.	

Attribute	Notes	Constraints
accrualStatusDate TS.DATETIME	The date (and time) on which the accrual status is established.	
dateRange 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.	
identifier II	The unique symbol that establishes identity of the study site.	
leadIndicator 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.	
statusCode 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.	
statusDate TS.DATETIME	The date (and time) on which the status is assigned to the study site.	

Attribute	Notes	Constraints
targetAccrualNumberRange URG<INT> «CTRR»	A range of integers specifying the minimum and maximum number of patients/subjects/participants needed for enrollment at this site.	

StudySiteContact

A person who provides or receives information on behalf of a study site.

Connections

Connector	Source	Target	Notes
Association handles communications for	communicating StudySiteContact	communicated StudySite	Each StudySiteContact always handles communications for one StudySite. Each StudySite sometimes has communications handled by one or more StudySiteContact.
Association is a function performed by	performed StudySiteContact	performing ResearchStaff	Each StudySiteContact sometimes is a function performed by one or more ResearchStaff. Each ResearchStaff sometimes functions as one StudySiteContact.

Attributes

Attribute	Notes	Constraints
postalAddress AD «CTRR»	A contact point used to send physical forms of communication to the study site contact.	
primaryIndicator BL	Specifies whether this is the main or principal study site contact.	

Attribute	Notes	Constraints
roleCode CD	The coded value specifying a type of responsibility for a study site contact. For example, Principal Investigator, Sub Investigator, Facility.	
statusCode CD	A coded value specifying the state of the study site contact. For example, normal (active, cancelled, completed, pending) and nullified.	
statusDate TS.DATETIME	The date (and time) the status is assigned to the study site contact.	
telecomAddress BAG<TEL>	A sequence of digits or characters used to identify a particular telephone, fax, or email of a study site contact.	

Persons

Persons - *(Logical diagram)*

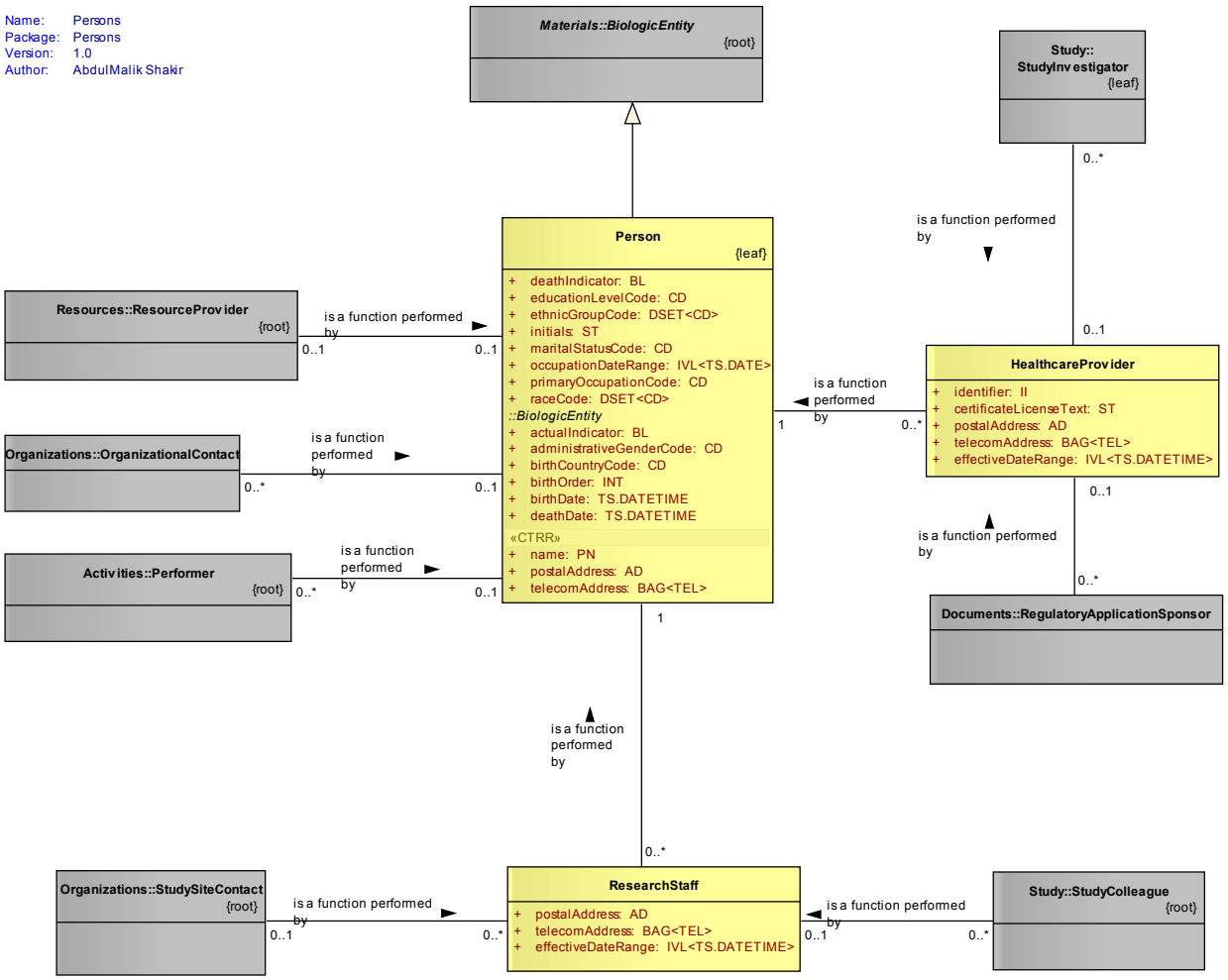

Figure: 14

Person

A human being.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed HealthcareProvider	performing Person	Each HealthcareProvider always is a function performed by one Person. Each Person sometimes functions as one or more HealthcareProvider.
Association is a function performed by	performed ResourceProvider	performing Person	Each ResourceProvider sometimes is a function performed by one Person. Each Person sometimes functions as one ResourceProvider.
Association is a function performed by	performed Performer	performing Person	Each Performer sometimes is a function performed by one Person. Each Person sometimes functions

Connector	Source	Target	Notes
			as one or more Performer. NOTE: A Performer may be played by either a Person, Organization or Device.
Generalization specializes	Person	BiologicEntity	Each Person always specializes one BiologicEntity. Each BiologicEntity sometimes is specialized by one Person.
Association is a function performed by	performed OrganizationalContact	performing Person	Each OrganizationalContact sometimes is a function performed by one Person. Each Person sometimes functions as one or more OrganizationalContact.
Association is a function performed by	performed ResearchStaff	performing Person	Each ResearchStaff always is a function performed by one Person. Each Person sometimes functions as one ResearchStaff.

Attributes

Attribute	Notes	Constraints
deathIndicator BL	Specifies whether the person is dead.	
educationLevelCode CD	A coded value specifying the highest level of education completed. For example, Less than High School Diploma, High School Diploma, Some College, etc.	
ethnicGroupCode 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.	

Attribute	Notes	Constraints
initials 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.	
maritalStatusCode CD	A coded value specifying the domestic partnership status of a person. For example, Married, Widowed, Single, Separated, etc.	
name PN «CTRR»	A non-unique textual identifier for the person. For example, proper name, nickname, legal name, etc.	
occupationDateRange 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.	
postalAddress AD «CTRR»	A contact point used to send physical forms of communication to the person.	
primaryOccupationCode CD	A coded value specifying the principal activity that a person does to earn money.	

Attribute	Notes	Constraints
raceCode 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.	
telecomAddress BAG<TEL> «CTRR»	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.	

ResearchStaff

Individual who is employed and/or involved in any aspect of conduct of protocol driven research.

For example, administrators, clinical and data managers, clinical research pharmacists, clinical research associates, clinical trials compliance coordinators, clinical trials specialists, laboratory technologists, nurses, research services consultants, study coordinators and others.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed ResearchStaff	performing Person	Each ResearchStaff always is a function performed by one Person. Each Person sometimes functions as one ResearchStaff.
Association is a function performed by	performed StudyColleague	performing ResearchStaff	Each StudyColleague sometimes is a function performed by one ResearchStaff. Each ResearchStaff sometimes functions as one or more StudyColleague. NOTE: a StudyColleague can be represented by either a ResearchStaff or a Person but not both.
Association is a function performed by	performed StudySiteContact	performing ResearchStaff	Each StudySiteContact sometimes is a function performed by one or more ResearchStaff. Each ResearchStaff sometimes functions as one StudySiteContact.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
postalAddress AD	A contact point used to send physical forms of communication to the research staff.	
telecomAddress BAG<TEL>	A sequence of digits or characters used to identify a particular telephone, fax, or email of the research staff.	
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the research staff is active.	

HealthcareProvider

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 healthcare in the ordinary course of business or practice of a profession.

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed HealthcareProvider	performing Person	Each HealthcareProvider always is a function performed by one Person. Each Person sometimes functions as one or more HealthcareProvider.
Association is a function performed by	performed StudyInvestigator	performing HealthcareProvider	Each StudyInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudyInvestigator.
Association is a function performed by	performed RegulatoryApplicationSponsor	performing HealthcareProvider	Each RegulatoryApplicationSponsor always is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more RegulatoryApplicationSponsor.

Attributes

Attribute	Notes	Constraints
identifier 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.	
certificateLicenseText ST	A character string that describes the credentials of the healthcare provider. For example, board certified, etc.	
postalAddress AD	A contact point used to send physical forms of communication to the healthcare provider.	
telecomAddress BAG<TEL>	A sequence of digits or characters used to identify a particular telephone, fax, or email of the healthcare provider.	
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the healthcare provider is active.	

Resources

Resources - *(Logical diagram)*

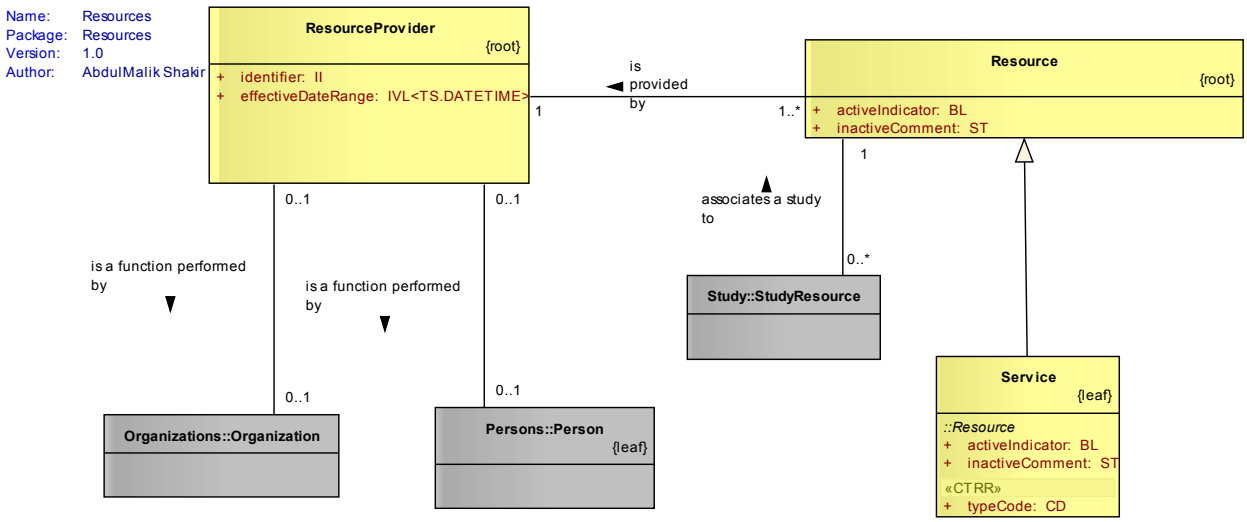

Figure: 15

Resource

Fiscal, material or labor support for research.

Connections

Connector	Source	Target	Notes
Association associates a study to	associating StudyResource	associated Resource	Each StudyResource always associates a study to one Resource. Each Resource sometimes is associated to a study by one or more StudyResource.
Generalization specializes	Service	Resource	Each Service always specializes one Resource. Each Resource sometimes is specialized by one Service.
Association is provided by	provided Resource	providing ResourceProvider	Each Resource always is provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource.

Attributes

Attribute	Notes	Constraints
activeIndicator BL	Specifies whether the resource is active.	

Attribute	Notes	Constraints
inactiveComment ST	Additional description why the resource is no longer active.	

ResourceProvider

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)

Connections

Connector	Source	Target	Notes
Association is a function performed by	performed ResourceProvider	performing Organization	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.
Association is a function performed by	performed ResourceProvider	performing Person	Each ResourceProvider sometimes is a function performed by one Person. Each Person sometimes functions as one ResourceProvider.
Association is provided by	provided Resource	providing ResourceProvider	Each Resource always is provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource.

Attributes

Attribute	Notes	Constraints
identifier II	A unique symbol that establishes identity of the resource provider.	

Attribute	Notes	Constraints
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the resource provider is active.	

Service

Labor support for research.

For example, protocol management, registration management, data management, and statistical management.

Connections

Connector	Source	Target	Notes
Generalization specializes	Service	Resource	Each Service always specializes one Resource. Each Resource sometimes is specialized by one Service.

Attributes

Attribute	Notes	Constraints
typeCode CD «CTRR»	A coded value specifying the kind of service. For example, Institutional Review Board (IRB) and Data Safety Monitoring Board (DSMB).	

Study

Studies - *(Logical diagram)*

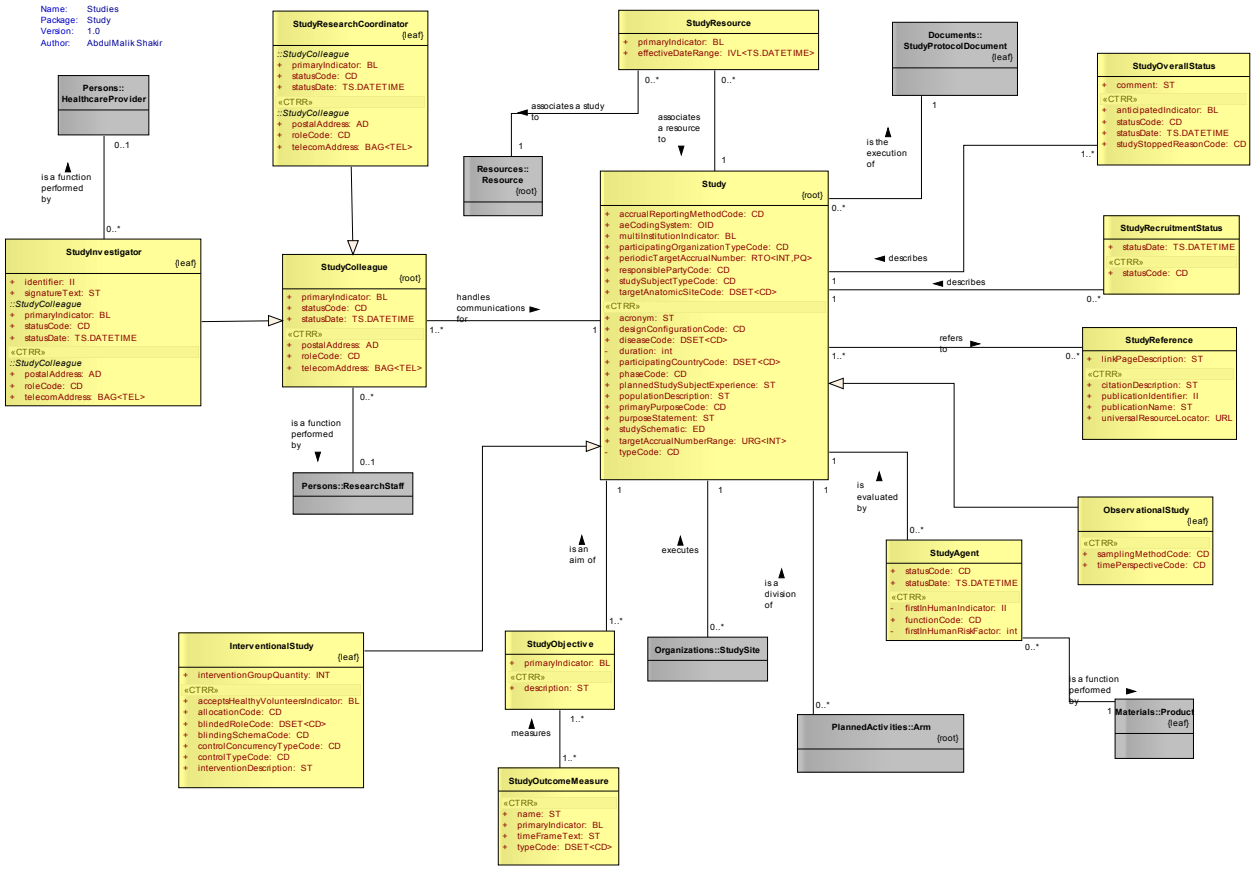

Figure: 16

InterventionalStudy

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. Study subjects 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.

Connections

Connector	Source	Target	Notes
Generalization specializes	InterventionalStudy	Study	Each InterventionalStudy always specializes one Study. Each Study sometimes is specialized by one InterventionalStudy.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
acceptsHealthyVolunteersIndicator BL «CTRR»	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.	
allocationCode CD «CTRR»	A coded value specifying the method of assigning subjects to treatment or control groups. For example, n/a, randomized controlled trial, non-randomized trial.	
blindedRoleCode DSET<CD> «CTRR»	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.	
blindingSchemaCode CD «CTRR»	A coded value specifying the type of masking used on a study 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 study subject 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.	
controlConcurrencyTypeCode CD «CTRR»	A coded value specifying the temporal relationships of the control to the study intervention. For example, concurrent, historical, pre/post (patient owned control).	

Attribute	Notes	Constraints
controlTypeCode CD «CTRR»	A coded value specifying the kind of comparison or comparator against which the study treatment is evaluated. For example, placebo, active, historical, uncontrolled, dose comparison.	
interventionDescription ST «CTRR»	A character string that provides the key details of the interventions. 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.)	
interventionGroupQuantity INT	An integer specifying the number of intervention groups. For example, enter 1 for single-arm study. NOTE: This attribute is potentially derivable once the study design has been defined.	

ObservationalStudy

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. Study subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the study subjects or experimental units of the study.

Connections

Connector	Source	Target	Notes
Generalization specializes	ObservationalStudy	Study	Each ObservationalStudy always specializes one Study. Each Study sometimes is specialized by one ObservationalStudy.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
samplingMethodCode CD «CTRR»	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.	
timePerspectiveCode CD «CTRR»	A coded value specifying the temporal relationship of observation period to time of subject enrollment. For example, prospective, retrospective, cross-sectional, other.	

StratumGroup

A designation used to segregate study subjects 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 study subjects to arms on a study.

Connections

Connector	Source	Target	Notes
Association randomizes	randomizing RandomizationBookEntry	randomized StratumGroup	Each RandomizationBookEntry always randomizes one StratumGroup. Each StratumGroup sometimes is randomized by one or more RandomizationBookEntry.

Attributes

Attribute	Notes	Constraints
groupNumber INT «CTRR»	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.	

Study

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.

Connections

Connector	Source	Target	Notes
Association executes	executing StudySite	executes Study	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).
Association is evaluated by	evaluated StudyAgent	evaluating Study	Each StudyAgent always is evaluated by one Study. Each Study sometimes is evaluating one or more StudyAgent.
Association is the execution of	instantiating Study	instantiated StudyProtocolDocument	Each Study always is the execution of one StudyProtocolDocument. Each StudyProtocolDocument sometimes is the plan for one or more Study.
Association refers to	referencing Study	referenced StudyReference	Each Study sometimes refers to one or more StudyReference. Each StudyReference always is referenced by one or more Study.
Association describes	describing StudyRecruitmentStatus	described Study	Each StudyRecruitmentStatus always describes one Study. Each Study sometimes is described by one or more StudyRecruitmentStatus.
Association describes	describing StudyOverallStatus	described Study	Each StudyOverallStatus always describes one Study. Each Study always is described by one or more StudyOverallStatus.
Association handles communications for	communicating StudyColleague	communicated Study	Each StudyColleague always handles communications for one Study. Each Study always has communications handled by one or more StudyColleague.
Association is a division	subdividing	subdivided	Each Arm always is a division of

Connector	Source	Target	Notes
of	Arm	Study	one Study. Each Study sometimes is divided into one or more Arm.
Association is an aim of	involved StudyObjective	involving Study	Each StudyObjective always is an aim of one Study. Each Study always aims to achieve one or more StudyObjective.
Generalization specializes	ObservationalStudy	Study	Each ObservationalStudy always specializes one Study. Each Study sometimes is specialized by one ObservationalStudy.
Generalization specializes	InterventionalStudy	Study	Each InterventionalStudy always specializes one Study. Each Study sometimes is specialized by one InterventionalStudy.
Association associates a resource to	associating StudyResource	associated Study	Each StudyResource always associates a resource to one Study. Each Study sometimes is associated to a resource by one or more StudyResource.

Attributes

Attribute	Notes	Constraints
accrualReportingMethodCode CD	A coded value specifying the technique that is used for reporting subject accrual data to the study sponsor. For example, complete, abbreviated.	
acronym ST «CTRR»	The non-unique initials or abbreviated name for identification of the study. For example, WHI for Women's Health Initiative	
aeCodingSystem OID	The coding system used for recording adverse events for a study.	

Attribute	Notes	Constraints
designConfigurationCode CD «CTRR»	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.	
diseaseCode DSET<CD> «CTRR»	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.	
duration int «CTRR»		
multiInstitutionIndicator 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.	
participatingCountryCode DSET<CD> «CTRR»	A coded value specifying the countries from which participants will be, are intended to be, or have been recruited for the study.	

Attribute	Notes	Constraints
participatingOrganizationTypeCode CD	A coded value specifying the kind of organizations planned to participate as study sites for this study. For example, Cancer Center, Clinical Center, Consortium, Group, Intergroup, Multi-Center, Network, or Single Institution.	
periodicTargetAccrualNumber 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.	
phaseCode CD «CTRR»	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	

Attribute	Notes	Constraints
	drug's risks, benefits, and optimal use. Phase 5: Post-marketing surveillance is sometimes referred to as Phase 5.	
plannedStudySubjectExperience ST «CTRR»	Sequence and duration of study epochs, including pre-randomization and post-treatment epochs, therapy withdrawal epochs, and single- and double-blind treatment epochs.	
populationDescription ST «CTRR»	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.	
primaryPurposeCode CD «CTRR»	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.	
purposeStatement ST «CTRR»	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.	

Attribute	Notes	Constraints
responsiblePartyCode 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.	
studySchematic ED «CTRR»	Diagram which outlines all study epochs, timing of randomization and duration of treatments.	
studySubjectTypeCode 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).	
targetAccrualNumberRange URG<INT> «CTRR»	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.	
targetAnatomicSiteCode DSET<CD>	A coded value specifying the anatomic location that is the focus of a study. For example, breast, ovary.	
typeCode CD «CTRR»		

StudyAgent

A product that is being used or tested as part of a study.

For example, Tamoxifen used in a breast cancer study, fish oil used in a heart health study, artificial knee joints used in a joint replacement study.

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

Connections

Connector	Source	Target	Notes
Association is evaluated by	evaluated StudyAgent	evaluating Study	Each StudyAgent always is evaluated by one Study. Each Study sometimes is evaluating one or more StudyAgent.
Association is a function performed by	performed StudyAgent	performing Product	Each StudyAgent always is a function performed by one Product. Each Product sometimes functions as one or more StudyAgent.

Attributes

Attribute	Notes	Constraints
firstInHumanIndicator II «CTRR»		
functionCode CD «CTRR»	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.	
statusCode CD	A coded value specifying the state of the study agent. For example, pending, active, complete, or cancelled.	

Attribute	Notes	Constraints
statusDate TS.DATETIME	The date (and time) on which the status is assigned to the study agent.	
firstInHumanRiskFactor int «CTRR»		

StudyColleague

A person who performs a particular role within the context of a specific study.

For example, Study Principal Investigator, Coordinating Investigator, Study Director, Study Chair, Public Queries, Scientific Queries, Scientific Leadership.

Connections

Connector	Source	Target	Notes
Generalization specializes	StudyInvestigator	StudyColleague	Each StudyInvestigator always specializes one StudyColleague. Each StudyColleague sometimes is specialized by one StudyInvestigator.
Association handles communications for	communicating StudyColleague	communicated Study	Each StudyColleague always handles communications for one Study. Each Study always has communications handled by one or more StudyColleague.
Generalization specializes	StudyResearchCoordinator	StudyColleague	Each StudyResearchCoordinator always specializes one StudyColleague. Each StudyColleague sometimes is specialized by one StudyResearchCoordinator.
Association is a function performed by	performed StudyColleague	performing ResearchStaff	Each StudyColleague sometimes is a function performed by one ResearchStaff. Each ResearchStaff sometimes functions as one or more StudyColleague. NOTE: a StudyColleague can be represented by either a ResearchStaff or a Person but not both.

Connector	Source	Target	Notes

Attributes

Attribute	Notes	Constraints
postalAddress AD «CTRR»	A contact point used to send physical forms of communication to the study colleague.	
primaryIndicator BL	Specifies whether this is the main or principal study colleague.	
roleCode CD «CTRR»	A coded value specifying the type of responsibility of the study colleague. For example, Study Principal Investigator, Coordinating Investigator, Study Director, Study Chair, Public Queries, Scientific Queries, Scientific Leadership.	
statusCode CD	A coded value specifying the state of the study colleague. For example, normal (active, cancelled, completed, pending) and nullified.	
statusDate TS.DATETIME	The date and time on which a status is assigned to the study colleague.	
telecomAddress BAG<TEL> «CTRR»	A sequence of digits or characters used to identify a particular telephone, fax, or email of the study colleague.	

StudyObjective

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

Connections

Connector	Source	Target	Notes
Association measures	measuring StudyOutcomeMeasure	measured StudyObjective	Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is measured by one or more StudyOutcomeMeasure.
Association is an aim of	involved StudyObjective	involving Study	Each StudyObjective always is an aim of one Study. Each Study always aims to achieve one or more StudyObjective.

Attributes

Attribute	Notes	Constraints
description ST «CTRR»	The textual representation of the study objective.	
primaryIndicator BL	Specifies whether this is a main or principal study objective.	

StudyOutcomeMeasure

Specific key measurement(s) or observation(s) used to measure the effect of experimental variables on the subjects 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.

Connections

Connector	Source	Target	Notes
Association measures	measuring StudyOutcomeMeasure	measured StudyObjective	Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is measured by one or more StudyOutcomeMeasure.

Attributes

Attribute	Notes	Constraints
name ST «CTRR»	A non-unique textual identifier for the study outcome measure. For example, all cause mortality.	
primaryIndicator BL «CTRR»	Specifies whether this is the main or principal study outcome measure.	
timeFrameText ST «CTRR»	Time point(s) at which the study outcome measure is assessed. For example, one year.	
typeCode DSET<CD> «CTRR»	A coded value specifying the type of study outcome measure. For example, n/a, safety, efficacy, bio-equivalence, bio-availability, pharmacokinetics, pharmacodynamics.	

StudyOverallStatus

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.

Connections

Connector	Source	Target	Notes
Association describes	describing StudyOverallStatus	described Study	Each StudyOverallStatus always describes one Study. Each Study always is described by one or more StudyOverallStatus.

Attributes

Attribute	Notes	Constraints

Attribute	Notes	Constraints
anticipatedIndicator BL «CTRR»	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.	
comment ST	Additional description of the overall status of the study.	
statusCode CD «CTRR»	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.	
statusDate TS.DATETIME «CTRR»	The date (and time) on which the overall status of the study is assigned.	
studyStoppedReasonCode CD «CTRR»	A coded value specifying why the study has been halted or terminated (for suspended, terminated or withdrawn studies).	

StudyRecruitmentStatus

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

Connections

Connector	Source	Target	Notes
Association describes	describing StudyRecruitmentStatus	described Study	Each StudyRecruitmentStatus always describes one Study. Each Study sometimes is described by one or more StudyRecruitmentStatus.

Connector	Source	Target	Notes

Attributes

Attribute	Notes	Constraints
statusCode CD «CTRR»	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.	
statusDate TS.DATETIME	The date (and time) on which the recruitment status is assigned.	

StudyReference

A citation to a publication 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.

Connections

Connector	Source	Target	Notes
Association refers to	referencing Study	referenced StudyReference	Each Study sometimes refers to one or more StudyReference. Each StudyReference always is referenced by one or more Study.

Attributes

Attribute	Notes	Constraints
citationDescription ST «CTRR»	A biblographical reference in a format acceptable to the registration authority. For example, studies performed in the United States may be required to conform to the National Library of Medicine's MEDLINE format.	

Attribute	Notes	Constraints
linkPageDescription ST	The textual representation of the linked page. For example, 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.	
publicationIdentifier II «CTRR»	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.	
publicationName ST «CTRR»	A non-unique textual identifier specifying the source of the publication identifier. For example, MEDLINE is the source for PMID 10987815	
universalResourceLocator URL «CTRR»	A complete reference to a website (including http://) that is directly relevant to the study. For example, "http://www.alzheimers.org/".	

StudyResearchCoordinator

A person who handles the administrative responsibilities of a study on behalf of the study investigator, acts as a liaison between study site and study sponsor, and reviews all data and records before a monitor's visit.

For example, trial coordinator, study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse.

NOTE: At some sites (primarily in academic settings) Clinical Research Coordinators are called (Clinical Research Associates) CRAs.

Connections

Connector	Source	Target	Notes
Generalization specializes	StudyResearchCoordinator	StudyColleague	Each StudyResearchCoordinator always specializes one StudyColleague. Each StudyColleague sometimes is specialized by one StudyResearchCoordinator.

StudyInvestigator

A researcher in a study who oversees multiple 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.

Connections

Connector	Source	Target	Notes
Generalization specializes	StudyInvestigator	StudyColleague	Each StudyInvestigator always specializes one StudyColleague. Each StudyColleague sometimes is specialized by one StudyInvestigator.
Association is a function performed by	performed StudyInvestigator	performing HealthcareProvider	Each StudyInvestigator sometimes is a function performed by one HealthcareProvider. Each HealthcareProvider sometimes functions as one or more StudyInvestigator.

Attributes

Attribute	Notes	Constraints
identifier II	A unique symbol that establishes identity of the study investigator.	
signatureText 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 activity as a specified role and that he or she agrees to assume the associated accountability.	

StudyResource

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

Connections

Connector	Source	Target	Notes
Association associates a study to	associating StudyResource	associated Resource	Each StudyResource always associates a study to one Resource. Each Resource sometimes is associated to a study by one or more StudyResource.
Association associates a	associating	associated	Each StudyResource always

Connector	Source	Target	Notes
resource to	StudyResource	Study	associates a resource to one Study. Each Study sometimes is associated to a resource by one or more StudyResource.

Attributes

Attribute	Notes	Constraints
primaryIndicator BL	Specifies whether this is the main or principal study resource. For example, this distinguishes between an organization that is the primary funder vs. a funder who provides less money for a study.	
effectiveDateRange IVL<TS.DATETIME>	The date and time span for when the study resource is active.	

CTRR DAM Objects

CTRR DAM objects is a specification of the information objects of interest to the clinical trial registration and results reporting domain.

Objects are an instantiation of classes depicted in the CTRR DAM classes specification and information flows included in CTRR DAM activities and interaction specifications.

CTRR DAM Objects - *(Package diagram)*

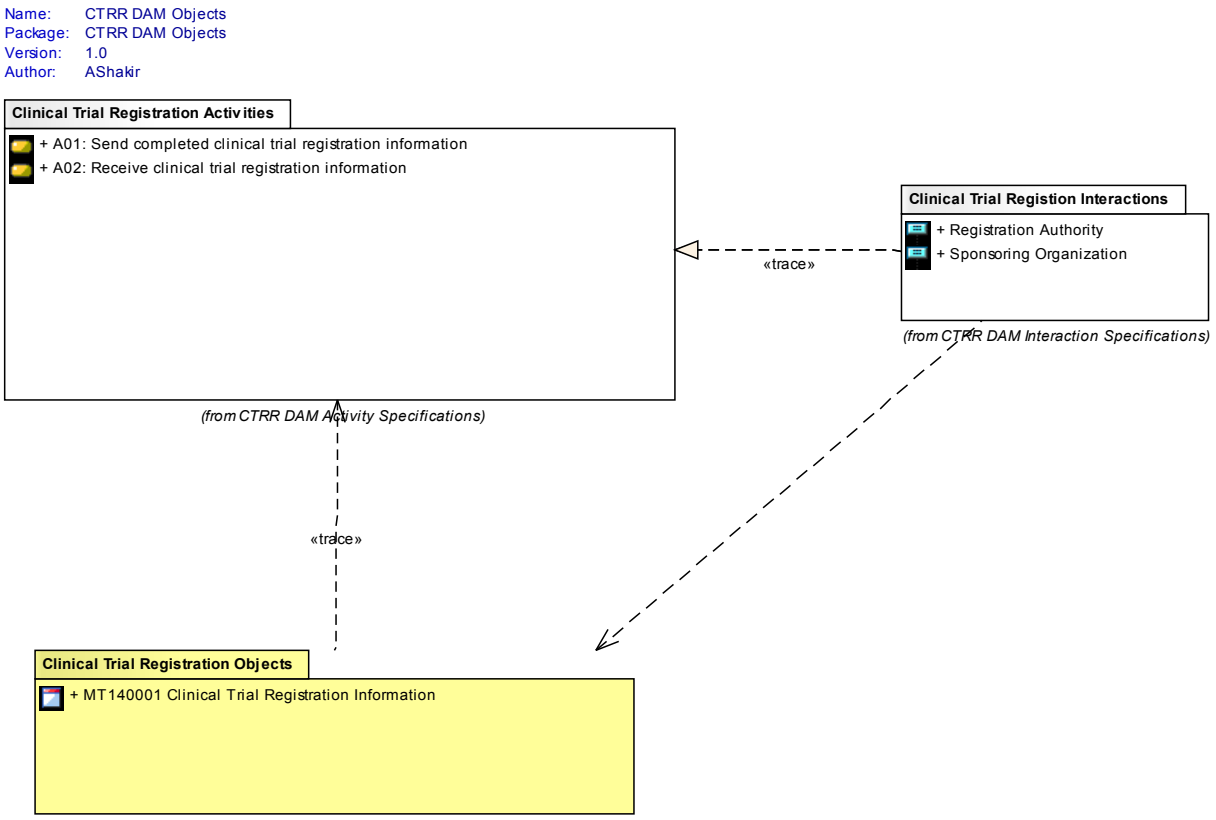

Figure: 17

Clinical Trial Registration Objects

The CTRR DAM registration objects are the set of objects referenced in the clinical trial registration activities and interactions specifications.

Clinical Trial Registration Objects - *(Object diagram)*

Name: Clinical Trial Registration Objects
Package: Clinical Trial Registration Objects
Version: 1.0
Author: AbdulMalik Shakir

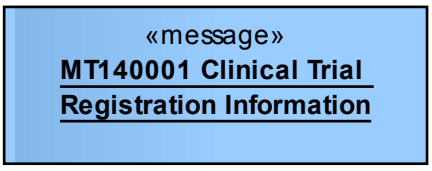

Figure: 18

MT140001 Clinical Trial Registration Information

Clinical trial descriptive information for use in registering a clinical trial with a clinical trail registration authority.

Connections

Connector	Source	Target	Notes
Information Flow	MT140001 Clinical Trial Registration Information	A02: Receive clinical trial registration information	
Information Flow	A01: Send completed clinical trial registration information	MT140001 Clinical Trial Registration Information	

