



BRIDG Model

<http://www.bridgmodel.org>

Release 5.0.1 BRIDG Model Report

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Biomedical Research Integrated Domain Group (BRIDG)

prepared by

Wendy Ver Hoef, Smita Hastak & Julie Evans
(Samvit Solutions/NCI [C]/HL7)
on behalf of the
HL7 Biomedical Research and Regulation (BR&R) Work Group



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BRIDG Domain Information Model

Package in package 'Model'

BRIDG Domain Information Model

UML-Based Comprehensive BRIDG Model Diagram diagram

Class diagram in package 'BRIDG Domain Information Model'

This View shows the complete BRIDG Model (current Release) and specifically shows, for each class where it's applicable, the complete set of attributes for the class, partitioning the attributes as to whether they are "local" to the class or inherited from the class' super-type hierarchy.

Please Note: This comprehensive view of the BRIDG model is not intended for users to learn the model. It is created by the BRIDG modelers to ensure model integrity. It is highly recommended that you look at the sub-domain views to learn and review the concepts and relationships in the BRIDG model.

UML-Based Comprehensive BRIDG Model Diagram

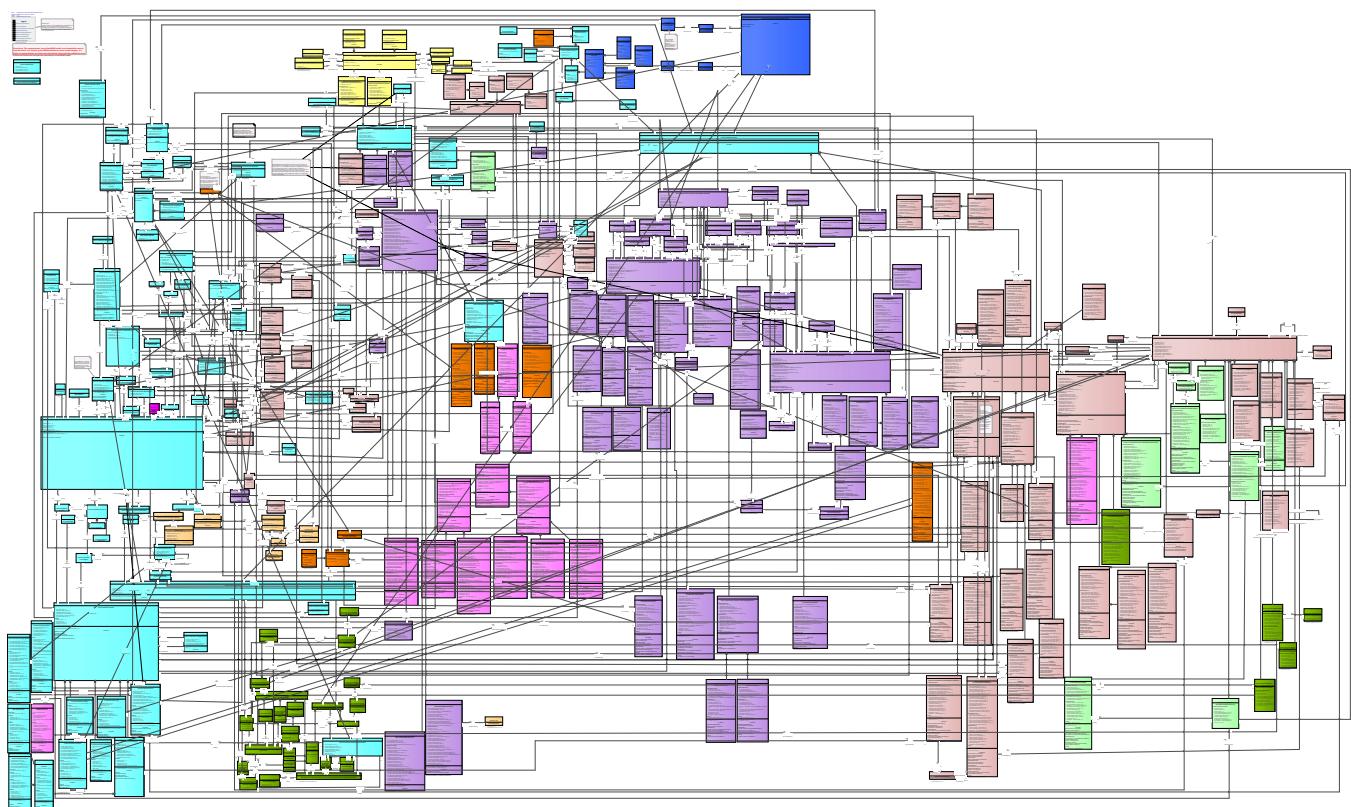


Figure 1: UML-Based Comprehensive BRIDG Model Diagram

BRIDG Sub-Domain Packages Diagram diagram

Class diagram in package 'BRIDG Domain Information Model'

BRIDG Sub-Domain Packages Diagram

Name: BRIDG Sub-Domain Packages Diagram
 Package: BRIDG Domain Information Model
 Version: 4.1
 Author: BRIDG SCC

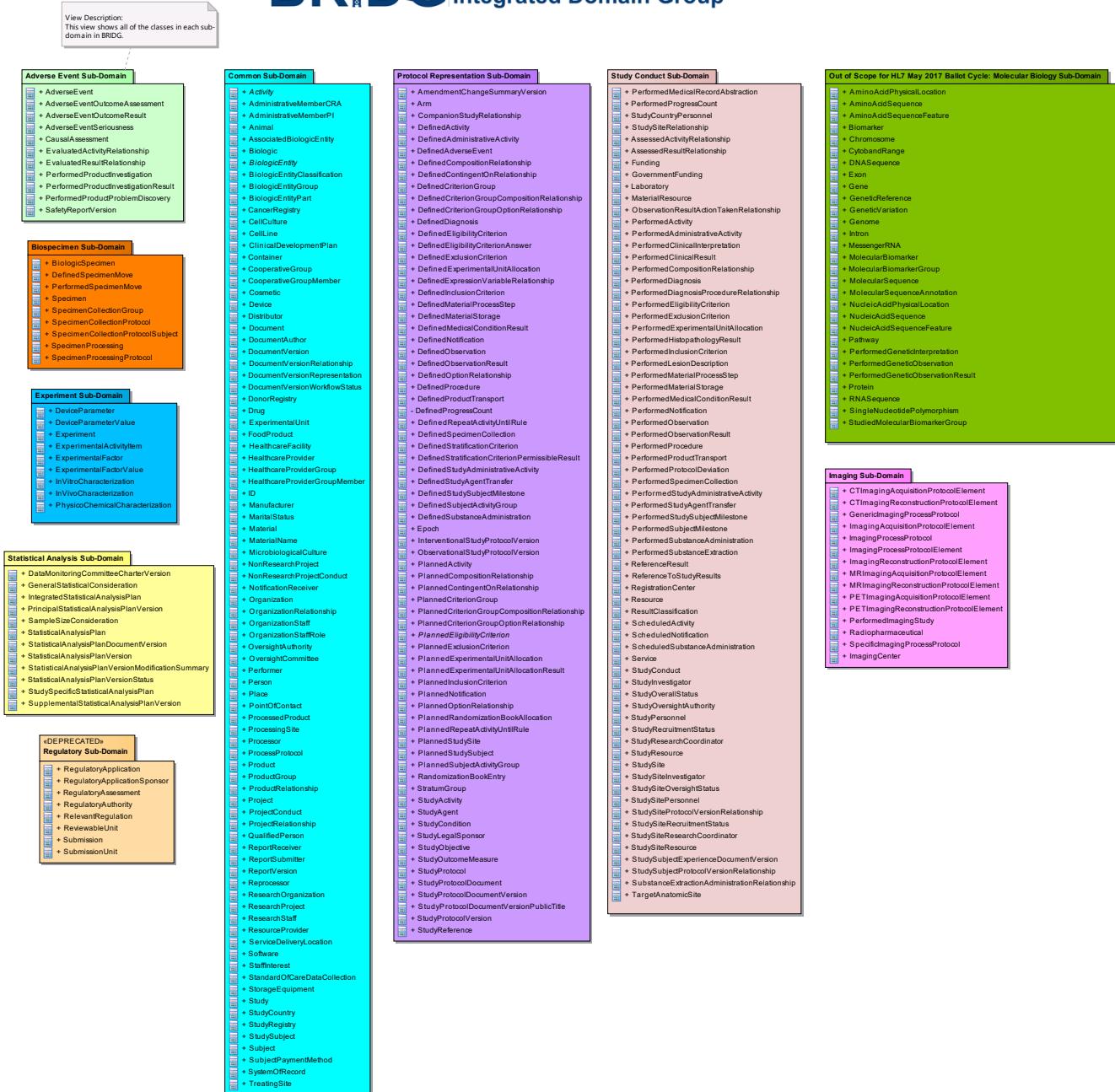


Figure 2: BRIDG Sub-Domain Packages Diagram

Adverse Event Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Adverse Event sub-domain is intended for those involved in safety related activities; such as detection, evaluation, follow-up and reporting. This includes safety issues involving people or products. It also includes activities during or after a research protocol.

Adverse Event Sub-Domain

View AE: Adverse Event diagram

Class diagram in package 'Adverse Event Sub-Domain'

The Adverse Event sub-domain is intended for those involved in safety related activities; such as detection, evaluation, follow-up and reporting. This includes safety issues involving people or products. It also includes activities during or after a research protocol.

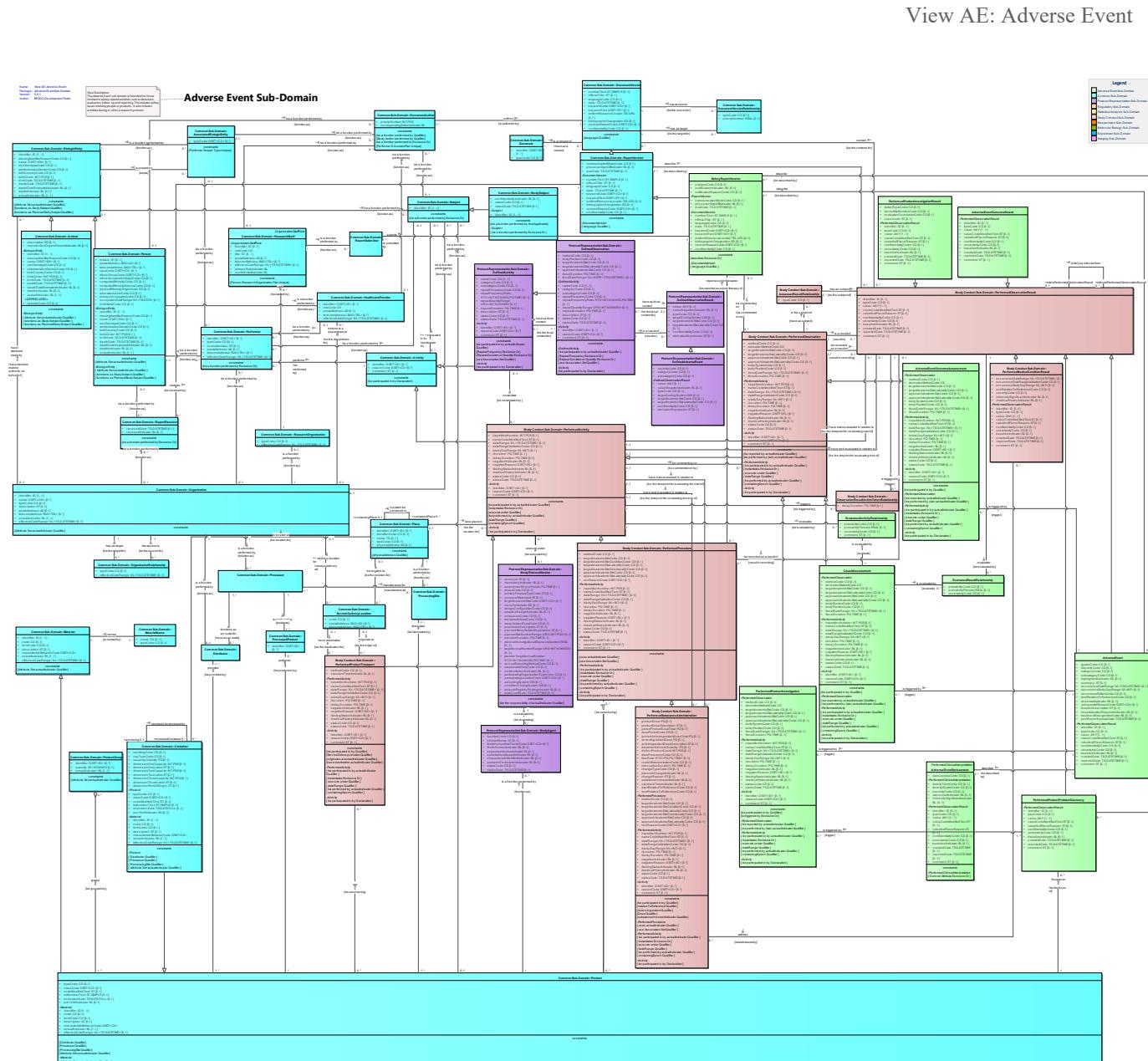


Figure 3: View AE: Adverse Event

Class: AdverseEvent

Package: Adverse Event Sub-Domain

DEFINITION:

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

EXAMPLE(S):

death, back pain, headache, pulmonary embolism, heart attack

OTHER NAME(S):**NOTE(S):**

The BRIDG SCC has a GForge Tracker Issue (#31893) indicating a need to validate the requirement that every AdverseEvent be described by a SafetyReportVersion.

Tagged Values:

- Map:AE = AdverseEvent
- Map:caAERSv2.2 = AdverseEvent
- Map:caAERSv2.2 = ReportedAdverseEvent
- Map:CTRv1.0 = AdverseEvent
- Map:ICSRr2 = AdverseEventAssessment (in IndividualCaseSafetyReport)
- Map:NCI CRF Standard = AdverseEvent
- Map:PSCv2.6 = AdverseEvent
- Map:SDTM IGv3.1.2 = AE.DOMAIN
- Map:SDTM IGv3.1.3 = AE
- Map:TDM = Incidents

Connectors

Source	Connector	Target	Notes
AdverseEvent	specializes	PerformedObservationResult	<p>DESCRIPTION: Each AdverseEvent always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one AdverseEvent.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdverseEventSeriousness 0..* describingAdverseEventSeriousness	describes	AdverseEvent 1 describedAdverseEvent	<p>DESCRIPTION: Each AdverseEventSeriousness always describes one AdverseEvent. Each AdverseEvent might be described by one or more AdverseEventSeriousness.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CausalAssessment 0..* triggeredCausalAssessment	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION: Each CausalAssessment always is triggered by one AdverseEvent. Each AdverseEvent might trigger</p>

Source	Connector	Target	Notes
			<p>one or more CausalAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdverseEventOutcomeAssessment 0..* triggeredAdverseEventOutcomeAssessment	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION: Each AdverseEventOutcomeAssessment always is triggered by one AdverseEvent. Each AdverseEvent might trigger one or more AdverseEventOutcomeAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SafetyReportVersion 0..* describingSafetyReportVersion	describe	AdverseEvent 0..* describedAdverseEvent	<p>DESCRIPTION: Each SafetyReportVersion might describe one or more AdverseEvent. Each AdverseEvent might be described by one or more SafetyReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductInvestigation 0..* triggeredPerformedProductInvestigation	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION: Each PerformedProductInvestigation always is triggered by one AdverseEvent. Each AdverseEvent might trigger one or more PerformedProductInvestigation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
gradeCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the level of injury suffered by the subject for whom the event is reported.</p> <p>EXAMPLE(S): The gradeCode could be 3 if the CTCAE coding system is being used.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedClinicalInterpretation.value(ANY=>CD).code WHERE PerformedObservationResult > PerformedObservation > DefinedObservation.nameCode = "grade assessment"</p>	Map:AE = AdverseEvent.gradeOrSeverity Map:caAERSv2.2 = AdverseEvent.grade Map:CDASHv1.1 = AE.AETOXGR Map:CTOM = AdverseEvent.ctcGradeCode Map:CTOM = AdverseEvent.ctcGradeCodeSystem Map:CTRv1.0 = AdverseEvent.gradeCode Map:NCI CRF Standard = CDE 2201188v1.0: Common Toxicity Criteria Adverse Event Reporting Grade Map:NCI CRF Standard = CDE 2944515v1.0: Adverse Event Severity Grade Map:PSCv2.6 = AdverseEvent.description Map:SDTM IGv3.1.1 = AE.AETOXGR Map:SDTM IGv3.1.2 = AE.AETOXGR Map:SDTM IGv3.1.3 = AE.AETOXGR
severityCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the intensity of the event.</p> <p>EXAMPLE(S): Moderate could be used to describe acne.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the maximum severity observed during the course of the AdverseEvent: PerformedClinicalInterpretation.value(ANY=>CD).code WHERE PerformedClinicalInterpretation > PerformedObservation > DefinedObservation.nameCode = "assess severity" AND PerformedObservation > AssessedResultRelationship > AdverseEvent.</p>	Map:AE = AdverseEvent.gradeOrSeverity Map:CDASHv1.1 = AE.AESEV Map:CTRv1.0 = AdverseEvent.severityCode Map:PSCv2.6 = AdverseEvent.description Map:SDTM IGv3.1.1 = AE.AESEV Map:SDTM IGv3.1.2 = AE.AESEV Map:SDTM IGv3.1.3 = AE.AESEV

Attribute	Notes	Constraints and Tags
categoryCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying a classification of the adverse event.</p> <p>EXAMPLE(S): bleeding, hypoglycemia</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p>	Map:CTRv1.0 = AdverseEvent.categoryCode Map:SDTM IGv3.1.1 = AE.AECAT Map:SDTM IGv3.1.2 = AE.AECAT Map:SDTM IGv3.1.3 = AE.AECAT
subcategoryCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying a subdivision within a larger category of an adverse event.</p> <p>EXAMPLE(S): neurologic</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p>	Map:CTRv1.0 = AdverseEvent.subcategoryCode Map:SDTM IGv3.1.1 = AE.AESCAT Map:SDTM IGv3.1.2 = AE.AESCAT Map:SDTM IGv3.1.3 = AE.AESCAT
highlightedIndicator <i>Class:</i> AdverseEvent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the adverse event or reaction term is a major concern or reason for reporting the adverse event.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = AdverseEvent.highlightedIndicator Map:CTRv1.0 = AdverseEvent.highlightedIndicator
summary <i>Class:</i> AdverseEvent <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A description of the adverse event and the treatment of the event.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = AdverseEventResponseDescription.eventDescription Map:CTRv1.0 = AdverseEvent.summary

Attribute	Notes	Constraints and Tags
occurrenceDateRange <i>Class:</i> AdverseEvent <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span in which the adverse event began and ended.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): onset date, resolution date, duration</p> <p>NOTE(S): These may be partial dates or durations (duration is the width property of the IVL<TS> data type).</p>	Map:AE = AdverseEvent.onsetDate Map:AE = AdverseEvent.resolutionDate Map:caAERSv2.2 = AdverseEvent.eventApproximateTime Map:caAERSv2.2 = AdverseEvent.startDate Map:caAERSv2.2 = AdverseEvent.endDate Map:CDASHv1.1 = AE.AEENDAT Map:CDASHv1.1 = AE.AEENTIM Map:CDASHv1.1 = AE.AESTDAT Map:CDASHv1.1 = AE.AESTTIM Map:CTOM = AdverseEvent.resolvedDate Map:CTOM = AdverseEvent.onsetDate Map:NCI CRF Standard = CDE 2189843v1.0: Adverse Event Resolved Alpha DVG Date Map:NCI CRF Standard = CDE 2746301v1.0: Adverse Event Resolution Time Map:NCI CRF Standard = CDE 2585234v1.0: Adverse Event Onset Time Map:NCI CRF Standard = CDE 2744993v1.0: Adverse Event Onset Date Map:SDTM IGv3.1.1 = AE.AESTDTC Map:SDTM IGv3.1.1 = AE.AEENDTC Map:SDTM IGv3.1.2 = AE.DUR Map:SDTM IGv3.1.2 = AE.AEDUR Map:SDTM IGv3.1.2 = AE.AEENRTPT Map:SDTM IGv3.1.2 = AE.AEENRF Map:SDTM IGv3.1.2 = AE.AESTDTC Map:SDTM IGv3.1.2 = AE.AEENDTC Map:SDTM IGv3.1.3 = AE.AEDUR Map:SDTM IGv3.1.3 = AE.AESTDTC Map:SDTM IGv3.1.3 = AE.AEENDTC

Attribute	Notes	Constraints and Tags
occurrenceStudyDayRange <i>Class:</i> AdverseEvent <i>Datatype:</i> IVL<INT> <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The relative timing for an adverse event expressed as the number of days offset from the study-defined reference activity (e.g., date of registration, start of treatment) for this particular experimental unit.</p> <p>EXAMPLE(S): Day 1, Days 10-20</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the occurrenceDateRange of this adverse event minus the dateRange of the reference activity + 1.</p> <p>The study-defined reference activity can be different from study to study. The study day for a date after this reference activity is a positive integer calculated as the difference in the two dates + 1. The study day for dates before the reference activity is a negative integer calculated as the difference between the two dates. Note that this means there is no "Day 0."</p>	Map:SDTM IGv3.1.3 = AE.AESTDY Map:SDTM IGv3.1.3 = AE.AEENDY
occurrencePatternCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the time recurrence by which an adverse event occurs.</p> <p>EXAMPLE(S): intermittent, continuous, single event</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = AdverseEvent.patternCode Map:caAERSv2.2 = AdverseEventResponseDescription.eventReappear Map:CTOM = AdverseEvent.conditionPatternCode Map:CTrv1.0 = AdverseEvent.occurrencePatternCode Map:NCI CRF Standard = CDE 2008418v1.0: Adverse Event Condition Pattern Map:PSCv2.6 = AdverseEvent.description Map:SDTM IGv3.1.1 = AE.AEPATT Map:SDTM IGv3.1.2 = AE.AEPATT Map:SDTM IGv3.1.3 = AE.AEPATT

Attribute	Notes	Constraints and Tags
endRelativeToReferenceCode <i>Class:</i> AdverseEvent <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the end of the adverse event with respect to the sponsor-defined reference period.</p> <p>EXAMPLE(S): before, during, during/after, after</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sponsors should define the reference period in the study metadata. This may be populated when a start date is not collected.</p> <p>Derived from AdverseEvent.occurrenceDateRange.IVL<TS.DATETIME>.high.TS.DATETIME.uncertainRange.IVL<TS.DATETIME>.high = PerformedStudySubjectMilestone.studyReferenceDateRange then "BEFORE" AND AdverseEvent.occurrenceDateRange.IVL<TS.DATETIME>.low.TS.DATETIME.uncertainRange.IVL<TS.DATETIME>.low = PerformedStudySubjectMilestone.studyReferenceDateRange then "AFTER"</p>	Map:PSCv2.6 = AdverseEvent.description Map:SDTM IGv3.1.1 = AE.ENRF Map:SDTM IGv3.1.2 = AE.ENRF Map:SDTM IGv3.1.3 = AE.AEENRF
expectedIndicator <i>Class:</i> AdverseEvent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the specificity (nature), frequency, or severity of an adverse event is consistent with the applicable study documentation (e.g., investigator's brochure, protocol document, or consent document) or product labeling (package insert).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = AdverseEvent.expectedIndicator Map:caAERSv2.2 = AdverseEvent.expected Map:CTRpV1.0 = AdverseEvent.expectedIndicator Map:CTRv1.0 = AdverseEvent.expectedIndicator Map:NCI CRF Standard = CDE 2183619v1.0: Adverse Event Expected Indicator
unexpectedReasonCode <i>Class:</i> AdverseEvent <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying why an adverse event (experience or reaction) is considered unanticipated.</p> <p>EXAMPLE(S): severity, frequency, or specificity from what has been previously documented</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = AdverseEvent.unexpectedReason Map:CTRv1.0 = AdverseEvent.unexpectedReasonCode Map:PSCv2.6 = AdverseEvent.description

Attribute	Notes	Constraints and Tags
locationDescription <i>Class:</i> AdverseEvent <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The textual representation of the physical location of the subject when the adverse event began. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = AdverseEvent.eventLocation Map:CTRv1.0 = AdverseEvent.locationDescription
hospitalizationRequiredIndicator <i>Class:</i> AdverseEvent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Specifies whether the subject requires hospitalization or prolongation of existing hospitalization as a result of the adverse event. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = AdverseEvent.hospitalizationRequired Indicator Map:caAERSv2.2 = AdverseEvent.hospitalization Map:CTRv1.0 = AdverseEvent.hospitalizationRequired Indicator Map:NCI CRF Standard = CDE 2552398v1.0: Patient Toxicity Hospitalization Indicator Map:SDTM IGV3.1.1 = AE.AESHOSP
treatmentEmergentIndicator <i>Class:</i> AdverseEvent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Specifies whether the adverse event is something that first arose or became more severe during the studied treatment. EXAMPLE(S): OTHER NAME(S): NOTE(S): This may be derivable if a complete subject history exists and it can be known with certainty whether (and with what severity) a condition may have pre-existed. However, this information is not always available and therefore the attribute has not been marked as derived.	Map:CTRv1.0 = AdverseEvent.treatmentEmergentIndicator
postReportUpdateDate <i>Class:</i> AdverseEvent <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the adverse event was updated after it had been submitted. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = AdverseEvent.postSubmissionUpdated Date Map:CTRv1.0 = AdverseEvent.postReportUpdateDate

Class: AdverseEventOutcomeAssessment

Package: Adverse Event Sub-Domain

DEFINITION:

The completed action of evaluating the final state of a subject who experienced an adverse event, which takes place after the adverse event occurs.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The final state can occur at any point in the study if the adverse event resolves, otherwise it occurs at the final visit.

Tagged Values:

- Map:AE = Outcome
- Map:CTRv1.0 = AdverseEventOutcomeAssessment

Connectors

Source	Connector	Target	Notes
AdverseEventOutcomeAssessment	specializes	PerformedObservation	<p>DESCRIPTION: Each AdverseEventOutcomeAssessment always specializes one PerformedObservation. Each PerformedObservation might be specialized by one AdverseEventOutcomeAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdverseEventOutcomeAssessment 0..* triggeredAdverseEventOutcomeAssessment	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION: Each AdverseEventOutcomeAssessment always is triggered by one AdverseEvent. Each AdverseEvent might trigger one or more AdverseEventOutcomeAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: AdverseEventOutcomeResult

Package: Adverse Event Sub-Domain

DEFINITION:

The result of evaluating the final state of a person who experienced an adverse event.

EXAMPLE(S):

Recovered/Resolved, Recovering/Resolving, Not Recovered/Not Resolved, Recovered/Resolved with Sequelae, Fatal, Unknown

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = AdverseEventResponseDescription
- Map:CTRv1.0 = AdverseEventOutcomeResult
- Map:SDTM IGV3.1.1 = AE.AEOUT

Connectors

Source	Connector	Target	Notes
AdverseEventOutcomeResult	specializes	PerformedObservationResult	<p>DESCRIPTION: Each AdverseEventOutcomeResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one AdverseEventOutcomeResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: AdverseEventSeriousness

Package: Adverse Event Sub-Domain

DEFINITION:

Specifies the degree or extent of the consequence suffered by the subject.

EXAMPLE(S):

resulted in death, required hospitalization, was life threatening

OTHER NAME(S):

NOTE(S):

While often not reported as a separate observation, seriousness codes are technically the result of assessing the subject and the adverse event they are experiencing. The association to the AdverseEvent should theoretically be derivable via the following path: AdverseEventSeriousness > PerformedObservation [assess seriousness] > AssessedResultRelationship > AdverseEvent. However, since this information is often not available, AdverseEventSeriousness has been modeled as both a subclass of PerformedClinicalInterpretation and as having an association directly to the AdverseEvent class.

Tagged Values:

- Map:caAERSv2.2 = Outcome
- Map:CTRv1.0 = AdverseEventSeriousness
- Map:SDTM IGV3.1.3 = AE.AESER

Connectors

Source	Connector	Target	Notes
AdverseEventSeriousness 0..*	describes	AdverseEvent 1	DESCRIPTION: Each

Source	Connector	Target	Notes
describingAdverseEventSeriousness		describedAdverseEvent	<p>AdverseEventSeriousness always describes one AdverseEvent. Each AdverseEvent might be described by one or more AdverseEventSeriousness.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdverseEventSeriousness	specializes	PerformedClinicalInterpretation	<p>DESCRIPTION: Each AdverseEventSeriousness always specializes one PerformedClinicalInterpretation. Each PerformedClinicalInterpretation might be specialized by one or more AdverseEventSeriousness.</p> <p>DEFINITION: Specifies the degree or extent of the consequence suffered by the subject.</p> <p>EXAMPLE(S): resulted in death, required hospitalization, was life threatening</p> <p>OTHER NAME(S):</p> <p>NOTE(S): While often not reported as a separate observation, seriousness codes are technically the result of assessing the subject and the adverse event they are experiencing. The association to the AdverseEvent should theoretically be derivable via the following path: AdverseEventSeriousness > PerformedObservation [assess seriousness] > AssessedResultRelationship > AdverseEvent. However, since this information is often not available, AdverseEventSeriousness has been modeled as both a subclass of PerformedClinicalInterpretation</p>

Source	Connector	Target	Notes
			tion and as having an association directly to the AdverseEvent class.

Attributes

Attribute	Notes	Constraints and Tags
seriousnessCode <i>Class:</i> AdverseEventSeriousness <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the degree or extent of the consequence suffered by the subject.</p> <p>EXAMPLE(S): resulted in death, required hospitalization, was life threatening</p> <p>Results in Death; Is life-threatening; Requires inpatient hospitalization or prolongation of existing hospitalization; Results in persistent or significant disability/incapacity; Is a congenital anomaly/birth defect; In the medical judgment of the treating physician and/or investigator, it may jeopardize the participant or require intervention to prevent one of these outcomes; Other, specify; Meets criteria per protocol but does not meet other criterion (NCI CRF Standard)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is derivable from AdverseEventSeriousness.value(ANY=>CD).code and is in the model to make the semantic explicit.</p>	Map:AE = AdverseEvent.seriousnessCode Map:caAERSv2.2 = Outcome.other Map:caAERSv2.2 = Outcome.type Map:CDASHv1.1 = AE.AESLIFE Map:CTOM = AdverseEvent.seriousReasonCode Map:CTRv1.0 = AdverseEventSeriousness.code Map:NCI CRF Standard = CDE 2179679v3.0: Serious Adverse Event Description Reason Text Map:SDTM IGv3.1.1 = AE.AESER Map:SDTM IGv3.1.1 = AE.AESHOSP Map:SDTM IGv3.1.2 = AE.AESLIFE Map:SDTM IGv3.1.3 = AE.AESER

Class: CausalAssessment

Package: Adverse Event Sub-Domain

DEFINITION:

The judgment of relatedness between an adverse event and an activity or observation result.

EXAMPLE(S):

The observation result of "diabetes" is assessed to have caused the AE.

The activity of administering a concomitant medication is assessed to have caused the AE.

The activity of administering the study drug is assessed to have caused the AE.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = CausalAssessment
- Map:CTRv1.0 = CausalAssessment
- Map:ICSRr2 = AdverseEffectReference (in IndividualCaseSafetyReport)
- Map:ICSRr2 = CausalityAssessment (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Component1 (in IndividualCaseSafetyReport)

- Map:ICSRr2 = Subject2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject4 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
CausalAssessment 0..* triggeredCausalAssessment	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION: Each CausalAssessment always is triggered by one AdverseEvent. Each AdverseEvent might trigger one or more CausalAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CausalAssessment	specializes	PerformedObservation	<p>DESCRIPTION: Each CausalAssessment always specializes one PerformedObservation. Each PerformedObservation might be specialized by one CausalAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
EvaluatedResultRelationship 0..* evaluatedEvaluatedResultRelationship	is evaluated by	CausalAssessment 1 evaluatingCausalAssessment	<p>DESCRIPTION: Each EvaluatedResultRelationship always is evaluated by one CausalAssessment. Each CausalAssessment might evaluate one or more EvaluatedResultRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
EvaluatedActivityRelationship 0..* evaluatedEvaluatedActivityRelationship	is evaluated by	CausalAssessment 1 evaluatingCausalAssessment	<p>DESCRIPTION: Each EvaluatedActivityRelationship always is evaluated by one CausalAssessment. Each CausalAssessment might evaluate one or more</p>

Source	Connector	Target	Notes
			EvaluatedActivityRelations hip. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: EvaluatedActivityRelationship

Package: Adverse Event Sub-Domain

DEFINITION:

Specifies the link between an adverse event causal assessment and the activity evaluated as a possible cause.

EXAMPLE(S):

Administration of cold medicine may be evaluated as a cause of an adverse event.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = SurgeryAttribution
- Map:caAERSv2.2 = CourseAgentAttribution
- Map:caAERSv2.2 = RadiationAttribution
- Map:caAERSv2.2 = ConcomitantMedicationAttribution
- Map:caAERSv2.2 = DeviceAttribution
- Map:caAERSv2.2 = AdverseEventAttribution
- Map:CTRpV3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = EvaluatedActivityRelationship
- Map:ICSRr2 = Subject11 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject3 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
EvaluatedActivityRelations hip 0..*	is evaluated by	CausalAssessment 1 evaluatingCausalAssessmen t	DESCRIPTION: Each EvaluatedActivityRelations hip always is evaluated by one CausalAssessment. Each CausalAssessment might evaluate one or more EvaluatedActivityRelations hip. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
EvaluatedActivityRelations	evaluates	PerformedActivity	DESCRIPTION:

Source	Connector	Target	Notes
hip 0..* evaluatingEvaluatedActivityRelationship		1 evaluatedPerformedActivity	Each EvaluatedActivityRelationship always evaluates one PerformedActivity. Each PerformedActivity might be evaluated by one or more EvaluatedActivityRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
probabilityCode <i>Class:</i> EvaluatedActivityRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the likelihood of the identified cause of an adverse event. EXAMPLE(S): unrelated, unlikely, possible, probable, definite (for adverse events in respect to CTEP and FAET) related, possibly related, unlikely related, not related (for adverse events in respect to SDTM & E2B) OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = AdverseEvent.attributionToStudy Map:caAERSv2.2 = AdverseEventAttribution.attribution Map:CTRv1.0 = EvaluatedActivityRelationship.probabilityCode Map:ICSRr2 = CausalityAssessment.value (in IndividualCaseSafetyReport) Map:NCI CRF Standard = CDE 1285v3.0: CTC Adverse Event Attribution Scale Map:SDTM IGv3.1.3 = AE.AEREL
probabilityPercent <i>Class:</i> EvaluatedActivityRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A number representing the likelihood of the identified cause of an adverse event. EXAMPLE(S): 60% likelihood that an adverse event was caused by an activity that was performed on the subject. OTHER NAME(S): NOTE(S):	Map:AE = CausalAssessment.probability Map:CTRv1.0 = EvaluatedActivityRelationship.probabilityPercent

Attribute	Notes	Constraints and Tags
uncertaintyCode <i>Class:</i> EvaluatedActivityRelations hip <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether and to what degree this evaluation or observation has been asserted to be in doubt in any way.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = CausalAssessment.certaintyCode Map:CDASHv1.1 = AE.AEREL Map:CTOM = AdverseEvent.ctcAttributionCodeSystem Map:CTOM = AdverseEvent.ctcAttributionCode Map:CTRv1.0 = EvaluatedActivityRelationship.uncertaintyCode Map:SDTM IGv3.1.2 = AE.AEREL Map:SDTM IGv3.1.2 = AE.AERELNST
comment <i>Class:</i> EvaluatedActivityRelations hip <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Additional description of the evaluated activity relationship recording the investigator's opinion as to whether the event may have been due to a treatment.</p> <p>EXAMPLE(S): More likely related to aspirin use</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = AE.AERELNST

Class: EvaluatedResultRelationship

Package: Adverse Event Sub-Domain

DEFINITION:

Specifies the link between an adverse event causal assessment and the observation result evaluated as a possible cause.

EXAMPLE(S):

A diagnosis of diabetes may be evaluated as a cause of an adverse event.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = AdverseEventAttribution
- Map:caAERSv2.2 = DiseaseAttribution
- Map:CTRv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = EvaluatedResultRelationship

Connectors

Source	Connector	Target	Notes
EvaluatedResultRelationship 0..* evaluatingEvaluatedResultRelationship	evaluates	PerformedObservationResult 1 evaluatedPerformedObservationResult	DESCRIPTION: Each EvaluatedResultRelationship always evaluates one PerformedObservationResult. Each PerformedObservationResult might be evaluated by one or more

Source	Connector	Target	Notes
			EvaluatedResultRelationship DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
EvaluatedResultRelationship 0..* evaluatedEvaluatedResultRelationship	is evaluated by	CausalAssessment 1 evaluatingCausalAssessment	DESCRIPTION: Each EvaluatedResultRelationship always is evaluated by one CausalAssessment. Each CausalAssessment might evaluate one or more EvaluatedResultRelationships. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
probabilityCode <i>Class:</i> EvaluatedResultRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the likelihood of the identified cause of an adverse event. EXAMPLE(S): unrelated, unlikely, possible, probable, definite (for adverse events in respect to CTEP and FAET) related, possibly related, unlikely related, not related (for adverse events in respect to SDTM & E2B) OTHER NAME(S): NOTE(S):	Constraints and Tags Map:caAERSv2.2 = AdverseEventAttribution.attribution Map:CTRv1.0 = EvaluatedResultRelationship.probabilityCode Map:NCI CRF Standard = CDE 1285v3.0: CTC Adverse Event Attribution Scale

Attribute	Notes	Constraints and Tags
probabilityPercent <i>Class:</i> EvaluatedResultRelationship <p><i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1</p>	<p>DEFINITION: A number representing the likelihood of the identified cause of an adverse event.</p> <p>EXAMPLE(S): 60% likelihood that an adverse event was caused by the evaluated result of diabetes.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = CausalAssessment.probability Map:CTRv1.0 = EvaluatedResultRelationship.probabilityPercent
uncertaintyCode <i>Class:</i> EvaluatedResultRelationship <p><i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1</p>	<p>DEFINITION: A coded value specifying whether and to what degree this evaluation or observation has been asserted to be in doubt in any way.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = CausalAssessment.certaintyCode Map:CTRv1.0 = EvaluatedResultRelationship.uncertaintyCode

Class: PerformedProductInvestigation

Package: Adverse Event Sub-Domain

DEFINITION:

The completed process of evaluating a product.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The evaluation process may occur either before or after the product is returned to the manufacturer or reprocessor.

Tagged Values:

- Map:AE = ProductInvestigation
- Map:CTRv1.0 = PerformedProductInvestigation
- Map:ICSRr2 = ProductDefectAssessment (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject5 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject6 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
PerformedProductInvestigation 0..* triggeredPerformedProductInvestigation	is triggered by	PerformedProductProblemDiscovery 1..* triggeringPerformedProductProblemDiscovery	<p>DESCRIPTION: Each PerformedProductInvestigation always is triggered by one or more PerformedProductProblemDiscovery. Each PerformedProductProblemDiscovery might trigger one or more PerformedProductInvestigation.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductInvestigation	specializes	PerformedObservation	<p>DESCRIPTION:</p> <p>Each PerformedProductInvestigation always specializes one PerformedObservation.</p> <p>Each PerformedObservation might be specialized by one PerformedProductInvestigation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductInvestigation 0..* triggeredPerformedProductInvestigation	is triggered by	AdverseEvent 1 triggeringAdverseEvent	<p>DESCRIPTION:</p> <p>Each PerformedProductInvestigation always is triggered by one AdverseEvent. Each AdverseEvent might trigger one or more PerformedProductInvestigation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedProductInvestigationResult

Package: Adverse Event Sub-Domain

DEFINITION:

Information captured while conducting research on a product.

EXAMPLE(S):

An electrical problem in a device.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedProductInvestigationResult

Connectors

Source	Connector	Target	Notes
PerformedProductInvestigationResult	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedProductInvestigationResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProductInvestigationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
defectTypeCode <i>Class:</i> PerformedProductInvestigationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of device-related events that characterize the reported event/problem.</p> <p>EXAMPLE(S): malfunction</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = ProductInvestigation.defectType Map:CTRv1.0 = PerformedProductInvestigationResult.defectTypeCode
deviceMalfunctionCode <i>Class:</i> PerformedProductInvestigationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the defect or malfunction that occurred during use of the suspect device whether or not the problem is associated with an adverse event.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Codes are FDA CDRH device codes.</p>	Map:AE = ProductInvestigation.deviceMalfunctionCode Map:CTRv1.0 = PerformedProductInvestigationResult.deviceMalfunctionCode

Attribute	Notes	Constraints and Tags
evaluationConclusionCode <i>Class:</i> PerformedProductInvestigationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the relevant fact within the context of the evaluation final results for a reported suspect medical device.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Based on FDA CDRH Conclusion Codes.</p>	Map:AE = ProductInvestigation.evaluationConclusionCode Map:CTRv1.0 = PerformedProductInvestigationResult.evaluationConclusionCode
conclusion <i>Class:</i> PerformedProductInvestigationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A text or otherwise formatted description of the final results drawn from the investigation.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = ProductInvestigation.conclusionsText Map:CTRv1.0 = PerformedProductInvestigationResult.conclusion Map:ICSRr2 = ProductDefectAssessment.text (in IndividualCaseSafetyReport)

Class: PerformedProductProblemDiscovery

Package: Adverse Event Sub-Domain

DEFINITION:

The recognition of a product defect that needs to be reported.

EXAMPLE(S):

An imaging device is discovered to be leaking radiation. This was discovered on Jan. 10th, but it suspected to have been leaking for a week. This element maps to the ProductDefectDiscovery class in ICSR and maps to the MedWatch Form 3500A section B1 (Product problem checkbox).

OTHER NAME(S):

NOTE(S):

The BRIDG SCC has a GForge Tracker Issue (#31893) indicating a need to validate the requirement that every PerformedProductProblemDiscovery be described by a SafetyReportVersion.

Tagged Values:

- Map:AE = ProductProblemDiscovery
- Map:CTRv1.0 = PerformedProductProblemDiscovery
- Map:ICSRr2 = DefectReference (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
PerformedProductProblemDiscovery	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedProductProblemDiscovery always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProductProblemDiscovery.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductProblemDiscovery 0..* involvingPerformedProductProblemDiscovery	focuses on	Product 1 involvedProduct	<p>DESCRIPTION:</p> <p>Each PerformedProductProblemDiscovery always focuses on one Product. Each Product might be the focus of one or more PerformedProductProblemDiscovery.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SafetyReportVersion 0..* describingSafetyReportVersion	describe	PerformedProductProblemDiscovery 0..* describedPerformedProductProblemDiscovery	<p>DESCRIPTION:</p> <p>Each SafetyReportVersion might describe one or more PerformedProductProblemDiscovery. Each PerformedProductProblemDiscovery might be described by one or more SafetyReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductInvestigation 0..* triggeredPerformedProductInvestigation	is triggered by	PerformedProductProblemDiscovery 1..* triggeringPerformedProductProblemDiscovery	<p>DESCRIPTION:</p> <p>Each PerformedProductInvestigation always is triggered by one or more PerformedProductProblemDiscovery. Each PerformedProductProblemDiscovery might trigger one or more PerformedProductInvestigation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Class: SafetyReportVersion

Package: Adverse Event Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

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.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = SafetyReport
- Map:AE = NullificationReport
- Map:AE = ProductProblemReport
- Map:caAERSv2.2 = ExpeditedAdverseEventReport
- Map:CTRr3 = SafetyReport
- Map:CTRv1.0 = SafetyReportVersion
- Map:ICSRr2 = Subject8 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = ControlActEvent (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject9 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
SafetyReportVersion 0..* reportingSafetyReportVersion	report as prior therapies	PerformedProcedure 0..* reportedPerformedProcedure	DESCRIPTION: Each SafetyReportVersion might report as prior therapies one or more PerformedProcedure. Each PerformedProcedure might be reported as a prior therapy in one or more SafetyReportVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SafetyReportVersion 0..* describingSafetyReportVersion	describe	PerformedProductProblemDiscovery 0..* describedPerformedProductProblemDiscovery	DESCRIPTION: Each SafetyReportVersion might describe one or more PerformedProductProblemDiscovery. Each

Source	Connector	Target	Notes
			PerformedProductProblemDiscovery might be described by one or more SafetyReportVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SafetyReportVersion 0..* describingSafetyReportVersion	describe	AdverseEvent 0..* describedAdverseEvent	DESCRIPTION: Each SafetyReportVersion might describe one or more AdverseEvent. Each AdverseEvent might be described by one or more SafetyReportVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SafetyReportVersion	specializes	ReportVersion	DESCRIPTION: Each SafetyReportVersion always specializes one ReportVersion. Each ReportVersion might be specialized by one SafetyReportVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ReportSubmitter 1..* submittingReportSubmitter	submits	SafetyReportVersion 1 submittedSafetyReportVersion	DESCRIPTION: Each ReportSubmitter always submits one SafetyReportVersion. Each SafetyReportVersion always is submitted by one or more ReportSubmitter. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Source	Connector	Target	Notes
PerformedObservation 0..* commentingPerformedObservation	be commenting on	SafetyReportVersion 0..1 commentedSafetyReportVersion	<p>DESCRIPTION: Each PerformedObservation might be commenting on one SafetyReportVersion. Each SafetyReportVersion might be commented on by one or more PerformedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
subtypeCode <i>Class:</i> SafetyReportVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying a further classification of type.</p> <p>EXAMPLE(S): “Adverse Event Report” would map to Document.typeCode and “7-day AE Report” would map to SafetyReportVersion.subtypeCode.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = SafetyReport.reportingCriteriaCode Map:AE = SafetyReport.problemType Map:AE = SafetyReport.spontaneousReportInd Map:AE = SafetyReport.expeditedReportCriteriaInd Map:CTRv1.0 = SafetyReportVersion.subtypeCode Map:ICSRr2 = InvestigativeEvent.code (in IndividualCaseSafetyReport) Map:ICSRr2 = RelatedInvestigation.code (in IndividualCaseSafetyReport)
nullificationIndicator <i>Class:</i> SafetyReportVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the report cancels a previously sent adverse event.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = SafetyReport.nullificationReportInd Map:CTRv1.0 = SafetyReportVersion.nullificationIndicator
nullificationReasonCode <i>Class:</i> SafetyReportVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying why the adverse event report is nullified.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = SafetyReport.reasonCode Map:AE = NullificationReport.nullificationReasonCode Map:CTRv1.0 = SafetyReportVersion.nullificationReasonCode

Biospecimen Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Biospecimen sub-domain includes concepts related to a biologic specimen, including collection and processing.

Biospecimen Sub-Domain

View BSP: Biospecimen diagram

Class diagram in package 'Biospecimen Sub-Domain'

The Biospecimen sub-domain includes concepts related to a biologic specimen, including collection and processing.

Collaboration with other HL7 Work Groups: With the broader scope of BRIDG 4.0 covering translational research and the harmonization of Life Sciences Model and CDISC Pharmogenomic & Pharmacogenetics domains, it is likely that there is some overlap of concepts between BRIDG Biospecimen subdomain concepts and the models being developed in the HL7 Clinical Genomics (CG), Orders & Observations and Anatomic pathology work groups. BRIDG recognizes these work group models as peer or sibling models and is committed to working with the work group members to align on common semantics. The BRIDG team has started the conversation with the work groups to this effect and plan to continue the dialogue on how to operationalize the collaboration and leverage the subject matter expertise of this HL7 group members.

[View BSP: Biospecimen](#)

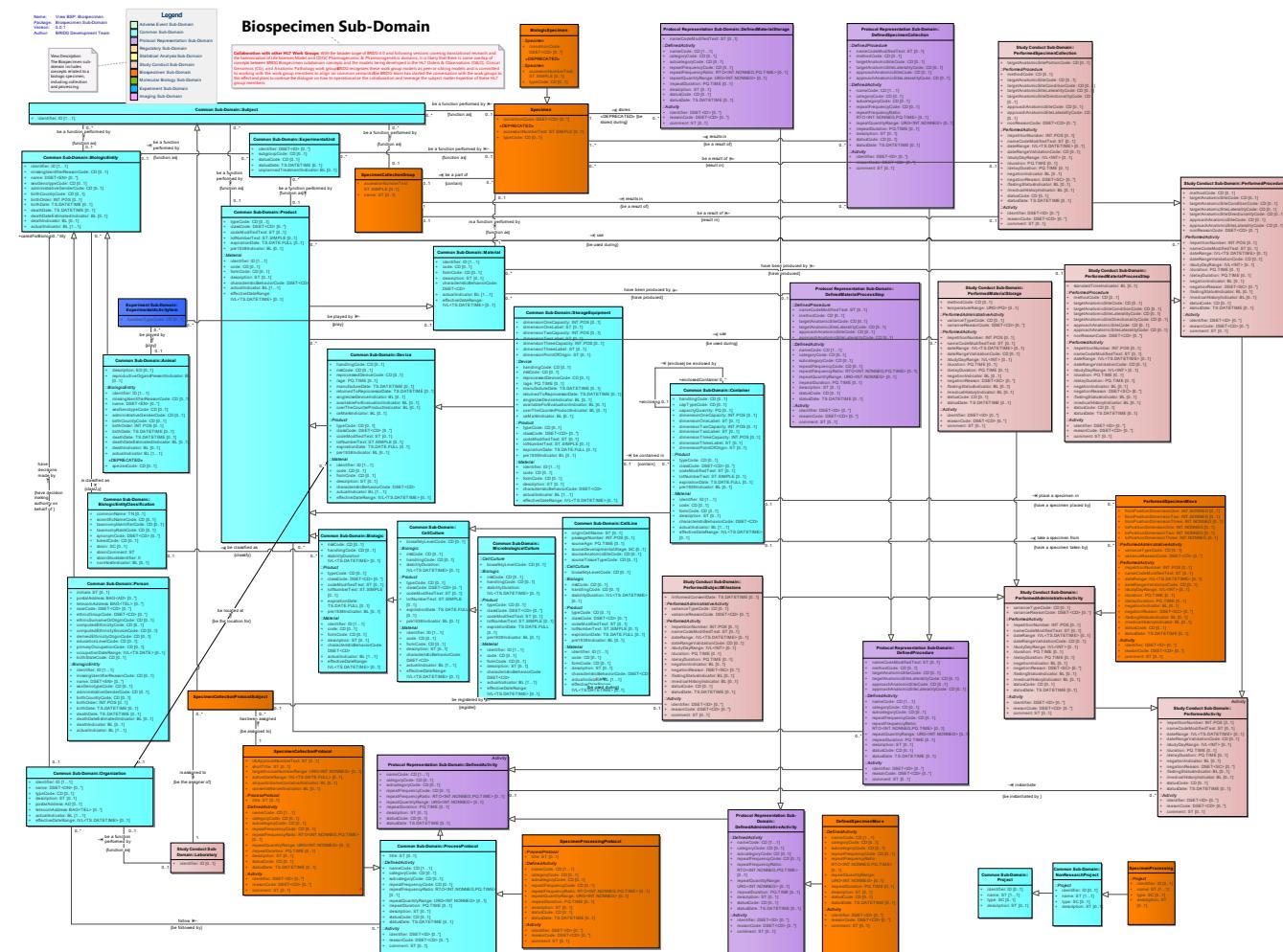


Figure 4: View BSP: Biospecimen

Class: BiologicSpecimen

Package: Biospecimen Sub-Domain

DEFINITION:

Any material sample taken from a biological entity, including a sample obtained from a living organism or taken from the biological object after halting of all its life functions. Biospecimen can contain one or more components including but not limited to cellular molecules, cells, tissues, organs, body fluids, embryos, and body excretory products (source: NCI, modified).

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = BiologicSpecimen
- Map:PGx v1.0 = RELSPEC

Connectors

Source	Connector	Target	Notes
BiologicSpecimen	specializes	Specimen	<p>DESCRIPTION: Each BiologicSpecimen always specializes one Specimen. Each Specimen might be specialized by one BiologicSpecimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedSpecimenMove

Package: Biospecimen Sub-Domain

DEFINITION:

The action of locating or relocating a specimen or specimen collection group from and/or to its storage location.

EXAMPLE(S):

Check-in, check-out, transfer from one location to another

OTHER NAME(S):

Specimen Check-in/Check-out

Specimen Return

Specimen Placement

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = DefinedSpecimenCheckInCheckOut

- Map:LSDAMv2.2.3Plus = DefinedSpecimenReturn

Connectors

Source	Connector	Target	Notes
DefinedSpecimenMove	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedSpecimenMove always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedSpecimenMove.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedSpecimenMove

Package: Biospecimen Sub-Domain

DEFINITION:

The completed action of locating or relocating a specimen or specimen collection group from and/or to its storage location.

EXAMPLE(S):

Check-in, check-out, transfer from one location to another

OTHER NAME(S):

Specimen Check-in/Check-out

Specimen Return

Specimen Placement

NOTE(S):

Note that attributes in this class are optional and can be used as needed for the type of transaction being recorded, e.g. check-in can represent the intake of a new specimen using the "to position" attributes only, likewise check-out can represent a specimen being taken out of a container using only the "from position" attributes.

Tagged Values:

- Map:LSDAMv2.2.3Plus = PerformedSpecimenCheckInCheckOut
- Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement
- Map:LSDAMv2.2.3Plus = PerformedSpecimenReturn

Connectors

Source	Connector	Target	Notes
PerformedSpecimenMove 0..* placingPerformedSpecimenMove	place a specimen in	Container 0..1 placedInContainer	<p>DESCRIPTION: Each PerformedSpecimenMove might place a specimen in one Container. Each Container might have a specimen placed by one or more PerformedSpecimenMove.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSpecimenMove 0..* takingPerformedSpecimenMove	take a specimen from	Container 0..1 takenFromContainer	<p>DESCRIPTION: Each PerformedSpecimenMove might take a specimen from one Container. Each Container might have a specimen taken by one or more PerformedSpecimenMove.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
fromPositionDimensionOne <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A reference to the first directional coordinate that describes the location of the specimen in the previous storage container before transfer.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.fromPositionDimensionOne</p>

Attribute	Notes	Constraints and Tags
fromPositionDimensionTwo ₀ <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A reference to the second directional coordinate that describes the location of the specimen in the previous storage container before transfer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.fromPositionDimensionTwo
fromPositionDimensionThree ₀ <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A reference to the third directional coordinate that describes the location of the specimen in the previous storage container before transfer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.fromPositionDimensionThree
toPositionDimensionOne ₀ <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A reference to the first directional coordinate that describes the location of the specimen in the new storage container after transfer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.toPositionDimensionOne
toPositionDimensionTwo ₀ <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A reference to the second directional coordinate that describes the location of the specimen in the new storage container after transfer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.toPositionDimensionTwo
toPositionDimensionThree ₀ <i>Class:</i> PerformedSpecimenMove <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A reference to the third directional coordinate that describes the location of the specimen in the new storage container after transfer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PerformedSpecimenPlacement.toPositionDimensionThree

Class: Specimen

Package: Biospecimen Sub-Domain

DEFINITION:

A substance or portion of material originally obtained from an entity for use in testing, examination, or study.

EXAMPLE(S):

Blood obtained by a specimen collection activity performed on a study subject.

A few grains of cattle feed obtained from a feed sack.

A randomly selected pill from a blister pack.

A serum specimen that resulted from Centrifugation procedure performed on a blood specimen.

A DNA specimen extraction from a saliva specimen.

A Formalin-Fixed, Paraffin-Embedded (FFPE) block that resulted from a paraffin embedding procedure performed on a formalin fixed tissue specimen.

A pooled blood sample that resulted from a mixing procedure performed on several blood samples taken from individual animals.

OTHER NAME(S):

Biologic specimen

Product specimen

NOTE(S):*Tagged Values:*

- Map:CTRPv1.0 = Material
- Map:CTRr3 = BiologicSpecimen
- Map:CTRv1.0 = Specimen
- Map:ICSRr2 = Specimen (in R_Specimen universal)
- Map:ICSRr2 = Product (in R_Specimen universal)
- Map:LabViewer2.2 = Specimen

Connectors

Source	Connector	Target	Notes
Specimen 0..1 performedSpecimen	is a function performed by	Material 1 performingMaterial	<p>DESCRIPTION: Each Specimen always is a function performed by one Material. Each Material might function as one Specimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Specimen 0..* producedSpecimen	be a result of	PerformedSpecimenCollecti on 0..1 producingPerformedSpecim enCollection	<p>DESCRIPTION: Each Specimen might be a result of one PerformedSpecimenCollecti on. Each PerformedSpecimenCollecti on might result in one or more Specimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
Specimen 0..* containedSpecimen	be a part of	SpecimenCollectionGroup 0..1 containingSpecimenCollecti onGroup	<p>DESCRIPTION: Each Specimen might be a part of one SpecimenCollectionGroup. Each SpecimenCollectionGroup might contain one or more Specimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
BiologicSpecimen	specializes	Specimen	<p>DESCRIPTION: Each BiologicSpecimen always specializes one Specimen. Each Specimen might be specialized by one BiologicSpecimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedSpecimenCollection 0..* producingDefinedSpecimen Collection	results in	Specimen 1..* producedSpecimen	<p>DESCRIPTION: Each DefinedSpecimenCollection always results in one or more Specimen. Each Specimen might be a result of one or more DefinedSpecimenCollection .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedMaterialStorage 0..* storingDefinedSpecimenSto rage	stores	Specimen 1 storedSpecimen	<p>DESCRIPTION: Each DefinedMaterialStorage always stores one Specimen. Each Specimen might be stored during one or more DefinedMaterialStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	Specimen 0..1 performingSpecimen	DESCRIPTION: Each ExperimentalUnit might be a function performed by one Specimen. Each Specimen might function as one or more ExperimentalUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Subject 0..* performedSubject	be a function performed by	Specimen 0..1 performingSpecimen	DESCRIPTION: Each Subject might be a function performed by one Specimen. Each Specimen might function as one or more Subject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
conditionCode <i>Class:</i> Specimen <i>Datatype:</i> DSET<CD> <i>Derived:</i> True <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying one of a discreet list of values describing the condition of the specimen at time of receipt at the lab.</p> <p>EXAMPLE(S): Hemolyzed, Icteric, Lipemic</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedObservationResult.value(ANY=>CD).code WHERE PerformedObservationResult > PerformedObservation > DefinedObservation.nameCode = "assess specimen condition"</p>	Map:CDASHv1.1 = LB.LBSPCCND Map:CTRv1.0 = Specimen.conditionCode Map:Lab = Specimen.condition Map:LabViewer2.2 = Specimen.condition Map:NCI CRF Standard = CDE 2829883v1.0: Laboratory Specimen Condition Gross Type Map:PGx v1.0 = BS.BSSPCCND Map:SDTM IGv3.1.1 = LB.LBSPCCND Map:SDTM IGv3.1.2 = PC.PCSPCCND Map:SDTM IGv3.1.2 = MB.MBSPCCND Map:SDTM IGv3.1.2 = LB.LBSPCCND Map:SDTM IGv3.1.3 = PC.PCSPCCND Map:SDTM IGv3.1.3 = MB.MBSPCCND Map:SDTM IGv3.1.3 = LB.LBSPCCND
accessionNumberText <i>Class:</i> Specimen <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An alphanumeric identifier assigned by a receiving lab to specimens that are received together as a set.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from SpecimenCollectionGroup.accessionNumberText if the specimen is part of a SpecimenCollectionGroup</p>	Map:CDASHv1.1 = LB.LBREFID Map:CTRv1.0 = Specimen.accessionNumberText Map:Lab = Specimen.accessionNumber Map:LabViewer2.2 = Specimen.accessionNumber Map:NCI CRF Standard = CDE 2230047v4.0: Specimen Accession Number Map:SDTM IGv3.1.2 = LB.LBREFID
typeCode <i>Class:</i> Specimen <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of the specimen derived from other specimens.</p> <p>EXAMPLE(S): specimen, aliquot, isolate</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The semantic represented by the Specimen.typeCode attribute has been clarified by the LSDAM team during harmonization of the LS DAM v2.2.3Plus model. The semantic actually is an identification of the kind of activity that produced the Specimen, which means it maps to PerformedMaterialProcessStep > DefineMaterialProcessStep.nameCode. Therefore, the Specimen.typeCode attribute is DEPRECATED.</p>	Map:CTRv1.0 = Specimen.typeCode Map:ICSRr2 = Specimen.code (in R_Specimen universal)

Class: SpecimenCollectionGroup

Package: Biospecimen Sub-Domain

DEFINITION:

A group of specimens collected from the same participant in the same accession event.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SpecimenCollectionGroup

Connectors

Source	Connector	Target	Notes
SpecimenCollectionGroup 0..1 producedSpecimenCollectio nGroup	be a result of	PerformedSpecimenCollecti on 0..1 producingPerformedSpecim enCollection	DESCRIPTION: Each SpecimenCollectionGroup might be a result of one PerformedSpecimenCollection. Each PerformedSpecimenCollection might result in one SpecimenCollectionGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedSpecimenCollection 0..* instantiatedDefinedSpecime nCollection	results in	SpecimenCollectionGroup 1 instantiatingSpecimenCollec tionGroup	DESCRIPTION: Each DefinedSpecimenCollection always results in one SpecimenCollectionGroup. Each SpecimenCollectionGroup might be a result of one or more DefinedSpecimenCollection. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Specimen 0..* containedSpecimen	be a part of	SpecimenCollectionGroup 0..1 containingSpecimenCollecti onGroup	DESCRIPTION: Each Specimen might be a part of one SpecimenCollectionGroup. Each

Source	Connector	Target	Notes
			<p>SpecimenCollectionGroup might contain one or more Specimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Subject 0..* performedSubject	be a function performed by	SpecimenCollectionGroup 0..1 performingSpecimenCollect ionGroup	<p>DESCRIPTION: Each Subject might be a function performed by one SpecimenCollectionGroup. Each SpecimenCollectionGroup might function as one or more Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
accessionNumberText <i>Class:</i> SpecimenCollectionGroup <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An alphanumeric identifier (not necessarily unique to the specimen) assigned by a receiving lab to specimens that are received together as a set.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:CDASHv1.1 = LB.LBREFID Map:CTRv1.0 = Specimen.accessionNumberText Map:Lab = Specimen.accessionNumber Map:LabViewer2.2 = Specimen.accessionNumber Map:NCI CRF Standard = CDE 2230047v4.0: Specimen Accession Number Map:SDTM IGv3.1.2 = LB.LBREFID</p>
name <i>Class:</i> SpecimenCollectionGroup <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A textual identifier given to the specimen collection group.</p> <p>EXAMPLE(S): Tumor/normal collection, Bacterial collection</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Specimen collection group names do not have to be globally unique, but rather are reused in many protocols. What must be unique for a specimen collection group are the case identifiers and pathology report numbers.</p>	<p>Map:LSDAMv2.2.3Plus = SpecimenCollectionGroup.name</p>

Class: SpecimenCollectionProtocol

Package: Biospecimen Sub-Domain

DEFINITION:

A set of procedures that govern the collection of biospecimens.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol

Connectors

Source	Connector	Target	Notes
SpecimenCollectionProtocol	specializes	ProcessProtocol	<p>DESCRIPTION: Each SpecimenCollectionProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one SpecimenCollectionProtocol .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenCollectionProtocol Subject 0..* havingSpecimenCollectionProtocolSubject	has been assigned	SpecimenCollectionProtocol 1 assignedSpecimenCollectionProtocol	<p>DESCRIPTION: Each SpecimenCollectionProtocol Subject always has been assigned one SpecimenCollectionProtocol . Each SpecimenCollectionProtocol might be assigned to one or more SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
irbApprovalNumberText <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An identifier indicating that an Institutional Review Board (IRB) has reviewed the protocol and determined it is acceptable for use within the constraints set forth by the IRB and other institutional and federal requirements. [adapted from NCIt, Institutional Review Board Approval (Code C70800), http://ncit.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&version=14.10d&code=C70800&ns=NCI_Thesaurus&key=878592761&b=1&n=null]</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Question for SMEs: Is the IRB approval site and version specific for specimen collection protocols?</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.irbIdentifier
shortTitle <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Abbreviated textual designation by which the specimen collection protocol is known.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.shortTitle
targetAccrualNumberRange <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many subjects are to be accrued for the protocol.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.enrollment
activeDateRange <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> IVL<TS.DATE.FULL> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) span within which the protocol is active (i.e., from activation through close).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.activeDateRange

Attribute	Notes	Constraints and Tags
aliquotInSameContainerIndicator <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether all aliquots in specimens which belong to that collection protocol are in the same container.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.aliquotInSameContainer
consentsWaivedIndicator <i>Class:</i> SpecimenCollectionProtocol <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether consent may be waived.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocol.consentsWaived

Class: SpecimenCollectionProtocolSubject

Package: Biospecimen Sub-Domain

DEFINITION:
An individual who participates in a specimen collection protocol.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SpecimenCollectionProtocolSubject

Connectors

Source	Connector	Target	Notes
SpecimenCollectionProtocol Subject 0..1 registeredSpecimenCollectionProtocolSubject	be registered by	PerformedSubjectMilestone 0..1 registeringPerformedSubjectMilestone	<p>DESCRIPTION: Each SpecimenCollectionProtocol Subject might be registered by one PerformedSubjectMilestone. Each PerformedSubjectMilestone might register one SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the CollectingLaboratory is the Performer of the</p>

Source	Connector	Target	Notes
			assignment of a Subject to a Protocol, and/or the collector of the informed consent (i.e. the performer of a PerformedSubjectMilestone) , then the association from SpecimenCollectionProtocol Subject to CollectingLaboratory is redundant and should NOT be used.
SpecimenCollectionProtocol Subject 0..* assignedSpecimenCollection ProtocolSubject	is assigned to	Laboratory 1 assigningLaboratory	<p>DESCRIPTION: Each SpecimenCollectionProtocol Subject always is assigned to one Laboratory. Each Laboratory might be the assigner of one or more SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the Laboratory is the Performer of the assignment of a Subject to a Protocol, and/or the collector of the informed consent (i.e. the performer of a PerformedSubjectMilestone) , then this association from SpecimenCollectionProtocol Subject to Laboratory is redundant and should NOT be used.</p>
SpecimenCollectionProtocol Subject 0..* havingSpecimenCollectionProtocolSubject	has been assigned	SpecimenCollectionProtocol 1 assignedSpecimenCollection Protocol	<p>DESCRIPTION: Each SpecimenCollectionProtocol Subject always has been assigned one SpecimenCollectionProtocol . Each SpecimenCollectionProtocol might be assigned to one or more SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
SpecimenCollectionProtocol Subject	specializes	Subject	<p>DESCRIPTION: Each SpecimenCollectionProtocol Subject always specializes one Subject. Each Subject might be specialized by one SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: SpecimenProcessing

Package: Biospecimen Sub-Domain

DEFINITION:

A non-research project with the ultimate goal of performing a continuous action, operation, or series of changes on a biological sample.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SpecimenProcessing

Connectors

Source	Connector	Target	Notes
SpecimenProcessing	specializes	NonResearchProject	<p>DESCRIPTION: Each SpecimenProcessing always specializes one NonResearchProject. Each NonResearchProject might be specialized by one SpecimenProcessing.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: SpecimenProcessingProtocol

Package: Biospecimen Sub-Domain

DEFINITION:

A defined set of procedures that governs the processing of biospecimens.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SpecimenProcessingProtocol

Connectors

Source	Connector	Target	Notes
SpecimenProcessingProtocol	specializes	ProcessProtocol	<p>DESCRIPTION: Each SpecimenProcessingProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one SpecimenProcessingProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Common Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Common sub-domain represents the semantics that are common to all (or most) of the other sub-domains. For example, it includes semantics for such things as people, organizations, places and materials.

Common Sub-Domain

View CM: Common diagram

Class diagram in package 'Common Sub-Domain'

The Common sub-domain represents the semantics that are common to all (or most) of the other sub-domains, for example, it includes semantics for such things as people, organizations, places and materials.

View CM: Common

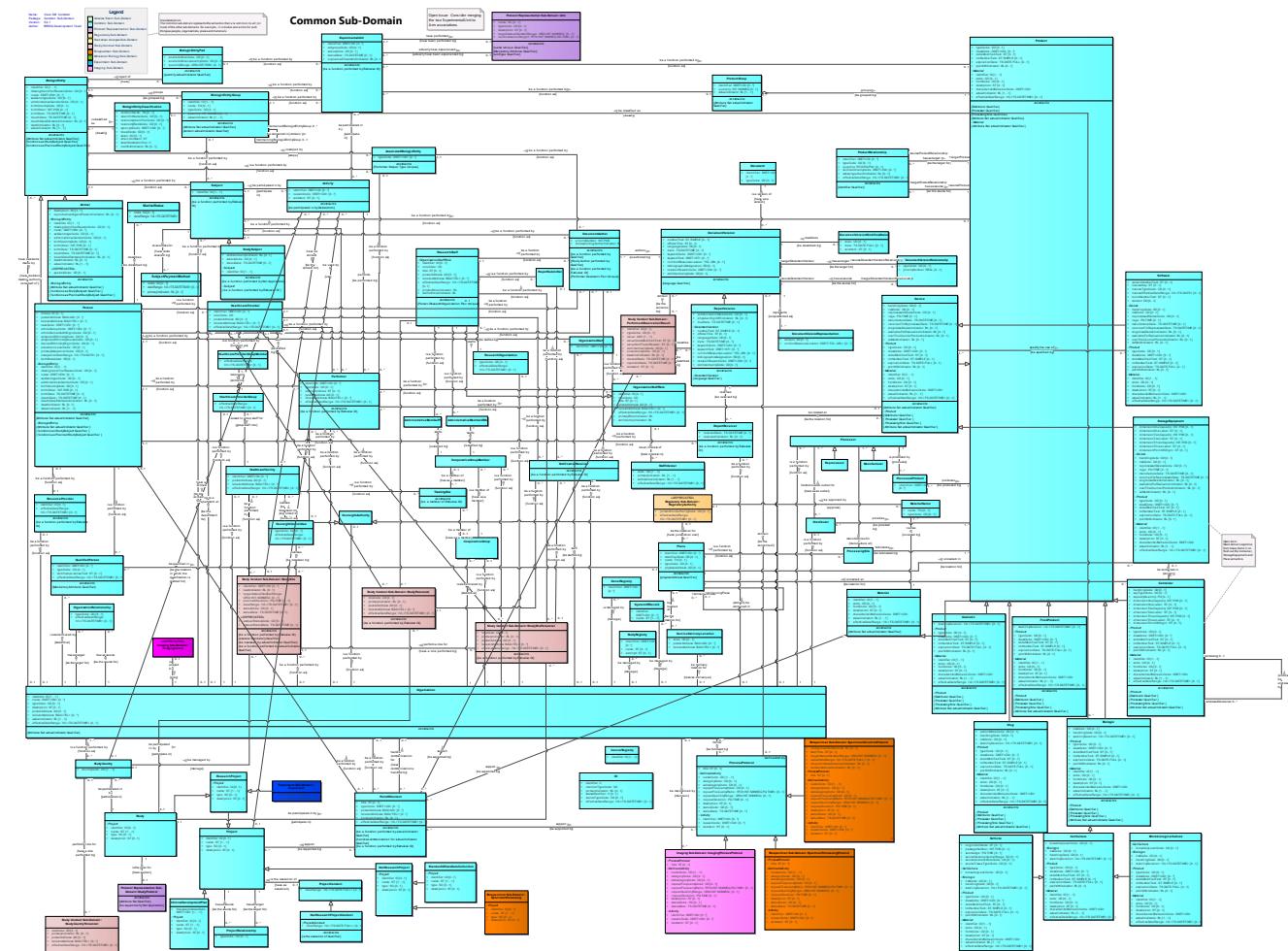


Figure 5: View CM: Common

BRIDG BackBone diagram

Class diagram in package 'Common Sub-Domain'

BRIDG BackBone

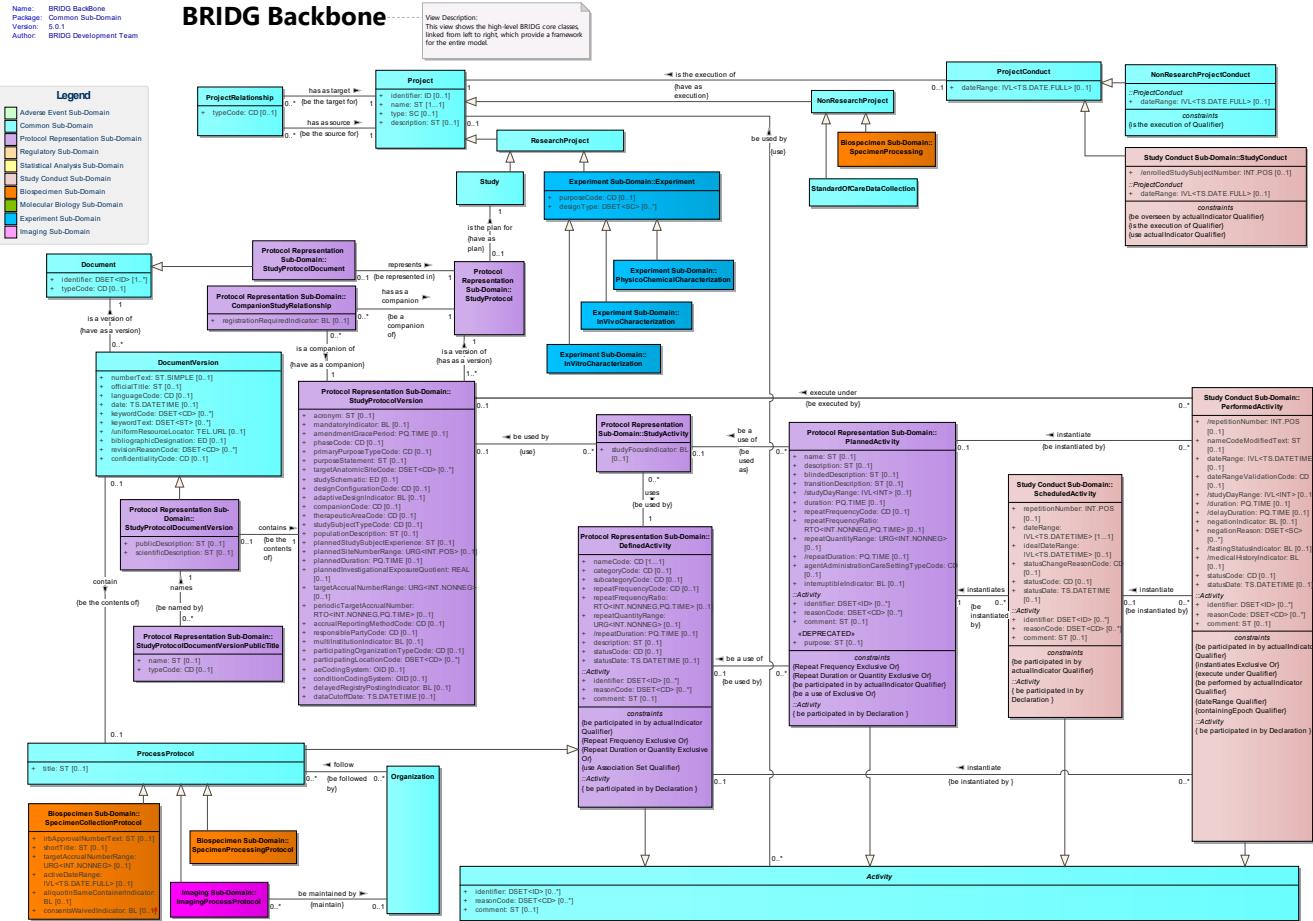


Figure 6: BRIDG BackBone

Class: Activity

Package: Common Sub-Domain

DEFINITION:

Any action that can, in the context of a study, experiment, post-marketing investigation, or disease registry, be defined, planned, scheduled or performed.

EXAMPLE(S):

Administrative activities such as subject registration or informed consent

Clinical activities such as surgical procedure, laboratory test, administration of a drug

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Activity
 - Map:CTRPv1.0 = Activity
 - Map:CTRPv3.8 = Activity
 - Map:CTRRr3 = Activity
 - Map:CTRv1.0 = Activity
 - Map:LSDAMv2.2.3Plus = Activity
 - Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE THERAPY INITIATED

Connectors

Source	Connector	Target	Notes
Activity 0..* hasContextActivity	have as context	StudySite 0..1 contextForStudySite	<p>DESCRIPTION: Each Activity might have as context one StudySite. Each StudySite might be the context for one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* hasContextActivity	have as context	StudyCountry 0..1 contextForStudyCountry	<p>DESCRIPTION: Each Activity might have as context one StudyCountry. Each StudyCountry might be the context for one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* involvingActivity	be participated in by	Subject 0..1 involvedSubject	<p>DESCRIPTION: Each Activity might be participated in by one Subject. Each Subject might participate in one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* involvingActivity	be participated in by	ExperimentalUnit 0..1 involvedExperimentalUnit	<p>DESCRIPTION: Each Activity might be participated in by one ExperimentalUnit. Each ExperimentalUnit might participate in one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
Activity 0..* usedActivity	be used by	Project 0..1 usingProject	<p>DESCRIPTION: Each Activity might be used by one Project. Each Project might use one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedActivity	specializes	Activity	<p>DESCRIPTION: Each PlannedActivity always specializes one Activity. Each Activity might be specialized by one PlannedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performingPerformer	performs	Activity 1 performedActivity	<p>DESCRIPTION: Each Performer always performs one Activity. Each Activity might be performed by one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedActivity	specializes	Activity	<p>DESCRIPTION: Each DefinedActivity always specializes one Activity. Each Activity might be specialized by one DefinedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity	specializes	Activity	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each PerformedActivity always specializes one Activity. Each Activity might be specialized by one PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* usedExperimentalActivityItem	is used in	Activity 1 usingActivity	<p>DESCRIPTION:</p> <p>Each ExperimentalActivityItem always is used in one Activity. Each Activity might use one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTES:</p> <p>The documented use cases from life sciences are limited to procedure and observations. Use cases for other kinds of activities in life sciences are needed to support this relationship at Activity level. In the next release, this relationship will have to be re-assessed.</p>
ScheduledActivity	specializes	Activity	<p>DESCRIPTION:</p> <p>Each ScheduledActivity always specializes one Activity. Each Activity might be specialized by one ScheduledActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Activity <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of an activity.</p> <p>EXAMPLE(S): 12345 is the identifier for a substance administration</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AIM v4 rv48 = Entity.uniqueIdentifier Map:AIM v4 rv48 = ActivityCollection.uniqueIdentifier Map:CTRPv1.0 = PlannedEligibilityCriterion.identifier Map:CTRPv1.0 = Activity.identifier Map:CTRPv1.0 = PlannedActivity.identifier Map:CTRPv1.0 = SubstanceAdministration.identifier Map:CTRPv1.0 = PlannedObservation.identifier Map:CTRPv3.8 = Activity.identifier Map:CTRRr3 = Activity.identifier Map:CTRv1.0 = Activity.identifier Map:DICOM = Patient Study Module - Issuer of Admission ID Sequence (0038,0014) Map:DICOM = Protocol Context Module - Predecessor Protocol Sequence (0018,990E) Map:DICOM = Clinical Trial Study Module - Clinical Trial Time Point ID (0012,0050) Map:DICOM = Patient Study Module - Admission ID (0038,0010) Map:DICOM = Patient Study Module - Service Episode ID (0038,0060) Map:DICOM = Patient Study Module - Issuer of Service Episode ID Sequence (0038,0064) Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Study Instance UID (0020,000D) Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > Activity Session Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Activity Session Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Activity Session Map:DICOM = TID 1502 TimePointContext > Subject Time Point Identifier Map:DICOM = TID 1502 TimePointContext > Protocol Time Point Identifier Map:DICOM = General Study Module - Study Instance UID (0020,000D) Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Act.id Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component4/timePointEventDefinition.id Map:FDA HL7 SD SD DSTU2012 =

Attribute	Notes	Constraints and Tags
		PlannedSubjectActivity/Observation.id Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.id Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Encounter.id Map:FDA HL7 SD SD DSTU2012 = StudyProtocol//plannedStudy/precondition/eligibilityCriterion.id Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.id Map:ICSRr2 = AdverseEffectReference.id (in IndividualCaseSafetyReport) Map:ICSRr2 = ProductEvent.id (in R_Product) Map:ICSRr2 = TransportationEvent.id (in R_Product) Map:Lab = Activity.identifier Map:LabViewer2.2 = LaboratoryTestIdentifier Map:LabViewer2.2 = Activity.identifier Map:LabViewer2.2 = SpecimenCollection.identifier Map:LSDAMv2.2.3Plus = Activity.identifier Map:SDTM IGv3.1.2 = DS.DSREFID Map:SDTM IGv3.1.3 = DS.DSREFID Map:SDTM IGv3.1.3 = MH.MHREFID

Attribute	Notes	Constraints and Tags
reasonCode <i>Class:</i> Activity <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the motivation, cause, or rationale of an activity.</p> <p>EXAMPLE(S): routine requirement, drug reaction, infectious disease reporting requirement, on patient request</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The key difference in how this attribute is used across the Activity subclasses is temporal and the attribute has essentially the same meaning wherever it is used. The most likely uses of reasonCode are with PlannedActivities, where it identifies why an activity should be done as part of the study or experiment plan, and with PerformedActivities, where it identifies why an activity was done. While it's possible for a DefinedActivity to have a reason, BRIDG has no use cases for the use of this attribute in a DefinedActivity, though some may come to harmonization in the future. Nor is it likely, based on existing use cases, to be used much, if at all, for ScheduledActivities.</p>	Map:AE = Indication Map:AE = ProductInvestigation.reasonCode Map:C3PRv2.9 = ScheduledArm.eligibilityWaiverReasonText Map:C3PRv2.9 = StudySubject.backDatedReasonCode Map:C3PRv2.9 = ScheduledEpoch.disapprovalReasonText Map:C3PRv2.9 = ScheduledEpoch.eligibilityWaiverReasonText Map:C3PRv2.9 = ScheduledEpoch.offEpochReasonText Map:CDASHv1.1 = CM.CMINDC Map:CTOM = SpecimenAcquisition.reasonCode Map:CTOM = Procedure.reasonCode Map:CTOM = SubstanceAdministration.reasonCode Map:CTOM = Radiation.reasonCode Map:CTOM = Activity.reasonCode Map:CTOM = Surgery.reasonCode Map:CTOM = FemaleReproductiveCharacteristic.menopauseReasonCode Map:CTOM = Imaging.reasonCode Map:CTOM = FemaleReproductiveCharacteristic.menopauseReasonOtherText Map:CTRPv1.0 = PlannedActivity.reasonCode Map:CTRPv1.0 = PlannedEligibilityCriterion.reasonCode Map:CTRPv1.0 = PlannedObservation.reasonCode Map:CTRPv1.0 = Activity.reasonCode Map:CTRPv1.0 = SubstanceAdministration.reasonCode Map:CTRPv3.8 = PerformedSubjectMilestone.reasonCode Map:CTRv1.0 = PlannedActivity.purpose Map:CTRv1.0 = Activity.reasonCode Map:DICOM = Protocol Context Module - Potential Reasons for Procedure (0018,9908) Map:DICOM = Protocol Context Mdule - Potential Reasons for Procedure Code Sequence (0018,9909) Map:DICOM = Performed CT Reconstruction Module - Protocol Element Identification Macro > Reconstruction Protocol Element Sequence (0018,9934) > Protocol Element Purpose (0018,9924)

Attribute	Notes	Constraints and Tags
		<p>Map:DICOM = General Study Module - Reason For Performed Procedure Code Sequence (0040,1012)</p> <p>Map:DICOM = Performed CT Acquisition Module - Protocol Element Identification Macro > Acquisition Protocol Element Sequence (0018,9920) > Protocol Element Purpose (0018,9924)</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.Specificity #2 of product</p> <p>Map:HCTv1.0 = CDE 3181140:Therapies.Therapeutic procedure administered begin reason:</p> <p>Map:HCTv1.0 = CDE 2691344:Therapies.Specify the indication for the other alternative HCT:</p> <p>Map:HCTv1.0 = CDE 2775979:Therapies.Specify the indication(s) for the supplemental intravenous immunoglobulin therapy:</p> <p>Map:HCTv1.0 = CDE 2680966:Therapies.DCI indication other: specify</p> <p>Map:HCTv1.0 = CDE 2744499:Therapies.Purpose of therapy:</p> <p>Map:HCTv1.0 = CDE 2771502:Therapies.Specify the other indication for the subsequent HSCT:</p> <p>Map:HCTv1.0 = CDE 2957528:Therapies.Specify the reason for the current HSCT:</p> <p>Map:HCTv1.0 = CDE 2861356:Therapies.Indication for therapy:</p> <p>Map:HCTv1.0 = CDE 2775984:Therapies.Specify the other indication type for the supplemental intravenous immunoglobulin therapy:</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.Specificity #1 of product</p> <p>Map:HCTv1.0 = CDE 2861364:Therapies.If code "4" other for indication of therapy, specify:</p> <p>Map:HCTv1.0 = CDE 2691434:Therapies.What was the indication for the alternative hematopoietic cell transplantation (HCT)?</p> <p>Map:HCTv1.0 = CDE 2680962:Therapies.Indication for DCI</p> <p>Map:HCTv1.0 = CDE 2737050:Therapies.Specify the other reason for the non-myeloablative / reduced intensity (NST / RIC) preparative regimen:</p> <p>Map:HCTv1.0 = CDE</p>

Attribute	Notes	Constraints and Tags
		<p>2737040:Preparative Regimen.What was the reason for the reduced intensity/ non-myeloablative preparative regimen? Map:HCTv1.0 = CDE</p> <p>2775815:Therapies.What was the reason hematopoietic, lymphoid growth factors or cytokines were administered? Map:HCTv1.0 = CDE</p> <p>2957419:Therapies.What was the reason for the current HSCT: Map:HCTv1.0 = CDE</p> <p>2771490:Therapies.What was the indication for the subsequent HSCT? Map:ICSRr2 = CausalityAssessment.reasonCode (in IndividualCaseSafetyReport) Map:Lab = Activity.reason Map:LabViewer2.2 = SpecimenCollection.reason Map:LabViewer2.2 = Activity.reason Map:LSDAMv2.2.3Plus = Activity.reasonCode Map:LSDAMv2.2.3Plus = PlannedActivity.purpose Map:NCI CRF Standard = CDE</p> <p>2003870v4.0: Concomitant Agent Concomitant Intervention or Procedure Reason Map:PSC = ScheduledEventState.reason Map:PSC = Occurred.reason Map:PSC = Scheduled.reason Map:SDTM IGv3.1.1 = CM.CMINDC Map:SDTM IGv3.1.1 = DS.DSTERM Map:SDTM IGv3.1.2 = CM.CMINDC Map:SDTM IGv3.1.3 = CM.CMINDC Map:TDM = ContactActivityPurpose.purposeType Map:TDMv2 = (New content - DefinedObservationResult.comment)</p>

Attribute	Notes	Constraints and Tags
comment <i>Class:</i> Activity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Additional description of the activity.</p> <p>EXAMPLE(S): Guidance on how to perform the observation. (for DefinedObservation.comment)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:caAERSv2.2 = TreatmentAssignment.comments Map:caAERSv2.2 = CourseAgent.comments Map:caAERSv2.2 = ReportReviewComment Map:CTRPv1.0 = SubstanceAdministration.comment Map:CTRPv1.0 = PlannedObservation.comment Map:CTRPv1.0 = PlannedEligibilityCriterion.comment Map:CTRPv1.0 = PlannedActivity.comment Map:CTRPv1.0 = Activity.comment Map:CTRv1.0 = Activity.comment Map:CTRv1.0 = DefinedObservationResult.commentText Map:DICOM = Patient Study Module - Service Episode Description (0038,0062) Map:ICSRr2 = CausalityAssessment.text (in IndividualCaseSafetyReport) Map:Lab = Specimen.commentsFromInvestigator Map:Lab = LabTest.comments Map:Lab = Specimen.commentsFromLaboratory Map:LabViewer2.2 = Specimen.commentFromLaboratory Map:LabViewer2.2 = LaboratoryTest.comment Map:LSDAMv2.2.3Plus = Activity.comment Map:LSDAMv2.2.3Plus = DefinedCompositionRelationship.comment Map:PSC = ScheduledEvent.notes Map:PSCv2.6 = ScheduledActivity.notes

Class: AdministrativeMemberCRA

Package: Common Sub-Domain

DEFINITION:

A clinical research associate (CRA) at a site who has the primary responsibility for communications and data related to a specific organizational network in which that site participates.

EXAMPLE(S):

Jane Doe is the Primary CRA for ECOG at Mayo Clinic; she receives all of the ECOG communications at Mayo and distributes them appropriately.

OTHER NAME(S):

NOTE(S)

Tagged Values:

- Map:CoopGrp = AdministrativeMemberCRA

Connectors

Source	Connector	Target	Notes
AdministrativeMemberCRA 1 staffingAdministrativeMem berCRA	staffs	CooperativeGroupMember 1 staffedCooperativeGroupMe mber	DESCRIPTION: Each AdministrativeMemberCRA always staffs one CooperativeGroupMember. Each CooperativeGroupMember always is staffed by one AdministrativeMemberCRA . . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdministrativeMemberCRA 0..* performedAdministrativeMe mberCRA	is a function performed by	ResearchStaff 1 performingResearchStaff	DESCRIPTION: Each AdministrativeMemberCRA always is a function performed by one ResearchStaff. Each ResearchStaff might function as one or more AdministrativeMemberCRA . . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: AdministrativeMemberPI

Package: Common Sub-Domain

DEFINITION:

The principal investigator (PI) at a site who is responsible for all activities related to a specific organizational network's research at that site.

EXAMPLE(S):

"Dr. Smith" is the ECOG site PI at Mayo Clinic. "Dr. Jones" is the site PI for the GOG network participation at Mayo Clinic. They are responsible for the overall management of the entire network's (ECOG, GOG) studies in which the Mayo Clinic participates.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CoopGrp = AdministrativeMemberPI

Connectors

Source	Connector	Target	Notes
AdministrativeMemberPI 1 staffingAdministrativeMemberPI	staffs	CooperativeGroupMember 1 staffedCooperativeGroupMember	DESCRIPTION: Each AdministrativeMemberPI always staffs one CooperativeGroupMember. Each CooperativeGroupMember always is staffed by one AdministrativeMemberPI. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdministrativeMemberPI 0..* performedAdministrativeMemberPI	is a function performed by	ResearchStaff 1 performingResearchStaff	DESCRIPTION: Each AdministrativeMemberPI always is a function performed by one ResearchStaff. Each ResearchStaff might function as one or more AdministrativeMemberPI. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: Animal*Package:* Common Sub-Domain

DEFINITION:

A non-human living organism that has membranous cell walls, requires oxygen and organic foods, and is capable of voluntary movement, as distinguished from a plant or mineral.

EXAMPLE(S):

dog, cat, mouse, microorganism

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Animal
- Map:CTRv1.0 = Animal
- Map:HL7SD = Animal

- Map:HL7SP = Animal
- Map:ICSRr2 = Animal (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = Animal

Connectors

Source	Connector	Target	Notes
Animal	specializes	BiologicEntity	<p>DESCRIPTION: Each Animal always specializes one BiologicEntity. Each BiologicEntity might be specialized by one Animal.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	Animal 0..1 playingAnimal	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one Animal. Each Animal might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
speciesCode <i>Class:</i> Animal <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying one of the basic units of biological classification and taxonomic rank that specifies a group of organisms that share similar characteristics and can interbreed with one another to produce fertile offspring.</p> <p>EXAMPLE(S): Canis lupus, Rattus rattus</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Assuming this is a two-part name, a "binomial name". The first part of a binomial name is the generic name, the genus of the species. The second part is also called the specific name. This attribute has been DEPRECATED. The Species of an Animal is now represented by BiologicEntityClassification.scientificNameCode</p>	Map:AE = Organism.species Map:CTRv1.0 = Animal.speciesCode Map:HCTv1.0 = CDE 2787415:Therapies.Specify the ALS, ALG, ATS, ATG animal source:x Map:HCTv1.0 = CDE 2787403:Therapies.Specify the ALS, ALG, ATS, ATG animal source: Map:HCTv1.0 = CDE 2960357:Therapies.What was the source of the preparative regimen medication? Map:HCTv1.0 = CDE 2753241:Preparative Regimen.Specify the source of the preparative regimen medication: Map:HCTv1.0 = CDE 2960362:Therapies.What was the other source of the preparative regimen medication? Map:HCTv1.0 = CDE 2753243:Therapies.Specify the other source of the preparative regimen medication: Map:HL7SD = Animal.code Map:HL7SP = Animal.code Map:HL7SP = Animal.name Map:ICSRr2 =
description <i>Class:</i> Animal <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A textual or media-based representation of the animal.</p> <p>EXAMPLE(S): paragraph description, digital photo, audio track</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Animal.description Map:HL7SP = Animal.desc Map:ICSRr2 = Animal.desc (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Animal.description
reproductiveOrgansPresentIndicator <i>Class:</i> Animal <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the anatomical parts of the body involved in reproduction are present.</p> <p>EXAMPLE(S): If the animal has been spayed or neutered, reproductiveOrgansPresentIndicator = "false".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Organism.genderStatus Map:CTRv1.0 = Animal.reproductiveOrgansPresentIndicator Map:DICOM = Patient Study Module - Patient's Sex Neutered (0010,2203) Map:HL7SP = Animal.genderStatusIndicator Map:ICSRr2 = Animal.genderStatusCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = reproductiveOrganPresentIndicator

Class: AssociatedBiologicEntity

Package: Common Sub-Domain

DEFINITION:
An individual biologic entity connected/linked to another biologic entity.

EXAMPLE(S):

family member, roommate, nursing home attendant

OTHER NAME(S):**NOTE(S):*****Tagged Values:***

- Map:AE = PersonalRelationship
- Map:CTRv1.0 = AssociatedBiologicEntity
- Map:HL7SD = Role
- Map:HL7SP = Role
- Map:HL7SP = LivingSubject
- Map:ICSRr2 = ContactParty2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Role2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Role (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = AssociatedBiologicEntity

Connectors

Source	Connector	Target	Notes
AssociatedBiologicEntity 0..* performedAssociatedBiologicEntity	is a function performed by	BiologicEntity 1 performingBiologicEntity	<p>DESCRIPTION: Each AssociatedBiologicEntity always is a function performed by one BiologicEntity. Each BiologicEntity might function as one or more AssociatedBiologicEntity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AssociatedBiologicEntity 0..* scopedAssociatedBiologicEntity	is scoped by	BiologicEntity 1 scopingBiologicEntity	<p>DESCRIPTION: Each AssociatedBiologicEntity always is scoped by one BiologicEntity. Each BiologicEntity might scope one or more AssociatedBiologicEntity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	AssociatedBiologicEntity 0..1 performingAssociatedBiologicEntity	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one AssociatedBiologicEntity. Each</p>

Source	Connector	Target	Notes
			<p>AssociatedBiologicEntity might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	AssociatedBiologicEntity 0..1 performingAssociatedBiologicEntity	<p>DESCRIPTION: Each Performer might be a function performed by one AssociatedBiologicEntity. Each AssociatedBiologicEntity might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> AssociatedBiologicEntity <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the kind of associated biologic entity.</p> <p>EXAMPLE(S): family member, roommate, guardian, nursing home attendant</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = PersonalRelationship.typeCode Map:AE = Reporter.relationshipToAEInvestigativeSubject Map:CTRv1.0 = AssociatedBiologicEntity.typeCode Map:DICOM = Patient Module - Responsible Person Role (0010,2298) Map:HCTv1.0 = CDE 2693219:Lab Results.Who is being tested for IDMs? Map:HCTv1.0 = CDE 2728894:Property or Attribute.Specify the other relationship between the donor and the recipient: Map:HCTv1.0 = CDE 2728852:Property or Attribute.What is the other relationship of the donor to the recipient: Map:HCTv1.0 = CDE 2784447:Property or Attribute.What is the relationship of the donor to the recipient? Map:HCTv1.0 = CDE 2705055:Lab Results.Please specify the person for whom this typing is being done: Map:HL7SD = Role.code Map:HL7SP = LivingSubject.role Map:HL7SP = Role.code Map:ICSRr2 = Role.code (in IndividualCaseSafetyReport) Map:ICSRr2 = ContactParty2.classCode (in IndividualCaseSafetyReport) Map:ICSRr2 = Role2.code (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = AssociatedBiologicEntity.typeCode

Class: Biologic

Package: Common Sub-Domain

DEFINITION:

A substance made from a living organism or thing it produces.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv1.0 = Biologic
- Map:CTRRr3 = Biologic
- Map:CTRv1.0 = Biologic

Connectors

Source	Connector	Target	Notes
Biologic	specializes	Product	<p>DESCRIPTION: Each Biologic always specializes one Product. Each Product might be specialized by one Biologic.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Biologic 0..* classifiedBiologic	be classified as	BiologicEntityClassification 0..1 classifyingBiologicEntityClassification	<p>DESCRIPTION: Each Biologic might be classified as one BiologicEntityClassification. Each BiologicEntityClassification might classify one or more Biologic.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HCT: Extracted Substance		Biologic	
PerformedSubstanceExtraction 0..* producingPerformedSubstanceExtraction	produces	Biologic 1 producedBiologic	<p>DESCRIPTION: Each PerformedSubstanceExtraction always produces one Biologic. Each Biologic might be produced by one or more PerformedSubstanceExtraction.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CellCulture	specializes	Biologic	<p>DESCRIPTION: Each CellCulture always specializes one Biologic. Each Biologic might be specialized by one CellCulture.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
riskCode <i>Class:</i> Biologic <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the type of hazard or threat associated with the biologic.</p> <p>EXAMPLE(S): flammable, explosive</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Biologic.riskCode Map:ICSRr2 = Product.riskCode (in R_Product)
handlingCode <i>Class:</i> Biologic <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a special handling requirement for the biologic.</p> <p>EXAMPLE(S): keep at room temperature, store upright</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Biologic.handlingCode Map:ICSRr2 = Product.handlingCode (in R_Product)
stabilityDuration <i>Class:</i> Biologic <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time during which the biologic is considered usable after it is activated (opened).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Biologic.stabilityDuration Map:ICSRr2 = ProductInstance.stabilityTime (in R_Product)

Class: BiologicEntity

Package: Common Sub-Domain

DEFINITION:
Any individual living (or previously living) being.

EXAMPLE(S):
animal, human being

OTHER NAME(S):
organism

NOTE(S):

Tagged Values:

- Map:AE = Organism
- Map:AIM v4 rv48 = Person
- Map:CTRr3 = BiologicEntity
- Map:CTRv1.0 = BiologicEntity
- Map:HL7SP = Access
- Map:LSDAMv2.2.3Plus = BiologicEntity

Connectors

Source	Connector	Target	Notes
BiologicEntity 0..* caredForBiologicEntity	have decisions made by	Organization 0..1 responsibleOrganization	<p>DESCRIPTION: Each BiologicEntity might have decisions made by one Organization. Each Organization might have decision making authority on behalf of one or more BiologicEntity.</p> <p>DEFINITION: The link between a person or animal and the organization who has decision making authority for them.</p> <p>EXAMPLE(S): In non-human primate research, such as at UC Davis Primate Center, the Center is responsible for the health and well-being of the primates, irrespective of the research.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
BiologicEntity 0..* classifiedBiologicEntity	is classified as	BiologicEntityClassification 1 classifyingBiologicEntityClassification	<p>DESCRIPTION: Each BiologicEntity always is classified as one BiologicEntityClassification. Each BiologicEntityClassification might classify one or more BiologicEntity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AssociatedBiologicEntity 0..* performedAssociatedBiologicEntity	is a function performed by	BiologicEntity 1 performingBiologicEntity	<p>DESCRIPTION: Each AssociatedBiologicEntity always is a function performed by one BiologicEntity. Each BiologicEntity might</p>

Source	Connector	Target	Notes
			function as one or more AssociatedBiologicEntity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Subject 0..* performedSubject	be a function performed by	BiologicEntity 0..1 performingBiologicEntity	DESCRIPTION: Each Subject might be a function performed by one BiologicEntity. Each BiologicEntity might function as one or more Subject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AssociatedBiologicEntity 0..* scopedAssociatedBiologicEntity	is scoped by	BiologicEntity 1 scopingBiologicEntity	DESCRIPTION: Each AssociatedBiologicEntity always is scoped by one BiologicEntity. Each BiologicEntity might scope one or more AssociatedBiologicEntity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Person	specializes	BiologicEntity	DESCRIPTION: Each Person always specializes one BiologicEntity. Each BiologicEntity might be specialized by one Person.: DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..*	be a function performed by	BiologicEntity 0..1	DESCRIPTION: Each ExperimentalUnit

Source	Connector	Target	Notes
performedExperimentalUnit		performingBiologicEntity	<p>might be a function performed by one BiologicEntity. Each BiologicEntity might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Animal	specializes	BiologicEntity	<p>DESCRIPTION: Each Animal always specializes one BiologicEntity. Each BiologicEntity might be specialized by one Animal.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
BiologicEntityPart 0..* containedBiologicEntityPart	is part of	BiologicEntity 1 containingBiologicEntity	<p>DESCRIPTION: Each BiologicEntityPart always is part of one BiologicEntity. Each BiologicEntity might have one or more BiologicEntityPart.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
BiologicEntityGroup 0..* groupingBiologicEntityGro up	groups	BiologicEntity 1..* groupedBiologicEntity	<p>DESCRIPTION: Each BiologicEntityGroup always groups one or more BiologicEntity. Each BiologicEntity might be grouped by one or more BiologicEntityGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> BiologicEntity <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the biologic entity.</p> <p>EXAMPLE(S): medical record number</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is different from the SubjectIdentifier.identifier.</p>	Map:AE = PersonIdentifier.sponsoringOrganization Map:AE = PersonIdentifier.identifier Map:AIM v4 rv48 = Person.id Map:C3PR = Participant.identifiers Map:C3PR = ResearchStaff.nciIdentifier Map:CTRPv1.0 = IdentifiedBiologicEntity.identifier Map:CTRPv3.8 = Person.identifier Map:CTRPv3.8 = IdentifiedEntity.assignedIdentifier Map:CTRv1.0 = BiologicEntityIdentifier.identifier Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Patient ID (0010,0020) Map:DICOM = Patient Module - Other Patient IDs Sequence > Patient ID (0010,0020) Map:DICOM = Patient Module - Patient ID (0010,0020) Map:DICOM = TID 1007 SubjectContext,Patient > Subject ID Map:HCTv1.0 = CDE 2527897:Recipient Identification.CIBMTR recipient ID (CRID) Universal Recipient ID Map:HCTv1.0 = CDE 2958200:Individuals.IUBMID # Map:HCTv1.0 = CDE 2735593:Individuals.Non-NMDP donor ID: Map:HCTv1.0 = MD Anderson Specific Content: Recipient.Recipient medical record number Map:HCTv1.0 = CDE 2220102:Individuals.Social Security Number Map:HCTv1.0 = CDE 2729076:Specimen Characteristics.Research sample recipient ID: Map:HL7SD = Animal.id Map:HL7SP = Animal.id Map:ICSRr2 = IdentifiedEntity2.id (in IndividualCaseSafetyReport) Map:ICSRr2 = IdentifiedEntity3.id (in IndividualCaseSafetyReport) Map:ICSRr2 = IdentifiedEntity.id (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = BiologicEntityIdentifier.identifier Map:NCI CRF Standard = CDE 2465308v1.0: Patient Multiple Clinical Trials Cooperative Group Identifier Number Map:NCI CRF Standard = CDE

Attribute	Notes	Constraints and Tags
		2746468v1.0: Healthcare Facility Participant Identifier Map:NCI CRF Standard = CDE 2822790v1.0: Participant Prior Clinical Study Identifier Map:PSC = Participant.personId Map:PSCv2.6 = Subject.personId
missingIdentifierReasonCode <i>Class:</i> BiologicEntity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying why the identifier was not provided.</p> <p>EXAMPLE(S): forgot to ask, subject refused</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value should only be populated if BiologicEntityIdentifier.identifier is null.</p>	Map:HCTv1.0 = CDE 3115786:Individuals.If necessary, please validate patient identifier response. Map:HCTv1.0 = CDE 3115593:Individuals.If necessary, please validate the Social Security number response:

Attribute	Notes	Constraints and Tags
name <i>Class:</i> BiologicEntity <i>Datatype:</i> DSET<EN> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A non-unique textual identifier for the biologic entity.</p> <p>EXAMPLE(S): assumed name of "Mark Twain", official registry name of "Samuel Clemens", customary name of "Sam Clemens"</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The EN.use attribute of the EN data type is used to distinguish the various types of names, such as official registry, customary, assumed.</p>	Map:AE = Reporter.personName Map:AE = Receiver.personName Map:AE = ContactPerson.name Map:AIM v4 rv48 = Person.name Map:C3PR = Person.lastName Map:C3PR = Person.firstName Map:C3PR = Person.middleName Map:C3PR = Person maidenName Map:C3PRv2.9 = Person.firstName Map:C3PRv2.9 = StudySubject.otherTreatingPhysician Map:C3PRv2.9 = Person.lastName Map:C3PRv2.9 = Person.middleName Map:C3PRv2.9 = Person maidenName Map:caAERSv2.2 = Person.firstName Map:caAERSv2.2 = Person maidenName Map:caAERSv2.2 = Recipient.name Map:caAERSv2.2 = Person.lastName Map:caAERSv2.2 = Participant maidenName Map:CTGOV = Investigators - FirstName Map:CTGOV = Investigators - LastName Map:CTGOV = Central Contact - FirstName Map:CTGOV = Overall Study Officials - Middle Initial Map:CTGOV = Central Contact - LastName Map:CTGOV = Overall Study Officials - LastName Map:CTGOV = Responsible Party - Name/Official Title Map:CTGOV = Investigators - Middle Initial Map:CTGOV = Central Contact - Middle Initial Map:CTGOV = Overall Study Officials - FirstName Map:CTGOV = Facility Contact - FirstName Map:CTGOV = Facility Contact - LastName Map:CTGOV = Facility Contact - Middle Initial Map:CTOM = Participant.firstName Map:CTOM = Investigator.middleName Map:CTOM = Person.firstName Map:CTOM = Person.lastName Map:CTOM = Person.middleName Map:CTOM = Participant.middleName Map:CTOM = Investigator.firstName Map:CTOM = Participant.lastName Map:CTOM = Investigator.lastName Map:CTR&Rr2 = Subcontractor Middle Name Map:CTR&Rr2 = Network Middle

Attribute	Notes	Constraints and Tags
		Name Map:CTR&Rr2 = IEC Applicant Given Name Map:CTR&Rr2 = Sponsor Contact Middle name Map:CTR&Rr2 = CTF Middle Name Map:CTR&Rr2 = Subcontractor Family Name Map:CTR&Rr2 = Legal Rep Given Name Map:CTR&Rr2 = CA Applicant Family Name Map:CTR&Rr2 = Investigator Family Name Map:CTR&Rr2 = CA Applicant Given Name Map:CTR&Rr2 = Network Family Name Map:CTR&Rr2 = CTF Family Name Map:CTR&Rr2 = IEC Applicant Middle Name Map:CTR&Rr2 = IEC Applicant Family Name Map:CTR&Rr2 = Subcontractor Given Name Map:CTR&Rr2 = CTF Given Name Map:CTR&Rr2 = Legal Rep Middle Name Map:CTR&Rr2 = CA Applicant Middle Name Map:CTR&Rr2 = Sponsor Contact Given name Map:CTR&Rr2 = Network Given Name Map:CTR&Rr2 = Investigator Given Name Map:CTR&Rr2 = Investigator Middle Name Map:CTR&Rr2 = Sponsor Contact Family Name Map:CTR&Rr2 = Legal Rep Family Name Map:CTRPv1.0 = Person.name Map:CTRPv3.8 = Person.name Map:CTRR = Secondary Sponsor Map:CTRR = Coordinating investigator Map:CTRR = Site Representative/Investigator Map:CTRR = Principal Investigator Map:CTRR = Responsible Contact Person Map:CTRR = Sponsor Map:CTRR = Financial Sponsor Map:CTRr3 = Person.name Map:CTRv1.0 = BiologicEntity.name Map:DICOM = TID 1007 SubjectContext,Patient > Subject Name Map:DICOM = Clinical Trial Context Module - Clinical Trial Sponsor Name

Attribute	Notes	Constraints and Tags
		<p>(0012,0010) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Other Patient Names (0010,1001) Map:DICOM = Patient Module - Patient's Name (0010,0010) Map:DICOM = Patient Module - Responsible Person (0010,2297) Map:DICOM = Patient Module - Other Patient Names (0010,1001) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Sponsor Name (0012,0010) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Patient's Name (0010,0010) Map:HCTv1.0 = CDE 3115634:UML DEFAULT CD.Mother's maiden name: Map:HSDBV1.0 = [Principal Investigator].Last Name Map:HSDBV1.0 = [Principal Investigator].Middle Name Map:HSDBV1.0 = [Sponsor Contact].First Name Map:HSDBV1.0 = [Study].Responsible Party Map:HSDBV1.0 = [Sponsor Contact].Middle Name Map:HSDBV1.0 = [Principal Investigator].First Name Map:HSDBV1.0 = [Sponsor Contact].Last Name Map:ICSRr2 = contactPerson.name (in R_Product) Map:ICSRr2 = Animal.name (in IndividualCaseSafetyReport) Map:ICSRr2 = ContactPerson.name (in E_Organization informational) Map:ICSRr2 = Person.name (in IndividualCaseSafetyReport) Map:ICSRr2 = Person2.name (in IndividualCaseSafetyReport) Map:Lab = Investigator.name Map:LabViewer2.2 = Investigator.middleName Map:LabViewer2.2 = Investigator.lastName Map:LabViewer2.2 = Investigator.firstName Map:LSDAMv2.2.3Plus = Person.name Map:NCI CRF Standard = CDE 2179589v2.0: Person Given/First Name Map:NCI CRF Standard = CDE 2179591v2.0: Person Family/Last Name Map:NCI CRF Standard = CDE </p>

Attribute	Notes	Constraints and Tags
		<p>2006475v2.0: Individual Genealogy Suffix Code Map:NCI CRF Standard = CDE 2452692v1.0: Clinical Research Associate Responsible Person Name Map:NCI CRF Standard = CDE 3008899v1.0: Reviewer Name Map:NCI CRF Standard = CDE 2006163v1.0: Responsible Person Name Map:NCI CRF Standard = CDE 2740424v1.0: Treating Physician Or Participating Investigator Name Map:NCI CRF Standard = CDE 62749v3.0: Treating Physician Name Map:NCI CRF Standard = CDE 2179590v2.0: Person Middle Name Map:NCI CRF Standard = CDE 2746480v1.0: Specialist Physician Name Map:NCI CRF Standard = CDE 2172v3.0: Protocol Registrar Name Map:PSC = Participant.lastName Map:PSC = Participant.firstName Map:PSCv2.6 = Subject.firstName Map:PSCv2.6 = Subject.lastName Map:SDTM IGv3.1.1 = DM.INVNAM Map:SDTM IGv3.1.2 = DM.INVNAM Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=SPONSOR Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SPONSOR" Map:SDTM IGv3.1.3 = DM.INVNAM Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - LAST NAME Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - FIRST NAME Map:Vendor1v1.1 = BiologicEntity.name Map:WHO = Contact for Public Queries - lastname Map:WHO = Contact for Scientific Queries - lastname Map:WHO = Contact for Public Queries - firstname Map:WHO = Primary Sponsor Map:WHO = Secondary Sponsor(s) Map:WHO = Contact for Public Queries - middlename Map:WHO = Contact for Scientific Queries - middlename Map:WHO = Contact for Scientific Queries - firstname Map:WHO = Source(s) of Monetary or Material Support</p>

Attribute	Notes	Constraints and Tags
sexGenotypeCode <i>Class:</i> BiologicEntity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the sex of a biologic entity based upon the characterization of the biologic entity's genes.</p> <p>EXAMPLE(S): For humans, the most common sex genotypes are XX and XY.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = BiologicEntity.sexGenotypeCode

Attribute	Notes	Constraints and Tags
administrativeGenderCode <i>Class:</i> BiologicEntity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the physical or societal properties by which male is distinguished from female.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): For humans, identification of sex is usually based upon self-report and may come from a form, questionnaire, interview, etc.</p>	Map:AE = Organism.sex Map:AIM v4 rv48 = Person.sex Map:C3PR = Participant.administrativeGenderCode Map:C3PRv2.9 = Participant.administrativeGenderCode Map:caAERSv2.2 = Participant.gender Map:CDASHv1.1 = DM.SEX Map:CTOM = Person.administrativeGenderCode Map:CTOM = Participant.administrativeGenderCode Map:CTOM = Investigator.administrativeGenderCode Map:CTRPv1.0 = Person.sexCode Map:CTRPv3.8 = Person.sexCode Map:CTRv1.0 = BiologicEntity.administrativeGenderCode Map:DICOM = Patient Module - Patient's Sex (0010,0040) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Patient's Sex (0010,0040) Map:DICOM = TID 1007 SubjectContext,Patient > Subject Sex Map:HCTv1.0 = CDE 2200604:Recipient Identification.Gender Map:HCTv1.0 = CDE 2180389:Physical Description of Individuals.Donor Gender Map:HCTv1.0 = CDE 3171628:Physical Description of Individuals.Person Gender: Map:HL7SP = Animal.administrativeGenderCode Map:ICSRr2 = Animal.administrativeGenderCode (in IndividualCaseSafetyReport) Map:ICSRr2 = Person2.administrativeGenderCode (in IndividualCaseSafetyReport) Map:LabViewer2.2 = ParticipantSex.codeSystemName Map:LabViewer2.2 = ParticipantSex.code Map:LabViewer2.2 = ParticipantSex.codeSystemVersion Map:LabViewer2.2 = ParticipantSex.displayName Map:LabViewer2.2 = ParticipantSex.codeSystem Map:LSDAMv2.2.3Plus = BiologicEntity.administrativeGenderCode Map:NCI CRF Standard = CDE 2200604v3.0: Person Gender Text

Attribute	Notes	Constraints and Tags
		Type Map:PSC = Participant.gender Map:PSCv2.6 = Subject.gender Map:SDTM IGv3.1.1 = DM.SEX Map:SDTM IGv3.1.2 = DM.SEX Map:SDTM IGv3.1.3 = DM.SEX Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - SEX
birthCountryCode <i>Class:</i> BiologicEntity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the name of the country in which the biologic entity is born. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Organism.birthCountry Map:CTRv1.0 = BiologicEntity.birthCountryCode Map:LSDAMv2.2.3Plus = BiologicEntity.birthCountryCode Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - BIRTHPLACE – COUNTRY
birthOrder <i>Class:</i> BiologicEntity <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Indicates the sequence of a biologic entity's birth in the family group. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Organism.birthOrder Map:CTRv1.0 = BiologicEntity.birthOrder Map:LSDAMv2.2.3Plus = BiologicEntity.birthOrder

Attribute	Notes	Constraints and Tags
birthDate <i>Class:</i> BiologicEntity <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the biologic entity is born.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Organism.birthDate Map:C3PR = Participant.birthDate Map:C3PRv2.9 = Participant.birthDate Map:caAERSv2.2 = Participant.birthDate Map:CDASHv1.1 = DM.BRTHYR Map:CDASHv1.1 = DM.BRTHDY Map:CDASHv1.1 = DM.BRTHMO Map:CDASHv1.1 = DM.BRTHDAT Map:CDASHv1.1 = DM.BRTHTIM Map:CTOM = Participant.birthDate Map:CTOM = Investigator.birthDate Map:CTOM = Person.birthDate Map:CTRPv3.8 = Person.birthDate Map:CTRv1.0 = BiologicEntity.birthDate Map:DICOM = Patient Module - Patient's Birth Date (0010,0030) Map:DICOM = Patient Module - Patient's Birth Time (0010,0032) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Patient's Birth Date (0010,0030) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Patient's Birth Time (0010,0032) Map:DICOM = TID 1007 SubjectContext,Patient > Subject Birth Date Map:HCTv1.0 = CDE 2180386:Individuals.Donor Birth Date Map:HCTv1.0 = CDE 3098934:Individuals.What is the reason for the mother's missing age? Map:HCTv1.0 = CDE 2883970:Individuals.What is the transplant donor or infant date of birth? Map:HCTv1.0 = CDE 2866121:Recipient Identification.Patient Date of Birth Map:HL7SP = Animal.birthtime Map:ICSRr2 = Animal.birthTime (in IndividualCaseSafetyReport) Map:ICSRr2 = Person2.birthTime (in IndividualCaseSafetyReport) Map:Lab = Investigator.dateOfBirth Map:Lab = Participant.dateOfBirth Map:Lab = Person.dateOfBirth Map:LabViewer2.2 = Person.dateOfBirth Map:LabViewer2.2 = Participant.dateOfBirth Map:LSDAMv2.2.3Plus = BiologicEntity.birthDate Map:NCI CRF Standard = CDE 793v5.1: Person Birth Date Map:PSC = Participant.birthDate

Attribute	Notes	Constraints and Tags
		Map:PSCv2.6 = Subject.dateOfBirth Map:SDTM IGv3.1.1 = DM.BRTHDTC Map:SDTM IGv3.1.2 = DM.BRTHDTC Map:SDTM IGv3.1.3 = DM.BRTHDTC Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - DATE OF BIRTH FLAG Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - DATE OF BIRTH
deathDate <i>Class:</i> BiologicEntity <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the biologic entity died.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This BRIDG SCC reserves the option of re-modeling this in future since death date itself might be better modeled as an observation result and this attribute might better be represented as an uncertaintyCode on that observation result.</p>	Map:AE = Organism.deathDate Map:CTOM = DeathSummary.deathDate Map:CTRv1.0 = BiologicEntity.deathDate Map:HCTv1.0 = CDE 2866512:Occurrences.Date of death: Map:HL7SP = Animal.deceasedTime Map:ICSRr2 = Animal.deceasedTime (in IndividualCaseSafetyReport) Map:ICSRr2 = Person2.deceasedTime (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = BiologicEntity.deathDate Map:SDTM IGv3.1.3 = DM.DTHDTC Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - DATE OF LAST FOLLOW UP OR DEATH FLAG Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - DATE OF LAST FOLLOW UP OR OF DEATH
deathDateEstimatedIndicator <i>Class:</i> BiologicEntity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the death date is approximate.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This BRIDG SCC reserves the option of re-modeling this in future since death date itself might be better modeled as an observation result and this attribute might better be represented as an uncertaintyCode on that observation result.</p>	Map:HCTv1.0 = CDE 2768794:Occurrences.If necessary, please validate the death date response

Attribute	Notes	Constraints and Tags
deathIndicator <i>Class:</i> BiologicEntity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the biologic entity is dead. EXAMPLE(S): OTHER NAME(S): NOTE(S): This BRIDG SCC reserves the option of re-modeling this in future since death date itself might be better modeled as an observation result and this attribute might better be represented as an uncertaintyCode on that observation result.	Map:CTOM = DeathSummary.deathDate (when date is not known but death is known) Map:CTRv1.0 = BiologicEntity.deathIndicator Map:ICSRr2 = Animal.deceasedInd (in IndividualCaseSafetyReport) Map:ICSRr2 = Person2.deceasedInd (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Person.deathIndicator Map:SDTM IGv3.1.3 = DM.DTHFL Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - VITAL STATUS
actualIndicator <i>Class:</i> BiologicEntity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether the biologic entity is a particular instance (actual) vs. universal kind. EXAMPLE(S): To indicate a particular BiologicEntity, actualIndicator = 'true'. To indicate a kind of BiologicEntity, actualIndicator = "false". OTHER NAME(S): NOTE(S):	Map:C3PR = StudySubject.actualSubjectIndicator Map:CTRv1.0 = BiologicEntity.actualIndicator Map:HL7SD = NonPersonLivingSubjectKind.determinerCode Map:HL7SD = ExperimentalUnit>ExperimentalUnit2 (choice box).determinerCode Map:HL7SD = R_AssignedEntity(Universal) Map:HL7SD = PersonKind.determinerCode Map:ICSRr2 = Person2.determinerCode (in IndividualCaseSafetyReport) Map:ICSRr2 = Person.determinerCode (in IndividualCaseSafetyReport) Map:ICSRr2 = Animal.determinerCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = BiologicEntity.actualIndicator

Class: BiologicEntityClassification

Package: Common Sub-Domain

DEFINITION:

A group within a system of categories distinguished by structure, origin, etc. to which organisms may be assigned. [adapted from <http://dictionary.reference.com/browse/classification?s=t>]

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Organism

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
MolecularSequence 0..* includedMolecularSequence	is included in	BiologicEntityClassification 1 includingBiologicEntityClassification	<p>DESCRIPTION: Each MolecularSequence always is included in one BiologicEntityClassification . Each BiologicEntityClassification might include one or more MolecularSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Chromosome 0..* containedChromosome	is part of	BiologicEntityClassification 1 containingBiologicEntityClassification	<p>DESCRIPTION: Each Chromosome always is part of one BiologicEntityClassification . Each BiologicEntityClassification might contain one or more Chromosome.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Biologic 0..* classifiedBiologic	be classified as	BiologicEntityClassification 0..1 classifyingBiologicEntityClassification	<p>DESCRIPTION: Each Biologic might be classified as one BiologicEntityClassification . Each BiologicEntityClassification might classify one or more Biologic.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Genome 0..* containedGenome	is part of	BiologicEntityClassification 1 containingBiologicEntityClassification	<p>DESCRIPTION: Each Genome always is part of one BiologicEntityClassification . Each BiologicEntityClassification might contain one or more Genome.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
Pathway 0..* includedPathway	be included by	BiologicEntityClassification 0..* includingBiologicEntityClassification	DESCRIPTION: Each Pathway might be included by one or more BiologicEntityClassification . Each BiologicEntityClassification might include one or more Pathway. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
BiologicEntity 0..* classifiedBiologicEntity	is classified as	BiologicEntityClassification 1 classifyingBiologicEntityClassification	DESCRIPTION: Each BiologicEntity always is classified as one BiologicEntityClassification . Each BiologicEntityClassification might classify one or more BiologicEntity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
commonName <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> TN <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The generally-used term for the organism type. EXAMPLE(S): human is the common name for the species Homo sapiens OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Organism.commonName

Attribute	Notes	Constraints and Tags
scientificNameCode <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the scientific term for the taxon, generally, the genus and species of the organism.</p> <p>EXAMPLE(S): Homo Sapiens or Mus.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Organism.species Map:CTRv1.0 = Animal.speciesCode Map:DICOM = Patient Module - Patient Species Description (0010,2201) Map:DICOM = TID 1007 SubjectContext, Patient > Subject Species Map:HCTv1.0 = CDE 2787415:Therapies.Specify the ALS, ALG, ATS, ATG animal source:x Map:HCTv1.0 = CDE 2753243:Therapies.Specify the other source of the preparative regimen medication: Map:HCTv1.0 = CDE 2960362:Therapies.What was the other source of the preparative regimen medication? Map:HCTv1.0 = CDE 2960357:Therapies.What was the source of the preparative regimen medication? Map:HCTv1.0 = CDE 2787403:Therapies.Specify the ALS, ALG, ATS, ATG animal source: Map:HL7SD = Animal.code Map:HL7SP = Animal.name Map:ICSRr2 = Map:LSDAMv2.2.3Plus = Organism.scientificName Map:PGx v1.0 = PB.PBNSPCES Map:PGx v1.0 = PG.PGNSPCES Map:PGx v1.0 = SB.SBNSPCES Map:PGx v1.0 = PF.PFNSPCES
taxonomyIdentifierCode <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the stable unique identifier for the taxon from a taxonomy database.</p> <p>EXAMPLE(S): A taxon identifier from the National Center for Biotechnology Information (NCBI)'s Taxonomy database</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Patient Module - Patient Species Code Sequence > URN Code Value (0008,0120) Map:DICOM = Patient Module - Patient Species Code Sequence > Long Code Value (0008,0119) Map:DICOM = Patient Module - Patient Species Code Sequence > Code Meaning (0008,0104) Map:DICOM = Patient Module - Patient Species Code Sequence > Coding Scheme Version (0008,0103) Map:DICOM = Patient Module - Patient Species Code Sequence > Coding Scheme Designator (0008,0102) Map:DICOM = Patient Module - Patient Species Code Sequence > Code Value (0008,0100) Map:DICOM = Patient Module - Patient Species Code Sequence (0010,2202) Map:LSDAMv2.2.3Plus = Organism.taxonomyIdentifier

Attribute	Notes	Constraints and Tags
taxonomyRankCode <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the name of the node in a taxonomic tree. EXAMPLE(S): genus, species OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Organism.taxonomyRange
synonymCode <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	DEFINITION: A coded value specifying an alternate common or scientific name by which the biologic entity classification is known. EXAMPLE(S): Mus muscaris (as a misnomer for "Mus musculus") as a coded value coming from NCBI Taxonomy Database OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Organism.(AdditionalOrganismName) Map:LSDAMv2.2.3Plus = AdditionalOrganismName.value Map:LSDAMv2.2.3Plus = AdditionalOrganism.value Map:LSDAMv2.2.3Plus = AdditionalOrganismName.source
breedCode <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying a group of animals presumably related by descent from common ancestors and visibly similar in most characteristics. EXAMPLE(S): Holstein, Angora, Himalayan cat, Labrador Retriever OTHER NAME(S): NOTE(S):	Map:AE = Animal.breed Map:CTRv1.0 = Animal.breedCode Map:DICOM = TID 1007 SubjectContext, Patient > Subject Breed Map:DICOM = Patient Module - Patient Breed Code Sequence (0010,2293) Map:DICOM = Patient Module - Patient Breed Description (0010,2292) Map:LSDAMv2.2.3Plus = Animal.breedCode

Attribute	Notes	Constraints and Tags
strain <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The text (and optional code) specifying a group of presumed common ancestry with clear-cut physiological but usually not morphological distinctions.</p> <p>EXAMPLE(S): Minnesota5 (swine strain), DXL (poultry strain) For DICOM's Strain Code Sequence (0010,0219): string = "C57BL/6J", code = "3028467". For DICOM's Strain Nomenclature (0010,0213): codeSystem(OID).extension = "MGI_2013", codeSystem(OID).root = <OID for DICOM assigned terms for strain nomenclature></p> <p>OTHER NAME(S):</p> <p>NOTE(S): The specific genotypic or phenotypic variant of an animal, microorganism, fungus, or pathogen. DICOM defines this to be a group of animals that are genetically uniform.</p>	Map:CTRV1.0 = Animal.strain Map:DICOM = Patient Module - Strain Nomenclature (0010,0213) Map:DICOM = Patient Module - Strain Code Sequence (0010,0219) Map:DICOM = Patient Module - Strain Description (0010,0212) Map:HL7SP = Animal.strainText Map:LSDAMv2.2.3Plus = BiologicEntity.subSpeciesRank Map:PGx v1.0 = PF.PFNSTRN Map:PGx v1.0 = SB.SBNSTRN Map:PGx v1.0 = PG.PGNSTRN Map:PGx v1.0 = PB.PBNSTRN
strainComment <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: Additional information about the strain.</p> <p>EXAMPLE(S): "Athymic nude" mouse which is not described by the nomenclature of "NCr-nu/nu"</p> <p>OTHER NAME(S): Strain Additional Information</p> <p>NOTE(S):</p>	Map:DICOM = Patient Module - Strain Additional Information (0010,0216)
strainStockIdentifier <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A unique symbol that establishes the identity of the sub-population of the strain as obtained from a particular source.</p> <p>EXAMPLE(S): II.extension = 000664 II.root = <OID for Jrep></p> <p>OTHER NAME(S): Strain Stock Sequence</p> <p>NOTE(S):</p>	Map:DICOM = Patient Module - Strain Stock Sequence > Strain Source (0010,0217) Map:DICOM = Patient Module - Strain Stock Sequence > Strain Stock Number (0010,0214)

Attribute	Notes	Constraints and Tags
nonHostIndicator <i>Class:</i> BiologicEntityClassification <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the biologic entity is an organism that is harbored or nourished by another organism (i.e. whether it is a parasite). EXAMPLE(S): OTHER NAME(S): NOTE(S): This concept does not include offspring.	Map:PGx v1.0 = PF.PFNSPCES Map:PGx v1.0 = PG.PGNSPCES

Class: BiologicEntityGroup

Package: Common Sub-Domain

DEFINITION:
A collection of biologic entities.

EXAMPLE(S):
flock of ducks, litter of mice, herd of cows, human cohort, bacterial colony

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Group
- Map:CTRv1.0 = BiologicEntityGroup
- Map:HL7SP = GroupKind
- Map:HL7SP = Member
- Map:LSDAMv2.2.3Plus = BiologicEntityGroup

Connectors

Source	Connector	Target	Notes
BiologicEntityGroup 0..1 containingBiologicEntityGroup	contain	BiologicEntityGroup 0..* containedBiologicEntityGroup	DESCRIPTION: Each BiologicEntityGroup might contain one or more BiologicEntityGroup. Each BiologicEntityGroup might be contained in one BiologicEntityGroup. DEFINITION: Indicates that one biologic entity group is composed of other groups. EXAMPLE(S): OTHER NAME(S): NOTE(S): Allows scenarios such as barn with stalls with crates of chickens - different therapies or observations might be made at different levels of grouping.

Source	Connector	Target	Notes
BiologicEntityGroup 0..* groupingBiologicEntityGroup	groups	BiologicEntity 1..* groupedBiologicEntity	<p>DESCRIPTION: Each BiologicEntityGroup always groups one or more BiologicEntity. Each BiologicEntity might be grouped by one or more BiologicEntityGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
BiologicEntityGroup 0..1 containingBiologicEntityGroup	contain	BiologicEntityGroup 0..* containedBiologicEntityGroup	<p>DESCRIPTION: Each BiologicEntityGroup might contain one or more BiologicEntityGroup. Each BiologicEntityGroup might be contained in one BiologicEntityGroup.</p> <p>DEFINITION: Indicates that one biologic entity group is composed of other groups.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Allows scenarios such as barn with stalls with crates of chickens - different therapies or observations might be made at different levels of grouping.</p>
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	BiologicEntityGroup 0..1 performingBiologicEntityGroup	<p>DESCRIPTION: Each ExperimentalUnit might be a function performed by one BiologicEntityGroup. Each BiologicEntityGroup might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Subject 0..*	be a function performed by	BiologicEntityGroup 0..1	DESCRIPTION: Each Subject might be a

Source	Connector	Target	Notes
performedSubject		performingBiologicEntityGroup	<p>function performed by one BiologicEntityGroup. Each BiologicEntityGroup might function as one or more Subject.</p> <p>DEFINITION: Indicates that a particular group of biologic entities is the subject of a particular activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Used when the activity is done to the group as a whole rather than individuals. E.g. drugs in shared feed, spraying, group therapy, etc.</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	BiologicEntityGroup 0..1 playingBiologicEntityGroup	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one BiologicEntityGroup. Each BiologicEntityGroup might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> BiologicEntityGroup <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the biologic entity group.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = IdentifiedBiologicEntityGroup.identifier

Attribute	Notes	Constraints and Tags
name <i>Class:</i> BiologicEntityGroup <i>Datatype:</i> TN <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A non-unique textual identifier for the biologic entity group. EXAMPLE(S): Litter1, X12, Farmer Brown's Cows OTHER NAME(S): NOTE(S):	Map:AE = Group.name Map:CTRv1.0 = BiologicEntityGroup.name Map:LSDAMv2.2.3Plus = BiologicEntityGroup.name
typeCode <i>Class:</i> BiologicEntityGroup <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the kind of biologic entity group. EXAMPLE(S): litter, herd OTHER NAME(S): NOTE(S):	Map:AE = Group.type Map:CTRv1.0 = BiologicEntityGroup.typeCode Map:LSDAMv2.2.3Plus = BiologicEntityGroup.typeCode
quantity <i>Class:</i> BiologicEntityGroup <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The number of members in a biologic entity group. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = InvestigativeSubject.quantity Map:CTRv1.0 = BiologicEntityGroup.quantity Map:HL7SD = Animal.quantity Map:HL7SP = Animal.quantity Map:ICSRr2 = Person2.quantity (in IndividualCaseSafetyReport) Map:ICSRr2 = Animal.quantity (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = BiologicEntityGroup.quantity
actualIndicator <i>Class:</i> BiologicEntityGroup <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	DEFINITION: Specifies whether the biologic entity group is a particular instance (actual) vs. universal kind. EXAMPLE(S): To indicate a particular BiologicEntityGroup, actualIndicator = "true". To indicate a kind of BiologicEntityGroup, actualIndicator = "false". OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = BiologicEntityGroup.actualIndicator Map:HL7SD = ExperimentalUnit>ExperimentalUnit2 (choice box).determinerCode Map:LSDAMv2.2.3Plus = BiologicEntityGroup.actualIndicator

Class: BiologicEntityPart

Package: Common Sub-Domain

DEFINITION:

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

EXAMPLE(S):

the left kidney of a person, a dog's right front paw, a patch of skin on a person's left forearm

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRr3 = BiologicEntityPart
- Map:CTRv1.0 = BiologicEntityPart
- Map:HL7SD = Access

Connectors

Source	Connector	Target	Notes
BiologicEntityPart 0..* containedBiologicEntityPart	is part of	BiologicEntity 1 containingBiologicEntity	<p>DESCRIPTION: Each BiologicEntityPart always is part of one BiologicEntity. Each BiologicEntity might have one or more BiologicEntityPart.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	BiologicEntityPart 0..1 performingBiologicEntityPart	<p>DESCRIPTION: Each ExperimentalUnit might be a function performed by one BiologicEntityPart. Each BiologicEntityPart might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
anatomicSiteCode <i>Class:</i> BiologicEntityPart <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the anatomic location or system of the biologic entity part.</p> <p>EXAMPLE(S): eye, skin, kidney</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CTRv1.0 = BiologicEntityPart.anatomicSiteCode Map:HL7SD = Access.targetSiteCode
anatomicSiteLateralityCode <i>Class:</i> BiologicEntityPart <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) where the anatomic site is in a biologic entity part.</p> <p>EXAMPLE(S): left, right, both</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is deprecated in BRIDG 3.1 since the only source use case for splitting out laterality from anatomic site comes from CTOM. All other source models had these concepts combined in one attribute. Therefore it was determined to combine these attributes to match the majority of use cases.</p>	Map:CTRv1.0 = BiologicEntityPart.anatomicSiteLateralityCode Map:HL7SD = Access.targetSiteCode
quantityRange <i>Class:</i> BiologicEntityPart <i>Datatype:</i> URG<INT.POS> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many parts that need to be present.</p> <p>EXAMPLE(S): 2 Skin patches</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Default is 1. Normally used during study design to indicate number of parts that will be used in a study or experiment. For example 100 study subjects with 3-5 skin patches.</p>	Map:CTRv1.0 = BiologicEntityPart.quantity

Class: CancerRegistry

Package: Common Sub-Domain

DEFINITION:

An archive that stores a wide variety of specific information on cancer patients that can later be leveraged and analyzed by researchers to identify health disparity trends in cancer incidence, mortality and patient survival, and/or that can be submitted

to a central repository for similar purposes.

EXAMPLE(S):

Alaska Native Tumor Registry, Utah Cancer Registry

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:SEER 2015 = SECTION I BASIC RECORD IDENTIFICATION - SEER PARTICIPANT

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> CancerRegistry <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the cancer registry.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = SECTION I BASIC RECORD IDENTIFICATION - SEER PARTICIPANT

Class: CellCulture

Package: Common Sub-Domain

DEFINITION:

Cells propagated in vitro in special media conducive to their growth. Cultured cells are used to study developmental, morphologic, metabolic, physiologic, and genetic processes, among others. [Source: Medical Subject Headings]

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = CellCulture

Connectors

Source	Connector	Target	Notes
CellCulture	specializes	Biologic	<p>DESCRIPTION: Each CellCulture always specializes one Biologic. Each Biologic might be specialized by one CellCulture.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MicrobiologicalCulture	specializes	CellCulture	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each MicrobiologicalCulture always specializes one CellCulture. Each CellCulture might be specialized by one MicrobiologicalCulture.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CellLine	specializes	CellCulture	<p>DESCRIPTION: Each CellLine always specializes one CellCulture. Each CellCulture might be specialized by one CellLine.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
biosafetyLevelCode <i>Class:</i> CellCulture <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying an assessment of the potential risk associated with the handling of the cell culture. [Source: ATCC]</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = CellCulture.biosafetyLevel</p>

Class: CellLine

Package: Common Sub-Domain

DEFINITION:

An established cell culture that has the potential to propagate indefinitely. [Source:
<http://www.solvobiotech.com/support/glossary?/Literature/glossary.html>]

EXAMPLE(S):

human HeLa cells, mouse fibroblast 3T3 cells

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = CellLine

Connectors

Source	Connector	Target	Notes
CellLine	specializes	CellCulture	<p>DESCRIPTION: Each CellLine always specializes one CellCulture. Each CellCulture might be specialized by one CellLine.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
originCellName <i>Class:</i> CellLine <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The name of the cell from which the cell line was derived.</p> <p>EXAMPLE(S): HEK293</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CellLine.originCellName
passageNumber <i>Class:</i> CellLine <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The number of sub-cultures the cells have gone through.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CellLine.passageNumber
sourceAge <i>Class:</i> CellLine <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The age of the organism from which the cell line was derived.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically the age could be derived if the cells were obtained from a known subject, however in practice the subject would be de-identified and/or no subject information would be available, so deriving this information would not be possible.</p>	Map:LSDAMv2.2.3Plus = CellLine.sourceAge

Attribute	Notes	Constraints and Tags
sourceDevelopmentalStage <i>Class:</i> CellLine <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The developmental stage of the organism from which the cell line was derived. EXAMPLE(S): embryo, blastocyst, fetal OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = CellLine.sourceDevelopmentalStage
sourceAnatomicSiteCode <i>Class:</i> CellLine <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the anatomic site from which the cell line is derived. EXAMPLE(S): lung, liver OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = CellLine.sourceAnatomicSiteCode
sourceTissueTypeCode <i>Class:</i> CellLine <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the type of tissue from which the cell line is derived. EXAMPLE(S): epithelium OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = CellLine.sourceTissueType

Class: ClinicalDevelopmentPlan

Package: Common Sub-Domain

DEFINITION:

An ordered program of clinical trials, each with specific objectives. This plan describes the collection of clinical studies that are to be performed in sequence, or in parallel, with a particular active substance, device, procedure, or treatment strategy, typically with the intention of submitting them as part of an application for a marketing authorization. (Adapted from ICH E8, E9)

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The plan should have appropriate decision points and allow modification as knowledge accumulates.

Tagged Values:

- Map:Vendor1v1.1 = Project

Connectors

Source	Connector	Target	Notes
ClinicalDevelopmentPlan	specializes	Project	DESCRIPTION: Each ClinicalDevelopmentPlan always specializes one

Source	Connector	Target	Notes
			<p>Project. Each Project might be specialized by one ClinicalDevelopmentPlan.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
therapeuticAreaCode <i>Class:</i> ClinicalDevelopmentPlan <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the field of knowledge that focuses on research and development of treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual.</p> <p>EXAMPLE(S): eye disease, nervous system disease</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The HL7 BR&R Work Group recognizes that there are other semantics related to this concept that may require more fully understanding and developing the relationships between therapeutic area, medical condition and organization-specific categorizations. Consequently, this concept may mature in future releases of BRIDG.</p>	Map:Vendor1v1.1 = Project.therapeuticAreaCode

Class: Container

Package: Common Sub-Domain

DEFINITION:
An object that can be used to hold things.

EXAMPLE(S):
slide, tube, box, rack, shipping carton, bottle

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Package
- Map:CTRv1.0 = Package
- Map:ICSRr2 = PackagedProduct (in R_Product)
- Map:LSDAMv2.2.3Plus = Container

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
Container	specializes	Product	<p>DESCRIPTION: Each Package always specializes one Product. Each Product might be specialized by one Package.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..* containedContainer	be contained in	StorageEquipment 0..1 containingStorageEquipment	<p>DESCRIPTION: Each Container might be contained in one StorageEquipment. Each StorageEquipment might contain one or more Container.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..* enclosedContainer	be enclosed by	Container 0..1 enclosing	<p>DESCRIPTION: Each Container might be enclosed by one Container. Each Container might enclose one or more Container.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..* residentContainer	is located at	Place 1 residingPlace	<p>DESCRIPTION: Each Container always is located at one Place. Each Place might be location for one or more Container.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..*	be enclosed by	Container 0..1	DESCRIPTION: Each Container might be

Source	Connector	Target	Notes
enclosedContainer		enclosing	<p>enclosed by one Container. Each Container might enclose one or more Container.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSpecimenMove 0..* placingPerformedSpecimenMove	place a specimen in	Container 0..1 placedInContainer	<p>DESCRIPTION: Each PerformedSpecimenMove might place a specimen in one Container. Each Container might have a specimen placed by one or more PerformedSpecimenMove.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSpecimenMove 0..* takingPerformedSpecimenMove	take a specimen from	Container 0..1 takenFromContainer	<p>DESCRIPTION: Each PerformedSpecimenMove might take a specimen from one Container. Each Container might have a specimen taken by one or more PerformedSpecimenMove.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
handlingCode <i>Class:</i> Container <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying special handling requirements for the package.</p> <p>EXAMPLE(S): keep at room temperature, store upright</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Package.handlingCode Map:ICSRr2 = Product.handlingCode (in R_Product)
capTypeCode <i>Class:</i> Container <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of container cap.</p> <p>EXAMPLE(S): film, foil</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In some cases, it is important for this to be consistent with decapping, piercing or other automated manipulation.</p>	Map:AE = Package.capTypeCode Map:CTRv1.0 = Package.capTypeCode Map:ICSRr2 = PackagedProduct.capTypeCode (in R_Product)
capacityQuantity <i>Class:</i> Container <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The maximum number of product units within a package.</p> <p>EXAMPLE(S): 1000 cc.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Package.capacityQuantity Map:CTRv1.0 = Package.capacityQuantity Map:ICSRr2 = PackagedProduct.capacityQuantity (in R_Product)
dimensionOneCapacity <i>Class:</i> Container <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The maximum amount that can be contained, in the first dimension of size of the container.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): When only one dimension is required to represent the capacity of a container, such as 100 pills in a bottle, this is the attribute to use.</p>	Map:AE = Package.capacityQuantity Map:CTRv1.0 = Package.capacityQuantity Map:ICSRr2 = PackagedProduct.capacityQuantity (in R_Product) Map:LSDAMv2.2.3Plus = Container.dimensionOneCapacity
dimensionOneLabel <i>Class:</i> Container <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A descriptive marker assigned to the first dimension of the container.</p> <p>EXAMPLE(S): rows, columns</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Container.dimensionOneLabel

Attribute	Notes	Constraints and Tags
dimensionTwoCapacity <i>Class:</i> Container <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The maximum amount that can be contained, in the second dimension of size of the container. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Container.dimensionTwoLabel
dimensionTwoLabel <i>Class:</i> Container <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A descriptive marker assigned to the second dimension of the container. EXAMPLE(S): rows, columns OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Container.dimensionTwoLabel
dimensionThreeCapacity <i>Class:</i> Container <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The maximum amount that can be contained, in the third dimension of size of the container. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Container.dimensionThreeCapacity
dimensionThreeLabel <i>Class:</i> Container <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A descriptive marker assigned to the third dimension of the container. EXAMPLE(S): rows, columns OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Container.dimensionThreeLabel
dimensionPointOfOrigin <i>Class:</i> Container <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The point within the container from which definition of container capacity originates. EXAMPLE(S): bottom left corner, upper left corner OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Container.dimensionPointOfOrigin

Class: CooperativeGroup

Package: Common Sub-Domain

DEFINITION:

A group of researchers, cancer centers, and community doctors who provide infrastructure for studies of new cancer treatment, prevention, early detection, quality of life, and rehabilitation.

EXAMPLE(S):

Eastern Cooperative Oncology Group (ECOG), Southwest Oncology Group (SWOG).

OTHER NAME(S):**NOTE(S):*****Tagged Values:***

- Map:CoopGrp = CooperativeGroup

Connectors

Source	Connector	Target	Notes
CooperativeGroup 0..1 performedCooperativeGroup	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each CooperativeGroup always is a function performed by one Organization. Each Organization might function as one CooperativeGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CooperativeGroup 0..* credentialedCooperativeGroup	is credentialed by	Organization 1 credentialingOrganization	<p>DESCRIPTION: Each CooperativeGroup always is credentialed by one Organization. Each Organization might credential one or more CooperativeGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CooperativeGroupMember 0..* groupedCooperativeGroupMember	is a member of	CooperativeGroup 1 groupingCooperativeGroup	<p>DESCRIPTION: Each CooperativeGroupMember always is a member of one CooperativeGroup. Each CooperativeGroup might have as a member one or more CooperativeGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
TreatingSite 0..* containedTreatingSite	be a member of	CooperativeGroup 0..1 containingCooperativeGroup	<p>DESCRIPTION: Each TreatingSite might be a member of one CooperativeGroup. Each CooperativeGroup might have as a member one or more TreatingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: CooperativeGroupMember

Package: Common Sub-Domain

DEFINITION:

An organization comprised of a group of treating sites.

EXAMPLE(S):

A group of cancer centers with outreach clinics forming a loose confederation for research purposes.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CoopGrp = MemberInstitution

Connectors

Source	Connector	Target	Notes
CooperativeGroupMember 0..* performedCooperativeGroupMember	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each CooperativeGroupMember always is a function performed by one Organization. Each Organization might function as one or more CooperativeGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CooperativeGroupMember 0..* groupedCooperativeGroupMember	is a member of	CooperativeGroup 1 groupingCooperativeGroup	<p>DESCRIPTION: Each CooperativeGroupMember always is a member of one</p>

Source	Connector	Target	Notes
			<p>CooperativeGroup. Each CooperativeGroup might have as a member one or more CooperativeGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdministrativeMemberCRA 1 staffingAdministrativeMem berCRA	staffs	CooperativeGroupMember 1 staffedCooperativeGroupMe mber	<p>DESCRIPTION:</p> <p>Each AdministrativeMemberCRA always staffs one CooperativeGroupMember.</p> <p>Each CooperativeGroupMember always is staffed by one AdministrativeMemberCRA .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
TreatingSite 1..* containedTreatingSite	be a member of	CooperativeGroupMember 0..1 containingCooperativeGrou pMember	<p>DESCRIPTION:</p> <p>Each TreatingSite might be a member of one CooperativeGroupMember.</p> <p>Each CooperativeGroupMember always has as a member one or more TreatingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdministrativeMemberPI 1 staffingAdministrativeMem berPI	staffs	CooperativeGroupMember 1 staffedCooperativeGroupMe mber	<p>DESCRIPTION:</p> <p>Each AdministrativeMemberPI always staffs one CooperativeGroupMember.</p> <p>Each CooperativeGroupMember always is staffed by one AdministrativeMemberPI.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Cosmetic

Package: Common Sub-Domain

DEFINITION:

An article intended to be rubbed, poured, sprinkled, or sprayed on or introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv1.0 = Cosmetic
- Map:CTRv1.0 = Cosmetic

Connectors

Source	Connector	Target	Notes
Cosmetic	specializes	Product	<p>DESCRIPTION: Each Cosmetic always specializes one Product. Each Product might be specialized by one Cosmetic.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
stabilityDuration <i>Class:</i> Cosmetic <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time during which the cosmetic is considered usable after it is activated (opened).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Cosmetic.stabilityDuration Map:ICSRr2 = ProductInstance.stabilityTime (in R_Product)

Class: Device

Package: Common Sub-Domain

DEFINITION:

An object intended for use whether alone or in combination for diagnostic, prevention, monitoring, therapeutic, scientific, and/or experimental purposes.

EXAMPLE(S):

tongue depressor, pacemaker, insulin pump, EKG machine, x-ray machine, mass spectrometer, polymerase chain reaction (PCR) machine, microscope, pH meter

OTHER NAME(S):

Equipment

NOTE(S):

Tagged Values:

- Map:AE = Device
- Map:AIM v4 rv48 = Equipment
- Map:caAERSv2.2 = MedicalDevice
- Map:CTRPv1.0 = Device
- Map:CTRr3 = Device
- Map:CTRv1.0 = Device
- Map:DICOM = General Equipment Module
- Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes
- Map:DICOM = Equipment Specification Module
- Map:ICSRr2 = DeviceInstance (in R_Product)
- Map:LSDAMv2.2.3Plus = Equipment

Connectors

Source	Connector	Target	Notes
Device 0..* locatedDevice	be located at	Organization 0..1 locatingOrganization	<p>DESCRIPTION: Each Device might be located at one Organization. Each Organization might be the location for one or more Device.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Device	specializes	Product	<p>DESCRIPTION: Each Device always is specialized by one Product. Each Product might be specialized by one Device.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Device 0..* specifyingDevice	specify the use of	Software 0..* specifiedSoftware	<p>DESCRIPTION: Each Device might specify the use of one or more</p>

Source	Connector	Target	Notes
			<p>Software. Each Software might be specified by one or more Device.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReferenceResult 0..* performedReferenceResult	apply to results produced by	Device 0..1 performingDevice	<p>DESCRIPTION: Each ReferenceResult might apply to results produced by one Device. Each Device might produce one or more ReferenceResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DeviceParameter 0..* definingDeviceParameter	defines the use of	Device 1 definedDevice	<p>DESCRIPTION: Each DeviceParameter always defines the use of one Device. Each Device might have use defined by one or more DeviceParameter.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StorageEquipment	specializes	Device	<p>DESCRIPTION: Each StorageEquipment always specializes one Device. Each Device might be specialized by one StorageEquipment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Software	specializes	Device	DESCRIPTION: Each Software always specializes one Device.

Source	Connector	Target	Notes
			Each Device might be specialized by one Software. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Device 0..1 performingDevice	DESCRIPTION: Each Performer might be a function performed by one Device. Each Device might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
handlingCode <i>Class:</i> Device <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying special handling requirements for the device. EXAMPLE(S): keep at room temperature, store upright OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Device.handlingCode Map:ICSRr2 = Product.handlingCode (in R_Product)
riskCode <i>Class:</i> Device <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the type of hazard or threat associated with the device. EXAMPLE(S): flammable, explosive OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Device.riskCode Map:ICSRr2 = Product.riskCode (in R_Product)

Attribute	Notes	Constraints and Tags
reprocessedDeviceCode <i>Class:</i> Device <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying whether a device is reconditioned. EXAMPLE(S): initial use of device, reuse, unknown OTHER NAME(S): NOTE(S):	Map:AE = Device.reprocessedDeviceCode Map:CTRPv1.0 = Device.reprocessedDeviceCode Map:CTRv1.0 = Device.reprocessedDeviceCode Map:LSDAMv2.2.3Plus = Equipment.reprocessedDeviceCode
age <i>Class:</i> Device <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	DEFINITION: A measure (or best estimate) of the length of time during which a device existed, measured from manufacture date (and time) to a given date (and time) of use. EXAMPLE(S): OTHER NAME(S): NOTE(S): Derived from the difference between the manufacture date and the date of the activity in which it is used. This is not really a characteristic of the device since the device could be used in multiple activities.	Map:AE = Device.deviceAge Map:CTRPv1.0 = Device.deviceAge Map:CTRv1.0 = Device.age
manufactureDate <i>Class:</i> Device <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the device is made. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Device.manufactureDate Map:CTRPv1.0 = Device.manufactureDate Map:CTRv1.0 = Device.manufactureDate Map:LSDAMv2.2.3Plus = Software.buildDate Map:LSDAMv2.2.3Plus = Equipment.manufactureDate
returnedToReprocessorDate <i>Class:</i> Device <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the device was returned to the manufacturer or reprocessor. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = MedicalDevice.returnedDate Map:CTRv1.0 = Device.returnedToReprocessorDate
singleUseDeviceIndicator <i>Class:</i> Device <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Specifies whether a device is intended to be used only one time. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Device.singleUseDeviceIndicator Map:CTRPv1.0 = Device.singleUseDeviceIndicator Map:CTRv1.0 = Device.singleUseDeviceIndicator

Attribute	Notes	Constraints and Tags
availableForEvaluationIndicator <i>Class:</i> Device <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether or not the device is accessible for assessment by the manufacturer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Device.availableForEvaluationIndicator or Map:CTRPv1.0 = Device.availableForEvaluationIndicator or Map:CTRv1.0 = Device.availableForEvaluationIndicator
overTheCounterProductIndicator <i>Class:</i> Device <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether a device is available over-the-counter. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Device.overTheCounterProductIndicator or Map:CTRPv1.0 = Device.overTheCounterProductIndicator or Map:CTRv1.0 = Device.overTheCounterProductIndicator
ceMarkIndicator <i>Class:</i> Device <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether this device bears a CE (Conformite Europeenne) mark. EXAMPLE(S): OTHER NAME(S): NOTE(S): CE is a mark for device products placed on the market in the European Economic Area (EEA). By placing the CE marking on a product, the manufacturer affirms that the product conforms with the requirements of the applicable European Community directives.	Map:CTRRr3 = Device.ceMarkIndicator

Class: Distributor

Package: Common Sub-Domain

DEFINITION:

An organization who takes part in the distribution chain for a product, as it is moved from its producer to the ultimate consumer.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Distributor

Connectors

Source	Connector	Target	Notes
Distributor 0..1 performedDistributor	is a function performed by	Organization 1 performingOrganization	DESCRIPTION: Each Distributor always is a function performed by one Organization. Each

Source	Connector	Target	Notes
			<p>Organization might function as one Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Distributor 0..* representingDistributor	functions as an outlet for	Processor 1..* representedProcessor	<p>DESCRIPTION: Each Distributor always functions as an outlet for one or more Processor. Each Processor might have as an outlet one or more Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Distributor 0..* providedDistributor	provides	Product 1..* providingProduct	<p>DESCRIPTION: Each Distributor always provides one or more Product. Each Product might be provided by one or more Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Document

Package: Common Sub-Domain

DEFINITION:

An organized representation of information in publishable, human-readable form (that persists over time).

EXAMPLE(S):

Study Protocol, Adverse Event Report, Expedited Adverse Event Report, Institutional Review Board (IRB) Report, X-Ray Report, Lab Summary Report, Autopsy Report

OTHER NAME(S):

NOTE(S):

A document groups the various document versions and has 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).

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).

Tagged Values:

- Map:AE = Document
- Map:C3PRv2.9 = Consent
- Map:CTRPv1.0 = Document
- Map:CTRPv3.8 = Document
- Map:CTRR = Protocol Title
- Map:CTRv1.0 = Document
- Map:ICSRr2 = document (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = Document
- Map:RPS1 = Documentation
- Map:Statistics v1.0 = Document

Connectors

Source	Connector	Target	Notes
DocumentVersion 0..* versioningDocumentVersion	is a version of	Document 1 versionedDocument	<p>DESCRIPTION: Each DocumentVersion always is a version of one Document. Each Document might have as a version one or more DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocument	specializes	Document	<p>DESCRIPTION: Each StudyProtocolDocument always specializes one Document. Each Document might be specialized by one StudyProtocolDocument.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Document <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 1 . . *	<p>DEFINITION: A unique symbol that establishes identity of the document.</p> <p>EXAMPLE(S): A study protocol identifier is assigned by the National Cancer Institute (NCI).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): A particular document can have one or more ID.</p>	Map:AE = SafetyReport.alternateIdentifier Map:AE = AmendmentFollowUpReport.reportAmendedIdentifier Map:AE = SafetyReport.identifier Map:AE = Study.additionalIdentifier Map:AE = Study.primaryIdentifier Map:C3PR = Identifier.value Map:C3PRv2.9 = Identifier.value Map:C3PRv2.9 = RemoteStudy.externalId Map:caAERSv2.2 = Identifier.value > Study Map:CDASHv1.1 = VS.STUDYID Map:CDASHv1.1 = PE.STUDYID Map:CDASHv1.1 = SC.STUDYID Map:CDASHv1.1 = MH.STUDYID Map:CDASHv1.1 = DM.STUDYID Map:CDASHv1.1 = AE.STUDYID Map:CDASHv1.1 = EG.STUDYID Map:CDASHv1.1 = QS.STUDYID Map:CDASHv1.1 = SU.STUDYID Map:CDASHv1.1 = MB.STUDYID Map:CDASHv1.1 = DV.STUDYID Map:CDASHv1.1 = EX.STUDYID Map:CDASHv1.1 = DA.STUDYID Map:CDASHv1.1 = IE.STUDYID Map:CDASHv1.1 = LB.STUDYID Map:CDASHv1.1 = CM.STUDYID Map:CDASHv1.1 = DS.STUDYID Map:CTGOV = Secondary IDs Map:CTGOV = IND/IDE Serial Number Map:CTGOV = Organization's Unique Protocol ID Map:CTOM = ParticipantEligibilityAnswer.checklistNumber Map:CTOM = StudySite.localProtocolIdentifier Map:CTOM = Protocol.nciIdentifier Map:CTOM = Protocol.navyNCIIdentifier Map:CTR&Rr2 = EudraCT number Map:CTR&Rr2 = Sponsor protocol number Map:CTR&Rr2 = US NCT number Map:CTR&Rr2 = Other Identifier Map:CTR&Rr2 = ISRCTN number Map:CTR&Rr2 = WHO UTRN Map:CTRPv1.0 = InterventionalStudyProtocol.identifier Map:CTRPv1.0 = ObservationalStudyProtocol.identifier Map:CTRPv1.0 = StudyProtocol.identifier Map:CTRPv1.0 = StudyParticipation.localStudyProtocol.Identifier Map:CTRPv1.0 = Document.identifier

Attribute	Notes	Constraints and Tags
		Map:CTRPv3.8 = StudyProtocol.assignedIdentifier Map:CTRPv3.8 = StudyProtocol.otherIdentifiers Map:CTRPv3.8 = Document.identifier Map:CTRR = Protocol Identifier Map:CTRR = Registry Protocol Identifier Map:CTRr3 = DocumentIdentifier.identifier Map:CTRr3 = StudyAgent.expandedAccessRecordId Map:CTRv1.0 = DocumentIdentifier.identifier Map:DICOM = Clinical Trial Subject Module - Clinical Trial Protocol ID (0012,0020) Map:DICOM = Clinical Trial Context Module - Clinical Trial Protocol ID (0012,0020) Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.setID Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.id Map:FDA HL7 SD SD DSTU2012 = relatedDocument.id Map:FDA HL7 SD SD DSTU2012 = relatedDocument.setId Map:HCTv1.0 = CDE 2692926:Recipient Identification.Study ID# What is the study ID number? Map:HL7SD = PlannedStudy.setID Map:HL7SP = PlannedStudy.id Map:HL7SP = Study.id Map:HSDBv1.0 = [Study].Unique Trial Identifier Map:HSDBv1.0 = [Study].Lead Organization Trial Identifier Map:HSDBv1.0 = [Sponsor].Sponsor protocol no Map:ICSRr2 = ResearchStudy.id (in IndividualCaseSafetyReport) Map:ICSRr2 = ControlActEvent.id (in IndividualCaseSafetyReport) Map:ICSRr2 = StudyRegistration.id Map:ICSRr2 = StudyRegistration.id (in IndividualCaseSafetyReport) Map:ICSRr2 = InvestigativeEvent.id (in IndividualCaseSafetyReport) Map:ICSRr2 = RelatedInvestigation.id (in IndividualCaseSafetyReport) Map:ICSRr2 = document.id (in IndividualCaseSafetyReport) Map:Lab = Study.identifier Map:LabViewer2.2 = Identifier.displayable Map:LabViewer2.2 = Identifier.extension Map:LabViewer2.2 = Identifier.root

Attribute	Notes	Constraints and Tags
		Map:LSDAMv2.2.3Plus = DocumentIdentifier.identifier Map:NCI CRF Standard = CDE 2746459v1.0: Protocol Clinical Study Identifier Number Map:NCI CRF Standard = CDE 3008882v1.0: Case Report Form Identifier Map:PGx v1.0 = PF.STUDYID Map:PGx v1.0 = BS.STUDYID Map:PGx v1.0 = PB.STUDYID Map:PGx v1.0 = PG.STUDYID Map:PGx v1.0 = RELSPEC.STUDYID Map:PGx v1.0 = SB.STUDYID Map:PGx v1.0 = BE.STUDYID Map:PSCv2.6 = Study.assignedIdentifier Map:PSCv2.6 = StudySecondaryIdentifier.value Map:SDTM IGv3.1.1 = SV.STUDYID Map:SDTM IGv3.1.1 = TS.STUDYID Map:SDTM IGv3.1.1 = PE.STUDYID Map:SDTM IGv3.1.1 = TE.STUDYID Map:SDTM IGv3.1.1 = QS.STUDYID Map:SDTM IGv3.1.1 = EX.STUDYID Map:SDTM IGv3.1.1 = TI.STUDYID Map:SDTM IGv3.1.1 = DM.STUDYID Map:SDTM IGv3.1.1 = DV.STUDYID Map:SDTM IGv3.1.1 = DS.STUDYID Map:SDTM IGv3.1.1 = SE.STUDYID Map:SDTM IGv3.1.1 = MH.STUDYID Map:SDTM IGv3.1.1 = TA.STUDYID Map:SDTM IGv3.1.1 = EG.STUDYID Map:SDTM IGv3.1.1 = SC.STUDYID Map:SDTM IGv3.1.1 = VS.STUDYID Map:SDTM IGv3.1.1 = DA.STUDYID Map:SDTM IGv3.1.1 = AE.STUDYID Map:SDTM IGv3.1.1 = CM.STUDYID Map:SDTM IGv3.1.1 = TV.STUDYID Map:SDTM IGv3.1.1 = SU.STUDYID Map:SDTM IGv3.1.1 = CO.STUDYID Map:SDTM IGv3.1.1 = LB.STUDYID Map:SDTM IGv3.1.1 = IE.STUDYID Map:SDTM IGv3.1.2 = SE.STUDYID Map:SDTM IGv3.1.2 = TI.STUDYID Map:SDTM IGv3.1.2 = MB.STUDYID Map:SDTM IGv3.1.2 = PP.STUDYID Map:SDTM IGv3.1.2 = PE.STUDYID

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = TV.STUDYID Map:SDTM IGv3.1.2 = TA.STUDYID Map:SDTM IGv3.1.2 = VS.STUDYID Map:SDTM IGv3.1.2 = QS.STUDYID Map:SDTM IGv3.1.2 = TE.STUDYID Map:SDTM IGv3.1.2 = MH.STUDYID Map:SDTM IGv3.1.2 = MS.STUDYID Map:SDTM IGv3.1.2 = FA.STUDYID Map:SDTM IGv3.1.2 = EG.STUDYID Map:SDTM IGv3.1.2 = CM.STUDYID Map:SDTM IGv3.1.2 = TS.STUDYID Map:SDTM IGv3.1.2 = SV.STUDYID Map:SDTM IGv3.1.2 = CO.STUDYID Map:SDTM IGv3.1.2 = EX.STUDYID Map:SDTM IGv3.1.2 = DA.STUDYID Map:SDTM IGv3.1.2 = IE.STUDYID Map:SDTM IGv3.1.2 = DS.STUDYID Map:SDTM IGv3.1.2 = DM.STUDYID Map:SDTM IGv3.1.2 = AE.STUDYID Map:SDTM IGv3.1.2 = PC.STUDYID Map:SDTM IGv3.1.2 = LB.STUDYID Map:SDTM IGv3.1.2 = SC.STUDYID Map:SDTM IGv3.1.2 = CE.STUDYID Map:SDTM IGv3.1.2 = DV.STUDYID Map:SDTM IGv3.1.2 = SU.STUDYID Map:SDTM IGv3.1.3 = VS.STUDYID Map:SDTM IGv3.1.3 = SV.STUDYID Map:SDTM IGv3.1.3 = TV.STUDYID Map:SDTM IGv3.1.3 = TU.STUDYID Map:SDTM IGv3.1.3 = TS.STUDYID Map:SDTM IGv3.1.3 = TE.STUDYID Map:SDTM IGv3.1.3 = TI.STUDYID Map:SDTM IGv3.1.3 = TR.STUDYID Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "REGID" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "REGID" Map:SDTM IGv3.1.3 = TA.STUDYID Map:SDTM IGv3.1.3 = FA.STUDYID Map:SDTM IGv3.1.3 = AE.AEREFID Map:SDTM IGv3.1.3 = AE.STUDYID Map:SDTM IGv3.1.3 = CE.STUDYID Map:SDTM IGv3.1.3 = CM.STUDYID Map:SDTM IGv3.1.3 =

Attribute	Notes	Constraints and Tags
		CO.STUDYID Map:SDTM IGv3.1.3 = DA.STUDYID Map:SDTM IGv3.1.3 = DM.STUDYID Map:SDTM IGv3.1.3 = DS.STUDYID Map:SDTM IGv3.1.3 = DV.STUDYID Map:SDTM IGv3.1.3 = MS.STUDYID Map:SDTM IGv3.1.3 = EX.STUDYID Map:SDTM IGv3.1.3 = SU.STUDYID Map:SDTM IGv3.1.3 = IE.STUDYID Map:SDTM IGv3.1.3 = LB.STUDYID Map:SDTM IGv3.1.3 = MB.STUDYID Map:SDTM IGv3.1.3 = MH.STUDYID Map:SDTM IGv3.1.3 = PC.STUDYID Map:SDTM IGv3.1.3 = PE.STUDYID Map:SDTM IGv3.1.3 = QS.STUDYID Map:SDTM IGv3.1.3 = RS.STUDYID Map:SDTM IGv3.1.3 = SC.STUDYID Map:SDTM IGv3.1.3 = SE.STUDYID Map:SDTM IGv3.1.3 = EG.STUDYID Map:Statistics v1.0 = DocumentIdentifier.identifier Map:Vendor1v1.1 = DocumentIdentifier.identifier Map:WHO = Secondary Identifying Numbers Map:WHO = Primary Registry and Trial Identifying Number
typeCode <i>Class:</i> Document <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of document.</p> <p>EXAMPLE(S): amendment, background material, guide, Data Clarification Form (DCF), regulatory record (see description in NOTE(S) section)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p> <p>The example "regulatory record" is described as "a document that meets a recording requirement of a regulatory authority and must be retained in accordance with that agency's records retention requirements".</p>	Map:AE = AmendmentFollowUpReport Map:C3PRv2.9 = StudyVersion.amendmentType Map:CTRPv1.0 = Document.typeCode Map:CTRPv3.8 = Document.typeCode Map:CTRRr3 = Document.typeCode Map:CTRv1.0 = Document.typeCode Map:HL7SD = ReplacementOf1.typeCode Map:ICSRr2 = document.code (in IndividualCaseSafetyReport) Map:ICSRr2 = ControlActEvent.code (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Document.typeCode Map:RPS1 = Documentation.context Map:Statistics v1.0 = Document.typeCode

Class: DocumentAuthor

Package: Common Sub-Domain

DEFINITION:

The individual who is responsible for the content of a document version.

EXAMPLE(S):

A healthcare provider could be the author of a version of a study protocol document

OTHER NAME(S):

Document Version Author

NOTE(S):

Document authors can change from version to version. The class name (without the word "Version") is retained because it is a domain friendly term.

Tagged Values:

- Map:AE = Reporter
- Map:caAERSv2.2 = Physician
- Map:caAERSv2.2 = RoleBasedRecipient.role
- Map:caAERSv2.2 = Reporter
- Map:CTRv1.0 = DocumentAuthor
- Map:ICSRr2 = LocatedEntity (in IndividualCaseSafetyReport)
- Map:ICSRr2 = LocatedEntity2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Author3 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = AssignedEntity (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Participant2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Participant1 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = AssignedEntity.code (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = DocumentAuthor

Connectors

Source	Connector	Target	Notes
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 1..* authoringDocumentAuthor	authors	DocumentVersion 1 authoredDocumentVersion	<p>DESCRIPTION: Each DocumentAuthor always authors one DocumentVersion. Each DocumentVersion always is authored by one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	Subject 0..1 performingSubject	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one Subject. Each Subject might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	AssociatedBiologicEntity 0..1 performingAssociatedBiologicEntity	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one AssociatedBiologicEntity. Each AssociatedBiologicEntity might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one Person. Each Person might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The direct association to Person was added in support of LSDAM use cases which didn't specify any specific role.</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	ResearchStaff 0..1 performingResearchStaff	DESCRIPTION: Each DocumentAuthor might be a function

Source	Connector	Target	Notes
			<p>performed by one ResearchStaff. Each ResearchStaff might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	DocumentAuthor 0..1 performingDocumentAuthor	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one DocumentAuthor. Each DocumentAuthor might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> DocumentAuthor <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A number that provides an indication as to the order in which the authors names must be listed when displayed.</p> <p>EXAMPLE(S): 1, 2, 3</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = DocumentAuthori.priorityNumber

Attribute	Notes	Constraints and Tags
correspondingAuthorIndicator <i>Class:</i> DocumentAuthor <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Specifies whether this is the person, typically chosen from within the group of several authors who worked on the paper or report, to be responsible for all contact and correspondence with the journal or periodical to which they have submitted. [Adapted from http://www.wisegeek.com/what-is-a-corresponding-author.htm]</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = DocumentAuthor.correspondingAuthorIndicator

Class: DocumentVersion

Package: Common Sub-Domain

DEFINITION:

A representation of a particular edition or snapshot of a document as it exists at a particular point in time.

EXAMPLE(S):

Version 3 of a case report form (CRF) for a physical exam, version 2 of an informed consent form.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = Consent
- Map:C3PRv2.9 = StudySubjectConsentVersion
- Map:caAERSv2.2 = NotificationAttachment
- Map:CTRRr3 = Document
- Map:CTRv1.0 = DocumentVersion
- Map:LSDAMv2.2.3Plus = DocumentVersion
- Map:Statistics v1.0 = DocumentVersion

Connectors

Source	Connector	Target	Notes
DocumentVersion 0..* versioningDocumentVersion	is a version of	Document 1 versionedDocument	<p>DESCRIPTION: Each DocumentVersion always is a version of one Document. Each Document might have as a version one or more DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersion 0..* containingDocumentVersion	contain	PerformedObservationResult 0..*	DESCRIPTION: Each DocumentVersion might contain one or more

Source	Connector	Target	Notes
		containedPerformedObservationResult	<p>PerformedObservationResult. Each PerformedObservationResult might be the contents for one or more DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): A finding might be published in a scientific journal.</p> <p>A data set produced by a computational process might be circulated as a document.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersion 0..1 containingDocumentVersion	contain	ProcessProtocol 0..1 containedProtocol	<p>DESCRIPTION: Each DocumentVersion might contain one ProcessProtocol. Each ProcessProtocol might be the contents of one DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DataMonitoringCommitteeCharterVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each DataMonitoringCommitteeCharterVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one DataMonitoringCommitteeCharterVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedNotification 0..* attachingDefinedNotification	have as an attachment	DocumentVersion 0..* attachedDocumentVersion	<p>DESCRIPTION: Each DefinedNotification might have as an attachment one or more</p>

Source	Connector	Target	Notes
			DocumentVersion. Each DocumentVersion might be an attachment on one or more DefinedNotification. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AmendmentChangeSummaryVersion	specializes	DocumentVersion	DESCRIPTION: Each AmendmentChangeSummaryVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one AmendmentChangeSummaryVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedStudySubjectMilestone 0..1 usingDefinedStudySubject Milestone	use	DocumentVersion 0..1 usedDocumentVersion	DESCRIPTION: Each DefinedStudySubjectMilestone might use one DocumentVersion. Each DocumentVersion might be used for one DefinedStudySubjectMilestone. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StatisticalAnalysisPlanDocumentVersion	specializes	DocumentVersion	DESCRIPTION: Each StatisticalAnalysisPlanDocumentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StatisticalAnalysisPlanDocumentVersion. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DocumentAuthor 1..* authoringDocumentAuthor	authors	DocumentVersion 1 authoredDocumentVersion	DESCRIPTION: Each DocumentAuthor always authors one DocumentVersion. Each DocumentVersion always is authored by one or more DocumentAuthor. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DocumentVersionRelations hip 0..* targetDocumentVersionRela tionship	has as source	DocumentVersion 1 sourceDocumentVersion	DESCRIPTION: Each DocumentVersionRelations hip always has as source one DocumentVersion. Each DocumentVersion might be the source for one or more DocumentVersionRelations hip. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySubjectExperienceDoc umentVersion	specializes	DocumentVersion	DESCRIPTION: Each StudySubjectExperienceDoc umentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StudySubjectExperienceDoc umentVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ReportVersion	specializes	DocumentVersion	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each ReportVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one ReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersionWorkflowStatus 0..* describingDocumentVersionWorkflowStatus	describes	DocumentVersion 1 describedDocumentVersion	<p>DESCRIPTION: Each DocumentVersionWorkflowStatus always describes one DocumentVersion. Each DocumentVersion might be described by one or more DocumentVersionWorkflowStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubjectMilestone 0..* usingPerformedStudySubjectMilestone	use	DocumentVersion 0..1 usedDocumentVersion	<p>DESCRIPTION: Each PerformedSubjectMilestone might use one DocumentVersion. Each DocumentVersion might be used for one or more PerformedSubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersionRelationship 0..* sourceDocumentVersionRelationship	has as target	DocumentVersion 1 targetDocumentVersion	<p>DESCRIPTION: Each DocumentVersionRelationship always has as target one DocumentVersion. Each DocumentVersion might be the target for one or more DocumentVersionRelationship.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DocumentVersionRepresentation 1..* representingDocumentVersionOnRepresentation	represents	DocumentVersion 1 representedDocumentVersion	DESCRIPTION: Each DocumentVersionRepresentation always represents one DocumentVersion. Each DocumentVersion always is represented as one or more DocumentVersionRepresentation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyProtocolDocumentVersion	specializes	DocumentVersion	DESCRIPTION: Each StudyProtocolDocumentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StudyProtocolDocumentVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SubmissionUnit 0..* includingSubmissionUnit	includes	DocumentVersion 1..* includedDocumentVersion	DESCRIPTION: Each SubmissionUnit always includes one or more DocumentVersion. Each DocumentVersion might be included in one or more SubmissionUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
numberText <i>Class:</i> DocumentVersion <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string that identifies a given document version.</p> <p>EXAMPLE(S): 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Different versions of the same document belong to the same document group.</p> <p>Over time, there may be multiple changes to a document, and the version allows an individual to capture relationships between changes in the instances of a document over time. There can be a new version every time the content changes.</p>	Map:AE = SafetyReport.initialReportIndicator Map:C3PR = StudySubject.informedConsentVersion Map:C3PR = Study.consentVersion Map:C3PRv2.9 = StudyVersion.name Map:caAERSv2.2 = ReportVersion.reportVersionId Map:CTOM = Protocol.amendmentIdentifier Map:CTR&Rr2 = Sponsor protocol version Map:CTRPv1.0 = InterventionalStudyProtocol.revision Map:CTRPv1.0 = ObservationalStudyProtocol.revision Map:CTRPv1.0 = StudyProtocol.revision Map:CTRPv1.0 = Document.revision Map:CTRPv3.8 = StudyProtocol.amendmentNumberText Map:CTRRr3 = Document.revisionNumberText Map:CTrv1.0 = DocumentVersion.numberText Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.versionNumber Map:FDA HL7 SD SD DSTU2012 = relatedDocument.versionNumber Map:HL7SD = PlannedStudy.versionNumber Map:LSDAMv2.2.3Plus = DocumentVersion.versionNumberText Map:NCI CRF Standard = CDE 3008888v1.0: Case Report Form Version Number Map:PSCv2.6 = Amendment.name Map:RPS1 = Documentation.version Map:Statistics v1.0 = DocumentVersion.numberText

Attribute	Notes	Constraints and Tags
officialTitle <i>Class:</i> DocumentVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The formal title of the document version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If there is only one title, use this attribute.</p>	Map:C3PR = Study.longTitleText Map:C3PRv2.9 = Consent.name Map:C3PRv2.9 = StudyVersion.longTitleText Map:caAERSv2.2 = Study.longTitleText Map:CTGOV = Official Title Map:CTOM = Protocol.longTitleText Map:CTR&Rr2 = Full title of the trial Map:CTRv1.0 = ObservationalStudyProtocol.officialTitle Map:CTRv1.0 = InterventionalStudyProtocol.officialTitle Map:CTRv3.8 = StudyProtocol.officialTitle Map:CTRr3 = Document.officialTitle Map:CTRv1.0 = DocumentVersion.officialTitle Map:DICOM = Clinical Trial Context Module - Clinical Trial Protocol Name (0012,0021) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Protocol Name (0012,0021) Map:HCTv1.0 = CDE 2978255:Research Protocols.Specify the research activity the recipient participates in: Map:HL7SD = PlannedStudy.title Map:HSDBv1.0 = [Study].Study Title Map:ICSRr2 = RelatedInvestigation.title (in IndividualCaseSafetyReport) Map:ICSRr2 = document.title (in IndividualCaseSafetyReport) Map:ICSRr2 = ResearchStudy.title (in IndividualCaseSafetyReport) Map:Lab = Study.name Map:LabViewer2.2 = Study.name Map:LSDAMv2.2.3Plus = DocumentVersion.officialTitle Map:NCI CRF Standard = CDE 3009034v1.0: Case Report Form Name Map:PSC = Study.name Map:RPS1 = Documentation.title Map:Statistics v1.0 = DocumentVersion.officialTitle Map:WHO = Scientific Title

Attribute	Notes	Constraints and Tags
languageCode <i>Class:</i> DocumentVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the language that the document is written in.</p> <p>EXAMPLE(S): English, German</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is used to indicate the language in which all (or most) of the discrete data elements that make up the document are expressed. This is distinct from the DocumentVersion.text(ED).languageCode property which expresses the language in which the document is rendered. This attribute is most important in circumstances where the document is not rendered.</p>	Map:CTRv1.0 = DocumentVersion.languageCode Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.languageCode Map:Statistics v1.0 = DocumentVersion.language
date <i>Class:</i> DocumentVersion <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the document is versioned.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = Report.createdOn Map:caAERSv2.2 = ReportVersion.createdOn Map:CTR&Rr2 = Sponsor protocol version date Map:CTRPv3.8 = StudyProtocol.amendmentDate Map:CTRR = Sponsor Protocol Version Date Map:CTRRr3 = Document.versionDate Map:CTRv1.0 = DocumentVersion.date Map:HCTv1.0 = CDE 2768219:Medical Records and Forms.What is the post transplantation time period for this follow up report? Map:ICSRr2 = InvestigativeEvent.availabilityTime (in IndividualCaseSafetyReport) Map:ICSRr2 = RelatedInvestigation.availabilityTime (in IndividualCaseSafetyReport) Map:LabViewer2.2 = Study.amendmentDate Map:LSDAMv2.2.3Plus = DocumentVersion.versionDate Map:NCI CRF Standard = CDE 3008890v1.0: Case Report Form Version Date Map:PSCv2.6 = Amendment.date Map:Statistics v1.0 = DocumentVersion.date

Attribute	Notes	Constraints and Tags
keywordCode <i>Class:</i> DocumentVersion <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying a word or phrase that describes the document version and/or its context. Keywords help users find documents of interest.</p> <p>EXAMPLE(S): species, indication, biocompatibility, drug substance, drug product</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:CTGOV = Keywords Map:CTRPv1.0 = ObservationalStudyProtocol.keywordCode Map:CTRPv1.0 = StudyProtocol.keywordCode Map:CTRPv1.0 = InterventionalStudyProtocol.keywordCode Map:CTR = Keywords Map:CTRv1.0 = DocumentVersion.keywordCode Map:LSDAMv2.2.3Plus = DocumentVersion.keywordCode Map:RPS1 = Keyword.code Map:Statistics v1.0 = DocumentVersion.keywordCode Map:WHO = Keyword
keywordText <i>Class:</i> DocumentVersion <i>Datatype:</i> DSET<ST> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A character string of a word or phrase that describes the document version and/or its context. Keywords help users find documents of interest.</p> <p>EXAMPLE(S): species, indication, biocompatibility, drug substance, drug product</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:CTGOV = Keywords Map:CTRPv1.0 = InterventionalStudyProtocol.keywordText Map:CTRPv1.0 = ObservationalStudyProtocol.keywordText Map:CTRPv1.0 = StudyProtocol.keywordText Map:CTRv3.8 = StudyProtocol.keywordText Map:CTR = Keywords Map:CTRr3 = Document.keywordText Map:CTRv1.0 = DocumentVersion.keywordText Map:LSDAMv2.2.3Plus = DocumentVersion.keywordText Map:RPS1 = Keyword.textValue Map:Statistics v1.0 = DocumentVersion.keywordText

Attribute	Notes	Constraints and Tags
uniformResourceLocator <i>Class:</i> DocumentVersion <i>Datatype:</i> TEL.URL <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A complete or local reference to a website, ftp, file path or other location from which the document version contents can be retrieved.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from DocumentVersion.text.ED.reference.</p> <p>Local references should only be used when communicating between systems capable of resolving the local reference.</p> <p>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.</p>	Map:AE = Document.universalResourceLocator Map:CTOM = Protocol.documentUri Map:CTRPv1.0 = Document.universalResourceLocator Map:CTRPv3.8 = Document.fileName Map:CTRPv3.8 = Document.universalResourceLocator Map:CTRv1.0 = DocumentVersion.uniformResourceLocator Map:PGx v1.0 = PF.PFXFN Map:PGx v1.0 = PG.PGXFN Map:RPS1 = Documentation.fileID Map:Statistics v1.0 = DocumentVersion.uniformResourceLocator
bibliographicDesignation <i>Class:</i> DocumentVersion <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A text block containing publishing and authoring information that allows receivers of this document version to refer appropriately to this document version.</p> <p>EXAMPLE(S): Good Health Hospital IRB Minutes, 18-Jan-2008</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyProtocol.bibliographicDesignation Map:CTRPv1.0 = InterventionalStudyProtocol.bibliographicDesignation Map:CTRPv1.0 = ObservationalStudyProtocol.bibliographicDesignation Map:CTRPv3.8 = StudyProtocol.bibliographicDesignation Map:CTRv1.0 = DocumentVersion.bibliographicDesignation Map:ICSRr2 = document.bibliographicDesignationText (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = DocumentVersion.bibliographicDesignation Map:Statistics v1.0 = DocumentVersion.bibliographicDesignation

Attribute	Notes	Constraints and Tags
revisionReasonCode <i>Class:</i> DocumentVersion <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying why the previous version of the document was revised to this version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = StudyVersion.AmendmentReason Map:CTRPv3.8 = Document.inactiveCommentText Map:CTRPv3.8 = StudyProtocol.amendmentReasonCode Map:CTRv1.0 = DocumentVersion.revisionReason Map:HL7SD = PlannedStudy.reasonCode Map:HL7SDr1 = ControlActEvent.reasonCode Map:ICSRr2 = ControlActEvent.reasonCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = DocumentVersion.revisionReason Map:Statistics v1.0 = DocumentVersion.revisionReasonCode
confidentialityCode <i>Class:</i> DocumentVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the degree of sensitivity associated with the document.</p> <p>EXAMPLE(S): Normal, Restricted, Very Restricted</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = DocumentVersion.confidentialityCode Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.confidentialityCode Map:ICSRr2 = ControlActEvent.confidentialityCode (in IndividualCaseSafetyReport)

Class: DocumentVersionRelationship

Package: Common Sub-Domain

DEFINITION:

Specifies the meaning (or semantics) of the relationship between one document version and another.

EXAMPLE(S):

decomposition (component), pre-condition, post-condition, sequel (replaces, modifies), attribution (cause and effect)

In a Regulated Product Submission (RPS), support of versioning can be accomplished by having two different revisions of a document related to each other through a "replaces" relationship. Another example is version 3 of a breast cancer protocol "uses" version 2 of a consent form.

OTHER NAME(S):

NOTE(S):

The DocumentVersions on either side of the DocumentVersionRelationship do not necessarily have to be related to the same Document, or even have the same Document.typeCode.

Tagged Values:

- Map:CTRPv3.8 = StudyRelationship
- Map:CTRPv3.8 = StudyProtocol.(StudyRelationship)
- Map:CTRv1.0 = DocumentVersionRelationship
- Map:HL7SD = ReplacementOf1
- Map:ICSRr2 = SourceOf2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = reference (in IndividualCaseSafetyReport)

- Map:ICSRr2 = SourceOf1 (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = DocumentVersionRelationship
- Map:RPS1 = RelatedDocumentation

Connectors

Source	Connector	Target	Notes
DocumentVersionRelations hip 0..* targetDocumentVersionRela tionship	has as source	DocumentVersion 1 sourceDocumentVersion	<p>DESCRIPTION: Each DocumentVersionRelationship always has as source one DocumentVersion. Each DocumentVersion might be the source for one or more DocumentVersionRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersionRelations hip 0..* sourceDocumentVersionRela tionship	has as target	DocumentVersion 1 targetDocumentVersion	<p>DESCRIPTION: Each DocumentVersionRelationship always has as target one DocumentVersion. Each DocumentVersion might be the target for one or more DocumentVersionRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> DocumentVersionRelations <i>hip</i> <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of document version relationship. Each value implies specific constraints to what kinds of objects can be related and in which way.</p> <p>EXAMPLE(S): decomposition (component), pre-condition, post-condition, sequel (replaces, modifies), attribution (cause and effect)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is HL7 structured vocabulary and is part of a controlled vocabulary set.</p>	Map:AE = SafetyReport.amendmentReportInd Map:CTRPv3.8 = StudyRelationship.typeCode Map:CTRv1.0 = DocumentVersionRelationship.typeCode Map:FDA HL7 SD SD DSTU2012 = outboundRelationship.typeCode Map:ICSRr2 = SourceOf1.typeCode (in IndividualCaseSafetyReport) Map:ICSRr2 = SourceOf2.typeCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = DocumentVersionRelationship.typeCode Map:RPS1 = RelatedDocumentation.relationship
priorityNumber <i>Class:</i> DocumentVersionRelations <i>hip</i> <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative rank for one document version before other similar documents having the same type of association to the same source document version.</p> <p>EXAMPLE(S): A report initiated by the primary physician may be ranked higher than reports initiated by specialty consultants or support staff.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>There may be multiple investigations (and therefore reports) into the same event, each initiated by a different party. The priorityNumber may be used to rank these investigations.</p> <p>The ordering may be a total ordering, in which all priority numbers are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p>	Map:CTRPv3.8 = StudyRelationship.sequenceNumber Map:CTRv1.0 = DocumentVersionRelationship.priorityNumber Map:ICSRr2 = SourceOf1.priorityNumber (in IndividualCaseSafetyReport)

Class: DocumentVersionRepresentation

Package: Common Sub-Domain

DEFINITION:

A format-specific representation of a particular edition of a document as it exists at a particular point in time. A particular edition may be available in multiple formats and each format may be available at multiple locations.

EXAMPLE(S):

A particular edition of a protocol may be available in MS Word, PDF, etc. and each format may be available at multiple

locations such as on a research facility's web site, on a cooperative groups web page, etc.

OTHER NAME(S):

NOTE(S):

This class does not go as far as making each copy posted on the web (or printed, for that matter) uniquely identifiable. That would require changes to the BRIDG model.

Tagged Values:

- Map:LSDAMv2.2.3Plus = DocumentVersionRepresentation

Connectors

Source	Connector	Target	Notes
DocumentVersionRepresentation 1..* representingDocumentVersionRepresentation	represents	DocumentVersion 1 representedDocumentVersion	<p>DESCRIPTION: Each DocumentVersionRepresentation always represents one DocumentVersion. Each DocumentVersion always is represented as one or more DocumentVersionRepresentation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
content <i>Class:</i> DocumentVersionRepresentation <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A textual or media-based representation that is the full or comprehensive narrative or substance of the document version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Document.text Map:AE = SafetyReport.narrativeText Map:caAERSv2.2 = NotificationAttachment.content Map:CTR&Rr2 = IMP modified specification Map:CTRPv1.0 = InterventionalStudyProtocol.text Map:CTRPv1.0 = ObservationalStudyProtocol.text Map:CTRPv1.0 = StudyProtocol.text Map:CTRRr3 = Document.text Map:CTRv1.0 = DocumentVersion.text Map:HL7SD = PlannedStudy.text Map:ICSRr2 = InvestigativeEvent.text (in IndividualCaseSafetyReport) Map:ICSRr2 = document.text (in IndividualCaseSafetyReport) Map:ICSRr2 = RelatedInvestigation.text (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = DocumentVersionRepresentation.content Map:Statistics v1.0 = DocumentVersion.text
uniformResourceLocator <i>Class:</i> DocumentVersionRepresentation <i>Datatype:</i> DSET<TEL.URL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: An indication of where the document contents can be retrieved from.</p> <p>EXAMPLE(S): a URL for a file or the location on a publicly available file system</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = DocumentVersionRepresentation.uniformResourceLocator

Class: DocumentVersionWorkflowStatus

Package: Common Sub-Domain

DEFINITION:

The workflow status associated with a document version from submission through abstraction.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Please refer to the Processing Status state transition diagram for further details.

Tagged Values:

- Map:CTRPv1.0 = DocumentWorkflowStatus
- Map:CTRPv3.8 = DocumentWorkflowStatus
- Map:CTRv1.0 = DocumentVersionWorkflowStatus
- Map:LSDAMv2.2.3Plus = DocumentVersionWorkflowStatus

- Map:RPS1 = Documentation.status

Connectors

Source	Connector	Target	Notes
DocumentVersionWorkflowStatus 0..* describingDocumentVersionWorkflowStatus	describes	DocumentVersion 1 describedDocumentVersion	<p>DESCRIPTION: Each DocumentVersionWorkflowStatus always describes one DocumentVersion. Each DocumentVersion might be described by one or more DocumentVersionWorkflowStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> DocumentVersionWorkflowStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the document version workflow.</p> <p>EXAMPLE(S): On-hold, Accepted, Rejected, Abstracted, Abstraction Verified, Abstraction not verified</p> <p>Created, available [examples for HL7 StudyDesign Structured Document]</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Processing Status state transition diagram for further details.</p> <p>A state transition diagram needs to be developed for the HL7 StudyDesign Structured Document examples.</p>	<p>Map:AE = SafetyReport.statusCode Map:C3PRv2.9 = StudyVersion.versionStatus Map:caAERSv2.2 = ReportVersion.status Map:CTOM = ProtocolStatus.statusCode Map:CTRPv1.0 = DocumentWorkflowStatus.statusCode Map:CTRPv3.8 = DocumentWorkflowStatus.statusCode Map:CTRv1.0 = DocumentVersionWorkflowStatus.code Map:LabViewer2.2 = Study.status Map:LSDAMv2.2.3Plus = DocumentVersionWorkflowStatus.code</p>

Attribute	Notes	Constraints and Tags
date <i>Class:</i> DocumentVersionWorkflowStatus <i>Datatype:</i> TS.DATE.FULL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the status is assigned to the document version workflow.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = SafetyReport.mostRecentInformation Date Map:AE = SafetyReport.timeReportCompleted Map:C3PRv2.9 = StudyVersion.versionDate Map:caAERSv2.2 = ReportVersion.withdrawOn Map:caAERSv2.2 = ReportVersion.submittedOn Map:caAERSv2.2 = Report.submittedDate Map:CTOM = ProtocolStatus.statusDate Map:CTOM = Protocol.amendmentDate Map:CTRPv1.0 = DocumentWorkflowStatus.statusDate Map:CTRPv3.8 = DocumentWorkflowStatus.statusDate Range Map:CTRv1.0 = DocumentVersionWorkflowStatus.date Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.availabilityTime Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.effectiveTime Map:ICSRr2 = ControlActEvent.effectiveTime (in IndividualCaseSafetyReport) Map:LabViewer2.2 = Study.statusDate Map:LSDAMv2.2.3Plus = DocumentVersionWorkflowStatus.date
comment <i>Class:</i> DocumentVersionWorkflowStatus <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Additional description of the workflow status.</p> <p>EXAMPLE(S): to capture the reasons of statuses or other notes</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = DocumentWorkflowStatus.commentText Map:CTRPv3.8 = DocumentWorkflowStatus.commentText Map:CTRv1.0 = DocumentVersionWorkflowStatus.comment Map:LSDAMv2.2.3Plus = DocumentVersionWorkflowStatus.comment

Class: DonorRegistry

Package: Common Sub-Domain

DEFINITION:

An organization that administers the registration of donors of materials for transplantation.

EXAMPLE(S):

'Be The Match' registry maintained by the National Marrow Donor Program (NMDP)

OTHER NAME(S):

NOTE(S):

The registry should contain basic information about each donor sufficient to identify duplicate entries and match donors to potential recipients.

There may be names for the registry, e.g., "Be The Match", however, we do not have a requirement for adding this at this time.

Tagged Values:

- Map:HCTv1.0 = (model integrity)

Connectors

Source	Connector	Target	Notes
DonorRegistry 0..* managedDonorRegistry	is managed by	Organization 1 managingOrganization	<p>DESCRIPTION: Each DonorRegistry always is managed by one Organization. Each Organization might manage one or more DonorRegistry.</p> <p>DEFINITION: Indicates the organization that manages the registry.</p> <p>EXAMPLE(S): OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> DonorRegistry <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of the donor registry.</p> <p>EXAMPLE(S): patient number 7 on a study</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:ID Datatype Change = Model Integrity

Class: Drug

Package: Common Sub-Domain

DEFINITION:

An article other than food intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or any function of the body.

EXAMPLE(S):
aspirin

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = ChemoAgent
- Map:CTRPv1.0 = Drug
- Map:CTRv1.0 = Drug

Connectors

Source	Connector	Target	Notes
Drug	specializes	Product	<p>DESCRIPTION: Each Drug always specializes one Product. Each Product might be specialized by one Drug.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarkerGroup 0..* affectingMolecularBiomarkerGroup	impact the effectiveness of	Drug 0..* affectedDrug	<p>DESCRIPTION: Each MolecularBiomarkerGroup might impact the effectiveness of one or more Drug. Each Drug might have effectiveness impacted by one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): Molecular Biomarker Group "L10I+K20R+M36I+A71V+V82T" links a set of mutations with the conclusion of drug resistance to the drug "Indinavir".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Radiopharmaceutical	specializes	Drug	<p>DESCRIPTION: Each Radiopharmaceutical always specializes one Drug. Each Drug might be specialized by one Radiopharmaceutical.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
actionModeCode <i>Class:</i> Drug <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the mode of action through which this substance produces a pharmacological effect.</p> <p>EXAMPLE(S): stimulating action, depressing action, blocking/antagonizing action, stabilizing action, exchanging/replacing substances, direct beneficial chemical reaction, direct harmful chemical reaction.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRRr3 = ProductPart.actionModeCode
handlingCode <i>Class:</i> Drug <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying special handling requirements for the drug.</p> <p>EXAMPLE(S): keep at room temperature, store upright</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Drug.handlingCode Map:ICSRr2 = Product.handlingCode (in R_Product)
riskCode <i>Class:</i> Drug <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of hazard or threat associated with the drug.</p> <p>EXAMPLE(S): flammable, explosive</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Drug.riskCode Map:ICSRr2 = Product.riskCode (in R_Product)
stabilityDuration <i>Class:</i> Drug <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The period of time during which the drug is considered usable after it is activated (opened).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Drug.stabilityDuration Map:ICSRr2 = ProductInstance.stabilityTime (in R_Product)

Class: ExperimentalUnit

Package: Common Sub-Domain

DEFINITION:

A physical entity which is the primary unit of interest in a specific research objective.

EXAMPLE(S):

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. [example from the CDISC/HL7 Study Participation message]

A human may have 10 patches of skin each considered an experimental unit. A product may have 10 bearings in it, each considered an experimental unit. Alternatively, the whole human or product may be an experimental unit.

OTHER NAME(S):

NOTE(S):

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

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.

Tagged Values:

- Map:CTRRr3 = ExperimentalUnit
- Map:CTRv1.0 = ExperimentalUnit
- Map:HL7SP = ExperimentalUnit

Connectors

Source	Connector	Target	Notes
ExperimentalUnit 0..* experiencingExperimentalU nit	actually have experienced	Arm 0..1 experienceArm	<p>DESCRIPTION: Each ExperimentalUnit might actually have experienced one Arm. Each Arm might actually have been experienced by one or more ExperimentalUnit.</p> <p>DEFINITION: The association between a ExperimentalUnit and an Arm that identifies the treatment plan actually received by the experimental unit as determined retrospectively regardless of what treatment plan was in fact assigned to the experimental unit.</p> <p>EXAMPLE(S): For an A/B cross-over study the arms may be “A-B” and “B-A”; if John Doe was assigned Arm “A-B”, but actually experienced Arm “B-A”, this association would link his role of ExperimentalUnit to the Arm he really participated in.</p> <p>OTHER NAME(S): Actual Arm</p> <p>NOTE(S): In most trials one would expect that the Arm linked to the ExperimentalUnit will be</p>

Source	Connector	Target	Notes
			<p>the same as the Arm.name that was assigned in the PerformedExperimentalUnit Allocation for that ExperimentalUnit. However, if what actually happened is different than what was assigned but is actually a valid arm in the trial arms table, i.e. the experimental unit was assigned A-B but actually received B-A, this association shows the connection to the treatment plan that actually was followed. Or alternatively, if CDISC's SDTM DM.ACTARMCD = "UNPLAN" (meaning "Unplanned Treatment"), then the treatment that occurred doesn't match any arm in trial arms table and this association would not be used. Rather the ExperimentalUnit.unplannedTreatmentIndicator would be "true". Note that this association has a retrospective nature – i.e. you might not know what treatment an experimental unit was actually on until after all treatments have been completed and the blind, if any, has been broken. This is typically the case for studies in which there may be more than one randomization.</p>
ExperimentalUnit 0..1 performingExperimentalUnit	have performed	Arm 0..1 performedArm	<p>DESCRIPTION: Each ExperimentalUnit might have performed one Arm. Each Arm might have been performed by one ExperimentalUnit.</p> <p>DEFINITION: Indicates that an ExperimentalUnit was, at the end of their participation in a study, assigned to a particular arm based on their actual path through the study.</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S): This is derivable if the set of performed activities the ExperimentalUnit participated in are available.
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	Product 0..1 performingProduct	DESCRIPTION: Each ExperimentalUnit might be a function performed by one Product. Each Product might function as one or more ExperimentalUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	BiologicEntityGroup 0..1 performingBiologicEntityGroup	DESCRIPTION: Each ExperimentalUnit might be a function performed by one BiologicEntityGroup. Each BiologicEntityGroup might function as one or more ExperimentalUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	ProductGroup 0..1 performingProductGroup	DESCRIPTION: Each ExperimentalUnit might be a function performed by one ProductGroup. Each ProductGroup might function as one or more ExperimentalUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	BiologicEntityPart 0..1 performingBiologicEntityPa	DESCRIPTION: Each ExperimentalUnit might be a function

Source	Connector	Target	Notes
		rt	<p>performed by one BiologicEntityPart. Each BiologicEntityPart might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	Specimen 0..1 performingSpecimen	<p>DESCRIPTION: Each ExperimentalUnit might be a function performed by one Specimen. Each Specimen might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	BiologicEntity 0..1 performingBiologicEntity	<p>DESCRIPTION: Each ExperimentalUnit might be a function performed by one BiologicEntity. Each BiologicEntity might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* involvingActivity	be participated in by	ExperimentalUnit 0..1 involvedExperimentalUnit	<p>DESCRIPTION: Each Activity might be participated in by one ExperimentalUnit. Each ExperimentalUnit might participate in one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ExperimentalUnit <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	DEFINITION: A unique symbol that establishes identity of the experimental unit. EXAMPLE(S): patient number 7 on a study OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ExperimentalUnit.identifier Map:HL7SP = ExperimentalUnit.id
subgroupCode <i>Class:</i> ExperimentalUnit <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the identification of uniform groups of experimental units for separate analysis or treatment. EXAMPLE(S): Clinical Data Update System (CDUS) Reporting (for the National Cancer Institute (NCI)) OTHER NAME(S): NOTE(S):	Map:C3PR = StudySubject.subgroup Map:CTOM = StudyParticipantAssignment.subgroupCode Map:CTRv1.0 = ExperimentalUnit.subgroupCode Map:NCI CRF Standard = CDE 1925v2.31: Patient Subgroup Code
statusCode <i>Class:</i> ExperimentalUnit <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the phase in the lifecycle of the experimental unit. EXAMPLE(S): active, cancelled, pending, suspended, terminated, nullified OTHER NAME(S): NOTE(S): Please refer to the HL7 Role Status state transition diagram for further details.	Map:CTRv1.0 = ExperimentalUnit.statusCode Map:HL7SP = ExperimentalUnit.statusCode
statusDate <i>Class:</i> ExperimentalUnit <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The date (and time) on which the status is assigned to the experimental unit. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ExperimentalUnit.statusDate Map:HL7SP = ExperimentalUnit.effectiveTime

Attribute	Notes	Constraints and Tags
unplannedTreatmentIndicator <i>Class:</i> ExperimentalUnit <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the treatment plan actually received by the experimental unit, as determined retrospectively, was not only NOT what was assigned, but was not even defined as a valid treatment plan.</p> <p>EXAMPLE(S): If an A/B cross-over study only has arms “A-B” and “B-A” and a given experimental unit has a treatment that is effectively “A-A”, then unplannedTreatmentIndicator = “true”. In SDTM, if DM.ACTARM = “Unplanned Treatment” or DM.ACTARMCD = “UNPLAN”, then unplannedTreatmentIndicator = “true”.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the treatment plan received by an experimental unit actually is a valid treatment plan, whether or not it was what was assigned in the experimental unit allocation activity, this is represented as an association from the ExperimentalUnit to the Arm, with unplannedTreatmentIndicator = “false”.</p> <p>Note that this attribute has a retrospective nature – i.e. you might not know what treatment an experimental unit was actually on until after all treatments have been completed and the blind, if any, has been broken. This is typically the case for studies in which there may be more than one randomization.</p>	Map:SDTM IGv3.1.3 = DM.ACTACRMCD Map:SDTM IGv3.1.3 = DM.ACTARM

Class: FoodProduct

Package: Common Sub-Domain

DEFINITION:

A substance consumed by a human or animal for nutritional purposes.

EXAMPLE(S):

broccoli, donuts, pet treats

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv1.0 = FoodProduct
- Map:CTRv1.0 = FoodProduct

Connectors

Source	Connector	Target	Notes
FoodProduct	specializes	Product	DESCRIPTION: Each FoodProduct always specializes one Product.

Source	Connector	Target	Notes
			<p>Each Product might be specialized by one FoodProduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
stabilityDuration <i>Class:</i> FoodProduct <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time during which the food product is considered usable after it is activated (opened).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = FoodProduct.stabilityDuration Map:ICSRr2 = ProductInstance.stabilityTime (in R_Product)

Class: HealthcareFacility

Package: Common Sub-Domain

DEFINITION:

An organization that devotes some or all of its resources (people, places, things) to the delivery of healthcare services (including the financial and administrative management of those resources).

EXAMPLE(S):

Northwestern Memorial Hospital

OTHER NAME(S):

NOTE(S):

A healthcare facility may be manifest as a single physical location (e.g. building), or, alternatively, as a distributed collection of physical spaces.

Tagged Values:

- Map:C3PRv2.9 = HealthcareSite
- Map:C3PRv2.9 = RemoteHealthcareSite
- Map:CTRv1.0 = HealthCareFacility
- Map:CTRv3.8 = HealthCareFacility
- Map:CTRv1.0 = HealthcareFacility
- Map:HL7SD = StudySite
- Map:HL7SP = Site
- Map:HL7SP = StudySite
- Map:LabViewer2.2 = HealthcareSite
- Map:PSCv2.6 = Site

Connectors

Source	Connector	Target	Notes
HealthcareFacility 0..1	is a function performed by	Organization 1	DESCRIPTION: Each HealthcareFacility

Source	Connector	Target	Notes
performedHealthcareFacility		performingOrganization	always is a function performed by one Organization. Each Organization might function as one HealthcareFacility. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
HealthcareProvider 0..* staffingHealthcareProvider	staff	HealthcareFacility 0..1 staffedHealthcareFacility	DESCRIPTION: Each HealthcareProvider might staff one HealthcareFacility. Each HealthcareFacility might be staffed by one or more HealthcareProvider. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedStudySite 0..* performedPlannedStudySite	be a function planned to be performed by	HealthcareFacility 0..1 performingHealthcareFacility	DESCRIPTION: Each PlannedStudySite might be a function planned to be performed by one HealthcareFacility. Each HealthcareFacility might plan to function as one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySite 0..* performedStudySite	be a function performed by	HealthcareFacility 0..1 performingHealthcareFacility	DESCRIPTION: Each StudySite might be a function performed by one HealthcareFacility. Each HealthcareFacility might function as one or more StudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
HealthcareProviderGroup 0..* usedHealthcareProviderGro up	is used to group staff for	HealthcareFacility 1 usingHealthcareFacility	DESCRIPTION: Each HealthcareProviderGroup always is used to group staff for one HealthcareFacility. Each HealthcareFacility might group staff into one or more HealthcareProviderGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
TreatingSite 0..* performedTreatingSite	is a function performed by	HealthcareFacility 1 performingHealthcareFacilit y	DESCRIPTION: Each TreatingSite always is a function performed by one HealthcareFacility. Each HealthcareFacility might function as one or more TreatingSite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
OversightCommittee 0..* overseeingOversightCommit tee	oversee	HealthcareFacility 0..* overseenHealthcareFacility	DESCRIPTION: Each OversightCommittee might oversee one or more HealthcareFacility. Each HealthcareFacility might be overseen by one or more OversightCommittee. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> HealthcareFacility <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of the healthcare facility.</p> <p>EXAMPLE(S): In Cancer Therapy Evaluation Program (CTEP), every site that interacts with the National Cancer Institute (NCI) gets an NCI unique identifier.</p> <p>Hospitals get an American Hospital Association (AHA) ID.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = HealthCareSite.identifier Map:CTOM = HealthcareSite.nciInstituteCode Map:CTRPv1.0 = HealthCareFacility.identifier Map:CTRv1.0 = HealthcareFacility.identifier Map:Lab = HealthCareSite.identifier Map:LabViewer2.2 = HealthcareSite.nciInstituteCode Map:NCI CRF Standard = CDE 2481533V1.0: Treating Institution Identifier Code Map:NCI CRF Standard = CDE 2003307v4.0: Registering Institution Identification Code
postalAddress <i>Class:</i> HealthcareFacility <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A contact point used to send physical forms of communication to the healthcare facility.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = HealthCareSite.postalAddress Map:CTOM = HealthcareSite.countryCode Map:CTOM = HealthcareSite.city Map:CTOM = HealthcareSite.stateCode Map:CTOM = HealthcareSite.postalCode Map:CTRPv3.8 = HealthCareFacility.postalAddress Map:CTRv1.0 = HealthcareFacility.postalAddress Map:LabViewer2.2 = HealthcareSite.postalCode Map:LabViewer2.2 = HealthcareSite.countryCode Map:LabViewer2.2 = HealthcareSite.city Map:LabViewer2.2 = HealthcareSite.stateCode Map:LabViewer2.2 = HealthcareSite.streetAddress
telecomAddress <i>Class:</i> HealthcareFacility <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the healthcare facility.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:CTRPv3.8 = HealthCareFacility.telecomAddress Map:CTRv1.0 = HealthcareFacility.telecomAddress Map:LabViewer2.2 = HealthcareSite.telecomAddress

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> HealthcareFacility <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the healthcare facility is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = HealthCareSite.startDate Map:CTOM = HealthcareSite.statusCode Map:CTOM = HealthcareSite.statusDate Map:CTRPv1.0 = HealthCareFacility.statusCode Map:CTRPv1.0 = HealthCareFacility.statusDateRange Map:CTRv1.0 = HealthcareFacility.effectiveDateRange

Class: HealthcareProvider

Package: Common Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

Physician, Physician Assistant, Psychologist, Nurse, Physical Therapist

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = HealthcareSiteInvestigator
- Map:C3PRv2.9 = Investigator
- Map:caAERSv2.2 = Investigator
- Map:caAERSv2.2 = RoleBasedRecipient.role
- Map:caAERSv2.2 = SiteInvestigator
- Map:CTRPv1.0 = HealthCareProvider
- Map:CTRPv3.8 = HealthCareProvider
- Map:CTRRr3 = HealthcareProvider
- Map:CTRv1.0 = HealthcareProvider
- Map:HL7SP = LicensedEntity
- Map:HL7SP = Investigator
- Map:LabViewer2.2 = Investigator

Connectors

Source	Connector	Target	Notes
HealthcareProvider 0..* staffingHealthcareProvider	staff	HealthcareFacility 0..1 staffedHealthcareFacility	<p>DESCRIPTION: Each HealthcareProvider might staff one HealthcareFacility. Each HealthcareFacility might be staffed by one or more HealthcareProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
HealthcareProvider 0..* performedHealthcareProvider	is a function performed by	Person 1 performingPerson	<p>DESCRIPTION: Each HealthcareProvider always is a function performed by one Person. Each Person might function as one or more HealthcareProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProvider 0..* employedHealthcareProvider	belong to a department at	Organization 0..1 employingOrganization	<p>DESCRIPTION: Each HealthcareProvider might belong to a department at one Organization. Each Organization might be the department for one or more HealthcareProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RegulatoryApplicationSponsor 0..* performedRegulatoryApplicationSponsor	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each RegulatoryApplicationSponsor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more RegulatoryApplicationSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more DocumentAuthor.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performedStudyPersonnel	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION:</p> <p>Each StudyPersonnel might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>Indicates that the StudyPersonnel role is being fulfilled by a HealthcareProvider</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyLegalSponsor 0..* performedStudyLegalSponsor	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION:</p> <p>Each StudyLegalSponsor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudyLegalSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProviderGroupMember 0..* performedHealthcareProviderGroupMember	is a function performed by	HealthcareProvider 1 performingHealthcareProvider	<p>DESCRIPTION:</p> <p>Each HealthcareProviderGroupMember always is a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more HealthcareProviderGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			<p>NOTE(S):</p> <p>DESCRIPTION: Each StudySitePersonnel might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudySitePersonnel.</p> <p>DEFINITION: Indicates that the StudySitePersonnel role is being fulfilled by a HealthcareProvider.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySitePersonnel 0..* performedStudySitePersonnel	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each Performer might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> HealthcareProvider <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	DEFINITION: A unique symbol that establishes identity of the healthcare provider. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = RemoteInvestigator.externalId Map:caAERSv2.2 = Investigator.nciIdentifier Map:CTOM = Investigator.nciIdentifier Map:CTRPv1.0 = HealthCareProvider.identifier Map:CTRv1.0 = HealthcareProvider.identifier Map:FDA HL7 SD SD DSTU2012 = plannedStudy/performer/assignedEntity.id Map:FDA HL7 SD SD DSTU2012 = assignedEntity.id Map:Lab = Investigator.identifier
roleCode <i>Class:</i> HealthcareProvider <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	DEFINITION: A coded value specifying the function) of the person in the context of this organization. EXAMPLE(S): physician, nurse, radiographer OTHER NAME(S): occupation NOTE(S):	Map:DICOM = TID 1003 PersonObserverIdentifyingAttributes > Person Observer's Role in the Organization
postalAddress <i>Class:</i> HealthcareProvider <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A contact point used to send physical forms of communication to the healthcare provider. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = HealthCareProvider.postalAddress Map:CTRv1.0 = HealthcareProvider.postalAddress Map:FDA HL7 SD SD DSTU2012 = plannedStudy/performer/assignedEntity.addr Map:FDA HL7 SD SD DSTU2012 = assignedEntity.addr Map:ICSRr2 = AssignedEntity.addr (in IndividualCaseSafetyReport) Map:LabViewer2.2 = Investigator.streetAddress Map:LabViewer2.2 = Investigator.countryCode Map:LabViewer2.2 = Investigator.state Map:LabViewer2.2 = Investigator.city Map:LabViewer2.2 = Investigator.postalCode

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> HealthcareProvider <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the healthcare provider.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:caAERSv2.2 = Investigator.phoneNumber Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:caAERSv2.2 = PersonContact.ReportPerson.Physician.contactMechanisms Map:caAERSv2.2 = SiteInvestigator.emailAddress Map:caAERSv2.2 = Investigator.faxNumber Map:caAERSv2.2 = PersonContact.ReportPerson.Reporter.contactMechanisms Map:CTRPv1.0 = HealthCareProvider.telecomAddress Map:CTRv1.0 = HealthcareProvider.telecomAddress Map:FDA HL7 SD SD DSTU2012 = plannedStudy/performer/assignedEntity.telecom Map:FDA HL7 SD SD DSTU2012 = assignedEntity.telecom Map:ICSRr2 = AssignedEntity.telecom (in IndividualCaseSafetyReport) Map:LabViewer2.2 = Investigator.phone Map:LabViewer2.2 = Investigator.telecomAddress
effectiveDateRange <i>Class:</i> HealthcareProvider <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the healthcare provider is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = HealthcareSiteInvestigator.statusDate Map:caAERSv2.2 = SiteInvestigator.statusCode Map:caAERSv2.2 = SiteInvestigator.statusDate Map:CTRPv1.0 = HealthCareProvider.statusCode Map:CTRPv1.0 = HealthCareProvider.statusDateRange Map:CTRv1.0 = HealthcareProvider.effectiveDateRange

Class: HealthcareProviderGroup

Package: Common Sub-Domain

DEFINITION:

A collection of healthcare providers loosely based upon a criterion (i.e., specialty, department, credentials).

EXAMPLE(S):

Department of Radiology, Oncology Nurses, Oncologists, Physicians

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = InvestigatorGroup
- Map:CoopGrp = HealthcareProviderGroup

Connectors

Source	Connector	Target	Notes
HealthcareProviderGroup 0..* usedHealthcareProviderGro up	is used to group staff for	HealthcareFacility 1 usingHealthcareFacility	<p>DESCRIPTION: Each HealthcareProviderGroup always is used to group staff for one HealthcareFacility. Each HealthcareFacility might group staff into one or more HealthcareProviderGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProviderGroup 0..1 performedHealthcareProvid erGroup	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each HealthcareProviderGroup always is a function performed by one Organization. Each Organization might function as one HealthcareProviderGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProviderGroupM ember 1..* groupedHealthcareProvider GroupMember	belongs to	HealthcareProviderGroup 1 groupingHealthcareProvider Group	<p>DESCRIPTION: Each HealthcareProviderGroupM ember always belongs to one HealthcareProviderGroup. Each HealthcareProviderGroup always contains one or more HealthcareProviderGroupM ember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> HealthcareProviderGroup <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the healthcare provider group is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = InvestigatorGroup.startDate Map:C3PR = InvestigatorGroup.endDate Map:C3PRv2.9 = InvestigatorGroup.startDate Map:C3PRv2.9 = InvestigatorGroup.endDate

Class: HealthcareProviderGroupMember

Package: Common Sub-Domain

DEFINITION:

The role of an individual healthcare provider as a constituent part of a group.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = SiteInvestigatorGroupAffiliation
- Map:CoopGrp = HealthcareProviderGroupMember

Connectors

Source	Connector	Target	Notes
HealthcareProviderGroupMember 0..* performedHealthcareProviderGroupMember	is a function performed by	HealthcareProvider 1 performingHealthcareProvider	<p>DESCRIPTION: Each HealthcareProviderGroupMember always is a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more HealthcareProviderGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProviderGroupMember 1..* groupedHealthcareProviderGroupMember	belongs to	HealthcareProviderGroup 1 groupingHealthcareProviderGroup	<p>DESCRIPTION: Each HealthcareProviderGroupMember always belongs to one HealthcareProviderGroup. Each HealthcareProviderGroup always contains one or more</p>

Source	Connector	Target	Notes
			<p>HealthcareProviderGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> HealthcareProviderGroupMember <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) span for when the healthcare provider group member is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:C3PR = SiteInvestigatorGroupAffiliation.startDate</p> <p>Map:C3PR = SiteInvestigatorGroupAffiliation.endDate</p> <p>Map:C3PRv2.9 = SiteInvestigatorGroupAffiliation.startDate</p> <p>Map:C3PRv2.9 = SiteInvestigatorGroupAffiliation.endDate</p>

Class: ID

Package: Common Sub-Domain

DEFINITION:

A complex identifier datatype that provides more information, including a type code, about an identifier than the instance identifier (II) datatype.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The use of this new datatype is an extension of the HL7 ADT R2 specification currently used in BRIDG. This extension allows the identifier attribute to reside in the "source" class instead of an additional class created to allow for additional identifier information such as type code, which is a common requirement. This approach simplifies the model by reducing the number of classes and relationships.

Tagged Values:

- Map:Vendor1v1.1 = ID

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ID <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A unique symbol that establishes identity of an entity, role, action, or other object.</p> <p>EXAMPLE(S): 12345 is the identifier for a substance administration.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ID.identifier
identierTypeCode <i>Class:</i> ID <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A coded value specifying the kind of identifier.</p> <p>EXAMPLE(S): NCBI identifier, system identifier, medical record number, national taxpayer identifier, US National Cancer Institute protocol identifier, Mayo Clinic protocol identifier, Ensembl database identifier (for human genes), UniProt Knowledgebase identifier (for proteins), GenBank (for transcript identifiers), US National Cancer Institute Cancer Therapy Evaluation Program (CTEP) identifier (for healthcare facilities participating in the program)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The purpose of this attribute is to distinguish different kinds of identifiers that can be assigned to the same object, e.g., the same person could have both an medical record number and a national taxpayer id.</p>	Map:Vendor1v1.1 = ID.typeCode
primaryIndicator <i>Class:</i> ID <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the main or principal identifier.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ID.primaryIndicator

Attribute	Notes	Constraints and Tags
sourceIdentifier <i>Class:</i> ID <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A unique symbol that establishes identity of a specific source that assigns or issues identifiers.</p> <p>EXAMPLE(S): 2.16.840.1.113883.3.184 (Identifier for United States Social Security Administration)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>-----</p> <p>Definition: This attribute provides a means to specify which particular instance of a system issued the value in the identifier attribute. It should be used alongside the sourceCode attribute which will specify the type of system (rather than the instance). The attribute uses the II datatype which gives it a root and an extension. This attribute may NOT be used to assess equality of two attributes and its value may be changed as required. The attribute has a data type of II, in most contexts only the extension value will be required, but there may be occasions where the root should also be given a value. This should be drawn from the OID catalogue as usual.</p>	Map:Vendor1v1.1 = ID.sourceIdentifier

Attribute	Notes	Constraints and Tags
sourceTypeCode <i>Class:</i> ID <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of originator of the identifier.</p> <p>EXAMPLE(S): study registry (that assigns document identifiers), cancer registry (that assigns registry identifiers), system of record (that assigns subject identifiers, document identifiers, organization identifiers), donor registry (that assigns subject identifiers), organization (that assigns or issues material identifiers, messenger RNA identifiers, document identifiers, gene identifiers, subject identifiers, biological group identifiers, pathway identifiers, protein identifiers, genetic variation identifiers, biological entity identifiers, organization identifiers)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ID.sourceCode
effectiveDateRange <i>Class:</i> ID <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the identifier is valid.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ID.effectiveDateRange

Class: Manufacturer

Package: Common Sub-Domain

DEFINTION:

The organization responsible for creating the product as stated on the package in which the product is supplied.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = Manufacturer
- Map:ICSRr2 = performance1 (in R_Product)

- Map:LSDAMv2.2.3Plus = Manufacturer

Connectors

Source	Connector	Target	Notes
Manufacturer	specializes	Processor	<p>DESCRIPTION: Each Manufacturer always specializes one Processor. Each Processor might be specialized by one Manufacturer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: MaritalStatus

Package: Common Sub-Domain

DEFINITION:

The domestic partnership status of a person.

EXAMPLE(S):

For the U.S. Census 2000:

Now Married, Widowed, Separated, Divorced, Never Married

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - MARITAL STATUS AT DIAGNOSIS

Connectors

Source	Connector	Target	Notes
MaritalStatus 0..* describingMaritalStatus	describes	Person 1 describedPerson	<p>DESCRIPTION: Each MaritalStatus always describes one Person. Each Person might be described by one or more MaritalStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
code <i>Class:</i> MaritalStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the marital status of a person.</p> <p>EXAMPLE(S): For the U.S. Census 2000: Now Married, Widowed, Separated, Divorced, Never Married</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Participant.maritalStatusCode Map:C3PRv2.9 = Participant.maritalStatusCode Map:CDASHv1.1 = SC.SCORIES Map:CTOM = Person.maritalStatusCode Map:CTOM = Investigator.maritalStatusCode Map:CTOM = Participant.maritalStatusCode Map:CTRv1.0 = Person.maritalStatusCode Map:HCTv1.0 = CDE 2815107:Individuals.What is the marital status of the person? Map:LSDAMv2.2.3Plus = Person.maritalStatusCode Map:NCI CRF Standard = CDE 2188083v2.0: Person Marital Status Category Map:SDTM IGv3.1.2 = SC.SCORIES Map:SDTM IGv3.1.2 = SC.SCSTRESC Map:SDTM IGv3.1.3 = SC.SCORIES Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - MARITAL STATUS AT DIAGNOSIS
dateRange <i>Class:</i> MaritalStatus <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: The date (and time) span for when the marital status is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = (Model integrity)

Class: Material

Package: Common Sub-Domain

DEFINITION:

A physical substance or system.

EXAMPLE(S):

drugs such as aspirin
devices such as pacemakers or freezers
systems such as software programs
biologics such as blood
food products such as broccoli
cosmetics such as lipstick
containers such as a blister pack or a test tube

OTHER NAME(S):

NOTE(S):

Materials may be naturally occurring or may be made by natural or engineered processes.

Tagged Values:

- Map:CTRPv1.0 = Material
- Map:CTRr3 = Material
- Map:CTRv1.0 = Material
- Map:ICSRr2 = Natural (in R_Specimen universal)
- Map:ICSRr2 = ManufacturedMaterial (in R_Specimen universal)
- Map:LSDAMv2.2.3Plus = Material

Connectors

Source	Connector	Target	Notes
Material 0..* producedMaterial	have been produced by	DefinedMaterialProcessStep 0..1 producingDefinedMaterialP rocessStep	<p>DESCRIPTION: Each Material might have been produced by one DefinedMaterialProcessStep . Each DefinedMaterialProcessStep might have produced one or more Material.</p> <p>DEFINITION: Indicates that material is produced by a process step.</p> <p>EXAMPLE(S): A blood product has anticoagulants added to it to preserve the product A blood product has growth factor added to it to induce cell growth</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Material 0..* producedMaterial	have been produced by	PerformedMaterialProcessSt ep 0..1 producingPerformedMateria lProcessStep	<p>DESCRIPTION: Each Material might have been produced by one PerformedMaterialProcessStep . Each PerformedMaterialProcessStep might have produced one or more Material.</p> <p>DEFINITION: Indicates that material was produced by a process step.</p> <p>EXAMPLE(S): A blood product has anticoagulants added to it to preserve the product A blood product has growth factor added to it to induce cell growth</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Product	specializes	Material	DESCRIPTION:

Source	Connector	Target	Notes
			Each Product always specializes one Material. Each Material might be specialized by one Product. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Protein 0..* characterizingProtein	characterize	Material 0..* characterizedMaterial	DESCRIPTION: Each Protein might characterize one or more Material. Each Material might be characterized by one or more Protein. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Specimen 0..1 performedSpecimen	is a function performed by	Material 1 performingMaterial	DESCRIPTION: Each Specimen always is a function performed by one Material. Each Material might function as one Specimen. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PointOfContact 0..* supportingPointOfContact	support	Material 0..* supportedMaterial	DESCRIPTION: Each PointOfContact might support one or more Material. Each Material might be supported by one or more PointOfContact. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
MessengerRNA 0..* characterizingMessengerRN	characterize	Material 0..* characterizedMaterial	DESCRIPTION: Each MessengerRNA might characterize one or more

Source	Connector	Target	Notes
A			<p>Material. Each Material might be characterized by one or more MessengerRNA.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	Material 0..1 playingMaterial	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one Material. Each Material might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MaterialName 1..* namingMaterialName	names	Material 1 namedMaterial	<p>DESCRIPTION: Each MaterialName always names one Material. Each Material always is named by one or more MaterialName.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequence 0..* characterizingMolecularSequence	characterize	Material 0..* characterizedMaterial	<p>DESCRIPTION: Each MolecularSequence might characterize one or more Material. Each Material might be characterized by one or more MolecularSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Material <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the material.</p> <p>EXAMPLE(S): serial number, product number, model number</p> <p>OTHER NAME(S):</p> <p>NOTE(S): There are multiple ways in which an identifier can be associated to a product; inherited from MaterialIdentifier.identifier, the association to ProcessedProduct.identifier, and the association to ProductRelationship.identifier. If there is no context associated with the identifier, then MaterialIdentifier.identifier should be used. However, if the identifier for a product would be different in different context, one of the other identifiers should be used. If a kind of product is produced by different processors, and each processor assigns the product a different identifier, then ProcessedProduct.identifier should be used. If the product is used in multiple assemblies, and in each assembly it would be assigned a different identifier, then ProductRelationship.identifier should be used.</p>	Map:AE = Component.batchNumber Map:AE = Ingredient.batchnumber Map:AE = Device.serialNumber Map:AE = Device.otherNumber Map:AE = Device.catalogNumber Map:AE = Device.modelNumber Map:AE = Package.identifier Map:AIM v4 rv48 = Equipment.deviceSerialNumber Map:C3PRv2.9 = ScheduledArm.kitNumber Map:caAERSv2.2 = Agent.nscNumber Map:caAERSv2.2 = MedicalDevice.catalogNumber Map:caAERSv2.2 = MedicalDevice.modelNumber Map:CDASHv1.1 = DA.DAREFID Map:CTOM = Specimen.sampleIdentifier Map:CTR&Rr2 = Related IMP sequence number Map:CTRPv1.0 = Cosmetic.identifier Map:CTRPv1.0 = Device.identifier Map:CTRPv1.0 = Product.identifier Map:CTRPv1.0 = Drug.identifier Map:CTRPv1.0 = Biologic.identifier Map:CTRPv1.0 = Material.identifier Map:CTRPv1.0 = FoodProduct.identifier Map:CTRRr3 = Material.identifier Map:CTRv1.0 = MaterialIdentifier.identifier Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes > Device Observer UID Map:DICOM = Equipment Specification Module - Model Specification Sequence (0018,9912) > Device Serial Number (0018,1000) Map:DICOM = General Equipment Module - Device Serial Number (0018,1000) Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes > Device Observer Serial Number Map:FDA HL7 SD SD DSTU2012 = manufacturedProduct.id Map:HCTv1.0 = MD Anderson Specific Content: Transplant.BMT# or GMP # Map:HCTv1.0 = CDE 2808120:Anatomic Structure, System, or Substance.NMDP Cord Blood Unit ID: Map:HCTv1.0 = CDE 2735595:Anatomic Structure, System, or Substance.Non-NMDP Cord Blood Unit (CBU) ID: Map:ICSRr2 = IdentifiedItem.id (in R_Product) Map:ICSRr2 =

Attribute	Notes	Constraints and Tags
		<p>ManufacturedProduct.id (in R_Product)</p> <p>Map:ICSRr2 = DeviceInstance.id (in R_Product)</p> <p>Map:ICSRr2 = ProductInstance.id (in R_Product)</p> <p>Map:ICSRr2 = Specimen.id (in R_Specimen universal)</p> <p>Map:Lab = Specimen.identifier</p> <p>Map:LabViewer2.2 = Specimen.identifier</p> <p>Map:LSDAMv2.2.3Plus = MaterialIdentifier.identifier</p> <p>Map:LSDAMv2.2.3Plus = Software.identifier</p> <p>Map:PGx v1.0 = BE.SPDEVID</p> <p>Map:PGx v1.0 = PF.PFREFID</p> <p>Map:PGx v1.0 = PG.PGRECID</p> <p>Map:PGx v1.0 = SB.SBREFID</p> <p>Map:PGx v1.0 = RELSPEC.PARENT</p> <p>Map:PGx v1.0 = RELSPEC.REFID</p> <p>Map:PGx v1.0 = BS.BSREFID</p> <p>Map:PGx v1.0 = BE.BEREFID</p> <p>Map:SDTM IGv3.1.2 = DA.DAREFID</p> <p>Map:SDTM IGv3.1.2 = MS.MSREFID</p> <p>Map:SDTM IGv3.1.2 = PC.PCREFID</p> <p>Map:SDTM IGv3.1.2 = MB.MBREFID</p> <p>Map:SDTM IGv3.1.3 = PC.PCREFID</p> <p>Map:SDTM IGv3.1.3 = MB.MBREFID</p> <p>Map:SDTM IGv3.1.3 = DA.DAREFID</p> <p>Map:SDTM IGv3.1.3 = MS.MSREFID</p> <p>Map:SDTM IGv3.1.3 = DA.DASPID</p> <p>Map:SDTM IGv3.1.3 = LB.LBREFID</p>

Attribute	Notes	Constraints and Tags
code <i>Class:</i> Material <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the non-unique textual identifier for the material.</p> <p>EXAMPLE(S): aspirin, tobacco, caffeine, tongue depressors, x-ray machine, olive oil, oats, lipstick, skin moisturizer, blisterpack, test tube, specimen slide, urine, blood, plasma, platelet rich plasma, serum, DNA, gDNA, RNA, gRNA, mRNA, Fluorodeoxyglucose F¹⁸</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The granularity of the code may vary depending on the specificity of the material. For example, acetaminophen, Tylenol, Tylenol 250 mg gel cap.</p>	Map:caAERSv2.2 = StudyParticipantPreExistingCondition > PriorTherapy.text Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.meddraTerm Map:caAERSv2.2 = StudyParticipantPriorTherapy.other Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.text Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.meddraCode Map:caAERSv2.2 = StudyParticipantPreExistingCondition > PriorTherapy.meddraTerm Map:caAERSv2.2 = SAEReportPriorTherapy.other Map:caAERSv2.2 = ChemoAgent.name Map:caAERSv2.2 = StudyParticipantPreExistingCondition > PriorTherapy.meddraCode Map:caAERSv2.2 = StudyAgent.otherAgent Map:CDASHv1.1 = CM.CMINGRD Map:CTR&Rr2 = AS current sponsor code Map:CTR&Rr2 = Tissue Engineered Other Map:CTR&Rr2 = Tissue Engineered type differentiated Map:CTR&Rr2 = Tissue Engineered type stem Map:CTR&Rr2 = Comparator a placebo Map:CTR&Rr2 = Placebo major ingredients Map:CTR&Rr2 = EV (EudraVigilance) Substance Code Map:CTR&Rr2 = Comparator another MP Map:CTR&Rr2 = EV Identifiable Product Code Map:CTR&Rr2 = Other comparator Map:CTRPv1.0 = SubstanceAdministration.treatmentVehicleCode Map:CTRPv1.0 = Drug.nameCode Map:CTRR = Intervention Name Map:CTRR = Comparator(s) product name(s) Map:CTRR = StudyAgent Map:CTRRr3 = Product.nameCode Map:CTRv1.0 = Material.code Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence (0018,0012) Map:DICOM = Enhanced PET

Attribute	Notes	Constraints and Tags
		Isotope Module - Radiopharmaceutical Information Sequence > Radiopharmaceutical Code Sequence (0054,0304) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Ingredient (0018,1048) Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast/Bolus Ingredient Code Sequence Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Agent (0018,0010) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Agent Sequence (0018,0012) Map:FDA HL7 SD SD DSTU2012 = manufacturedMaterial.code Map:HCTv1.0 = CDE 2739625:Preparative Regimen.What was the type of preparative regimen medication? Map:ICSRr2 = Natural.code (in R_Specimen universal) Map:ICSRr2 = ManufacturedMaterial.code (in R_Specimen universal) Map:ICSRr2 = MaterialKind.code (in R_Product) Map:LabViewer2.2 = SpecimenMaterialType.codeSystemName Map:LabViewer2.2 = SpecimenMaterialType.code Map:LabViewer2.2 = SpecimenMaterialType.codeSystem Map:LabViewer2.2 = SpecimenMaterialType.displayName Map:LabViewer2.2 = SpecimenMaterialType.codeSystemVersion Map:LSDAMv2.2.3Plus = Place.locatorTypeCode Map:LSDAMv2.2.3Plus = Material.nameCode Map:NCI CRF Standard = CDE 2867247v1.0: Agent NCI Enterprise Vocabulary Services Code Map:PGx v1.0 = PF.PFSPEC Map:PGx v1.0 = RELSPEC.SPEC Map:PGx v1.0 = PG.PGSPEC Map:PGx v1.0 = BS.BSSPEC Map:SDTM IGv3.1.1 = EX.EXTRTV Map:SDTM IGv3.1.1 = CM.CMTRT Map:SDTM IGv3.1.2 = CM.CMDECOD Map:SDTM IGv3.1.2 = PC.PCSPEC Map:SDTM IGv3.1.2 = LB.LBSPEC Map:SDTM IGv3.1.2 = EX.EXTRTV

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = MB.MBSPEC Map:SDTM IGv3.1.2 = SU.SUDECOD Map:SDTM IGv3.1.2 = PP.PPSPEC Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = CM.CMDECOD Map:SDTM IGv3.1.3 = CM.CMTRT Map:SDTM IGv3.1.3 = EX.EXTRTV Map:SDTM IGv3.1.3 = SU.SUTRT Map:SDTM IGv3.1.3 = MB.MBSPEC Map:SDTM IGv3.1.3 = LB.LBSPEC Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = MB.MBSPEC Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "COMPTRT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TRT" Map:SDTM IGv3.1.3 = PC.PCSPEC Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TRT" Map:SDTM IGv3.1.3 = SU.SUDECOD Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TRT" Map:SDTM IGv3.1.3 = SU.SUTRT Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "COMPTRT" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "COMPTRT" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "ADDON"

Attribute	Notes	Constraints and Tags
formCode <i>Class:</i> Material <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the state and nature of the material.</p> <p>EXAMPLE(S): solid, liquid, gas, tablet, ointment, gel</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Component.formCode Map:AE = Product.formCode Map:AE = Package.formCode Map:caAERSv2.2 = CourseAgent.formulation Map:CDASHv1.1 = EX.EXDOSFRM Map:CDASHv1.1 = CM.CMDOSFRM Map:CTOM = AgentOccurrence.formCode Map:CTR&Rr2 = IMP Pharmaceutical Form Map:CTR&Rr2 = Placebo Pharmaceutical form Map:CTRPv1.0 = Device.formCode Map:CTRPv1.0 = Cosmetic.formCode Map:CTRPv1.0 = Biologic.formCode Map:CTRPv1.0 = FoodProduct.formCode Map:CTRPv1.0 = Material.formCode Map:CTRPv1.0 = Drug.formCode Map:CTRPv1.0 = Product.formCode Map:CTRPv3.8 = PlannedSubstanceAdministration.doseFormCode Map:CTRRr3 = Material.formCode Map:CTRv1.0 = Material.formCode Map:FDA HL7 SD SD DSTU2012 = manufacturedMaterial.formCode Map:HL7SD = Product.formCode Map:ICSRr2 = Container.formCode (in R_Product) Map:ICSRr2 = Product.formCode (in R_Product) Map:ICSRr2 = PackagedProduct.formCode (in R_Product) Map:LSDAMv2.2.3Plus = Material.formCode Map:NCI CRF Standard = CDE 2179618v1.0: Agent Formulation Descriptive Text Map:SDTM IGv3.1.1 = CM.CMDOSFRM Map:SDTM IGv3.1.1 = EX.EXDOSFRM Map:SDTM IGv3.1.1 = SU.SUDOSFRM Map:SDTM IGv3.1.1 = LB.LBSPEC Map:SDTM IGv3.1.2 = EX.EXDOSFRM Map:SDTM IGv3.1.2 = SU.SUDOSFRM Map:SDTM IGv3.1.2 = CM.CMDOSFRM Map:SDTM IGv3.1.3 = SU.SUDOSFRM Map:SDTM IGv3.1.3 = CM.CMDOSFRM Map:SDTM IGv3.1.3 = EX.EXDOSFRM

Attribute	Notes	Constraints and Tags
description <i>Class:</i> Material <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the material.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = Agent.descriptionText Map:CTGOV = Biospecimen Description Map:CTOM = Agent.descriptionText Map:CTR&Rr2 = AS description Map:CTR&Rr2 = Tissue Engineered differentiated specification Map:CTR&Rr2 = Other comparator specification Map:CTR&Rr2 = Device Other specification Map:CTR&Rr2 = Device description Map:CTR&Rr2 = Tissue Engineered Other specification Map:CTRPv1.0 = FoodProduct.description Map:CTRPv1.0 = Cosmetic.description Map:CTRPv1.0 = Device.description Map:CTRPv1.0 = Biologic.description Map:CTRPv1.0 = Product.description Map:CTRPv1.0 = Drug.description Map:CTRPv1.0 = Material.description Map:CTRPv1.0 = ObservationalStudyProtocol.biospecimenDescription Map:CTR&Rr3 = Material.description Map:CTRv1.0 = Material.description Map:ICSRr2 = DeviceInstance.desc (in R_Product) Map:ICSRr2 = Product.desc (in R_Product) Map:ICSRr2 = Container.desc (in R_Product) Map:ICSRr2 = Substance.desc (in R_Product) Map:ICSRr2 = ProductInstance.desc (in R_Product) Map:ICSRr2 = PackagedProduct.desc (in R_Product) Map:LSDAMv2.2.3Plus = Material.description Map:LSDAMv2.2.3Plus = Container.description

Attribute	Notes	Constraints and Tags
characteristicBehaviorCode <i>Class:</i> Material <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the essential traits of the material that result from the chemical and physical composition and properties of the entity.</p> <p>EXAMPLE(S): kinase, RNase</p> <p>properties of gold might include: good conductor, unaffected by air or moisture, almost insoluble, etc.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Material.functionTypeCode
actualIndicator <i>Class:</i> Material <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Specifies whether the material is a particular instance (actual) vs. universal kind.</p> <p>EXAMPLE(S): To indicate a particular Material, actualIndicator = "true". To indicate a kind of Material, actualIndicator = "false".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Material.actualIndicator Map:HL7SD = R_AssignedEntity(Universal) Map:HL7SD = ExperimentalUnit>ExperimentalUnit2 (choice box).determinerCode Map:ICSRr2 = Product.determinerCode (in R_Product) Map:ICSRr2 = MaterialKind.determinerCode (in R_Product) Map:LSDAMv2.2.3Plus = Material.actualIndicator

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> Material <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the material is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = Agent.statusCode Map:CTRPv1.0 = Drug.statusDateRange Map:CTRPv1.0 = Product.statusDateRange Map:CTRPv1.0 = Drug.statusCode Map:CTRPv1.0 = Product.statusCode Map:CTRPv1.0 = Material.statusCode Map:CTRPv1.0 = FoodProduct.statusDateRange Map:CTRPv1.0 = TherapeuticAgent.StatusCode Map:CTRPv1.0 = Device.statusDateRange Map:CTRPv1.0 = Biologic.statusDateRange Map:CTRPv1.0 = Cosmetic.statusCode Map:CTRPv1.0 = Device.statusCode Map:CTRPv1.0 = Material.statusCode Map:CTRPv1.0 = TherapeuticProduct.statusDateRange Map:CTRPv1.0 = Biologic.statusCode Map:CTRPv1.0 = Cosmetic.statusCode Map:CTRPv1.0 = FoodProduct.statusCode Map:CTRv1.0 = Material.effectiveDateRange Map:ICSRr2 = DeviceInstance.existenceTime (in R_Product) Map:ICSRr2 = ProductInstance.existenceTime (in R_Product) Map:LSDAMv2.2.3Plus = Software.effectiveDateRange Map:LSDAMv2.2.3Plus = Material.effectiveDateRange

Class: MaterialName

Package: Common Sub-Domain

DEFINITION:

The non-unique textual identification of a material in a specified context.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = MaterialName
- Map:ICSRr2 = NamedEntity (in R_Product)
- Map:LSDAMv2.2.3Plus = MaterialName

Connectors

Source	Connector	Target	Notes
MaterialName 1..* namingMaterialName	names	Material 1 namedMaterial	<p>DESCRIPTION: Each MaterialName always names one Material. Each Material always is named by one or more MaterialName.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MaterialName 0..* approvedMaterialName	be approved by	RegulatoryAuthority 0..1 approvingRegulatoryAuthority	<p>DESCRIPTION: Each MaterialName might be approved by one RegulatoryAuthority. Each RegulatoryAuthority might approve one or more MaterialName.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
name <i>Class:</i> MaterialName <i>Datatype:</i> TN <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier for the material.</p> <p>EXAMPLE(S): The therapeutic agent used in a chemotherapy clinical trial.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Product.name Map:AE = Component.name Map:AE = Ingredient.name Map:AE = Package.name Map:AIM v4 rv48 = Equipment.manufacturerModelName Map:caAERSv2.2 = ConcomitantMedication.agentName Map:caAERSv2.2 = MedicalDevice.brandName Map:caAERSv2.2 = Agent.name Map:caAERSv2.2 = MedicalDevice.commonName Map:CDASHv1.1 = SU.SUTRT Map:CDASHv1.1 = EX.EXTRT Map:CDASHv1.1 = CM.CMTRT Map:CTGOV = Other Names Map:CTOM = Agent.name Map:CTR&Rr2 = Device name Map:CTR&Rr2 = IMP Code Map:CTR&Rr2 = AS other descriptive name Map:CTR&Rr2 = AS INN Map:CTR&Rr2 = IMP Trade name Map:CTR&Rr2 = IMP Name Map:CTRPv1.0 = Drug.alternateName Map:CTRPv1.0 = Drug.name Map:CTRPv1.0 = Biologic.name Map:CTRPv1.0 = FoodProduct.alternateName Map:CTRPv1.0 = Device.name Map:CTRPv1.0 = FoodProduct.name Map:CTRPv1.0 = Biologic.alternateName Map:CTRPv1.0 = Material.name Map:CTRPv1.0 = Cosmetic.alternateName Map:CTRPv1.0 = Product.name Map:CTRPv1.0 = Cosmetic.name Map:CTRPv1.0 = Device.alternateName Map:CTRR = Intervention Name Map:CTRR = Comparator(s) product name(s) Map:CTRr3 = Material.name Map:CTRv1.0 = MaterialName.name Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes > Device Observer Model Name Map:DICOM = General Equipment Module - Manufacturer's Model Name (0008,1090) Map:DICOM = Equipment Specification Module - Model Specification Sequence (0018,9912) > Manufacturer's Model Name (0008,1090) Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes > Device Observer Name Map:FDA HL7 SD SD DSTU2012 =

Attribute	Notes	Constraints and Tags
		manufacturedMaterial.name Map:HCTv1.0 = CDE 2775819:Therapies.What was the specific erythropoietin drug administered? Map:HCTv1.0 = CDE 2787579:Therapies.Specify the other in vivo monoclonal antibody administered: Map:HCTv1.0 = CDE 2787667:Therapies.Specify the in vivo immunotoxin administered: Map:HCTv1.0 = CDE 2741578:Drug or Chemical.What anticoagulants were added to the product during collection? Map:HCTv1.0 = CDE 2594484:Pharmacologic Substance.Specify the other agent used after the start of the preparative regimen to prevent acute GVHD or graft rejection Map:HCTv1.0 = CDE 2780779:Therapies.Specify the other additives that are included in volume of infused product Map:HCTv1.0 = CDE 2816469:Disease, Disorder or Finding.Specify the drugs pharmacokinetics were performed on to determine dosing: Map:HCTv1.0 = CDE 2794436:Therapies.Specify the agent types received for infection prophylaxis: Map:HCTv1.0 = CDE 2861458:Therapies.Specify other cytokine: Map:HCTv1.0 = CDE 2787872:Therapies.Specify the blinded randomized trial agent administered: Map:HCTv1.0 = CDE 2775817:Therapies.What was the specific G-CSF drug administered? Map:HCTv1.0 = CDE 2741610:Therapies.Specify the other type of the radiolabeled monoclonal antibody preparative regimen: Map:HCTv1.0 = CDE 2794100:Therapies.Specify the other agent received for infection prophylaxis: Map:HCTv1.0 = CDE 2775844:Therapies.What was the other hematopoietic, lymphoid growth factors, or cytokines administered? Map:HCTv1.0 = CDE 2741515:Therapies.Specify the other type of the monoclonal antibody preparative regimen:

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2816476:Disease, Disorder or Finding.Specify other drug pharmacokinetics performed on to determine dosing: Map:HCTv1.0 = CDE 2960392:Therapies.What was the type of intrathecal chemotherapy given for the preparative regimen? Map:HCTv1.0 = CDE 2746348:Techniques.Specify other CD3 antibody: Map:HCTv1.0 = CDE 2974115:Therapies.Specify the drug used to induce aplastic anemia: Map:HCTv1.0 = CDE 2740983:Therapies.Specify the other type of preparative regimen medication: Map:HCTv1.0 = CDE 2786707:Diagnostic, Therapeutic, and Research Equipment.Specify other cell selection system Map:HCTv1.0 = CDE 2741589:Therapies.Specify the other anticoagulants Map:HCTv1.0 = CDE 2740356:Therapies.What kind of additives are included in volume of infused product? Map:HCTv1.0 = CDE 3057651:Therapies.Specify the other retinoids given: Map:HCTv1.0 = CDE 2958252:Therapies.What type of corticosteroids were administered for the preparative regimen? Map:HCTv1.0 = CDE 2960478:Therapies.What type of nitrosourea compound was administered? Map:HCTv1.0 = CDE 2787876:Therapies.Specify the other agent administered: Map:HCTv1.0 = CDE 2860920:Therapies.Specify the other monoclonal antibody: Map:HCTv1.0 = CDE 3057634:Therapies.Specify the other radioisotope given: Map:HCTv1.0 = CDE 2594466:Pharmacologic Substance.Specify the other in vivo monoclonal antibody used after the start of the preparative regimen to prevent acute GVHD or graft rejection Map:HCTv1.0 = CDE 2775782:Therapies.Type(s) of hematopoietic growth factor or cytokine agents given: Map:HCTv1.0 = CDE </p>

Attribute	Notes	Constraints and Tags
		<p>2960398:Therapies.What was the other drug given for the preparative regimen?</p> <p>Map:HL7SD = Product.name Map:ICSRr2 = MaterialKind.name (in R_Product) Map:ICSRr2 = Product.name (in R_Product) Map:ICSRr2 = Substance.name (in R_Product) Map:ICSRr2 = NamedEntity.name (in R_Product) Map:ICSRr2 = DeviceInstance.manufacturerModelName (in R_Product) Map:ICSRr2 = DeviceInstance.softwareName (in R_Product) Map:ICSRr2 = PackagedProduct.name (in R_Product) Map:LSDAMv2.2.3Plus = Container.name Map:LSDAMv2.2.3Plus = MaterialName.name Map:LSDAMv2.2.3Plus = Place.locatorValue Map:LSDAMv2.2.3Plus = Software.name Map:NCI CRF Standard = CDE 10v4.0: Agent Name Map:NCI CRF Standard = CDE 2179777v2.0: Concomitant Agent Name Map:NCI CRF Standard = CDE 2871652v1.0: Ingredient Name Map:PGx v1.0 = PB.PBDRUG Map:SDTM IGv3.1.1 = CM.CMDECOD Map:SDTM IGv3.1.1 = CM.CMTRT Map:SDTM IGv3.1.1 = SU.SUDECOD Map:SDTM IGv3.1.1 = EX.EXTRT Map:SDTM IGv3.1.1 = SU.SUTRT Map:SDTM IGv3.1.2 = CM.CMTRT Map:SDTM IGv3.1.2 = SU.SUTRT Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=CURTRT Map:SDTM IGv3.1.2 = EX.EXTRT Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "CURRT" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TRT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TRT" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "COMPTRT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "COMPTRT"</p>

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "CURTRT" Map:SDTM IGv3.1.3 = EX.EXTRT Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "CURTRT"
typeCode <i>Class:</i> MaterialName <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the kind of material name. EXAMPLE(S): brand name OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = MedicalDevice.brandName Map:CTRv1.0 = MaterialName.typeCode Map:LSDAMv2.2.3Plus = MaterialName.typeCode

Class: MicrobiologicalCulture

Package: Common Sub-Domain

DEFINITION:

A cell culture obtained from multiplying microbial organisms by letting them reproduce in predetermined culture media under controlled laboratory conditions. [Source NCI-T: Cell Line + Wikipedia]

EXAMPLE(S):

yeast, bacteria, and viral cultures

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = MicrobiologicalCulture

Connectors

Source	Connector	Target	Notes
MicrobiologicalCulture	specializes	CellCulture	DESCRIPTION: Each MicrobiologicalCulture always specializes one CellCulture. Each CellCulture might be specialized by one MicrobiologicalCulture. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: NonResearchProject

Package: Common Sub-Domain

DEFINITION:

A project that does not have a specific hypothesis or discovery objective and typically supports research projects. Supporting projects can be one-time or ongoing operations.

EXAMPLE(S):

Institutional biobanking project that includes running operations such as receiving, processing, quality control, and storage of biospecimens.

Deployment of an enterprise software system, e.g., laboratory information management system, a biorepository that stores biological samples (usually human) for use in research

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:LSDAMv2.2.3Plus = ActivityCollection

Connectors

Source	Connector	Target	Notes
NonResearchProject	specializes	Project	<p>DESCRIPTION: Each NonResearchProject always specializes one Project. Each Project might be specialized by one NonResearchProject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenProcessing	specializes	NonResearchProject	<p>DESCRIPTION: Each SpecimenProcessing always specializes one NonResearchProject. Each NonResearchProject might be specialized by one SpecimenProcessing.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StandardOfCareDataCollection	specializes	NonResearchProject	<p>DESCRIPTION: Each StandardOfCareDataCollection always specializes one NonResearchProject. Each NonResearchProject might be specialized by one StandardOfCareDataCollection.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: NonResearchProjectConduct

Package: Common Sub-Domain

DEFINITION:

An ongoing and/or past performance of a non-research project.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

Connectors

Source	Connector	Target	Notes
NonResearchProjectConduc t	specializes	ProjectConduct	<p>DESCRIPTION:</p> <p>Each NonResearchProjectState always specializes one ProjectState. Each ProjectState might be specialized by one NonResearchProjectState.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: NotificationReceiver

Package: Common Sub-Domain

DEFINITION:

A person or organization that is the target of a notification.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = UserBasedRecipient

- Map:C3PRv2.9 = Recipient
- Map:caAERSv2.2 = Recipient
- Map:caAERSv2.2 = ContactMechanismBasedRecipient
- Map:caAERSv2.2 = RoleBasedRecipient

Connectors

Source	Connector	Target	Notes
NotificationReceiver 0..* receivingNotificationReceiv er	be the receiver of	DefinedNotification 0..1 receivedDefinedNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one DefinedNotification. Each DefinedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiv er	be a function performed by	ReportSubmitter 0..1 performingReportSubmitter	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one ReportSubmitter. Each ReportSubmitter might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* receivingNotificationReceiv er	be the receiver of	PerformedNotification 0..1 receivedPerformedNotificati on	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one PerformedNotification. Each PerformedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiv er	be a function performed by	StudyPersonnel 0..1 performingStudyPersonnel	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one StudyPersonnel. Each StudyPersonnel might</p>

Source	Connector	Target	Notes
			<p>function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one Organization. Each Organization might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	DocumentAuthor 0..1 performingDocumentAuthor	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one DocumentAuthor. Each DocumentAuthor might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
NotificationReceiver 0..* receivingNotificationReceiver	be the receiver of	PlannedNotification 0..1 receivedPlannedNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one PlannedNotification. Each PlannedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	StudySitePersonnel 0..1 performingStudySitePersonnel	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one StudySitePersonnel. Each StudySitePersonnel might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* receivingNotificationReceiver	be the receiver of	ScheduledNotification 0..1 receivedScheduledNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one ScheduledNotification. Each ScheduledNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Organization

Package: Common Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

US National Cancer Institute (NCI); CDISC; HL7, ACME Corporation

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = Organization
- Map:C3PRv2.9 = HealthcareSite
- Map:CTRPv1.0 = Organization
- Map:CTRPv3.8 = OrganizationalGroup
- Map:CTRPv3.8 = Organization
- Map:CTRR = Protocol Identifier Source
- Map:CTRRr3 = Organization
- Map:CTRv1.0 = Organization
- Map:DICOM = Protocol Context Module - Custodial Organization Sequence (0040,A07C)
- Map:HL7SP = Organization
- Map:HL7SP = LicenseIssuer
- Map:ICSRr2 = Organization (in E_Organization informational)
- Map:ICSRr2 = ProductIdentifierIssuer (in R_Product)
- Map:ICSRr2 = Organization (in R_Product)
- Map:ICSRr2 = TerritorialAuthority (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Organization (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Agency (in R_Product)
- Map:LabViewer2.2 = Organization
- Map:LSDAMv2.2.3Plus = Organization

Connectors

Source	Connector	Target	Notes
Organization 0..*	follow	ProcessProtocol 0..* followedProtocol	<p>DESCRIPTION: Each Organization might follow one or more ProcessProtocol. Each ProcessProtocol might be followed by one or more Organization.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): An imaging center may follow a given image acquisition protocol</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CooperativeGroupMember 0..* performedCooperativeGrou pMember	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each CooperativeGroupMember always is a function performed by one Organization. Each Organization might function as one or more CooperativeGroupMember.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each Performer might be a function performed by one Organization. Each Organization might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Laboratory 0..1 performedLaboratory	be a function performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each Laboratory might be a function performed by one Organization. Each Organization might function as one Laboratory. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DonorRegistry 0..* managedDonorRegistry	is managed by	Organization 1 managingOrganization	DESCRIPTION: Each DonorRegistry always is managed by one Organization. Each Organization might manage one or more DonorRegistry. DEFINITION: Indicates the organization that manages the registry. EXAMPLE(S): OTHER NAME(S): NOTE(S):
SystemOfRecord 0..* managedSystemOfRecord	be managed by	Organization 0..1 managingOrganization	DESCRIPTION: Each SystemOfRecord might be managed by one Organization. Each Organization might manage one or more SystemOfRecord. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
Device 0..* locatedDevice	be located at	Organization 0..1 locatingOrganization	DESCRIPTION: Each Device might be located at one Organization. Each Organization might be the location for one or more Device. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
HealthcareFacility 0..1 performedHealthcareFacility	is a function performed by	Organization 1 performingOrganization	DESCRIPTION: Each HealthcareFacility always is a function performed by one Organization. Each Organization might function as one HealthcareFacility. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ImagingCenter 0..1 performedImagingCenter	is played by	Organization 1 performingOrganization	DESCRIPTION: Each ImagingCenter always is played by one Organization. Each Organization might play one ImagingCenter. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ResearchOrganization 0..1 performedResearchOrganization	is a function performed by	Organization 1 performingOrganization	DESCRIPTION: Each ResearchOrganization always is a function performed by one Organization. Each Organization might function as one ResearchOrganization.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Distributor 0..1 performedDistributor	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION:</p> <p>Each Distributor always is a function performed by one Organization. Each Organization might function as one Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportReceiver 0..* performedReportReceiver	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION:</p> <p>Each ReportReceiver might be a function performed by one Organization. Each Organization might function as one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CooperativeGroup 0..1 performedCooperativeGroup	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION:</p> <p>Each CooperativeGroup always is a function performed by one Organization. Each Organization might function as one CooperativeGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
QualifiedPerson 0..* credentialedQualifiedPerson	is credentialed by	Organization 1 credentialingOrganization	<p>DESCRIPTION:</p> <p>Each QualifiedPerson always is credentialed by one Organization. Each Organization might credential one or more</p>

Source	Connector	Target	Notes
			QualifiedPerson. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
CooperativeGroup 0..* credentialedCooperativeGro up	is credentialed by	Organization 1 credentialingOrganization	DESCRIPTION: Each CooperativeGroup always is credentialed by one Organization. Each Organization might credential one or more CooperativeGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySite 0..* performedStudySite	be a function performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each StudySite might be a function performed by one Organization. Each Organization might function as one or more StudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PointOfContact 0..* supportingPointOfContact	handle communication for	Organization 0..1 supportedOrganization	DESCRIPTION: Each PointOfContact might handle communication for one Organization. Each Organization might have communications handled by one or more PointOfContact. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
HealthcareProviderGroup 0..1 performedHealthcareProvid	is a function performed by	Organization 1 performingOrganization	DESCRIPTION: Each HealthcareProviderGroup

Source	Connector	Target	Notes
erGroup			<p>always is a function performed by one Organization. Each Organization might function as one HealthcareProviderGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RegulatoryApplicationSponsor 0..* performedRegulatoryApplicationSponsor	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each RegulatoryApplicationSponsor might be a function performed by one Organization. Each Organization might function as one or more RegulatoryApplicationSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* performedPointOfContact	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each PointOfContact might be a function performed by one Organization. Each Organization might function as one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyLegalSponsor 0..* performedStudyLegalSponsor	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each StudyLegalSponsor might be a function performed by one Organization. Each Organization might function as one or more StudyLegalSponsor.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
OversightAuthority 0..1 performedOversightAuthorit y	is a function performed by	Organization 1 performingOrganization	DESCRIPTION: Each OversightAuthority always is a function performed by one Organization. Each Organization might function as one OversightAuthority. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
BiologicEntity 0..* caredForBiologicEntity	have decisions made by	Organization 0..1 responsibleOrganization	DESCRIPTION: Each BiologicEntity might have decisions made by one Organization. Each Organization might have decision making authority on behalf of one or more BiologicEntity. DEFINITION: The link between a person or animal and the organization who has decision making authority for them. EXAMPLE(S): In non-human primate research, such as at UC Davis Primate Center, the Center is responsible for the health and well-being of the primates, irrespective of the research. OTHER NAME(S): NOTE(S):
ResourceProvider 0..1 performedResourceProvider	be a function performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each ResourceProvider might be a function performed by one Organization. Each Organization might function as one ResourceProvider. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
OrganizationRelationship 0..* sourceOrganizationRelationship	has as target	Organization 1 targetOrganization	DESCRIPTION: Each OrganizationRelationship always has as target one Organization. Each Organization might be the target for one or more OrganizationRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
OrganizationStaff 0..* staffingOrganizationStaff	staff	Organization 0..1 staffedOrganization	DESCRIPTION: Each OrganizationStaff might staff one Organization. Each Organization might be staffed by one or more OrganizationStaff. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
HealthcareProvider 0..* employedHealthcareProvider	belong to a department at	Organization 0..1 employingOrganization	DESCRIPTION: Each HealthcareProvider might belong to a department at one Organization. Each Organization might be the department for one or more HealthcareProvider. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
OrganizationRelationship 0..* targetOrganizationRelationship	has as source	Organization 1 sourceOrganization	DESCRIPTION: Each OrganizationRelationship always has as source one Organization. Each

Source	Connector	Target	Notes
			<p>Organization might be the source for one or more OrganizationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ServiceDeliveryLocation 0..* locatingServiceDeliveryLoca tion	be delivery location for	Organization 0..1 locatedOrganization	<p>DESCRIPTION: Each ServiceDeliveryLocation might be delivery location for one Organization. Each Organization might receive delivery at one or more ServiceDeliveryLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ImagingProcessProtocol 0..* maintainedImagingProcessP rotocol	be maintained by	Organization 0..1 maintainingOrganization	<p>DESCRIPTION: Each ImagingProcessProtocol might be maintained by one Organization. Each Organization might maintain one or more ImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyRegistry 0..* managedStudyRegistry	be managed by	Organization 0..1 managingOrganization	<p>DESCRIPTION: Each StudyRegistry might be managed by one Organization. Each Organization might manage one or more StudyRegistry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
Subject 0..* performedSubject	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each Subject might be a function performed by one Organization. Each Organization might function as one or more Subject.</p> <p>DEFINITION: Indicates that the Organization is participating as the subject of an activity.</p> <p>EXAMPLE(S): Audit</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one Organization. Each Organization might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyCountry 0..* performedStudyCountry	is a function performed by	Organization 1..* performingOrganization	<p>DESCRIPTION: Each StudyCountry always is a function performed by one or more Organization. Each Organization might function as one or more StudyCountry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Processor 0..* performedProcessor	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each Processor always is a function performed by one Organization. Each Organization might function as one or more Processor.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedStudySite 0..* performedPlannedStudySite	be a function planned to be performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each PlannedStudySite might be a function planned to be performed by one Organization. Each Organization might plan to function as one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Organization <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the organization.</p> <p>EXAMPLE(S): 03008 is the U.S. National Cancer Institute Cancer Therapy Evaluation Program (CTEP) ID for Sacred Heart Hospice in Darlinghurst, New South Wales, Australia</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = OrganizationAssignedIdentifier Map:C3PR = Organization.nciInstituteCode Map:C3PRv2.9 = Identifier.value Map:caAERSv2.2 = Organization.nciInstituteCode Map:CTOM = Protocol.monitorCode Map:CTR&Rr2 = EV Sender ID Map:CTRv1.0 = Organization.identifier Map:CTRv3.8 = StudyResourcing.organizationIdentifier Map:CTRv3.8 = IdentifiedEntity.assignedIdentifier Map:CTRv3.8 = Organization.identifier Map:CTRRr3 = Organization.identifier Map:CTRv1.0 = OrganizationIdentifier.identifier Map:DICOM = Patient Module - Issuer of Patient ID (0010,0021) Map:DICOM = Patient Module - Other Patient IDs Sequence > Issuer of Patient ID (0010,0021) Map:DICOM = Protocol Context Module - Custodial Organization Sequence (0040,A07C) > Institution Code Sequence (0008,0082) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Issuer of Patient ID (0010,0021) Map:FDA HL7 SD SD DSTU2012 = representedOrganization.id Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization.id Map:FDA HL7 SD SD DSTU2012 = StudyProtocol//plannedStudy/location/serviceDeliveryLocation.id Map:HCTv1.0 = CDE 3115737:Medical Records and Forms.If necessary, please validate the patient and clinic and hospital ID response. Map:HCTv1.0 = CDE 3115632:Medical Records and Forms.Clinic and Hospital ID: Map:HCTv1.0 = CDE 2688251:Data Source.EBMT Code (CIC) Number Map:HCTv1.0 = CDE 2527895:Individuals.Hematopoietic Stem Cell Transplantation Recipient CIBMTR Center Number: Map:HCTv1.0 = CDE 3126035:Medical Records and Forms.European Group for Blood And Marrow Transplantation Center Number:

Attribute	Notes	Constraints and Tags
		Map:HL7SP = EthicalCommittee.id Map:HL7SP = Organization.id Map:HSDBV1.0 = [Sponsor].Federal employer ID no Map:HSDBV1.0 = [Sponsor].IORG number Map:HSDBV1.0 = [Summary 4 Funder].IORG number Map:HSDBV1.0 = [Lead Organization].IORG number Map:ICSR2 = TerritorialAuthority.id (in IndividualCaseSafetyReport) Map:ICSR2 = ProductIdentifierIssuer.id (in R_Product) Map:ICSR2 = Agency.id (in R_Product) Map:ICSR2 = IdentifiedEntity2.id (in IndividualCaseSafetyReport) Map:ICSR2 = Organization.id (in R_Product) Map:Lab = Organization.identifier Map:LabViewer2.2 = HealthcareSite.identifier Map:LabViewer2.2 = Organization.identifier Map:PGx v1.0 = BE.BEPARTYID

Attribute	Notes	Constraints and Tags
name <i>Class:</i> Organization <i>Datatype:</i> DSET<ON> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A non-unique textual identifier for the organization.</p> <p>EXAMPLE(S): St. Marys Hospital; US National Cancer Institute (NCI); CDISC; HL7, ACME Corporation, Eastern Cooperative Oncology Group</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Reporter.organizationDepartment Map:AE = Authorization.authorizationHolder Map:AE = Authorization.responsibleAuthority Map:AE = Receiver.organizationDepartment Map:AIM v4 rv48 = Equipment.manufacturerName Map:C3PR = Study.SponsorCode Map:C3PR = InvestigatorGroup.name Map:C3PR = HealthCareSite.name Map:C3PR = Organization.name Map:C3PRv2.9 = InvestigatorGroup.name Map:C3PRv2.9 = Organization.name Map:caAERSv2.2 = MedicalDevice.manufacturerName Map:caAERSv2.2 = MedicalDevice.reprocessorName Map:caAERSv2.2 = Organization.name Map:caAERSv2.2 = Recipient.name Map:CDASHv1.1 = LB.LBNAM Map:CTGOV = Overall Study Officials - Organizational Affiliation Map:CTGOV = IND/IDE Grantor Map:CTGOV = Sponsor Map:CTGOV = Oversight Authorities Map:CTGOV = Board Affiliation Map:CTGOV = Board Name Map:CTGOV = Collaborators Map:CTGOV = Responsible Party - Organization Map:CTGOV = Facility - Name Map:CTOM = Organization.name Map:CTOM = HealthcareSite.name Map:CTR&Rr2 = Source of Monetary or Material Support organisation name Map:CTR&Rr2 = Legal Rep Organisation Map:CTR&Rr2 = Investigator Institution Department Map:CTR&Rr2 = NCA Organisation Map:CTR&Rr2 = Sponsor Organisation Map:CTR&Rr2 = Investigator Institution Name Map:CTR&Rr2 = Network Organisation Map:CTR&Rr2 = CTF Department Map:CTR&Rr2 = Subcontractor Department Name Map:CTR&Rr2 = EV Sender ID organisation Map:CTR&Rr2 = IEC Applicant Organisation Map:CTR&Rr2 = CA Applicant Organisation Map:CTR&Rr2 = IEC Organisation

Attribute	Notes	Constraints and Tags
		Map:CTR&Rr2 = Further information contact Organisation Map:CTR&Rr2 = CTF Organisation Map:CTR&Rr2 = Responsible Site Organisation Map:CTR&Rr2 = Subcontractor Organisation Name Map:CTR&Rr2 = Application NCA (National Competent Authority) Map:CTR&Rr2 = MA Holder Map:CTRPv1.0 = Organization.abbreviatedName Map:CTRPv1.0 = Organization.name Map:CTRPv3.8 = Organization.name Map:CTRPv3.8 = StudySite.reviewBoardOrganizationalAffiliation Map:CTRPv3.8 = HealthCareFacility.name Map:CTRPv3.8 = ResearchOrganization.name Map:CTRPv3.8 = StudyIndIde.nciDivProgHolderCode Map:CTRPv3.8 = StudyIndIde.grantorCode Map:CTRPv3.8 = OrganizationalGroup.name Map:CTRPv3.8 = RegulatoryAuthority.name Map:CTRPv3.8 = StudyIndIde.nihInstholderCode Map:CTRR = Oversight Authority Map:CTRR = Trial Site Map:CTRR = Data Monitoring Committee Map:CTRR = IRB Affiliation Map:CTRR = Secondary Sponsor Map:CTRR = Regulatory Investigational Product Application Identifier Source Map:CTRR = Financial Sponsor Map:CTRR = IRB Organization Map:CTRR = Sponsor Map:CTRRr3 = Organization.name Map:CTRRr3 = StudyColleague.affiliatedOrganization Map:CTRv1.0 = Organization.name Map:DICOM = Clinical Trial Subject Module - Clinical Trial Site Name (0012,0031) Map:DICOM = Protocol Context Module - Custodial Organization Sequence (0040,A07C) > Institution Name (0008,0080) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Sponsor Name (0012,0010) Map:DICOM = Patient Module - Responsible Organization (0010,2299) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Protocol

Attribute	Notes	Constraints and Tags
		<p>Ethics Committee Name (0012,0081) Map:DICOM = General Equipment Module - Manufacturer (0008,0070) Map:DICOM = TID 1004 DeviceObserverIdentifyingAttributes > Device Observer Manufacturer Map:DICOM = General Equipment Module - Institutional Department Name (0008,1040) Map:DICOM = TID 1003 PersonObserverIdentifyingAttributes > Person Observer's Organization Name Map:DICOM = Equipment Specification Module - Model Specification Sequence (0018,9912) > Manufacturer (0008,0070) Map:DICOM = General Equipment Module - Institution Name (0008,0080) Map:DICOM = Clinical Trial Context Module - Clinical Trial Sponsor Name (0012,0010) Map:DICOM = Clinical Trial Context Module - Clinical Trial Site Name (0012,0031) Map:DICOM = Clinical Trial Context Module - Clinical Trial Protocol Ethics Committee Name (0012,0081) Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization.name Map:FDA HL7 SD SD DSTU2012 = representedOrganization.name Map:HCTv1.0 = CDE 2786700:Techniques.Which cell selection system was used to manipulated the product? Map:HCTv1.0 = CDE 2770870:Research Organizations.Specify the name of the institution that performed the subsequent HSCT: Map:HCTv1.0 = CDE 2682159:DONOR'.Registry or UCB Bank: Map:HCTv1.0 = CDE 2693488:Property or Attribute.Specify the organization that assigned the universal recipient ID: Map:HCTv1.0 = MD Anderson Specific Content: Product.Source of Product Map:HCTv1.0 = CDE 2771539:Research Organizations.What was the name of the institution that performed the DCI: Map:HCTv1.0 = CDE 2684895:DONOR'.Specify other Registry or UCB Bank: Map:HCTv1.0 = CDE 2693479:Recipient Identification.ID Assigned By:</p>

Attribute	Notes	Constraints and Tags
		<p>Specify the Organization that assigned the universal recipient ID Map:HCTv1.0 = CDE 2688301:Techniques.Transplant Hospital Unit Name Map:HCTv1.0 = CDE 3158520:Protocol Administration.Specify the other group that is administering the clinical trial: Map:HCTv1.0 = CDE 2688299:Techniques.Transplant Hospital Name Map:HCTv1.0 = CDE 2150//C:Protocol Administration.Coordinating Group Map:HCTv1.0 = CDE 2532036:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.If the institution where previous HSCT was performed is different from the current HSCT, what is the name of the institution? Map:HCTv1.0 = CDE 2691464:Techniques.Specify the transplant hospital unit name: Map:HCTv1.0 = CDE 2951981:Lab Results.Laboratory Procedure Source Map:HL7SP = EthicalCommittee.name Map:HL7SP = Organization.name Map:HSDBv1.0 = [Lead Organization].Name Map:HSDBv1.0 = [IRB].IRB of record Map:HSDBv1.0 = [Summary 4 Funder].Organization Name Map:HSDBv1.0 = [IND/IDE] .Holder Type Map:HSDBv1.0 = [Sponsor].Organization Name Map:HSDBv1.0 = [IND/IDE] .NIH Institution Map:HSDBv1.0 = [Study].Responsible Party Map:ICSRr2 = ProductIdentifierIssuer.name (in R_Product) Map:ICSRr2 = Organization.name (in IndividualCaseSafetyReport) Map:ICSRr2 = Organization.name (in R_Product) Map:ICSRr2 = Agency.name (in R_Product) Map:Lab = CentralLaboratory.name Map:Lab = PerformingLaboratory.name Map:Lab = HealthCareSite.name Map:Lab = Organization.name Map:LabViewer2.2 = PerformingLaboratory.name</p>

Attribute	Notes	Constraints and Tags
		Map:LabViewer2.2 = Identifier.assigningAuthorityName Map:LabViewer2.2 = HealthcareSite.name Map:LabViewer2.2 = CentralLaboratory.name Map:LabViewer2.2 = Organization.name Map:LSDAMv2.2.3Plus = Organization.name Map:NCI CRF Standard = CDE 2551737v1.0: Registration Name Institution Institution Name Map:NCI CRF Standard = CDE 2841282v1.0: Performing Laboratory Name Text Map:PGx v1.0 = SB.SBNAM Map:PGx v1.0 = PF.PFNAM Map:PGx v1.0 = PG.PGNAM Map:PGx v1.0 = BS.BSNAM Map:PGx v1.0 = BE.BEPARTY Map:PSC = Site.name Map:PSCv2.6 = Site.name Map:SDTM IGv3.1.1 = LB.LBNAM Map:SDTM IGv3.1.1 = EG.EGNAM Map:SDTM IGv3.1.2 = MS.MSNAM Map:SDTM IGv3.1.2 = LB.LBNAM Map:SDTM IGv3.1.2 = EG.EGNAM Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=SPONSOR Map:SDTM IGv3.1.2 = PC.PCNAM Map:SDTM IGv3.1.2 = MB.MBNAM Map:SDTM IGv3.1.3 = PC.PCNAM Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SPONSOR" Map:SDTM IGv3.1.3 = TR.TRNAM Map:SDTM IGv3.1.3 = EG.EGNAM Map:SDTM IGv3.1.3 = LB.LBNAM Map:SDTM IGv3.1.3 = MB.MBNAM Map:SDTM IGv3.1.3 = TU.TUNAM Map:SDTM IGv3.1.3 = MS.MSNAM Map:SDTM IGv3.1.3 = RS.RSNAM Map:WHO = Primary Sponsor Map:WHO = Secondary Sponsor(s) Map:WHO = Source(s) of Monetary or Material Support Map:WHO = Contact for Public Queries - affiliation

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> Organization <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of organization.</p> <p>EXAMPLE(S): academic, pharmaceutical industry, government, other commercial, non-commercial [example from EudraCT]</p> <p>consortium (an organization composed of other organizations that collaborate on a common goal, such as The Cancer Genome Atlas (TCGA))</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTR&Rr2 = Sponsor Status Map:CTRPv3.8 = StudyIndIde.holderTypeCode Map:CTRR = Sponsor Organization Type Map:CTRv1.0 = Organization.typeCode Map:FDA HL7 SD SD DSTU2012 = serviceDeliveryLocation/serviceProviderOrganizationKind.code Map:HSDBv1.0 = [IND/IDE] .Holder Type Map:LSDAMv2.2.3Plus = Organization.typeCode Map:PRM = Sponsor Organization Type Map:SDTM IGv3.1.3 = TU.TUEVAL Map:SDTM IGv3.1.3 = TR.TREVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = FA.FAEVAL Map:SDTM IGv3.1.3 = EG.EGEVAL
description <i>Class:</i> Organization <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the organization.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = InvestigatorGroup.descriptionText Map:C3PR = Organization.descriptionText Map:C3PRv2.9 = InvestigatorGroup.descriptionText Map:C3PRv2.9 = Organization.descriptionText Map:caAERSv2.2 = Organization.descriptionText Map:CTOM = Organization.descriptionText Map:CTOM = HealthcareSite.descriptionText Map:CTRPv1.0 = Organization.description Map:CTRv1.0 = Organization.description Map:LSDAMv2.2.3Plus = Organization.description

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> Organization <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A contact point used to send physical forms of communication to the organization.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Address.cityCode Map:C3PR = Address.countryCode Map:C3PR = Address.postalCode Map:C3PR = Address.streetAddress Map:C3PR = Address.stateCode Map:C3PRv2.9 = Address Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:CTGOV = Facility - Country Map:CTGOV = Facility - Postal Code Map:CTGOV = Facility - City Map:CTGOV = Facility - State/Province Map:CTOM = Organization.city Map:CTOM = Organization.stateCode Map:CTOM = Organization.countryCode Map:CTOM = Organization.postalCode Map:CTR&Rr2 = IEC Street Address Map:CTR&Rr2 = Responsible Site Street Address Map:CTR&Rr2 = IEC Post Code Map:CTR&Rr2 = IEC Town/City Map:CTR&Rr2 = NCA Town/City Map:CTR&Rr2 = Source of Monetary or Material Support country Map:CTR&Rr2 = Application MS (member state) Map:CTR&Rr2 = Responsible Site Country Map:CTR&Rr2 = NCA Post Code Map:CTR&Rr2 = Responsible Site Town/City Map:CTR&Rr2 = IEC Country Map:CTR&Rr2 = NCA Country Map:CTR&Rr2 = NCA Street Address Map:CTR&Rr2 = Responsible Site Post Code Map:CTRPv1.0 = Organization.postalAddress Map:CTRPv3.8 = ResearchOrganization.postalAddress Map:CTRPv3.8 = Organization.postalAddress Map:CTRr3 = Organization.postalAddress Map:CTRv1.0 = Organization.postalAddress Map:DICOM = General Equipment Module - Institution Address (0008,0081) Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization.addr Map:FDA HL7 SD SD DSTU2012 = representedOrganization.addr Map:HCTv1.0 = CDE 2684981:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.If the institution where previous HSCT was

Attribute	Notes	Constraints and Tags
		<p>performed is different from the current HSCT, what is the country where the institution is located?</p> <p>Map:HCTv1.0 = CDE 2532039:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.If the institution where previous HSCT was performed is different from the current HSCT, what is the city where the institution is located?</p> <p>Map:HCTv1.0 = CDE 2686045:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.If the institution where previous HSCT was performed is different from the current HSCT, what is the state where the institution is located?</p> <p>Map:HL7SP = EthicalCommittee.addr Map:HL7SP = Organization.addr Map:HSDBv1.0 = [Summary 4 Funder].State/Province Map:HSDBv1.0 = [Summary 4 Funder].City Map:HSDBv1.0 = [Lead Organization]. State/Province Map:HSDBv1.0 = [Summary 4 Funder].Country Map:HSDBv1.0 = [Lead Organization]. City Map:HSDBv1.0 = [Lead Organization].Street Address Map:HSDBv1.0 = [Sponsor].Country Map:HSDBv1.0 = [Sponsor].Zip/Postal code Map:HSDBv1.0 = [Sponsor].Street Address Map:HSDBv1.0 = [Sponsor].State/Province Map:HSDBv1.0 = [Summary 4 Funder].Zip/Postal code Map:HSDBv1.0 = [Summary 4 Funder].Street Address Map:HSDBv1.0 = [Lead Organization]. Zip/Postal code Map:HSDBv1.0 = [Sponsor].City Map:HSDBv1.0 = [Lead Organization].Country Map:ICSRr2 = Organization.addr (in R_Product) Map:ICSRr2 = Organization.addr (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Organization.postalAddress Map:SDTM IGv3.1.1 = DM.COUNTRY Map:SDTM IGv3.1.2 = DM.COUNTRY Map:SDTM IGv3.1.3 = DM.COUNTRY </p>

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> Organization <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the organization.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:C3PRv2.9 = ContactMechanism.type Map:C3PRv2.9 = ContactMechanismBasedRecipient Map:C3PRv2.9 = ContactMechanism.value Map:caAERSv2.2 = ReportVersion.email Map:caAERSv2.2 = ReportDelivery.address Map:caAERSv2.2 = ScheduledEmailNotification.to Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:CTOM = HealthcareSite.telecomAddress Map:CTOM = Organization.telecomAddress Map:CTRPv1.0 = Organization.telecomAddress Map:CTRPv3.8 = Organization.telecomAddress Map:CTRPv3.8 = ResearchOrganization.telecomAddress Map:CTRr3 = Organization.telecomAddress Map:CTRv1.0 = Organization.telecomAddress Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization.telecom Map:FDA HL7 SD SD DSTU2012 = representedOrganization.telecom Map:HL7SP = EthicalCommittee.telecom Map:HSDBv1.0 = [Lead Organization].TTY Map:HSDBv1.0 = [Summary 4 Funder].Phone Map:HSDBv1.0 = [Sponsor].TTY Map:HSDBv1.0 = [Sponsor].Phone Map:HSDBv1.0 = [Summary 4 Funder].TTY Map:HSDBv1.0 = [Sponsor].URL Map:HSDBv1.0 = [Sponsor].FAX Map:HSDBv1.0 = [Lead Organization].Phone Map:HSDBv1.0 = [Lead Organization].Email Address Map:HSDBv1.0 = [Summary 4 Funder].URL Map:HSDBv1.0 = [Lead Organization].URL Map:HSDBv1.0 = [Summary 4 Funder].FAX Map:HSDBv1.0 = [Lead Organization].FAX Map:HSDBv1.0 = [Sponsor].Email Address Map:HSDBv1.0 = [Summary 4 Funder].Email Address

Attribute	Notes	Constraints and Tags
		Map:ICSRr2 = Organization.telecom (in R_Product) Map:ICSRr2 = Organization.telecom (in IndividualCaseSafetyReport) Map:Lab = HealthcareSite.telecomAddress Map:LSDAMv2.2.3Plus = Organization.telecomAddress
actualIndicator <i>Class:</i> Organization <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1...1	DEFINITION: Specifies whether the organization is a particular instance (actual) vs. universal kind. EXAMPLE(S): To indicate a particular Organization, actualIndicator = "true". To indicate a kind of Organization, actualIndicator = "false". OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Organization.actualIndicator Map:HL7SD = R_AssignedEntity(Universal) Map:HL7SP = R_AssignedEntity(Universal)_COCT_ RM_090000UV Map:ICSRr2 = Organization.determinerCode (in IndividualCaseSafetyReport) Map:ICSRr2 = Organization.determinerCode (in R_Product) Map:LSDAMv2.2.3Plus = Organization.actualIndicator
effectiveDateRange <i>Class:</i> Organization <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0...1	DEFINITION: The date (and time) span for when the organization is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv3.8 = OrganizationalGroup.effectiveDateRa nge

Class: OrganizationRelationship

Package: Common Sub-Domain

DEFINITION:

Specifies the link between one organization and another.

EXAMPLE(S):

The relationship between an organization and its legal representative, the whole/part relationship between an organization and its sub organizations (e.g. departments, divisions).

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = OrganizationalGroupRelationship
- Map:CTRPv3.8 = OrganizationalRelationship
- Map:CTRr3 = OrganizationRelationship
- Map:CTRv1.0 = OrganizationRelationship
- Map:HL7SD = E_Organization(Universal)
- Map:ICSRr2 = AssignedEntity (in R_Product)
- Map:ICSRr2 = AssignedEntity3 (in R_Product)
- Map:ICSRr2 = AssignedEntity2 (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = OrganizationRelationship

Connectors

Source	Connector	Target	Notes
OrganizationRelationship 0..* sourceOrganizationRelationship	has as target	Organization 1 targetOrganization	<p>DESCRIPTION: Each OrganizationRelationship always has as target one Organization. Each Organization might be the target for one or more OrganizationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OrganizationRelationship 0..* targetOrganizationRelationship	has as source	Organization 1 sourceOrganization	<p>DESCRIPTION: Each OrganizationRelationship always has as source one Organization. Each Organization might be the source for one or more OrganizationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> OrganizationRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of organization relationship.</p> <p>EXAMPLE(S): part, department, center, legal representative</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is HL7 structured vocabulary and is part of a controlled vocabulary set.</p>	Map:CTR&Rr2 = IEC (Independent Ethics Committee) Applicant Type Map:CTRPv3.8 = OrganizationalGroupRelationship.typeCode Map:CTRPv3.8 = OrganizationRelationship.typeCode Map:CTRRr3 = OrganizationRelationship.typeCode Map:CTRv1.0 = OrganizationRelationship.typeCode Map:HL7SP = E_Organization(Universal)_COCT_RM_150000UV Map:ICSRr2 = AssignedEntity3.code (in R_Product) Map:ICSRr2 = AssignedEntity.code (in R_Product) Map:LSDAMv2.2.3Plus = OrganizationRelationship.typeCode

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> OrganizationRelationship <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the organization relationship is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv3.8 = OrganizationRelationship.effectiveDateRange Map:CTRPv3.8 = OrganizationRelationship.effectiveDateRange Map:CTRv1.0 = OrganizationRelationship.effectiveDateRange Map:HL7SP = E_Organization(Universal)_COCT_RM_150000UV Map:LSDAMv2.2.3Plus = OrganizationRelationship.effectiveDateRange

Class: OrganizationStaff

Package: Common Sub-Domain

DEFINITION:

An individual who is employed and/or involved in any aspect of conduct of an organization's business.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Vendor1v1.1 = StaffMember

Connectors

Source	Connector	Target	Notes
OrganizationStaff 0..* staffingOrganizationStaff	staff	Organization 0..1 staffedOrganization	<p>DESCRIPTION: Each OrganizationStaff might staff one Organization. Each Organization might be staffed by one or more OrganizationStaff.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OrganizationStaff 0..* performedOrganizationStaff	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each OrganizationStaff might be a function performed by one Person. Each Person might function as one or more OrganizationStaff.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
OrganizationStaffRole 0..* performedOrganizationStaffRole	is a function performed by	OrganizationStaff 1 performingOrganizationStaff	DESCRIPTION: Each OrganizationStaffRole always is a function performed by one OrganizationStaff. Each OrganizationStaff might function as one or more OrganizationStaffRole. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> OrganizationStaff <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	DEFINITION: The unique identification of a staff member in the context of working for an organization. EXAMPLE(S): Organization staff number 7 OTHER NAME(S): NOTE(S): This identifier is valid as long as the staff works for the organization.	Map:C3PRv2.9 = ResearchStaff.assignedIdentifier Map:caAERSv2.2 = ResearchStaff.nciIdentifier Map:CTRv1.0 = ResearchStaff.identifier Map:Vendor1v1.1 = StaffMember

Class: OrganizationStaffRole

Package: Common Sub-Domain

DEFINITION:

A function performed by an individual on behalf of an organization who is employing them.

EXAMPLE(S):

Grants Manager, Project Assistant, Visit Report Reviewer

OTHER NAME(S):

NOTE(S):

Note that a function is not the same as a job title; a person may perform multiple different roles simultaneously and the function may not have an obvious relation to their job title.

Tagged Values:

- Map:Vendor1v1.1 = StaffMember

Connectors

Source	Connector	Target	Notes
OrganizationStaffRole 0..* performedOrganizationStaffRole	is a function performed by	OrganizationStaff 1 performingOrganizationStaff	<p>DESCRIPTION: Each OrganizationStaffRole always is a function performed by one OrganizationStaff. Each OrganizationStaff might function as one or more OrganizationStaffRole.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StaffInterest 0..* ofInterestStaffInterest	be an interest of	OrganizationStaffRole 0..1 interestedOrganizationStaffRole	<p>DESCRIPTION: Each StaffInterest might be an interest of one OrganizationStaffRole. Each OrganizationStaffRole might have interest in one or more StaffInterest.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ResearchStaff	specializes	OrganizationStaffRole	<p>DESCRIPTION: Each ResearchStaff always specializes one OrganizationStaffRole. Each OrganizationStaffRole might be specialized by one ResearchStaff.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	OrganizationStaffRole 0..1 performingOrganizationStaffRole	<p>DESCRIPTION: Each Performer might be a function performed by one OrganizationStaffRole. Each OrganizationStaffRole might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A unique symbol that establishes identity of a staff member working in a particular role.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This identifier is valid as long as the staff works in the particular role.</p>	Map:C3PRv2.9 = ResearchStaff.assignedIdentifier Map:caAERSv2.2 = ResearchStaff.nciIdentifier Map:CTRv1.0 = ResearchStaff.identifier Map:Vendor1v1.1 = StaffMember
roleCode <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the type of responsibility the organization staff performs in this context.</p> <p>EXAMPLE(S): Clinical Research Associate, Data Manager, Laboratory technician</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	fixed = "Staff - 3rd Party" Map:CTGOV = Board Contact Map:CTRPv1.0 = OrganizationalContact.typeCode Map:CTRPv3.8 = OrganizationalContact.typeCode Map:CTRRr3 = OrganizationalContact.typeCode Map:CTRv1.0 = OrganizationalContact.typeCode Map:Vendor1v1.1 = StaffMember.roleCode
title <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A local text name for the organization staff in this context.</p> <p>EXAMPLE(S): Head of Cardiology, Department Chair (Cardiology)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is distinct from the roleCode, which is a standardized way of representing the function of the organization staff in the context of the organization. This local name may vary greatly from organization to organization. This is typically what is printed on a business card.</p>	Map:caAERSv2.2 = Person.title Map:CTRRr3 = StudyColleague.officialTitle Map:CTRv1.0 = ResearchStaff.jobTitle Map:SDTM IGv3.1.3 = TU.TUEVAL Map:SDTM IGv3.1.3 = TR.TREVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = PE.PEEVAL Map:SDTM IGv3.1.3 = FA.FAEVAL Map:SDTM IGv3.1.3 = EG.EGEVAL Map:Vendor1v1.1 = StaffMember.title

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A contact point used to send physical forms of communication to the organization staff.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = Address.country > ResearchStaff Map:caAERSv2.2 = Address.state > ResearchStaff Map:caAERSv2.2 = Address.street > ResearchStaff Map:caAERSv2.2 = Address.zip > ResearchStaff Map:caAERSv2.2 = Address.city > ResearchStaff Map:CTRPv1.0 = ClinicalResearchStaff.postalAddress Map:CTRv1.0 = ResearchStaff.postalAddress Map:ICSRr2 = AssignedEntity.addr (in IndividualCaseSafetyReport) Map:Vendor1v1.1 = StaffMember.postalAddress
telecomAddress <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the organization staff.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:C3PRv2.9 = SiteResearchStaff.phoneNumber Map:caAERSv2.2 = ResearchStaff.faxNumber Map:caAERSv2.2 = ResearchStaff.phoneNumber Map:caAERSv2.2 = PersonContact.ReportPerson.Reporter.contactMechanisms Map:caAERSv2.2 = PersonContact.ReportPerson.Submitter.contactMechanisms Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:caAERSv2.2 = SiteResearchStaff.faxNumber Map:caAERSv2.2 = SiteResearchStaff.emailAddress Map:CTRPv1.0 = ClinicalResearchStaff.telecomAddress Map:CTRv1.0 = ResearchStaff.telecomAddress Map:ICSRr2 = AssignedEntity.telecom (in IndividualCaseSafetyReport) Map:Vendor1v1.1 = StaffMember.telecomAddress
effectiveDateRange <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the organization staff is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = ClinicalResearchStaff.statusDateRange Map:CTRPv1.0 = ClinicalResearchStaff.statusCode Map:CTRv1.0 = ResearchStaff.effectiveDateRange Map:Vendor1v1.1 = StaffMember.effectiveDateRange

Attribute	Notes	Constraints and Tags
primaryRoleIndicator <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Specifies whether the role is the one that the organization staff usually plays.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = StaffMember.isPrimaryRole
confidentialIndicator <i>Class:</i> OrganizationStaffRole <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: DEFINITION: A role performed by an individual on behalf of an organization who is employing them.</p> <p>EXAMPLE(S): Grants Manager, Project Assistant, Visit Report Reviewer</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Note that a role is not the same as a job title; a person may perform multiple different roles simultaneously and the roles may not have an obvious relation to their job title.</p>	Map:Vendor1v1.1 = StaffMember.isConfidential

Class: OversightAuthority

Package: Common Sub-Domain

DEFINITION:

An organization with monitoring, regulatory, or supervisory authority over biomedical research at the local, regional, national, or international level.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRR = Oversight Authority
- Map:CTRRr3 = OversightAuthority
- Map:CTRv1.0 = OversightAuthority

Connectors

Source	Connector	Target	Notes
OversightAuthority 0..1 performedOversightAuthorit y	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each OversightAuthority always is a function performed by one Organization. Each Organization might function as one OversightAuthority.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
OversightCommittee	specializes	OversightAuthority	DESCRIPTION: Each OversightCommittee always specializes one OversightAuthority. Each OversightAuthority might be specialized by one OversightCommittee. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyOversightAuthority 0..* performedStudyOversightA uthority	is a function performed by	OversightAuthority 1 performingOversightAuthori ty	DESCRIPTION: Each StudyOversightAuthority always is a function performed by one OversightAuthority. Each OversightAuthority might function as one or more StudyOversightAuthority. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
RegulatoryAuthority	specializes	OversightAuthority	DESCRIPTION: Each RegulatoryAuthority always specializes one OversightAuthority. Each OversightAuthority might be specialized by one RegulatoryAuthority. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: OversightCommittee

Package: Common Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

Institutional Review Board (IRB), ethics committee, research ethics board

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTOM = HealthcareSiteParticipantRole.roleCode
- Map:CTRPv1.0 = OversightCommittee
- Map:CTRPv3.8 = OversightCommittee
- Map:CTRr3 = OversightCommittee
- Map:CTRv1.0 = OversightCommittee
- Map:HL7SP = EthicalCommittee
- Map:HL7SP = ServiceProvider
- Map:HL7SP = Verifier
- Map:HSDBv1.0 = [Lead Organization] .Organization Type

Connectors

Source	Connector	Target	Notes
OversightCommittee	specializes	OversightAuthority	<p>DESCRIPTION: Each OversightCommittee always specializes one OversightAuthority. Each OversightAuthority might be specialized by one OversightCommittee.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OversightCommittee 0..* overseeingOversightCommittee	oversee	StudySite 0..* overseenStudySite	<p>DESCRIPTION: Each OversightCommittee might oversee one or more StudySite. Each StudySite might be overseen by one or more OversightCommittee.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OversightCommittee 0..* overseeingOversightCommittee	oversee	HealthcareFacility 0..* overseenHealthcareFacility	<p>DESCRIPTION: Each OversightCommittee might oversee one or more HealthcareFacility. Each</p>

Source	Connector	Target	Notes
			<p>HealthcareFacility might be overseen by one or more OversightCommittee.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DataMonitoringCommitteeC harterVersion 0..* governingDataMonitoringC ommitteeCharterVersion	governs	OversightCommittee 1 governedOversightCommitt ee	<p>DESCRIPTION: Each DataMonitoringCommitteeC harterVersion always governs one OversightCommittee. Each OversightCommittee might be governed by one or more DataMonitoringCommitteeC harterVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteOversightStatus 0..* assignedStudySiteOversight Status	be assigned by	OversightCommittee 0..1 assigningOversightCommitt ee	<p>DESCRIPTION: Each StudySiteOversightStatus might be assigned by one OversightCommittee. Each OversightCommittee might assign one or more StudySiteOversightStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	OversightCommittee 0..1 performingOversightCommi ttee	<p>DESCRIPTION: Each Performer might be a function performed by one OversightCommittee. Each OversightCommittee might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> OversightCommittee <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of oversight committee.</p> <p>EXAMPLE(S): Adjudication Committee, IRB, Data Safety Monitoring Board</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = Data Monitoring Committee Map:CTRPv1.0 = OversightCommittee.typeCode Map:CTRPv3.8 = OversightCommittee.typeCode Map:CTRR = IRB Organization Map:CTRR = Oversight Authority Map:CTRR = IRB Affiliation Map:CTRr3 = OversightCommittee.typeCode Map:CTRv1.0 = OversightCommittee.typeCode Map:HSDBV1.0 = [IRB].IRB type Map:SDTM IGv3.1.3 = TU.TUEVAL Map:SDTM IGv3.1.3 = TR.TREVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = FA.FAEVAL Map:SDTM IGv3.1.3 = EG.EGEVAL
effectiveDateRange <i>Class:</i> OversightCommittee <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the oversight committee is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = OversightCommittee.statusCode Map:CTRPv1.0 = OversightCommittee.statusDateRange Map:CTRv1.0 = OversightCommittee.effectiveDateRange

Class: Performer

Package: Common Sub-Domain

DEFINITION:

The person, organization, or device that executes or accomplishes an activity.

EXAMPLE(S):

surgeon, performing laboratory, monitoring device, healthcare provider, adjudication committee, family member, radiologist, vendor (may provide a uniform assessment for all sites participating in a study), heart rate monitor, pace maker.

OTHER NAME(S):Assessor

NOTE(S):A Performer may be simply a person, organization or device or it may be a person, organization or device in a particular role that is important for understanding or interpreting the significance of the activity or its results, such as with observations.

Tagged Values:

- Map:AE = PerformingParty
- Map:AIM v4 rv48 = User
- Map:caAERSv2.2 = MedicalDevice.otherDeviceOperator
- Map:CTRr3 = Performer
- Map:CTRv1.0 = Assessor

- Map:CTRv1.0 = Performer
- Map:DICOM = TID 1003 PersonObserverIdentifyingAttributes
- Map:DICOM = TID 1002 ObserverContext > Include TID 1004 DeviceObserverIdentifyingAttributes
- Map:DICOM = TID 1002 ObserverContext > Include TID 1003 PersonObserverIdentifyingAttributes
- Map:DICOM = TID 1002 ObserverContext
- Map:HL7SD = R_AssignedEntity(Universal)
- Map:ICSRr2 = Author2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = performer (in R_Product)
- Map:ICSRr2 = AssignedEntity.Code (in IndividualCaseSafetyReport)
- Map:ICSRr2 = AssignedEntity (in IndividualCaseSafetyReport)
- Map:ICSRr2 = participant3 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = author (in R_Product)
- Map:ICSRr2 = Author1 (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = Performer
- Map:SDTM IGv3.1.1 = PE.EVAL
- Map:SDTM IGv3.1.1 = EG.EVAL
- Map:SDTM IGv3.1.1 = CO.EVAL
- Map:TDM = PlannedSubjectActivity.whoPerforms

Connectors

Source	Connector	Target	Notes
Performer 0..* performedPerformer	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each Performer might be a function performed by one Organization. Each Organization might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performingPerformer	performs	Activity 1 performedActivity	<p>DESCRIPTION: Each Performer always performs one Activity. Each Activity might be performed by one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each Performer might be a function performed by one Person. Each Person might function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Subject 0..1 performingSubject	DESCRIPTION: Each Performer might be a function performed by one Subject. Each Subject might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	OrganizationStaffRole 0..1 performingOrganizationStaffRole	DESCRIPTION: Each Performer might be a function performed by one OrganizationStaffRole. Each OrganizationStaffRole might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	DESCRIPTION: Each Performer might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	OversightCommittee 0..1 performingOversightCommittee	DESCRIPTION: Each Performer might be a function performed by one OversightCommittee. Each OversightCommittee might function as one or more Performer. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Laboratory 0..1 performingLaboratory	DESCRIPTION: Each Performer might be a function performed by one Laboratory. Each Laboratory might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	AssociatedBiologicEntity 0..1 performingAssociatedBiologicEntity	DESCRIPTION: Each Performer might be a function performed by one AssociatedBiologicEntity. Each AssociatedBiologicEntity might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Device 0..1 performingDevice	DESCRIPTION: Each Performer might be a function performed by one Device. Each Device might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Performer <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	DEFINITION: A unique symbol that establishes identity of the performer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Performer.identifier Map:HL7SD = R_AssignedEntity(Universal) Map:LSDAMv2.2.3Plus = Performer.identifier
typeCode <i>Class:</i> Performer <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the kind of performer. EXAMPLE(S): surgeon, monitoring device, performing laboratory OTHER NAME(S): NOTE(S):	Map:AE = PerformingParty.roleType Map:CDASHv1.1 = PE.PEEVAL Map:CTR&Rr2 = Responsible Site Role Map:CTRRr3 = Performer.typeCode Map:CTRv1.0 = Performer.typeCode Map:DICOM = TID 1003 PersonObserverIdentifyingAttributes > Person Observer's Role in this Procedure Map:ICSRr2 = AssignedEntity.code (in IndividualCaseSafetyReport) Map:ICSRr2 = performer.typeCode (in R_Product) Map:ICSRr2 = author.typeCode (in R_Product) Map:LSDAMv2.2.3Plus = Performer.typeCode Map:SDTM IGv3.1.1 = PE.PEEVAL Map:SDTM IGv3.1.1 = CO.COEVAL Map:SDTM IGv3.1.1 = EG.EGEVAL Map:SDTM IGv3.1.2 = PE.PEEVAL Map:SDTM IGv3.1.2 = FA.FAEVAL Map:SDTM IGv3.1.2 = EG.EGEVAL Map:SDTM IGv3.1.2 = CO.COEVAL Map:SDTM IGv3.1.3 = CO.COEVAL Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - STAGED BY (PATHOLOGIC STAGE) Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - STAGED BY (CLINICAL STAGE)
evaluatorAlias <i>Class:</i> Performer <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A non-unique textual identifier for the performer. EXAMPLE(S): OTHER NAME(S): NOTE(S): When multiple performers assess the same activity or result, the value of Performer.evaluatorAlias will attribute an assessment result to a particular performer.	Map:AIM v4 rv48 = User.roleInTrial Map:AIM v4 rv48 = User.numberWithinRoleOfClinicalTrial Map:DICOM = TID 1001 ObservationContext > Include TID 1002 ObserverContext Map:SDTM IGv3.1.3 = TU.TUEVALID Map:SDTM IGv3.1.3 = TR.TREVALID Map:SDTM IGv3.1.3 = RS.RSEVALID

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> Performer <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A contact point used to send physical forms of communication to the performer. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Performer.postalAddress Map:HL7SD = R_AssignedEntity(Universal) Map:ICSRr2 = AssignedEntity.addr (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Performer.postalAddress
telecomAddress <i>Class:</i> Performer <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the performer. EXAMPLE(S): OTHER NAME(S): NOTE(S): The set of digits that serves as the address for a telephone device. Included in the phone number are country, city, and area codes needed to uniquely address the telephone. A URL or e-mail would be similarly described.	Map:caAERSv2.2 = PlannedEmailNotification.from Map:CTRv1.0 = Performer.telecomAddress Map:HCTv1.0 = CDE 2518194:Individuals.Outside Contact Phone Number Map:HL7SD = R_AssignedEntity(Universal) Map:ICSRr2 = AssignedEntity.telecom (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Performer.telecomAddress
effectiveDateRange <i>Class:</i> Performer <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) span for when the performer is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Performer.effectiveDateRange Map:HL7SD = R_AssignedEntity(Universal) Map:LSDAMv2.2.3Plus = Performer.effectiveDateRange

Class: Person

Package: Common Sub-Domain

DEFINITION:

A human being.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Person
- Map:C3PRv2.9 = Person
- Map:caAERSv2.2 = Person
- Map:CTRv1.0 = Person
- Map:CTRv3.8 = Person
- Map:CTRRr3 = Person
- Map:CTRv1.0 = Person
- Map:HL7SD = Person
- Map:HL7SP = InvestigativePerson
- Map:HL7SP = Person

- Map:ICSRr2 = Person (in IndividualCaseSafetyReport)
- Map:ICSRr2 = contactPerson (in R_Product)
- Map:ICSRr2 = Person2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = AssignedEntity2 (in R_Product)
- Map:ICSRr2 = ContactPerson (in E_Organization informational)
- Map:LabViewer2.2 = Person
- Map:LSDAMv2.2.3Plus = Person
- Map:NCI CRF Standard = Demography
- Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION

Connectors

Source	Connector	Target	Notes
Person	specializes	BiologicEntity	<p>DESCRIPTION: Each Person always specializes one BiologicEntity. Each BiologicEntity might be specialized by one Person.:</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MaritalStatus 0..* describingMaritalStatus	describes	Person 1 describedPerson	<p>DESCRIPTION: Each MaritalStatus always describes one Person. Each Person might be described by one or more MaritalStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
QualifiedPerson 0..* performedQualifiedPerson	is a function performed by	Person 1 performingPerson	<p>DESCRIPTION: Each QualifiedPerson always is a function performed by one Person. Each Person might function as one or more QualifiedPerson.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Performer 0..* performedPerformer	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each Performer might be a function performed by one Person. Each Person might</p>

Source	Connector	Target	Notes
			<p>function as one or more Performer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportReceiver 0..* performedReportReceiver	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each ReportReceiver might be a function performed by one Person. Each Person might function as one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
HealthcareProvider 0..* performedHealthcareProvider	is a function performed by	Person 1 performingPerson	<p>DESCRIPTION: Each HealthcareProvider always is a function performed by one Person. Each Person might function as one or more HealthcareProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each DocumentAuthor might be a function performed by one Person. Each Person might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The direct association to Person was added in support of LSDAM use cases which didn't specify any specific</p>

Source	Connector	Target	Notes
			role.
PointOfContact 0..* performedPointOfContact	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each PointOfContact might be a function performed by one Person. Each Person might function as one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ResourceProvider 0..1 performedResourceProvider	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each ResourceProvider might be a function performed by one Person. Each Person might function as one ResourceProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OrganizationStaff 0..* performedOrganizationStaff	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each OrganizationStaff might be a function performed by one Person. Each Person might function as one or more OrganizationStaff.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
initials <i>Class:</i> Person <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The first letters of the person's first name, middle name, and last name.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the person does not have a middle name or initial, the initials will only be two characters.</p>	Map:CTOM = Participant.initials Map:CTRv1.0 = Person.initials Map:Lab = Investigator.initials Map:Lab = Participant.initials Map:Lab = Person.initials Map:LabViewer2.2 = Investigator.initials Map:LabViewer2.2 = Participant.initials Map:LabViewer2.2 = Person.initials Map:LSDAMv2.2.3Plus = Person.initials Map:NCI CRF Standard = CDE 2001039v4.0: Patient Initials Name

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> Person <i>Datatype:</i> BAG<AD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A contact point used to send physical forms of communication to the person.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Address.cityCode Map:C3PR = ContactMechanism.type Map:C3PR = Address.countryCode Map:C3PR = ContactMechanism.value Map:C3PR = Address.stateCode Map:C3PR = Address.postalCode Map:C3PR = Address.streetAddress Map:C3PRv2.9 = Address Map:caAERSv2.2 = Address.country > PersonContact Map:caAERSv2.2 = Address.street > PersonContact Map:caAERSv2.2 = Address.zip > PersonContact Map:caAERSv2.2 = Address.city > PersonContact Map:caAERSv2.2 = Address.state > ResearchStaff Map:CTOM = Participant.countryCode Map:CTOM = Participant.zipCode Map:CTOM = Person.city Map:CTOM = Investigator.state Map:CTOM = Person.state Map:CTOM = Person.streetAddress Map:CTOM = Investigator.zipCode Map:CTOM = Participant.streetAddress Map:CTOM = Person.zipCode Map:CTOM = Participant.state Map:CTOM = Participant.city Map:CTOM = Investigator.countryCode Map:CTOM = Investigator.streetAddress Map:CTOM = Investigator.city Map:CTOM = Person.countryCode Map:CTRv1.0 = Person.postalAddress Map:CTRv3.8 = Person.postalAddress Map:CTRRr3 = Person.postalAddress Map:CTRv1.0 = Person.postalAddress Map:HCTv1.0 = CDE 2179603:Geographic Locations.State Map:HCTv1.0 = CDE 2816450:Geographic Locations.Specify other country: Map:HCTv1.0 = CDE 3119139:Geographic Locations.City Map:HCTv1.0 = CDE 2797862:Geographic Locations.US state of residence: Map:HCTv1.0 = CDE 2797876:Geographic Locations.Country of residence: Map:ICSRr2 = AssignedEntity.addr (in IndividualCaseSafetyReport) Map:ICSRr2 = AssignedEntity2.addr (in R_Product)

Attribute	Notes	Constraints and Tags
		Map:ICSRr2 = Person2.addr (in IndividualCaseSafetyReport) Map:ICSRr2 = ContactParty2.addr (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Person.postalAddress Map:NCI CRF Standard = CDE 62587v3.0: Street Address Map:NCI CRF Standard = CDE 2179603v2.0: Address State/Province Name Map:NCI CRF Standard = CDE 315v4.0: Person Address Country Name Map:NCI CRF Standard = CDE 2943243v1.0: Person Enrollment Address United States Integer::2000 Census Tract Code Map:NCI CRF Standard = CDE 2179606v2.0: Address Postal Code Identifier Map:NCI CRF Standard = CDE 2179601v1.0: Address City Name Map:NCI CRF Standard = CDE 2179606v2.0: Address Postal Code Identifier Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - CENSUS TRACT CERTAINTY 2010 Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - PLACE OF RESIDENCE AT DIAGNOSIS Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - COUNTY Map:SEET 2015 = SECTION III DEMOGRAPHIC INFORMATION - CENSUS TRACT 2010

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> Person <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the person.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:C3PR = ContactMechanism.type Map:C3PR = ContactMechanism.value Map:C3PRv2.9 = ReportVersion.email Map:C3PRv2.9 = ContactMechanismBasedRecipient Map:C3PRv2.9 = ContactMechanism.type Map:C3PRv2.9 = ContactMechanism.value Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:caAERSv2.2 = ScheduledEmailNotification.to Map:caAERSv2.2 = PersonContact.ReportPerson.Reporter.contactMechanisms Map:caAERSv2.2 = User.emailAddress Map:caAERSv2.2 = ReportDelivery.address Map:CTOM = Participant.phone Map:CTOM = Person.telecomAddress Map:CTOM = Investigator.telecomAddress Map:CTOM = Person.phone Map:CTOM = Participant.telecomAddress Map:CTOM = Investigator.phone Map:CTRPv1.0 = Person.telecomAddress Map:CTRPv3.8 = Person.telecomAddress Map:CTRr3 = Person.telecomAddress Map:CTRv1.0 = Person.telecomAddress Map:HCTv1.0 = CDE 2828513:Individuals.Telephone number: Map:HCTv1.0 = CDE 2828511:Individuals.Fax number: Map:HCTv1.0 = CDE 58319//:Telecommunications.Fax Number Map:ICSRr2 = AssignedEntity.telecom (in IndividualCaseSafetyReport) Map:ICSRr2 = ContactParty2.telecom (in IndividualCaseSafetyReport) Map:ICSRr2 = AssignedEntity2.telecom (in R_Product) Map:ICSRr2 = Person2.telecom (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Person.telecomAddress Map:NCI CRF Standard = CDE 2179593v3.0: Telephone Number

Attribute	Notes	Constraints and Tags
		Map:NCI CRF Standard = CDE 2179594v4.0: Telephone Number Type
raceCode <i>Class:</i> Person <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying a self-declared racial origination, independent of ethnic origination.</p> <p>EXAMPLE(S): Office of Management and Budget (OMB) approved categories [example from National Cancer Institute]</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Participant.raceCode Map:C3PRv2.9 = Participant.raceCode Map:caAERSv2.2 = Participant.race Map:CDASHv1.1 = DM.RACE Map:CDASHv1.1 = DM.RACEOTH Map:CTOM = Person.raceCode Map:CTOM = Participant.raceCode Map:CTOM = Investigator.raceCode Map:CTRPv1.0 = Person.raceCode Map:CTRPv3.8 = Person.raceCode Map:CTRv1.0 = Person.raceCode Map:HCTv1.0 = CDE 106 // :Recipient Identification.Race Map:HCTv1.0 = CDE 2786681:Personal attributes.Donor's race Map:HCTv1.0 = CDE 2798213:UML DEFAULT CD.Race group the person belongs to: Map:ICSRr2 = Person2.raceCode (in IndividualCaseSafetyReport) Map:LabViewer2.2 = ParticipantRace.codeSystemVersion Map:LabViewer2.2 = ParticipantRace.codeSystem Map:LabViewer2.2 = ParticipantRace.code Map:LabViewer2.2 = ParticipantRace.codeSystemName Map:LabViewer2.2 = ParticipantRace.displayName Map:LSDAMv2.2.3Plus = Person.raceCode Map:NCI CRF Standard = CDE 2192199v1.0: Race Category Text Map:NCI CRF Standard = CDE 2200286v1.0: Centers for Disease Control and Prevention Race Unique Identifier Code Map:SDTM IGv3.1.1 = DM.RACE Map:SDTM IGv3.1.2 = DM.RACE Map:SDTM IGv3.1.3 = DM.RACE Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - RACE-NAPIIA Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - RACE 1, 2, 3, 4, 5

Attribute	Notes	Constraints and Tags
ethnicGroupCode <i>Class:</i> Person <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the self-declared ethnic origination, independent of racial origination.</p> <p>EXAMPLE(S): Office of Management and Budget (OMB) approved categories [example from National Cancer Institute]</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Participant.ethnicGroup Map:C3PRv2.9 = Participant.ethnicGroupCode Map:caAERSv2.2 = Participant.ethnicity Map:CDASHv1.1 = DM.ETHNIC Map:CTOM = Investigator.ethnicGroupCode Map:CTOM = Person.ethnicGroupCode Map:CTOM = Participant.ethnicGroupCode Map:CTRPv3.8 = Person.ethnicGroupCode Map:CTRv1.0 = Person.ethnicGroupCode Map:DICOM = Patient Module - Ethnic Group (0010,2160) Map:DICOM = Patient Level Attributes for the Patient Root Query/Retrieve Information Model - Ethnic Group (0010,2160) Map:HCTv1.0 = CDE 3186998:Physical Description of Individuals.What is the patient's ethnic group? Map:HCTv1.0 = CDE 2769672:Individuals.Donor's ethnicity: Map:HCTv1.0 = CDE 2002440:Recipient Identification.Ethnicity Map:ICSRr2 = Person2.ethnicGroupCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Person.ethnicGroupCode Map:NCI CRF Standard = CDE 2192217v2.0: Ethnic Group Category Text Map:NCI CRF Standard = CDE 2200284v2.0: Centers for Disease Control and Prevention Ethnicity Unique Identifier Codes Map:SDTM IGv3.1.1 = DM.ETHNIC Map:SDTM IGv3.1.2 = DM.ETHNIC Map:SDTM IGv3.1.3 = DM.ETHNIC

Attribute	Notes	Constraints and Tags
ethnicSurnameOrOriginCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying patients with a surname or origin of a particular ethnicity.</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program, patients of Hispanic origin are sometimes of particular interest: 0 = Non-Spanish/Non-Hispanic 1 = Mexican (includes Chicano) 2 = Puerto Rican 3 = Cuban 4 = South or Central American (except Brazil) 5 = Other specified Spanish/Hispanic origin (includes European; excludes Dominican Republic) 6 = Spanish, NOS; Hispanic, NOS; Latino, NOS There is evidence, other than surname or maiden name, that the person is Hispanic but he/she cannot be assigned to any of the categories 1-5. 7 = Spanish surname only (effective with diagnosis on or after 1/1/1994) The only evidence of the person's Hispanic origin is the surname or maiden name and there is no evidence that he/she is not Hispanic. 8 = Dominican Republic (effective with diagnosis on or after 1/1/2005) 9 = Unknown whether Spanish/Hispanic or not</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Surname and/or origin may or may not correspond to any particular race.</p>	Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - SPANISH SURNAME OR ORIGIN

Attribute	Notes	Constraints and Tags
computedEthnicityCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the ethnicity determined by a computer algorithm based on last name and/or maiden name. [adapted from NCI SEER Program Coding and Staging Manual 2015]</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 0 = No match [linkage] was run (for 1994 and later cases) 1 = Non-Hispanic last name and non-Hispanic maiden name 2 = Non-Hispanic last name, did not check maiden name, or patient was male 3 = Non-Hispanic last name, missing maiden name 4 = Hispanic last name, non-Hispanic maiden name 5 = Hispanic last name, did not check maiden name or patient was male 6 = Hispanic last name, missing maiden name 7 = Hispanic maiden name (females only) (regardless of last name) Blank = 1993 and earlier cases; no match [linkage] was run</p> <p>OTHER NAME(S):</p> <p>NOTE(S): For SEER, Computed Ethnicity records the ethnicity based on last name and/or maiden name using a computer algorithm. The computer algorithm compares a list of names with the patient's surname and/or maiden name to test for Hispanic ethnicity. A computer algorithm must be used to compute ethnicity for all cases diagnosed January 1, 1994 and later. This data item is used in conjunction with the data item Computed Ethnicity Source.</p>	Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - COMPUTED ETHNICITY

Attribute	Notes	Constraints and Tags
computedEthnicitySourceCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the database, method, or computer algorithm that was used to determine ethnicity as recorded in the Computed Ethnicity Code. [adapted from NCI SEER Program Coding and Staging Manual 2015]</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 0 = No match [linkage] was run for 1994 and later cases 1 = Census Bureau list of Spanish surnames, NOS 2 = 1980 Census Bureau list of Spanish surnames 3 = 1990 Census Bureau list of Spanish surnames 4 = GUESS program 5 = Combination list including South Florida names 6 = Combination of Census and other locally generated list 7 = Combination of Census and GUESS, with or without other lists 8 = Other type of match (Do not record results of NHIA in this field) 9 = Unknown type of match Blank = 1993 and earlier cases, no match [linkage] was run</p> <p>OTHER NAME(S):</p> <p>NOTE(S): For SEER, blank is allowed only for tumors diagnosed in 1993 and earlier.</p>	Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - COMPUTED ETHNICITY SOURCE

Attribute	Notes	Constraints and Tags
derivedEthnicityOriginCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the result of a computerized algorithm that uses a combination of variables to directly or indirectly classify cases as a particular ethnicity or origin for analytic purposes.</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 0 = Non-Hispanic 1 = Mexican, by birthplace or other specific identifier 2 = Puerto Rican, by birthplace or other specific identifier 3 = Cuban, by birthplace or other specific identifier 4 = South or Central American (except Brazil), by birthplace or other specific identifier 5 = Other specified Spanish/Hispanic origin (includes European; excludes Dominican Republic), by birthplace or other specific identifier 6 = Spanish, NOS; Hispanic, NOS; Latino, NOS 7 = NHIA surname match only 8 = Dominican Republic Blank = Algorithm has not been run</p> <p>OTHER NAME(S): NAACCR Hispanic Identification Algorithm (NHIA) Derived Hispanic Origin</p> <p>NOTE(S):</p>	Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - NHIA DERIVED HISPANIC ORIGIN
educationLevelCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the highest level of education completed.</p> <p>EXAMPLE(S): Less than High School Diploma, High School Diploma, Some College</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = SC.SCORRES Map:CTOM = Person.educationLevelCode Map:CTOM = Participant.educationLevelCode Map:CTOM = Investigator.educationLevelCode Map:CTRv1.0 = Person.educationLevelCode Map:HCTv1.0 = CDE 2815244:Property or Attribute.Education level Map:LSDAMv2.2.3Plus = Person.educationLevelCode Map:NCI CRF Standard = CDE 2674076v2.0: Person Education Level Type Map:NCI CRF Standard = CDE 2681552v1.0: Person Education Level Summary Type Map:SDTM IGv3.1.2 = SC.SCORRES Map:SDTM IGv3.1.2 = SC.SCSTRESC Map:SDTM IGv3.1.3 = SC.SCORRES

Attribute	Notes	Constraints and Tags
primaryOccupationCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the principal activity that a person does to earn money.</p> <p>EXAMPLE(S): Adult Education Teachers have an occupation code of 25-3011 in the Bureau of Labor Statistics Standard Occupational Classification system.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = SC.SCORRES Map:CTOM = PersonOccupation.primaryTypeCode Map:CTOM = PersonOccupation.primaryTypeCodeSystem Map:CTRv1.0 = Person.primaryOccupationCode Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Occupation (0010,2180) Map:DICOM = Patient Study Module - Occupation (0010,2180) Map:HCTv1.0 = CDE 2798174:Personal attributes.What is the current or most recent work status? Map:HCTv1.0 = CDE 2815112:Jobs.What category best describes the occupation of the person? Map:HCTv1.0 = CDE 2222677:Jobs.Other Map:LSDAMv2.2.3Plus = Person.primaryOccupationCode Map:SDTM IGv3.1.2 = SC.SCSTRESC Map:SDTM IGv3.1.2 = SC.SCORRES Map:SDTM IGv3.1.3 = SC.SCORRES
occupationDateRange <i>Class:</i> Person <i>Datatype:</i> IVL<TS.DATE> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) span specifying the start and end of a person's occupation.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The occupation is determined by the Person.primaryOccupationCode.</p>	Map:CTOM = PersonOccupation.stopDate Map:CTOM = PersonOccupation.startDate Map:CTRv1.0 = Person.occupationDateRange Map:LSDAMv2.2.3Plus = Person.occupationDateRange
birthStateCode <i>Class:</i> Person <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the name of the state in which the person is born.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - BIRTHPLACE – STATE

Class: Place

Package: Common Sub-Domain

DEFINITION:
A bounded physical location which may contain structures.

EXAMPLE(S):

ambulance, helicopter, manufacturing site, service delivery location, home, emergency department, surgical suite, patient room

OTHER NAME(S):

NOTE(S):

Constraints: Place may be natural or man-made. The geographic position of a place may or may not be constant.

Discussion: Places may be work facilities (where relevant acts occur), homes (where people live) or offices (where people work). Places may contain sub-places (floor, room, booth, bed). Places may also be sites that are investigated in the context of health care, social work, public health administration (e.g., buildings, picnic grounds, day care centers, prisons, counties, states, and other focuses of epidemiological events).

Tagged Values:

- Map:AE = ServiceDeliveryLocation
- Map:CTRv1.0 = Place
- Map:ICSRr2 = Location (in A_ProductReportingRelevantInformation)
- Map:ICSRr2 = LocatedEntity (in A_ProductReportingRelevantInformation)
- Map:ICSRr2 = Place (in E_Place universal)
- Map:ICSRr2 = Place (in IndividualCaseSafetyReport)
- Map:ICSRr2 = territory (in R_Product)
- Map:LSDAMv2.2.3Plus = Place

Connectors

Source	Connector	Target	Notes
Place 0..* containedPlace	be contained in	Place 0..1 containingPlace	<p>DESCRIPTION: Each Place might be contained in one Place. Each Place might contain one or more Place.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Place 0..* locatingPlace	be the location for	RegulatoryAuthority 0..1 locatedRegulatoryAuthority	<p>DESCRIPTION: Each Place might be the location for one RegulatoryAuthority. Each RegulatoryAuthority might have jurisdiction over one or more Place.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StorageEquipment 0..* residentStorageEquipment	is located in	Place 1 residingPlace	<p>DESCRIPTION: Each StorageEquipment always is located in one Place. Each Place might be location for one or more StorageEquipment.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessingSite 0..* performedProcessingSite	is a function performed by	Place 1 performingPlace	<p>DESCRIPTION:</p> <p>Each ProcessingSite always is a function performed by one Place. Each Place might function as one or more ProcessingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..* residentContainer	is located at	Place 1 residingPlace	<p>DESCRIPTION:</p> <p>Each Container always is located at one Place. Each Place might be location for one or more Container.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
QualifiedPerson 0..* locatedQualifiedPerson	be qualified in	Place 0..1 locatingPlace	<p>DESCRIPTION:</p> <p>Each QualifiedPerson might be qualified in one Place. Each Place might be the location in which the qualification is granted for one or more QualifiedPerson.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* locatedPerformedActivity	take place in	Place 0..1 locatingPlace	<p>DESCRIPTION:</p> <p>Each PerformedActivity might take place in one Place. Each Place might be the location for one or more PerformedActivity.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Place 0..* containedPlace	be contained in	Place 0..1 containingPlace	<p>DESCRIPTION: Each Place might be contained in one Place. Each Place might contain one or more Place.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ServiceDeliveryLocation 0..* locatingServiceDeliveryLocation	be located at	Place 0..1 locatedPlace	<p>DESCRIPTION: Each ServiceDeliveryLocation might be located at one Place. Each Place might be the location for one or more ServiceDeliveryLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Place <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A unique symbol that establishes identity of the place.</p> <p>EXAMPLE(S): The license plate number of an ambulance, an identifier for a bed in a hospital ward</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = Place.identifier Map:LSDAMv2.2.3Plus = Place.identifier

Attribute	Notes	Constraints and Tags
identifierCode <i>Class:</i> Place <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value uniquely specifying the place.</p> <p>EXAMPLE(S): United States (US), European Union (EU)</p> <p>OTHER NAME(S): jurisdiction territory code</p> <p>NOTE(S): The only current use case for this attribute is to specify the geographical area an authority has to make laws and enforce them. For example, the Food and Drug Administration (FDA) exercises responsibility for pharmacovigilance (RegulatoryAuthority.jurisdictionAuthorityCode) in the United States (Place.identifierCode).</p>	Map:AE = Reporter.jurisdiction Map:AE = Receiver.jurisdiction Map:CTR&Rr2 = SUSAR Reporting to NCAs Map:CTR&Rr2 = Country granting MA Map:CTR&Rr2 = SUSAR Reporting to EVCTM Map:CTRv1.0 = RegulatoryAuthority.jurisdictionCode Map:CTRv3.8 = RegulatoryAuthority.countryCode Map:CTRv1.0 = Place.code Map:ICSRr2 = territory.code (in R_Product)
name <i>Class:</i> Place <i>Datatype:</i> TN <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier for the place</p> <p>EXAMPLE(S): "European Union" might be the name of the territory comprised by the EU member states.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Place.name Map:HCTv1.0 = MD Anderson Specific Content: Product.Manufacturing site Map:ICSRr2 = Place.name (in IndividualCaseSafetyReport) Map:ICSRr2 = Territory.name (in R_Product) Map:ICSRr2 = Place.name (in E_Place universal)
typeCode <i>Class:</i> Place <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of place.</p> <p>EXAMPLE(S): emergency department, surgical suite, patient room</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = ServiceDeliveryLocation.locationType Code Map:CTRv1.0 = Place.typeCode Map:HCTv1.0 = MD Anderson Specific Content: Product.Product thawed at bedside Map:ICSRr2 = Place.code (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = Place.typeCode
physicalAddress <i>Class:</i> Place <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A representation of the location of the place.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The physicalAddress attribute is meant to provide sufficient information to allow someone to visit a place; it is not intended to provide geographic categorization, a postal address, or a simple name by which a country/state/city is referenced (for a simple name use Place.name).</p>	Map:caAERSv2.2 = MedicalDevice.manufacturerCity Map:caAERSv2.2 = MedicalDevice.manufacturerState Map:caAERSv2.2 = MedicalDevice.reprocessorAddress Map:CTRv1.0 = Place.physicalAddress Map:ICSRr2 = Place.addr (in E_Place universal) Map:LSDAMv2.2.3Plus = Place.physicalAddress

Class: PointOfContact

Package: Common Sub-Domain

DEFINITION:

A person or organization that provides or receives information on behalf of, or regarding, an organization, material, project, or standard operating procedure.

EXAMPLE(S):

Safety Representative, Sales Representative, Financial Representative, Manufacturing Representative, Review Board Contact, Research Technician, Service Representative

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:AE = ContactPerson
- Map:CTRPv1.0 = OrganizationalContact
- Map:CTRPv3.8 = OrganizationalContact
- Map:CTRRr3 = OrganizationalContact
- Map:CTRv1.0 = OrganizationalContact
- Map:ICSRr2 = ContactParty (in E_Organization informational)
- Map:ICSRr2 = contactParty (in R_Product)
- Map:ICSRr2 = ContactParty (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = PointOfContact
- Map:LSDAMv2.2.3Plus = OrganizationalContact

Connectors

Source	Connector	Target	Notes
PointOfContact 0..* supportingPointOfContact	support	ProcessProtocol 0..* supportedProtocol	<p>DESCRIPTION: Each PointOfContact might support one or more ProcessProtocol. Each ProcessProtocol might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* supportingPointOfContact	support	Material 0..* supportedMaterial	<p>DESCRIPTION: Each PointOfContact might support one or more Material. Each Material might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* supportingPointOfContact	handle communication for	Organization 0..1 supportedOrganization	<p>DESCRIPTION: Each PointOfContact might handle communication for one Organization. Each Organization might have</p>

Source	Connector	Target	Notes
			<p>communications handled by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* performedPointOfContact	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each PointOfContact might be a function performed by one Organization. Each Organization might function as one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* supportingPointOfContact	support	Project 0..* supportedProject	<p>DESCRIPTION: Each PointOfContact might support one or more Project. Each Project might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* performedPointOfContact	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each PointOfContact might be a function performed by one Person. Each Person might function as one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* supportingPointOfContact	support	PerformedObservationResult 0..*	<p>DESCRIPTION: Each PointOfContact might support one or more</p>

Source	Connector	Target	Notes
		supportedPerformedObservationResult	<p>PerformedObservationResult. Each PerformedObservationResult might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
title <i>Class:</i> PointOfContact <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A descriptive or distinctive appellation, especially one belonging to a person by right of rank, office, attainment, etc.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = OragnizationalContact.title Map:CTRPv3.8 = OrganizationalContact.title Map:CTRv1.0 = OrganizationalContact.title Map:LSDAMv2.2.3Plus = OrganizationalContact.title
typeCode <i>Class:</i> PointOfContact <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying the kind of contact.</p> <p>EXAMPLE(S): safety, sales, financial, manufacturing, Review Board contact</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Board Contact Map:CTRPv1.0 = OrganizationalContact.typeCode Map:CTRPv3.8 = OrganizationalContact.typeCode Map:CTRr3 = OrganizationalContact.typeCode Map:CTRv1.0 = OrganizationalContact.typeCode Map:LSDAMv2.2.3Plus = PointOfContact.typeCode Map:LSDAMv2.2.3Plus = OrganizationalContact.typeCode

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> PointOfContact <i>Datatype:</i> BAG<AD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A mailing designation used to send physical forms of communication to the contact.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = ContactPerson.address Map:CTGOV = Board Contact mailing address Map:CTR&Rr2 = CA Applicant Street Address Map:CTR&Rr2 = Network Town/City Map:CTR&Rr2 = CA Applicant Post Code Map:CTR&Rr2 = Legal Rep Street Address Map:CTR&Rr2 = Network Street Address Map:CTR&Rr2 = Subcontractor Street Address Map:CTR&Rr2 = Sponsor Town/City Map:CTR&Rr2 = Sponsor Post Code Map:CTR&Rr2 = CA Applicant Country Map:CTR&Rr2 = Network Country Map:CTR&Rr2 = IEC Applicant Post Code Map:CTR&Rr2 = CTF Post Code Map:CTR&Rr2 = IEC Applicant Town/City Map:CTR&Rr2 = Subcontractor Country Map:CTR&Rr2 = CA Applicant Town/City Map:CTR&Rr2 = CTF Country Map:CTR&Rr2 = Legal Rep Post Code Map:CTR&Rr2 = Network Post Code Map:CTR&Rr2 = CTF Street Address Map:CTR&Rr2 = CTF Street Town/City Map:CTR&Rr2 = Sponsor Street Address Map:CTR&Rr2 = Legal Rep Town/City Map:CTR&Rr2 = Subcontractor Town/City Map:CTR&Rr2 = Subcontractor Post Code Map:CTR&Rr2 = Legal Rep Country Map:CTR&Rr2 = IEC Applicant Street Address Map:CTR&Rr2 = IEC Applicant Country Map:CTR&Rr2 = Sponsor Country Map:CTRPv1.0 = OrganizationalContact.postalAddress Map:CTRPv3.8 = PersonRole.postalAddress Map:CTRr3 = OrganizationalContact.postalAddress Map:CTRv1.0 = OrganizationalContact.postalAddress Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization/contactPart.y.addr Map:FDA HL7 SD SD DSTU2012 =

Attribute	Notes	Constraints and Tags
		contactParty.addr Map:HSDBv1.0 = [Sponsor Contact].State/Province Map:HSDBv1.0 = [Sponsor Contact].Zip/Postal code Map:HSDBv1.0 = [Sponsor Contact].Street Address Map:HSDBv1.0 = [Sponsor Contact].Country Map:HSDBv1.0 = [Sponsor Contact].City Map:ICSRr2 = contactParty.addr (in R_Product) Map:ICSRr2 = ContactParty.addr (in IndividualCaseSafetyReport) Map:ICSRr2 = ContactParty.addr (in E_Organization informational) Map:LSDAMv2.2.3Plus = PointOfContact.postalAddress Map:LSDAMv2.2.3Plus = OrganizationalContact.postalAddress

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> PointOfContact <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the contact.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:AE = ContactPerson.phoneNumber Map:C3PR = ContactMechanism.value Map:C3PR = ContactMechanism.type Map:CTGOV = Board Contact Email Map:CTGOV = Board Contact Phone Map:CTGOV = Board Contact Ext Map:CTR&Rr2 = Network Telephone Map:CTR&Rr2 = Subcontractor Telephone Map:CTR&Rr2 = Subcontractor Email Map:CTR&Rr2 = Sponsor Fax Map:CTR&Rr2 = IEC Applicant Email Map:CTR&Rr2 = Legal Rep Telephone Map:CTR&Rr2 = Sponsor Telephone Map:CTR&Rr2 = Network Email Map:CTR&Rr2 = IEC Applicant Telephone Map:CTR&Rr2 = CTF Telephone Map:CTR&Rr2 = CA Applicant Telephone Map:CTR&Rr2 = IEC Applicant Fax Map:CTR&Rr2 = Subcontractor Fax Map:CTR&Rr2 = Network Fax Map:CTR&Rr2 = CTF Fax Map:CTR&Rr2 = CA Applicant Fax Map:CTR&Rr2 = CA Applicant Email Map:CTR&Rr2 = Legal Rep Fax Map:CTR&Rr2 = Legal Rep Email Map:CTR&Rr2 = Sponsor Email Map:CTR&Rr2 = CTF Email Map:CTRv3.8 = PersonRole.telecomAddress Map:CTRr3 = OrganizationalContact.telecomAddress Map:CTRv1.0 = OrganizationalContact.telecomAddress Map:FDA HL7 SD SD DSTU2012 = manufacturerOrganization/contactParty.telecom Map:FDA HL7 SD SD DSTU2012 = contactParty.telecom Map:HSDBv1.0 = [Sponsor Contact].Email Address Map:HSDBv1.0 = [Sponsor Contact].TTY Map:HSDBv1.0 = [Sponsor Contact].URL Map:HSDBv1.0 = [Sponsor Contact].FAX Map:HSDBv1.0 = [Sponsor Contact].Phone Map:ICSRr2 = ContactParty.telecom (in E_Organization informational) Map:ICSRr2 = ContactParty.telecom (in IndividualCaseSafetyReport)

Attribute	Notes	Constraints and Tags
		Map:ICSRr2 = contactParty.telecom (in R_Product) Map:LSDAMv2.2.3Plus = PointOfContact.telecomAddress Map:LSDAMv2.2.3Plus = OrganizationalContact.telecomAddres s
primaryIndicator <i>Class:</i> PointOfContact <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether this is the main or principal contact. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = OrganizationalContact.primaryIndicat or Map:CTRv1.0 = OrganizationalContact.primaryIndicat or Map:LSDAMv2.2.3Plus = PointOfContact.primaryIndicator Map:LSDAMv2.2.3Plus = OrganizationalContact.primaryIndicat or
effectiveDateRange <i>Class:</i> PointOfContact <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The date (and time) span for when the contact is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = OrganizationalContact.statusDateRang e Map:CTRPv3.8 = StructuralRole.statusCode Map:CTRv1.0 = OrganizationalContact.effectiveDateR ange Map:LSDAMv2.2.3Plus = PointOfContact.effectiveDateRange Map:LSDAMv2.2.3Plus = OrganizationalContact.effectiveDateR ange

Class: ProcessedProduct

Package: Common Sub-Domain

DEFINITION:

Specifies the link between a processor and a product produced by that processor.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = ProcessedProduct
- Map:ICSRr2 = ManufacturedProduct2 (in R_Product)
- Map:LSDAM = Processor.producing(Product)
- Map:LSDAMv2.2.3Plus = Processor.(CellCulture)

Connectors

Source	Connector	Target	Notes
ProcessedProduct 1..* producedProcessedProduct	is produced by	Processor 1 producingProcessor	DESCRIPTION: Each ProcessedProduct always is produced by one Processor. Each Processor

Source	Connector	Target	Notes
			always produces one or more ProcessedProduct. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ProcessedProduct 0..* producingProcessedProduct	produces	Product 1 producedProduct	DESCRIPTION: Each ProcessedProduct always produces one Product. Each Product might be produced by one or more ProcessedProduct. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ProcessedProduct <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A unique symbol used by the processor to establish identify of a particular product type or line.</p> <p>EXAMPLE(S): catalog number</p> <p>OTHER NAME(S):</p> <p>NOTE(S): There are multiple ways in which an identifier can be associated to a product; inherited from MaterialIdentifier.identifier, the association to ProcessedProduct.identifier, and the association to ProductRelationship.identifier. If there is no context associated with the identifier, then MaterialIdentifier.identifier should be used. However, if the identifier for a product would be different in a different context, one of the other identifiers should be used. If a kind of product is produced by different processors, and each processor assigns the product a different identifier, then ProcessedProduct.identifier should be used. If the product is used in multiple assemblies, and in each assembly it would be assigned a different identifier, then ProductRelationship.identifier should be used.</p>	Map:CTRv1.0 = ProcessedProduct.identifier Map:ICSRr2 = ManufacturedProduct2.id (in R_Product)

Class: ProcessingSite

Package: Common Sub-Domain

DEFINITION:

The particular plant or processing location at which the product was processed

EXAMPLE(S):

GSK Zebulon, NC

OTHER NAME(S):

NOTE(S):

The site could pertain to a different corporation than the one which is the formal manufacturer.

Tagged Values:

- Map:AE = ManufacturingSite

Connectors

Source	Connector	Target	Notes
ProcessingSite 0..* performedProcessingSite	is a function performed by	Place 1 performingPlace	<p>DESCRIPTION: Each ProcessingSite always is a function performed by one Place. Each Place might function as one or more ProcessingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessingSite 0..* fabricatedProcessingSite	fabricates	Product 1..* fabricatingProduct	<p>DESCRIPTION: Each ProcessingSite always fabricates one or more Product. Each Product might be fabricated by one or more ProcessingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessingSite 0..* operatedProcessingSite	manufactures for	Processor 1..* operatingProcessor	<p>DESCRIPTION: Each ProcessingSite always manufactures for one or more Processor. Each Processor might manufacture at one or more ProcessingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Class: Processor

Package: Common Sub-Domain

DEFINITION:

An organization defined as being responsible for making, assembling, refurbishing, packaging, etc. a product.

EXAMPLE(S):

The maker identified on the product's box.

OTHER NAME(S):

NOTE(S):

In some cases, the responsible organization will actually be listed as a reprocessor of the item.

Tagged Values:

- Map:AE = Manufacturer
- Map:CTRv1.0 = Processor
- Map:LSDAMv2.2.3Plus = Processor

Connectors

Source	Connector	Target	Notes
Processor 0..* performedProcessor	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each Processor always is a function performed by one Organization. Each Organization might function as one or more Processor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Manufacturer	specializes	Processor	<p>DESCRIPTION: Each Manufacturer always specializes one Processor. Each Processor might be specialized by one Manufacturer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Distributor 0..* representingDistributor	functions as an outlet for	Processor 1..* representedProcessor	<p>DESCRIPTION: Each Distributor always functions as an outlet for one or more Processor. Each</p>

Source	Connector	Target	Notes
			<p>Processor might have as an outlet one or more Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Reprocessor	specializes	Processor	<p>DESCRIPTION: Each Reprocessor always specializes one Processor. Each Processor might be specialized by one Reprocessor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessedProduct 1..* producedProcessedProduct	is produced by	Processor 1 producingProcessor	<p>DESCRIPTION: Each ProcessedProduct always is produced by one Processor. Each Processor always produces one or more ProcessedProduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessingSite 0..* operatedProcessingSite	manufactures for	Processor 1..* operatingProcessor	<p>DESCRIPTION: Each ProcessingSite always manufactures for one or more Processor. Each Processor might manufacture at one or more ProcessingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ProcessProtocol

Package: Common Sub-Domain

DEFINITION:

A standard operating procedure (SOP) that is a collection of activities and the rules that describe when each activity is performed to achieve a specific purpose or objective(s).

EXAMPLE(S): Specimen Collection Protocol; Specimen Processing Protocol; Image Acquisition Protocol

OTHER NAME(S):

NOTE(S):

In modeling, often the same term is used to mean different things and a single concept can have more than one name. In the healthcare arena, the term "protocol" is somewhat overloaded and must be qualified to provide semantic context. Therefore during the early years of the BRIDG project, the term "study protocol" was chosen to disambiguate the concept of the detailed plan for a clinical study (the scope of BRIDG at that time) from other kinds of protocols such as are common in life sciences. In BRIDG, the notion of a study protocol is very specific in purpose and includes (but is not limited to) the design, statistical considerations, activities to test a particular hypothesis or answer a particular question that is the basis of the study, characteristics, specifications, objective(s), background, pre-study/study/post-study portions of the plan (including the design, methodology, statistical considerations, organization). For a more complete discussion of the notion of the study protocol see the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion, StudyConduct and all their associations.

With the addition of life sciences to the scope of the BRIDG model, there came along (with that scope) the need to identify the kind of protocol that represents a more simple or atomic concept, that of "a composite activity that serves as a rule that guides how activities should be performed." This concept, represented by the ProcessProtocol class, has a more limited size than the concept of a study protocol does and represents a standardized approach to doing tasks or activities that are not as big as the plan for a whole study.

The BRIDG SCC acknowledges that overloaded terms are problematic. The SCC recognizes that many different users within the BRIDG community will have differing opinions on what the meaning of a term is, which term is the best to use for each concept, and how to define them most effectively. Given that the real "meat" of a concept is in the definition, the BRIDG SCC aims to choose the most unambiguous term to use as the class name, to make the class definition as explicit and clear as possible, to provide sufficient examples and other names to illustrate the range of possible instances that could be represented by the class. So the BRIDG model is maintaining the distinction between a ProcessProtocol and a StudyProtocol because there is a distinction in the domain that we're trying to disambiguate - the concepts, attributes and relationships that describe an SOP-like, atomic, reusable ProcessProtocol are very different than those of a full-blown clinical trial StudyProtocol. Linking the classes because they both contain the same overloaded word would create artificial complexity in the model and not serve the ultimate purpose of interoperability across systems that need to exchange biomedical research data.

Tagged Values:

- Map:LSDAMv2.2.3Plus = Protocol

Connectors

Source	Connector	Target	Notes
ProcessProtocol	specializes	DefinedActivity	<p>DESCRIPTION: Each ProcessProtocol always specializes one DefinedActivity. Each DefinedActivity might be specialized by one ProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PointOfContact 0..* supportingPointOfContact	support	ProcessProtocol 0..* supportedProtocol	<p>DESCRIPTION: Each PointOfContact might support one or more ProcessProtocol. Each ProcessProtocol might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenProcessingProtocol 1	specializes	ProcessProtocol	<p>DESCRIPTION: Each SpecimenProcessingProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one SpecimenProcessingProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenCollectionProtocol	specializes	ProcessProtocol	<p>DESCRIPTION: Each SpecimenCollectionProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one SpecimenCollectionProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Organization 0..* followingOrganization	follow	ProcessProtocol 0..* followedProtocol	<p>DESCRIPTION: Each Organization might follow one or more ProcessProtocol. Each ProcessProtocol might be followed by one or more Organization.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S): An imaging center may follow a given image acquisition protocol</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ImagingProcessProtocol	specializes	ProcessProtocol	<p>DESCRIPTION: Each ImagingProcessProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one ImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersion 0..1 containingDocumentVersion	contain	ProcessProtocol 0..1 containedProtocol	<p>DESCRIPTION: Each DocumentVersion might contain one ProcessProtocol. Each ProcessProtocol might be the contents of one DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
title <i>Class:</i> ProcessProtocol <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual designation by which the protocol is referenced.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Protocol Context Module - Protocol Name (0018,1030) Map:DICOM = General Series Module - Protocol Name (0018,1030) Map:LSDAMv2.2.3Plus = Protocol.name

Class: Product

Package: Common Sub-Domain

DEFINITION:

A material produced by or resulting from a process.

EXAMPLE(S):

animal and human drugs; therapeutic biologics; allergenics; cell, tissue and gene therapy products; blood components; blood derivative products; devices; animal (pets and livestock) and human food/feed (medicated and un-medicated); cosmetics; pet treats; dietary supplements [examples from FDA's list of regulated products]

Therapeutic devices, software programs, diagnostic or storage equipment, pill bottle, tube rack

Natural or Synthesized DNA

The HeLa cell line, the HEK-293 cell line

OTHER NAME(S):**NOTE(S):**

The term “Product” as a class name in BRIDG is not intended to imply commercial products only, but rather any material that is produced by a process. This includes biologics collected for testing, transplant or replication, as well as tissue that is banked.

Tagged Values:

- Map:AE = Component
- Map:AE = Ingredient
- Map:AE = Product
- Map:caAERSv2.2 = StudyParticipantPriorTherapyAgent
- Map:caAERSv2.2 = CourseAgent
- Map:caAERSv2.2 = Agent
- Map:caAERSv2.2 = ConcomitantMedication
- Map:caAERSv2.2 = PriorTherapyAgent
- Map:CTRPv1.0 = Product
- Map:CTRRr3 = Product
- Map:CTRv1.0 = Product
- Map:HL7SD = Product
- Map:HL7SP = Product
- Map:ICSRr2 = ProductInstance (in R_Product)
- Map:ICSRr2 = product (in A_ProductReportingRelevantInformation)
- Map:ICSRr2 = ManufacturedProduct (in R_Product)
- Map:ICSRr2 = Container (in R_Product)
- Map:ICSRr2 = Substance (in R_Product)
- Map:ICSRr2 = Product (in R_Product)
- Map:ICSRr2 = InstanceOfKind (in R_Product)
- Map:LSDAMv2.2.3Plus = Product

Connectors

Source	Connector	Target	Notes
Product	specializes	Material	<p>DESCRIPTION: Each Product always specializes one Material. Each Material might be specialized by one Product.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedProcedure	use	Product	DESCRIPTION:

Source	Connector	Target	Notes
0..* usingDefinedProcedure		0..* usedProduct	Each DefinedProcedure might use one or more Product. Each Product might be used during one or more DefinedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
FoodProduct	specializes	Product	DESCRIPTION: Each FoodProduct always specializes one Product. Each Product might be specialized by one FoodProduct. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ProductGroup 0..* groupingProductGroup	groups	Product 1..* groupedProduct	DESCRIPTION: Each ProductGroup always groups one or more Product. Each Product might be grouped by one or more ProductGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Biologic	specializes	Product	DESCRIPTION: Each Biologic always specializes one Product. Each Product might be specialized by one Biologic. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Container	specializes	Product	DESCRIPTION: Each Package always specializes one Product.

Source	Connector	Target	Notes
			Each Product might be specialized by one Package. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProcedure 0..* usingPerformedProcedure	use	Product 0..* usedProduct	DESCRIPTION: Each PerformedProcedure might use one or more Product. Each Product might be used during one or more PerformedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	Product 0..1 performingProduct	DESCRIPTION: Each ExperimentalUnit might be a function performed by one Product. Each Product might function as one or more ExperimentalUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyAgent 0..* performedStudyAgent	is a function performed by	Product 1 performingProduct	DESCRIPTION: Each StudyAgent always is a function performed by one Product. Each Product might function as one or more StudyAgent. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedMaterialStorage 0..* usingPerformedMaterialStorage	use	Product 0..* usedProduct	DESCRIPTION: Each PerformedMaterialStorage might use one or more

Source	Connector	Target	Notes
			<p>Product. Each Product might be used during one or more PerformedMaterialStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* usingPerformedProductTransport	use	Product 0..* usedProduct	<p>DESCRIPTION: Each PerformedProductTransport might use one or more Product. Each Product might be used during one or more PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Distributor 0..* providedDistributor	provides	Product 1..* providingProduct	<p>DESCRIPTION: Each Distributor always provides one or more Product. Each Product might be provided by one or more Distributor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Submission 0..* describingSubmission	has as subject	Product 1 describedProduct	<p>DESCRIPTION: Each Submission always has as subject one Product. Each Product might be the subject for one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Device	specializes	Product	<p>DESCRIPTION: Each Device always is specialized by one Product.</p>

Source	Connector	Target	Notes
			<p>Each Product might be specialized by one Device.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductProblemDiscovery 0..* involvingPerformedProductProblemDiscovery	focuses on	Product 1 involvedProduct	<p>DESCRIPTION:</p> <p>Each PerformedProductProblemDiscovery always focuses on one Product. Each Product might be the focus of one or more PerformedProductProblemDiscovery.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedStudyAgentTransfer 0..* transferringPerformedStudyAgentTransfer	is a transfer of	Product 1 transferredProduct	<p>DESCRIPTION:</p> <p>Each PerformedStudyAgentTransfer always is a transfer of one Product. Each Product might be transferred during one or more PerformedStudyAgentTransfer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedStudyAgentTransfer 0..* transferringDefinedStudyAgentTransfer	is a transfer of	Product 1 transferredProduct	<p>DESCRIPTION:</p> <p>Each DefinedStudyAgentTransfer always is a transfer of one Product. Each Product might be transferred during one or more DefinedStudyAgentTransfer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
ProductRelationship 0..* targetProductRelationship	has as source	Product 1 sourceProduct	DESCRIPTION: Each ProductRelationship always has as source one Product. Each Product might be the source for one or more ProductRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ProcessedProduct 0..* producingProcessedProduct	produces	Product 1 producedProduct	DESCRIPTION: Each ProcessedProduct always produces one Product. Each Product might be produced by one or more ProcessedProduct. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Cosmetic	specializes	Product	DESCRIPTION: Each Cosmetic always specializes one Product. Each Product might be specialized by one Cosmetic. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Subject 0..* performedSubject	be a function performed by	Product 0..1 performingProduct	DESCRIPTION: Each Subject might be a function performed by one Product. Each Product might function as one or more Subject. DEFINITION: EXAMPLE(S):

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
ProcessingSite 0..* fabricatedProcessingSite	fabricates	Product 1..* fabricatingProduct	DESCRIPTION: Each ProcessingSite always fabricates one or more Product. Each Product might be fabricated by one or more ProcessingSite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Drug	specializes	Product	DESCRIPTION: Each Drug always specializes one Product. Each Product might be specialized by one Drug. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ProductRelationship 0..* sourceProductRelationship	has as target	Product 1 targetProduct	DESCRIPTION: Each ProductRelationship always has as target one Product. Each Product might be the target for one or more ProductRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> Product <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of product.</p> <p>EXAMPLE(S): veterinary medicine, diagnostic device, tissue, fluid, cell, molecule, protein, clot tube, KEDTA, ACD, sterile specimen cup, data analysis software, instrument controlling software</p> <p>OTHER NAME(S):</p> <p>NOTE(S): All members of a type share similar functions and general characteristics, especially the purpose for which they are used.</p>	Map:AE = Ingredient.typeCode Map:AE = Package.typeCode Map:AE = Product.typeCode Map:AE = Component.typeCode Map:caAERSv2.2 = MedicalDevice.deviceType Map:CTR&Rr2 = Contains Scaffolds Map:CTR&Rr2 = Device implantable Map:CTR&Rr2 = Herbal MP Map:CTR&Rr2 = Device Other Map:CTR&Rr2 = Contains Bio-materials Map:CTR&Rr2 = Contains Matrices Map:CTR&Rr2 = Contains medical device Map:CTR&Rr2 = Other MP Map:CTR&Rr2 = Homeopathic MP Map:CTR&Rr2 = Other MP Specification Map:CTRPv1.0 = Product.typeCode Map:CTRPv1.0 = Cosmetic.typeCode Map:CTRPv1.0 = Device.typeCode Map:CTRPv1.0 = Drug.typeCode Map:CTRPv1.0 = FoodProduct.typeCode Map:CTRPv1.0 = Biologic.typeCode Map:CTRPv3.8 = Intervention.typeCode Map:CTRPv3.8 = PlannedSubstanceAdministration.radiationMachineType Map:CTRr3 = Product.typeCode Map:CTrv1.0 = Product.typeCode Map:DICOM = CT Series Module - Modality (0008,0060) Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Modalities in Study (0008,0061) Map:DICOM = General Series Module - Modality (0008,0060) Map:DICOM = Enhanced PET Series Module - Modality (0008,0060) Map:DICOM = MR Series Module - Modality (0008,0060) Map:DICOM = Equipment Specification Module - Equipment Modality (0008,0221) Map:HCTv1.0 = CDE 2741552:Preparative Regimen.What type of radiolabeled monoclonal antibody was used as a preparative regimen? Map:HCTv1.0 = CDE 2741209:Preparative Regimen.What was the type of preparative regimen monoclonal antibody (MAb)? Map:HCTv1.0 = CDE 2705055:Lab Results.Please specify the person for whom this typing is being done: Map:HCTv1.0 = CDE 2730912:Cell

Attribute	Notes	Constraints and Tags
		<p>Source.What type of hematopoietic stem cell transplant was used?</p> <p>Map:HCTv1.0 = CDE 2693219:LabResults.Who is being tested for IDMs?</p> <p>Map:HCTv1.0 = CDE 2750847:Preparative Regimen.What was the type of anthracycline preparative regimen?</p> <p>Map:HCTv1.0 = CDE 2746489:Techniques.Specify other antibody.</p> <p>Map:HCTv1.0 = CDE 2527917:Cell Source.Specify the other hematopoietic stem cell transplant type:</p> <p>Map:HL7SD = Product.code</p> <p>Map:ICSRr2 = Substance.code (in R_Product)</p> <p>Map:ICSRr2 = Product.code (in R_Product)</p> <p>Map:ICSRr2 = PackagedProduct.code (in R_Product)</p> <p>Map:ICSRr2 = Container.code (in R_Product)</p> <p>Map:LSDAMv2.2.3Plus = Product.typeCode</p> <p>Map:LSDAMv2.2.3Plus = DefinedSpecimenEmbedded.embeddingMediumType</p> <p>Map:LSDAMv2.2.3Plus = Container.containerType</p> <p>Map:LSDAMv2.2.3Plus = PerformedSpecimenEmbedded.embeddingMediumType</p> <p>Map:LSDAMv2.2.3Plus = Material.typeCode</p> <p>Map:LSDAMv2.2.3Plus = InvitroCharacterization.cellType</p> <p>Map:LSDAMv2.2.3Plus = Software.typeCode</p>

Attribute	Notes	Constraints and Tags
classCode <i>Class:</i> Product <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying a group of products that are homogeneous or generally considered as substitutes for each other.</p> <p>EXAMPLE(S): stents, breakfast cereals, cox-2 inhibitors</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The class is considered as narrow or broad depending on how substitutable the various products are.</p>	Map:AE = ProductClass.typeCode Map:AE = ProductClass Map:AE = ProductClass.name Map:CDASHv1.1 = CM.CMCLAS Map:CDASHv1.1 = CM.CMCLASCD Map:CTR&Rr2 = Radiopharmaceutical MP Map:CTR&Rr2 = Immunological MP Map:CTR&Rr2 = Extractive MP Map:CTR&Rr2 = Advanced Therapy MP Map:CTR&Rr2 = Gene therapy MP Map:CTR&Rr2 = Somatic cell therapy MP Map:CTR&Rr2 = Recombinant MP Map:CTR&Rr2 = CAT Classification Map:CTR&Rr2 = GMO (Genetically Modified Organism) MP Map:CTR&Rr2 = Plasma derived MP Map:CTR&Rr2 = IMP ATC Code Map:CTR&Rr2 = Tissue Engineered MP Map:CTR&Rr2 = AS CAS (Chemical Abstract Service) number Map:CTR&Rr2 = Combination ATIMP Map:CTR&Rr2 = CAT (committee for Advanced therapies) Classification issued Map:CTRPv1.0 = Biologic.classCode Map:CTRPv1.0 = Cosmetic.classCode Map:CTRPv1.0 = Product.classCode Map:CTRPv1.0 = Device.classCode Map:CTRPv1.0 = Drug.classCode Map:CTRPv1.0 = FoodProduct.classCode Map:CTRr3 = Product.classCode Map:CTrv1.0 = Product.classCode Map:dicom = Equipment Specification Module - Model Specification Sequence (0018,9912) > Manufacturer's Related Model Group (0008,0222) Map:FDA HL7 SD DSTU2012 = manufacturedProduct.classCode Map:FDA HL7 SD DSTU2012 = ingredient.classCode Map:HL7SD = Product.classCode Map:LSDAMv2.2.3Plus = DefinedSpecimenEmbedded.embeddingMediumType Map:PGx v1.0 = PB.PBDRUG Map:SDTM IGv3.1.1 = CM.CMCLAS Map:SDTM IGv3.1.1 = SU.SUCLAS Map:SDTM IGv3.1.1 = CM.CMCLASCD Map:SDTM IGv3.1.1 = SU.SUCLASCD Map:SDTM IGv3.1.2 = CM.CMCLASCD Map:SDTM IGv3.1.2 =

Attribute	Notes	Constraints and Tags
		SU.SUCLASCD Map:SDTM IGv3.1.2 = CM.CMCLAS Map:SDTM IGv3.1.2 = SU.SUCLAS Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "PCLAS" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "PCLAS" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "PCLAS" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "PCLAS" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "PCLAS" Map:SDTM IGv3.1.3 = SU.SUCLASCD Map:SDTM IGv3.1.3 = SU.SUCLAS Map:SDTM IGv3.1.3 = CM.CMCLAS Map:SDTM IGv3.1.3 = CM.CMCLASCD
codeModifiedText <i>Class:</i> Product <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string that is a revision of the original text of the product to enable the coding of the text.</p> <p>EXAMPLE(S): If the original text is "aspriin", the CodeModifiedText could be set to "aspirin", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p>	Map:CTRv1.0 = Product.codeModifiedText Map:SDTM IGv3.1.1 = CM.CMMODIFY Map:SDTM IGv3.1.1 = SU.SUMODIFY Map:SDTM IGv3.1.2 = CM.CMMODIFY Map:SDTM IGv3.1.2 = SU.SUMODIFY Map:SDTM IGv3.1.3 = SU.SUMODIFY Map:SDTM IGv3.1.3 = CM.CMMODIFY

Attribute	Notes	Constraints and Tags
lotNumberText <i>Class:</i> Product <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An alphanumeric string used to identify a particular batch of the product.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Product.lotNumber Map:AE = Package.lotNumber Map:caAERSv2.2 = MedicalDevice.lotNumber Map:caAERSv2.2 = CourseAgent.lotNumber Map:CDASHv1.1 = EX.EXLOT Map:CTOM = AgentOccurrence.lotNumber Map:CTRPv1.0 = FoodProduct.lotNumberText Map:CTRPv1.0 = Drug.lotNumberText Map:CTRPv1.0 = Cosmetic.lotNumberText Map:CTRPv1.0 = Biologic.lotNumberText Map:CTRp1.0 = Product.lotNumberText Map:ICSRr2 = DeviceInstance.lotNumberText (in R_Product) Map:ICSRr2 = ProductInstance.lotNumberText (in R_Product) Map:ICSRr2 = Container.lotNumberText (in R_Product) Map:LSDAMv2.2.3Plus = Product.lotNumberText Map:NCI CRF Standard = CDE 62592v3.0: Agent Lot Identifier Number Map:SDTM IGv3.1.1 = EX.EXLOT Map:SDTM IGv3.1.2 = EX.EXLOT Map:SDTM IGv3.1.3 = EX.EXLOT

Attribute	Notes	Constraints and Tags
expirationDate <i>Class:</i> Product <i>Datatype:</i> TS.DATE.FULL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The date (and time), assigned by the manufacturer, on which the product should not be used. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Product.expirationDate Map:CTOM = AgentOccurrence.expirationDate Map:CTRPv1.0 = Drug.expirationDate Map:CTRPv1.0 = FoodProduct.expirationDate Map:CTRPv1.0 = Device.expirationDate Map:CTRPv1.0 = Biologic.expirationDate Map:CTRPv1.0 = Cosmetic.expirationDate Map:CTRPv1.0 = Product.expirationDate Map:CTRv1.0 = Product.expirationDate Map:ICSRr2 = ProductInstance.expirationTime (in R_Product) Map:ICSRr2 = Product.expirationTime (in R_Product) Map:ICSRr2 = DeviceInstance.expirationTime (in R_Product) Map:LSDAMv2.2.3Plus = Product.expirationDate
pre1938Indicator <i>Class:</i> Product <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the product qualifies under the 1938 Grandfather Clause, contained in section 201(p)(l) of the U.S. Federal Food, Drug and Cosmetic Act. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Product.pre1938Indicator Map:CTRPv1.0 = Product.pre1938Indicator Map:CTRPv1.0 = Cosmetic.pre1938Indicator Map:CTRPv1.0 = Device.pre1938Indicator Map:CTRPv1.0 = Drug.pre1938Indicator Map:CTRPv1.0 = FoodProduct.pre1938Indicator Map:CTRPv1.0 = Biologic.pre1938Indicator Map:CTRv1.0 = Product.pre1938Indicator

Class: ProductGroup

Package: Common Sub-Domain

DEFINITION:
A collection of instances of a product.

EXAMPLE(S):
10 pills, 5 pace makers

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:HL7SD = GroupKind

Connectors

Source	Connector	Target	Notes
ProductGroup 0..* groupingProductGroup	groups	Product 1..* groupedProduct	<p>DESCRIPTION: Each ProductGroup always groups one or more Product. Each Product might be grouped by one or more ProductGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalUnit 0..* performedExperimentalUnit	be a function performed by	ProductGroup 0..1 performingProductGroup	<p>DESCRIPTION: Each ExperimentalUnit might be a function performed by one ProductGroup. Each ProductGroup might function as one or more ExperimentalUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ProductGroup <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A unique symbol that establishes identity of the product group.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HL7SD = GroupKind.id
quantity <i>Class:</i> ProductGroup <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The number of members in a product group.</p> <p>EXAMPLE(S): 10 pills, 5 pace makers</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HL7SD = GroupKind.quantity

Attribute	Notes	Constraints and Tags
actualIndicator <i>Class:</i> ProductGroup <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: Specifies whether the product group is a particular instance (actual) vs. universal kind.</p> <p>EXAMPLE(S): To indicate a particular ProductGroup, actualIndicator = "true". To indicate a kind of ProductGroup, actualIndicator = "false".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HL7SD = ExperimentalUnit>ExperimentalUnit2 (choice box).determinerCode

Class: ProductRelationship

Package: Common Sub-Domain

DEFINITION:
Specifies the link between one product and another.

EXAMPLE(S):
lot, content, kind, part, ingredient, package, assembly, specialized, equivalent

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:BRIDGSCC = Model Integrity
- Map:CTRRr3 = ProductPart
- Map:CTRv1.0 = ProductRelationship
- Map:ICSRr2 = Member1 (in R_Product)
- Map:ICSRr2 = ingredient1 (in R_Product)
- Map:ICSRr2 = Ingredient (in R_Product)
- Map:ICSRr2 = Member (in R_Product)
- Map:ICSRr2 = Content (in R_Product)
- Map:ICSRr2 = Content1 (in R_Product)
- Map:ICSRr2 = InstanceOfKind2 (in R_Product)
- Map:ICSRr2 = EquivalentEntity (in R_Product)
- Map:ICSRr2 = SpecializedKind (in R_Product)
- Map:ICSRr2 = Content3 (in R_Product)
- Map:ICSRr2 = Content2 (in R_Product)
- Map:ICSRr2 = PartOfAssembly (in R_Product)
- Map:ICSRr2 = part (in R_Product)
- Map:ICSRr2 = EquivalentSubstance (in R_Product)
- Map:ICSRr2 = part1 (in R_Product)
- Map:LSDAMv2.2.3Plus = MaterialRelationship
- Map:LSDAMv2.2.3Plus = Equipment.(Software)
- Map:LSDAMv2.2.3Plus = Container.(Container)

Connectors

Source	Connector	Target	Notes
ProductRelationship 0..* targetProductRelationship	has as source	Product 1 sourceProduct	<p>DESCRIPTION: Each ProductRelationship always has as source one Product. Each Product might be the source for one or more ProductRelationship.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProductRelationship 0..* sourceProductRelationship	has as target	Product 1 targetProduct	<p>DESCRIPTION: Each ProductRelationship always has as target one Product. Each Product might be the target for one or more ProductRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ProductRelationship <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A unique symbol that establishes identity of the product within the context of another product.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): There are multiple ways in which an identifier can be associated to a product; inherited from MaterialIdentifier.identifier, the association to ProcessedProduct.identifier, and the association to ProductRelationship.identifier. If there is no context associated with the identifier, then MaterialIdentifier.identifier should be used. However, if the identifier for a product would be different in different context, one of the other identifiers should be used. If a kind of product is produced by different processors, and each processor assigns the product a different identifier, then ProcessedProduct.identifier should be used. If the product is used in multiple assemblies, and in each assembly it would be assigned a different identifier, then ProductRelationship.identifier should be used.</p>	<p>Map: CTRv1.0 = ProductRelationship.identifier Map: ICSRr2 = Ingredient.id (in R_Product) Map: ICSRr2 = Part.id (in R_Product)</p>

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> ProductRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of relationship a product has with another product.</p> <p>EXAMPLE(S): lot, content, kind, part, ingredient, package, assembly, specialized, equivalent</p> <p>For Life Science: linkage using entrapment, linkage using encapsulation; core part, shell part, coat part</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = ProductRelationship.typeCode Map:ICSRr2 = EquivalentEntity.code (in R_Product) Map:ICSRr2 = SpecializedKind.code (in R_Product) Map:LSDAMv2.2.3Plus = MaterialRelationship.typeCode Map:LSDAMv2.2.3Plus = MaterialRelationship.subTypeCode

Attribute	Notes	Constraints and Tags
quantity <i>Class:</i> ProductRelationship <i>Datatype:</i> RTO<PQ,PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An indication of the amount of one product contained in another product.</p> <p>EXAMPLE(S): 50 mg per tablet, 300 ml / liter</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Ingredient.strength Map:CTRPv1.0 = FoodProduct.strength Map:CTRPv1.0 = Cosmetic.strength Map:CTRPv1.0 = Biologic.strength Map:CTRPv1.0 = Drug.strength Map:CTRr3 = ProductPart.strength Map:CTRv1.0 = ProductRelationship.quantity Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast/Bolus Ingredient Concentration (0018,1049) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Ingredient Concentration (0018, 1049) Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast/Bolus Ingredient Percent by Volume (0052,0001) Map:FDA HL7 SD SD DSTU2012 = ingredient.quantity Map:ICSRr2 = Content1.quantity (in R_Product) Map:ICSRr2 = Container.capacityQuantity (in R_Product) Map:ICSRr2 = Ingredient1.quantity (in R_Product) Map:ICSRr2 = ProductInstance.quantity (in R_Product) Map:ICSRr2 = InstanceOfKind.quantity (in R_Product) Map:ICSRr2 = Content.quantity (in R_Product) Map:ICSRr2 = Ingredient.quantity (in R_Product) Map:ICSRr2 = part.quantity (in R_Product) Map:ICSRr2 = Content2.quantity (in R_Product) Map:ICSRr2 = EquivalentSubstance.quantity (in R_Product) Map:ICSRr2 = DeviceInstance.quantity (in R_Product)

Attribute	Notes	Constraints and Tags
confidentialityCode <i>Class:</i> ProductRelationship <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	DEFINITION: A coded value specifying the privacy requirements for information about this relationship. EXAMPLE(S): A manufacturer considers an ingredient in a product to be a trade secret. OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ProductRelationship.confidentialityCode Map:ICSRr2 = Ingredient.confidentialityCode (in R_Product)
activeIngredientIndicator <i>Class:</i> ProductRelationship <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the ingredient is an active ingredient. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:AE = Ingredient.activeIngredientIndicator Map:CTR&Rr2 = Biological origin AS Map:CTR&Rr2 = Chemical origin AS Map:CTRPv1.0 = Drug.activeIngredientIndicator Map:CTRPv1.0 = Cosmetic.activeIngredientIndicator Map:CTRPv1.0 = FoodProduct.activeIngredientIndicator Map:CTRRr3 = ProductPart.activeIngredientIndicator Map:CTRv1.0 = ProductRelationship.activeIngredientIndicator
effectiveDateRange <i>Class:</i> ProductRelationship <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The date (and time) span for when the product relationship is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ProductRelationship.effectiveDateRange Map:ICSRr2 = Ingredient.effectiveTime (in R_Product)

Class: Project

Package: Common Sub-Domain

DEFINITION:
A set of coordinated activities that is intended to achieve one or more objectives.

EXAMPLE(S):
The Cancer Genome Atlas (TCGA)
The Breast and Colon Cancer Family Registries

OTHER NAME(S):

NOTE(S):

- Tagged Values:*
- Map:LSDAMv2.2.3Plus = InvestigationalStudy

Connectors

Source	Connector	Target	Notes
ClinicalDevelopmentPlan	specializes	Project	<p>DESCRIPTION: Each ClinicalDevelopmentPlan always specializes one Project. Each Project might be specialized by one ClinicalDevelopmentPlan.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ResearchProject	specializes	Project	<p>DESCRIPTION: Each ResearchProject always specializes one Project. Each Project might be specialized by one ResearchProject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NonResearchProject	specializes	Project	<p>DESCRIPTION: Each NonResearchProject always specializes one Project. Each Project might be specialized by one NonResearchProject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProjectRelationship 0..* sourceProjectRelationship	has as target	Project 1 targetProject	<p>DESCRIPTION: Each ProjectRelationship always has as target one Project. Each Project might be the target for one or more ProjectRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PointOfContact 0..* supportingPointOfContact	support	Project 0..* supportedProject	<p>DESCRIPTION: Each PointOfContact might support one or more Project. Each Project might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* usedActivity	be used by	Project 0..1 usingProject	<p>DESCRIPTION: Each Activity might be used by one Project. Each Project might use one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProjectRelationship 0..* targetProjectRelationship	has as source	Project 1 sourceProject	<p>DESCRIPTION: Each ProjectRelationship always has as source one Project. Each Project might be the source for one or more ProjectRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProjectConduct 0..1 instantiatedProjectExecution	is the execution of	Project 1 instantiatingProject	<p>DESCRIPTION: Each ProjectConduct always is the execution of one Project. Each Project might have as execution one ProjectConduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Project <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A unique symbol that establishes the identity of the project. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:Vendor1v1.1 = Project.identifier
name <i>Class:</i> Project <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A non-unique identifier by which the investigational study or experiment is known or referred. EXAMPLE(S): The Cancer Genome Atlas (TCGA) The Breast and Colon Cancer Family Registries OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = InvestigationalStudy.name Map:LSDAMv2.2.3Plus = ActivityCollection.name Map:Vendor1v1.1 = Project.name
type <i>Class:</i> Project <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A term allowing the classification of projects into categories. EXAMPLE(S): WAS (genome wide association study, e.g., for colon cancer biomarkers) Na ⁺ Channel activity in yfg knockout mouse Pharmacological activity of compound XYZ microarray experiment model organism experiment Clinical Development Plan for compound XYZ OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = InvestigationalStudy.typeCode Map:LSDAMv2.2.3Plus = ActivityCollection.typeCode Map:Vendor1v1.1 = Study.typeCode Map:Vendor1v1.1 = Project.typeCode
description <i>Class:</i> Project <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A textual explanation of the project, with components, such as objectives or goals. [source: ISA-TAB] EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = InvestigationalStudy.description Map:LSDAMv2.2.3Plus = ActivityCollection.description Map:Vendor1v1.1 = Project.description

Class: ProjectConduct

Package: Common Sub-Domain

DEFINITION:
An ongoing and/or past performance of a project.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = InvestigationalStudy.activeDateRange

Connectors

Source	Connector	Target	Notes
ProjectConduct 0..1 instantiatedProjectExecution	is the execution of	Project 1 instantiatingProject	<p>DESCRIPTION: Each ProjectConduct always is the execution of one Project. Each Project might have as execution one ProjectConduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyConduct	specializes	ProjectConduct	<p>DESCRIPTION: Each StudyConduct always specializes one ProjectState. Each ProjectState might be specialized by one StudyConduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NonResearchProjectConduc t	specializes	ProjectConduct	<p>DESCRIPTION: Each NonResearchProjectState always specializes one ProjectState. Each ProjectState might be specialized by one NonResearchProjectState.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
dateRange <i>Class:</i> ProjectConduct <i>Datatype:</i> IVL<TS.DATE.FULL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies the period of time over which the project was executed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): May specify the start and/or end or duration. For the StudyConduct subclass, this attribute can be derived from the StudyOverallStatus.date values where StudyOverallStatus.code = "Study Activated" and "Study Completed".</p>	Map:CTRv1.0 = StudyExecution.effectiveDateRange Map:LSDAMv2.2.3Plus = InvestigationalStudy.activeDateRange Map:LSDAMv2.2.3Plus = ActivityCollection.activeDateRange Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "SSTDTC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SSTDTC" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "SENDTC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SENDTC" Map:Vendor1v1.1 = StudyExecution.effectiveDateRange

Class: ProjectRelationship

Package: Common Sub-Domain

DEFINITION:
Specifies the link between one project and another.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = InvestigationalStudy.(ActivityCollection)

Connectors

Source	Connector	Target	Notes
ProjectRelationship 0..* sourceProjectRelationship	has as target	Project 1 targetProject	<p>DESCRIPTION: Each ProjectRelationship always has as target one Project. Each Project might be the target for one or more ProjectRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProjectRelationship 0..* targetProjectRelationship	has as source	Project 1 sourceProject	<p>DESCRIPTION: Each ProjectRelationship always has as source one Project. Each Project might be the source for one or more ProjectRelationship.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> ProjectRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of project relationship.</p> <p>EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>	Map:LSDAMv2.2.3Plus = (model integrity)

Class: QualifiedPerson

Package: Common Sub-Domain

DEFINITION:

A person that has been recognized as having certain training/experience or other characteristics that would make that person an appropriate performer for a certain activity.

EXAMPLE(S):

board certification, academic degree, medical license

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTGOV = Investigators - Degrees
- Map:CTGOV = Facility Contact - Degree
- Map:CTGOV = Overall State Officials - Degree
- Map:CTGOV = Central Contact - Degrees
- Map:CTRv1.0 = QualifiedPerson
- Map:ICSRr2 = QualifiedEntity (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
QualifiedPerson 0..* performedQualifiedPerson	is a function performed by	Person 1 performingPerson	<p>DESCRIPTION: Each QualifiedPerson always is a function performed by one Person. Each Person might function as one or more QualifiedPerson.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
QualifiedPerson 0..* credentialedQualifiedPerson	is credentialed by	Organization 1 credentialingOrganization	<p>DESCRIPTION: Each QualifiedPerson always is credentialed by one Organization. Each Organization might credential one or more QualifiedPerson.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
QualifiedPerson 0..* locatedQualifiedPerson	be qualified in	Place 0..1 locatingPlace	<p>DESCRIPTION: Each QualifiedPerson might be qualified in one Place. Each Place might be the location in which the qualification is granted for one or more QualifiedPerson.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> QualifiedPerson <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A unique symbol that establishes identity of the qualified person.</p> <p>EXAMPLE(S): The identifier assigned in the NCI investigator registry (National Cancer Institute Principal Investigator Identifier Number) to a physician approved for conducting a clinical study.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = RemoteResearchStaff.externalId Map:C3PRv2.9 = Investigator.assignedIdentifier Map:CTGOV = Central Contact - Degrees Map:CTGOV = Investigators - Degrees Map:CTGOV = Facility Contact - Degree Map:CTGOV = Overall State Officials - Degree Map:CTRv1.0 = QualifiedPerson.identifier Map:LabViewer2.2 = Investigator.identifier

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> QualifiedPerson <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the kind of qualification a person has. EXAMPLE(S): license, academic degree OTHER NAME(S): NOTE(S):	Map:CTGOV = Investigators - Degrees Map:CTGOV = Facility Contact - Degree Map:CTGOV = Central Contact - Degrees Map:CTGOV = Overall State Officials - Degree Map:CTRv1.0 = QualifiedPerson.typeCode Map:ICSRr2 = QualifiedEntity.code (in IndividualCaseSafetyReport)
certificateLicenseText <i>Class:</i> QualifiedPerson <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A character string that describes the specific credentials of the qualified person. EXAMPLE(S): MD from the John Hopkins University School of Medicine, Medical license from the state of Maryland, Certification from the American Board of Pediatrics OTHER NAME(S): NOTE(S):	Map:AE = Reporter.qualificationForReporting Map:CTGOV = Facility Contact - Degree Map:CTGOV = Investigators - Degrees Map:CTGOV = Central Contact - Degrees Map:CTGOV = Overall State Officials - Degree Map:CTR&Rr2 = Investigator qualifications Map:CTRv1.0 = HealthCareProvider.certificateLicenseText Map:CTRv3.8 = HealthCareProvider.certificateLicenseText Map:CTRv1.0 = QualifiedPerson.certificateLicenseText
effectiveDateRange <i>Class:</i> QualifiedPerson <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) span for when the qualification of this person is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTGOV = Facility Contact - Degree Map:CTGOV = Overall State Officials - Degree Map:CTGOV = Central Contact - Degrees Map:CTGOV = Investigators - Degrees Map:CTRv1.0 = QualifiedPerson.effectiveDateRange

Class: ReportReceiver

Package: Common Sub-Domain

DEFINITION:

A role of a person or an organization that receives or is intended to receive a report..

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Receiver
- Map:caAERSv2.2 = ReportDelivery
- Map:CTRv1.0 = ReportReceiver
- Map:ICSRr2 = AssignedEntity (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Participant1 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = LocatedEntity2 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = PrimaryInformationRecipient (in IndividualCaseSafetyReport)
- Map:ICSRr2 = LocatedEntity (in IndividualCaseSafetyReport)
- Map:ICSRr2 = AssignedEntity.code (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
ReportReceiver 0..* receivingReportReceiver	receives	ReportVersion 1 receivedReportVersion	<p>DESCRIPTION: Each ReportReceiver always receives one ReportVersion. Each ReportVersion might be received by one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportReceiver 0..* performedReportReceiver	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each ReportReceiver might be a function performed by one Organization. Each Organization might function as one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportReceiver 0..* performedReportReceiver	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each ReportReceiver might be a function performed by one Person. Each Person might function as one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
receivedDate <i>Class:</i> ReportReceiver <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the report was received. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ReportReceiver.receivedDate Map:ICSR2 = PrimaryInformationRecipient.time (in IndividualCaseSafetyReport)
receivedIndicator <i>Class:</i> ReportReceiver <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Specifies whether the receiver received the report. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = ReportReceiver.receivedIndicator Map:ICSR2 = PrimaryInformationRecipient.negationInd (in IndividualCaseSafetyReport)

Class: ReportSubmitter

Package: Common Sub-Domain

DEFINITION:
A role of a person who submits a report.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = RoleBasedRecipient.role
- Map:caAERSv2.2 = Submitter
- Map:CTRv1.0 = ReportSubmitter

Connectors

Source	Connector	Target	Notes
ReportSubmitter 1..* submittingReportSubmitter	submits	SafetyReportVersion 1 submittedSafetyReportVersion	DESCRIPTION: Each ReportSubmitter always submits one SafetyReportVersion. Each SafetyReportVersion always is submitted by one or more ReportSubmitter. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ReportSubmitter 0..* performedReportSubmitter	is a function performed by	ResearchStaff 1 performingResearchStaff	DESCRIPTION: Each ReportSubmitter always is a function

Source	Connector	Target	Notes
			<p>performed by one ResearchStaff. Each ResearchStaff might function as one or more ReportSubmitter.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	ReportSubmitter 0..1 performingReportSubmitter	<p>DESCRIPTION: Each NotificationReceiver might be a function performed by one ReportSubmitter. Each ReportSubmitter might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ReportVersion

Package: Common Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Safety Report, Study Report

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = ReportReceipt
- Map:C3PRv2.9 = ReportVersion
- Map:caAERSv2.2 = Report
- Map:CTRRr3 = Report
- Map:CTRv1.0 = ReportVersion

Connectors

Source	Connector	Target	Notes
ReportVersion 0..* describingReportVersion	describe	PerformedObservationResult 0..*	DESCRIPTION: Each ReportVersion might describe one or more

Source	Connector	Target	Notes
		describedPerformedObservationResult	<p>PerformedObservationResult. Each PerformedObservationResult might be described by one or more ReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): surgical pathology report describes observations about a specimen collection group</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each ReportVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one ReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportReceiver 0..* receivingReportReceiver	receives	ReportVersion 1 receivedReportVersion	<p>DESCRIPTION: Each ReportReceiver always receives one ReportVersion. Each ReportVersion might be received by one or more ReportReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SafetyReportVersion	specializes	ReportVersion	<p>DESCRIPTION: Each SafetyReportVersion always specializes one ReportVersion. Each ReportVersion might be specialized by one SafetyReportVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
communicationModeCode <i>Class:</i> ReportVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the form in which the report version is transmitted.</p> <p>EXAMPLE(S): physically present, over the telephone, written communication, electronic</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Constraints and Tags</p> <p>Map:AE = ReportReceipt.modeCode Map:CTRv1.0 = ReportVersion.communicationModeCode Map:ICSRr2 = PrimaryInformationRecipient.modeCode (in IndividualCaseSafetyReport)</p>
physicianSignOffIndicator <i>Class:</i> ReportVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the physician has reviewed and signed off on a version of a report.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the physicianSignoffIndicator could be derived from the existence of an authenticating person for the report. However, authenticating person is not represented in the BRIDG model because this use case has not yet been formally presented to BRIDG. If and when this use case is presented to BRIDG the physicianSignoffIndicator will be marked as derived, but for now this attribute will remain as not derivable.</p>	<p>Map:caAERSv2.2 = ReportVersion.physicianSignOff Map:CTRv1.0 = ReportVersion.physicianSignOffIndicator</p>
dueDate <i>Class:</i> ReportVersion <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the report version is expected or scheduled to be submitted.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:caAERSv2.2 = Report.dueDate Map:caAERSv2.2 = ReportVersion.dueOn Map:CTRv1.0 = ReportVersion.dueDate</p>

Class: Reprocessor

Package: Common Sub-Domain

DEFINITION:

An organization that is typically in the business of re-using or refurbishing a product (such as a medical device) so that it can be used again. These kind of organizations must comply with the same requirements that apply to original equipment manufacturers.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

These organizations are typically referred to as third part or hospital reprocessors. Reprocessing of medical devices is done to save costs and reduce wastes.

Tagged Values:

- Map:CTRv1.0 = Reprocessor
- Map:LSDAMv2.2.3Plus = Reprocessor

Connectors

Source	Connector	Target	Notes
Reprocessor	specializes	Processor	<p>DESCRIPTION: Each Reprocessor always specializes one Processor. Each Processor might be specialized by one Reprocessor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ResearchOrganization

Package: Common Sub-Domain

DEFINITION:

An organization whose purpose is to support systemic, rigorous study and investigation into a particular field or fields.

EXAMPLE(S):

Clinical Research Organization (CRO)

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = ResearchInstitution
- Map:CTRPv1.0 = ResearchOrganization
- Map:CTRPv3.8 = ResearchOrganization
- Map:CTRv1.0 = ResearchOrganization

Connectors

Source	Connector	Target	Notes
ResearchOrganization 0..1 performedResearchOrganiza tion	is a function performed by	Organization 1 performingOrganization	<p>DESCRIPTION: Each ResearchOrganization always is a function performed by one Organization. Each Organization might function as one ResearchOrganization.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
ResearchStaff 0..* staffingResearchStaff	staffs	ResearchOrganization 1 staffedResearchOrganization n	DESCRIPTION: Each ResearchStaff always staffs one ResearchOrganization. Each ResearchOrganization might be staffed by one or more ResearchStaff. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> ResearchOrganization <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the kind of research organization. EXAMPLE(S): cancer center, institute, drug company, clinical center OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = ResearchOrganization.typeCode Map:CTRPv3.8 = ResearchOrganization.typeCode Map:CTRv1.0 = ResearchOrganization.typeCode Map:HL7SP = Service Provider.code
effectiveDateRange <i>Class:</i> ResearchOrganization <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) span for when the research organization is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = ResearchOrganization.statusDateRange Map:CTRPv1.0 = ResearchOrganization.statusCode Map:CTRv1.0 = ResearchOrganization.effectiveDateRange Map:HL7SP = Service Provider.effectiveTime Map:HL7SP = Service Provider.statusCode

Class: ResearchProject

Package: Common Sub-Domain

DEFINITION:

A project that is intended to generate or test one or more hypotheses or lead to discoveries.

EXAMPLE(S):

A project to identify genetic biomarkers for cancer prognosis

A phase 2 clinical trial to test whether an experimental treatment is effective.

An epidemiological study to determine whether there is a correlation between an exposure and a disease.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = ActivityCollection

Connectors

Source	Connector	Target	Notes
ResearchProject	specializes	Project	<p>DESCRIPTION: Each ResearchProject always specializes one Project. Each Project might be specialized by one ResearchProject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Experiment	specializes	ResearchProject	<p>DESCRIPTION: Each Experiment always specializes one ResearchProject. Each ResearchProject might be specialized by one Experiment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Study	specializes	ResearchProject	<p>DESCRIPTION: Each Study always specializes one ResearchProject. Each ResearchProject might be specialized by one Study.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ResearchStaff

Package: Common Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = ResearchStaff
- Map:caAERSv2.2 = SiteResearchStaff
- Map:caAERSv2.2 = ResearchStaff
- Map:CTRPv1.0 = ClinicalResearchStaff
- Map:CTRPv3.8 = ClinicalResearchStaff
- Map:CTRr3 = ResearchStaff
- Map:CTRv1.0 = ResearchStaff

Connectors

Source	Connector	Target	Notes
ResearchStaff 0..* staffingResearchStaff	staffs	ResearchOrganization 1 staffedResearchOrganization	<p>DESCRIPTION: Each ResearchStaff always staffs one ResearchOrganization. Each ResearchOrganization might be staffed by one or more ResearchStaff.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ResearchStaff	specializes	OrganizationStaffRole	<p>DESCRIPTION: Each ResearchStaff always specializes one OrganizationStaffRole. Each OrganizationStaffRole might be specialized by one ResearchStaff.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySitePersonnel 0..* performedStudySitePersonnel	be a function performed by	ResearchStaff 0..1 performingResearchStaff	<p>DESCRIPTION: Each StudySitePersonnel might be a function</p>

Source	Connector	Target	Notes
el			<p>performed by one ResearchStaff. Each ResearchStaff might function as one or more StudySitePersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performedStudyPersonnel	be a function performed by	ResearchStaff 0..1 performingResearchStaff	<p>DESCRIPTION: Each StudyPersonnel might be a function performed by one ResearchStaff. Each ResearchStaff might function as one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReportSubmitter 0..* performedReportSubmitter	is a function performed by	ResearchStaff 1 performingResearchStaff	<p>DESCRIPTION: Each ReportSubmitter always is a function performed by one ResearchStaff. Each ResearchStaff might function as one or more ReportSubmitter.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdministrativeMemberPI 0..* performedAdministrativeMe mberPI	is a function performed by	ResearchStaff 1 performingResearchStaff	<p>DESCRIPTION: Each AdministrativeMemberPI always is a function performed by one ResearchStaff. Each ResearchStaff might function as one or more AdministrativeMemberPI.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	ResearchStaff 0..1 performingResearchStaff	DESCRIPTION: Each DocumentAuthor might be a function performed by one ResearchStaff. Each ResearchStaff might function as one or more DocumentAuthor. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdministrativeMemberCRA 0..* performedAdministrativeMe mberCRA	is a function performed by	ResearchStaff 1 performingResearchStaff	DESCRIPTION: Each AdministrativeMemberCRA always is a function performed by one ResearchStaff. Each ResearchStaff might function as one or more AdministrativeMemberCRA . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: ResourceProvider

Package: Common Sub-Domain

DEFINITION:

An organization or person that provides financial or other resources for the conduct of research.

EXAMPLE(S):

National Cancer Institute, National Institutes of Health [Federal Agency examples]

Pharmaceutical companies [private industry example]

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyOrganization
- Map:caAERSv2.2 = StudyOrganization
- Map:CTRPv1.0 = ResourceProvider

- Map:CTRRr3 = ResourceProvider
- Map:CTRv1.0 = ResourceProvider
- Map:HL7SP = Study.performer2
- Map:HL7SP = Service Provider
- Map:HSDBv1.0 = [Lead Organization].Organization Type

Connectors

Source	Connector	Target	Notes
ResourceProvider 0..1 performedResourceProvider	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each ResourceProvider might be a function performed by one Organization. Each Organization might function as one ResourceProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ResourceProvider 0..1 performedResourceProvider	be a function performed by	Person 0..1 performingPerson	<p>DESCRIPTION: Each ResourceProvider might be a function performed by one Person. Each Person might function as one ResourceProvider.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Resource 1..* providedResource	be provided by	ResourceProvider 0..1 providingResourceProvider	<p>DESCRIPTION: Each Resource might be provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> ResourceProvider <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes identity of the resource provider.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Study.sponsorCode Map:CTOM = Protocol.sponsorCode Map:CTRPv1.0 = ResourceProvider.identifier Map:CTRv1.0 = ResourceProvider.identifier Map:HL7SP = StudyParticipation RMIM
effectiveDateRange <i>Class:</i> ResourceProvider <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) span for when the resource provider is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = ResourceProvider.statusCode Map:CTRPv1.0 = ResourceProvider.statusDateRange Map:CTRv1.0 = ResourceProvider.effectiveDateRange Map:HL7SP = StudyParticipation RMIM

Class: ServiceDeliveryLocation

Package: Common Sub-Domain

DEFINITION:

A place at which services are provided by, or on behalf of, an organization.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = ServiceDeliveryLocation
- Map:ICSRr2 = ServiceDeliveryLocation (in R_ServiceDeliveryLocation informational)

Connectors

Source	Connector	Target	Notes
ServiceDeliveryLocation 0..* locatingServiceDeliveryLoc ation	be delivery location for	Organization 0..1 locatedOrganization	<p>DESCRIPTION: Each ServiceDeliveryLocation might be delivery location for one Organization. Each Organization might receive delivery at one or more ServiceDeliveryLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ServiceDeliveryLocation 0..* locatingServiceDeliveryLoc	be located at	Place 0..1 locatedPlace	<p>DESCRIPTION: Each ServiceDeliveryLocation</p>

Source	Connector	Target	Notes
ation			<p>might be located at one Place. Each Place might be the location for one or more ServiceDeliveryLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* destinedPerformedProductT ransport	have destination	ServiceDeliveryLocation 0..1 destinationServiceDeliveryL ocation	<p>DESCRIPTION: Each PerformedProductTransport might have destination one ServiceDeliveryLocation.</p> <p>Each ServiceDeliveryLocation might be the destination for one or more PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* originatedPerformedProduct Transport	originate at	ServiceDeliveryLocation 0..1 originServiceDeliveryLocati on	<p>DESCRIPTION: Each PerformedProductTransport might originate at one ServiceDeliveryLocation.</p> <p>Each ServiceDeliveryLocation might be the origin of one or more PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedActivity 0..* locatedPlannedActivity	take place in	ServiceDeliveryLocation 0..1 locatingServiceDeliveryLoc ation	<p>DESCRIPTION: Each PlannedActivity might take place in one ServiceDeliveryLocation.</p> <p>Each ServiceDeliveryLocation might be the location for one or more PlannedActivity.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> ServiceDeliveryLocation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of service delivery location.</p> <p>EXAMPLE(S): incidental, dedicated, clinical, non-clinical</p> <p>OTHER NAME(S):</p> <p>NOTE(S): A service delivery location may be either an incidental service delivery location (a place at which services may be provided without prior designation or authorization) or a dedicated service delivery location (a place that is intended to house the provision of services). Dedicated service delivery locations can be further characterized as either clinical or non-clinical.</p>	Map:CTRv1.0 = ServiceDeliveryLocation.code Map:ICSRr2 = ServiceDeliveryLocation.code (in R_ServiceDeliveryLocation informational)
postalAddress <i>Class:</i> ServiceDeliveryLocation <i>Datatype:</i> BAG<AD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A contact point used to send physical forms of communication to the service delivery location.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = ServiceDeliveryLocation.postalAddress Map:ICSRr2 = ServiceDeliveryLocation.addr (in R_ServiceDeliveryLocation informational)
telecomAddress <i>Class:</i> ServiceDeliveryLocation <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the service delivery location.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:CTRv1.0 = ServiceDeliveryLocation.telecomAddress Map:ICSRr2 = ServiceDeliveryLocation.telecom (in R_ServiceDeliveryLocation informational)

Class: Software

Package: Common Sub-Domain

DEFINITION:

A set of coded instructions that a computer follows in processing data, performing an operation, or solving a logical problem, upon execution of the program.

EXAMPLE(S):**OTHER NAME(S):****NOTE(S):***Tagged Values:*

- Map:LSDAMv2.2.3Plus = Software

Connectors

Source	Connector	Target	Notes
Software	specializes	Device	<p>DESCRIPTION: Each Software always specializes one Device. Each Device might be specialized by one Software.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Device 0..* specifyingDevice	specify the use of	Software 0..* specifiedSoftware	<p>DESCRIPTION: Each Device might specify the use of one or more Software. Each Software might be specified by one or more Device.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
versionNumberText <i>Class:</i> Software <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string identifying a form or variant of a type or original; one of a sequence of copies of a software each incorporating new modifications.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AIM v4 rv48 = Equipment.softwareVersion Map:dicom = Equipment Specification Module - Model Specification Sequence (0018,9912) > Software Versions (0018,1020) Map:dicom = General Equipment Module - Software Versions (0018,1020) Map:LSDAMv2.2.3Plus = Software.version

Attribute	Notes	Constraints and Tags
licenseKey <i>Class:</i> Software <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A non-unique textual key that certifies that the copy of the program is original. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Software.licenseKey
licenseTypeCode <i>Class:</i> Software <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the kind of license through which the software is available. EXAMPLE(S): multi-site, open source, single user OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Software.licenseTypeCode
licenseEffectiveDateRange <i>Class:</i> Software <i>Datatype:</i> IVL<TS.DATE> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date and time span for when the license for this software is active. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Software.licenseEffectiveDateRange
buildNumberText <i>Class:</i> Software <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A non-unique identifier assigned to identify the compiled version of the software. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Software.buildNumber
content <i>Class:</i> Software <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The source or binary file. EXAMPLE(S): OTHER NAME(S): NOTE(S): Question for SMEs: Is "content" the right name for this attribute?	Map:LSDAMv2.2.3Plus = Software.content

Class: StaffInterest

Package: Common Sub-Domain

DEFINITION:
An area of interest or speciality that a staff member has.

EXAMPLE(S):

Paediatric neurology, Diabetes mellitus, Imaging biostatistics

OTHER NAME(S):

NOTE(S):

StaffInterest is usually a clinical specialty, but may be a different type of specialty (e.g. imaging biostatistics).

Tagged Values:

- Map:Vendor1v1.1 = StaffInterest

Connectors

Source	Connector	Target	Notes
StaffInterest 0..* ofInterestStaffInterest	be an interest of	OrganizationStaffRole 0..1 interestedOrganizationStaffRole	<p>DESCRIPTION: Each StaffInterest might be an interest of one OrganizationStaffRole. Each OrganizationStaffRole might have interest in one or more StaffInterest.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> StaffInterest <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the area of interest that an individual has.</p> <p>EXAMPLE(S): Paediatric neurology, Diabetes mellitus, Imaging biostatistics</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is usually a clinical specialty, but may be a different type of specialty (e.g. imaging biostatistics).</p>	Map:Vendor1v1.1 = StaffInterest.typeCode
primaryIndicator <i>Class:</i> StaffInterest <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: Specifies whether this is the main or principal staff interest.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = StaffInterest.isPrimary

Attribute	Notes	Constraints and Tags
confidentialIndicator <i>Class:</i> StaffInterest <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Specifies whether the staff interest is considered sensitive information.</p> <p>EXAMPLE(S): Staff interests may be considered confidential when a company is entering into a new market.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = StaffInterest.isConfidential
effectiveDateRange <i>Class:</i> StaffInterest <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the staff interest is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = StaffInterest.effectiveDateTime

Class: StandardOfCareDataCollection

Package: Common Sub-Domain

DEFINITION:

A non-research project with the ultimate goal of collecting healthcare results that can later be leveraged and analyzed by researchers to identify health disparity trends in disease incidence, mortality and patient survival.

EXAMPLE(S):

U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) Program

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:SEER 2015 = SECTION I BASIC RECORD IDENTIFICATION - SEER PARTICIPANT

Connectors

Source	Connector	Target	Notes
StandardOfCareDataCollection	specializes	NonResearchProject	<p>DESCRIPTION: Each StandardOfCareDataCollection always specializes one NonResearchProject. Each NonResearchProject might be specialized by one StandardOfCareDataCollection.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes

Class: StorageEquipment

Package: Common Sub-Domain

DEFINITION:

A physical structure or device capable of holding objects or samples. [NCIt definition for Storage Unit]

EXAMPLE(S):

freezers

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = StorageEquipment

Connectors

Source	Connector	Target	Notes
StorageEquipment 0..* residentStorageEquipment	is located in	Place 1 residingPlace	<p>DESCRIPTION: Each StorageEquipment always is located in one Place. Each Place might be location for one or more StorageEquipment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StorageEquipment	specializes	Device	<p>DESCRIPTION: Each StorageEquipment always specializes one Device. Each Device might be specialized by one StorageEquipment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Container 0..* containedContainer	be contained in	StorageEquipment 0..1 containingStorageEquipment	<p>DESCRIPTION: Each Container might be contained in one StorageEquipment. Each StorageEquipment might contain one or more Container.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
dimensionOneCapacity <i>Class:</i> StorageEquipment <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>The maximum amount that can be contained, in the first dimension of size of the equipment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionOneCapacity</p>
dimensionOneLabel <i>Class:</i> StorageEquipment <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>A descriptive marker assigned to the first dimension of the equipment.</p> <p>EXAMPLE(S): rows, columns</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionOneLabel</p>
dimensionTwoCapacity <i>Class:</i> StorageEquipment <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>The maximum amount that can be contained, in the second dimension of size of the equipment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionTwoCapacity</p>
dimensionTwoLabel <i>Class:</i> StorageEquipment <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>A descriptive marker assigned to the second dimension of the equipment.</p> <p>EXAMPLE(S): rows, columns</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionTwoLabel</p>

Attribute	Notes	Constraints and Tags
dimensionThreeCapacity <i>Class:</i> StorageEquipment <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The maximum amount that can be contained, in the third dimension of size of the equipment. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionThreeCapacity
dimensionThreeLabel <i>Class:</i> StorageEquipment <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A descriptive marker assigned to the third dimension of the equipment. EXAMPLE(S): rows, columns OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionThreeLabel
dimensionPointOfOrigin <i>Class:</i> StorageEquipment <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The point within the equipment from which definition of equipment capacity originates. EXAMPLE(S): bottom left corner, upper left corner OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = StorageEquipment.dimensionPointOfOrigin

Class: Study

Package: Common Sub-Domain

DEFINITION:

A research project whose objectives are to test or confirm hypotheses concerning 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.

EXAMPLE(S):

A vaccine therapy study looking at treating patients with previously treated stage II-III HER2-positive breast cancer

OTHER NAME(S):

NOTE(S):

The comprehensive notion of a study is represented in BRIDG by the classes Study, StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion, StudyConduct and all their associations.

- The Study class represents the core concept from a clinician's perspective and functions technically as an anchor or entry point for all the related concepts and aspects that may be considered characteristics of a study. The study protocol may be of any type that involves subjects, including prevention, therapeutic, interventional or observational.
- The StudyProtocol class represents the plan for the study which includes characteristics and planned activities which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the study protocol in a textual, possibly graphical, and human-readable form and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is contains the details of the study protocol document as they exist[ed] at a particular point in time.

- The StudyConduct class represents the execution of a study based on a study protocol definition which includes the scheduled and performed activities that are subject-specific as well as study-level and site-level activities.
- Each of these main classes may have other associations and attributes that further detail out aspects of the overall study.

Tagged Values:

- Map:Vendor1v1.1 = Study

Connectors

Source	Connector	Target	Notes
Study 0..1 participatedStudy	be participated in by	StudySitePersonnel 0..* participatingStudySitePersonnel	DESCRIPTION: Each Study might be participated in by one or more StudySitePersonnel. Each StudySitePersonnel might participate in one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Study 1 participatedStudy	be participated in by	StudyCountry 0..* participatingStudyCountry	DESCRIPTION: Each Study might be participated in by one or more StudyCountry. Each StudyCountry always participates in one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Study	specializes	ResearchProject	DESCRIPTION: Each Study always specializes one ResearchProject. Each ResearchProject might be specialized by one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Study 0..1 participatedStudy	be participated in by	StudyPersonnel 0..* participatingStudyPersonnel	DESCRIPTION: Each Study might be participated in by one or more StudyPersonnel. Each StudyPersonnel might participate in one Study.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocol 0..1 planningStudyProtocol	is the plan for	Study 1 plannedStudy	<p>DESCRIPTION: Each StudyProtocol always is the plan for one Study. Each Study might have as plan one StudyProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudyCountry

Package: Common Sub-Domain

DEFINITION:

An entity with management and reporting responsibilities in the context of a particular study for a set of study sites which may or may not be physically located within the geographic location, state or nation of the entity.

EXAMPLE(S):

United Kingdom - acting as a Study Country for all study sites in the UK and Republic of Ireland for the Phase III Study of Exotocillin in community acquired pneumonia in patients over 65

France - acting as a Study Country for all study sites in mainland France and its offshore departments, plus two sites in French-speaking Belgium for the Phase II Study of Exotomumab in treatment of rheumatoid arthritis

OTHER NAME(S):

NOTE(S):

A Study Country exists as a business object in the context of planning and management of specific individual studies.

Tagged Values:

- Map:Vendor1v1.0 = StudyCountry

Connectors

Source	Connector	Target	Notes
StudyCountry 0..* performedStudyCountry	is a function performed by	Organization 1..* performingOrganization	<p>DESCRIPTION: Each StudyCountry always is a function performed by one or more Organization. Each Organization might function as one or more StudyCountry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
Study 1 participatedStudy	be participated in by	StudyCountry 0..* participatingStudyCountry	DESCRIPTION: Each Study might be participated in by one or more StudyCountry. Each StudyCountry always participates in one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Activity 0..* hasContextActivity	have as context	StudyCountry 0..1 contextForStudyCountry	DESCRIPTION: Each Activity might have as context one StudyCountry. Each StudyCountry might be the context for one or more Activity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySite 0..* managedStudySite	be managed by	StudyCountry 0..1 managingStudyCountry	DESCRIPTION: Each StudySite might be managed by one StudyCountry. Each StudyCountry might manage one or more StudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyCountryPersonnel 0..* performingStudyCountryPersonnel	perform a role for	StudyCountry 0..1 performedStudyCountry	DESCRIPTION: Each StudyCountryPersonnel might perform a role for one StudyCountry. Each StudyCountry might have a role performed by one or more StudyCountryPersonnel. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
countryCode <i>Class:</i> StudyCountry <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the country that is the home base of the study country.</p> <p>EXAMPLE(S): FR as the ISO 3166 Country Code for France. BE as the ISO 3166 Country Code for Belgium.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): ISO 3166 Country codes can be used</p>	Map:Vendor1v1.0 = StudyCountry.countryCode

Class: StudyRegistry

Package: Common Sub-Domain

DEFINITION:

An organization (typically a government agency) that administers the registration of studies.

EXAMPLE(S):

ClinicalTrials.gov (CT.gov), Netherlands National Trial Register (NTR)

OTHER NAME(S):

NOTE(S):

The study registry should contain basic information about each study sufficient to inform potential subjects (and their healthcare providers) how to enroll in the study.

Tagged Values:

- Map:CTOM = HealthcareSiteParticipantRole.roleCode
- Map:CTRR = Registry Protocol Identifier Source
- Map:CTRrr3 = StudyRegistry
- Map:CTRv1.0 = StudyRegistry
- Map:HL7SP = Author4 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
StudyRegistry 0..* managedStudyRegistry	be managed by	Organization 0..1 managingOrganization	<p>DESCRIPTION: Each StudyRegistry might be managed by one Organization. Each Organization might manage one or more StudyRegistry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> StudyRegistry <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of the study registry.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ID
name <i>Class:</i> StudyRegistry <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A non-unique textual identifier for the registry.</p> <p>EXAMPLE(S): ClinicalTrials.gov</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRR = Registry Map:CTRRr3 = StudyRegistry.name Map:CTRv1.0 = StudyRegistry.name Map:WHO = Primary Registry
acronym <i>Class:</i> StudyRegistry <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The non-unique initials or abbreviated name used for identification of the registry.</p> <p>EXAMPLE(S): NTR (Netherlands National Trial Register)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRR = Registry Map:CTRRr3 = StudyRegistry.acronym Map:CTRv1.0 = StudyRegistry.acronym Map:WHO = Primary Registry

Class: StudySubject

Package: Common Sub-Domain

DEFINITION:

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

EXAMPLE(S):

A person who is registered in a study as a recipient of an investigational product or as a control.

Individuals who are being screened for studies.

Individuals participating in observational or other studies.

A pacemaker, a fuse that can be used in medical devices, a cow, a pen of pigs, or a tissue sample from a tissue bank.

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:C3PRv2.9 = StudySubject
- Map:CTRPv3.8 = StudySubject
- Map:CTRPv3.8 = StudySite.(StudySubject)
- Map:CTRPv3.8 = Patient.(StudySubject)
- Map:CTRv1.0 = StudySubject
- Map:DICOM = Clinical Trial Subject Module
- Map:DICOM = Clinical Trial Context Module
- Map:HL7SP = Study.subject
- Map:ICSRR2 = Subject (in IndividualCaseSafetyReport)
- Map:NCI CRF Standard = ParticipantIdentifier
- Map:PSCv2.6 = StudySubjectAssignment
- Map:PSCv2.6 = Subject
- Map:SDTM IGV3.1.2 = DM.DOMAIN
- Map:SDTM IGV3.1.3 = DM

Connectors

Source	Connector	Target	Notes
StudySubject	specializes	Subject	<p>DESCRIPTION: Each StudySubject always specializes one Subject. Each Subject might be specialized by one StudySubject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySubjectProtocolVersionRelationship 0..* assignedStudySubjectProtocolVersionRelationship	is the assigned version for	StudySubject 1 assigningStudySubject	<p>DESCRIPTION: Each StudySubjectProtocolVersionRelationship always is the assigned version for one StudySubject. Each StudySubject might be assigned to one or more StudySubjectProtocolVersionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySubjectExperienceDocumentVersion 0..* describingStudySubjectExperienceDocumentVersion	describes experience of	StudySubject 1 describedStudySubject	<p>DESCRIPTION: Each StudySubjectExperienceDocumentVersion always describes experience of one StudySubject. Each StudySubject might have experience described by one or more StudySubjectExperienceDocumentVersion</p>

Source	Connector	Target	Notes
			<p>umentVersion.</p> <p>DEFINITION: Indicates the subject whose experience is recounted in the study subject experience document.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
confidentialityIndicator <i>Class:</i> StudySubject <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the study subject, or their legally acceptable representative, has not authorized the use and disclosure of their protected health information (i.e., the study subject's data is private and confidential).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:CTOM = Participant.confidentialityIndicator</p> <p>Map:CTRv1.0 = StudySubject.confidentialityIndicator</p>

Attribute	Notes	Constraints and Tags
statusCode <i>Class:</i> StudySubject <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the study subject.</p> <p>EXAMPLE(S): candidate, eligible, follow-up, ineligible, not registered, off-study, on-study, pending on-study, potential candidate, screening, withdrawn</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Study Subject Status state transition diagram for further details.</p> <p>If in CDISC's SDTM DM.ACTARMCD = "NOTRT" (meaning "Not Treated"), this is a subject who passed eligibility, was assigned a treatment but never started, e.g. withdrew before treatment started, etc., so a PerformedExperimentalUnitAllocation exists for this subject.</p> <p>If in CDISC's SDTM DM.ACTARMCD = "NOTASSGN" (meaning "Not Assigned"), this is a case where DMARM = DMACTARM, meaning after eligibility was determined, the subject may be left over/unneeded, or withdraws, or doesn't pass further eligibility criteria, or is in a wait period between eligibility/intake and assignment – all are possible statusCode values. And all those values could be fine grained statuses in a BRIDG-based system that each roll up into "NOT ASSIGNED" to be reported in SDTM data sets. In this case PerformedExperimentalUnitAllocation doesn't exist.</p>	Map:C3PR = StudySubject.status Map:C3PR = StudySubject.state Map:C3PRv2.9 = StudySubject.regWorkflowStatus Map:CTRPv3.8 = FunctionalRole.statusCode Map:CTRv1.0 = StudySubject.statusCode Map:SDTM IGv3.1.3 = DM.ACTARMCD Map:SDTM IGv3.1.3 = DM.ACTARM
statusDate <i>Class:</i> StudySubject <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the status is assigned to the study subject.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = StudyPersonnel.startDate Map:C3PR = StudyPersonnel.endDate Map:C3PR = StudySubject.statusDateRange Map:CTRPv3.8 = FunctionalRole.statusDateRange Map:CTRv1.0 = StudySubject.statusDate

Class: Subject

Package: Common Sub-Domain

DEFINITION:
An entity of interest, either biological or otherwise.

EXAMPLE(S):
A human being who might be of interest because they are on a study
A sheep who might have experienced an adverse event

A pacemaker that failed
 Tissue that is undergoing gross evaluation
 Tissue that is to be embedded in paraffin

OTHER NAME(S):

NOTE(S):

Tagged Values:

- AE:Alias = InvestigativeSubject
- Map:AE = InvestigativeSubject
- Map:C3PRv2.9 = Participant
- Map:caAERSv2.2 = Participant
- Map:CTRPv3.8 = Subject
- Map:CTRPv3.8 = Patient
- Map:CTRv1.0 = Subject
- Map:DICOM = TID 1007 SubjectContext,Patient
- Map:DICOM = TID 1006 SubjectContext
- Map:DICOM = Patient Study Module
- Map:DICOM = Patient Module
- Map:DICOM = TID 1001 ObservationContext > Include TID 1006 SubjectContext
- Map:DICOM = TID 1006 SubjectContext > Include TID 1007 SubjectContext,Patient
- Map:HCTv1.0 = CDE 2705055:Lab Results.Please specify the person for whom this typing is being done:
- Map:HCTv1.0 = CDE 2693219:Lab Results.Who is being tested for IDMs?
- Map:ICSRr2 = Subject14 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = PrimaryRole (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject6 (in R_Product)
- Map:ICSRr2 = Subject1 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject5 (in R_Product)
- Map:ICSRr2 = Subject13 (in IndividualCaseSafetyReport)
- Map:LabViewer2.2 = Participant
- Map:LSDAMv2.2.3Plus = Subject
- Map:LSDAMv2.2.3Plus = SpecimenCollectionGroup.performingOnPerformedMaterialProcessStep(PerformedMaterialProcessStep)
- Map:LSDAMv2.2.3Plus = SpecimenCollectionGroup.(PerformedObservation)

Connectors

Source	Connector	Target	Notes
Subject 0..* performedSubject	be a function performed by	BiologicEntity 0..1 performingBiologicEntity	<p>DESCRIPTION: Each Subject might be a function performed by one BiologicEntity. Each BiologicEntity might function as one or more Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Subject 0..* performedSubject	be a function performed by	BiologicEntityGroup 0..1 performingBiologicEntityGroup	<p>DESCRIPTION: Each Subject might be a function performed by one BiologicEntityGroup. Each BiologicEntityGroup might function as one or more Subject.</p>

Source	Connector	Target	Notes
			<p>DEFINITION: Indicates that a particular group of biologic entities is the subject of a particular activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Used when the activity is done to the group as a whole rather than individuals. E.g. drugs in shared feed, spraying, group therapy, etc.</p>
Subject 0..* performedSubject	be a function performed by	Specimen 0..1 performingSpecimen	<p>DESCRIPTION: Each Subject might be a function performed by one Specimen. Each Specimen might function as one or more Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Subject 0..* performedSubject	be a function performed by	SpecimenCollectionGroup 0..1 performingSpecimenCollectionGroup	<p>DESCRIPTION: Each Subject might be a function performed by one SpecimenCollectionGroup. Each SpecimenCollectionGroup might function as one or more Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Subject 0..* performedSubject	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each Subject might be a function performed by one Organization. Each Organization might function as one or more Subject.</p> <p>DEFINITION: Indicates that the Organization is participating as the subject of an activity.</p>

Source	Connector	Target	Notes
			EXAMPLE(S): Audit OTHER NAME(S): NOTE(S):
Subject 0..* performedSubject	be a function performed by	Product 0..1 performingProduct	DESCRIPTION: Each Subject might be a function performed by one Product. Each Product might function as one or more Subject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SubjectPaymentMethod 0..* coveringSubjectPaymentMe thod	covers costs for	Subject 1 coveredSubject	DESCRIPTION: Each SubjectPaymentMethod always covers costs for one Subject. Each Subject might have costs covered by one or more SubjectPaymentMethod. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySubject	specializes	Subject	DESCRIPTION: Each StudySubject always specializes one Subject. Each Subject might be specialized by one StudySubject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Performer 0..* performedPerformer	be a function performed by	Subject 0..1 performingSubject	DESCRIPTION: Each Performer might be a function performed by one Subject. Each Subject might function as one or more Performer.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* involvingActivity	be participated in by	Subject 0..1 involvedSubject	<p>DESCRIPTION:</p> <p>Each Activity might be participated in by one Subject. Each Subject might participate in one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentAuthor 0..* performedDocumentAuthor	be a function performed by	Subject 0..1 performingSubject	<p>DESCRIPTION:</p> <p>Each DocumentAuthor might be a function performed by one Subject. Each Subject might function as one or more DocumentAuthor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedStudySubject	specializes	Subject	<p>DESCRIPTION:</p> <p>Each PlannedStudySubject always specializes one Subject. Each Subject might be specialized by one PlannedStudySubject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenCollectionProtocol Subject	specializes	Subject	<p>DESCRIPTION:</p> <p>Each SpecimenCollectionProtocol Subject always specializes one Subject. Each Subject might be specialized by one SpecimenCollectionProtocol</p>

Source	Connector	Target	Notes
			Subject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Subject <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes identity of the subject.</p> <p>EXAMPLE(S): study subject number 7 on a specific study</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AIM v4 rv48 = Person.id Map:C3PR = Identifier.value Map:C3PR = StudySubject.identifier Map:C3PRv2.9 = Identifier.value Map:caAERSv2.2 = Identifier.value > Participant Map:caAERSv2.2 = StudyParticipantAssignment.studySubjectIdentifier Map:CDASHv1.1 = DM.SUBJID Map:CDASHv1.1 = DM.USUBJID Map:CTOM = HealthcareSiteParticipant.participantIdentifier Map:CTOM = StudyParticipantAssignment.studyParticipantIdentifier Map:CTRv3.8 = StudySubject.assignedIdentifier Map:CTRv1.0 = SubjectIdentifier.identifier Map:DICOM = Clinical Trial Subject Module - Clinical Trial Subject ID (0012,0040) Map:DICOM = TID 1007 SubjectContext,Patient > Subject ID Map:DICOM = Clinical Trial Subject Module - Clinical Trial Subject Reading ID (0012,0042) Map:FDA HL7 SD SD DSTU2012 = plannedStudy//subject/researchSubject.id Map:HCTv1.0 = CDE 2729085:Specimen Characteristics.Research sample donor ID: Map:HCTv1.0 = CDE 2889049:Anatomic Structure, System, or Substance.Non-NMDP unrelated donor / cord blood unit ID: Map:HCTv1.0 = CDE 3118479:Medical Records and Forms.CRID processing result: Map:HCTv1.0 = CDE 2856315:Anatomic Structure, System, or Substance.NMDP donor ID: Map:ICSRr2 = PrimaryRole.id (in IndividualCaseSafetyReport) Map:Lab = SubjectAssignment.studySubjectIdentifier Map:LabViewer2.2 = Identifier.root Map:LabViewer2.2 = Identifier.extension Map:LabViewer2.2 = Identifier.displayable Map:LSDAMv2.2.3Plus = SubjectIdentifier.identifier Map:NCI CRF Standard = CDE 2746468v1.0: Healthcare Facility Participant Identifier

Attribute	Notes	Constraints and Tags
		Map:NCI CRF Standard = CDE 2003301v3.0: Patient Identifier Map:NCI CRF Standard = CDE 2465308v1.0: Patient Multiple Clinical Trials Cooperative Group Identifier Number Map:PGx v1.0 = PF.USUBJID Map:PGx v1.0 = BE.USUBJID Map:PGx v1.0 = BS.USUBJID Map:PGx v1.0 = PG.USUBJID Map:PGx v1.0 = RELSPEC.USUBJID Map:PGx v1.0 = SB.USUBJID Map:PSC = StudyParticipantAssignment.studyPart icipantIdentifier Map:PSCv2.6 = StudySubjectAssignment.studySubject Identifier Map:SDTM IGv3.1.1 = DM.USUBJID Map:SDTM IGv3.1.1 = SE.USUBJID Map:SDTM IGv3.1.1 = AE.USUBJID Map:SDTM IGv3.1.1 = SV.USUBJID Map:SDTM IGv3.1.1 = PE.USUBJID Map:SDTM IGv3.1.1 = IE.USUBJID Map:SDTM IGv3.1.1 = SU.USUBJID Map:SDTM IGv3.1.1 = CO.USUBJID Map:SDTM IGv3.1.1 = LB.USUBJID Map:SDTM IGv3.1.1 = QS.USUBJID Map:SDTM IGv3.1.1 = DA.USUBJID Map:SDTM IGv3.1.1 = CM.USUBJID Map:SDTM IGv3.1.1 = DM.SUBJID Map:SDTM IGv3.1.1 = DS.USUBJID Map:SDTM IGv3.1.1 = EX.USUBJID Map:SDTM IGv3.1.1 = MH.USUBJID Map:SDTM IGv3.1.1 = DV.USUBJID Map:SDTM IGv3.1.1 = SC.USUBJID Map:SDTM IGv3.1.1 = EG.USUBJID Map:SDTM IGv3.1.1 = VS.USUBJID Map:SDTM IGv3.1.2 = SE.USUBJID Map:SDTM IGv3.1.2 = PE.USUBJID Map:SDTM IGv3.1.2 = CE.USUBJID Map:SDTM IGv3.1.2 = PP.USUBJID Map:SDTM IGv3.1.2 = FA.USUBJID Map:SDTM IGv3.1.2 = SU.USUBJID Map:SDTM IGv3.1.2 = MB.USUBJID Map:SDTM IGv3.1.2 = QS.USUBJID Map:SDTM IGv3.1.2 = DM.SUBJID Map:SDTM IGv3.1.2 = EX.USUBJID Map:SDTM IGv3.1.2 = DM.USUBJID Map:SDTM IGv3.1.2 = IE.USUBJID Map:SDTM IGv3.1.2 = DV.USUBJID Map:SDTM IGv3.1.2 = DA.USUBJID Map:SDTM IGv3.1.2 = CM.USUBJID Map:SDTM IGv3.1.2 = LB.USUBJID Map:SDTM IGv3.1.2 = MH.USUBJID Map:SDTM IGv3.1.2 = CO.USUBJID Map:SDTM IGv3.1.2 = SC.USUBJID

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = SV.USUBJID Map:SDTM IGv3.1.2 = EG.USUBJID Map:SDTM IGv3.1.2 = VS.USUBJID Map:SDTM IGv3.1.2 = DS.USUBJID Map:SDTM IGv3.1.2 = PC.USUBJID Map:SDTM IGv3.1.2 = MS.USUBJID Map:SDTM IGv3.1.3 = SE.USUBJID Map:SDTM IGv3.1.3 = TU.USUBJID Map:SDTM IGv3.1.3 = TR.USUBJID Map:SDTM IGv3.1.3 = SU.USUBJID Map:SDTM IGv3.1.3 = RS.USUBJID Map:SDTM IGv3.1.3 = SV.USUBJID Map:SDTM IGv3.1.3 = QS.USUBJID Map:SDTM IGv3.1.3 = VS.USUBJID Map:SDTM IGv3.1.3 = SC.USUBJID Map:SDTM IGv3.1.3 = EG.USUBJID Map:SDTM IGv3.1.3 = AE.USUBJID Map:SDTM IGv3.1.3 = CE.USUBJID Map:SDTM IGv3.1.3 = CM.USUBJID Map:SDTM IGv3.1.3 = CO.USUBJID Map:SDTM IGv3.1.3 = DA.USUBJID Map:SDTM IGv3.1.3 = DM.SUBJID Map:SDTM IGv3.1.3 = DM.USUBJID Map:SDTM IGv3.1.3 = FA.USUBJID Map:SDTM IGv3.1.3 = DV.USUBJID Map:SDTM IGv3.1.3 = PE.USUBJID Map:SDTM IGv3.1.3 = EX.USUBJID Map:SDTM IGv3.1.3 = IE.USUBJID Map:SDTM IGv3.1.3 = LB.USUBJID Map:SDTM IGv3.1.3 = MB.USUBJID Map:SDTM IGv3.1.3 = MH.USUBJID Map:SDTM IGv3.1.3 = MS.USUBJID Map:SDTM IGv3.1.3 = PC.USUBJID Map:SDTM IGv3.1.3 = DS.USUBJID Map:SEER 2015 = SECTION I BASIC RECORD IDENTIFICATION - PATIENT ID NUMBER

Class: SubjectPaymentMethod

Package: Common Sub-Domain

DEFINITION:

A kind of payer/insurance carrier assigned to the subject.

EXAMPLE(S):

Private Insurance, Medicare, Medicare And Private Insurance, Medicaid

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - PRIMARY PAYER AT DIAGNOSIS

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
SubjectPaymentMethod 0..* coveringSubjectPaymentMethod	covers costs for	Subject 1 coveredSubject	<p>DESCRIPTION: Each SubjectPaymentMethod always covers costs for one Subject. Each Subject might have costs covered by one or more SubjectPaymentMethod.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
code <i>Class:</i> SubjectPaymentMethod <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of payment method for this subject.</p> <p>EXAMPLE(S): Private Insurance, Medicare, Medicare And Private Insurance, Medicaid</p> <p>For the U.S. National Cancer Institute: (NCI) Surveillance, Epidemiology, and End Results (SEER) program (Code = Label - Definition):</p> <p>01 = Not insured - Patient has no insurance and is declared a charity write-off</p> <p>02 = Not insured, self-pay - Patient has no insurance and is declared responsible for charges</p> <p>10 = Insurance, NOS - Type of insurance is unknown or other than types listed in codes 20, 21, 31, 35, 60-68</p> <p>20 = Private Insurance: Managed care, HMO, or PPO - An organized system of prepaid care for a group of enrollees usually within a defined geographic area. Generally formed as one of four types: a group model, an independent physician association (IPA), a network, or a staff model. "Gate-keeper model" is another term for describing this type of insurance.</p> <p>21 = Private Insurance: Fee-for-service - An insurance plan that does not have negotiated fee structure with the participating hospital. Type of insurance plan not coded as 20.</p> <p>31 = Medicaid - State government administered insurance for persons who are uninsured, below the poverty level, or covered under entitlement programs</p> <p>Medicaid other than Medicaid described in code 35</p> <p>Etc.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = StudySubject.paymentMethod Map:CTOM = Participant.paymentMethodCode Map:CTRPv3.8 = StudySubject.paymentMethodCode Map:CTRv1.0 = StudySubject.paymentMethodCode Map:NCI CRF Standard = CDE 2865130v1.0: Person Healthcare Payer Type Map:SEER 2015 = SECTION III DEMOGRAPHIC INFORMATION - PRIMARY PAYER AT DIAGNOSIS
dateRange <i>Class:</i> SubjectPaymentMethod <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) span for when the subject's payment method is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = (Model integrity)

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> SubjectPaymentMethod <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the main or principal payment method for this subject.</p> <p>EXAMPLE(S): If a patient carries both Medicare and an Acme Private Insurance plan and this private insurance plan will kick in after Medicare covers initial costs, then Medicare is the primary payment method and primaryIndicator = "true" where code = "Medicare".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = (Model integrity)

Class: SystemOfRecord

Package: Common Sub-Domain

DEFINITION:
The system that assigned the identifier.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

This concept will be re-visited again in the next release. It may be an implementation-oriented concept.

Tagged Values:

- Map:caAERSv2.2 = SystemAssignedIdentifier
- Map:CTRv1.0 = SystemOfRecord

Connectors

Source	Connector	Target	Notes
SystemOfRecord 0..* managedSystemOfRecord	be managed by	Organization 0..1 managingOrganization	<p>DESCRIPTION: Each SystemOfRecord might be managed by one Organization. Each Organization might manage one or more SystemOfRecord.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> SystemOfRecord <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	DEFINITION: A unique symbol that establishes identity of the system of record. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:Vendor1v1.1 = ID
name <i>Class:</i> SystemOfRecord <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A non-unique textual identifier for the system that assigned the identifier. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = SystemAssignedIdentifier.systemName Map:caAERSv2.2 = SystemAssignedIdentifier.systemName Map:CTRv1.0 = SystemOfRecord.name

Class: TreatingSite

Package: Common Sub-Domain

DEFINITION:

Any healthcare facility where care is provided as part of a cooperative group organizational network.

EXAMPLE(S):

A cancer center that is part of the North Central Cancer Treatment Group (NCCTG).

OTHER NAME(S):

NOTE(S):

There are two ways a TreatingSite can be associated to a CooperativeGroup: either directly or through a CooperativeGroupMember.

Tagged Values:

- Map:C3PR = StudyCoordinatingCenter
- Map:CoopGrp = TreatingSite
- Map:CTOM = HealthcareSiteParticipantRole.roleCode

Connectors

Source	Connector	Target	Notes
TreatingSite 1..* containedTreatingSite	be a member of	CooperativeGroupMember 0..1 containingCooperativeGroupMember	DESCRIPTION: Each TreatingSite might be a member of one CooperativeGroupMember. Each CooperativeGroupMember always has as a member one or more TreatingSite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Source	Connector	Target	Notes
TreatingSite 0..* performedTreatingSite	is a function performed by	HealthcareFacility 1 performingHealthcareFacilit y	<p>DESCRIPTION: Each TreatingSite always is a function performed by one HealthcareFacility. Each HealthcareFacility might function as one or more TreatingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
TreatingSite 0..* containedTreatingSite	be a member of	CooperativeGroup 0..1 containingCooperativeGrou p	<p>DESCRIPTION: Each TreatingSite might be a member of one CooperativeGroup. Each CooperativeGroup might have as a member one or more TreatingSite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Experiment Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Experiment sub-domain includes concepts related to the design, planning, resourcing and execution of experiments, which are intended to test hypotheses or lead to discoveries.

Experiment Sub-Domain

View EX: Experiment diagram

Class diagram in package 'Experiment Sub-Domain'

The Experiment sub-domain includes concepts related to the design, planning, resourcing and execution of experiments, which are intended to test hypotheses or lead to discoveries.

View EX: Experiment

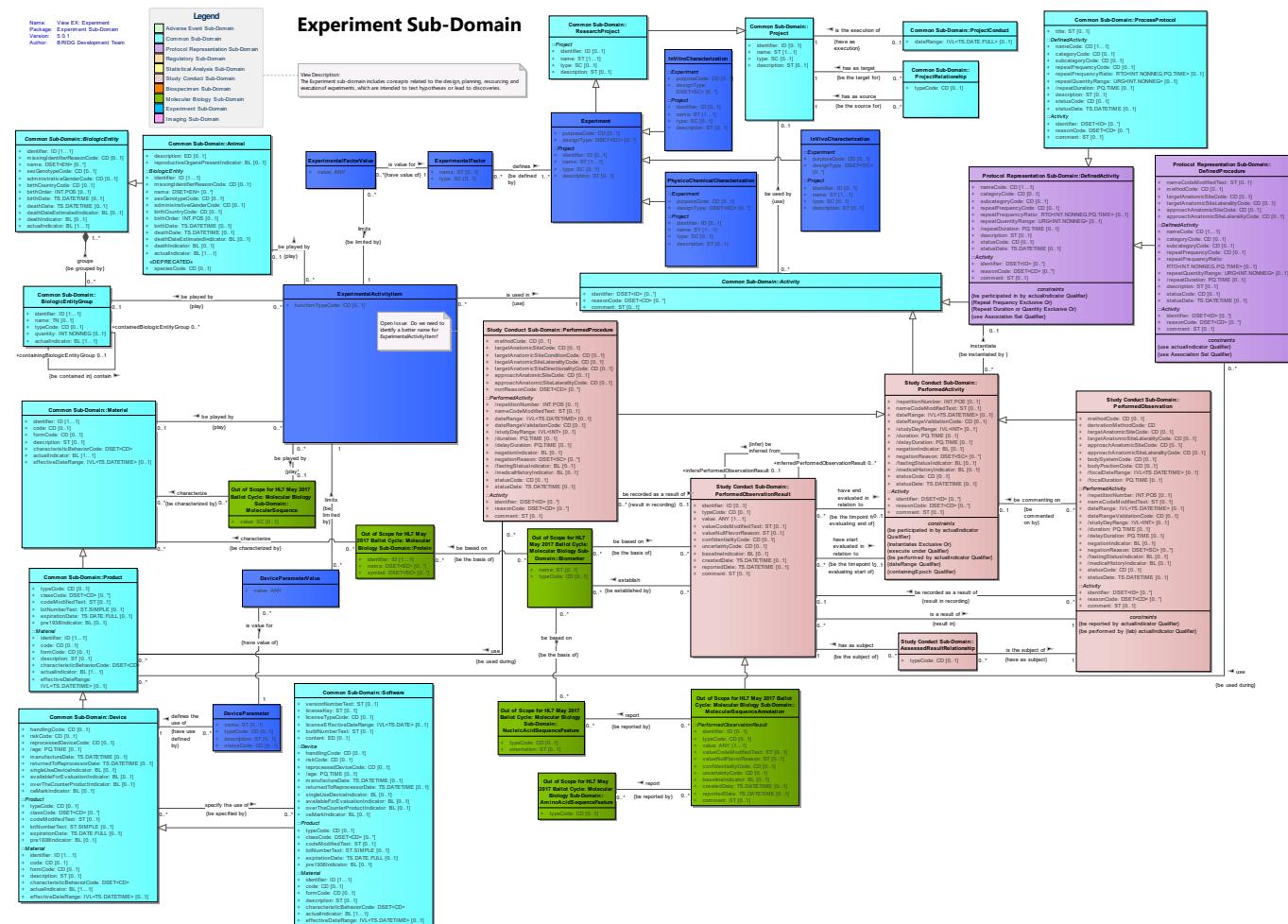


Figure 7: View EX: Experiment

Class: DeviceParameter

Package: Experiment Sub-Domain

DEFINITION:

Any factor that defines a system and determines (or limits) its performance.

EXAMPLE(S):

incubation temperature, number of mismatches in a BLAST search, scanning wavelength

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:LSDAMv2.2.3Plus = ExperimentalParameter

Connectors

Source	Connector	Target	Notes
DeviceParameter 0..* definingDeviceParameter	defines the use of	Device 1 definedDevice	<p>DESCRIPTION: Each DeviceParameter always defines the use of one Device. Each Device might have use defined by one or more DeviceParameter.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DeviceParameterValue 0..* valuingDeviceParamaterVal ue	is value for	DeviceParameter 1 valuedDeviceParamater	<p>DESCRIPTION: Each DeviceParameterValue always is value for one DeviceParameter. Each DeviceParameter might have value of one or more DeviceParameterValue.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
name <i>Class:</i> DeviceParameter <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A word or phrase that constitutes the distinctive designation of a parameter. EXAMPLE(S): incubation temperature, scanning wavelength OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = ExperimentalParameter.name
typeCode <i>Class:</i> DeviceParameter <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the classification of the parameter. EXAMPLE(S): centrifuge input, software analysis OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = ExperimentalParameter.typeCode
description <i>Class:</i> DeviceParameter <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The textual representation of the parameter. EXAMPLE(S): temperature setting for centrifugation procedure; analysis start point for GeneMapper 3.7 OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = ExperimentalParameter.description
statusCode <i>Class:</i> DeviceParameter <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the condition of use of the parameter at the current time. EXAMPLE(S): active, inactive, deprecated OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = ExperimentalParameter.statusCode

Class: DeviceParameterValue

Package: Experiment Sub-Domain

DEFINITION:

The value of a parameter setting for a given use.

EXAMPLE(S):

5 degrees Celsius, 5-10 minutes

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = QuantitativeParameterValue

- Map:LSDAMv2.2.3Plus = ExperimentalParameterValue
- Map:LSDAMv2.2.3Plus = StringParameterValue

Connectors

Source	Connector	Target	Notes
DeviceParameterValue 0..* limitingDeviceParameterValue	limits	ExperimentalActivityItem 1 limitedExperimentalActivityItem	<p>DESCRIPTION: Each DeviceParameterValue always limits one ExperimentalActivityItem. Each ExperimentalActivityItem might be limited by one or more DeviceParameterValue.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DeviceParameterValue 0..* valuingDeviceParameterValue	is value for	DeviceParameter 1 valuedDeviceParameter	<p>DESCRIPTION: Each DeviceParameterValue always is value for one DeviceParameter. Each DeviceParameter might have value of one or more DeviceParameterValue.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
value <i>Class:</i> DeviceParameterValue <i>Datatype:</i> ANY <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: The value assigned to the parameter in the context of the use of the device or software.</p> <p>EXAMPLE(S): "2100" for the analysis end point for GeneMapper v3.7, "G5" for the GeneMapper v3.7 Dye Set G5 for 5 color dye analysis modules.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = StringParameterValue.value</p> <p>Map:LSDAMv2.2.3Plus = QuantitativeParameterValue.singleValue</p> <p>Map:LSDAMv2.2.3Plus = QuantitativeParameterValue.rangeValue</p> <p>Map:LSDAMv2.2.3Plus = PerformedSpecimenSpun.gravityForce</p> <p>Map:LSDAMv2.2.3Plus = DefinedSpecimenSpun.gravityForce</p>

Class: Experiment

Package: Experiment Sub-Domain

DEFINITION:

A Research Project whose objectives are to generate hypotheses or lead to discoveries.

EXAMPLE(S):

Gene expression experiment intended to discover novel genetic biomarkers.

Physicochemical characterization of nanoparticles.

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:LSDAMv2.2.3Plus = Experiment

Connectors

Source	Connector	Target	Notes
Experiment	specializes	ResearchProject	<p>DESCRIPTION: Each Experiment always specializes one ResearchProject. Each ResearchProject might be specialized by one Experiment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PhysicoChemicalCharacterization	specializes	Experiment	<p>DESCRIPTION: Each PhysicoChemicalCharacterization always specializes one Experiment. Each Experiment might be specialized by one PhysicoChemicalCharacterization .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalFactor 0..* definingExperimentalFactor	defines	Experiment 1..* definedExperiment	<p>DESCRIPTION: Each ExperimentalFactor always defines one or more Experiment. Each Experiment might be defined by one or more ExperimentalFactor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
InVivoCharacterization	specializes	Experiment	DESCRIPTION: Each InVivoCharacterization always specializes one Experiment. Each Experiment might be specialized by one InVivoCharacterization . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
InVitroCharacterization	specializes	Experiment	DESCRIPTION: Each InVitroCharacterization always specializes one Experiment. Each Experiment might be specialized by one InVitroCharacterization . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
purposeCode <i>Class:</i> Experiment <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the overall intent or rationale of the activity collection.</p> <p>EXAMPLE(S): diagnostic testing, hypothesis testing, discovery, specimen processing, in vitro characterization</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = ActivityCollection.purposeCode

Attribute	Notes	Constraints and Tags
designType <i>Class:</i> Experiment <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A term allowing the classification of the experiment based on the overall experimental design.</p> <p>EXAMPLE(S): factorial designs, covariance designs, blocking designs, titration study</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Experiment.designType

Class: ExperimentalActivityItem

Package: Experiment Sub-Domain

DEFINITION:

The role the entity (specifically an Animal, a BiologicEntityGroup, a Material, or a MolecularSequence) plays within the execution of an activity.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = ActivityItem
- ObjectClassConceptCode = C44278
- ObjectClassQualifierConceptCode1 = C28296

Connectors

Source	Connector	Target	Notes
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	Animal 0..1 playingAnimal	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one Animal. Each Animal might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	MolecularSequence 0..1 playingMolecularSequence	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one MolecularSequence. Each MolecularSequence might play one or more ExperimentalActivityItem.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	Material 0..1 playingMaterial	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one Material. Each Material might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalActivityItem 0..* usedExperimentalActivityItem	is used in	Activity 1 usingActivity	<p>DESCRIPTION: Each ExperimentalActivityItem always is used in one Activity. Each Activity might use one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTES: The documented use cases from life sciences are limited to procedure and observations. Use cases for other kinds of activities in life sciences are needed to support this relationship at Activity level. In the next release, this relationship will have to be re-assessed.</p>
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	BiologicEntityGroup 0..1 playingBiologicEntityGroup	<p>DESCRIPTION: Each ExperimentalActivityItem might be played by one BiologicEntityGroup. Each BiologicEntityGroup might play one or more ExperimentalActivityItem.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DeviceParameterValue 0..* limitingDeviceParameterValue	limits	ExperimentalActivityItem 1 limitedExperimentalActivityItem	DESCRIPTION: Each DeviceParameterValue always limits one ExperimentalActivityItem. Each ExperimentalActivityItem might be limited by one or more DeviceParameterValue. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalFactorValue 0..* limitingExperimentalFactorValue	limits	ExperimentalActivityItem 1 limitedExperimentalActivityItem	DESCRIPTION: Each ExperimentalFactorValue always limits one ExperimentalActivityItem. Each ExperimentalActivityItem might be limited by one or more ExperimentalFactorValue. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
functionTypeCode <i>Class:</i> ExperimentalActivityItem <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the role an entity plays in an activity that is part of an experiment or non-research project.</p> <p>EXAMPLE(S): reagent, host, sample, data collection tool, analytical tool, a molecular sequence functioning as a reference sequence</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = PerformedSpecimenEmbedded.embeddingMediumType Map:LSDAMv2.2.3Plus = ActivityItem.typeCode

Class: ExperimentalFactor

Package: Experiment Sub-Domain

DEFINITION:

An independent variable manipulated by the experimentalist with the intention to affect biological systems in a way that can be measured by an assay.

EXAMPLE(S):

genotype, time as a factor in time series studies, dose a factor in dose response studies, compound as a factor in compound treatment studies, or disease state in disease studies

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = ExperimentalFactor

Connectors

Source	Connector	Target	Notes
ExperimentalFactor 0..* definingExperimentalFactor	defines	Experiment 1..* definedExperiment	<p>DESCRIPTION: Each ExperimentalFactor always defines one or more Experiment. Each Experiment might be defined by one or more ExperimentalFactor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalFactorValue 0..* assertedExperimentalFactorValue	is value for	ExperimentalFactor 1 assertingExperimentalFactor	<p>DESCRIPTION: Each ExperimentalFactorValue always is value for one ExperimentalFactor. Each ExperimentalFactor might have value of one or more ExperimentalFactorValue.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
name <i>Class:</i> ExperimentalFactor <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier containing a word or phrase that constitutes the distinctive designation of a factor.</p> <p>EXAMPLE(S): genotype, time, compound, dose</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = ExperimentalFactor.name
type <i>Class:</i> ExperimentalFactor <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The text (and optional code) specifying the classification of the factor.</p> <p>EXAMPLE(S): temporal, stressor as in OBI, and biological, environmental, methodological as in MGED Ontology</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = ExperimentalFactor.typeCode

Class: ExperimentalFactorValue

Package: Experiment Sub-Domain

DEFINITION:

A specific type, time period, compound, dose, temperature, magnitude, quantity, element, aspect or other item in a variable manipulated by the experimentalist.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = ExperimentalFactorValue

Connectors

Source	Connector	Target	Notes
ExperimentalFactorValue 0..* assertedExperimentalFactorValue	is value for	ExperimentalFactor 1 assertingExperimentalFactor	<p>DESCRIPTION: Each ExperimentalFactorValue always is value for one ExperimentalFactor. Each ExperimentalFactor might have value of one or more ExperimentalFactorValue.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
ExperimentalFactorValue 0..* limitingExperimentalFactorValue	limits	ExperimentalActivityItem 1 limitedExperimentalActivityItem	NOTE(S): DESCRIPTION: Each ExperimentalFactorValue always limits one ExperimentalActivityItem. Each ExperimentalActivityItem might be limited by one or more ExperimentalFactorValue. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
value <i>Class:</i> ExperimentalFactorValue <i>Datatype:</i> ANY <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	DEFINITION: The value for this use of the factor. EXAMPLE(S): wild_type (for genotype), 24 hours (for time between doses), Aspirin (for compound), Low Dose (dose), 1C (for temperature) OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = ExperimentalFactorValue.value

Class: InVitroCharacterization

Package: Experiment Sub-Domain

DEFINITION:

An Experiment whose objective is to describe distinctive characteristics or essential features of the assay which is conducted in an artificial environment, such as in a test tube, under a defined and controlled set of solvent and solute conditions.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = InvitroCharacterization

Connectors

Source	Connector	Target	Notes
InVitroCharacterization	specializes	Experiment	DESCRIPTION: Each InVitroCharacterization always specializes one

Source	Connector	Target	Notes
			<p>Experiment. Each Experiment might be specialized by one InVitroCharacterization .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: InVivoCharacterization

Package: Experiment Sub-Domain

DEFINITION:

An Experiment whose objective is the appraisal of the biological properties or activities of a substance by testing its effect on an organism.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = InvivoCharacterization

Connectors

Source	Connector	Target	Notes
InVivoCharacterization	specializes	Experiment	<p>DESCRIPTION: Each InVivoCharacterization always specializes one Experiment. Each Experiment might be specialized by one InVivoCharacterization .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PhysicoChemicalCharacterization

Package: Experiment Sub-Domain

DEFINITION:

An Experiment whose objective is to determine the material, structural and chemical properties of a substance.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = PhysicoChemicalCharacterization

Connectors

Source	Connector	Target	Notes
PhysicoChemicalCharacterization	specializes	Experiment	<p>DESCRIPTION: Each PhysicoChemicalCharacterization always specializes one Experiment. Each Experiment might be specialized by one PhysicoChemicalCharacterization .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Imaging Sub-Domain

Package in package 'BRIDG Domain Information Model'

Imaging Sub-Domain

View IM: Imaging diagram

Class diagram in package 'Imaging Sub-Domain'

The Imaging sub-domain represents the core concepts related to this domain, including imaging protocols, imaging activities, images and other related concepts.

Collaboration with other Imaging work groups: With the broader scope of BRIDG 4.0 covering translational research and the harmonization of Life Sciences Model and CDISC Pharmogenomic & Pharmacogenetics domains, it is likely that there is some overlap of concepts between BRIDG Imaging sub-domain concepts and the models being developed in the NCI Imaging Workspace community, HL7 Imaging work group, etc. BRIDG recognizes these group models as peers or sibling models and is committed to working with the teams to align on common semantics. The BRIDG team has started the conversation with the NCI Imaging community to this effect and plans to continue the dialogue on how to operationalize the collaboration and leverage the subject matter expertise of this and other groups.

View IM: Imaging

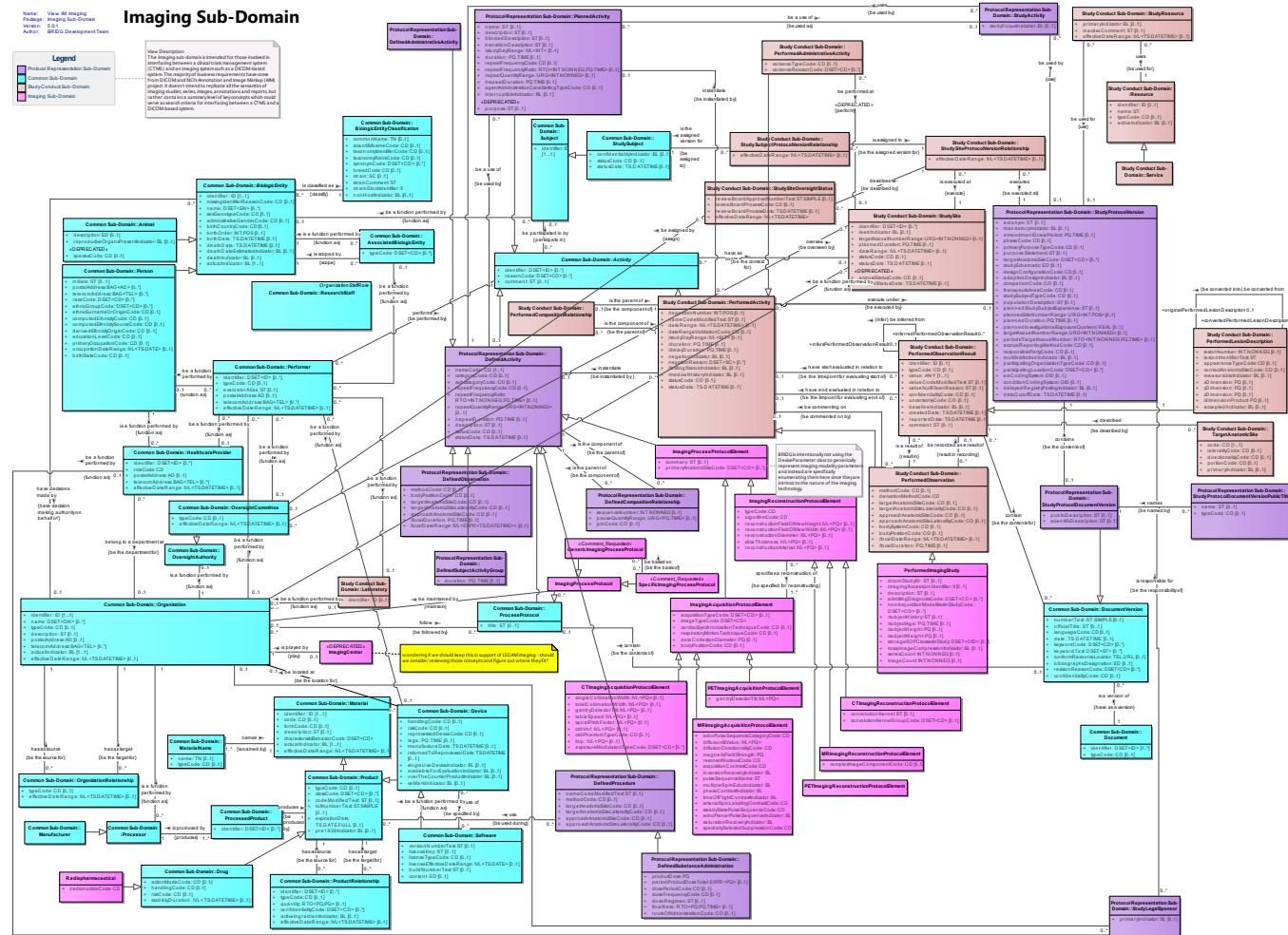


Figure 8: View IM: Imaging

Imaging Acquisition diagram

Class diagram in package 'Imaging Sub-Domain'

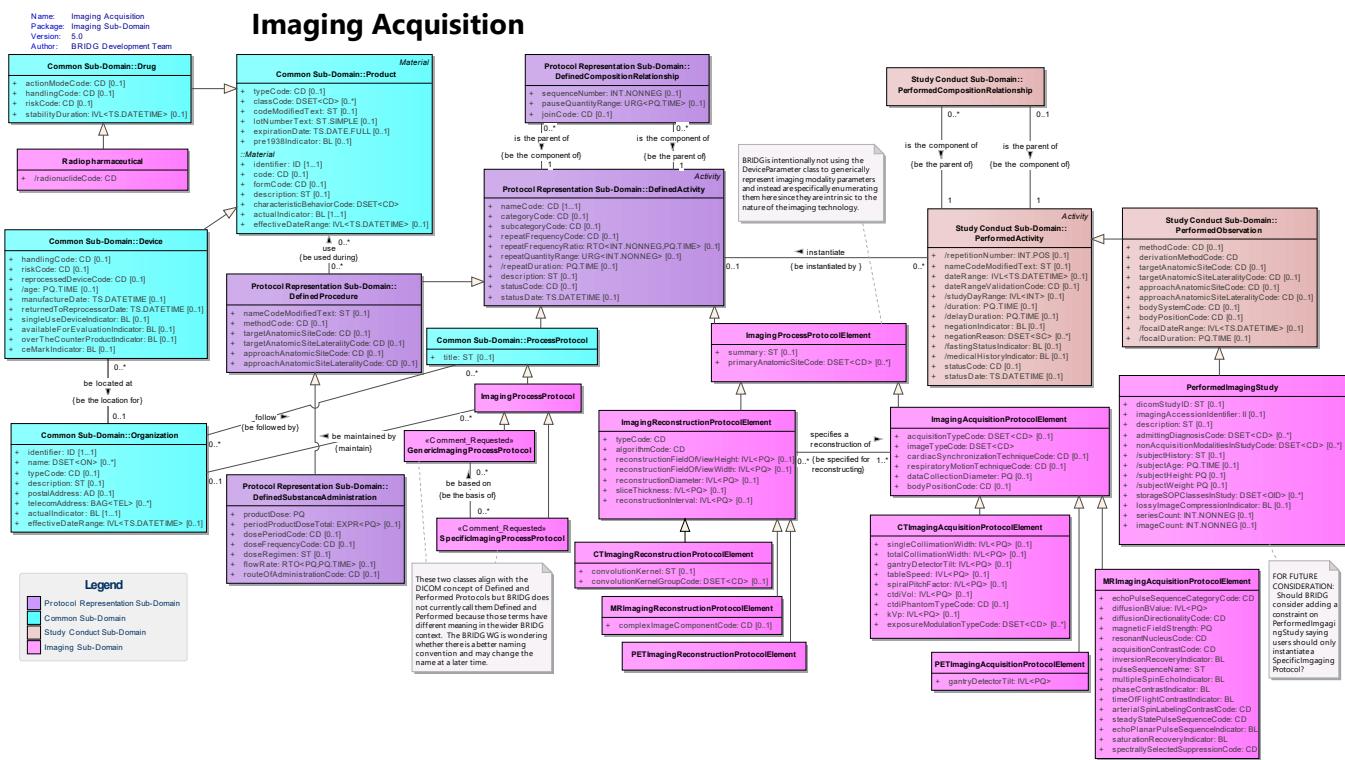


Figure 9: Imaging Acquisition

DICOM SR TID 1500 BRIDG Class Diagram diagram

Class diagram in package 'Imaging Sub-Domain'

DICOM SR TID 1500 BRIDG Class Diagram

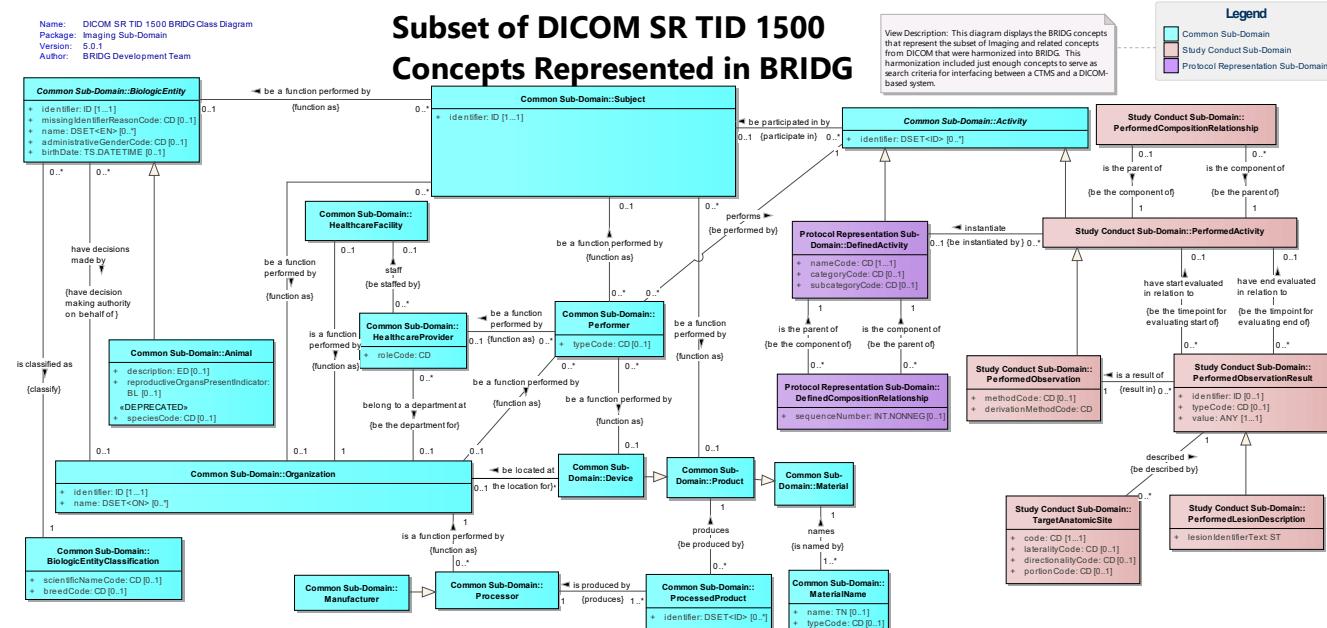


Figure 10: DICOM SR TID 1500 BRIDG Class Diagram

Class: CTImagingAcquisitionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of scanning parameter values necessary to perform a single CT scan in the acquisition protocol. [adapted from NEMA XR 25-2010, <https://www.nema.org/Standards/Pages/Computed-Tomography-Dose-Check.aspx>]

EXAMPLE(S):

A chest Protocol might include three elements: two localizer CT radiographs (AP and Lateral) and a single helical scan, each of which would be described in separate steps with different parameter values.

OTHER NAME(S):

NOTE(S):

Given that this sub-subclass of ImagingProcessProtocolElement actually names the process as Acquisition and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920)
- Map:DICOM = CT Acquisition Details Macro - CT Acquisition Details Sequence (0018,9304)

Connectors

Source	Connector	Target	Notes
CTImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each CTImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specialized by one CTImagingAcquisitionProtocolElement.</p>

Source	Connector	Target	Notes
			<p>colElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
singleCollimationWidth <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The width of a single row of acquired data.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of linear distince, e.g. mm.</p>	Map:DICOM = CT Acquisition Details Macro - CT Acquisition Details Sequence > Single Collimation Width (0018,9306) Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Single Collimation Width (0018,9306)
totalCollimationWidth <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The width of the total collimation over the area of active x-ray detection.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of linear distince, e.g. mm.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Total Collimation Width (0018,9307) Map:DICOM = CT Acquisition Details Macro - CT Acquisition Details Sequence > Total Collimation Width (0018,9307)
gantryDetectorTilt <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Nominal angle of tilt in degrees of the scanning gantry.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of plane angle , e.g. degrees. Zero degrees means the gantry is not tilted, negative degrees are when the top of the gantry is tilted away from where the table enters the gantry.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Gantry/Detector Tilt (0018,1120) Map:DICOM = CT Acquisition Details Macro - CT Acquisition Details Sequence > Gantry/Detector Tilt (0018,1120)
tableSpeed <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The distance that the table moves per unit of time during the gathering of data.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of linear distance divided by time.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Table Speed (0018,9309) Map:DICOM = CT Table Dynamics Macro - CT Table Dynamics Sequence > Table Speed (0018,9309)

Attribute	Notes	Constraints and Tags
spiralPitchFactor <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Ratio of the distance that the table moves during a complete revolution of the source around the gantry orbit, to the width of the total collimation over the area of active x-ray detection.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of unity.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Spiral Pitch Factor (0018,9311) Map:DICOM = CT Table Dynamics Macro - CT Table Dynamics Sequence > Spiral Pitch Factor (0018,9311)
ctdiVol <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The average dose over the total volume scanned for the selected CT conditions of operation (calculated according to IEC 60601-2-44, Ed.2.1 (Clause 29.1.103.4)).</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Computed Tomography Dose Index (CTDI) Volume</p> <p>NOTE(S): The units are energy dose, e.g. mGy.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CTDIVol (0018,9345) Map:DICOM = CT Exposure Macro - CT Exposure Sequence > CTDIVol (0018,9345) Map:DICOM = CT Acquisition Details Macro - CT Exposure Sequence > CTDIVol (0018,9345)
ctdiPhantomTypeCode <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The type of phantom to use for CTDI measurement according to IEC 60601-2-44.</p> <p>EXAMPLE(S): (113690, DCM, "IEC Head Dosimetry Phantom") (113691, DCM, "IEC Body Dosimetry Phantom")</p> <p>OTHER NAME(S): Computed Tomography Dose Index (CTDI) Phantom Type Code</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CTDI Phantom Type Code Sequence (0018,9346) Map:DICOM = CT Exposure Macro - CT Exposure Sequence > CTDI Phantom Type Code Sequence (0018,9346)
kVp <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Peak kilovoltage output of the x-ray generator.</p> <p>EXAMPLE(S): 140 kv</p> <p>OTHER NAME(S): KVP (0018,0060)</p> <p>NOTE(S): The units are of electrical potential.</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CT X-Ray Details Sequence (0018,9325) > KVP (0018,0060) Map:DICOM = CT XRay Details Sequence Macro - CT X-Ray Details Sequence > KVP (0018,0060)

Attribute	Notes	Constraints and Tags
exposureModulationType Code <i>Class:</i> CTImagingAcquisitionProto colElement <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: The manner in which tube current is varied in order to limit the dose.</p> <p>EXAMPLE(S): NONE ANGULAR = current is modulated over different tube angles LONGITUDINAL = current is modulated along the axis of the table ECG_BASED = current is modulated based on the cardiac phase ORGAN_BASED = current is modulated based on the organs in the field of view</p> <p>OTHER NAME(S): Exposure Modulation Type (0018,9323)</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CT X-Ray Details Sequence (0018,9325) > Exposure Modulation Type (0018,9323) Map:DICOM = CT Exposure Macro - CT Exposure Sequence > Exposure Modulation Type (0018,9323)

Class: CTImagingReconstructionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of image generation parameter values necessary to create a single set of images from a single CT scan.

EXAMPLE(S):

A CT Protocol frequently specifies multiple reconstructions. For example, a single helical Acquisition Element may be reconstructed once as thin slices and a second time as thick slices.

OTHER NAME(S):

NOTE(S):

Given that this sub-subclass of ImagingProcessProtocolElement actually names the process as Reconstruction and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence (0018,9314)
- Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934)

Connectors

Source	Connector	Target	Notes
CTImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	<p>DESCRIPTION: Each CTImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement. Each ImagingReconstructionProtocolElement might be specialized by one CTImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
convolutionKernel <i>Class:</i> CTImagingReconstructionProtocolElement <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A label describing the mathematical operations used to reconstruct images from the acquired data.</p> <p>EXAMPLE(S): For soft tissue: B30 (Seimens), Standard (GE), FC03 (Toshiba)</p> <p>OTHER NAME(S): Convolution Kernel (0018,1210)</p> <p>NOTE(S): The values for this attribute are vendor specific and not coded.</p>	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Convolution Kernel (0018,1210)
convolutionKernelGroupCode <i>Class:</i> CTImagingReconstructionProtocolElement <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the family of mathematical operations to use to reconstruct images from the acquired data.</p> <p>EXAMPLE(S): BRAIN SOFT_TISSUE LUNG BONE CONSTANT_ANGLE</p> <p>OTHER NAME(S): Convolution Kernel Group (0018,9316)</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Reconstruction Macro - CT Reconstruction Sequence > Convolution Kernel Group (0018,9316)

Class: GenericImagingProcessProtocol

Package: Imaging Sub-Domain

DEFINITION:

Provides the details for how the images in the imaging study are to be captured and reconstructed, such as a complete description of imaging parameters, instrumentation, subject positioning, etc.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

This class includes content from both the DICOM CT Defined Acquisition Technique Module and the DICOM CT Defined Reconstruction Technique Module.

Tagged Values:

- Map:DICOM = Defined CT Reconstruction Module
- Map:DICOM = Defined CT Acquisition Module

Connectors

Source	Connector	Target	Notes
GenericImagingProcessProtocol	specializes	ImagingProcessProtocol	<p>DESCRIPTION: Each GenericImagingProcessProtocol always specializes one ImagingProcessProtocol.</p> <p>Each ImagingProcessProtocol might be specialized by one GenericImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecificImagingProcessProtocol 0..* basingSpecificImagingProtocol	be based on	GenericImagingProcessProtocol 0..* basedGenericImaginProtocol	<p>DESCRIPTION: Each SpecificImagingProcessProtocol might be based on one or more GenericImagingProcessProtocol. Each GenericImagingProcessProtocol might be the basis of one or more SpecificImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ImagingAcquisitionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of scanning parameter values necessary to perform a single scan in the acquisition protocol. [adapted from NEMA XR 25-2010, <https://www.nema.org/Standards/Pages/Computed-Tomography-Dose-Check.aspx>]

EXAMPLE(S):

A chest Protocol might include three elements: two localizer CT radiographs (AP and Lateral) and a single helical scan, each of which would be described in separate steps with different parameter values.

OTHER NAME(S):

NOTE(S):

Given that this subclass of ImagingProcessProtocolElement actually names the process as Acquisition and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = Defined CT Acquisition Module - Acquisition Protocol Element Specification Sequence (0018,991F)
- Map:DICOM = CT Image Module - Image Type (0008,0008)

Connectors

Source	Connector	Target	Notes
ImagingAcquisitionProtocolElement	specializes	ImagingProcessProtocolElement	<p>DESCRIPTION: Each ImagingAcquisitionProtocolElement always specializes one ImagingProcessProtocolElement. Each ImagingProcessProtocolElement might be specialized by one ImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ImagingReconstructionProtocolElement 0..* reconstructingImagingReconstructionProtocolElement	specifies a reconstruction of	ImagingAcquisitionProtocolElement 1..* reconstructedImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each ImagingReconstructionProtocolElement always specifies a reconstruction of one or more ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specified for reconstructing one or more ImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PETImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each PETImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocol</p>

Source	Connector	Target	Notes
			<p>Element might be specialized by one PETImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CTImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each CTImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specialized by one CTImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MRIImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each MRIImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specialized by one MRIImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
acquisitionTypeCode <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying spatial aspects of the mechanism of data collection.</p> <p>EXAMPLE(S): For CT, this specifies the trajectory of the X-Ray source relative to the object being imaged, e.g. SEQUENCED, SPIRAL, CONSTANT_ANGLE, STATIONARY, FREE For MRI, this specifies the spatial encoding scheme, e.g. 1D, 2D, 3D</p> <p>OTHER NAME(S): Acquisition Type (0018,9302)</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Acquisition Type (0018,9302) Map:DICOM = MR Pulse Sequence Module - MR Acquisition Type (0018,0023) Map:DICOM = CT Acquisition Details Macro - CT Acquisition Type Sequence > Acquisition Type (0018,9302) Map:DICOM = MR Image Module - MR Acquisition Type (0018,0023)
imageTypeCode <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value that specifies the most important aspect of the images or their derivation.</p> <p>EXAMPLE(S): DYNAMIC, STRESS, RCBV</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = PET Frame Type Macro - PET Frame Type Sequence > Frame Type (0008,9007) Map:DICOM = MR Image Frame Type Macro - MR Image Frame Type Sequence > Frame Type (0008,9007) Map:DICOM = Enhanced PET Image Module - Image Type (0008,0008) Map:DICOM = Enhanced MR Image Module - Image Type (0008,0008) Map:DICOM = Enhanced CT Image Module - Image Type (0008,0008) Map:DICOM = CT Image Frame Type Macro - CT Image Frame Type Sequence > Frame Type (0008,9007) Map:DICOM = PET Image Module - Image Type (0008,0008) Map:DICOM = MR Image Module - Image Type (0008,0008) Map:DICOM = General Image Module - Image Type (0008,0008) Map:DICOM = CT Image Module - Image Type (0008,0008)
cardiacSynchronizationTechniqueCode <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The means used to coordinate the collection or reconstruction of data with the cardiac cycle.</p> <p>EXAMPLE(S): NONE, REALTIME, PROSPECTIVE, RETROSPECTIVE, PACED</p> <p>OTHER NAME(S): Cardiac Synchronization Technique (0018,9037)</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CT X-Ray Details Sequence (0018,9325) > Cardiac Synchronization Technique (0018,9037)

Attribute	Notes	Constraints and Tags
respiratoryMotionTechniqueCode <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The means to be used to coordinate the collection or reconstruction of data with breathing.</p> <p>EXAMPLE(S): NONE, BREATH HOLD, REALTIME, GATING, TRACKING, RETROSPECTIVE, CORRECTION</p> <p>OTHER NAME(S): Respiratory Motion Compensation Technique (0018,9170)</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CT X-Ray Details Sequence (0018,9325) > Respiratory Motion Compensation Technique (0018,9170) Map:DICOM = Respiratory Synchronization Module - Respiratory Motion Compensation Technique (0018,9170)
dataCollectionDiameter <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The diameter of the region over which information is acquired.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Exposure Modulation Type (0018,9323)</p> <p>NOTE(S): The units are of linear distince, e.g. mm..</p>	Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > CT X-Ray Details Sequence (0018,9325) > Data Collection Diameter (0018,0090) Map:DICOM = PET Frame Acquisition Macro - PET Frame Acquisition Sequence > Data Collection Diameter (0018,0090) Map:DICOM = CT Acquisition Details Macro - CT Acquisition Details Sequence > Data Collection Diameter (0018,0090)
bodyPositionCode <i>Class:</i> ImagingAcquisitionProtocol Element <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the 3-dimensional spatial orientation of a subject during this imaging acquisition protocol element.</p> <p>EXAMPLE(S): supine, trendelenburg, standing</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Patient Positioning Module - Protocol Defined Patient Position (0018,9947)

Class: ImagingProcessProtocol

Package: Imaging Sub-Domain

DEFINITION:

A collection of activities for the purpose of obtaining images of the subject, including purpose and objectives, and a description of the appropriate equipment characteristics, subject preparation and positioning, anatomical location, functional conditions, acquisition and reconstruction techniques and other parameters.

EXAMPLE(S):

CT of chest/abdomen/pelvis for oncology follow-up, using intravenous and oral contrast, with the subject positioned supine with arms up, in helical mode with tube current modulation, with single breath hold during entire scan, reconstructed in 2.5 mm thick slices using soft tissue and bone algorithms.

OTHER NAME(S):

NOTE(S):

This class combines the common concept of an imaging protocol underlying the DICOM Defined and Performed Acquisition and Reconstruction Protocols.

In modeling, often the same term is used to mean different things and a single concept can have more than one name. In the healthcare arena, the term "protocol" is somewhat overloaded and must be qualified to provide semantic context. Therefore during the early years of the BRIDG project, the term "study protocol" was chosen to disambiguate the concept of the detailed plan for a clinical study (the scope of BRIDG at that time) from other kinds of protocols such as are common in life sciences. In BRIDG, the notion of a study protocol is very specific in purpose and includes (but is not limited to) the design, statistical considerations, activities to test a particular hypothesis or answer a particular question that is the basis of the study, characteristics, specifications, objective(s), background, pre-study/study/post-study portions of the plan (including the design, methodology, statistical considerations, organization). For a more complete discussion of the notion of the study protocol see the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion, StudyConduct and all their associations.

With the addition of life sciences to the scope of the BRIDG model, there came along (with that scope) the need to identify the kind of protocol that represents a more simple or atomic concept, that of "a composite activity that serves as a rule that guides how activities should be performed." This concept, represented by the ProcessProtocol class, has a more limited size than the concept of a study protocol does and represents a standardized approach to doing tasks or activities that are not as big as the plan for a whole study.

With the further addition of imaging concepts to the BRIDG model, there came the need to add further specific types of process protocols. So the same term, ProcessProtocol has been leveraged with a prefix to indicate the scope of this subclass - ImagingProcessProtocol.

The BRIDG team acknowledges that overloaded terms are problematic. The team recognizes that many different users within the BRIDG community will have differing opinions on what the meaning of a term is, which term is the best to use for each concept, and how to define them most effectively. Given that the real "meat" of a concept is in the definition, the BRIDG team aims to choose the most unambiguous term to use as the class name, to make the class definition as explicit and clear as possible, to provide sufficient examples and other names to illustrate the range of possible instances that could be represented by the class. So the BRIDG model is maintaining the distinction between a ProcessProtocol and a StudyProtocol because there is a distinction in the domain that we're trying to disambiguate - the concepts, attributes and relationships that describe an SOP-like, atomic, reusable ProcessProtocol are very different than those of a full-blown clinical trial StudyProtocol. Linking the classes because they both contain the same overloaded word would create artificial complexity in the model and not serve the ultimate purpose of interoperability across systems that need to exchange biomedical research data.

Tagged Values:

- Map:DICOM = Defined CT Reconstruction Module
- Map:DICOM = Performed CT Acquisition Module
- Map:DICOM = Performed CT Reconstruction Module
- Map:DICOM = Defined CT Acquisition Module
- Map:DICOM = Protocol Context Module
- Map:DICOM = General Series Module - Protocol Name (0018,1030)
- Map:LSDAMv2.2.3Plus = ImageAcquisitionProtocol

Connectors

Source	Connector	Target	Notes
ImagingProcessProtocol	specializes	ProcessProtocol	<p>DESCRIPTION: Each ImagingProcessProtocol always specializes one ProcessProtocol. Each ProcessProtocol might be specialized by one ImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
ImagingProcessProtocol 0..* maintainedImagingProcessProtocol	be maintained by	Organization 0..1 maintainingOrganization	<p>DESCRIPTION: Each ImagingProcessProtocol might be maintained by one Organization. Each Organization might maintain one or more ImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecificImagingProcessProtocol	specializes	ImagingProcessProtocol	<p>DESCRIPTION: Each SpecificImagingProcessProtocol always specializes one ImagingProcessProtocol. Each ImagingProcessProtocol might be specialized by one SpecificImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
GenericImagingProcessProtocol	specializes	ImagingProcessProtocol	<p>DESCRIPTION: Each GenericImagingProcessProtocol always specializes one ImagingProcessProtocol. Each ImagingProcessProtocol might be specialized by one GenericImagingProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ImagingProcessProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of parameter values necessary to obtain or reconstruct a set of images for an imaging process protocol.

EXAMPLE(S):

A chest Protocol might include three elements: two localizer CT radiographs (AP and Lateral) and a single helical scan, each of which would be described in separate steps with different parameter values.

A CT Protocol frequently specifies multiple reconstructions. For example, a single helical Acquisition Element may be reconstructed once as thin slices and a second time as thick slices.

OTHER NAME(S):**NOTE(S):**

This class combines the common concept for the process protocol element from the DICOM CT Defined Acquisition Technique Module, the DICOM CT Defined Reconstruction Technique Module, DICOM CT Performed Acquisition Technique Module and the DICOM CT Performed Reconstruction Technique Module.

Tagged Values:

- Map:DICOM = Performed CT Reconstruction Module - Protocol Element Identification Macro > Reconstruction Protocol Element Sequence (0018,9934) > Protocol Element Characteristics Summary (0018,9923)

Connectors

Source	Connector	Target	Notes
ImagingProcessProtocolElement	specializes	DefinedActivity	<p>DESCRIPTION: Each ImagingProcessProtocolElement always specializes one DefinedActivity. Each DefinedActivity might be specialized by one ImagingProcessProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ImagingAcquisitionProtocolElement	specializes	ImagingProcessProtocolElement	<p>DESCRIPTION: Each ImagingAcquisitionProtocolElement always specializes one ImagingProcessProtocolElement. Each ImagingProcessProtocolElement might be specialized by one ImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
ImagingReconstructionProto colElement	specializes	ImagingProcessProtocolEle ment	<p>NOTE(S):</p> <p>DESCRIPTION: Each ImagingReconstructionProto colElement always specializes one ImagingProcessProtocolEle ment. Each ImagingProcessProtocolEle ment might be specialized by one ImagingReconstructionProto colElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
summary <i>Class:</i> ImagingProcessProtocolEle ment <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A brief statement about the characteristics of this element, which is intended for use by the radiologist, technologist and/or physicist during management of the imaging protocol to understand the characteristics of the element in the protocol.</p> <p>EXAMPLE(S): "dose-optimized pelvis" (acquisition protocol element) "thin slides for cardiac 3D" (reconstruction protocol element)</p> <p>OTHER NAME(S): From DICOM: Protocol Element Characteristics Summary (0018,9923)</p> <p>NOTE(S):</p>	<p>Map:DICOM = Performed CT Reconstruction Module - Protocol Element Identification Macro > Reconstruction Protocol Element Sequence (0018,9934) > Protocol Element Characteristics Summary (0018,9923)</p> <p>Map:DICOM = CT Performed Acquisition Technique Module - Acquisition Element Sequence > Element Summary Description</p>

Attribute	Notes	Constraints and Tags
primaryAnatomicSiteCode <i>Class:</i> ImagingProcessProtocolElement <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of this imaging process protocol element.</p> <p>EXAMPLE(S): Kidney</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Multiple contiguous sites within the same organ system may be referenced.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:DICOM = Patient Positioning Module - Primary Anatomic Structure Sequence (0008,2228)

Class: ImagingReconstructionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of image generation parameter values necessary to create a single set of images from a single scan.

EXAMPLE(S):

A CT Protocol frequently specifies multiple reconstructions. For example, a single helical Acquisition Element may be reconstructed once as thin slices and a second time as thick slices.

OTHER NAME(S):

Reconstruction Element Sequence (XXXX, XXXX)

NOTE(S):

Given that this subclass of ImagingProcessProtocolElement actually names the process as Reconstruction and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = Defined CT Reconstruction Module - Reconstruction Protocol Element Specification Sequence (0018,9933)
- Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence > Reconstruction Algorithm (0018,9315)

Connectors

Source	Connector	Target	Notes
ImagingReconstructionProtocolElement 0..* reconstructingImagingReconstructionProtocolElement	specifies a reconstruction of	ImagingAcquisitionProtocolElement 1..* reconstructedImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each ImagingReconstructionProtocolElement always specifies a reconstruction of one or more ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specified for reconstructing one or</p>

Source	Connector	Target	Notes
			<p>more ImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ImagingReconstructionProtocolElement	specializes	ImagingProcessProtocolElement	<p>DESCRIPTION: Each ImagingReconstructionProtocolElement always specializes one ImagingProcessProtocolElement. Each ImagingProcessProtocolElement might be specialized by one ImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MRImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	<p>DESCRIPTION: Each MRImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement. Each ImagingReconstructionProtocolElement might be specialized by one MRImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PETImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	<p>DESCRIPTION: Each PETImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement. Each</p>

Source	Connector	Target	Notes
			<p>ImagingReconstructionProtocolElement might be specialized by one PETImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CTImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	<p>DESCRIPTION: Each CTImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement. Each ImagingReconstructionProtocolElement might be specialized by one CTImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A coded value specifying the kind of algorithm used when reconstructing the image from the data acquired during the acquisition process.</p> <p>EXAMPLE(S): For PET: 2D, 3D, 3D_REBINNED</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence > Reconstruction Type (0018,9756)

Attribute	Notes	Constraints and Tags
algorithmCode <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the algorithm to use when reconstructing the image from the data acquired during the acquisition process.</p> <p>EXAMPLE(S): For CT: FILTER_BACK_PROJ, ITERATIVE For PET: FILTER_BACK_PROJ, REPROJECTION, RAMLA, MLEM</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Reconstruction Algorithm Sequence (0018,993D) Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence > Reconstruction Algorithm (0018,9315) Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence > Reconstruction Algorithm (0018,9315)
reconstructionFieldOfView <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The vertical dimension of the rectangular region from which data is used in creating the reconstruction of the image.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Reconstruction Field of View (0018,9317) - second value</p> <p>NOTE(S): The units are of linear distance, e.g. mm.</p>	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Reconstruction Field of View (0018,9317) Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence > Reconstruction Field of View (0018,9317) Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence > Reconstruction Field of View (0018,9317)
reconstructionFieldOfView <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The horizontal dimension of the rectangular region from which data is used in creating the reconstruction of the image.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Reconstruction Field of View (0018,9317) - first value</p> <p>NOTE(S): The units are of linear distance, e.g. mm.</p>	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Reconstruction Field of View (0018,9317) Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence > Reconstruction Field of View (0018,9317) Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence > Reconstruction Field of View (0018,9317)
reconstructionDiameter <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The diameter of the region from which data is used in creating the reconstruction of the image.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Reconstruction Diameter (0018,1100)</p> <p>NOTE(S): The units are of linear distance, e.g. mm.</p>	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Reconstruction Diameter (0018,1100) Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence > Reconstruction Diameter (0018,1100) Map:DICOM = CT Reconstruction Macro - CT Reconstruction Sequence > Reconstruction Diameter (0018,1100)

Attribute	Notes	Constraints and Tags
sliceThickness <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The cross plane dimension of the reconstructed image. EXAMPLE(S): OTHER NAME(S): Slice Thickness (0018,0050) NOTE(S): The units are of linear distance, e.g. mm.	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Slice Thickness (0018,0050)
reconstructionInterval <i>Class:</i> ImagingReconstructionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The cross plane distance between the centers of adjacent, parallel reconstructed images. EXAMPLE(S): OTHER NAME(S): Spacing Between Slices (0018,0088) NOTE(S): The units are of linear distance, e.g. mm.	Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Spacing Between Slices (0018,0088)

Class: MRIImagingAcquisitionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of scanning parameter values necessary to perform a single MR scan in the acquisition protocol. [adapted from NEMA XR 25-2010, <https://www.nema.org/Standards/Pages/Computed-Tomography-Dose-Check.aspx>]

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:DICOM = MR Modifier Macro - MR Modifier Sequence (0018,9115)

Connectors

Source	Connector	Target	Notes
MRIImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION: Each MRIImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocolElement. Each ImagingAcquisitionProtocolElement might be specialized by one MRIImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
echoPulseSequenceCategoryCode <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A coded value specifying an echo category of pulse sequences. EXAMPLE(S): SPIN, GRADIENT, BOTH OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Echo Pulse Sequence (0018,9008)
diffusionBValue <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: The factor by which the acquisition is sensitized to the Brownian motion of water molecules. EXAMPLE(S): OTHER NAME(S): diffusion sensitization factor NOTE(S): The units are of time/area, e.g. s/mm ² .	Map:DICOM = MR Diffusion Macro - MR Diffusion Sequence > Diffusion b-value (0018,9087)
diffusionDirectionalityCode <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A coded value specifying whether diffusion conditions for the frame are directional, or isotropic with respect to direction.. EXAMPLE(S): DIRECTIONAL, BMATRIX, ISOTROPIC, NONE OTHER NAME(S): NOTE(S):	Map:DICOM = MR Diffusion Macro - MR Diffusion Sequence > Diffusion Directionality (0018,9075)
magneticFieldStrength <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A vector quantity indicating the ability of a magnetic field to exert a force on moving electric charges. [The American Heritage® Science Dictionary] EXAMPLE(S): OTHER NAME(S): NOTE(S): The units are of magnetic flux density, e.g. tesla.	Map:DICOM = MR Image and Spectroscopy Instance Macro - Magnetic Field Strength (0018,0087)

Attribute	Notes	Constraints and Tags
resonantNucleusCode <i>Class:</i> MRImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the atomic nucleus that is the target of the acquisition.</p> <p>EXAMPLE(S): 1H, 3HE, 7LI, 13C, 19F, 23NA, 31P, 129XE</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = MR Image and Spectroscopy Instance Macro - Resonant Nucleus (0018,9100)
acquisitionContrastCode <i>Class:</i> MRImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the inherent (as opposed to exogenous) contrast in the acquisition.</p> <p>EXAMPLE(S): DIFFUSION FLOW_ENCODED - Flow Encoded contrast FLUID_ATTENUATED - Fluid Attenuated T2 weighted contrast PERFUSION - Perfusion weighted contrast PROTON_DENSITY - Proton Density weighted contrast STIR - Short Tau Inversion Recovery TAGGING - Superposition of thin saturation bands onto image T1 - T1 weighted contrast T2 - T2 weighted contrast T2_STAR - T2* weighted contrast TOF - Time Of Flight weighted contrast</p> <p>OTHER NAME(S): inherent contrast</p> <p>NOTE(S):</p>	Map:DICOM = MR Image Description Macro - Acquisition Contrast (0008,9209)
inversionRecoveryIndicator <i>Class:</i> MRImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Specifies whether an inversion recovery preparatory sequence is used in the acquisition.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = MR Modifier Macro - MR Modifier Sequence > Inversion Recovery (0018,9009)
pulseSequenceName <i>Class:</i> MRImagingAcquisitionProtocolElement <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Name of the pulse sequence that is used for the acquisition.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is usually a vendor-specific name.</p>	Map:DICOM = MR Pulse Sequence Module - Pulse Sequence Name (0018,9005)

Attribute	Notes	Constraints and Tags
multipleSpinEchoIndicator <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether different lines in k-space are collected for a single frame. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Multiple Spin Echo (0018,9011)
phaseContrastIndicator <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether this is a pulse sequence in which the flowing spins are velocity encoded in phase. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Phase Contrast (0018,9014)
timeOfFlightContrastIndicator <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether contrast is created by the inflow of blood in the saturated plane. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Time of Flight Contrast (0018,9015)
arterialSpinLabelingContrastCode <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A coded value specifying how arterial water is used as a diffusible tracer. EXAMPLE(S): CONTINUOUS - a single long low powered RF pulse PSEUDOCONTINUOUS - multiple short low powered RF pulses PULSED - a single short high powered RF pulse OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Arterial Spin Labeling Contrast (0018,9250)
steadyStatePulseSequenceCode <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A coded value specifying how residual transverse magnetization is maintained during the acquisition. EXAMPLE(S): FREE_PRECESSION, TRANSVERSE, TIME_REVERSED, LONGITUDINAL, NONE OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Steady State Pulse Sequence (0018,9017)

Attribute	Notes	Constraints and Tags
echoPlanarPulseSequenceIndicator <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether multiple echos of different phase steps are acquired using rephasing gradients instead of repeated 180-degree pulses. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Echo Planar Pulse Sequence (0018,9018)
saturationRecoveryIndicator <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: Specifies whether a saturation recovery pulse sequence is used. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Saturation Recovery (0018,9024)
spectrallySelectedSuppressionCode <i>Class:</i> MRIImagingAcquisitionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A coded value specifying the type of substance-specific signal suppression is used. EXAMPLE(S): FAT, WATER, FAT_AND_WATER, SILICON_GEL, NONE OTHER NAME(S): NOTE(S):	Map:DICOM = MR Pulse Sequence Module - Spectrally Selected Suppression (0018,9025)

Class: MRIImagingReconstructionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of image generation parameter values necessary to create a single set of images from a single MR scan.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Given that this sub-subclass of ImagingProcessProtocolElement actually names the process as Reconstruction and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = MR Image Description Macro - Complex Image Component (0008,9208)

Connectors

Source	Connector	Target	Notes
MRIImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	DESCRIPTION: Each MRIImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement

Source	Connector	Target	Notes
			<p>colElement. Each ImagingReconstructionProto colElement might be specialized by one MRIImagingReconstructionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
complexImageComponent Code <i>Class:</i> MRIImagingReconstructionProtocolElement <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>A coded value specifying the channel of the quadrature detected data, or the combination derived from those channels, used to reconstruct the image</p> <p>EXAMPLE(S):: REAL, IMAGINARY, PHASE or MAGNITUDE</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:DICOM = MR Image Description Macro - Complex Image Component (0008,9208)</p>

Class: PETImagingAcquisitionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of scanning parameter values necessary to perform a single PET scan in the acquisition protocol. [adapted from NEMA XR 25-2010, <https://www.nema.org/Standards/Pages/Computed-Tomography-Dose-Check.aspx>]

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Given that this sub-subclass of ImagingProcessProtocolElement actually names the process as Acquisition and includes that word in the name of the class, the word Process is omitted from the class name.

Tagged Values:

- Map:DICOM = PET Frame Acquisition Macro - PET Frame Acquisition Sequence (0018,9732)

Connectors

Source	Connector	Target	Notes
PETImagingAcquisitionProtocolElement	specializes	ImagingAcquisitionProtocolElement	<p>DESCRIPTION:</p> <p>Each PETImagingAcquisitionProtocolElement always specializes one ImagingAcquisitionProtocol</p>

Source	Connector	Target	Notes
			<p>Element. Each ImagingAcquisitionProtocol Element might be specialized by one PETImagingAcquisitionProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
gantryDetectorTilt <i>Class:</i> PETImagingAcquisitionProtocolElement <i>Datatype:</i> IVL<PQ> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: Nominal angle of tilt in degrees of the scanning gantry.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The units are of plane angle , e.g. degrees. Zero degrees means the gantry is not tilted, negative degrees are when the top of the gantry is tilted away from where the table enters the gantry.</p>	<p>Map:DICOM = PET Frame Acquisition Macro - PET Frame Acquisition Sequence > Gantry/Detector Tilt (0018,1120)</p>

Class: PETImagingReconstructionProtocolElement

Package: Imaging Sub-Domain

DEFINITION:

A set of image generation parameter values necessary to create a single set of images from a single PET scan.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:DICOM = PET Reconstruction Macro - PET Reconstruction Sequence (0018,9749)

Connectors

Source	Connector	Target	Notes
PETImagingReconstructionProtocolElement	specializes	ImagingReconstructionProtocolElement	<p>DESCRIPTION: Each PETImagingReconstructionProtocolElement always specializes one ImagingReconstructionProtocolElement. Each ImagingReconstructionProtocolElement might be</p>

Source	Connector	Target	Notes
			<p>specialized by one PETImagingReconstruction ProtocolElement.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedImagingStudy

Package: Imaging Sub-Domain

DEFINITION:

A collection of images and information that are logically related for the purpose of diagnosing an imaging study subject.
 [Source: http://dicom.nema.org/medical/dicom/current/output/chtml/part03/chapter_A.html#sect_A.1.2.2]

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The BRIDG modelers acknowledge that the term "study" is somewhat overloaded and must be qualified to provide semantic context. That said, "Imaging Study" is a very commonly used term in the imaging community. Any given Imaging Study does necessarily have to be associated with a clinical trial or study protocol. The definition of this class should be sufficient to distinguish from other uses of the term "study".

Tagged Values:

- Map:CTRv1.0 = PerformedImaging
- Map:DICOM = Clinical Trial Study Module
- Map:DICOM = General Study Module
- Map:LSDAMv2.2.3Plus = PerformedImaging

Connectors

Source	Connector	Target	Notes
PerformedImagingStudy	specializes	PerformedObservation	<p>DESCRIPTION: Each PerformedImagingStudy always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedImagingStudy.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
dicomStudyID <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The user- or equipment-generated identifier of an instance of a DICOM study entity that corresponds to the performed imaging study.</p> <p>EXAMPLE(S): 1234</p> <p>OTHER NAME(S): FHIR ImagingStudy.identifier</p> <p>NOTE(S): This is intended to be a human readable identifier.</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Study ID (0020,0010) Map:DICOM = General Study Module - Study ID (0020,0010)
imagingAccessionIdentifier <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An order filler system-generated identifier for the order for the imaging study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Accession Number (0008,0050) Map:DICOM = General Study Module - Issuer of Accession Number Sequence (0008,0051) Map:DICOM = General Study Module - Accession Number (0008,0050)
description <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the certain or salient aspects, characteristics, or features of the imaging study. [Adapted from www.businessdictionary.com]</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Usually this describes the manner in which the imaging study was performed.</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Study Description (0008,1030) Map:DICOM = General Study Module - Study Description (0008,1030)
admittingDiagnosisCode <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: The identified disease(s) or illness(es) at the time of the admission during which imaging was performed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is derived from the path: PerformedImagingStudy > Subject > PerformedObservation > PerformedDiagnosis.value (ANY=>PQ.TIME) WHERE PerformedObservation > DefinedObservation.nameCode = "diagnosis"</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Admitting Diagnoses Description (0008,1080) Map:DICOM = Patient Study Module - Admitting Diagnoses Code Sequence (0008,1084) Map:DICOM = Patient Study Module - Admitting Diagnoses Description (0008,1080)

Attribute	Notes	Constraints and Tags
nonAcquisitionModalitiesInStudyCode <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the type of equipment that created the images in this imaging study other than that used to acquire the original data.</p> <p>EXAMPLE(S): SR (Structured Report), KO (Key Object), SEG (Segmentation), DOC (document)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is a characterization of those devices other than those devices that are used to acquire the images which are encoded in Device.typeCode.</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Modalities in Study (0008,0061) Map:DICOM = General Series Module - Modality (0008,0060)
subjectHistory <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> ST <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Information about the subject obtained by asking questions [Adapted from: https://en.wikipedia.org/wiki/Medical_history]</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is derived from the path: Subject > PerformedObservation > PerformedObservationResult.value (ANY=>PQ.TIME) WHERE PerformedObservation > DefinedObservation.nameCode = "patient history"</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Additional Patient History (0010,21B0) Map:DICOM = Patient Study Module - Additional Patient History (0010,21B0)
subjectAge <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The length of time since the birth of the imaging subject in completed units. [Adapted from: Google and caDSR Public ID 2423393]</p> <p>EXAMPLE(S): 17 years (years completed)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is derived from the path: Subject > PerformedObservation > PerformedObservationResult.value (ANY=>PQ.TIME) WHERE PerformedObservation > DefinedObservation.nameCode = "age"</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Patient's Age (0010,1010) Map:DICOM = Patient Study Module - Patient's Age (0010,1010)

Attribute	Notes	Constraints and Tags
subjectHeight <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The distance from the bottom to the top of the imaging study subject. [adapted from http://www.merriam-webster.com/dictionary/height]</p> <p>EXAMPLE(S): 1.75 meters</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is derived from the path: Subject > PerformedObservation > PerformedObservationResult.value (ANY=>PQ.TIME) WHERE PerformedObservation > DefinedObservation.nameCode = "height"</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Patient's Size (0010,1020) Map:DICOM = Patient Study Module - Patient's Size (0010,1020)
subjectWeight <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The measurement that indicates how heavy an imaging study subject is. [adapted from http://www.merriam-webster.com/dictionary/weight]</p> <p>EXAMPLE(S): 75 kg</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is derived from the path: Subject > PerformedObservation > PerformedObservationResult.value (ANY=>PQ.TIME) WHERE PerformedObservation > DefinedObservation.nameCode = "weight"</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Patient's Weight (0010, 1030) Map:DICOM = Patient Study Module - Patient's Weight (0010, 1030)
storageSOPClassesInStudy <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> DSET<OID> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: The unique identifier of a DICOM Storage Service-Object Pair Class used to encode an instance of the imaging study.</p> <p>EXAMPLE(S): 1.2.840.10008.5.1.4.1.1.2 (CT Image Storage SOP Class)</p> <p>OTHER NAME(S): SOP Classes in Study (0008,0062)</p> <p>NOTE(S):</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - SOP Classes in Study (0008,0062)

Attribute	Notes	Constraints and Tags
lossyImageCompressionIndicator <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether any images in the study are irreversibly altered during encoding at any time during its life.</p> <p>EXAMPLE(S): If even just one image in the study has been lossy compressed, the lossyImageCompressionIndicator = "true".</p> <p>OTHER NAME(S): Number of Study Related Series (0020,1206)</p> <p>NOTE(S):</p>	Map:DICOM = Enhanced PET Image Module - Lossy Image Compression (0028,2110) Map:DICOM = Enhanced MR Image Module - Lossy Image Compression (0028,2110) Map:DICOM = Enhanced CT Image Module - Lossy Image Compression (0028,2110) Map:DICOM = General Image Module - Lossy Image Compression (0028,2110)
seriesCount <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The number of DICOM series in the performed imaging study.</p> <p>EXAMPLE(S): Number of Study Related Series (0020,1206)</p> <p>OTHER NAME(S): Number of Study Related Instances (0020,1208)</p> <p>NOTE(S):</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Number of Study Related Series (0020,1206)
imageCount <i>Class:</i> PerformedImagingStudy <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The number of DICOM instances in the performed imaging study.</p> <p>EXAMPLE(S): Number of Study Related Instances (0020,1208)</p> <p>OTHER NAME(S): Number of Study Related Instances (0020,1208)</p> <p>NOTE(S):</p>	Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Number of Study Related Instances (0020,1208)

Class: Radiopharmaceutical

Package: Imaging Sub-Domain

DEFINITION:
A radioactive drug that is used for the diagnosis or treatment of disease.

EXAMPLE(S):
Technetium^{99m} DMSA
Sodium fluoride F¹⁸
Fluorodeoxyglucose F¹⁸

OTHER NAME(S):
Medicinal radiocompounds
Radioactive tracer

NOTE(S):

Tagged Values:

- Map:DICOM = Enhanced PET Isotope Module - Radiopharmaceutical Information Sequence (0054,0016)

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
Radiopharmaceutical	specializes	Drug	<p>DESCRIPTION: Each Radiopharmaceutical always specializes one Drug. Each Drug might be specialized by one Radiopharmaceutical.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
radionuclideCode <i>Class:</i> Radiopharmaceutical <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A coded value that specifies the radioactive isotope in the radiopharmaceutical.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived by tracing the radiopharmaceutical through its ingredients to the radionuclide, i.e. Radiopharmaceutical > ProductRelationship > Product.code WHERE Product.typeCode = "radionuclide"</p>	Map:DICOM = Enhanced PET Isotope Module - Radiopharmaceutical Information Sequence > Radionuclide Code Sequence (0054,0300)

Class: SpecificImagingProcessProtocol

Package: Imaging Sub-Domain

DEFINITION:

Provides the details for how the images in the imaging study were captured and reconstructed previously so that the process can be replicated, such as a complete description of imaging parameters, instrumentation, subject positioning, etc.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

This class includes content from both the DICOM CT Performed Acquisition Technique Module and the DICOM CT Performed Reconstruction Technique Module.

Tagged Values:

- Map:DICOM = Performed CT Acquisition Module
- Map:DICOM = General Series Module - Protocol Name (0018,1030)

Connectors

Source	Connector	Target	Notes
SpecificImagingProcessProtocol 0..*	be based on basingSpecificImagingProtocol	GenericImagingProcessProtocol 0..*	<p>DESCRIPTION: Each SpecificImagingProtocol might be based on one</p>

Source	Connector	Target	Notes
col		1	or more GenericImagingProcessProtocol. Each GenericImagingProcessProtocol might be the basis of one or more SpecificImagingProcessProtocol. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SpecificImagingProcessProtocol	specializes	ImagingProcessProtocol	DESCRIPTION: Each SpecificImagingProcessProtocol always specializes one ImagingProcessProtocol. Each ImagingProcessProtocol might be specialized by one SpecificImagingProcessProtocol. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: ImagingCenter

Package: Imaging Sub-Domain

DEFINITION:

The facility that performs imaging activities on subjects.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = ImagingCenter

Connectors

Source	Connector	Target	Notes
ImagingCenter 0..1 performedImagingCenter	is played by	Organization 1 performingOrganization	DESCRIPTION: Each ImagingCenter always is played by one Organization. Each

Source	Connector	Target	Notes
			Organization might play one ImagingCenter. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Molecular Biology sub-domain represents the core concepts related to this domain, including gene, protein, molecular sequence, chromosome, genome, and numerous other related concepts. Also includes the representation of these concepts in bioinformatics resources, such as public databases.

Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

[View MB: Molecular Biology diagram](#)

Class diagram in package 'Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain'

The Molecular Biology sub-domain represents the core concepts related to this domain, including gene, protein, molecular sequence, chromosome, genome, and numerous other related concepts. Also includes the representation of these concepts in bioinformatics resources, such as public databases.

Collaboration with other HL7 Work Groups: With the broader scope of BRIDG 4.0 covering translational research and the harmonization of Life Sciences Model and CDISC Pharmogenomic & Pharmacogenetics domains, it is likely that there is some overlap of concepts between BRIDG Molecular Biology subdomain concepts and the models being developed in the HL7 Clinical Genomics (CG) work group. BRIDG recognizes the Clinical Genomics work group models as peer or sibling models and is committed to working with the CG team to align on common semantics. The BRIDG team has started the conversation with the CG work group to this effect and plan to continue the dialogue on how to operationalize the collaboration and leverage the subject matter expertise of this HL7 CG group members.

View MB: Molecular Biology

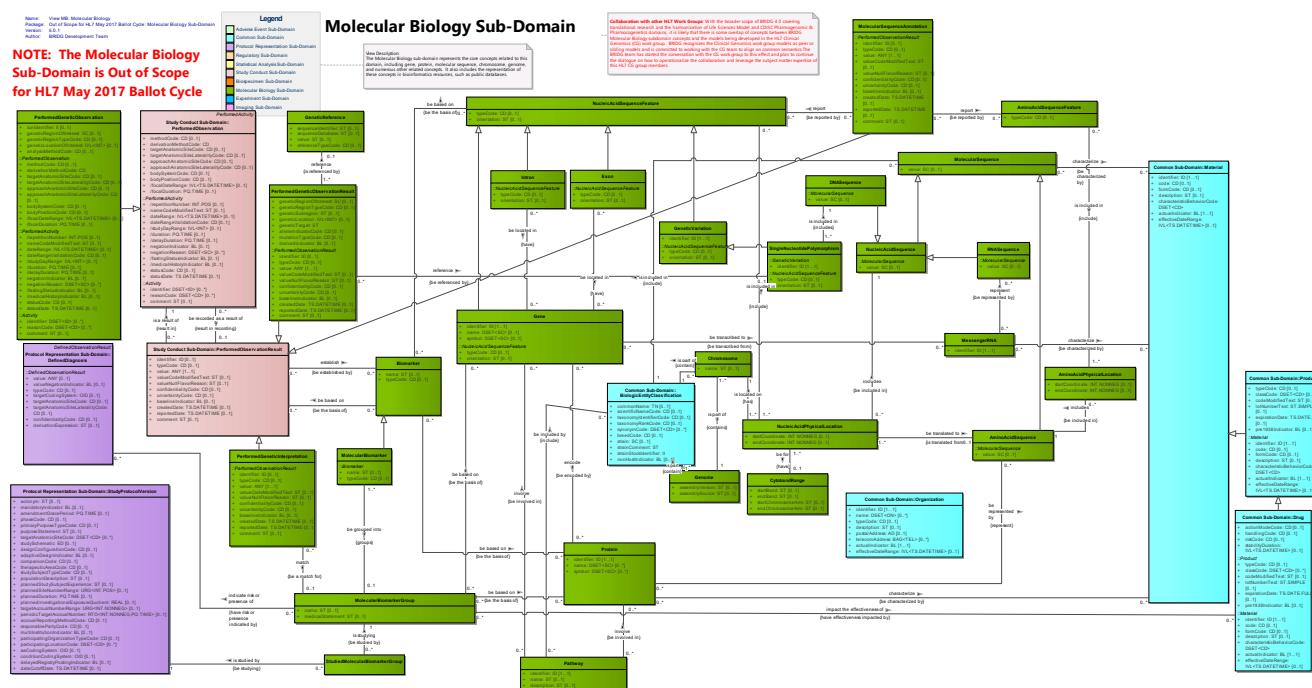


Figure 11: View MB: Molecular Biology

Class: AminoAcidPhysicalLocation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A position or a region on an amino acid sequence.

EXAMPLE(S):

amino acids 3 to 10 of TP53 protein, amino acids 102 to 292 of TP53 protein defining a DNA binding region.

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:LSDAMv2.2.3Plus = AminoAcidPhysicalLocation

Connectors

Source	Connector	Target	Notes
AminoAcidPhysicalLocatio n 0..* includingAminoAcidPhysic alLocation	includes	AminoAcidSequence 1 includedAminoAcidSequenc e	DESCRIPTION: Each AminoAcidPhysicalLocatio n always includes one AminoAcidSequence. Each AminoAcidSequence might be included in one or more AminoAcidPhysicalLocatio n. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AminoAcidSequenceFeature 0..* includedAminoAcidSequenc eFeature	is included in	AminoAcidPhysicalLocatio n 1..* includingAminoAcidPhysic alLocation	DESCRIPTION: Each AminoAcidSequenceFeature always is included in one or more AminoAcidPhysicalLocatio n. Each AminoAcidPhysicalLocatio n might include one or more AminoAcidSequenceFeature . . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
startCoordinate <i>Class:</i> AminoAcidPhysicalLocation <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The beginning coordinate of the range (inclusive), given as an integer offset from the start of the sequence.</p> <p>EXAMPLE(S): For amino acids 3 to 10 of the TP53 protein the start coordinate would be 3. For amino acids 102 to 292 of the TP53 protein defining a DNA binding region the start coordinate would be 102.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = AminoAcidPhysicalLocation.startCoordinate
endCoordinate <i>Class:</i> AminoAcidPhysicalLocation <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The terminal coordinate of the range (inclusive), given as an integer offset from the start of the sequence.</p> <p>EXAMPLE(S): For amino acids 3 to 10 of the TP53 protein the end coordinate would be 10. For amino acids 102 to 292 of the TP53 protein defining a DNA binding region the end coordinate would be 292.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = AminoAcidPhysicalLocation.endCoordinate

Class: AminoAcidSequence

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A representation of a linear arrangement of amino acids represented in single notation.

EXAMPLE(S):

The first 10 amino acids of the protein BRCA1 are MDLSALRVEE.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = AminoAcidSequence

Connectors

Source	Connector	Target	Notes
AminoAcidSequence	specializes	MolecularSequence	<p>DESCRIPTION: Each AminoAcidSequence always specializes one MolecularSequence. Each MolecularSequence might be specialized by one AminoAcidSequence.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Protein 0..* representedProtein	be represented by	AminoAcidSequence 0..* representingAminoAcidSequence	<p>DESCRIPTION:</p> <p>Each Protein might be represented by one or more AminoAcidSequence. Each AminoAcidSequence might represent one or more Protein.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AminoAcidPhysicalLocatio n 0..* includingAminoAcidPhys icalAllocation	includes	AminoAcidSequence 1 includedAminoAcidSequenc e	<p>DESCRIPTION:</p> <p>Each AminoAcidPhysicalLocation always includes one AminoAcidSequence. Each AminoAcidSequence might be included in one or more AminoAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidPhysicalLocatio n 1..* translatedNucleicAcidPhys icalLocation	be translated to	AminoAcidSequence 0..1 translatingAminoAcidSeque nce	<p>DESCRIPTION:</p> <p>Each NucleicAcidPhysicalLocation might be translated to one AminoAcidSequence. Each AminoAcidSequence always is translated from one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: AminoAcidSequenceFeature

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

An annotation assigned to a defined amino acid physical location.

EXAMPLE(S):

alpha helices, glycosylation sites, DNA binding domains

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = AminoAcidSequenceFeature

Connectors

Source	Connector	Target	Notes
AminoAcidSequenceFeature 0..* includedAminoAcidSequenceFeature	is included in	AminoAcidPhysicalLocation 1..* includingAminoAcidPhysicalLocation	<p>DESCRIPTION: Each AminoAcidSequenceFeature always is included in one or more AminoAcidPhysicalLocation. Each AminoAcidPhysicalLocation might include one or more AminoAcidSequenceFeature .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequenceAnnotation 0..* reportingMolecularSequenceAnnotation	report	AminoAcidSequenceFeature 0..* reportedAminoAcidSequenceFeature	<p>DESCRIPTION: Each MolecularSequenceAnnotation might report one or more AminoAcidSequenceFeature . Each AminoAcidSequenceFeature might be reported by one or more MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> AminoAcidSequenceFeature <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value that specifies a group of amino acids within a protein that confer certain characteristics upon that protein, and may be important for its overall function.</p> <p>EXAMPLE(S): glycosylation site, binding site, phosphorylation site, ubiquitination site, sumoylation site</p> <p>OTHER NAME(S):</p> <p>NOTE(S): [Glycosylation Site:C16643, C37901; Binding Site:C13671]</p>	Map:LSDAMv2.2.3Plus = AminoAcidSequenceFeature.typeCode

Class: Biomarker

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A measurable and quantifiable biological parameter which serves as index for health- and physiology-related assessments, such as disease risk, psychiatric disorders, environmental exposure and its effects, disease diagnosis, metabolic processes, substance abuse, pregnancy, cell line development, epidemiologic studies, etc. [Source: adapted from MESH]

EXAMPLE(S):

Specific enzyme concentration

Specific hormone concentration

Specific gene phenotype distribution in a population

Presence of biological substances

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Biomarker

Connectors

Source	Connector	Target	Notes
Biomarker 0..* basingBiomarker	be based on	NucleicAcidSequenceFeature 0..* basedNucleicAcidSequenceFeature	<p>DESCRIPTION: Each Biomarker might be based on one or more NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be the basis of one or more Biomarker.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Biomarker	be based on	Protein	DESCRIPTION:

Source	Connector	Target	Notes
0..* basingBiomarker		0..* basedProtein	Each Biomarker might be based on one or more Protein. Each Protein might be the basis of one or more Biomarker. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Biomarker 0..* basingBiomarker	be based on	PerformedObservationResult 0..* basedPerformedObservationResult	DESCRIPTION: Each Biomarker might be based on one or more PerformedObservationResult. Each PerformedObservationResult might be the basis of one or more Biomarker. DEFINITION: EXAMPLE(S): An image annotation might be the basis for a biomarker. OTHER NAME(S): NOTE(S):
MolecularBiomarker	specializes	Biomarker	DESCRIPTION: Each MolecularBiomarker always specializes one Biomarker. Each Biomarker might be specialized by one MolecularBiomarker. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservationResult 0..* establishingPerformedObservationResult	establish	Biomarker 0..* establishedBiomarker	DESCRIPTION: Each PerformedObservationResult might establish one or more Biomarker. Each Biomarker might be established by one or more PerformedObservationResult. DEFINITION: Identifies the finding that results in the identification

Source	Connector	Target	Notes
			of a biomarker. EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
name <i>Class:</i> Biomarker <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The textual identifier for the biomarker as provided by the assigning source. EXAMPLE(S): p.G48V p.L10I p.K20R p.M36I p.A71V p.V82T OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Biomarker.name Map:PGx v1.0 = PB.PBMRKR
typeCode <i>Class:</i> Biomarker <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the basis of the biomarker. EXAMPLE(S): Genetic, Protein, Image-based OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Biomarker.typeCode

Class: Chromosome

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A structural unit composed of a nucleic acid molecule which controls its own replication through the interaction of specific proteins at one or more origins of replication. [Sequence Ontology: SO:0000340 (SOWiki)
http://www.sequenceontology.org/browser/current_svn/term/SO:0000340]

EXAMPLE(S):

Most humans have 23 pairs of chromosomes--22 pairs of numbered chromosomes, called autosomes, and one pair of sex chromosomes, X and Y.

OTHER NAME(S):

NOTE(S):

This class can represent eukaryotic (e.g. human), mitochondrial, bacterial, and viral chromosomes, for example.

Tagged Values:

- Map:LSDAMv2.2.3Plus = Chromosome

Connectors

Source	Connector	Target	Notes
Chromosome 0..* containedChromosome	is part of	BiologicEntityClassification 1 containingBiologicEntityClassification	<p>DESCRIPTION: Each Chromosome always is part of one BiologicEntityClassification. Each BiologicEntityClassification might contain one or more Chromosome.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Chromosome 1..* containedChromosome	is part of	Genome 1 containingGenome	<p>DESCRIPTION: Each Chromosome always is part of one Genome. Each Genome always contains one or more Chromosome.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidPhysicalLocation 1..* locatedNucleicAcidPhysicalLocation	is located on	Chromosome 1 locatingChromosome	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation always is located on one Chromosome. Each Chromosome always has one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
name <i>Class:</i> Chromosome <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier for the chromosome.</p> <p>EXAMPLE(S): X, Y, 1, 2</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Autosomes are usually indicated by numbers and sex chromosomes by letters.</p>	Map:LSDAMv2.2.3Plus = Chromosome.name

Class: CytobandRange

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A region within a nucleic acid sequence that is specified using the microscopically visible transverse lines. These lines appear when differential staining techniques are applied to a metaphase chromosome.

EXAMPLE(S):

"1q2.3-1q2.4", where "1" indicates the chromosome, "q" indicates the arm, and the start and end bands are specified as "2.3" and "2.4" respectively

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = CytobandRange

Connectors

Source	Connector	Target	Notes
NucleicAcidPhysicalLocation 1..* locatingNucleicAcidPhysicalLocation	be for	CytobandRange 0..1 locatedCytobandRange	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation might be for one CytobandRange. Each CytobandRange always have one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
startBand <i>Class:</i> CytobandRange <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The cytoband that contains the beginning of the range, expressed without the chromosome or arm designation.</p> <p>EXAMPLE(S): the band portion of "1q2.3" is "2.3".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CytobandRange.startBand
endBand <i>Class:</i> CytobandRange <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The cytoband that contains the terminus of the range, expressed without the chromosome or arm designation.</p> <p>EXAMPLE(S): the band portion of "1q2.3" is "2.3".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CytobandRange.endBand
startChromosomeArm <i>Class:</i> CytobandRange <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The chromosomal arm that contains the beginning of the range. In humans, this is either "p" or "q", which represents the short or long arms of the chromosome, respectively.</p> <p>EXAMPLE(S): 17q12</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CytobandRange.startChromosomeRange
endChromosomeArm <i>Class:</i> CytobandRange <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The chromosomal arm that contains the terminus of the range. In humans, this is either "p" or "q", which represents the short or long arms of the chromosome, respectively.</p> <p>EXAMPLE(S): 17q21</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = CytobandRange.endChromosomeArm

Class: DNASequence

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:
A representation of the linear arrangement of deoxyribonucleotides.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = DNASequence

Connectors

Source	Connector	Target	Notes
DNASequence	specializes	NucleicAcidSequence	<p>DESCRIPTION: Each DNASequence always specializes one NucleicAcidSequence. Each NucleicAcidSequence might be specialized by one DNASequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SingleNucleotidePolymorphism 1..* includedSingleNucleotidePolymorphism	is included in	DNASequence 1 includingDNASequence	<p>DESCRIPTION: Each SingleNucleotidePolymorphism always is included in one DNASequence. Each DNASequence always includes one or more SingleNucleotidePolymorphism.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Exon

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A portion of a gene sequence that is transcribed into the final mRNA product.

EXAMPLE(S):

Dystrophin exon 23

OTHER NAME(S):

NOTE(S): An image showing splicing may be a better example of this class.

Tagged Values:

- Map:LSDAMv2.2.3Plus = Exon

Connectors

Source	Connector	Target	Notes
Exon	specializes	NucleicAcidSequenceFeature	<p>DESCRIPTION: Each Exon always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one Exon.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Exon 0..* locatedExon	be located in	Gene 0..* locatingGene	<p>DESCRIPTION: Each Exon might be located in one or more Gene. Each Gene might have one or more Exon.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Gene

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A functional unit of heredity that occupies a specific position (locus) on a particular chromosome, is capable of reproducing itself exactly at each cell division, and directs the formation of a protein or other product.

Comment Requested: In interest of re-using existing standards, should the above definition of Gene be replaced by the following from the NLM - **The basic physical and functional unit of heredity. It is made up of DNA and act as instructions to make molecules called proteins.** [Source: <http://ghr.nlm.nih.gov/handbook/basics/gene>]

EXAMPLE(S):

BRCA1 gene

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Gene
- Map:PGx v1.0 = PB.PBGENTYP

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
Gene 0..* transcribedFromGene	be transcribed to	MessengerRNA 0..* transcribedToMessengerRN A	<p>DESCRIPTION: Each Gene might be transcribed to one or more MessengerRNA. Each MessengerRNA might be transcribed from one or more Gene.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Gene	specializes	NucleicAcidSequenceFeatur e	<p>DESCRIPTION: Each Gene always specializes one NucleicAcidSequenceFeatur e. Each NucleicAcidSequenceFeatur e might be specialized by one Gene.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Gene 0..* encodingGene	encode	Protein 0..* encodedProtein	<p>DESCRIPTION: Each Gene might encode one or more Protein. Each Protein might be encoded by one or more Gene.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Intron 0..* locatedIntron	be located in	Gene 0..* locatingGene	<p>DESCRIPTION: Each Intron might be located in one or more Gene. Each Gene might have one or more Intron.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
MolecularBiomarkerGroup 0..* basingMolecularBiomarkerGroup	be based on	Gene 0..* basedGene	DESCRIPTION: Each MolecularBiomarkerGroup might be based on one or more Gene. Each Gene might be the basis of one or more MolecularBiomarkerGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Pathway 0..* involvingPathway	involve	Gene 0..* involvedGene	DESCRIPTION: Each Pathway might involve one or more Gene. Each Gene might be involved in one or more Pathway. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Exon 0..* locatedExon	be located in	Gene 0..* locatingGene	DESCRIPTION: Each Exon might be located in one or more Gene. Each Gene might have one or more Exon. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Gene <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A unique symbol that establishes the identity of the gene.</p> <p>EXAMPLE(S): For the 14-3-3 eta gene (a protein), here are some identifiers from various organizations:</p> <ul style="list-style-type: none"> • ENSG00000128245 from Ensembl • 12853 from HGNC • 00215 from HPRD • 7533 from NCBI <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = GeneIdentifier.identifier
name <i>Class:</i> Gene <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The English language identifier of a gene as defined by the specified source.</p> <p>EXAMPLE(S): Breast cancer type 1 susceptibility gene</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Gene.name Map:PGx v1.0 = PB.PBGENRI
symbol <i>Class:</i> Gene <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A conventional sign used for representing the gene, based on the identified source.</p> <p>EXAMPLE(S): As a string with an optional code, an example of Gene.symbol is as follows: the value "BRCA1" is both the string and the code and the code system name is "HGNC".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Gene.symbol

Class: GeneticReference

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

An assembly of nucleotides used to identify genetic variations.

EXAMPLE(S):

Different versions of genomic references exist for many species. For example, Homo sapiens reference genome utilized by the UCSC Genome Browser hg38 was released in 2013 and hg19 in 2009. Older versions of the assembled reference include, but are not limited to, hg18.

OTHER NAME(S):

Reference Sequence ID for a sequence in a database

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = PF.PFREFSEQ

Connectors

Source	Connector	Target	Notes
PerformedGeneticObservationResult 1..* referencingPerformedGeneticObservationResult	reference	GeneticReference 0..1 referencedGeneticReference	<p>DESCRIPTION: Each PerformedGeneticObservationResult might reference one GeneticReference. Each GeneticReference always is referenced by one or more PerformedGeneticObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): "A" might be the reference if the test result is a Nucleotide. "Trp" might be the reference if the test result is an Amino Acid.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
sequenceIdentifier <i>Class:</i> GeneticReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique identifier, within a specified database, representing an assembly of nucleotides used to identify a genetic variation.</p> <p>EXAMPLE(S): NP_751919 is an identifier in GENBANK</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The genetic variation may be documented and versioned in a public database or in the protocol document.</p>	Map:PGx v1.0 = PF.PFREFSEQ

Attribute	Notes	Constraints and Tags
sequenceDatabase <i>Class:</i> GeneticReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The name of a repository representing a collection of assemblies of nucleotides used to identify genetic variations.</p> <p>EXAMPLE(S): GENBANK Entrez Gene OMIM</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFREFSEQ
value <i>Class:</i> GeneticReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Reference result or expected value for the measurement or finding in the location of interest.</p> <p>EXAMPLE(S): A, C, G, T are possible values if the test is Nucleotide Ile, Trp, Gyl, Ser are possible values if the test is Amino Acid</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The type of values represented by this attribute corresponds to the kind of test being performed.</p>	Map:PGx v1.0 = PF.PFLLOQ Map:PGx v1.0 = PF.PFORREF
referenceTypeCode <i>Class:</i> GeneticReference <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of genetic reference the value is.</p> <p>EXAMPLE(S): lower limit of quantitation</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFLLOQ

Class: GeneticVariation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

The difference(s) in the nucleotide sequence of a biologic entity relative to a reference sequence.

EXAMPLE(S):

A single nucleotide change from adenine to cytosine, of the CAG trinucleotides repeats in the Huntington gene. The BRCA1 gene can contain an insertion at position 5382, BRCA1 gene.c.5382insC, or a single nucleotide polymorphism, at position 61 converting a to a G, 61C->G.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = GeneticVariation

Connectors

Source	Connector	Target	Notes
GeneticVariation	specializes	NucleicAcidSequenceFeature	<p>DESCRIPTION: Each GeneticVariation always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one GeneticVariation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SingleNucleotidePolymorphism	specializes	GeneticVariation	<p>DESCRIPTION: Each SingleNucleotidePolymorphism always specializes one GeneticVariation. Each GeneticVariation might be specialized by one SingleNucleotidePolymorphism.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> GeneticVariation <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A unique symbol that establishes the identity of the genetic variation.</p> <p>EXAMPLE(S): An rs identifier in dbSNP, a mutation identifier in COSMIC, or a variant identifier in OMIM</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:LSDAMv2.2.3Plus = SingleNucleotidePolymorphismIdentifier</p> <p>Map:PGx v1.0 = PF.PFSRNUM</p>

Class: Genome

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

The sum of genetic material within a cell or virion.

[http://www.sequenceontology.org/browser/current_svn/term/SO:0001026]

EXAMPLE(S):
Human Genome

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Genome

Connectors

Source	Connector	Target	Notes
Genome 0..* containedGenome	is part of	BiologicEntityClassification 1 containingBiologicEntityClassification	<p>DESCRIPTION: Each Genome always is part of one BiologicEntityClassification. Each BiologicEntityClassification might contain one or more Genome.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Chromosome 1..* containedChromosome	is part of	Genome 1 containingGenome	<p>DESCRIPTION: Each Chromosome always is part of one Genome. Each Genome always contains one or more Chromosome.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
assemblyVersion <i>Class:</i> Genome <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The source-specific version of the genome assembly.</p> <p>EXAMPLE(S): (Human Genome) Build 35</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Genome.assemblyVersion

Attribute	Notes	Constraints and Tags
assemblySource <i>Class:</i> Genome <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The originating source of the genome assembly.</p> <p>EXAMPLE(S): National Center for Biotechnology Information (NCBI)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = Genome.assemblySource

Class: Intron

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A portion of a gene sequence that is transcribed but excised from the mature mRNA during processing.

EXAMPLE(S):

Human KIT Gene Intron 10

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Intron

Connectors

Source	Connector	Target	Notes
Intron 0..* locatedIntron	be located in	Gene 0..* locatingGene	<p>DESCRIPTION: Each Intron might be located in one or more Gene. Each Gene might have one or more Intron.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Intron	specializes	NucleicAcidSequenceFeature	<p>DESCRIPTION: Each Intron always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one Intron.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Class: MessengerRNA

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A representation of a member of the class of RNA molecules that contains protein-coding information in its nucleotide sequence.

EXAMPLE(S):

Homo sapiens BRCA1 transcript variant 1 mRNA, GenBank identifier NM_007294.3, is available at http://www.ncbi.nlm.nih.gov/nuccore/NM_007294.3

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = MessengerRNA

Connectors

Source	Connector	Target	Notes
MessengerRNA 0..* representingMessengerRNA	represent	RNASequence 0..* representedRNASequence	<p>DESCRIPTION: Each MessengerRNA might represent one or more RNASequence. Each RNASequence might be represented by one or more MessengerRNA.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MessengerRNA 0..* characterizingMessengerRN A	characterize	Material 0..* characterizedMaterial	<p>DESCRIPTION: Each MessengerRNA might characterize one or more Material. Each Material might be characterized by one or more MessengerRNA.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Gene 0..* transcribedFromGene	be transcribed to	MessengerRNA 0..* transcribedToMessengerRN	DESCRIPTION: Each Gene might be transcribed to one or more

Source	Connector	Target	Notes
		A	MessengerRNA. Each MessengerRNA might be transcribed from one or more Gene. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> MessengerRNA <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	DEFINITION: A unique symbol that establishes the identity of the mRNA. EXAMPLE(S): The identifier from the Ensembl or GenBank database OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = MessengerRNAIdentifier.identifier

Class: MolecularBiomarker

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A molecular biological characteristic that can be evaluated as an indicator of biological functions, processes, or therapeutic responses.

EXAMPLE(S):

L10I, K20R, M36I, A71V, and V82T are all amino acid changes resulting from genetic mutations in the HIV-1 protease protein that are associated with resistance to the drug "Indinavir".

OTHER NAME(S):

Biological State

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = PB

Connectors

Source	Connector	Target	Notes
MolecularBiomarker 1..* groupedMolecularBiomarker	be grouped into	MolecularBiomarkerGroup 0..1 groupingMolecularBiomarkerGroup	DESCRIPTION: Each MolecularBiomarker might be grouped into one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup always groups one or more MolecularBiomarker.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarker	specializes	Biomarker	<p>DESCRIPTION: Each MolecularBiomarker always specializes one Biomarker. Each Biomarker might be specialized by one MolecularBiomarker.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: MolecularBiomarkerGroup

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A collection of molecular biomarkers that often associates observed molecular characteristics with medical conclusions or serves as an indicator of a particular biological condition or process.

EXAMPLE(S):

Molecular Biomarker Group "L10I+K20R+M36I+A71V+V82T" links a set of mutations with the conclusion of drug resistance to the drug "Indinavir".

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = PB.STUDYID

Connectors

Source	Connector	Target	Notes
MolecularBiomarkerGroup 0..* basingMolecularBiomarker Group	be based on	Protein 0..* basedProtein	<p>DESCRIPTION: Each MolecularBiomarkerGroup might be based on one or more Protein. Each Protein might be the basis of one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
MolecularBiomarkerGroup 0..* affectingMolecularBiomarkerGroup	impact the effectiveness of	Drug 0..* affectedDrug	<p>DESCRIPTION: Each MolecularBiomarkerGroup might impact the effectiveness of one or more Drug. Each Drug might have effectiveness impacted by one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): Molecular Biomarker Group "L10I+K20R+M36I+A71V +V82T" links a set of mutations with the conclusion of drug resistance to the drug "Indinavir".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarkerGroup 0..* basingMolecularBiomarkerGroup	be based on	Gene 0..* basedGene	<p>DESCRIPTION: Each MolecularBiomarkerGroup might be based on one or more Gene. Each Gene might be the basis of one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarkerGroup 0..* indicatingMolecularBiomarkerGroup	indicate risk or presence of	DefinedDiagnosis 0..* indicatedDefinedDiagnosis	<p>DESCRIPTION: Each MolecularBiomarkerGroup might indicate risk or presence of one or more DefinedDiagnosis. Each DefinedDiagnosis might have risk or presence indicated by one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): The MolecularBiomarkerGroup</p>

Source	Connector	Target	Notes
			<p>consisting of the individual biomarker "2073A>T" indicates a decreased risk of "Diffusely Infiltrating Astrocytoma".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarker 1..* groupedMolecularBiomarker	be grouped into	MolecularBiomarkerGroup 0..1 groupingMolecularBiomarkerGroup	<p>DESCRIPTION: Each MolecularBiomarker might be grouped into one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup always groups one or more MolecularBiomarker.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudiedMolecularBiomarker Group 0..* studyingStudiedMolecularBiomarkerGroup	is studying	MolecularBiomarkerGroup 1 studiedMolecularBiomarkerGroup	<p>DESCRIPTION: Each StudiedMolecularBiomarker Group always is studying one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup might be studied by one or more StudiedMolecularBiomarker Group.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedGeneticInterpretation 0..* matchingPerformedGeneticInterpretation	match	MolecularBiomarkerGroup 0..1 matchedMolecularBiomarkerGroup	<p>DESCRIPTION: Each PerformedGeneticInterpretation might match one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup might be a match for one or more PerformedGeneticInterpretation.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
name <i>Class:</i> MolecularBiomarkerGroup <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A symbol that establishes identity of the molecular biomarker group.</p> <p>EXAMPLE(S): The identifier L10I+K20R+M36I+A71V+V82T is the concatenation of the names of individual biomarkers. [borrowed from CDISC's PGx IG]</p> <p>OTHER NAME(S):</p> <p>NOTE(S): At a minimum, this name should be unique within the submission, if not within the organization submitting it, but it is not necessarily intended to be globally unique.</p>	Map:PGx v1.0 = SB.SBMRKRID Map:PGx v1.0 = PB.PBMRKRID
medicalStatement <i>Class:</i> MolecularBiomarkerGroup <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A medical conclusion associated with a molecular biomarker group.</p> <p>EXAMPLE(S): Resistant, Poor Metabolizer, Susceptible, Good Metabolizer (when biomarker is related to a drug) Positive, Negative, Increased Risk, Decreased Risk, Medium Risk, High Risk (when biomarker is related to a diagnosis).</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PB.PBSTMT

Class: MolecularSequence

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:
A representation of a linear arrangement of organic compounds.

EXAMPLE(S):
The sequence of TP53 protein, the sequence of TP53 gene, the first 20 nucleotides of a BRCA1 mRNA

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = MolecularSequence

Connectors

Source	Connector	Target	Notes
MolecularSequence 0..* includedMolecularSequence	is included in	BiologicEntityClassification 1 includingBiologicEntityClassification	<p>DESCRIPTION: Each MolecularSequence always is included in one BiologicEntityClassification. Each BiologicEntityClassification might include one or more MolecularSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequence 0..* characterizingMolecularSequence	characterize	Material 0..* characterizedMaterial	<p>DESCRIPTION: Each MolecularSequence might characterize one or more Material. Each Material might be characterized by one or more MolecularSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidSequence	specializes	MolecularSequence	<p>DESCRIPTION: Each AminoAcidSequence always specializes one MolecularSequence. Each MolecularSequence might be specialized by one AminoAcidSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AminoAcidSequence	specializes	MolecularSequence	<p>DESCRIPTION: Each AminoAcidSequence always specializes one MolecularSequence. Each MolecularSequence might be specialized by one AminoAcidSequence.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
ExperimentalActivityItem 0..* playedExperimentalActivityItem	be played by	MolecularSequence 0..1 playingMolecularSequence	DESCRIPTION: Each ExperimentalActivityItem might be played by one MolecularSequence. Each MolecularSequence might play one or more ExperimentalActivityItem. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
value <i>Class:</i> MolecularSequence <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A representation of the molecular sequence, usually in abbreviated form and expressed according to conventional practices.</p> <p>EXAMPLE(S): DNA sequences are usually expressed as a string of A, C, G, and T characters starting from the 5' end of the sequence, while protein sequences are usually given as a string of single character amino acid codes starting at the N-terminus. In both cases, IUPAC codes are generally used to represent the sequence.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = MolecularSequence.value

Class: MolecularSequenceAnnotation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

An annotation representing a feature of a biological sequence such as a motif or a biological function.

EXAMPLE(S):

DNA binding region on the human TP53 protein

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = MolecularSequenceAnnotation

Connectors

Source	Connector	Target	Notes
MolecularSequenceAnnotation	specializes	PerformedObservationResult	<p>DESCRIPTION: Each MolecularSequenceAnnotation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequenceAnnotation 0..* reportingMolecularSequenceAnnotation	report	AminoAcidSequenceFeature 0..* reportedAminoAcidSequenceFeature	<p>DESCRIPTION: Each MolecularSequenceAnnotation might report one or more AminoAcidSequenceFeature. Each AminoAcidSequenceFeature might be reported by one or more MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequenceAnnotation 0..* reportingMolecularSequenceAnnotation	report	NucleicAcidSequenceFeature 0..* reportedNucleicAcidSequenceFeature	<p>DESCRIPTION: Each MolecularSequenceAnnotation might report one or more NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be reported by one or more MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Class: NucleicAcidPhysicalLocation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A position or a region on a nucleic acid sequence.

EXAMPLE(S):

the first 20 bases of the BRCA1 gene

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = NucleicAcidPhysicalLocation

Connectors

Source	Connector	Target	Notes
NucleicAcidPhysicalLocatio n 1..* translatedNucleicAcidPhys icalLocation	be translated to	AminoAcidSequence 0..1 translatingAminoAcidSeque nce	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation might be translated to one AminoAcidSequence. Each AminoAcidSequence always is translated from one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidPhysicalLocatio n 1..* locatingNucleicAcidPhysica lLocation	be for	CytobandRange 0..1 locatedCytobandRange	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation might be for one CytobandRange. Each CytobandRange always have one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
NucleicAcidPhysicalLocation 1..* locatedNucleicAcidPhysicalLocation	is located on	Chromosome 1 locatingChromosome	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation always is located on one Chromosome. Each Chromosome always has one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidPhysicalLocation 0..* includingNucleicAcidPhysicalLocation	includes	NucleicAcidSequence 1 includedNucleicAcidSequence	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation always includes one NucleicAcidSequence. Each NucleicAcidSequence might be included in one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidSequenceFeature 0..* includedNucleicAcidSequenceFeature	is included in	NucleicAcidPhysicalLocation 1..* includingNucleicAcidPhysicalLocation	<p>DESCRIPTION: Each NucleicAcidSequenceFeature always is included in one or more NucleicAcidPhysicalLocation. Each NucleicAcidPhysicalLocation might include one or more NucleicAcidSequenceFeature.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
startCoordinate <i>Class:</i> NucleicAcidPhysicalLocation <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The beginning coordinate of the range (inclusive), given as an integer offset from the start of the sequence.</p> <p>EXAMPLE(S): 12</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = NucleicAcidPhysicalLocation.startCoordinate
endCoordinate <i>Class:</i> NucleicAcidPhysicalLocation <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The terminal coordinate of the range (inclusive), given as an integer offset from the start of the sequence.</p> <p>EXAMPLE(S): 100</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:LSDAMv2.2.3Plus = NucleicAcidPhysicalLocation.endCoordinate

Class: NucleicAcidSequence

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A representation of a linear arrangement of nucleotides.

EXAMPLE(S):

the sequence of TP53 gene, the first 20 nucleotide of a BRCA1 mRNA, microarray probe for BRCA2 mRNA

OTHER NAME(S):

NOTE(S):

Nucleotides are organic compounds containing nitrogenous base (adenine, guanine, uracil, or cytosine in RNA), a phosphate molecule, and a sugar molecule (deoxyribose in DNA and ribose in RNA).

Tagged Values:

- Map:LSDAMv2.2.3Plus = NucleicAcidSequence

Connectors

Source	Connector	Target	Notes
NucleicAcidSequence	specializes	MolecularSequence	<p>DESCRIPTION: Each AminoAcidSequence always specializes one MolecularSequence. Each MolecularSequence might be specialized by one AminoAcidSequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
DNASequence	specializes	NucleicAcidSequence	<p>DESCRIPTION: Each DNASequence always specializes one NucleicAcidSequence. Each NucleicAcidSequence might be specialized by one DNASequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NucleicAcidPhysicalLocation 0..* includingNucleicAcidPhysicalLocation	includes	NucleicAcidSequence 1 includedNucleicAcidSequence	<p>DESCRIPTION: Each NucleicAcidPhysicalLocation always includes one NucleicAcidSequence. Each NucleicAcidSequence might be included in one or more NucleicAcidPhysicalLocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RNASequence	specializes	NucleicAcidSequence	<p>DESCRIPTION: Each RNASequence always specializes one NucleicAcidSequence. Each NucleicAcidSequence might be specialized by one RNASequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: NucleicAcidSequenceFeature

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

An annotation assigned to a defined nucleic acid physical location.

EXAMPLE(S):
promoter region, protein binding domains

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = NucleicAcidSequenceFeature

Connectors

Source	Connector	Target	Notes
NucleicAcidSequenceFeature 0..* includedNucleicAcidSequenceFeature	is included in	NucleicAcidPhysicalLocation 1..* includingNucleicAcidPhysicalLocation	<p>DESCRIPTION: Each NucleicAcidSequenceFeature always is included in one or more NucleicAcidPhysicalLocation. Each NucleicAcidPhysicalLocation might include one or more NucleicAcidSequenceFeature.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>
Biomarker 0..* basingBiomarker	be based on	NucleicAcidSequenceFeature 0..* basedNucleicAcidSequenceFeature	<p>DESCRIPTION: Each Biomarker might be based on one or more NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be the basis of one or more Biomarker.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>
GeneticVariation	specializes	NucleicAcidSequenceFeature	<p>DESCRIPTION: Each GeneticVariation always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one GeneticVariation.</p> <p>DEFINITION: EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
Gene	specializes	NucleicAcidSequenceFeature	DESCRIPTION: Each Gene always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one Gene. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Intron	specializes	NucleicAcidSequenceFeature	DESCRIPTION: Each Intron always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one Intron. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Exon	specializes	NucleicAcidSequenceFeature	DESCRIPTION: Each Exon always specializes one NucleicAcidSequenceFeature. Each NucleicAcidSequenceFeature might be specialized by one Exon. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
MolecularSequenceAnnotation 0..* reportingMolecularSequenceAnnotation	report	NucleicAcidSequenceFeature 0..* reportedNucleicAcidSequenceFeature	DESCRIPTION: Each MolecularSequenceAnnotation might report one or more NucleicAcidSequenceFeature

Source	Connector	Target	Notes
			<p>e. Each NucleicAcidSequenceFeature might be reported by one or more MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> NucleicAcidSequenceFeature <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the category of the nucleic acid sequence feature.</p> <p>EXAMPLE(S): DNA methylation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): [Glycosylation Site:C16643, C37901; Binding Site:C13671]</p>	Map:LSDAMv2.2.3Plus = NucleicAcidSequenceFeature.typeCode
orientation <i>Class:</i> NucleicAcidSequenceFeature <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The orientation of the feature relative to the sequence upon which it is annotated.</p> <p>EXAMPLE(S): "forward", "for", "F", "+", "reverse", "rev", "R", "-"</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Features that are annotated on the same strand as the underlying sequence are usually indicated by "forward", "for", "F", or "+". Features that are on the opposite strand (the reverse-complement of the underlying sequence) are usually indicated by "reverse", "rev", "R", or "-".</p>	Map:LSDAMv2.2.3Plus = NucleicAcidSequenceFeature.orientation

Class: Pathway

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

'A series of actions among molecules in or associated with a cell that leads to a certain product or a change in a cell. Such a pathway can trigger the assembly of new molecules, such as a fat or protein. Pathways can also turn genes on and off, or spur a cell to move. [Adapted from: <http://www.genome.gov/27530687>]

EXAMPLE(S):

Notch signaling pathway

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Pathway

Connectors

Source	Connector	Target	Notes
Pathway 0..* includedPathway	be included by	BiologicEntityClassification 0..* includingBiologicEntityClassification	<p>DESCRIPTION: Each Pathway might be included by one or more BiologicEntityClassification. Each BiologicEntityClassification might include one or more Pathway.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Pathway 0..* involvingPathway	involve	Protein 0..* involvedProtein	<p>DESCRIPTION: Each Pathway might involve one or more Protein. Each Protein might be involved in one or more Pathway.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Pathway 0..* involvingPathway	involve	Gene 0..* involvedGene	<p>DESCRIPTION: Each Pathway might involve one or more Gene. Each Gene might be involved in one or more Pathway.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Pathway <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	DEFINITION: A unique symbol that establishes the identity of the pathway. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = PathwayIdentifier.identifier
name <i>Class:</i> Pathway <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A non-unique textual identifier for the pathway. EXAMPLE(S): Notch signaling pathway OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Pathway.name
description <i>Class:</i> Pathway <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The textual summary or explanation of the pathway. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Pathway.description
type <i>Class:</i> Pathway <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A generalized classification of the pathway. EXAMPLE(S): metabolic pathway, signaling pathway OTHER NAME(S): NOTE(S):	Map:LSDAMv2.2.3Plus = Pathway.type

Class: PerformedGeneticInterpretation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

The result of assessing the meaning of one or more genetic observation results.

EXAMPLE(S):

The result of assessing a set of genetic variations might be a decreased risk of a given disease.

OTHER NAME(S):

NOTE(S):

Most labs perform this assessment using either an automated or semi-automated process or human interpretation. The process of interpretation is varied, depending on a number of things including intended use, degree of evidence for genotype/phenotype associations, and complexity the testing context. Where the test is highly targeted and findings simple with clear phenotype association, the interpretation process will likely be more automated.

Tagged Values:

- Map:PGx v1.0 = SB.SBMRKRID

Connectors

Source	Connector	Target	Notes
PerformedGeneticInterpretation	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedGeneticInterpretation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedGeneticInterpretation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedGeneticInterpretation 0..* matchingPerformedGeneticInterpretation	match	MolecularBiomarkerGroup 0..1 matchedMolecularBiomarkerGroup	<p>DESCRIPTION: Each PerformedGeneticInterpretation might match one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup might be a match for one or more PerformedGeneticInterpretation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedGeneticObservation

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

The completed action of assessing a genetic characteristic of a biologic specimen or assessing a contextual characteristic of the genetic test itself.

EXAMPLE(S):

For CDISC's PG domain, Exon Sequenced, Sequence Start, Sequence Length

For CDISC's PF domain, Amino Acid, Nucleotide, Allele, Observed Level, Raw Ct Value, Copy Number, Normalized Intensity 1 Value, Fold Change, New Assessment

OTHER NAME(S):

NOTE(S):

Because of their similar attributes, observations about genetic tests themselves as well as genetic observations about

specimens are both represented by this single class.

Tagged Values:

- Map:PGx v1.0 = PG
- Map:PGx v1.0 = PF
- Map:PGx v1.0 = SB

Connectors

Source	Connector	Target	Notes
PerformedGeneticObservation	specializes	PerformedObservation	<p>DESCRIPTION: Each PerformedGeneticObservation always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedGeneticObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
runIdentifier <i>Class:</i> PerformedGeneticObservation <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes identity of a particular execution of a test on a biospecimen.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The clinical genomics community is encouraged to comment on whether this is the correct data type for this concept. It is assumed that even if a RUNID is not unique across multiple labs, if that lab can be uniquely identified, then the RUNID has a namespace in which it is unique and an OID or UUID or LSID could be constructed.</p>	Map:PGx v1.0 = PF.PFRUNID Map:PGx v1.0 = PG.PGRUNID

Attribute	Notes	Constraints and Tags
geneticRegionOfInterest <i>Class:</i> PerformedGeneticObservation <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The portion of the genome serving as a locus for the test, often a gene.</p> <p>EXAMPLE(S): EGFR, KRAS, CYP2D6, MYC, MFNG</p> <p>OTHER NAME(S):</p> <p>NOTE(S): These are typically obtained from the gene symbol list maintained by the Human Genome Variation Society (HGVS) => HUGO Genome Nomenclature Consortium (HGNC), a committee of the Human Genome Organization (HUGO). This can be a gene, a protein, or a sector as described by geneticRegionTypeCode.</p>	Map:PGx v1.0 = PF.PFGENRI Map:PGx v1.0 = SB.SBGENRI
geneticRegionTypeCode <i>Class:</i> PerformedGeneticObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of portion of the genome serving as a locus for the test.</p> <p>EXAMPLE(S): GENE, SECTOR, DOMAIN, PROTEIN</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFGENTYP Map:PGx v1.0 = SB.SBGENTYP
geneticLocationOfInterest <i>Class:</i> PerformedGeneticObservation <i>Datatype:</i> IVL<INT> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The portion of the sequence that is the focus of this test or observation.</p> <p>EXAMPLE(S): In CDISC's PGx domains, a PFGENLI of "34" would be 34, or "2235_2249" would be 2235-2249.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFGENLI
analysisMethodCode <i>Class:</i> PerformedGeneticObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the technique used for secondary processing applied to a complex observation result (e.g. an image or a genetic sequence) to obtain a summarized result.</p> <p>EXAMPLE(S): Lowess, Paired-end mapping, Probe Signal Intensity, SNP Genotyping</p> <p>OTHER NAME(S):</p> <p>NOTE(S): There are often a range of analysis method codes that are appropriate for a given method code.</p>	Map:PGx v1.0 = PF.PFANMETH

Class: PerformedGeneticObservationResult

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

The result of assessing a genetic characteristic of a biologic specimen.

EXAMPLE(S):

For an Amino Acid test the result might be "Arg".

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = PF.PFGENTRG

Connectors

Source	Connector	Target	Notes
PerformedGeneticObservationResult	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedGeneticObservationResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedGeneticObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedGeneticObservationResult 1..* referencingPerformedGeneticObservationResult	reference	GeneticReference 0..1 referencedGeneticReference	<p>DESCRIPTION: Each PerformedGeneticObservationResult might reference one GeneticReference. Each GeneticReference always is referenced by one or more PerformedGeneticObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): "A" might be the reference if the test result is a Nucleotide. "Trp" might be the reference if the test result is an Amino Acid.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PerformedGeneticObservationResult 0..* referencingPerformedGeneticObservationResult	reference	SingleNucleotidePolymorphism 0..1 referencedSingleNucleotidePolymorphism	<p>DESCRIPTION: Each PerformedGeneticObservationResult might reference one SingleNucleotidePolymorphism. Each SingleNucleotidePolymorphism might be referenced by one or more PerformedGeneticObservationResult.</p> <p>DEFINITION: The link between the observed variation in test result and the documented variation in the dbSNP database as identified by an rs number.</p> <p>EXAMPLE(S): A given subject, Joe, may have a genetic variation detected by a test result which is a match to a dbSNP variation identified with the rs number "rs1570360". The dbSNP variation ("NM_001025367.2:c.-614A>G") tells us that NM_001025367.2 is the most current reference sequence ("." means it's version 2). The "c.-614A>G" tells us a nucleotide changed in position "-614" from A to G.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
geneticRegionOfInterest <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The portion of the genome serving as a locus for the test result, often a gene.</p> <p>EXAMPLE(S): EGFR, KRAS, CYP2D6, MYC, MFNG</p> <p>OTHER NAME(S):</p> <p>NOTE(S): These are typically obtained from the gene symbol list maintained by the Human Genome Variation Society (HGVS) => HUGO Genome Nomenclature Consortium (HGNC), a committee of the Human Genome Organization (HUGO). This can be a gene, a protein, or a sector as described by geneticRegionTypeCode.</p>	Map:PGx v1.0 = PG.PGGENRI
geneticRegionTypeCode <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of portion of the genome serving as a locus for the test result.</p> <p>EXAMPLE(S): GENE, SECTOR, DOMAIN, PROTEIN</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PG.PGGENTYP
geneticSubregion <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The portion of the genetic region of interest in which the variation was found when the genetic region of interest is a gene.</p> <p>EXAMPLE(S): Exon 15, Intron 1</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is only used if geneticRegionTypeCode = "GENE".</p>	Map:PGx v1.0 = PF.PFGENSR
geneticLocation <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> IVL<INT> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The portion of the sequence that is described by this test result.</p> <p>EXAMPLE(S): 65 213-215 71 213 152 454 -614 -2055</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFGENLOC

Attribute	Notes	Constraints and Tags
geneticTarget <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: The nucleotide or amino acid within the genetic location of interest that is to be compared to the subject's test result.</p> <p>EXAMPLE(S): In CDISC's PGx domains, a PFGENTRG of "A" indicates that you are checking to see if the biospecimen tested has an A in the location specified by the geneticLocationOfInterest, or a value of "del" in PFGENTRG means you are looking for a deletion in that location of interest.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFGENTRG
alleleIndicatorCode <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying one copy of a gene used to differentiate between copies of a gene on a homologous chromosome pair.</p> <p>EXAMPLE(S): 1, 2, A, B</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The convention used to label the copy is often 1 or 2, A or B, because whether a given copy is maternal or paternal is not usually known. The code system used for this concept is expected to be local since there is currently no industry standard.</p>	Map:PGx v1.0 = PF.PFALLELC
mutationTypeCode <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Coded value defining the genomic source of the variant, which can indicate the variant context including inherited germline mutations, acquired tumor specific mutations, mutations within a fetus, or unknown origin.</p> <p>EXAMPLE(S): Germline Somatic Prenatal Likely Germline Likely Somatic Likely Prenatal Unknown Genomic Origin</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFMUTYP

Attribute	Notes	Constraints and Tags
derivedIndicator <i>Class:</i> PerformedGeneticObservationResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether a result represents a calculation performed on other results.</p> <p>EXAMPLE(S): For CDISC PGx domains, a lab may report a codon (consists of 3 nucleotides) as a result, e.g. TTT, and the sponsor can derive the fact that this codon codes for an amino acid, Phenylalanine in this case; the sponsor is using the codon to derive the amino acid. Therefore for the record reporting the amino acid, the derivedIndicator = "true".</p> <p>OTHER NAME(S): Derived Flag</p> <p>NOTE(S):</p>	Map:PGx v1.0 = PF.PFDRVFL

Class: Protein

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A representation of an organic macromolecule in public resources (e.g., UniProt or NCBI RefSeq) composed of one or more chains (linear polymers) of alpha-L-amino acids linked by peptide bonds and ranging in size from a few thousand to over 1 million Daltons.

Comment Requested: In interest of re-using existing standards, should the above definition of Protein be replaced by the following from the NLM -- : A molecule made up of amino acids that are needed for the body to function properly. Proteins are the basis of body structures such as skin and hair and of substances such as enzymes, cytokines, and antibodies.

[Source: <http://ghr.nlm.nih.gov/glossary=protein>]

EXAMPLE(S):

A protein record from UniProt Knowledgebase: <http://www.uniprot.org/uniprot/P38398>

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = Protein
- Map:PGx v1.0 = PB.PBGENTYP

Connectors

Source	Connector	Target	Notes
Protein 0..* representedProtein	be represented by	AminoAcidSequence 0..* representingAminoAcidSequence	<p>DESCRIPTION: Each Protein might be represented by one or more AminoAcidSequence. Each AminoAcidSequence might represent one or more Protein.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
Protein 0..* characterizingProtein	characterize	Material 0..* characterizedMaterial	DESCRIPTION: Each Protein might characterize one or more Material. Each Material might be characterized by one or more Protein. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
MolecularBiomarkerGroup 0..* basingMolecularBiomarkerGroup	be based on	Protein 0..* basedProtein	DESCRIPTION: Each MolecularBiomarkerGroup might be based on one or more Protein. Each Protein might be the basis of one or more MolecularBiomarkerGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Biomarker 0..* basingBiomarker	be based on	Protein 0..* basedProtein	DESCRIPTION: Each Biomarker might be based on one or more Protein. Each Protein might be the basis of one or more Biomarker. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Gene 0..* encodingGene	encode	Protein 0..* encodedProtein	DESCRIPTION: Each Gene might encode one or more Protein. Each Protein might be encoded by one or more Gene. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
			NOTE(S):
Pathway 0..* involvingPathway	involve	Protein 0..* involvedProtein	DESCRIPTION: Each Pathway might involve one or more Protein. Each Protein might be involved in one or more Pathway. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Protein <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 1...1	DEFINITION: A unique symbol that establishes the identity of the protein. EXAMPLE(S): The identifier from the Ensembl or GenBank database OTHER NAME(S): NOTE(S): The identifier needs to be fully qualified with version and source, if available as part of the standard. It is anticipated that at some point in the future a use case will arise for a type code to be added to the identifiers allowing a single database to issue more than one kind of identifier, but it is also hoped that this need may be addressed by a change in the HL7 data type definition for II. The current pattern of pairing an II attribute with a CD attribute does not support the anticipated use case.	Map:LSDAMv2.2.3Plus = ProteinIdentifier.identifier
name <i>Class:</i> Protein <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0...*	DEFINITION: A textual identifier using human-readable language identifying a protein defined by an organization that assigns such things. EXAMPLE(S): Breast cancer type 1 susceptibility protein OTHER NAME(S): NOTE(S): Question for SMEs: Question for SMEs: Should this attribute be remodeled in a related class with an association to the Organization class to represent the organization assigning the name?	Map:LSDAMv2.2.3Plus = Protein.name Map:PGx v1.0 = PB.PBGENRI

Attribute	Notes	Constraints and Tags
symbol <i>Class:</i> Protein <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: An acronym, abbreviation or other short name for a protein defined by an organization that assigns such things.</p> <p>EXAMPLE(S): BRCA1 protein</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Question for SMEs: Should this attribute be remodeled in a related class with an association to the Organization class to represent the organization assigning the symbol?</p>	Map:LSDAMv2.2.3Plus = Protein.symbol

Class: RNASequence

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A representation of the linear arrangement of ribonucleotides.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = RNASequence

Connectors

Source	Connector	Target	Notes
RNASequence	specializes	NucleicAcidSequence	<p>DESCRIPTION: Each RNASequence always specializes one NucleicAcidSequence. Each NucleicAcidSequence might be specialized by one RNASequence.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MessengerRNA 0..* representingMessengerRNA	represent	RNASequence 0..* representedRNASequence	<p>DESCRIPTION: Each MessengerRNA might represent one or more RNASequence. Each RNASequence might be represented by one or more MessengerRNA.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: SingleNucleotidePolymorphism

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A variation defined by the substitution of one base, present at an appreciable frequency between individuals of a single interbreeding population.

EXAMPLE(S):

The A to G change in the TPMT gene, identified by dbSNP rs1142345

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = SingleNucleotidePolymorphism

Connectors

Source	Connector	Target	Notes
SingleNucleotidePolymorphism	specializes	GeneticVariation	<p>DESCRIPTION:</p> <p>Each SingleNucleotidePolymorphism always specializes one GeneticVariation. Each GeneticVariation might be specialized by one SingleNucleotidePolymorphism.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SingleNucleotidePolymorphism 1..* includedSingleNucleotidePolymorphism	is included in	DNASequence 1 includingDNASequence	<p>DESCRIPTION:</p> <p>Each SingleNucleotidePolymorphism always is included in one DNASequence. Each DNASequence always includes one or more SingleNucleotidePolymorphism.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
PerformedGeneticObservationResult 0..* referencingPerformedGeneticObservationResult	reference	SingleNucleotidePolymorphism 0..1 referencedSingleNucleotidePolymorphism	<p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>DESCRIPTION: Each PerformedGeneticObservationResult might reference one SingleNucleotidePolymorphism. Each SingleNucleotidePolymorphism might be referenced by one or more PerformedGeneticObservationResult.</p> <p>DEFINITION: The link between the observed variation in test result and the documented variation in the dbSNP database as identified by an rs number.</p> <p>EXAMPLE(S): A given subject, Joe, may have a genetic variation detected by a test result which is a match to a dbSNP variation identified with the rs number "rs1570360". The dbSNP variation ("NM_001025367.2:c.-614 A>G") tells us that NM_001025367.2 is the most current reference sequence ("." means it's version 2). The "c.-614A>G" tells us a nucleotide changed in position "-614" from A to G.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudiedMolecularBiomarkerGroup

Package: Out of Scope for HL7 May 2017 Ballot Cycle: Molecular Biology Sub-Domain

DEFINITION:

A collection of molecular biomarkers that is a focus of research in a particular study.

EXAMPLE(S):

Molecular Biomarker Group "L10I+K20R+M36I+A71V+V82T" might be a focus of study in protocol "STDY-505357"

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = PB.STUDYID

Connectors

Source	Connector	Target	Notes
StudiedMolecularBiomarker Group 0..* studiedStudiedMolecularBiomarkerGroup	is studied by	StudyProtocolVersion 1 studyingStudyProtocolVersion	<p>DESCRIPTION: Each StudiedMolecularBiomarker Group always is studied by one StudyProtocolVersion. Each StudyProtocolVersion might be studying one or more StudiedMolecularBiomarker Group.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudiedMolecularBiomarker Group 0..* studyingStudiedMolecularBiomarkerGroup	is studying	MolecularBiomarkerGroup 1 studiedMolecularBiomarkerGroup	<p>DESCRIPTION: Each StudiedMolecularBiomarker Group always is studying one MolecularBiomarkerGroup. Each MolecularBiomarkerGroup might be studied by one or more StudiedMolecularBiomarker Group.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Protocol Representation Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Protocol Representation sub-domain is intended for those involved in the planning and design of a research protocol. The majority of business requirements have come from those involved in clinical trial protocols. It focuses on the characteristics of a study and the definition and association of activities within the protocols, including "arms" and "epochs". It also includes the definitions of the roles that participate in those activities.

Protocol Representation Sub-Domain

View PR: Protocol Representation diagram

Class diagram in package 'Protocol Representation Sub-Domain'

The Protocol Representation sub-domain is intended for those involved in the planning and design of a research protocol. The majority of business requirements have come from those involved in clinical trial protocols. It focuses on the characteristics of a study and the definition and association of activities within the protocols, including "arms" and "epochs". It also includes the definitions of the roles that participate in those activities.

View PR: Protocol Representation

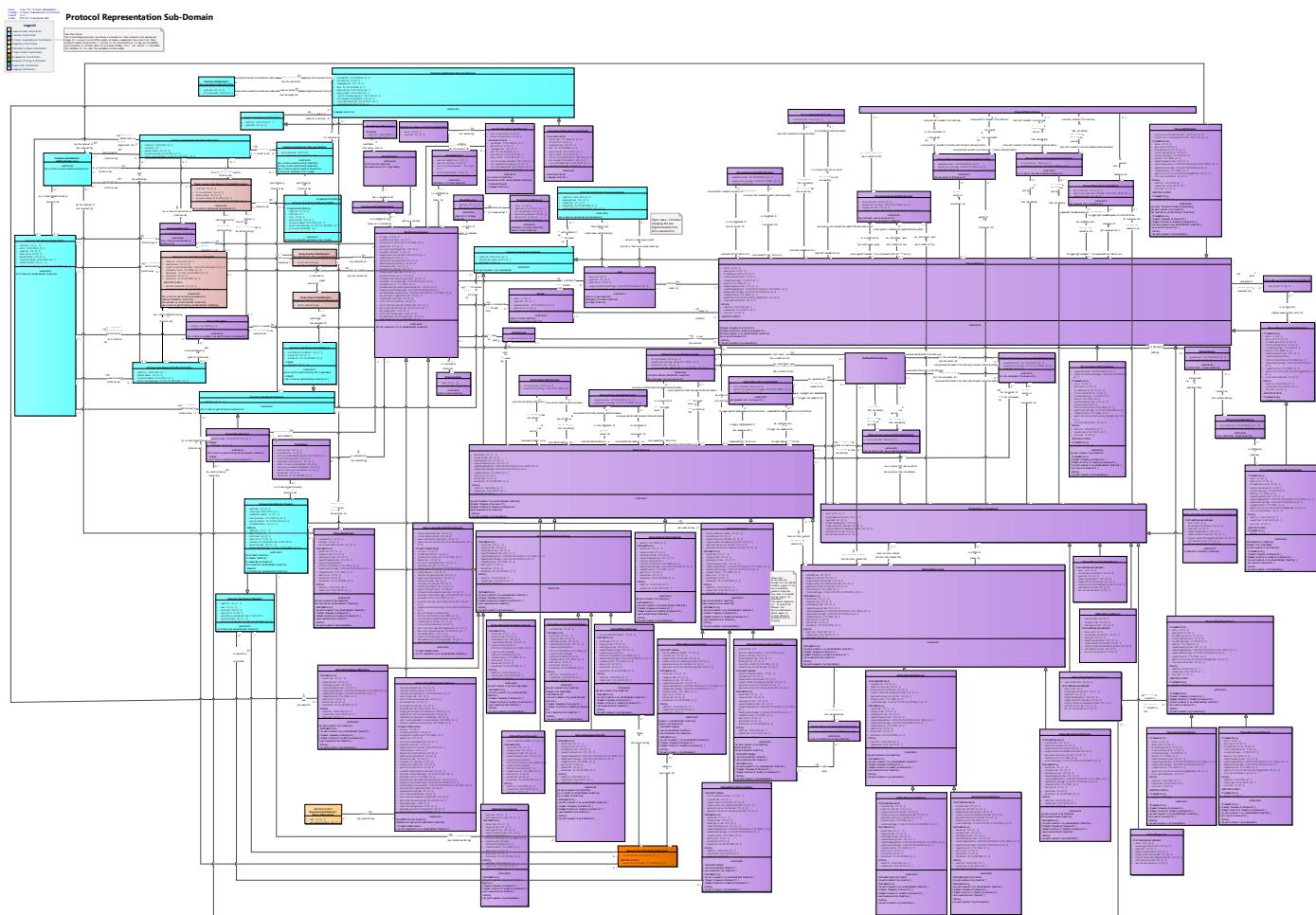


Figure 12: View PR: Protocol Representation

Study Versioning View diagram

Class diagram in package 'Protocol Representation Sub-Domain'

View Description:

The Study Versioning View is intended to show the concepts within BRIDG that are related to a change in a study protocol; that is if a study protocol changes what information needs to be kept about the old version. The majority of business requirements come from the C3PR project.

Study Versioning View

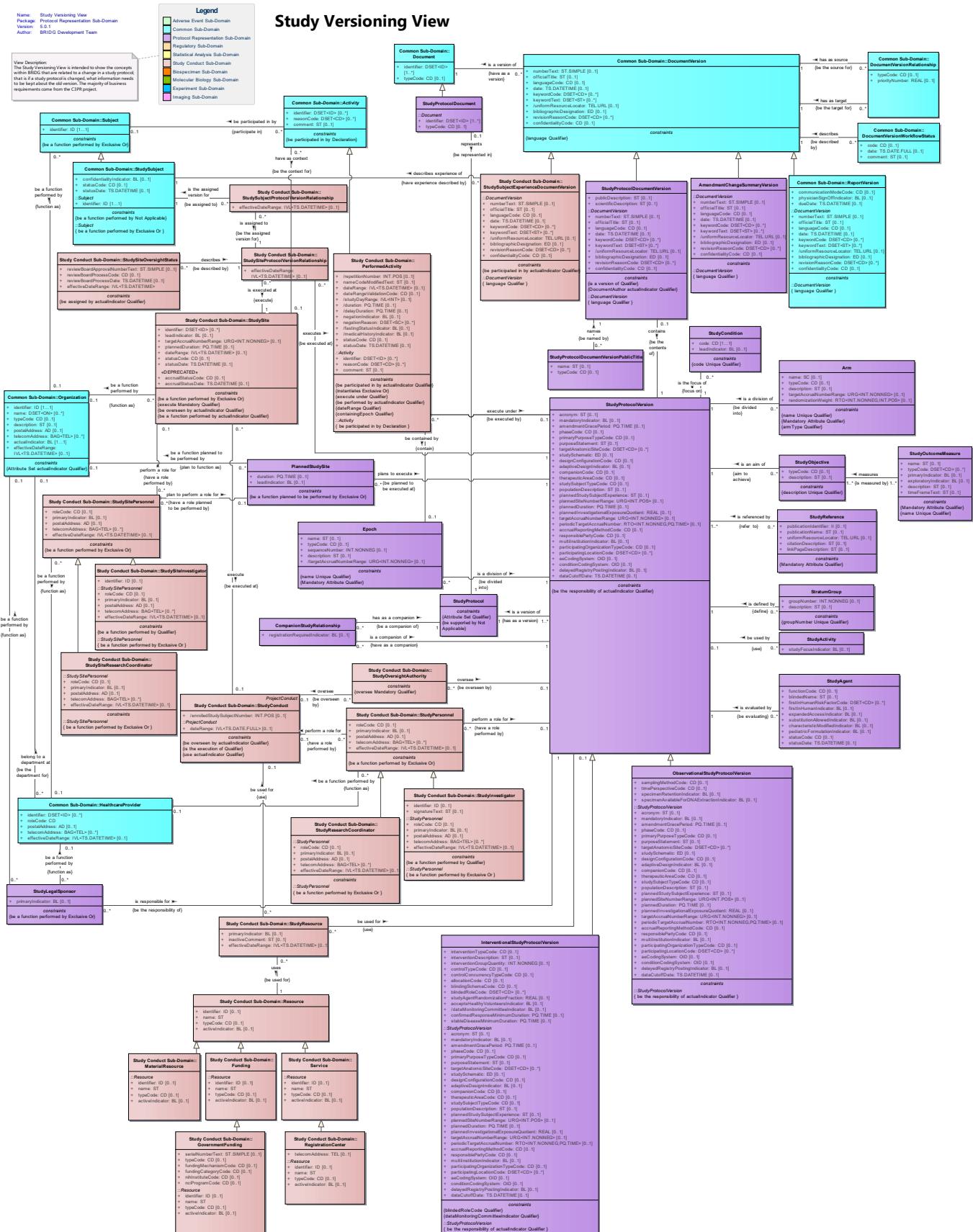


Figure 13: Study Versioning View

Class: AmendmentChangeSummaryVersion

Package: Protocol Representation Sub-Domain

DEFINITION:

A version of a document, memo or brief that enumerates the differences between two versions of a study protocol document.

EXAMPLE(S):

OTHER NAME(S):

Amendment

NOTE(S):

The term "Amendment" needs to be disambiguated since it sometimes refers to the amended version of the protocol (StudyProtocolDocumentVersion) and other times refers to the summary of changes (AmendmentChangeSummaryVersion) that are applied to a protocol to create a new version of the protocol.

Tagged Values:

- Map:CTRv1.0 = AmendmentChangeSummaryVersion
- Map:PSCv2.6 = Amendment

Connectors

Source	Connector	Target	Notes
AmendmentChangeSummaryVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each AmendmentChangeSummaryVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one AmendmentChangeSummaryVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: Arm

Package: Protocol Representation Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

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.

OTHER NAME(S):

Group [CTRR Observational Studies]

NOTE(S):

An Arm is typically equivalent to a treatment group in a parallel design study. 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 through which the subject progresses in a study 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.

Tagged Values:

- Map:CTRPv1.0 = Arm
- Map:CTRPv3.8 = Arm
- Map:CTRRr3 = Arm
- Map:CTRv1.0 = Arm
- Map:HL7SD = Arm
- Map:SDTM IGv3.1.2 = TA.DOMAIN
- Map:SDTM IGv3.1.3 = TA

Connectors

Source	Connector	Target	Notes
Arm 0..* containingArm	contains	PlannedActivity 1..* containedPlannedActivity	<p>DESCRIPTION: Each Arm always contains one or more PlannedActivity. Each PlannedActivity might occur in one or more Arm.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Arm 0..* subdividingArm	is a division of	StudyProtocolVersion 1 subdividedStudyProtocolVersion	<p>DESCRIPTION: Each Arm always is a division of one StudyProtocolVersion. Each StudyProtocolVersion might be divided into one or more Arm.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ExperimentalUnit 0..* experiencingExperimentalUnit	actually have experienced	Arm 0..1 experiencedArm	<p>DESCRIPTION: Each ExperimentalUnit might actually have experienced one Arm. Each Arm might actually have been experienced by one or more ExperimentalUnit.</p> <p>DEFINITION: The association between a ExperimentalUnit and an Arm that identifies the treatment plan actually received by the experimental unit as determined retrospectively regardless of what treatment</p>

Source	Connector	Target	Notes
			<p>plan was in fact assigned to the experimental unit.</p> <p>EXAMPLE(S): For an A/B cross-over study the arms may be "A-B" and "B-A"; if John Doe was assigned Arm "A-B", but actually experienced Arm "B-A", this association would link his role of ExperimentalUnit to the Arm he really participated in.</p> <p>OTHER NAME(S): Actual Arm</p> <p>NOTE(S): In most trials one would expect that the Arm linked to the ExperimentalUnit will be the same as the Arm.name that was assigned in the PerformedExperimentalUnit Allocation for that ExperimentalUnit. However, if what actually happened is different than what was assigned but is actually a valid arm in the trial arms table, i.e. the experimental unit was assigned A-B but actually received B-A, this association shows the connection to the treatment plan that actually was followed. Or alternatively, if CDISC's SDTM DM.ACTARMCD = "UNPLAN" (meaning "Unplanned Treatment"), then the treatment that occurred doesn't match any arm in trial arms table and this association would not be used. Rather the ExperimentalUnit.unplannedTreatmentIndicator would be "true". Note that this association has a retrospective nature – i.e. you might not know what treatment an experimental unit was actually on until after all treatments have been completed and the blind, if any, has been broken. This is typically the case for</p>

Source	Connector	Target	Notes
			<p>studies in which there may be more than one randomization.</p>
ExperimentalUnit 0..1 performingExperimentalUnit	have performed	Arm 0..1 performedArm	<p>DESCRIPTION: Each ExperimentalUnit might have performed one Arm. Each Arm might have been performed by one ExperimentalUnit.</p> <p>DEFINITION: Indicates that an ExperimentalUnit was, at the end of their participation in a study, assigned to a particular arm based on their actual path through the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is derivable if the set of performed activities the ExperimentalUnit participated in are available.</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
name <i>Class:</i> Arm <i>Datatype:</i> SC <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The text and/or code that identifies the arm.</p> <p>EXAMPLE(S): “Treatment A” with an optional code “A”</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value is at minimum a string with an optional code attached. The codes are likely to be local to the study rather than a standard of any kind.</p>	Map:C3PR = ScheduledArm.name Map:C3PR = PlannedArm.name Map:C3PR = Arm.name Map:caAERSv2.2 = RadiationIntervention.treatmentArm Map:CTGOV = Arms/Groups Map:CTGOV = Group/Cohort Number or Label Map:CTGOV = Arm Number or Label Map:CTOM = StudyParticipantAssignment.armIdentifier Map:CTRPv1.0 = Arm.name Map:CTRPv3.8 = Arm.name Map:CTRr3 = Arm.name Map:CTRv1.0 = Arm.name Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component2/arm.title Map:HL7SD = Arm.title Map:NCI CRF Standard = CDE 2454528v1.0: Protocol Arm Assignment Text Map:SDTM IGv3.1.1 = DM.ARMCD Map:SDTM IGv3.1.1 = TA.ARMCD Map:SDTM IGv3.1.1 = TV.ARMCD Map:SDTM IGv3.1.2 = TA.ARMCD Map:SDTM IGv3.1.2 = DM.ARMCD Map:SDTM IGv3.1.2 = TV.ARMCD Map:SDTM IGv3.1.3 = TV.ARMCD Map:SDTM IGv3.1.3 = DM.ACTARM Map:SDTM IGv3.1.3 = DM.ACTARMCD Map:SDTM IGv3.1.3 = DM.ARM Map:SDTM IGv3.1.3 = DM.ARMCD Map:SDTM IGv3.1.3 = TA.ARM Map:SDTM IGv3.1.3 = TA.ARMCD Map:SDTM IGv3.1.3 = TV.ARM Map:TDM = StudyDesignArm.name
typeCode <i>Class:</i> Arm <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of arm.</p> <p>EXAMPLE(S): Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No intervention, Other</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Arm Type Map:CTR&Rr2 = Number Treatment Arms Map:CTRPv1.0 = Arm.typeCode Map:CTRPv3.8 = Arm.typeCode Map:CTRr3 = Arm.typeCode Map:CTRv1.0 = Arm.typeCode

Attribute	Notes	Constraints and Tags
description <i>Class:</i> Arm <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the arm. This is a description of the pathway followed by all subjects, study subjects, or experimental units in a particular treatment regimen.</p> <p>EXAMPLE(S): Study subjects receive Drug X Experimental units receive Placebo Study subjects receive drug A IV in the first phase, drug B Oral in the second phase</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This description should point out what is different between the Arms, if there is more than one Arm.</p>	Map:C3PR = Arm.descriptionText Map:C3PR = ScheduledArm.description Map:C3PR = PlannedArm.description Map:CTGOV = Arm Description Map:CTRPv1.0 = Arm.description Map:CTRPv3.8 = Arm.description Map:CTRr3 = Arm.description Map:CTRv1.0 = Arm.description Map:SDTM IGv3.1.1 = DM.ARM Map:SDTM IGv3.1.1 = TA.ARM Map:SDTM IGv3.1.1 = TV.ARM Map:SDTM IGv3.1.2 = TA.ARM Map:SDTM IGv3.1.2 = TV.ARM Map:SDTM IGv3.1.2 = DM.ARM Map:TDM = StudyDesignArm.description
targetAccrualNumberRange <i>Class:</i> Arm <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many study subjects are to be accrued for the arm.</p> <p>EXAMPLE(S): For a 2-arm study with non-weighted randomization needing 500 subjects to provide the appropriate statistical power to answer the study question, each Arm should have a target accrual of 250 subjects.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This may represent the minimum number of study subjects needed to support data analysis and/or the maximum number of study subjects that may be accrued to this arm.</p>	Map:C3PR = Arm.targetAccrualNumber Map:C3PR = PlannedArm.targetAccrual Map:CTGOV = Number of Subjects per Treatment Arm Map:CTR = Number of subjects per treatment arm Map:CTRv1.0 = Arm.targetAccrualNumberRange Map:TDM = StudyDesignArm.plannedArmAccrual
randomizationWeight <i>Class:</i> Arm <i>Datatype:</i> RTO<INT.NONNEG,INT.POSS> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The relative proportion of study subjects to be randomized to the arm.</p> <p>EXAMPLE(S): If 1/3 of study 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Arm.randomizationWeight Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=RANDRAT Map:TDM = StudyDesignArm.randomizationWeightForArm

Class: CompanionStudyRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

Specifies the link between a parent or master study and a companion or ancillary study.

EXAMPLE(S):

Embedded, Non-Stand-Alone Companion
 Non-Embedded, Non-Stand-Alone Companion
 Non-Embedded, Stand-Alone Companion

OTHER NAME(S):**NOTE(S):**

The relationship exists between the version of the parent study and the non-versioned concept of the companion study because the relationship may be added in a new version of the parent study and references the overall notion of the companion study, not a particular version of the companion study. Note that additional semantics about the companion study are captured in the StudyProtocolVersion.companionCode attribute.

Tagged Values:

- Map:C3PRv2.9 = CompanionStudyAssociation
- Map:CTRv1.0 = CompanionStudyRelationship

Connectors

Source	Connector	Target	Notes
CompanionStudyRelationship 0..* accompanyingCompanionStudyRelationship	is a companion of	StudyProtocolVersion 1 accompanyingStudyProtocolVersion	<p>DESCRIPTION: Each CompanionStudyRelationship always is a companion of one StudyProtocolVersion. Each StudyProtocolVersion might have as a companion one or more CompanionStudyRelationships.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>
CompanionStudyRelationship 0..* accompanyingCompanionStudyRelationship	has as a companion	StudyProtocol 1 accompanyingStudyProtocol	<p>DESCRIPTION: Each CompanionStudyRelationship always has as a companion one StudyProtocol. Each StudyProtocol might be a companion of one or more CompanionStudyRelationships.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
registrationRequiredIndicator <i>Class:</i> CompanionStudyRelationship <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether registration to the companion study is mandatory when registering to the parent study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = CompanionStudyAssociation.mandatoryIndicator Map:CTRv1.0 = CompanionStudyRelationship.registrationRequiredIndicator

Class: DefinedActivity

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that frequently occurs in studies (e.g. more than one time in more than one arm) and/or experiments and therefore is called out as a reusable template in a global library of activities outside the context of any particular study or experiment, and may be used in the composition of a defined subject activity group. A defined activity is a "kind of" activity rather than an "instance of" an activity.

EXAMPLE(S):

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.

OTHER NAME(S):

NOTE(S):

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.

Tagged Values:

- Map:CTRr3 = DefinedActivity
- Map:CTRv1.0 = DefinedActivity
- Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Act.priorityCode
- Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Encounter.priorityCode
- Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Supply.quality
- Map:LSDAMv2.2.3Plus = DefinedActivity
- Map:PSCv2.6 = Activity

Connectors

Source	Connector	Target	Notes
DefinedActivity	specializes	Activity	<p>DESCRIPTION: Each DefinedActivity always specializes one Activity. Each Activity might be specialized by one DefinedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntil	triggers the cessation of	DefinedActivity	DESCRIPTION:

Source	Connector	Target	Notes
Rule 0..* triggeringDefinedRepeatActivityUntilRule		1 repeatedDefinedActivity	Each DefinedRepeatActivityUntil Rule always triggers the cessation of one DefinedActivity. Each DefinedActivity might be repeated until one or more DefinedRepeatActivityUntil Rule. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedAdministrativeActivity	specializes	DefinedActivity	DESCRIPTION: Each DefinedAdministrativeActivity always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedAdministrativeActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedOptionRelationship 0..* optionDefinedOptionRelationship	is an option that can satisfy	DefinedActivity 1 choiceDefinedActivity	DESCRIPTION: Each DefinedOptionRelationship always is an option that can satisfy one DefinedActivity. Each DefinedActivity might be a choice that has as option one or more DefinedOptionRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCompositionRelationship 0..* compositeDefinedCompositionRelationship	is the parent of	DefinedActivity 1 componentDefinedActivity	DESCRIPTION: Each DefinedCompositionRelationship always is the parent of one DefinedActivity. Each DefinedActivity might be the component of one or

Source	Connector	Target	Notes
			<p>more DefinedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..* prerequisiteDefinedContingentOnRelationship	is a condition for	DefinedActivity 1 contingentDefinedActivity	<p>DESCRIPTION: Each DefinedContingentOnRelationship always is a condition for one DefinedActivity. Each DefinedActivity might be contingent upon one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedProductTransport	specializes	DefinedActivity	<p>DESCRIPTION: Each DefinedProductTransport always specializes oneDefinedActivity. Each DefinedActivity might be specialized by oneDefinedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedActivity 0..1 optionDefinedActivity	<p>DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedActivity. Each DefinedActivity might be an option that can satisfy one or more DefinedCriterionGroupOpti onRelationship.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ProcessProtocol	specializes	DefinedActivity	<p>DESCRIPTION:</p> <p>Each ProcessProtocol always specializes one DefinedActivity. Each DefinedActivity might be specialized by one ProcessProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservation	specializes	DefinedActivity	<p>DESCRIPTION:</p> <p>Each DefinedObservation always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedOptionRelationship 0..* choiceDefinedOptionRelationship	is a choice that has as option	DefinedActivity 1 optionDefinedActivity	<p>DESCRIPTION:</p> <p>Each DefinedOptionRelationship always is a choice that has as option one DefinedActivity. Each DefinedActivity might be an option that can satisfy one or more DefinedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyActivity 0..*	uses	DefinedActivity 1	<p>DESCRIPTION:</p> <p>Each StudyActivity always</p>

Source	Connector	Target	Notes
usingStudyActivity		usedDefinedActivity	<p>uses one DefinedActivity. Each DefinedActivity might be used by one or more StudyActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..* contingentDefinedContingentOnRelationship	be contingent upon	DefinedActivity 0..1 prerequisiteDefinedActivity	<p>DESCRIPTION: Each DefinedContingentOnRelationship might be contingent upon one DefinedActivity. Each DefinedActivity might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCompositionRelationship 0..* compositeDefinedCriterionGroupCompositionRelationship	be the parent of	DefinedActivity 0..1 componentDefinedActivity	<p>DESCRIPTION: Each DefinedCriterionGroupCompositionRelationship might be the parent of one DefinedActivity. Each DefinedActivity might be the component of one or more DefinedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	DefinedActivity 0..1 instantiatedDefinedActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one DefinedActivity. Each DefinedActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedRepeatActivityUntil Rule 0..* repeatedDefinedRepeatActivityUntilRule	be repeated until	DefinedActivity 0..1 triggeringDefinedActivity	DESCRIPTION: Each DefinedRepeatActivityUntil Rule might be repeated until one DefinedActivity. Each DefinedActivity might trigger the cessation of one or more DefinedRepeatActivityUntil Rule. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedProcedure	specializes	DefinedActivity	DESCRIPTION: Each DefinedProcedure always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedSubjectActivityGroup	specializes	DefinedActivity	DESCRIPTION: Each SubjectActivityGroup always specializes one DefinedActivity. Each DefinedActivity might be specialized by one SubjectActivityGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedActivity 0..* usingPlannedActivity	be a use of	DefinedActivity 0..1 usedDefinedActivity	DESCRIPTION: Each PlannedActivity might be a use of one

Source	Connector	Target	Notes
			DefinedActivity. Each DefinedActivity might be used by one or more PlannedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCompositionRelationship 0..* componentDefinedCompositionRelationship	is the component of	DefinedActivity 1 compositeDefinedActivity	DESCRIPTION: Each DefinedCompositionRelationship always is the component of one DefinedActivity. Each DefinedActivity might be the parent of one or more DefinedCompositionRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedActivity 0..1 focusingDefinedActivity	DESCRIPTION: Each DefinedObservation might have as focal context one DefinedActivity. Each DefinedActivity might be the focal context for one or more DefinedObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ImagingProcessProtocolElement	specializes	DefinedActivity	DESCRIPTION: Each ImagingProcessProtocolElement always specializes one DefinedActivity. Each DefinedActivity might be specialized by one ImagingProcessProtocolElement. DEFINITION: EXAMPLE(S):

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
nameCode <i>Class:</i> DefinedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the non-unique textual identifier for the activity.</p> <p>EXAMPLE(S): CPT4 or SNOMED term for a surgical procedure.</p> <p>Coded value for a single analytic procedure in a lab test.</p> <p>The code and text of an individual question on the eligibility checklist of a protocol.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The textual description of the activity is captured in the complex data type CD.</p>	Map:AE = ProductObservation.typeCode Map:AIM v4 rv48 = InferenceEntity.label Map:AIM v4 rv48 = AnnotationEntity.typeCode Map:AIM v4 rv48 = CalculationEntity.description Map:AIM v4 rv48 = CalculationEntity.typeCode Map:AIM v4 rv48 = ImagingObservationCharacteristic.label Map:AIM v4 rv48 = ImagingObservationCharacteristic.questionTypeCode Map:AIM v4 rv48 = InformationObservationEntity.label Map:AIM v4 rv48 = ImagingObservationEntity.questionTypeCode Map:AIM v4 rv48 = InferenceEntity.questionTypeCode Map:C3PR = StratificationCriterion.questionText Map:C3PR = EligibilityCriterion.questionText Map:C3PRv2.9 = EligibilityCriteria.questionText Map:C3PRv2.9 = StratificationCriterion.questionText Map:C3PRv2.9 = SolicitedAdverseEvent Map:C3PRv2.9 = Arm.name Map:C3PRv2.9 = ScheduledEpoch.scEpochWorkflowStatus Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.meddraTerm Map:caAERSv2.2 = CtcTerm.select > SolicitedAdverseEvent Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.meddraCode Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > SolicitedAdverseEvent (otherTerm) Map:caAERSv2.2 = StudyParticipantPriorTherapy.other Map:caAERSv2.2 = Lab > LabTerm Map:caAERSv2.2 = StudyParticipantPreExistingCondition > PriorTherapy.meddraCode Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > SolicitedAdverseEvent (meddraTerm) Map:caAERSv2.2 = Lab.other Map:caAERSv2.2 = StudyParticipantPreExistingCondition

Attribute	Notes	Constraints and Tags
		> PriorTherapy.text Map:caAERSv2.2 = CtcTerm.ctepCode > SolicitedAdverseEvent Map:caAERSv2.2 = SAEReportPriorTherapy.other Map:caAERSv2.2 = Study > AbstractExpectedAE Map:caAERSv2.2 = Therapy.name Map:caAERSv2.2 = TreatmentAssignment.code Map:caAERSv2.2 = StudyParticipantPreExistingCondition > PriorTherapy.meddraTerm Map:caAERSv2.2 = SAEReportPreExistingCondition > PriorTherapy.text Map:caAERSv2.2 = CtcTerm.term > SolicitedAdverseEvent Map:CDASHv1.1 = IE.IETESTCD Map:CDASHv1.1 = SC.SCTEST Map:CDASHv1.1 = DA.DATEST Map:CDASHv1.1 = PE.PETEST Map:CDASHv1.1 = IE.IETEST Map:CDASHv1.1 = AE.AEACNOTH Map:CDASHv1.1 = EG.EGTEST Map:CDASHv1.1 = AE.AEACN Map:CDASHv1.1 = LB.LBTEST Map:CDASHv1.1 = VS.VSTEST Map:CTOM = Activity.name Map:CTOM = Surgery.name Map:CTOM = AdverseEventTherapy.id Map:CTOM = Imaging.name Map:CTOM = Diagnosis.name Map:CTOM = Radiation.name Map:CTOM = AdverseEvent.actionTakenCode Map:CTOM = SpecimenAcquisition.name Map:CTOM = Procedure.name Map:CTOM = ClinicalResult.panelName Map:CTR&Rr2 = Principal exclusion criteria Map:CTR&Rr2 = Principal inclusion criteria Map:CTRPv1.0 = PlannedEligibilityCriterion.alternateN ame Map:CTRPv1.0 = PlannedActivity.alternateName Map:CTRPv1.0 = SubstanceAdministration.nameCode Map:CTRPv1.0 = PlannedObservation.alternateName Map:CTRPv3.8 = PlannedActivity.name Map:CTRPv3.8 = PerformedActivity.name Map:CTRPv3.8 =

Attribute	Notes	Constraints and Tags
		<p>PerformedActivity.nameCode Map:CTRR = Intervention Name Map:CTRRr3 = DefinedActivity.nameCode Map:CTRv1.0 = DefinedActivity.nameCode Map:DICOM = Performed CT Reconstruction Module - Protocol Element Identification Macro > Reconstruction Protocol Element Sequence (0018,9934) > Protocol Element Name (0018,9922) Map:DICOM = TID 1500 MeasurementReport > Procedure reported Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Procedure Code Sequence (0008,1032) Map:DICOM = General Study Module - Procedure Code Sequence (0008,1032) Map:DICOM = Performed CT Acquisition Module - Protocol Element Identification Macro > Acquisition Protocol Element Sequence (0018,9920) > Protocol Element Name (0018,9922) Map:DICOM = Protocol Context Module - Potential Requested Procedure Code Sequence (0018,9907) Map:DICOM = TID 1500 MeasurementReport > Qualitative Evaluations > (unconstrained name/value pair) Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Finding Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Finding Map:DICOM = TID 1500 MeasurementReport > DCID 7021 Measurement Report Document Titles Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 300 Measurement > \$Measurement parameter Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 1410</p>

Attribute	Notes	Constraints and Tags
		<p>PlanarROIMeasurements > Measurement Group > Finding Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component4/timePointEventDefinition.code</p> <p>Map:HCTv1.0 = CDE 2797534:Diagnosis.Specify the clinical sign, symptom or evaluation used to diagnose liver toxicity:</p> <p>Map:HCTv1.0 = CDE 2749868:Lab Results.For the antiphospholipid syndrome, what was the laboratory procedure type?</p> <p>Map:HCTv1.0 = CDE 2980360:Therapies.What type of surgical procedure was performed?</p> <p>Map:HCTv1.0 = CDE 2426129:Therapies.Other, specify - chem</p> <p>Map:HCTv1.0 = CDE 2969578:Lab Results.Specify tumor marker laboratory procedure performed:</p> <p>Map:HCTv1.0 = CDE 2875714:Therapies.Classify the preparative regimen:</p> <p>Map:HCTv1.0 = CDE 2403909:Therapies.Other, specify - rad</p> <p>Map:HCTv1.0 = CDE 2749880:Lab Results.For the polyarteritis nodosa, classical or microscopic, what was the laboratory procedure type?</p> <p>Map:HCTv1.0 = CDE 3087995:Therapies.Specify the other systemic and or intrathecal therapy administered:</p> <p>Map:HCTv1.0 = CDE 2769598:Adverse Events.What is the most likely cause of the adverse event?</p> <p>Map:HCTv1.0 = CDE 2738393:Chronic Myelogenous Leukemia (CML): Part 1 of 2.Specify the other type of therapy that the recipient received prior to this hematopoietic stem cell transplantation (HSCT):</p> <p>Map:HCTv1.0 = CDE 3061476:Therapies.Specify other treatment:</p> <p>Map:HCTv1.0 = CDE 2953828:Therapies.Specify the other immune therapy</p> <p>Map:HCTv1.0 = CDE 2980753:Therapies.Specify the treatment given:</p> <p>Map:HCTv1.0 = CDE 2630451:Procedures.Specify test and method for test performed on other infectious disease marker:</p> <p>Map:HCTv1.0 = CDE</p>

Attribute	Notes	Constraints and Tags
		<p>2797522:Therapies.Specify the treatment received for VOD: Map:HCTv1.0 = CDE 2756917:Lab Results.Type of immunologic laboratory procedure performed: Map:HCTv1.0 = CDE 2934613:Organism.Select the infection organism: Map:HCTv1.0 = CDE 2770346:Procedures.Specify the other diagnostic procedure: Map:HCTv1.0 = CDE 2749841:Lab Results.For the systemic sclerosis, what was the laboratory procedure type? Map:HCTv1.0 = CDE 2978238:Surgery.Specify other surgical procedure Map:HCTv1.0 = CDE 2793799:Diagnosis.Diagnosis of chronic GVHD was based on: Map:HCTv1.0 = CDE 2772167:Therapies.Specify the other growth factor treatment that the donor received to enhance the product collection: Map:HCTv1.0 = CDE 2705093:Lab Results.Specify person and typing: Map:HCTv1.0 = CDE 3102448:Therapies.Specify the other systemic therapy administered: Map:HCTv1.0 = CDE 2934733:Organism.Specify the infection organism: Map:HCTv1.0 = CDE 2787410:Therapy Results.What is the follow-up timepoint of this form? Map:HCTv1.0 = CDE 2762041:Therapies.Specify other central nervous system type of treatment given: Map:HCTv1.0 = CDE 2744936:Techniques.Other manipulation specify: Map:HCTv1.0 = CDE 2737666:Chronic Myelogenous Leukemia (CML): Part 1 of 2.What type of treatment did the recipient receive prior to the hematopoietic stem cell transplantation (HSCT)? Map:HCTv1.0 = CDE 2936192:Lab Results.Specify the type of test used for BCR/ABL or other molecular markers: Map:HCTv1.0 = CDE 2980366:Therapies.Specify the surgical procedure performed: Map:HCTv1.0 = CDE 2769634:Adverse Events.Specify other most likely cause of the adverse event:</p>

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2705055:Lab Results.Please specify the person for whom this typing is being done:</p> <p>Map:HCTv1.0 = CDE 2936196:Lab Results.Specify other BCR/ABL or other molecular testing performed:</p> <p>Map:HCTv1.0 = CDE 2729156:Lab Results.What is the hematopoietic stem cell graft timepoint type at laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 2682940:Lab Results.For the systemic lupus erythematosus, specify the other antibody:</p> <p>Map:HCTv1.0 = CDE 2963496:Lab Results.Specify the bone marrow procedure performed:</p> <p>Map:HCTv1.0 = CDE 2749874:Lab Results.For the wegener granulomatosis, what was the laboratory procedure type?</p> <p>Map:HCTv1.0 = CDE 2932822:Therapies.Which treatment(s) were used?</p> <p>Map:HCTv1.0 = CDE 2738487:Therapies.What was the type of post-hematopoietic stem cell transplantation (HSCT) therapy?</p> <p>Map:HCTv1.0 = CDE 2467549:Therapies.Type of Procedure</p> <p>Map:HCTv1.0 = CDE 2932826:Therapies.Specify treatment:</p> <p>Map:HCTv1.0 = CDE 2673840:Therapies.Specify the other planned post-HSCT therapy:</p> <p>Map:HCTv1.0 = CDE 2963613:Procedures.What type of excisional biopsy/surgical procedure was performed?</p> <p>Map:HCTv1.0 = CDE 2761989:Therapies.Specify treatment(s) given for central nervous system:</p> <p>Map:HCTv1.0 = CDE 65292 -:Therapies.Therapy type other specify</p> <p>Map:HCTv1.0 = CDE 2762109:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify other organism :</p> <p>Map:HCTv1.0 = CDE 2769592:Procedures.What is the reserved portion end point?</p> <p>Map:HCTv1.0 = CDE 2980793:Therapies.Specify the therapeutic procedure administered:</p> <p>Map:HCTv1.0 = CDE 2773880:Therapies.Specify other treatment that the donor received to enhance the product collection:</p> <p>Map:HCTv1.0 = CDE 2801066:Diagnosis.Specify the</p>

Attribute	Notes	Constraints and Tags
		<p>diagnosis of liver toxicity by the type of clinical signs, symptoms or evaluation:</p> <p>Map:HCTv1.0 = CDE 3108801:Therapies.Specify other reserved portion end point</p> <p>Map:HCTv1.0 = CDE 2201768:Medical Imaging.Type of imaging</p> <p>Map:ICSRr2 = ProductEvent.code (in R_Product)</p> <p>Map:ICSRr2 = ProductDefectAssessment.code (in IndividualCaseSafetyReport)</p> <p>Map:ICSRr2 = CausalityAssessment.code (in IndividualCaseSafetyReport)</p> <p>Map:ICSRr2 = TransportationEvent.code (in R_Product)</p> <p>Map:LabViewer2.2 = LaboratoryTestIdentifier.codeSystem Name</p> <p>Map:LabViewer2.2 = LaboratoryTestIdentifier.displayName</p> <p>Map:LabViewer2.2 = LaboratoryTestIdentifier.codeSystem Version</p> <p>Map:LabViewer2.2 = LaboratoryTestIdentifier.code</p> <p>Map:LabViewer2.2 = LaboratoryTestIdentifier.codeSystem</p> <p>Map:LabViewer2.2 = SubjectAssignment.type</p> <p>Map:LSDAMv2.2.3Plus = DefinedSpecimenCheckInCheckOut.storageStatus</p> <p>Map:LSDAMv2.2.3Plus = PerformedSpecimenCheckInCheckOut.storageStatus</p> <p>Map:LSDAMv2.2.3Plus = PerformedSpecimenReviewResult.nameCode</p> <p>Map:LSDAMv2.2.3Plus = DefinedActivity.nameCode</p> <p>Map:NCI CRF Standard = CDE 2847352v1.0: Disease Staging Timepoint Name</p> <p>Map:NCI CRF Standard = CDE 2179892v1.0: Adverse Event Cancer Treatment Related Type</p> <p>Map:NCI CRF Standard = CDE 3608v4.0: Study Stratification Text</p> <p>Map:NCI CRF Standard = CDE 3437657v1.0: Concomitant Medication Form Data Collection Use Reason</p> <p>Map:NCI CRF Standard = CDE 2201348v1.0: Adverse Event Suspected Other Attribution Text Name</p>

Attribute	Notes	Constraints and Tags
		Map:NCI CRF Standard = CDE 2435042v1.2: Protocol Deviation Action Text Map:NCI CRF Standard = CDE 2003746v5.0: Laboratory Finding Test Name Map:PGx v1.0 = BS.BSTEST Map:PGx v1.0 = BE.BETERM Map:PGx v1.0 = BS.BTESTCD Map:PGx v1.0 = PG.PGTESTCD Map:PGx v1.0 = PG.PGTEST Map:PGx v1.0 = PF.PFTESTCD Map:PGx v1.0 = PF.PFTEST Map:PGx v1.0 = BE.BEDECOD Map:PSC = Activity.name Map:PSCv2.6 = Source.name Map:PSCv2.6 = Activity.code Map:PSCv2.6 = Activity.name Map:SDTM IGv3.1.1 = QS.QSTEST Map:SDTM IGv3.1.1 = SC.SCTEST Map:SDTM IGv3.1.1 = VS.VTESTCD Map:SDTM IGv3.1.1 = TI.TITEST Map:SDTM IGv3.1.1 = VS.VTEST Map:SDTM IGv3.1.1 = SE.ETCD Map:SDTM IGv3.1.1 = PE.PTESTCD Map:SDTM IGv3.1.1 = EG.EGTESTCD Map:SDTM IGv3.1.1 = PE.PTEST Map:SDTM IGv3.1.1 = IE.IETEST Map:SDTM IGv3.1.1 = EX.EXTPTREF Map:SDTM IGv3.1.1 = EG.EGTEST Map:SDTM IGv3.1.1 = IE.IETESTCD Map:SDTM IGv3.1.1 = QS.QSTESTCD Map:SDTM IGv3.1.1 = AE.AEACNOTH Map:SDTM IGv3.1.1 = DS.DSTERM Map:SDTM IGv3.1.1 = AE.AEACN Map:SDTM IGv3.1.1 = SC.SCTESTCD Map:SDTM IGv3.1.1 = DA.DATESTCD Map:SDTM IGv3.1.1 = LB.LBTESTCD Map:SDTM IGv3.1.1 = LB.LBTEST Map:SDTM IGv3.1.1 = DA.DATEST Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=RANDSTR Map:SDTM IGv3.1.2 = SC.SCTEST Map:SDTM IGv3.1.2 = VS.VSTPTREF Map:SDTM IGv3.1.2 = PE.PTESTCD Map:SDTM IGv3.1.2 = VS.VTESTCD Map:SDTM IGv3.1.2 = MS.MTESTCD Map:SDTM IGv3.1.2 = TE.ETCD

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = PC.PCTEST Map:SDTM IGv3.1.2 = QS.QSTTESTCD Map:SDTM IGv3.1.2 = DA.DATESTCD Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=RANDSTR Map:SDTM IGv3.1.2 = MS.MSTEST Map:SDTM IGv3.1.2 = CE.CEOCUR Map:SDTM IGv3.1.2 = AE.AEACNOTH Map:SDTM IGv3.1.2 = MB.MBTPTREF Map:SDTM IGv3.1.2 = PE.PETEST Map:SDTM IGv3.1.2 = IE.IETESTCD Map:SDTM IGv3.1.2 = TI.IETEST Map:SDTM IGv3.1.2 = EG.EGTEST Map:SDTM IGv3.1.2 = MS.MSLOINC Map:SDTM IGv3.1.2 = PC.PCTPTREF Map:SDTM IGv3.1.2 = TS.TSPARMCD where TSPARMCD=CURTRT Map:SDTM IGv3.1.2 = MS.MSTPTREF Map:SDTM IGv3.1.2 = EG.EGTPTREF Map:SDTM IGv3.1.2 = QS.QSTTEST Map:SDTM IGv3.1.2 = DA.DATEST Map:SDTM IGv3.1.2 = FA.FATESTCD Map:SDTM IGv3.1.2 = SE.ETCD Map:SDTM IGv3.1.2 = EX.EXTPTRREF Map:SDTM IGv3.1.2 = PP.PPTESTCD Map:SDTM IGv3.1.2 = VS.VSTEST Map:SDTM IGv3.1.2 = TA.ETCD Map:SDTM IGv3.1.2 = EG.EGTESTCD Map:SDTM IGv3.1.2 = PC.PCTESTCD Map:SDTM IGv3.1.2 = FA.FATEST Map:SDTM IGv3.1.2 = IE.IETEST Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=CURTRT Map:SDTM IGv3.1.2 = LB.LBTESTCD Map:SDTM IGv3.1.2 = MB.MBTEST Map:SDTM IGv3.1.2 = AE.AEACN Map:SDTM IGv3.1.2 = SE.SEUPDES Map:SDTM IGv3.1.2 = QS.QSTPTRREF Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=CURTRT Map:SDTM IGv3.1.2 = LB.LBTEST Map:SDTM IGv3.1.2 = LB.LBTPTRREF Map:SDTM IGv3.1.2 =

Attribute	Notes	Constraints and Tags
		<p>TS.TSPARMCD where TSPARMCD=RANDSTR Map:SDTM IGv3.1.2 = TI.IETESTCD Map:SDTM IGv3.1.2 = PP.PPTEST Map:SDTM IGv3.1.2 = MB.MBLOINC Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=AGEMIN Map:SDTM IGv3.1.2 = LB.LBLOINC Map:SDTM IGv3.1.2 = SC.SCTESTCD Map:SDTM IGv3.1.2 = AE.AECONTRT Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "STRATFCT" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "STRATFCT" Map:SDTM IGv3.1.3 = TR.TRTESTCD Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TR.TRTEST Map:SDTM IGv3.1.3 = TI.IETESTCD Map:SDTM IGv3.1.3 = TI.IETEST Map:SDTM IGv3.1.3 = TE.ETCD Map:SDTM IGv3.1.3 = TE.ELEMENT Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "STRATFCT" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "STRATFCT" Map:SDTM IGv3.1.3 = TS.TSPARM WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSPARMCD WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSPARMCD WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TU.TUTESTCD Map:SDTM IGv3.1.3 = VS.VSTESTCD Map:SDTM IGv3.1.3 = TU.TUTEST Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "CURRT" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "CURRT" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "CURRT" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "CURRT" </p>

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "CURTRT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "STRATFCT" Map:SDTM IGv3.1.3 = TS.TSPARMCD WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSPARM WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVCDCREF WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = TS.TSPARMCD WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = VS.VSTEST Map:SDTM IGv3.1.3 = TS.TSPARM WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSPARM WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "ADDON" Map:SDTM IGv3.1.3 = EG.EGTEST Map:SDTM IGv3.1.3 = MS.MSTESTCD Map:SDTM IGv3.1.3 = MB.MBLOINC Map:SDTM IGv3.1.3 = LB.LBTESTCD Map:SDTM IGv3.1.3 = LB.LBTEST Map:SDTM IGv3.1.3 = LB.LBLOINC Map:SDTM IGv3.1.3 = IE.IETESTCD Map:SDTM IGv3.1.3 = IE.IETEST Map:SDTM IGv3.1.3 = FA.FATESTCD Map:SDTM IGv3.1.3 = MB.MBTESTCD Map:SDTM IGv3.1.3 = EG.EGTESTCD Map:SDTM IGv3.1.3 = MH.MHDECOD Map:SDTM IGv3.1.3 = DS.DSTERM Map:SDTM IGv3.1.3 = DS.DSDECOD Map:SDTM IGv3.1.3 = DA.DATESTCD Map:SDTM IGv3.1.3 = DA.DATEST Map:SDTM IGv3.1.3 = CE.CESTPTP Map:SDTM IGv3.1.3 = CE.CEENTPT Map:SDTM IGv3.1.3 = AE.AEENTPT Map:SDTM IGv3.1.3 = AE.AEACN Map:SDTM IGv3.1.3 = AE.AEACNOTH Map:SDTM IGv3.1.3 = FA.FATEST Map:SDTM IGv3.1.3 =

Attribute	Notes	Constraints and Tags
		QS.QTESTCD Map:SDTM IGv3.1.3 = TA.ELEMENT Map:SDTM IGv3.1.3 = SV.SVUPDES Map:SDTM IGv3.1.3 = SU.SUSTTPT Map:SDTM IGv3.1.3 = SU.SUENTPT Map:SDTM IGv3.1.3 = SE.SEUPDES Map:SDTM IGv3.1.3 = SE.ETCD Map:SDTM IGv3.1.3 = SC.SCTESTCD Map:SDTM IGv3.1.3 = SC.SCTEST Map:SDTM IGv3.1.3 = MB.MBTEST Map:SDTM IGv3.1.3 = RS.RSTEST Map:SDTM IGv3.1.3 = TA.ETCD Map:SDTM IGv3.1.3 = QS.QTEST Map:SDTM IGv3.1.3 = PE.PETESTCD Map:SDTM IGv3.1.3 = PE.PETEST Map:SDTM IGv3.1.3 = PC.PCTESTCD Map:SDTM IGv3.1.3 = PC.PCTEST Map:SDTM IGv3.1.3 = MS.MSTEST Map:SDTM IGv3.1.3 = MS.MSLOINC Map:SDTM IGv3.1.3 = MH.MHTERM Map:SDTM IGv3.1.3 = MH.MHENTPT Map:SDTM IGv3.1.3 = RS.RSTESTCD Map:TDM = TDMPlannedActivity.codedDescription

Attribute	Notes	Constraints and Tags
categoryCode <i>Class:</i> DefinedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a classification of activities.</p> <p>EXAMPLE(S): In the case where categoryCode = "anti-cancer treatment", the subcategoryCode may = "radiotherapy", and the nameCode may = "external beam radiotherapy".</p> <p>In Procedure, categoryCode may = "abdominal surgery".</p> <p>In AdministrativeActivity, the categoryCode may = "Disposition" (off study, epoch completion), "Milestone" (informed consent, enrollment, registry, randomization) or "Other" (unblinding) activities.</p> <p>For lab procedures, categoryCode may = "hematology", "urinalysis", or "chemistry".</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the categoryCode should be derivable from the subcategoryCode, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p> <p>When value sets are defined for this attribute, we may need to move it to the DefinedActivity subclasses so that the different value domains can be bound to the correct subclass.</p>	Map:CDASHv1.1 = SU.SUCAT Map:CDASHv1.1 = DA.DACAT Map:CDASHv1.1 = IE.IECAT Map:CDASHv1.1 = LB.LBCAT Map:CDASHv1.1 = MH.MHCAT Map:CTOM = SpecimenAcquisition.type Map:CTOM = SubstanceAdministration.type Map:CTOM = Radiation.type Map:CTOM = Activity.type Map:CTOM = Imaging.type Map:CTOM = Procedure.type Map:CTOM = SubstanceAdministration.name Map:CTRPv1.0 = PlannedObservation.categoryCode Map:CTRPv1.0 = PlannedActivity.categoryCode Map:CTRPv1.0 = InterventionalStudyProtocol.interventionTypeCode Map:CTRPv1.0 = Activity.categoryCode Map:CTRPv1.0 = SubstanceAdministration.categoryCode Map:CTRPv1.0 = PlannedEligibilityCriterion.categoryCode Map:CTRPv3.8 = Activity.categoryCode Map:CTRv1.0 = DefinedActivity.categoryCode Map:DICOM = TID 1502 TimePointContext > Time Point Type Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Act.code Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.code Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.code Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Encounter.code Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Observation.code Map:Lab = Activity.typeModifier Map:Lab = SubjectAssignment.type Map:LabViewer2.2 = Activity.type Map:LSDAMv2.2.3Plus = DefinedActivity.categoryCode Map:PGx v1.0 = BS.BSCAT Map:PGx v1.0 = PG.PGCAT Map:PGx v1.0 = PF.PFCAT Map:PGx v1.0 = BE.BECAT Map:PSC = ActivityType.name Map:PSCv2.6 = ActivityType.name

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.1 = EX.EXCAT Map:SDTM IGv3.1.1 = TI.IECAT Map:SDTM IGv3.1.1 = IE.IECAT Map:SDTM IGv3.1.1 = CM.CMCAT Map:SDTM IGv3.1.1 = QS.QSCAT Map:SDTM IGv3.1.1 = DA.DACAT Map:SDTM IGv3.1.1 = MH.MHCAT Map:SDTM IGv3.1.1 = VS.VSCAT Map:SDTM IGv3.1.1 = SU.SUCAT Map:SDTM IGv3.1.1 = EG.EGCAT Map:SDTM IGv3.1.1 = SC.SCCAT Map:SDTM IGv3.1.1 = PE.PECAT Map:SDTM IGv3.1.1 = LB.LBCAT Map:SDTM IGv3.1.1 = DS.DSCAT Map:SDTM IGv3.1.2 = TI.IECAT Map:SDTM IGv3.1.2 = CE.CECAT Map:SDTM IGv3.1.2 = DA.DACAT Map:SDTM IGv3.1.2 = EG.EGCAT Map:SDTM IGv3.1.2 = PE.PECAT Map:SDTM IGv3.1.2 = MS.MSCAT Map:SDTM IGv3.1.2 = FA.FACAT Map:SDTM IGv3.1.2 = PC.PCCAT Map:SDTM IGv3.1.2 = MH.MHCAT Map:SDTM IGv3.1.2 = SC.SCCAT Map:SDTM IGv3.1.2 = LB.LBCAT Map:SDTM IGv3.1.2 = QS.QSCAT Map:SDTM IGv3.1.2 = EX.EXCAT Map:SDTM IGv3.1.2 = VS.VSCAT Map:SDTM IGv3.1.2 = IE.IECAT Map:SDTM IGv3.1.2 = PP.PPCAT Map:SDTM IGv3.1.2 = MB.MBCAT Map:SDTM IGv3.1.2 = CM.CMCAT Map:SDTM IGv3.1.2 = SU.SUCAT Map:SDTM IGv3.1.3 = PC.PCCAT Map:SDTM IGv3.1.3 = PE.PECAT Map:SDTM IGv3.1.3 = QS.QSCAT Map:SDTM IGv3.1.3 = RS.RSCAT Map:SDTM IGv3.1.3 = SC.SCCAT Map:SDTM IGv3.1.3 = SU.SUCAT Map:SDTM IGv3.1.3 = MS.MSCAT Map:SDTM IGv3.1.3 = VS.VSCAT Map:SDTM IGv3.1.3 = EG.EGCAT Map:SDTM IGv3.1.3 = TI.IECAT Map:SDTM IGv3.1.3 = MH.MHCAT Map:SDTM IGv3.1.3 = MB.MBCAT Map:SDTM IGv3.1.3 = LB.LBCAT Map:SDTM IGv3.1.3 = IE.IECAT Map:SDTM IGv3.1.3 = EX.EXCAT Map:SDTM IGv3.1.3 = DS.DSCAT Map:SDTM IGv3.1.3 = DA.DACAT Map:SDTM IGv3.1.3 = CM.CMCAT Map:SDTM IGv3.1.3 = CE.CECAT Map:SDTM IGv3.1.3 = FA.FACAT

Attribute	Notes	Constraints and Tags
subcategoryCode <i>Class:</i> DefinedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a subdivision within a larger category of activities.</p> <p>EXAMPLE(S): chemotherapy, radiotherapy, hormonal therapy, alternative therapy</p> <p>In the case where categoryCode = "anti-cancer treatment", subcategoryCode may = "radiotherapy", and nameCode may = "external beam radiotherapy".</p> <p>If categoryCode = "Intervention", subcategoryCode may = "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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the categoryCode should be derivable from the subcategoryCode, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p>	Map:CDASHv1.1 = LB.LBSCAT Map:CDASHv1.1 = MH.MHSCAT Map:CDASHv1.1 = DA.DASCAT Map:CTOM = Surgery.type Map:CTR&Rr2 = Specific paediatric formulation Map:CTRPv1.0 = PlannedActivity.subcategoryCode Map:CTRPv1.0 = Activity.subcategoryCode Map:CTRPv1.0 = SubstanceAdministration.subcategoryCode Map:CTRPv1.0 = PlannedEligibilityCriterion.subcategoryCode Map:CTRPv1.0 = PlannedObservation.subcategoryCode Map:CTRPv3.8 = Activity.subcategoryCode Map:CTRv1.0 = DefinedActivity.subcategoryCode Map:Lab = Activity.typeModifier Map:PGx v1.0 = PG.PGSCAT Map:PGx v1.0 = BS.BSSCAT Map:PGx v1.0 = PF.PFSCAT Map:PGx v1.0 = BE.BESCAT Map:SDTM IGv3.1.1 = MH.MHSCAT Map:SDTM IGv3.1.1 = LB.LBSCAT Map:SDTM IGv3.1.1 = DA.DASCAT Map:SDTM IGv3.1.1 = SU.SUSCAT Map:SDTM IGv3.1.1 = SC.SCSCAT Map:SDTM IGv3.1.1 = EX.EXSCAT Map:SDTM IGv3.1.1 = IE.IESCAT Map:SDTM IGv3.1.1 = VS.VSSCAT Map:SDTM IGv3.1.1 = QS.QSSCAT Map:SDTM IGv3.1.1 = DS.DSSCAT Map:SDTM IGv3.1.1 = EG.EGSCAT Map:SDTM IGv3.1.1 = CM.CMSCAT Map:SDTM IGv3.1.1 = PE.PESCAT Map:SDTM IGv3.1.2 = SC.SCSCAT Map:SDTM IGv3.1.2 = PP.PPSCAT Map:SDTM IGv3.1.2 = CM.CMSCAT Map:SDTM IGv3.1.2 = PE.PESCAT Map:SDTM IGv3.1.2 = QS.QSSCAT Map:SDTM IGv3.1.2 = MH.MHSCAT Map:SDTM IGv3.1.2 = MS.MSSCAT Map:SDTM IGv3.1.2 = VS.VSSCAT Map:SDTM IGv3.1.2 = DS.DSSCAT Map:SDTM IGv3.1.2 = EG.EGSCAT Map:SDTM IGv3.1.2 = MB.MBSCAT Map:SDTM IGv3.1.2 = SU.SUSCAT Map:SDTM IGv3.1.2 = EX.EXSCAT Map:SDTM IGv3.1.2 = DS.DSCAT Map:SDTM IGv3.1.2 = DA.DASCAT Map:SDTM IGv3.1.2 = CE.CESCAT Map:SDTM IGv3.1.2 = FA.FASCAT Map:SDTM IGv3.1.2 = PC.PCSCAT Map:SDTM IGv3.1.2 = IE.IESCAT

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = TI.IESCAT Map:SDTM IGv3.1.2 = LB.LBSCAT Map:SDTM IGv3.1.3 = MS.MSSCAT Map:SDTM IGv3.1.3 = PC.PCSCAT Map:SDTM IGv3.1.3 = PE.PESCAT Map:SDTM IGv3.1.3 = QS.QSSCAT Map:SDTM IGv3.1.3 = MH.MHSCAT Map:SDTM IGv3.1.3 = SU.SUSCAT Map:SDTM IGv3.1.3 = EG.EGSCAT Map:SDTM IGv3.1.3 = TI.IESCAT Map:SDTM IGv3.1.3 = SC.SCSCAT Map:SDTM IGv3.1.3 = MB.MBSCAT Map:SDTM IGv3.1.3 = LB.LBSCAT Map:SDTM IGv3.1.3 = IE.IESCAT Map:SDTM IGv3.1.3 = EX.EXSCAT Map:SDTM IGv3.1.3 = DS.DSSCAT Map:SDTM IGv3.1.3 = DA.DASCAT Map:SDTM IGv3.1.3 = CM.CMSCAT Map:SDTM IGv3.1.3 = CE.CESCAT Map:SDTM IGv3.1.3 = VS.VSSCAT Map:SDTM IGv3.1.3 = FA.FASCAT
repeatFrequencyCode <i>Class:</i> DefinedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the number of occurrences of an activity within a given time period.</p> <p>EXAMPLE(S): BID = Two times per day, at unspecified times (does not necessarily imply that these are 12 hours apart)</p> <p>Q12H = Every twelve hours</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = PlannedNotification.frequency Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRv1.0 = DefinedActivity.repeatFrequencyCode Map:TDM = CyclingRule
repeatFrequencyRatio <i>Class:</i> DefinedActivity <i>Datatype:</i> RTO<INT.NONNEG,PQ.TI ME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A ratio representing the number of occurrences of an activity within a given time period.</p> <p>EXAMPLE(S): Once per 12 hours 2 times per day</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRv1.0 = DefinedActivity.repeatFrequencyRatio Map:TDM = CyclingRule

Attribute	Notes	Constraints and Tags
repeatQuantityRange <i>Class:</i> DefinedActivity <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many times the activity occurs.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the frequency is more than once a day, this is still interpreted per time, e.g. BID for 5 days = 10 repeats.</p>	Map:CTR&Rr2 = Maximum dose Total Dose Number Map:CTR&Rr2 = First dose in FIH Total Dose Number Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:TDM = CyclingRule.repeatCount
repeatDuration <i>Class:</i> DefinedActivity <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time over which the activity is repeated.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from repeatQuantity and repeatFrequencyCode or repeatFrequencyRatio (constraint allows only one). 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 for a domain analysis model.</p>	Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRv1.0 = DefinedActivity.repeatDuration Map:TDM = CyclingRule

Attribute	Notes	Constraints and Tags
description <i>Class:</i> DefinedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This may contain more detail than the description present in the text part of a coded concept.</p>	Map:AE = ProductInvestigation.description Map:BRIDGv2.2 = ExperimentalUnitAllocationMethod.description Map:caAERSv2.2 = SurgeryIntervention.description Map:caAERSv2.2 = TreatmentInformation.treatmentDescription Map:caAERSv2.2 = RadiationIntervention.description Map:caAERSv2.2 = TreatmentAssignment.description Map:CTOM = Imaging.descriptionText Map:CTOM = Surgery.descriptionText Map:CTOM = SpecimenAcquisition.descriptionText Map:CTOM = Activity.descriptionText Map:CTOM = Procedure.descriptionText Map:CTOM = Radiation.descriptionText Map:CTOM = Histopathology.reportDescriptiveText Map:CTRPv1.0 = SubstanceAdministration.textDescription Map:CTRPv1.0 = Activity.textDescription Map:CTRPv1.0 = PlannedActivity.textDescription Map:CTRPv1.0 = PlannedObservation.textDescription Map:CTRPv1.0 = PlannedEligibilityCriterion.textDescription Map:CTRPv3.8 = Intervention.descriptionText Map:CTRR3 = DefinedActivity.description Map:CTRv1.0 = DefinedActivity.description Map:DICOM = Performed CT Acquisition Module - Acquisition Protocol Element Sequence (0018,9920) > Requested Series Description (0018,9937) Map:DICOM = Performed CT Reconstruction Module - Reconstruction Protocol Element Sequence (0018,9934) > Requested Series Description (0018,9937) Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Observation.text Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Act.text

Attribute	Notes	Constraints and Tags
		Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Encounter.text Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.text Map:FDA HL7 SD SD DSTU2012 = StudyProtocol//plannedStudy/precondition/eligibilityCriterion.text Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.text Map:HL7SD = EligibilityCriterion.text Map:ICSRr2 = TransportationEvent.text (in R_Product) Map:ICSRr2 = ProductEvent.text (in R_Product) Map:Lab = LabTest.additionalTestDescription Map:LabViewer2.2 = LaboratoryTest.additionalDescription Map:LSDAMv2.2.3Plus = DefinedActivity.description Map:PGx v1.0 = Pf.PFTSTDTL Map:PSC = Activity.description Map:PSCv2.6 = Activity.description Map:PSCv2.6 = ScheduledActivity.details Map:SDTM IGv3.1.1 = SE.ELEMENT Map:SDTM IGv3.1.1 = SV.SVUPDES Map:SDTM IGv3.1.2 = SV.SVUPDES Map:SDTM IGv3.1.2 = TE.ELEMENT Map:SDTM IGv3.1.2 = SE.ELEMENT Map:SDTM IGv3.1.2 = TA.ELEMENT Map:TDM = TDMPlannedActivity.description
statusCode <i>Class:</i> DefinedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the activity as part of a global library.</p> <p>EXAMPLE(S): Draft New, Released, Retired Archived</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Defined Activity Status state transition diagram for further details.</p>	Map:CTRPv1.0 = PlannedActivity.statusCode Map:CTRPv1.0 = PlannedObservation.statusCode Map:CTRPv1.0 = PlannedEligibilityCriterion.statusCode Map:CTRv1.0 = DefinedActivity.statusCode Map:FDA HL7 SD SD DSTU2012 = StudyProtocol//plannedStudy/precondition/eligibilityCriterion.statusCode Map:LSDAMv2.2.3Plus = DefinedActivity.statusCode

Attribute	Notes	Constraints and Tags
statusDate <i>Class:</i> DefinedActivity <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the status is assigned to the activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = PlannedEligibilityCriterion.statusDateRange Map:CTRPv1.0 = PlannedActivity.statusDateRange Map:CTRPv1.0 = PlannedObservation.statusDateRange Map:CTRv1.0 = DefinedActivity.statusDate Map:LSDAMv2.2.3Plus = DefinedActivity.statusDate

Class: DefinedAdministrativeActivity

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that is not directly related to hypothesis evaluation or testing, but is typically essential to the efficient and/or effective coordination and execution of a study or experiment.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = DefinedAdministrativeActivity
- Map:LSDAMv2.2.3Plus = DefinedAdministrativeActivity

Connectors

Source	Connector	Target	Notes
DefinedAdministrativeActivity	specializes	DefinedActivity	<p>DESCRIPTION: Each DefinedAdministrativeActivity always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedMaterialStorage	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedSpecimenStorage always specializes one DefinedAdministrativeActivity. Each</p>

Source	Connector	Target	Notes
			DefinedAdministrativeActivity might be specialized by one DefinedSpecimenStorage. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedSpecimenMove	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedSpecimenMove always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedSpecimenMove. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedProgressCount	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedProgressCount always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedProgressCount. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedStudyAgentTransfer	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedStudyAgentTransfer always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedStudyAgentTransfer . DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedNotification	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedNotification always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedNotification. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedStudySubjectMilestone	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedStudySubjectMilestone always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedStudySubjectMilestone. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedStudyAdministrativeActivity	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedStudyAdministrativeActivity always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedStudyAdministrativeActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
			NOTE(S):
DefinedExperimentalUnitAI location	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedExperimentalUnitAI location always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedExperimentalUnitAI location.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedAdverseEvent

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

death, back pain, headache, pulmonary embolism, heart attack

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = DefinedAdverseEvent
- Map:SDTM IGv3.1.2 = AE.AEOCCUR

Connectors

Source	Connector	Target	Notes
DefinedAdverseEvent	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedAdverseEvent always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedAdverseEvent.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
severityCode <i>Class:</i> DefinedAdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the intensity of the event.</p> <p>EXAMPLE(S): Moderate could be used to describe acne.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = DefinedAdverseEvent.severityCode Map:SDTM IGv3.1.2 = AE.AESEV
categoryCode <i>Class:</i> DefinedAdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a classification of the adverse event.</p> <p>EXAMPLE(S): bleeding, hypoglycemia</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p>	Map:CTRv1.0 = DefinedAdverseEvent.categoryCode Map:SDTM IGv3.1.2 = AE.AECAT
subcategoryCode <i>Class:</i> DefinedAdverseEvent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a subdivision within a larger category of an adverse event.</p> <p>EXAMPLE(S): neurologic</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Theoretically speaking, the category should be derivable from the subcategory, however if there may only be a category and not a subcategory, then both attributes must be present in the model.</p>	Map:CTRv1.0 = DefinedAdverseEvent.subcategoryCode Map:SDTM IGv3.1.2 = AE.AESCAT

Class: DefinedCompositionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedCompositionRelationship
- Map:ICSRr2 = Component (in R_Product)
- Map:LSDAMv2.2.3Plus = DefinedCompositionRelationship
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
DefinedCompositionRelationship 0..* compositeDefinedCompositionRelationship	is the parent of	DefinedActivity 1 compositeDefinedActivity	<p>DESCRIPTION: Each DefinedCompositionRelationship always is the parent of one DefinedActivity. Each DefinedActivity might be the component of one or more DefinedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCompositionRelationship 0..* componentDefinedCompositionRelationship	is the component of	DefinedActivity 1 compositeDefinedActivity	<p>DESCRIPTION: Each DefinedCompositionRelationship always is the component of one DefinedActivity. Each DefinedActivity might be the parent of one or more DefinedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
sequenceNumber <i>Class:</i> DefinedCompositionRelationship <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): From DICOM: Protocol Element Number (0018,9921)</p> <p>NOTE(S): In a course of treatment (a composite activity) that is composed of a chemotherapy activity and a radiotherapy activity, the sequence number indicates which component activity precedes the other.</p>	Map:C3PR = EligibilityCriterion.questionNumber Map:C3PRv2.9 = EligibilityCriteria.questionNumber Map:CTOM = ActivityRelationship.sequenceNumber Map:CTRv1.0 = DefinedCompositionRelationship.sequenceNumber Map:CTRv1.0 = PerformedEligibilityCriterion.displayOrder Map:DICOM = TID 1502 TimePointContext > Time Point Order Map:DICOM = Performed CT Acquisition Module - Protocol Element Identification Macro > Acquisition Protocol Element Sequence (0018,9920) > Protocol Element Number (0018,9921) Map:DICOM = Performed CT Reconstruction Module - Protocol Element Identification Macro > Reconstruction Protocol Element Sequence (0018,9934) > Protocol Element Number (0018,9921) Map:DICOM = CT Performed Acquisition Technique Module - Acquisition Element Sequence > Element Number Map:LSDAMv2.2.3Plus = DefinedCompositionRelationship.sequenceNumber

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> DefinedCompositionRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A visit is composed of 3 activities: a physical exam at the beginning <u>of the visit</u>, a drug administration 30 minutes <u>into the visit</u>, and a blood test 2 hours <u>into the visit</u> – the pauseQuantityRange for the physical exam is 0 minutes, 30 minutes for the drug administration and 2 hours for the blood test</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed Map:LSDAMv2.2.3Plus = DefinedCompositionRelationship.pauseQuantity Map:TDMv2 = (New content)
joinCode <i>Class:</i> DefinedCompositionRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether, and how, a specific activity in a set of parallel activities should come together before subsequent activities can begin.</p> <p>EXAMPLE(S): Wait for this activity to complete before the subsequent activity; Terminate this activity as soon as all parallel "wait" activities are completed (and if this activity hasn't started yet, don't start it at all); Continue this activity after all "wait" activities complete, but don't wait for it to complete before beginning subsequent activities.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = DefinedCompositionRelationship.joinCode

Class: DefinedContingentOnRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between an activity and some criteria to determine if the activity should occur where all activities are part of the global library of activities.

EXAMPLE(S):

Only perform a certain lab test if drug X was administered. (target = another activity)

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)

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))".

OTHER NAME(S):**NOTE(S):**

The criteria to evaluate the relationship could be one of the following:

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

To evaluate whether the contingency was satisfied, the simple existence of a PerformedActivity (or subclass) related to the DefinedActivity (or subclass) is not enough by itself. The PerformedActivity.statusCode and PerformedActivity.negativeIndicator must also be checked to ensure that the activity was actually performed. PerformedActivity.statusCode must be "Completed" and PerformedActivity.negativeIndicator must not be "true".

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedContingentOnRelationship
- Map:HL7SD = EligibilityCriterion.Precondition2
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
DefinedContingentOnRelationship 0..*	is a condition for	DefinedActivity 1 contingentDefinedActivity	<p>DESCRIPTION: Each DefinedContingentOnRelationship always is a condition for one DefinedActivity. Each DefinedActivity might be contingent upon one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..*	be contingent upon	DefinedCriterionGroup 0..1 prerequisiteDefinedCriterionGroup	<p>DESCRIPTION: Each DefinedContingentOnRelationship might be contingent upon one DefinedCriterionGroup.</p>

Source	Connector	Target	Notes
			<p>Each DefinedCriterionGroup might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..* contingentDefinedContingentOnRelationship	be contingent upon	DefinedActivity 0..1 prerequisiteDefinedActivity	<p>DESCRIPTION: Each DefinedContingentOnRelationship might be contingent upon one DefinedActivity. Each DefinedActivity might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..* contingentDefinedContingentOnRelationship	be contingent upon	DefinedObservationResult 0..1 prerequisiteDefinedObservationResult	<p>DESCRIPTION: Each DefinedContingentOnRelationship might be contingent upon one DefinedObservationResult. Each DefinedObservationResult might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> DefinedContingentOnRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S): OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:HL7SDr1 = Precondition3.priorityNumber

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> DefinedContingentOnRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): If drug X was administered, perform lab test Y 1 hour afterwards (contingency target = another activity) – the pauseQuantityRange is 1 hour (minimum and maximum bounds of the range are the same)</p> <p>Only perform a substance administration of drug X within 10 minutes if the blood pressure was over some threshold number (target = observation result from another activity that is an observation) – the pauseQuantityRange is 0-10 minutes</p> <p>Only perform a substance administration of drug Y within 10 minutes 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 (target = group of criteria, i.e. "(A and (B or C))" – the pauseQuantityRange is 0-10 minutes</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed

Attribute	Notes	Constraints and Tags
checkpointCode <i>Class:</i> DefinedContingentOnRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the points in the course of an activity when a precondition for the activity is evaluated.</p> <p>EXAMPLE(S) When the checkpointCode for a criterion of a repeatable activity is "end," the criterion is tested only at the end of each repetition of that activity. When the condition holds true, the next repetition is ready for execution.</p> <p>When the checkpointCode is "entry," the criterion is checked at the beginning of each repetition, if any, whereas "beginning" means the criterion is checked only once before the repetition "loop" starts.</p> <p>NOTE(S): The checkpointCode specifies when the precondition is to be checked; it is analogous to the various conditional statements and loop constructs in programming languages "while-do" vs. "do-while" or "repeat-until" vs. "loop-exit."</p>	Map:HL7SDr1 = Precondition3.checkpointCode
completionRequiredBeforeStartingIndicator <i>Class:</i> DefinedContingentOnRelationship <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the target activity must have completed prior to starting the source activity.</p> <p>EXAMPLE(S): OTHER NAME(S):</p> <p>NOTE(S): This attribute may only be used if the target is an activity, not if the target is an observation result or a criterion group.</p>	Map:CTRv1.0 = DefinedContingentOnRelationship.completionRequiredBeforeStartingIndicator Map:TDM = TriggeringRule

Class: DefinedCriterionGroup

Package: Protocol Representation Sub-Domain

DEFINITION:

A collection of conditions joined together via composition (ANDed) and/or optionality (ORed) to form a logical expression upon which the execution of an activity is based or upon which the cessation of a repeated activity is based, where components of the group may include other activities, observation results and/or other criterion groups, and where both the criterion group and its components are defined as part of the global library.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTRv1.0 = DefinedCriterionGroup

- Map:TDMv2 = DefinedCriterionGroup

Connectors

Source	Connector	Target	Notes
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedCriterionGroup 0..1 optionDefinedCriterionGrou p	<p>DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedCriterionGroup. Each DefinedCriterionGroup might be an option that can satisfy one or more DefinedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCom positionRelationship 0..* componentDefinedCriterion GroupCompositionRelations hip	is the component of	DefinedCriterionGroup 1 compositeDefinedCriterion Group	<p>DESCRIPTION: Each DefinedCriterionGroupCom positionRelationship always is the component of one DefinedCriterionGroup. Each DefinedCriterionGroup might be the parent of one or more DefinedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedCriterionGroup 0..1 focusingDefinedCriterionGr oup	<p>DESCRIPTION: Each DefinedObservation might have as focal context one DefinedCriterionGroup. Each DefinedCriterionGroup might be the focal context for one or more DefinedObservation.</p> <p>EXAMPLE(S): Was there a liver chemistry event for the lab samples collected at this visit?</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			<p>NOTE(S):</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCompositionRelationship 0..* compositeDefinedCriterionGroupCompositionRelationship	be the parent of	DefinedCriterionGroup 0..1 componentDefinedCriterionGroup	<p>DESCRIPTION:</p> <p>Each DefinedCriterionGroupCompositionRelationship might be the parent of one DefinedCriterionGroup.</p> <p>Each DefinedCriterionGroup might be the component of one or more DefinedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedContingentOnRelationship 0..* contingentDefinedContingentOnRelationship	be contingent upon	DefinedCriterionGroup 0..1 prerequisiteDefinedCriterionGroup	<p>DESCRIPTION:</p> <p>Each DefinedContingentOnRelationship might be contingent upon one DefinedCriterionGroup.</p> <p>Each DefinedCriterionGroup might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupOptionRelationship 0..* optionDefinedCriterionGroupOptionRelationship	is an option that can satisfy	DefinedCriterionGroup 1 choiceDefinedCriterionGroup	<p>DESCRIPTION:</p> <p>Each DefinedCriterionGroupOptionRelationship always is an option that can satisfy one DefinedCriterionGroup.</p> <p>Each DefinedCriterionGroup</p>

Source	Connector	Target	Notes
			<p>might be a choice that has as option one or more DefinedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntil Rule 0..* repeatedDefinedRepeatActi vityUntilRule	be repeated until	DefinedCriterionGroup 0..1 triggeringDefinedCriterionG roup	<p>DESCRIPTION:</p> <p>Each DefinedRepeatActivityUntil Rule might be repeated until one DefinedCriterionGroup.</p> <p>Each DefinedCriterionGroup might trigger the cessation of one or more DefinedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedCriterionGroupCompositionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedCriterionGroupCompositionRelationship
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
DefinedCriterionGroupCom positionRelationship 0..* componentDefinedCriterion GroupCompositionRelations hip	is the component of	DefinedCriterionGroup 1 compositeDefinedCriterion Group	<p>DESCRIPTION: Each DefinedCriterionGroupCom positionRelationship always is the component of one DefinedCriterionGroup. Each DefinedCriterionGroup might be the parent of one or more DefinedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCom positionRelationship 0..* compositeDefinedCriterion GroupCompositionRelations hip	be the parent of	DefinedCriterionGroup 0..1 componentDefinedCriterion Group	<p>DESCRIPTION: Each DefinedCriterionGroupCom positionRelationship might be the parent of one DefinedCriterionGroup. Each DefinedCriterionGroup might be the component of one or more DefinedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCom positionRelationship 0..* compositeDefinedCriterion GroupCompositionRelations hip	be the parent of	DefinedActivity 0..1 componentDefinedActivity	<p>DESCRIPTION: Each DefinedCriterionGroupCom positionRelationship might be the parent of one DefinedActivity. Each DefinedActivity might be the component of one or more DefinedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
DefinedCriterionGroupCom positionRelationship 0..* compositeDefinedCriterion GroupCompositionRelationship	be the parent of	DefinedObservationResult 0..1 componentDefinedObservationResult	<p>NOTE(S):</p> <p>DESCRIPTION: Each DefinedCriterionGroupCom positionRelationship might be the parent of one DefinedObservationResult. Each DefinedObservationResult might be the component of one or more DefinedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
sequenceNumber <i>Class:</i> DefinedCriterionGroupCom <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.</p> <p>EXAMPLE(S): In a criterion group that is composed of a substance administration activity and a lab test activity, the sequence number indicates which activity precedes the other.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ActivityRelationship.sequenceNumber Map:CTRv1.0 = DefinedCriterionGroupCompositionRelationship.sequenceNumber

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> DefinedCriterionGroupCom <i>positionRelationship</i> <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A battery of tests, composed of multiple routine labs that are always ordered together as a group, may be the criterion group for another activity. The tests in the battery may be staggered in time such that test 1 starts <u>right away</u> (i.e. 0 minutes after the start of the battery), test 2 starts <u>10 minutes later</u>, test 3 starts 20 minutes <u>into the battery</u>, etc. – the pauseQuantityRanges would be 0 minutes, 10 minutes and 20 minutes respectively (with minimum and maximum bounds being the same)</p> <p>A glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose – the timing of each blood sample is the pauseQuantityRange on the relationship between that blood sample collection activity and the composite glucose tolerance test (DefinedCriterionGroup).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:TDMv2 = (New content)

Attribute	Notes	Constraints and Tags
joinCode <i>Class:</i> DefinedCriterionGroupCom positionRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether, and how, a specific activity in a set of parallel activities should come together before subsequent activities can begin.</p> <p>EXAMPLE(S): Wait for this activity to complete before the subsequent activity; Terminate this activity as soon as all parallel "wait" activities are completed (and if this activity hasn't started yet, don't start it at all); Continue this activity after all "wait" activities complete, but don't wait for it to complete before beginning subsequent activities.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = DefinedCriterionGroupCompositionRelationship.joinCode

Class: DefinedCriterionGroupOptionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedCriterionGroupOptionRelationship
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedCriterionGroup 0..1 optionDefinedCriterionGrou p	<p>DESCRIPTION:</p> <p>Each</p> <p>DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedCriterionGroup.</p> <p>Each</p> <p>DefinedCriterionGroup might be an option that can satisfy one or more</p>

Source	Connector	Target	Notes
			DefinedCriterionGroupOpti onRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedActivity 0..1 optionDefinedActivity	DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedActivity. Each DefinedActivity might be an option that can satisfy one or more DefinedCriterionGroupOpti onRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedObservationResult 0..1 optionDefinedObservationR esult	DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedObservationResult. Each DefinedObservationResult might be an option that can satisfy one or more DefinedCriterionGroupOpti onRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCriterionGroupOpti onRelationship 0..* optionDefinedCriterionGrou pOptionRelationship	is an option that can satisfy	DefinedCriterionGroup 1 choiceDefinedCriterionGrou p	DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship always is an option that can satisfy one DefinedCriterionGroup. Each DefinedCriterionGroup might be a choice that has as

Source	Connector	Target	Notes
			<p>option one or more DefinedCriterionGroupOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> DefinedCriterionGroupOptionRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	<p>Map:CTRv1.0 = DefinedCriterionGroupOptionRelationship.priorityNumber</p> <p>Map:TDM = AbstractRule.isExclusive</p>

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> DefinedCriterionGroupOpti onRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A pain management criterion group may be comprised of two options, one for substance administration of drug X after waiting 24 hours and one for substance administration of drug Y after waiting 48 hours – the pauseQuantityRange on the 2 option relationships are 24 hours and 48 hours respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed

Class: DefinedDiagnosis

Package: Protocol Representation Sub-Domain

DEFINITION:

The definition of the identification of a disease or illness by examining the signs, symptoms and/or biomarkers.

EXAMPLE(S):

Adenocarcinoma

Diffusely Infiltrating Astrocytoma

OTHER NAME(S):

NOTE(S):

This class was added to the model in support of MolecularBiomarkerGroups which may indicate risk or presence of one or more diagnoses.

Tagged Values:

- Map:PGx v1.0 = PB.PBDIAG

Connectors

Source	Connector	Target	Notes
DefinedDiagnosis	specializes	DefinedObservationResult	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each DefinedDiagnosis always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularBiomarkerGroup 0..* indicatingMolecularBiomarkerGroup	indicate risk or presence of	DefinedDiagnosis 0..* indicatedDefinedDiagnosis	<p>DESCRIPTION: Each MolecularBiomarkerGroup might indicate risk or presence of one or more DefinedDiagnosis. Each DefinedDiagnosis might have risk or presence indicated by one or more MolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): The MolecularBiomarkerGroup consisting of the individual biomarker "2073A>T" indicates a decreased risk of "Diffusely Infiltrating Astrocytoma".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedEligibilityCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that 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.

EXAMPLE(S):

- At least one pathologically confirmed positive lymph node identified
- There must be no evidence of residual involved lymph node disease
- At least one lymph node must be found in the pathologic specimen
- At least 5 cm of the esophagus must be in the 60 Gy isodose volume in 1.6 to 2.0 Gy fractions

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = EligibilityCriteria.questionText
- Map:CTRr3 = DefinedEligibilityCriterion
- Map:CTRv1.0 = DefinedEligibilityCriterion
- Map:HL7SD = EligibilityCriterion

Connectors

Source	Connector	Target	Notes
DefinedEligibilityCriterion	specializes	DefinedObservation	<p>DESCRIPTION: Each DefinedEligibilityCriterion always specializes one DefinedObservation. Each DefinedObservation might be specialized by one DefinedEligibilityCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedExclusionCriterion	specializes	DefinedEligibilityCriterion	<p>DESCRIPTION: Each DefinedExclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion might be specialized by one DefinedExclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedInclusionCriterion	specializes	DefinedEligibilityCriterion	<p>DESCRIPTION: Each DefinedInclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion might be specialized by one DefinedInclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedEligibilityCriterionAnswer

Package: Protocol Representation Sub-Domain

DEFINITION:

A reusable, "template" description of an allowable response to an eligibility criterion question.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

Connectors

Source	Connector	Target	Notes
DefinedEligibilityCriterion Answer	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedEligibilityCriterion Answer always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedEligibilityCriterion Answer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedStudySubject 0..* constrainedPlannedStudySubject	be constrained by	DefinedEligibilityCriterion Answer 0..* constrainingDefinedEligibilityCriterion	<p>DESCRIPTION: Each PlannedStudySubject might be constrained by one or more DefinedEligibilityCriterion Answer. Each DefinedEligibilityCriterion Answer might constrain one or more PlannedStudySubject.</p> <p>DEFINITION: Indicates the specific criteria a particular PlannedStudySubject is expected to adhere to.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PlannedEligibilityCriterion 0..* requiringPlannedEligibilityCriterion	requires for eligibility	DefinedEligibilityCriterion Answer 1 requiredDefinedEligibilityCriterionAnswer	<p>DESCRIPTION: Each PlannedEligibilityCriterion always requires for eligibility one DefinedEligibilityCriterion Answer. Each DefinedEligibilityCriterion Answer might be required for eligibility for one or more PlannedEligibilityCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
requiredIndicator <i>Class:</i> DefinedEligibilityCriterion Answer <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this reply is necessary to include/exclude a potential subject on a study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is only intended to be used when the required answer is defined in the context of the question, regardless of in which study it is used.</p>	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = DefinedEligibilityCriterion.requiredResponse

Class: DefinedExclusionCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that identifies a characteristic or requirement intended to be applied to a potential study subject to determine whether they may not participate in a study.

EXAMPLE(S):

Must be over the age of 18.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRr3 = DefinedExclusionCriterion
- Map:CTRv1.0 = DefinedExclusionCriterion

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
DefinedExclusionCriterion	specializes	DefinedEligibilityCriterion	<p>DESCRIPTION: Each DefinedExclusionCriterion always specializes one DefinedEligibilityCriterion. Each DefinedEligibilityCriterion might be specialized by one DefinedExclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedExperimentalUnitAllocation

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level 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).

EXAMPLE(S):

randomization, direct assignment based on eligibility criteria, etc.

"Escalating dose cohort studies" enroll subjects in successive arms, i.e., one arm is completely filled before any subjects are enrolled in the next arm. In such a study, allocation depends on which arms have been fully enrolled and which are currently open for enrollment. Note that this example assumes that the experimental unit is the subject (rather than a part of a subject or a group of subjects).

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = Randomization
- Map:CTRv1.0 = DefinedExperimentalUnitAllocation

Connectors

Source	Connector	Target	Notes
DefinedExperimentalUnitAllocation	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedExperimentalUnitAllocation always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedExperimentalUnitAllocation.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> DefinedExperimentalUnitAllocation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the technique that is used for allocating experimental units.</p> <p>EXAMPLE(S): adaptive, blocked, stratified, allocation based on past response.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGv2.2 = ExperimentalUnitAllocationMethod.typeCode Map:CTRv1.0 = DefinedExperimentalUnitAllocation.methodCode

Class: DefinedExpressionVariableRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a DefinedSubstanceAdministration and a DefinedObservation that identifies a factor used in a relative dose expression to calculate an absolute dose.

EXAMPLE(S):

Relationship of a calculated dose on a substance administration and a weight observation.

Relationship of a calculated dose on a substance administration and a body surface area observation.

OTHER NAME(S):

NOTE(S):

Formulas are used for direct mathematical calculations. Conditional assertions make use of the DefinedContingentOnRelationship class.

Tagged Values:

- Map:CTRv1.0 = DefinedExpressionVariableRelationship

Connectors

Source	Connector	Target	Notes
DefinedExpressionVariableRelationship 0..* referencingDefinedExpressionVariableRelationship	is a reference to	DefinedObservation 1 referencedDefinedObservation	<p>DESCRIPTION: Each DefinedExpressionVariableRelationship always is a reference to one DefinedObservation. Each DefinedObservation might be referenced by one or more DefinedExpressionVariableRelationship.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedExpressionVariableRelationship 0..* usedDefinedExpressionVariableRelationship	is used in	DefinedSubstanceAdministration 1..* usingDefinedSubstanceAdministration	DESCRIPTION: Each DefinedExpressionVariableRelationship always is used in one or more DefinedSubstanceAdministration. Each DefinedSubstanceAdministration might use one or more DefinedExpressionVariableRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
localVariableName <i>Class:</i> DefinedExpressionVariableRelationship <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A label that represents the result value of an observation and serves as an input parameter used in a dose expression.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The local variable name is used in the DefinedSubstanceAdministration.dose.EXPR<P Q> and will ultimately be substituted with the result of the observation to which the DefinedExpressionVariableRelationship points.</p>	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = DefinedExpressionVariableRelationship.localVariableName

Class: DefinedInclusionCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that identifies a characteristic or requirement intended to be applied to a potential study subject to determine whether they may participate in a study.

EXAMPLE(S):
pregnancy

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRr3 = DefinedInclusionCriterion
- Map:CTRv1.0 = DefinedInclusionCriterion

Connectors

Source	Connector	Target	Notes
DefinedInclusionCriterion	specializes	DefinedEligibilityCriterion	<p>DESCRIPTION: Each DefinedInclusionCriterion always specializes one DefinedEligibilityCriterion.</p> <p>Each DefinedEligibilityCriterion might be specialized by one DefinedInclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedMaterialProcessStep

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that is an action of processing a material.

EXAMPLE(S):

freezing, thawing, spinning, embedding, dividing, aliquot, adding additives or growth factors

OTHER NAME(S):

product manipulation

NOTE(S):

Material process may be performed on any kind of material, such as a specimen, nanomaterial, or biologic. The result of the process may be a similar or different kind of material, for instance a specimen may be the result of a specimen processing step (e.g., aliquot or division of a specimen), or alternatively a blood product has anticoagulants added to it to preserve the product. Other processing steps, such as adding growth factor to induce cell growth, may be performed on the blood product.

Note that DefinedMaterialProcessStep inherits two associations that perhaps should be mutually exclusive - 1) the association between a DefinedProcedure and a Product that it uses, and 2) the association between an Activity and an ExperimentalActivityItem that it uses.

Question for SMEs: Should this be made a constraint on this class, or even on a higher level superclass?

Tagged Values:

- Map:LSDAMv2.2.3Plus = DefinedSpecimenFixed
- Map:LSDAMv2.2.3Plus = DefinedMaterialProcessStep
- Map:LSDAMv2.2.3Plus = DefinedSpecimenSpun
- Map:LSDAMv2.2.3Plus = DefinedSpecimenEmbedded
- Map:LSDAMv2.2.3Plus = DefinedSpecimenThaw
- Map:LSDAMv2.2.3Plus = DefinedSpecimenFrozen

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
DefinedMaterialProcessStep	specializes	DefinedProcedure	<p>DESCRIPTION: Each DefinedMaterialProcessStep always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedMaterialProcessStep .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Material 0..* producedMaterial	have been produced by	DefinedMaterialProcessStep 0..1 producingDefinedMaterialP rocessStep	<p>DESCRIPTION: Each Material might have been produced by one DefinedMaterialProcessStep . Each DefinedMaterialProcessStep might have produced one or more Material.</p> <p>DEFINITION: Indicates that material is produced by a process step.</p> <p>EXAMPLE(S): A blood product has anticoagulants added to it to preserve the product A blood product has growth factor added to it to induce cell growth</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedMaterialStorage

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level that is an action of safekeeping harvested material in a repository or depository.

EXAMPLE(S):

refrigeration, cryopreservation, dehydration

OTHER NAME(S):

NOTE(S):

There is a difference between the act of changing the state of material, which is represented by DefinedMaterialProcessStep, and the act of maintaining state of the material by storing it, which is represented by DefinedMaterialStorage.

Tagged Values:

Connectors

Source	Connector	Target	Notes
DefinedMaterialStorage	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedSpecimenStorage always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedSpecimenStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedMaterialStorage 0..* storingDefinedSpecimenStorage	stores	Specimen 1 storedSpecimen	<p>DESCRIPTION: Each DefinedMaterialStorage always stores one Specimen. Each Specimen might be stored during one or more DefinedMaterialStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
nameCodeModifiedText <i>Class:</i> DefinedMaterialStorage <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string that is a revision of the original text of the material storage action to enable the coding of the text.</p> <p>EXAMPLE(S): If the original text is "sotre", the nameCodeModifiedText could be set to "store", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p>	Map:PGx v1.0 = BE.BEMODIFY

Class: DefinedMedicalConditionResult

Package: Protocol Representation Sub-Domain

DEFINITION:

A reusable template description of a sign, symptom, disease, or other medical occurrence.

EXAMPLE(S):

death, back pain, headache, pulmonary embolism, heart attack, pregnancy, flu, broken bone, menstrual period, depression

OTHER NAME(S):

Clinical Events

Medical History

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = DefinedMedicalConditionResult

Connectors

Source	Connector	Target	Notes
DefinedMedicalConditionResult	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedMedicalConditionResult always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedMedicalConditionResult.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>

Class: DefinedNotification

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at the global library level that represents the communication of a message to a recipient.

EXAMPLE(S):

An alert sent to a study PI that the study has reached 75% of target subject accrual.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = PlannedEmailNotification
- Map:caAERSv2.2 = PlannedNotification

Connectors

Source	Connector	Target	Notes
DefinedNotification 0..* attachingDefinedNotification	have as an attachment	DocumentVersion 0..* attachedDocumentVersion	<p>DESCRIPTION: Each DefinedNotification might have as an attachment one or more DocumentVersion. Each DocumentVersion might be an attachment on one or more DefinedNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedNotification	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedNotification always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* receivingNotificationReceiver	be the receiver of	DefinedNotification 0..1 receivedDefinedNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one DefinedNotification. Each DefinedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
messageTitle <i>Class:</i> DefinedNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The topic of the notification. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = PlannedNotification.title Map:caAERSv2.2 = PlannedEmailNotification.subjectLine
message <i>Class:</i> DefinedNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The text that is to be included in the notification. EXAMPLE(S): OTHER NAME(S): NOTE(S): The message text may contain substitution tags that when used in the context of a particular study are replaced with study name or study site, etc.	Map:C3PRv2.9 = PlannedNotification.message
deliveryMechanismCode <i>Class:</i> DefinedNotification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying how the notification message is to be delivered. EXAMPLE(S): email OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = PlannedNotification.deliveryMechanism

Class: DefinedObservation

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level 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 subject's physiologic or psychologic state.

EXAMPLE(S):

blood chemistry panel, body mass index calculation, blood pressure measurement, obtaining DNA sequence, genotyping a genetic variant, measuring the pH of a solution, specimen quality review

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = PlannedObservation
- Map:CTRRr3 = DefinedObservation
- Map:CTRv1.0 = DefinedObservation
- Map:LSDAMv2.2.3Plus = DefinedObservation
- Map:LSDAMv2.2.3Plus = DefinedSpecimenQuantityReview

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedObservationResult 0..1 focusingDefinedObservationResult	<p>DESCRIPTION: Each DefinedObservation might have as focal context one DefinedObservationResult. Each DefinedObservationResult might be the focal context for one or more DefinedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedCriterionGroup 0..1 focusingDefinedCriterionGroup	<p>DESCRIPTION: Each DefinedObservation might have as focal context one DefinedCriterionGroup. Each DefinedCriterionGroup might be the focal context for one or more DefinedObservation.</p> <p>EXAMPLE(S): Was there a liver chemistry event for the lab samples collected at this visit?</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservation	specializes	DefinedActivity	<p>DESCRIPTION: Each DefinedObservation always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedActivity 0..1 focusingDefinedActivity	<p>DESCRIPTION: Each DefinedObservation might have as focal context one DefinedActivity. Each DefinedActivity might be the focal context for one or more DefinedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedExpressionVariableRelationship 0..* referencingDefinedExpressionVariableRelationship	is a reference to	DefinedObservation 1 referencedDefinedObservation	<p>DESCRIPTION: Each DefinedExpressionVariableRelationship always is a reference to one DefinedObservation. Each DefinedObservation might be referenced by one or more DefinedExpressionVariableRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedStratificationCriterion	specializes	DefinedObservation	<p>DESCRIPTION: Each DefinedStratificationCriterion always specializes one DefinedObservation. Each DefinedObservation might be specialized by one DefinedStratificationCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedEligibilityCriterion	specializes	DefinedObservation	<p>DESCRIPTION: Each DefinedEligibilityCriterion always specializes one DefinedObservation. Each DefinedObservation might</p>

Source	Connector	Target	Notes
			<p>be specialized by one DefinedEligibilityCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservationResult 0..* producedDefinedObservatio nResult	is a result of	DefinedObservation 1 producingDefinedObservati on	<p>DESCRIPTION:</p> <p>Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation might result in one or more DefinedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> DefinedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION:</p> <p>A coded value specifying the technique that is used for the observation.</p> <p>EXAMPLE(S):</p> <p>Arterial puncture, sphygmomanometry (for blood pressure measurement)</p> <p>Global introspection, algorithm, bayesian (for Adverse Event causality)</p> <p>Estrogen Receptor Assay, Progesterone Receptor Assay, p53 Assay (for clinical result assay)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:AE = PerformedProductInvestigation.evaluationMethodCode</p> <p>Map:AE = CausalAssessment.methodCode</p> <p>Map:AIM v4 rv48 = Algorithm.type</p> <p>Map:AIM v4 rv48 = Algorithm.name</p> <p>Map:CTOM = ClinicalResult.assayMethodCode</p> <p>Map:CTOM = ClinicalResult.meansVitalStatusObtainedCode</p> <p>Map:CTOM = LesionDescription.methodCode</p> <p>Map:CTOM = ClinicalResult.labTechniqueCode</p> <p>Map:CTRv1.0 = DefinedObservation.methodCode</p> <p>Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Observation.methodCode</p> <p>Map:LSDAMv2.2.3Plus = DefinedObservation.methodCode</p>

Attribute	Notes	Constraints and Tags
bodyPositionCode <i>Class:</i> DefinedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the 3-dimensional spatial orientation of a subject during a particular observation.</p> <p>EXAMPLE(S): supine, trendelenburg, standing</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:CTOM = ClinicalResult.bodyPositionCode Map:CTRV1.0 = DefinedObservation.bodyPositionCode Map:LSDAMv2.2.3Plus = DefinedObservation.bodyPositionCode Map:PSC = VS.VSPOS Map:SDTM IGv3.1.1 = EG.EGPOS
targetAnatomicSiteCode <i>Class:</i> DefinedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of the observation.</p> <p>EXAMPLE(S): lung, leg</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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). Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:AE = AdverseEvent.bodyLocation Map:CTOM = LesionDescription.anatomicSiteCodeSystem Map:CTOM = Diagnosis.primaryAnatomicSiteCodeSystem Map:CTOM = Diagnosis.primaryAnatomicSiteCode Map:CTOM = LesionDescription.anatomicSiteCode Map:CTOM = Diagnosis.primaryAnatomicSiteLateralityCode Map:CTRV1.0 = DefinedObservation.targetAnatomicSiteCode Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Observation.TargetSiteCode Map:LSDAMv2.2.3Plus = DefinedObservation.targetAnatomicSiteCode
targetAnatomicSiteLateralityCode <i>Class:</i> DefinedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for an observation.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:AE = AdverseEvent.bodyLocation Map:CTOM = Diagnosis.primaryAnatomicSiteLateralityCode Map:CTRV1.0 = DefinedObservation.targetAnatomicSiteLateralityCode Map:LSDAMv2.2.3Plus = DefinedObservation.targetAnatomicSiteLateralityCode

Attribute	Notes	Constraints and Tags
approachAnatomicSiteCode <i>Class:</i> DefinedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the anatomic location or access point for an observation.</p> <p>EXAMPLE(S): Anus for a colonoscopy observation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Neither target anatomic site nor approach anatomic site is necessarily required or relevant for certain observations, however if either or both are present then the distinction between them is that the approach site is the access point for the measurement or observation and the target site is what is ultimately being evaluated.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CDASHv1.1 = VS.VSLOC Map:SDTM IGv3.1.2 = VS.VSLOC Map:SDTM IGv3.1.2 = EG.EGLOC Map:SDTM IGv3.1.2 = FA.FALOC
focalDuration <i>Class:</i> DefinedObservation <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A quantity of time in which the observation result is held to be true.</p> <p>EXAMPLE(S): 2 months is the focalDuration for the question, "Have you smoked in the last 2 months?"</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The focalDuration can be derived from the expression captured in the focalDateRange.IVL<EXPR<TS.DATETIME>.</p>	AE:Exclude = True Map:CTOM = DiseaseResponse.progressionPeriod Map:CTOM = DiseaseResponse.progressionPeriodUnitOfMeasureCode Map:CTRv1.0 = DefinedObservation.focalDuration Map:LSDAMv2.2.3Plus = DefinedObservation.focalDuration Map:SDTM IGv3.1.1 = QS.QSEVLINT Map:SDTM IGv3.1.3 = QS.QSEVLINT Map:SDTM IGv3.1.3 = PC.PCEVLINT

Attribute	Notes	Constraints and Tags
focalDateRange <i>Class:</i> DefinedObservation <i>Datatype:</i> IVL<EXPR<TS.DATETIM E>> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: 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.</p> <p>EXAMPLE(S): For a survey question, "Have you traveled to Europe between 1990 and 1999?", the focalDateRange would be "January 1, 1990 to December 31, 1999".</p> <p>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).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): As an attribute with data type IVL<EXPR<TS.DATETIME>>, focalDateRange can be used to express a simple date range such as "January 1, 1990 to December 31, 1999" or a relative time expression that includes a variable that represents another date in the model that is a study-defined anchor point. The other date may or may not be known at the time the DefinedObservation is created, but will be known by the time the PerformedObservation is created.</p>	AE:Exclude = True Map:CTOM = Diagnosis.confirmationDate Map:CTOM = DiseaseResponse.progressionDate Map:CTOM = DiseaseResponse.evaluationDate Map:CTOM = Histopathology.reportingDate Map:CTRv1.0 = DefinedObservation.focalDateRange Map:LSDAMv2.2.3Plus = DefinedObservation.focalDateRange Map:SDTM IGv3.1.2 = QS.QSEVLINT

Class: DefinedObservationResult

Package: Protocol Representation Sub-Domain

DEFINITION:

A reusable, "template" description of possible findings of an observation.

EXAMPLE(S):

A blood pressure measurement may result in a diastolic number and a systolic number.

OTHER NAME(S):

NOTE(S):

The DefinedObservationResult class can be used to represent defined ranges for contingencies by constraining the value 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.

Tagged Values:

- Map:CTRr3 = DefinedObservationResult
- Map:CTRv1.0 = DefinedObservationResult

Connectors

Source	Connector	Target	Notes
DefinedObservationResult 0..* producedDefinedObservationResult	is a result of	DefinedObservation 1 producingDefinedObservation	<p>DESCRIPTION: Each DefinedObservationResult always is a result of one DefinedObservation. Each DefinedObservation might result in one or more DefinedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOptionRelationship 0..* choicePlannedCriterionGroupOptionRelationship	be a choice that has as option	DefinedObservationResult 0..1 optionDefinedObservationResult	<p>DESCRIPTION: Each PlannedCriterionGroupOptionRelationship might be a choice that has as option one DefinedObservationResult. Each DefinedObservationResult might be an option that can satisfy one or more PlannedCriterionGroupOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCompositionRelationship 0..* compositePlannedCriterionGroupCompositionRelationship	be the parent of	DefinedObservationResult 0..1 componentDefinedObservationResult	<p>DESCRIPTION: Each PlannedCriterionGroupCompositionRelationship might be the parent of one DefinedObservationResult. Each DefinedObservationResult might be the component of one or more PlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
PlannedRepeatActivityUntil Rule 0..* repeatedPlannedRepeatActivityUntilRule	be repeated until	DefinedObservationResult 0..1 triggeringDefinedObservationResult	<p>NOTE(S):</p> <p>DESCRIPTION: Each PlannedRepeatActivityUntil Rule might be repeated until one DefinedObservationResult. Each DefinedObservationResult might trigger the cessation of one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedEligibilityCriterion Answer	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedEligibilityCriterion Answer always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedEligibilityCriterion Answer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedObservation 0..* focusedDefinedObservation	have as focal context	DefinedObservationResult 0..1 focusingDefinedObservationResult	<p>DESCRIPTION: Each DefinedObservation might have as focal context one DefinedObservationResult. Each DefinedObservationResult might be the focal context for one or more DefinedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
DefinedMedicalConditionResult	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedMedicalConditionResult always specializes one DefinedObservationResult.</p> <p>Each DefinedObservationResult might be specialized by one DefinedMedicalConditionResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedAdverseEvent	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedAdverseEvent always specializes one DefinedObservationResult.</p> <p>Each DefinedObservationResult might be specialized by one DefinedAdverseEvent.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedDiagnosis	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedDiagnosis always specializes one DefinedObservationResult.</p> <p>Each DefinedObservationResult might be specialized by one DefinedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelationship 0..* contingentPlannedContingentOnRelationship	be contingent upon	DefinedObservationResult 0..1 prerequisiteDefinedObservationResult	<p>DESCRIPTION: Each PlannedContingentOnRelationship might be contingent upon one DefinedObservationResult.</p> <p>Each</p>

Source	Connector	Target	Notes
			DefinedObservationResult might be a condition for one or more PlannedContingentOnRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedCriterionGroupOpti onRelationship 0..* choiceDefinedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedObservationResult 0..1 optionDefinedObservationR esult	DESCRIPTION: Each DefinedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedObservationResult. Each DefinedObservationResult might be an option that can satisfy one or more DefinedCriterionGroupOpti onRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedStratificationCriteri onPermissibleResult	specializes	DefinedObservationResult	DESCRIPTION: Each DefinedStratificationCriteri onPermissibleResult always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedStratificationCriteri onPermissibleResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedContingentOnRelati onship 0..* contingentDefinedContinge ntOnRelationship	be contingent upon	DefinedObservationResult 0..1 prerequisiteDefinedObserva tionResult	DESCRIPTION: Each DefinedContingentOnRelati onship might be contingent upon one DefinedObservationResult.

Source	Connector	Target	Notes
			<p>Each DefinedObservationResult might be a condition for one or more DefinedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedCriterionGroupCompositeRelationship 0..* compositeDefinedCriterionGroupCompositionRelationship	be the parent of	DefinedObservationResult 0..1 componentDefinedObservationResult	<p>DESCRIPTION: Each DefinedCriterionGroupCompositeRelationship might be the parent of one DefinedObservationResult. Each DefinedObservationResult might be the component of one or more DefinedCriterionGroupCompositeRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntilRule 0..* repeatedDefinedRepeatActivityUntilRule	be repeated until	DefinedObservationResult 0..1 triggeringDefinedObservationResult	<p>DESCRIPTION: Each DefinedRepeatActivityUntilRule might be repeated until one DefinedObservationResult. Each DefinedObservationResult might trigger the cessation of one or more DefinedRepeatActivityUntilRule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
value <i>Class:</i> DefinedObservationResult <i>Datatype:</i> ANY <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Data or information that is determined by an act of observation.</p> <p>EXAMPLE(S): The result of a lab test, physical finding, self-reported symptom.</p> <p>The adverse event term code.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:AE = Animal.overallStateOfHealthCode Map:AE = InvestigativeSubject.gestationPeriod Map:AE = Assessment.codedInterpretation Map:AE = ProductObservation.value Map:AE = AdverseEvent.reactionText Map:AE = Person.numberOfSiblings Map:AE = AdverseEvent.adverseEventTermCode Map:AE = Assessment.textInterpretation Map:AE = ProductInvestigation.evaluationResult Code Map:C3PR = StratificationCriterionPermissibleAnswer.permissibleAnswer Map:C3PRv2.9 = StratificationCriterionPermissibleAnswer.permissibleAnswer Map:caAERSv2.2 = AbstractMeddraDomain.meddraTerm Map:caAERSv2.2 = AbstractMeddraDomain.costartSymbol Map:caAERSv2.2 = MeddraVersion.name > SolicitedAdverseEvent (meddraTerm) Map:caAERSv2.2 = MeddraVersion.name > ExpectedAEMeddraLowLevelTerm Map:caAERSv2.2 = Ctc.name > ExpectedAECtcTerm Map:caAERSv2.2 = CtcTerm.select > AbstractExpectedAE Map:caAERSv2.2 = AbstractMeddraDomain.version_id Map:caAERSv2.2 = AbstractMeddraDomain.whoArtCode Map:caAERSv2.2 = Ctc.name > SolicitedAdverseEvent Map:caAERSv2.2 = CtcTerm.term > AbstractExpectedAE Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > ExpectedAEMeddraLowLevelTerm Map:caAERSv2.2 = AbstractMeddraDomain.hartsCode Map:caAERSv2.2 = AbstractMeddraDomain.jartCode Map:caAERSv2.2 = MeddraVersion.name > ExpectedAECtcTerm Map:caAERSv2.2 = AbstractMeddraDomain.icd9Code Map:caAERSv2.2 = MeddraVersion.name > SolicitedAdverseEvent (otherTerm) Map:caAERSv2.2 =

Attribute	Notes	Constraints and Tags
		AbstractMeddraDomain.icd10Code Map:caAERSv2.2 = AbstractMeddraDomain.icd9CmCode Map:caAERSv2.2 = CtcTerm.ctepCode > AbstractExpectedAE Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > ExpectedAECtcTerm Map:CTOM = DiseaseResponse.responseCodeSystem Map:CTOM = DeathSummary.deathCauseText Map:CTOM = QualitativeEvaluation.survivalStatusDescriptionText Map:CTOM = FemaleReproductiveCharacteristic.liveBirthCount Map:CTOM = Diagnosis.recurrenceIndicator Map:CTOM = QualitativeEvaluation.menstrualPatternTypeCode Map:CTOM = FemaleReproductiveCharacteristic.menopauseAge Map:CTOM = CancerStage.stageCodeSystem Map:CTOM = CancerStage.stageCode Map:CTOM = QualitativeEvaluation.menstrualIndicator Map:CTOM = DeathSummary.deathCauseCode Map:CTOM = Diagnosis.diseaseDiagnosisCode Map:CTOM = ParticipantEligibilityAnswer.answerText Map:CTOM = AdverseEvent.descriptionText Map:CTOM = Histopathology.grossExamResultCode Map:CTOM = Diagnosis.diseaseDiagnosisCodeSystem Map:CTOM = QualitativeEvaluation.survivalStatusCode Map:CTOM = DiseaseResponse.courseDispositionCode Map:CTOM = DiseaseResponse.responseCode Map:CTOM = LesionEvaluation.evaluationCode Map:CTOM = FemaleReproductiveCharacteristic.abortionIndicator

Attribute	Notes	Constraints and Tags
		Map:CTOM = FemaleReproductiveCharacteristic.stillBirthCount Map:CTOM = ClinicalResult.valueUnitOfMeasureCode Map:CTOM = ClinicalResult.value Map:CTOM = Participant.householdIncomeCode Map:CTOM = QualitativeEvaluation.painIndexCodeSystem Map:CTOM = QualitativeEvaluation.performanceStatusCodeSystem Map:CTOM = Specimen.volume Map:CTOM = QualitativeEvaluation.painIndexCode Map:CTOM = FemaleReproductiveCharacteristic.firstLiveBirthAge Map:CTOM = AdverseEvent.outcomeCode Map:CTOM = Diagnosis.diseaseStatusCode Map:CTOM = QualitativeEvaluation.performanceStatusCode Map:CTOM = QualitativeEvaluation.anamResultAccuracyPercent Map:CTRPv1.0 = PlannedEligibilityCriterion.requiredResponse Map:CTRPv3.8 = PlannedEligibilityCriterion.textValue Map:CTRPv3.8 = PlannedEligibilityCriterion.value Map:CTRPv3.8 = PlannedEligibilityCriterion.eligibleGenderCode Map:CTRR = Lifestyle Choices Map:CTRR = Prior and Concomitant Medication(s) Map:CTRR = Substance Use Map:CTRR = Special Populations Map:CTRR = Gestational Age Map:CTRR = BMI Map:CTRR = Maximum Age Map:CTRR = Ethical Considerations (e.g. informed consent) Map:CTRR = Past Population Disease Condition Map:CTRR = Current Population Disease Condition Map:CTRR = Subject Gender Map:CTRR = Subject Race(s) Map:CTRR = Minimum Age Map:CTRR = Pregnancy Map:CTRR = Subject Ethnicity Map:CTRR = Nursing

Attribute	Notes	Constraints and Tags
		Map:CTRr3 = DefinedObservationResult.result Map:CTRv1.0 = DefinedEligibilityCriterion.requiredResponse Map:CTRv1.0 = DefinedObservationResult.value Map:FDA HL7 SD SD DSTU2012 = StudyProtocol//plannedStudy/precondition/eligibilityCriterion.value Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Observation.value Map:HL7SP = VerificationEvent.value Map:Lab = LabResult.numericPrecision Map:Lab = LabResult.textResult Map:Lab = LabResult.referenceTextList Map:Lab = LabResult.numericResult Map:PGx v1.0 = PB.PBDIAG Map:PSCv2.6 = PlannedActivity.condition Map:PSCv2.6 = Population.abbreviation Map:PSCv2.6 = ScheduledActivity.condition Map:PSCv2.6 = Population.name Map:SDTM IGv3.1.1 = EG.EGORRESU Map:SDTM IGv3.1.1 = LB.LBORRES Map:SDTM IGv3.1.1 = QS.QSSTRESP Map:SDTM IGv3.1.1 = LB.LBORTRESU Map:SDTM IGv3.1.1 = VS.VSLOINC Map:SDTM IGv3.1.1 = LB.LBORTRESP Map:SDTM IGv3.1.1 = TS.TSVAL Map:SDTM IGv3.1.1 = DS.DSTERM Map:SDTM IGv3.1.1 = EG.EGORRES Map:SDTM IGv3.1.1 = PE.PESTRESP Map:SDTM IGv3.1.1 = LB.LBLOINC Map:SDTM IGv3.1.1 = PE.PEORRESP Map:SDTM IGv3.1.1 = SC.SCORRESP Map:SDTM IGv3.1.1 = IE.IESTRESP Map:SDTM IGv3.1.1 = DV.DVDECOD Map:SDTM IGv3.1.1 = QS.QSORRESP Map:SDTM IGv3.1.1 = VS.VSORRESP Map:SDTM IGv3.1.1 = QS.QSORRESP Map:SDTM IGv3.1.1 = EG.EGSTRESP

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.1 = PE.PESTRESN Map:SDTM IGv3.1.1 = LB.LBSTRESU Map:SDTM IGv3.1.1 = MH.MHTERM Map:SDTM IGv3.1.1 = MH.MHOCCUR Map:SDTM IGv3.1.1 = IE.IEORRES Map:SDTM IGv3.1.1 = SC.SCSTRESP Map:SDTM IGv3.1.1 = VS.VSSTRESP Map:SDTM IGv3.1.1 = SC.SCSTRESP Map:SDTM IGv3.1.1 = VS.VSSTRESP Map:SDTM IGv3.1.1 = VS.VSORRESP Map:SDTM IGv3.1.1 = LB.LBSTRESP Map:SDTM IGv3.1.1 = SC.SCSTRESP Map:SDTM IGv3.1.1 = QS.QSSTRESP Map:SDTM IGv3.1.1 = QS.QSSTRESP Map:SDTM IGv3.1.1 = VS.VSSTRESP Map:SDTM IGv3.1.1 = EG.EGLOINC Map:SDTM IGv3.1.1 = PE.PESTRESP Map:SDTM IGv3.1.1 = CM.CMOCCUR Map:SDTM IGv3.1.1 = EG.EGSTRESP Map:SDTM IGv3.1.1 = MH.MHDECOD Map:SDTM IGv3.1.1 = PE.PEORRES Map:SDTM IGv3.1.1 = EG.EGSTRESP Map:SDTM IGv3.1.1 = SC.SCORRESP Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=AGEMAX Map:SDTM IGv3.1.2 = TS.TSPARMCD where TSPARMCD=TDIGRP Map:SDTM IGv3.1.2 = TS.TSPARMCD where TSPARMCD=SEXPOP Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=TDIGRP Map:SDTM IGv3.1.2 = TS.TSPARMCD where TSPARMCD=AGEMIN Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=TDIGRP Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=SEXPOP

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = TS.TSPARM where TSPARMCD=AGEMIN Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=SEXPOP Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=AGEMAX Map:SDTM IGv3.1.2 = TS.TSPARMCD where TSPARMCD=AGEMAX Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "HLTSUBJI" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "TDIGRP" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "HLTSUBJI" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SEXPOP" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "AGEMIN" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "AGEMAX"

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "AGEMAX" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "AGEMIN"
valueNegationIndicator <i>Class:</i> DefinedObservationResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether, when the observation event occurred, the finding communicated by the value attribute was NOT found.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute should only be used when the terminology used for DefinedObservationResult.value is not itself capable of expressing negated findings (e.g., ICD9).</p>	Map:HL7SDr1 = TimePointEventDefinition.negationInd
typeCode <i>Class:</i> DefinedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of observation result.</p> <p>EXAMPLE(S): 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ClinicalResult.value Map:CTRr3 = DefinedObservationResult.typeCode Map:CTRv1.0 = DefinedObservationResult.typeCode
targetCodingSystem <i>Class:</i> DefinedObservationResult <i>Datatype:</i> OID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The coding system to use for recording results for the associated activity or evaluation.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGv2.2 = PlannedObservationResult.targetCodingSystem Map:CTRv1.0 = DefinedObservationResult.targetCodingSystem

Attribute	Notes	Constraints and Tags
targetAnatomicSiteCode <i>Class:</i> DefinedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of an observation result.</p> <p>EXAMPLE(S): Arm for skin rash.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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).</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CTOM = LesionDescription.contactAnatomicSiteCode Map:CTOM = LesionDescription.contactAnatomicSiteCodeSystem Map:CTRv1.0 = DefinedObservationResult.targetAnatomicSiteCode Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC
targetAnatomicSiteLateralityCode <i>Class:</i> DefinedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for a procedure.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CTRv1.0 = DefinedObservationResult.targetAnatomicSiteLateralityCode Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC
confidentialityCode <i>Class:</i> DefinedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the degree of privacy applicable for the observation result.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ClinicalResult.confidentialityCode Map:CTOM = Observation.confidentialityCode Map:CTOM = LesionDescription.confidentialityCode Map:CTOM = Histopathology.confidentialityCode Map:CTRv1.0 = DefinedObservationResult.confidentialityCode

Attribute	Notes	Constraints and Tags
derivationExpression <i>Class:</i> DefinedObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: 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.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = DefinedObservationResult.derivationExpression Map:TDMv2 = (New content)

Class: DefinedOptionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedOptionRelationship
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
DefinedOptionRelationship 0..* optionDefinedOptionRelationship	is an option that can satisfy	DefinedActivity 1 choiceDefinedActivity	<p>DESCRIPTION: Each DefinedOptionRelationship always is an option that can satisfy one DefinedActivity. Each DefinedActivity might be a choice that has as option one or more DefinedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
DefinedOptionRelationship 0..* choiceDefinedOptionRelationship	is a choice that has as option	DefinedActivity 1 optionDefinedActivity	<p>DESCRIPTION: Each DefinedOptionRelationship always is a choice that has as option one DefinedActivity. Each DefinedActivity might be an option that can satisfy one or more DefinedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> DefinedOptionRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:CTRv1.0 = DefinedOptionRelationship.priorityNumber Map:TDM = AbstractRule.isExclusive

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> DefinedOptionRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A pain management activity consists of either administering drug A after waiting 30 minutes or drug B after waiting 60 minutes – the pauseQuantityRanges are 30 minutes and 60 minutes respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed

Class: DefinedProcedure

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that is an action whose immediate and primary intention is the alteration of the physical condition of the subject.

EXAMPLE(S):

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.

OTHER NAME(S):

NOTE(S):

The documented use cases from life sciences are limited to procedure and observations. Use cases for other kinds of activities in life sciences are needed to support this relationship at Activity level. In the next release, this relationship will have to be re-assessed.

Tagged Values:

- Map:CTRPv3.8 = PlannedProcedure
- Map:CTRR = Intervention Name
- Map:CTRr3 = DefinedProcedure

- Map:CTRv1.0 = DefinedProcedure
- Map:LSDAMv2.2.3Plus = DefinedProcedure

Connectors

Source	Connector	Target	Notes
DefinedProcedure 0..* usingDefinedProcedure	use	Product 0..* usedProduct	<p>DESCRIPTION: Each DefinedProcedure might use one or more Product. Each Product might be used during one or more DefinedProcedure.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedProcedure	specializes	DefinedActivity	<p>DESCRIPTION: Each DefinedProcedure always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedProcedure.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedMaterialProcessStep	specializes	DefinedProcedure	<p>DESCRIPTION: Each DefinedMaterialProcessStep always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedMaterialProcessStep .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedSpecimenCollection	specializes	DefinedProcedure	<p>DESCRIPTION: Each DefinedSpecimenCollection always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedSpecimenCollection</p>

Source	Connector	Target	Notes
			<p>.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedSubstanceAdministration	specializes	DefinedProcedure	<p>DESCRIPTION:</p> <p>Each DefinedSubstanceAdministration always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
nameCodeModifiedText <i>Class:</i> DefinedProcedure <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>A character string that is a revision of the original text of the procedure to enable the coding of the text.</p> <p>EXAMPLE(S):</p> <p>If the original text is "message", the nameCodeModifiedText could be set to "massage", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p>	<p>Map:BRIDGSCC = Model Integrity</p> <p>Map:PGx v1.0 = BE.BEMODIFY</p>

Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> DefinedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the technique that is used for the procedure.</p> <p>EXAMPLE(S): Finger stick, veni puncture, Abdominal/ ascites effusion, Biopsy, Bronchial alveolar lavage (BAL) (for specimen collection)</p> <p>Capillary electrophoresis and HPLC (for In Vitro Characterization)</p> <p>Cell counting, flow cytometry (for In Vivo Characterization)</p> <p>Open, laparoscopic (for cholecystectomy)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGv2.2 = PlannedProcedure.methodCode Map:CTRPv3.8 = PlannedProcedure.methodCode Map:CTRv1.0 = DefinedProcedure.methodCode Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.methodCode Map:HCTv1.0 = CDE 2750692:Graft Manipulation.Specify the ex vivo graft manipulation other than for RBC removal or volume reduction: Map:HCTv1.0 = CDE 2748795:Therapies.What malignant cell removal method was used to treat the product? Map:HCTv1.0 = CDE 2774742:Techniques.Specify the other T-cell depletion method: Map:HCTv1.0 = CDE 2750679:Graft Manipulation.What was the method of ex vivo graft manipulation other than for RBC removal or volume reduction? Map:HCTv1.0 = CDE 2774532:Techniques.Specify the other erythrocyte reduced methods Map:LSDAMv2.2.3Plus = InvivoCharacterization.procedureCode Map:LSDAMv2.2.3Plus = InvitroCharacterization.assayType Map:LSDAMv2.2.3Plus = DefinedSpecimenFixed.fixationType
targetAnatomicSiteCode <i>Class:</i> DefinedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of a procedure.</p> <p>EXAMPLE(S): Kidney for a nephrectomy</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Multiple contiguous sites within the same organ system may be referenced.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:BRIDGv2.2 = PlannedProcedure.targetSiteCode Map:CTRPv3.8 = PlannedProcedure.targetSiteCode Map:CTRv1.0 = DefinedProcedure.targetAnatomicSiteCode Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.TargetSiteCode Map:LSDAMv2.2.3Plus = DefinedProcedure.targetAnatomicSiteCode Map:PGx v1.0 = BE.BELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = EX.EXLOC

Attribute	Notes	Constraints and Tags
targetAnatomicSiteLateralityCode <i>Class:</i> DefinedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for a procedure.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CTRv1.0 = DefinedProcedure.targetAnatomicSiteLateralityCode Map:PGx v1.0 = BE.BELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC
approachAnatomicSiteCode <i>Class:</i> DefinedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the anatomic location or access point for a procedure.</p> <p>EXAMPLE(S): Arm for an injection Trans-abdominal for a nephrectomy</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:BRIDGv2.2 = PlannedProcedure.approachSiteCode Map:CTRv1.0 = DefinedProcedure.approachAnatomicSiteCode Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/Procedure.approachSiteCode Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.approachSiteCode Map:LSDAMv2.2.3Plus = DefinedProcedure.approachAnatomicSiteCode Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = PE.PELOC
approachAnatomicSiteLateralityCode <i>Class:</i> DefinedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is an access point for a procedure.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CTRv1.0 = DefinedProcedure.approachAnatomicSiteLateralityCode Map:LSDAMv2.2.3Plus = DefinedProcedure.approachAnatomicSiteLateralityCode Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = AE.AELOC

Class: DefinedProductTransport

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that represents transporting a product between a point of origin and a point of destination.

EXAMPLE(S):

Delivery of drugs from the manufacturer to a medical facility.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:PGx v1.0 = BE.BEMODIFY

Connectors

Source	Connector	Target	Notes
DefinedProductTransport	specializes	DefinedActivity	<p>DESCRIPTION: Each DefinedProductTransport always specializes oneDefinedActivity. Each DefinedActivity might be specialized by oneDefinedProductTranspor t.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
nameCodeModifiedText <i>Class:</i> DefinedProductTransport <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A character string that is a revision of the original text of the product transport action to enable the coding of the text.</p> <p>EXAMPLE(S): If the original text is "rtanspotr", the nameCodeModifiedText could be set to "transport", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p>	Map:PGx v1.0 = BE.BEMODIFY

Class: DefinedProgressCount

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level that is an action in which a set of quantitative information (counts of objects) is produced, and which, when gathered and recorded over a period of time, reflects the progress of a project.

EXAMPLE(S):

The number of subjects that have completed the screening process in a study; the number of study sites that have received their site initiation visit.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Vendor1v1.1 = ProgressCount

Connectors

Source	Connector	Target	Notes
DefinedProgressCount	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedProgressCount always specializes one DefinedActivity. Each DefinedActivity might be specialized by one DefinedProgressCount.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> DefinedProgressCount <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the kind of progress count.</p> <p>EXAMPLE(S): Subjects, Study Sites, Issues</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ProgressCount.typeCode

Attribute	Notes	Constraints and Tags
countTypeDetailCode <i>Class:</i> DefinedProgressCount <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value that provides further description of the type of item being counted.</p> <p>EXAMPLE(S): For subjects: "completed screening"; "entered treatment"; completed follow-up For Study Sites: "completed initiation visit"; "completed hard data lock"</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = ProgressCount.countTypeDetail

Class: DefinedRepeatActivityUntilRule

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a defined repeating activity and the criteria that may trigger the repeating activity to stop, where all items are part of a global library.

EXAMPLE(S):

Continue repeating kidney dialysis until kidney transplant surgery. Continue performing a certain lab test weekly until the three-month checkup occurs. (target = another activity) Continue substance administration of drug X until the blood pressure is over some minimum threshold number. (target = observation result from another activity that is an observation) Continue substance administration of drug Y until the blood pressure is over some minimum threshold number and either the result of a certain lab test is positive or the subject's temperature is elevated, i.e. "(A and (B or C))".

OTHER NAME(S):

NOTE(S):

The criteria to stop the repeating activity by be one of the following:

- another defined activity where the repeating activity stops if this other activity occurs
- a defined observation result where the repeating activity stops if this observation result occurs
- a defined criteria group where the repeating activity stops if this group logically evaluates to true based on its components

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = DefinedRepeatActivityUntilRule
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
DefinedRepeatActivityUntil Rule 0..* triggeringDefinedRepeatActivityUntilRule	triggers the cessation of	DefinedActivity 1 repeatedDefinedActivity	<p>DESCRIPTION: Each DefinedRepeatActivityUntil Rule always triggers the cessation of one DefinedActivity. Each DefinedActivity might be repeated until one or more DefinedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntil Rule 0..* repeatedDefinedRepeatActi vityUntilRule	be repeated until	DefinedActivity 0..1 triggeringDefinedActivity	<p>DESCRIPTION:</p> <p>Each DefinedRepeatActivityUntil Rule might be repeated until one DefinedActivity. Each DefinedActivity might trigger the cessation of one or more DefinedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntil Rule 0..* repeatedDefinedRepeatActi vityUntilRule	be repeated until	DefinedCriterionGroup 0..1 triggeringDefinedCriterionG roup	<p>DESCRIPTION:</p> <p>Each DefinedRepeatActivityUntil Rule might be repeated until one DefinedCriterionGroup. Each DefinedCriterionGroup might trigger the cessation of one or more DefinedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DefinedRepeatActivityUntil Rule 0..* repeatedDefinedRepeatActi vityUntilRule	be repeated until	DefinedObservationResult 0..1 triggeringDefinedObservati onResult	<p>DESCRIPTION:</p> <p>Each DefinedRepeatActivityUntil Rule might be repeated until one DefinedObservationResult. Each DefinedObservationResult might trigger the cessation of one or more DefinedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> DefinedRepeatActivityUntilRule <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:HL7SDr1 = Precondition3.priorityNumber
cessationPauseQuantityRange <i>Class:</i> DefinedRepeatActivityUntilRule <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time after the observed result occurs and before the cessation of repeating the activity.</p> <p>EXAMPLE(S): Stop 20 days after the observed event occurs.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Lab = Activity.plannedTimeElapsed

Attribute	Notes	Constraints and Tags
checkpointCode <i>Class:</i> DefinedRepeatActivityUntil Rule <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the points in the course of an activity when a precondition for the activity is evaluated.</p> <p>EXAMPLE(S) When the checkpointCode for a criterion of a repeatable activity is "end," the criterion is tested only at the end of each repetition of that activity. When the condition holds true, the next repetition is ready for execution.</p> <p>When the checkpointCode is "entry," the criterion is checked at the beginning of each repetition, if any, whereas "beginning" means the criterion is checked only once before the repetition "loop" starts.</p> <p>NOTE(S): The checkpointCode specifies when the precondition is to be checked; it is analogous to the various conditional statements and loop constructs in programming languages "while-do" vs. "do-while" or "repeat-until" vs. "loop-exit."</p>	Map:HL7SDr1 = Precondition3.checkpointCode

Class: DefinedSpecimenCollection

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that is an action of gathering samples that may be used for subsequent analysis.

EXAMPLE(S):

blood draw

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:BRIDGSCC = Model Integrity
- Map:CTRv1.0 = DefinedSpecimenCollection
- Map:LSDAMv2.2.3Plus = DefinedSpecimenCollection

Connectors

Source	Connector	Target	Notes
DefinedSpecimenCollection 0..* producingDefinedSpecimenCollection	results in	Specimen 1..* producedSpecimen	<p>DESCRIPTION: Each DefinedSpecimenCollection always results in one or more Specimen. Each Specimen might be a result of one or more DefinedSpecimenCollection .</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedSpecimenCollection	specializes	DefinedProcedure	DESCRIPTION: Each DefinedSpecimenCollection always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedSpecimenCollection . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
DefinedSpecimenCollection 0..* instantiatedDefinedSpecime nCollection	results in	SpecimenCollectionGroup 1 instantiatingSpecimenCollec tionGroup	DESCRIPTION: Each DefinedSpecimenCollection always results in one SpecimenCollectionGroup. Each SpecimenCollectionGroup might be a result of one or more DefinedSpecimenCollection . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: DefinedStratificationCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that identifies pre-treatment factors by which study subjects are segregated to assure balance of these factors during analysis or before randomization to a study arm or some smaller segment of a study. The decisive factor used to help segregate the study subject into a stratum group for analysis or randomization purposes.

EXAMPLE(S):

- Age Years: 18 to 59 vs. = 60.
- Extra-Cranial Disease Controlled in Months: = 3 vs. > 3.
- Number of Brain Metastases: 1 vs. 2 vs. 3.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StratificationCriterion
- Map:CTRv1.0 = DefinedStratificationCriterion
- Map:NCI CRF Standard = CDE 3608v4.0: Study Stratification Text

Connectors

Source	Connector	Target	Notes
DefinedStratificationCriterion	specializes	DefinedObservation	<p>DESCRIPTION: Each DefinedStratificationCriterion always specializes one DefinedObservation. Each DefinedObservation might be specialized by one DefinedStratificationCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedStratificationCriterionPermissibleResult

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

The stratification criterion for gender can have permissible answers of male and female

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StratificationCriterionAnswerCombination
- Map:C3PRv2.9 = StratificationCriterionPermissibleAnswer
- Map:CTRv1.0 = DefinedStratificationCriterionPermissibleResult

Connectors

Source	Connector	Target	Notes
DefinedStratificationCriterionPermissibleResult	specializes	DefinedObservationResult	<p>DESCRIPTION: Each DefinedStratificationCriterionPermissibleResult always specializes one DefinedObservationResult. Each DefinedObservationResult might be specialized by one DefinedStratificationCriterion</p>

Source	Connector	Target	Notes
			onPermissibleResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StratumGroup 1..* characterizedStratumGroup	is characterized by	DefinedStratificationCriteria onPermissibleResult 1..* characterizingDefinedStratificationCriterionPermissibleResult	DESCRIPTION: Each StratumGroup always is characterized by one or more DefinedStratificationCriteria onPermissibleResult. Each DefinedStratificationCriteria onPermissibleResult always characterizes one or more StratumGroup. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: DefinedStudyAdministrativeActivity

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level that is independent of a study subject but is necessary for the conduct of the study.

EXAMPLE(S):

IRB Approval, site enrollment, FDA audit

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = DefinedStudyAdministrativeActivity

Connectors

Source	Connector	Target	Notes
DefinedStudyAdministrativeActivity	specializes	DefinedAdministrativeActivity	DESCRIPTION: Each DefinedStudyAdministrativeActivity always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by

Source	Connector	Target	Notes
			<p>one DefinedStudyAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedStudyAgentTransfer

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level that is an action in which an authorized party at a designated study site dispenses or receives a study agent to/from a study subject, though as a defined activity, no actual study subject is identified.

EXAMPLE(S):

Dispensing a bottle of pills

OTHER NAME(S):

NOTE(S):

The term "study agent" only pertains within the context of a given study. To make this explicit in BRIDG it was determined that the StudyAgent class would only be used to connect Product to StudyProtocolVersion. All activity-related classes would be associated directly to Product to avoid the issues of activities that may cross study boundaries. To determine if a given activity uses a study agent one need only compare the product used in the activity with the list of products associated to StudyAgent for a given StudyProtocolVersion. It should be noted that this determination could be different for different studies and could evolve over the course of a given study.

Tagged Values:

Connectors

Source	Connector	Target	Notes
DefinedStudyAgentTransfer	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedStudyAgentTransfer always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedStudyAgentTransfer . </p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
DefinedStudyAgentTransfer 0..* transferringDefinedStudyAgentTransfer	is a transfer of	Product 1 transferredProduct	DESCRIPTION: Each DefinedStudyAgentTransfer always is a transfer of one Product. Each Product might be transferred during one or more DefinedStudyAgentTransfer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: DefinedStudySubjectMilestone

Package: Protocol Representation Sub-Domain

DEFINITION:

An administrative activity defined at a global library level that represents a common administrative landmark for a study subject in the course of a study.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = ScheduledEpoch.scEpochWorkflowStatus
- Map:CTRv1.0 = DefinedStudySubjectMilestone

Connectors

Source	Connector	Target	Notes
DefinedStudySubjectMilestone 0..1 usingDefinedStudySubjectMilestone	use	DocumentVersion 0..1 usedDocumentVersion	DESCRIPTION: Each DefinedStudySubjectMilestone might use one DocumentVersion. Each DocumentVersion might be used for one DefinedStudySubjectMilestone. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Source	Connector	Target	Notes
DefinedStudySubjectMilestone	specializes	DefinedAdministrativeActivity	<p>DESCRIPTION: Each DefinedStudySubjectMilestone always specializes one DefinedAdministrativeActivity. Each DefinedAdministrativeActivity might be specialized by one DefinedStudySubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: DefinedSubjectActivityGroup

Package: Protocol Representation Sub-Domain

DEFINITION:

A collection of activities from a global library that would be performed on a common subject.

EXAMPLE(S):

Clinic visit during which a physical exam, a blood test, and a substance administration occur

Telephone contact during which temperature, blood pressure and adverse events are reported

Recording multiple observation results in a diary

A treatment strategy that consists of drug administrations with rules for modifying doses

OTHER NAME(S):

study segment, course, treatment strategy, period, cycle

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = Arm.name
- Map:caAERSv2.2 = Arm
- Map:caAERSv2.2 = TreatmentAssignment
- Map:CTRv1.0 = DefinedSubjectActivityGroup

Connectors

Source	Connector	Target	Notes
DefinedSubjectActivityGroup	specializes	DefinedActivity	<p>DESCRIPTION: Each SubjectActivityGroup always specializes one DefinedActivity. Each DefinedActivity might be specialized by one SubjectActivityGroup.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
duration <i>Class:</i> DefinedSubjectActivityGroup <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The intended length of time for the activity.</p> <p>EXAMPLE(S): 6 weeks may be the duration for a composite activity.</p> <p>P7D may be used to represent a duration of 7 days.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TE.TEDUR

Class: DefinedSubstanceAdministration

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity defined at a global library level that is an action of applying, introducing or otherwise giving medications or other substances to a subject or experimental unit.

EXAMPLE(S):

Administration of methotrexate as part of chemotherapy.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = PlannedSubstanceAdministration
- Map:CTRr3 = DefinedSubstanceAdministration
- Map:CTRv1.0 = DefinedSubstanceAdministration
- Map:DICOM = Enhanced Contrast/Bolus Module
- Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast Administration Profile Sequence (0018,9340)
- Map:DICOM = Contrast/Bolus Module

Connectors

Source	Connector	Target	Notes
DefinedSubstanceAdministration	specializes	DefinedProcedure	<p>DESCRIPTION: Each DefinedSubstanceAdministration always specializes one DefinedProcedure. Each DefinedProcedure might be specialized by one DefinedSubstanceAdministration.</p>

Source	Connector	Target	Notes
DefinedExpressionVariableRelationship 0..* usedDefinedExpressionVariableRelationship	is used in	DefinedSubstanceAdministration 1..* usingDefinedSubstanceAdministration	<p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p> <p>DESCRIPTION: Each DefinedExpressionVariableRelationship always is used in one or more DefinedSubstanceAdministration. Each DefinedSubstanceAdministration might use one or more DefinedExpressionVariableRelationship.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
productDose <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: The quantity of a substance or medication to be administered.</p> <p>EXAMPLE(S): 5 mg 20 mg of drug per kg of subject weight 370MBq</p> <p>OTHER NAME(S):</p> <p>NOTE(S): DefinedSubstanceAdministration.productDose can contain a dose expressed in absolute or relative terms (e.g., mg or mg/kg). ScheduledSubstanceAdministration.activeIngredientDose and PerformedSubstanceAdministration.productDose must contain a dose expressed in absolute terms (e.g., mg). If the DefinedSubstanceAdministration.productDose was expressed in relative terms (e.g., mg/kg), then the absolute dose must have been calculated using one or more observed factors as identified by the DefinedExpressionVariableRelationship.</p>	

Attribute	Notes	Constraints and Tags
periodProductDoseTotal <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> EXPR<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Total of all doses of this agent in a given period of time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The given period of time is defined in dosePeriodCode.</p> <p>This is needed because the dose may not always be derivable, e.g., if it is a string, and because it is often used as a cross-check on dose to ensure mistakes are not made in dosing subjects.</p>	Map:CTR&Rr2 = First dose in FIH Total Dose Unit Map:CTR&Rr2 = First dose in FIH Dose per Day or Total Map:CTR&Rr2 = Maximum dose per Day or Total Map:CTRPv1.0 = SubstanceAdministration.doseTotal Map:CTRPv3.8 = PlannedSubstanceAdministration.doseTotal Map:CTRRr3 = DefinedSubstanceAdministration.dailyDoseTotal Map:CTRv1.0 = DefinedSubstanceAdministration.periodProductDoseTotal Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.doseCheckQuantity Map:HCTv1.0 = CDE 2685005:Preparative Regimen.What was the unit of measure for the total prescribed cumulative dose of total nodal or total abdominal irradiation for the preparative regimen (per the protocol)? Map:HCTv1.0 = CDE 2685003:Preparative Regimen.What was the total prescribed cumulative dose of total nodal or total abdominal irradiation for the preparative regimen (per the protocol)? Map:HCTv1.0 = CDE 3040323:Preparative Regimen.What was the total dose of the planned preparative regimen per the protocol? Map:HCTv1.0 = CDE 3040382:Preparative Regimen.What was the planned total dosage of the radiolabeled monoclonal antibody preparative regimen?
dosePeriodCode <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the period during which the dose total is administered.</p> <p>EXAMPLE(S): daily, course</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGSCC = Model Integrity Map:CTRPv3.8 = PlannedSubstanceAdministration.doseDuration Map:CTRv1.0 = DefinedSubstanceAdministration.dosePeriodCode

Attribute	Notes	Constraints and Tags
doseFrequencyCode <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying how often doses are administered.</p> <p>EXAMPLE(S): BID, TID, QID</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = SubstanceAdministration.doseFrequencyCode Map:CTRPv3.8 = PlannedSubstanceAdministration.doseFrequencyCode Map:CTRv1.0 = DefinedSubstanceAdministration.doseFrequencyCode Map:HCTv1.0 = CDE 2965486.Therapies.What was the fractional schedule of radiation therapy? Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=DOSFRQ Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "DOSFRQ" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "DOSFRQ" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "DOSFRQ" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "DOSFRQ" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "DOSFRQ"
doseRegimen <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Text description of the intended schedule for administering a substance.</p> <p>EXAMPLE(S): 2 weeks on, 2 weeks off</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:CTRPv1.0 = SubstanceAdministration.doseRegimen Map:CTRPv3.8 = PlannedSubstanceAdministration.doseRegimen Map:CTR = Dose regimen Map:CTR = Comparator Route of administration - Add dosage/regimen info Map:CTRr3 = DefinedSubstanceAdministration.doseRegimen Map:CTRv1.0 = DefinedSubstanceAdministration.doseRegimen Map:NCI CRF Standard = CDE 2871669v1.0: Treatment Regimen Name Map:SDTM IGv3.1.1 = CM.CMDOSRGM Map:SDTM IGv3.1.2 = CM.CMDOSRGM Map:SDTM IGv3.1.2 = EX.EXDOSRGM Map:SDTM IGv3.1.3 = EX.EXDOSRGM Map:SDTM IGv3.1.3 = CM.CMDOSRGM

Attribute	Notes	Constraints and Tags
flowRate <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> RTO<PQ,PQ,TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A ratio specifying the speed with which the substance is introduced into the subject.</p> <p>EXAMPLE(S): 100 mL/h 1 g/d 40 mmol/h</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast Administration Profile Sequence > Contrast Flow Rate (0018,1046) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Flow Rate (0018, 1046) Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.rateQuantity

Attribute	Notes	Constraints and Tags
routeOfAdministrationCode <i>Class:</i> DefinedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the physiological path or method of introducing the substance.</p> <p>EXAMPLE(S): oral, intravenous, nasal, intradermal, intracardial</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = Dose.route Map:CTR&Rr2 = IMP Routes of Administration Map:CTR&Rr2 = Placebo Route of administration Map:CTR&Rr2 = First dose in FIH RoA Map:CTR&Rr2 = Maximum dose RoA Map:CTRPv1.0 = SubstanceAdministration.routeOfAdministrationCode Map:CTRPv3.8 = PlannedSubstanceAdministration.routeOfAdministrationCode Map:CTRR = Comparator Route of administration - Add dosage/regimen info Map:CTRR = Route of administration Map:CTRRr3 = DefinedSubstanceAdministration.routeOfAdministrationCode Map:CTRv1.0 = DefinedSubstanceAdministration.routeOfAdministrationCode Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast/Bolus Ingredient Code Sequence (0018,9338) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Route (0018,1040) Map:DICOM = Contrast/Bolus Module - Contrast/Bolus Administration Route Sequence (0018,0014) Map:DICOM = Enhanced PET Isotope Module - Radiopharmaceutical Information Sequence > Administration Route Code Sequence (0054,0302) Map:DICOM = Enhanced Contrast/Bolus Module - Contrast/Bolus Agent Sequence > Contrast/Bolus Administration Route Sequence (0018,0014) Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.routeCode Map:HCTv1.0 = CDE 2740971:Preparative Regimen.What was the route of administration for the planned preparative regimen medication? Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=ROUTE Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "ROUTE" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "ROUTE"

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "ROUTE" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "ROUTE" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "ROUTE"

Class: Epoch

Package: Protocol Representation Sub-Domain

DEFINITION:

One of a set of ordered partitions of a subject's participation in a study. An Epoch represents a state within a study such that subjects in separate arms within that state are comparable.

Each epoch serves a purpose in the study as a whole, typically exposing the subject to a treatment or preparing them for a treatment, or gathering post-treatment data. Activities and activity results control the subject's movement from one epoch to another.

EXAMPLE(S):

A study designed to assess the effects of treatments might have 3 epochs.

A Screening Epoch in which subjects' eligibility is determined and baseline measurements are made.

A Treatment Epoch during which treatments are given and effects of treatment are assessed.

A Follow-up Epoch during which post-treatment assessments are conducted.

OTHER NAME(S):

NOTE(S):

A subject moves from one epoch to another and can only be in one epoch at a time. The subject can only move to an epoch with a greater sequenceNumber. Activities in the same epoch but a different arm need not be similar in time and pattern. Subjects in different arms will not necessarily pass through the same epochs.

Tagged Values:

- Map:C3PRv2.9 = Epoch
- Map:caAERSv2.2 = Epoch
- Map:CTRPv3.8 = Epoch
- Map:CTRv1.0 = Epoch
- Map:PSCv2.6 = Epoch

Connectors

Source	Connector	Target	Notes
Epoch 0..* subdividingEpoch	is a division of	StudyProtocolVersion 1 subdividedStudyProtocolVersion	<p>DESCRIPTION: Each Epoch always is a division of one StudyProtocolVersion. Each StudyProtocolVersion might be divided into one or more Epoch.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PlannedActivity 0..* containedPlannedActivity	occur in	Epoch 0..1 containingEpoch	<p>DESCRIPTION: Each PlannedActivity might occur in one Epoch. Each Epoch might contain one or more PlannedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* containedPerformedActivity	be contained by	Epoch 0..1 containingEpoch	<p>DESCRIPTION: Each PerformedActivity might be contained by one Epoch. Each Epoch might contain one or more PerformedActivity.</p> <p>DEFINITION: Indicates that a performed but unplanned activity is categorized as part of a particular Epoch.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This cannot be derived by looking at the corresponding planned activity because this association is only used for unplanned activities.</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
name <i>Class:</i> Epoch <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A non-unique textual identifier for the epoch.</p> <p>EXAMPLE(S): first treatment epoch, second treatment epoch, first wash-out epoch, second wash-out epoch</p> <p>OTHER NAME(S):</p> <p>NOTE(S): When multiple Epochs have the same purpose (e.g., treatment), then the titles will probably include order numbers to distinguish them.</p>	Map:C3PR = Epoch.name Map:C3PR = PlannedEpoch.name Map:C3PRv2.9 = Epoch.name Map:caAERSv2.2 = Epoch.name Map:CDASHv1.1 = DS.EPOCH Map:CDASHv1.1 = DS.DSNEXT Map:CTOM = StudyTimePoint.epochName Map:CTRPv3.8 = Epoch.name Map:CTRv1.0 = Epoch.name Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component1/epoch.title Map:HL7SD = Epoch.title Map:PSC = Period.name Map:PSC = Epoch.name Map:PSCv2.6 = Epoch.name Map:SDTM IGv3.1.1 = DS.EPOCH Map:SDTM IGv3.1.1 = TA.EPOCH Map:SDTM IGv3.1.2 = EX.EPOCH Map:SDTM IGv3.1.2 = DV.EPOCH Map:SDTM IGv3.1.2 = SE.EPOCH Map:SDTM IGv3.1.2 = TA.EPOCH Map:SDTM IGv3.1.2 = DS.EPOCH Map:SDTM IGv3.1.3 = EX.EPOCH Map:SDTM IGv3.1.3 = DV.EPOCH Map:SDTM IGv3.1.3 = TU.EPOCH Map:SDTM IGv3.1.3 = SE.EPOCH Map:SDTM IGv3.1.3 = TA.EPOCH Map:SDTM IGv3.1.3 = TR.EPOCH Map:SDTM IGv3.1.3 = DS.EPOCH Map:SDTM IGv3.1.3 = RS.EPOCH Map:TDM = StudyDesignEpoch.name
typeCode <i>Class:</i> Epoch <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of epoch.</p> <p>EXAMPLE(S): screening, treatment, follow-up</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = PlannedEpoch.type Map:C3PRv2.9 = Epoch.treatmentIndicator Map:CTRPv3.8 = Epoch.typeCode Map:CTRv1.0 = Epoch.typeCode
sequenceNumber <i>Class:</i> Epoch <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the relative sequential or temporal ordering of this epoch among other similar epochs in a study.</p> <p>EXAMPLE(S): In a Study that has Screening, Treatment and Follow-Up epochs, the sequence number indicates which Epoch precedes the other.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Epoch.epochOrder Map:C3PR = PlannedEpoch.firstEpochIndicator Map:C3PRv2.9 = Epoch.epchOrder Map:caAERSv2.2 = Epoch.order Map:CTRv1.0 = Epoch.sequenceNumber Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component1.sequenceN umber Map:HL7SD = Component2.sequenceNumber Map:TDM = StudyDesignEpoch.epochSequenceNu mber

Attribute	Notes	Constraints and Tags
description <i>Class:</i> Epoch <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the epoch.</p> <p>EXAMPLE(S): "A 2-week period during which eligibility is determined and baseline measurements are taken".</p> <p>"The first treatment epoch is a one-week period during which a single dose of one of the three investigational treatments is administered".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Epoch.descriptionText Map:C3PR = PlannedEpoch.description Map:C3PRv2.9 = Epoch.descriptionText Map:caAERSv2.2 = Epoch.description Map:CTRv1.0 = Epoch.description Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component1/epoch.text Map:HL7SD = Epoch.text Map:TDM = StudyDesignEpoch.description
targetAccrualNumberRange <i>Class:</i> Epoch <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many study subjects to be accrued for the epoch.</p> <p>EXAMPLE(S): The Phase II, one-armed study has a target accrual of 60 accruals.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the summary of all arm accruals in that Epoch. This will be the same as the study level target accrual unless this study has parallel Epochs, in which case the summary will only count the accruals for arms in this Epoch.</p>	Map:C3PRv2.9 = Epoch.accrualCeiling Map:CTRv1.0 = Epoch.targetAccrualNumberRange

Class: InterventionalStudyProtocolVersion

Package: Protocol Representation Sub-Domain

DEFINITION:

A study protocol version in which study subjects or experimental units are assigned by an investigator based on a protocol to receive specific interventions.

EXAMPLE(S):

Version dates for "A Randomized Phase 3 Trial of Treatment 1 and Treatment 2 in Patients with Stage III Colon Cancer"

VERSION 1: Activation February 10, 2004

VERSION 2: Addendum 7 January 4, 2008

VERSION 3: Addendum 8 May 12, 2008

OTHER NAME(S):

NOTE(S):

Study subjects or experimental units may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The study subjects or experimental units are then followed and biomedical and/or health outcomes are assessed.

Tagged Values:

- Map:C3PR = Study.type
- Map:CTGOV = Study Type - Interventional
- Map:CTRPv1.0 = InterventionalStudyProtocol

- Map:CTRPv3.8 = InterventionalStudyProtocol
- Map:CTR = Study Type
- Map:CTRr3 = InterventionalStudy
- Map:CTRr3 = Study.typeCode
- Map:CTRr3 = Study.typeCode
- Map:CTRv1.0 = InterventionalStudyProtocolVersion
- Map:WHO = Study Type

Connectors

Source	Connector	Target	Notes
InterventionalStudyProtocol Version	specializes	StudyProtocolVersion	<p>DESCRIPTION: Each InterventionalStudyProtocol Version always specializes one StudyProtocolVersion. Each StudyProtocolVersion might be specialized by one InterventionalStudyProtocol Version.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RelevantRegulation 0..* governingRelevantRegulatio n	governs	InterventionalStudyProtocol Version 1 governedInterventionalStud yProtocolVersion	<p>DESCRIPTION: Each RelevantRegulation always governs one InterventionalStudyProtocol Version. Each InterventionalStudyProtocol Version might be governed by one or more RelevantRegulation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
interventionTypeCode <i>Class:</i> InterventionalStudyProtocol Version <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of intervention being studied.</p> <p>EXAMPLE(S): Drug, Radiation, Lifestyle</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relevant for categorization or when not conveying the details of the studied intervention.</p>	Map:CTRPv3.8 = InterventionalStudyProtocol.interventionTypeCode Map:CTRRr3 = PlannedIntervention.typeCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.interventionCategoryCode Map:NCI CRF Standard = CDE 2008450v2.0: Prior Therapy Administered Type Map:NCI CRF Standard = CDE 65292v4.0: Systemic Therapy Type Specify Map:NCI CRF Standard = CDE 64208v3.0: Therapy Name Type Map:NCI CRF Standard = CDE 2542520v1.0: Prior Therapy Other Administered Specify Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "INTTYPE" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "INTTYPE" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "INTTYPE" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "INTTYPE" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "INTTYPE"
interventionDescription <i>Class:</i> InterventionalStudyProtocol Version <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A character string that provides the key details of the intervention.</p> <p>EXAMPLE(S): 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).</p> <p>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.)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Intervention Description Map:CTRPv1.0 = InterventionalStudyProtocol.primaryPurposeCode Map:CTRR = Intervention Description Map:CTRR = Description of investigational treatments Map:CTRRr3 = InterventionalStudy.interventionDescription Map:CTRv1.0 = InterventionalStudyProtocolVersion.interventionDescription

Attribute	Notes	Constraints and Tags
interventionGroupQuantity <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the number of intervention groups.</p> <p>EXAMPLE(S): Enter 1 for single-arm study.</p> <p>OTHER NAME(S): Number of Arms</p> <p>NOTE(S): This attribute is potentially derivable once the study design has been defined.</p>	Map:CTGOV = Number of Arms Map:CTRPv1.0 = InterventionalStudyProtocol.numberOfInterventionGroups Map:CTRp3.8 = InterventionalStudyProtocol.numberOfInterventionGroups Map:CTRR = Number of Arms Map:CTRRr3 = InterventionalStudy.interventionGroupQuantity Map:CTRv1.0 = InterventionalStudyProtocolVersion.interventionGroupQuantity Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "NARMS" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "NARMS"
controlTypeCode <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of comparison or comparator against which the study treatment is evaluated.</p> <p>EXAMPLE(S): placebo, active, historical, uncontrolled, dose comparison</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = InterventionalStudyProtocol.controlType Map:CTRR = Control Map:CTRRr3 = InterventionalStudy.controlTypeCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.controlTypeCode Map:SDTM IGv3.1.2 = TSVAL where TSPARMCD=TCNTRL Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TCNTRL" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TCNTRL" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TCNTRL" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TCNTRL" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TCNTRL"
controlConcurrencyTypeCode <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the temporal relationships of the control to the study intervention.</p> <p>EXAMPLE(S): concurrent, historical, pre/post (patient owned control)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = InterventionalStudyProtocol.controlConcurrencyType Map:CTRR = Concurrency Map:CTRRr3 = InterventionalStudy.controlConcurrencyTypeCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.controlConcurrencyTypeCode

Attribute	Notes	Constraints and Tags
allocationCode <i>Class:</i> InterventionalStudyProtocol <i>Version</i> <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the method of assigning experimental units to treatment or control groups.</p> <p>EXAMPLE(S): n/a, randomized controlled study, non-randomized study</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Study Design Allocation Map:CTOM = Protocol.randomizedIndicator Map:CTRPv1.0 = InterventionalStudyProtocol.allocationCode Map:CTRPv3.8 = InterventionalStudyProtocol.allocationCode Map:CTR = Randomization Map:CTRr3 = InterventionalStudy.allocationCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.allocationCode Map:SDTM IGv3.1.2 = TSVAL where TSPARMCD=RANDOM Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "RANDOM" Map:SDTM IGv3.1.3 = TS.TSVCDEF WHERE TSPARMCD = "RANDOM" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "RANDOM" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "RANDOM" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "RANDOM"

Attribute	Notes	Constraints and Tags
blindingSchemaCode <i>Class:</i> InterventionalStudyProtocol Version <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the type of masking used to ensure that the results are not biased by the study subjects or investigators.</p> <p>EXAMPLE(S): 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.</p> <p>Open Label, Double Blind, Single Blind</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Study.blindedIndicator Map:CTGOV = Study Design Masking Map:CTOM = Protocol.blindedIndicator Map:CTR&Rr2 = Trial design Single blind Map:CTR&Rr2 = Trial design Double blind Map:CTR&Rr2 = Trial design Parallel group Map:CTRPv1.0 = InterventionalStudyProtocol.blindingSchemaCode Map:CTRPv3.8 = InterventionalStudyProtocol.blindingSchemaCode Map:CTRR = Blinding Design Map:CTRRr3 = InterventionalStudy.blindingSchemaCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.blindingSchemaCode Map:SDTM IGv3.1.2 = TSVAL where TSPARMCD=TBLIND Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TBLIND" Map:SDTM IGv3.1.3 = TS.TSVALNCF WHERE TSPARMCD = "TBLIND" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TBLIND" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TBLIND" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TBLIND" Map:WHO = Masking
blindedRoleCode <i>Class:</i> InterventionalStudyProtocol Version <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the roles of individuals who are masked for single or double blind studies.</p> <p>EXAMPLE(S): subject, caregiver, investigator, outcomes assessor</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Masking Role Map:CTRPv1.0 = InterventionalStudyProtocol.blindedRoleCode Map:CTRPv3.8 = InterventionalStudyProtocol.blindedRoleCode Map:CTRR = Blinded Roles Map:CTRRr3 = InterventionalStudy.blindedRoleCode Map:CTRv1.0 = InterventionalStudyProtocolVersion.blindedRoleCode Map:WHO = Study Type Masking Who is Blinded

Attribute	Notes	Constraints and Tags
studyAgentRandomizationFraction <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A number representing the quantity of study subjects in the overall study who receive at least one study agent (as opposed to placebo) divided by the quantity of subjects in the study overall - independent of dosage or other protocol variations.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value can be thought of as the percentage of study subjects who will be exposed to the study agent(s), though it is expressed as a real number with a maximum value of 1.0.</p>	Map:CTRv1.0 = InterventionalStudyProtocolVersion.randomizationQuotient
acceptsHealthyVolunteersIndicator <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: 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.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Accepts Healthy Volunteers? Map:CTOM = Accepts healthy volunteers Map:CTRv1.0 = InterventionalStudyProtocol.acceptsHealthyVolunteersIndicator Map:CTRv3.8 = StudyProtocol.acceptsHealthyVolunteersIndicator Map:CTRr3 = InterventionalStudy.acceptsHealthyVolunteersIndicator Map:CTRv1.0 = InterventionalStudyProtocolVersion.acceptsHealthyVolunteersIndicator
dataMonitoringCommitteeIndicator <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether a data monitoring committee is appointed to the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the existence of an association between StudyProtocolVersion and StudyOversightAuthority where the associated OversightCommittee.typeCode= "data monitoring committee".</p>	Map:CTRv3.8 = StudyProtocol.dataMonitoringCommitteeAppointedIndicator Map:CTRr3 = Study.dataMonitoringCommitteeIndicator
confirmedResponseMinimumDuration <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The protocol specified minimum amount of time needed to meet the definition of a confirmed response to treatment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "CRMDUR" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "CRMDUR"

Attribute	Notes	Constraints and Tags
stableDiseaseMinimumDuration <i>Class:</i> InterventionalStudyProtocolVersion <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The protocol specified minimum amount of time needed to meet the definition of stable disease.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "SDMDUR" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "SDMDUR"

Class: ObservationalStudyProtocolVersion

Package: Protocol Representation Sub-Domain

DEFINITION:

A study protocol version in which biomedical and/or health outcomes are assessed in pre-defined groups of study subjects or experimental units. Study subjects or experimental units 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.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = Study.type
- Map:CTGOV = Study Type - Observational
- Map:CTRR = Study Type
- Map:CTRr3 = Study.typeCode
- Map:CTRr3 = ObservationalStudy
- Map:CTRv1.0 = ObservationalStudyProtocolVersion
- Map:WHO = Study Type

Connectors

Source	Connector	Target	Notes
ObservationalStudyProtocolVersion	specializes	StudyProtocolVersion	<p>DESCRIPTION: Each ObservationalStudyProtocolVersion always specializes one StudyProtocolVersion. Each StudyProtocolVersion might be specialized by one ObservationalStudyProtocolVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
samplingMethodCode <i>Class:</i> ObservationalStudyProtocol Version <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the process used to define a representative set of a population for a study.</p> <p>EXAMPLE(S): 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.</p> <p>A Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Sampling Method Map:CTRPv1.0 = ObservationalStudyProtocol.samplingMethodCode Map:CTRr3 = ObservationalStudy.samplingMethodCode Map:CTRv1.0 = ObservationalStudyProtocolVersion.samplingMethodCode
timePerspectiveCode <i>Class:</i> ObservationalStudyProtocol Version <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the temporal relationship of observation period to time of subject enrollment.</p> <p>EXAMPLE(S): prospective, retrospective, cross-sectional, other</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Time Perspective Map:CTRPv1.0 = ObservationalStudyProtocol.timePerspectiveCode Map:CTRr3 = ObservationalStudy.timePerspectiveCode Map:CTRv1.0 = ObservationalStudyProtocolVersion.timePerspectiveCode
specimenRetentionIndicator <i>Class:</i> ObservationalStudyProtocol Version <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether a biological specimen is retained beyond the duration of the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRr3 = StudyAgent.retentionCode
specimenAvailableForDNAExtractionIndicator <i>Class:</i> ObservationalStudyProtocol Version <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether any biological specimen has the potential for DNA extraction.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Specimens with the potential for DNA extraction include frozen tissue and whole blood whereas specimens without the potential for DNA extraction include fixed tissue and plasma.</p>	Map:CTRr3 = StudyAgent.retentionCode

Class: PlannedActivity

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur or start at some point in the context of a particular study or experiment.

EXAMPLE(S):

Pregnancy tests are planned for study subjects who are females of childbearing potential.

OTHER NAME(S):**NOTE(S):**

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 the representation of concepts in previous versions of BRIDG such as StudyCells, StudySegments and StudySubjectEncounters. A PlannedActivity 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 PlannedActivity is not assigned to a particular Subject, StudySubject, or ExperimentalUnit, but to a "kind of" Subject, StudySubject, or ExperimentalUnit.

Tagged Values:

- Map:C3PRv2.9 = InclusionEligibilityCriteria
- Map:C3PRv2.9 = EligibilityCriteria
- Map:C3PRv2.9 = Arm
- Map:C3PRv2.9 = PhoneCallRandomization
- Map:C3PRv2.9 = Randomization
- Map:C3PRv2.9 = ExclusionEligibilityCriteria
- Map:CTRPv3.8 = Intervention
- Map:CTRPv3.8 = PlannedActivity
- Map:CTRRr3 = PlannedActivity
- Map:CTRRr3 = PlannedIntervention
- Map:CTRv1.0 = PlannedActivity
- Map:LabViewer2.2 = Activity.plannedIndicator
- Map:LabViewer2.2 = SpecimenCollection.plannedIndicator
- Map:LSDAMv2.2.3Plus = PlannedActivity
- Map:PSCv2.6 = StudySegment
- Map:PSCv2.6 = PlannedActivity
- Map:PSCv2.6 = Period
- Map:SDTM IGV3.1.2 = TI.DOMAIN

Connectors

Source	Connector	Target	Notes
PlannedActivity	specializes	Activity	<p>DESCRIPTION: Each PlannedActivity always specializes one Activity. Each Activity might be specialized by one PlannedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedActivity 0..* locatedPlannedActivity	take place in	ServiceDeliveryLocation 0..1 locatingServiceDeliveryLocation	<p>DESCRIPTION: Each PlannedActivity might take place in one ServiceDeliveryLocation. Each ServiceDeliveryLocation might be the location for one or more</p>

Source	Connector	Target	Notes
			PlannedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedActivity 0..* containedPlannedActivity	occur in	Epoch 0..1 containingEpoch	DESCRIPTION: Each PlannedActivity might occur in one Epoch. Each Epoch might contain one or more PlannedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedActivity 0..* usingPlannedActivity	be a use of	DefinedActivity 0..1 usedDefinedActivity	DESCRIPTION: Each PlannedActivity might be a use of one DefinedActivity. Each DefinedActivity might be used by one or more PlannedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedActivity 0..* usingPlannedActivity	be a use of	StudyActivity 0..1 usedStudyActivity	DESCRIPTION: Each PlannedActivity might be a use of one StudyActivity. Each StudyActivity might be used as one or more PlannedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedCompositionRelatio nship 0..* componentPlannedComposit ionRelationship	is the component of	PlannedActivity 1 compositePlannedActivity	DESCRIPTION: Each PlannedCompositionRelatio nship always is the component of one

Source	Connector	Target	Notes
			<p>PlannedActivity. Each PlannedActivity might be the parent of one or more PlannedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedNotification	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedNotification always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCompositionRelationship 0..* compositePlannedCompositionRelationship	is the parent of	PlannedActivity 1 componentPlannedActivity	<p>DESCRIPTION: Each PlannedCompositionRelationship always is the parent of one PlannedActivity. Each PlannedActivity might be the component of one or more PlannedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ScheduledActivity 0..* instantiatingScheduledActivity	instantiates	PlannedActivity 1 instantiatedPlannedActivity	<p>DESCRIPTION: Each ScheduledActivity always instantiates one PlannedActivity. Each PlannedActivity might be instantiated by one or more ScheduledActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
PlannedExperimentalUnitAllocationResult 0..* assigningPlannedExperimentalUnitAllocationResult	is an option through which experimental units are assigned to	PlannedActivity 1 assignedPlannedActivity	<p>DESCRIPTION: Each PlannedExperimentalUnitAllocationResult always is an option through which experimental units are assigned to one PlannedActivity. Each PlannedActivity might be the activity executed for one or more PlannedExperimentalUnitAllocationResult.</p> <p>DEFINITION: This association identifies a relationship between an allocation option and the path through which an experimental unit will go if assigned to this option.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCompositionRelationship 0..* compositePlannedCriterionGroupCompositionRelationship	be the parent of	PlannedActivity 0..1 componentPlannedActivity	<p>DESCRIPTION: Each PlannedCriterionGroupCompositionRelationship might be the parent of one PlannedActivity. Each PlannedActivity might be the component of one or more PlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedSubjectActivityGroup	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedSubjectActivityGroup always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedSubjectActivityGroup.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Arm 0..* containingArm	contains	PlannedActivity 1..* containedPlannedActivity	<p>DESCRIPTION: Each Arm always contains one or more PlannedActivity. Each PlannedActivity might occur in one or more Arm.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedOptionRelationship 0..* optionPlannedOptionRelationship	is an option that can satisfy	PlannedActivity 1 choicePlannedActivity	<p>DESCRIPTION: Each PlannedOptionRelationship always is an option that can satisfy one PlannedActivity. Each PlannedActivity might be a choice that has as option one or more PlannedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	PlannedActivity 0..1 instantiatedPlannedActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one PlannedActivity. Each PlannedActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedExperimentalUnitAI location	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedExperimentalUnitAI</p>

Source	Connector	Target	Notes
			<p>location always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedExperimentalUnitAl location.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* choicePlannedCriterionGrou pOptionRelationship	be a choice that has as option	PlannedActivity 0..1 optionPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupOpti onRelationship might be a choice that has as option one PlannedActivity. Each PlannedActivity might be an option that can satisfy one or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelati onship 0..* contingentPlannedContinge ntOnRelationship	be contingent upon	PlannedActivity 0..1 prerequisitePlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedContingentOnRelati onship might be contingent upon one PlannedActivity. Each PlannedActivity might be a condition for one or more PlannedContingentOnRelati onship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedOptionRelationship 0..* choicePlannedOptionRelatio nship	is a choice that has as option	PlannedActivity 1 optionPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedOptionRelationship always is a choice that has as option one PlannedActivity. Each PlannedActivity might be an</p>

Source	Connector	Target	Notes
			<p>option that can satisfy one or more PlannedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedRepeatActivityUntilRule 0..* triggeringPlannedRepeatActivityUntilRule	triggers the cessation of	PlannedActivity 1 repeatedPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedRepeatActivityUntil Rule always triggers the cessation of one PlannedActivity. Each PlannedActivity might be repeated until one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedRepeatActivityUntilRule 0..* repeatedPlannedRepeatActivityUntilRule	be repeated until	PlannedActivity 0..1 triggeringPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedRepeatActivityUntil Rule might be repeated until one PlannedActivity. Each PlannedActivity might trigger the cessation of one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedEligibilityCriterion	specializes	PlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedEligibilityCriterion always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedEligibilityCriterion.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedContingentOnRelationship 0..* prerequisitePlannedContingentOnRelationship	is a condition for	PlannedActivity 1 contingentPlannedActivity	DESCRIPTION: Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity might be contingent upon one or more PlannedContingentOnRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
name <i>Class:</i> PlannedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A non-unique textual identifier for the planned activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = PlannedStudyCell.name Map:C3PRv2.9 = PlannedNotification.eventName Map:C3PRv2.9 = Arm.name Map:CDASHv1.1 = EG.VISIT Map:CDASHv1.1 = PE.VISIT Map:CDASHv1.1 = EG.EGTPT Map:CDASHv1.1 = VS.VISIT Map:CDASHv1.1 = LB.LBTPT Map:CDASHv1.1 = VS.VSTPT Map:CDASHv1.1 = IE.VISIT Map:CDASHv1.1 = EX.EXTPT Map:CDASHv1.1 = DA.VISIT Map:CDASHv1.1 = LB.VISIT Map:CTOM = StudyTimePoint.visitName Map:CTOM = StudyTimePoint.courseNumber Map:CTRPv1.0 = SubstanceAdministration.name Map:CTRPv1.0 = PlannedActivity.name Map:CTRPv1.0 = PlannedObservation.name Map:CTRPv3.8 = Intervention.name Map:CTRPv3.8 = PlannedEligibilityCriterion.criterionName Map:CTRPv3.8 = PerformedActivity.name Map:CTRPv3.8 = PlannedActivity.alternateName Map:CTRr3 = PlannedIntervention.name Map:CTRv1.0 = PlannedActivity.name Map:DICOM = Clinical Trial Study Module - Clinical Trial Time Point Description (0012,0051) Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component4/timePointEventDefinition.title Map:LSDAMv2.2.3Plus = PlannedActivity.name Map:PGx v1.0 = PG.VISIT Map:PGx v1.0 = BS.VISIT Map:PGx v1.0 = PF.VISIT Map:PGx v1.0 = PF.PFTPTREF Map:PGx v1.0 = BE.VISIT Map:PGx v1.0 = SB.VISIT Map:PSC = Arm.name Map:PSCv2.6 = StudySegment.name Map:PSCv2.6 = Period.name Map:SDTM IGv3.1.1 = VS.VSTPTNUM Map:SDTM IGv3.1.1 = QS.QSTPTNUM Map:SDTM IGv3.1.1 = LB.LBTPTNUM Map:SDTM IGv3.1.1 = SU.VISIT Map:SDTM IGv3.1.1 = QS.VISIT

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.1 = LB.VISIT Map:SDTM IGv3.1.1 = DA.VISIT Map:SDTM IGv3.1.1 = VS.VISIT Map:SDTM IGv3.1.1 = TV.VISIT Map:SDTM IGv3.1.1 = TA.ETCD Map:SDTM IGv3.1.1 = MH.VISIT Map:SDTM IGv3.1.1 = SV.VISIT Map:SDTM IGv3.1.1 = TE.ETCD Map:SDTM IGv3.1.1 = PE.VISIT Map:SDTM IGv3.1.1 = EG.EGTPTNUM Map:SDTM IGv3.1.1 = IE.VISIT Map:SDTM IGv3.1.1 = EG.VISIT Map:SDTM IGv3.1.2 = EG.EGTPT Map:SDTM IGv3.1.2 = PC.VISIT Map:SDTM IGv3.1.2 = DA.VISIT Map:SDTM IGv3.1.2 = MS.VISIT Map:SDTM IGv3.1.2 = PC.PCTPT Map:SDTM IGv3.1.2 = MB.MBTPT Map:SDTM IGv3.1.2 = IE.VISIT Map:SDTM IGv3.1.2 = FA.VISIT Map:SDTM IGv3.1.2 = QS.QSTPT Map:SDTM IGv3.1.2 = TV.VISIT Map:SDTM IGv3.1.2 = QS.VISIT Map:SDTM IGv3.1.2 = EX.EXTP Map:SDTM IGv3.1.2 = VS.VISIT Map:SDTM IGv3.1.2 = LB.LBTPT Map:SDTM IGv3.1.2 = SV.VISIT Map:SDTM IGv3.1.2 = LB.VISIT Map:SDTM IGv3.1.2 = MS.MSTPT Map:SDTM IGv3.1.2 = VS.VSTPT Map:SDTM IGv3.1.2 = MB.VISIT Map:SDTM IGv3.1.2 = EG.VISIT Map:SDTM IGv3.1.2 = PE.VISIT Map:SDTM IGv3.1.3 = SE.ELEMENT. Map:SDTM IGv3.1.3 = QS.QSTPTREF Map:SDTM IGv3.1.3 = QS.VISIT Map:SDTM IGv3.1.3 = RS.VISIT Map:SDTM IGv3.1.3 = PE.VISIT Map:SDTM IGv3.1.3 = SV.VISIT Map:SDTM IGv3.1.3 = TR.VISIT Map:SDTM IGv3.1.3 = TU.VISIT Map:SDTM IGv3.1.3 = PC.VISIT Map:SDTM IGv3.1.3 = VS.VISIT Map:SDTM IGv3.1.3 = IE.VISIT Map:SDTM IGv3.1.3 = VS.VSTPTREF Map:SDTM IGv3.1.3 = TV.VISIT Map:SDTM IGv3.1.3 = PC.PCTRTRREF Map:SDTM IGv3.1.3 = MS.VISIT Map:SDTM IGv3.1.3 = MB.VISIT Map:SDTM IGv3.1.3 = MB.MBTPTREF Map:SDTM IGv3.1.3 = LB.LBTPTREF Map:SDTM IGv3.1.3 = FA.VISIT Map:SDTM IGv3.1.3 = EX.EXTPREF

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = EG.VISIT Map:SDTM IGv3.1.3 = EG.EGTPTRREF Map:SDTM IGv3.1.3 = DA.VISIT Map:SDTM IGv3.1.3 = LB.VISIT Map:TDM = StudyDesignElement.name Map:TDM = SubjectTrialContact.eventAlias
description <i>Class:</i> PlannedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the planned activity.</p> <p>EXAMPLE(S): In a migraine study, the Wait activity may have a description of "Wait until first grade 2 or 3 migraine".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = Arm.descriptionText Map:caAERSv2.2 = TreatmentAssignment.doseLevelOrder Map:CTRPv3.8 = Activity.textDescription Map:CTRPv3.8 = PlannedSubstanceAdministration.doseDescription Map:CTRr3 = PlannedIntervention.description Map:CTRr3 = PlannedActivity.description Map:CTRv1.0 = PlannedActivity.description Map:LSDAMv2.2.3Plus = PlannedActivity.description Map:PSCv2.6 = PlannedActivity.details Map:SDTM IGv3.1.1 = TA.ELEMENT Map:SDTM IGv3.1.1 = TE.ELEMENT Map:TDM = StudyDesignElement.description

Attribute	Notes	Constraints and Tags
blindedDescription <i>Class:</i> PlannedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the planned activity from the point of view of a blinded participant (study subject or study investigator).</p> <p>EXAMPLE(S): 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.</p> <p>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".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = PlannedStudyCell.blindedDescription Map:CTRRr3 = PlannedActivity.blindedDescription Map:CTRv1.0 = PlannedActivity.blindedDescription Map:TDM = TrialCell.blindedDescription
transitionDescription <i>Class:</i> PlannedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the possible alternative paths or sequences of elements with associated conditions through which the subject may traverse.</p> <p>EXAMPLE(S): "If disease progression, go to Follow-up Epoch." "If progression, skip to Follow-up. If no progression, but subject is ineligible for or does not consent to surgery, skip to Addl Chemo." "Responders go to washout."</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TA.TATRANS

Attribute	Notes	Constraints and Tags
purpose <i>Class:</i> PlannedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The reason for the planned activity.</p> <p>EXAMPLE(S): treating a disease (treatment), determining eligibility for a study (screening)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Per GForge Tracker item 31402, this attribute is redundant and we're deprecating it in favor of the existing Activity.reasonCode.</p>	Map:CTRv1.0 = PlannedActivity.purpose Map:TDMv2 = (New content)
studyDayRange <i>Class:</i> PlannedActivity <i>Datatype:</i> IVL<INT> <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The relative timing for a planned activity expressed as the number of days offset from the study-defined reference activity (e.g., date of registration, start of treatment) for a particular subject, study subject or experimental unit.</p> <p>EXAMPLE(S): Day 1, Days 10-20</p> <p>OTHER NAME(S): Visit Day</p> <p>NOTE(S): Derived from all the pauseQuantity values of the composite activity structures that this activity is a part of minus the offset of the reference activity.</p> <p>The study-defined reference activity can be different from study to study. The study day for a date after this reference activity is a positive integer calculated as the difference in the two dates + 1. The study day for dates before the reference activity is a negative integer calculated as the difference between the two dates. Note that this means there is no "Day 0."</p>	Map:CTRv1.0 = PlannedActivity.studyDayRange Map:PGx v1.0 = SB.VISITDY Map:PGx v1.0 = BE.VISITDY Map:PGx v1.0 = PG.VISITDY Map:PGx v1.0 = PF.VISITDY Map:PGx v1.0 = BS.VISITDY Map:SDTM IGv3.1.2 = TV.VISITDY Map:SDTM IGv3.1.2 = QS.VISITDY Map:SDTM IGv3.1.2 = PC.VISITDY Map:SDTM IGv3.1.2 = FA.VISITDY Map:SDTM IGv3.1.2 = SV.VISITDY Map:SDTM IGv3.1.2 = EG.VISITDY Map:SDTM IGv3.1.2 = DA.VISITDY Map:SDTM IGv3.1.2 = PE.VISITDY Map:SDTM IGv3.1.2 = MS.VISITDY Map:SDTM IGv3.1.2 = VS.VISITDY Map:SDTM IGv3.1.2 = IE.VISITDY Map:SDTM IGv3.1.2 = MB.VISITDY Map:SDTM IGv3.1.2 = LB.VISITDY Map:SDTM IGv3.1.3 = RS.VISITDY Map:SDTM IGv3.1.3 = TR.VISITDY Map:SDTM IGv3.1.3 = VS.VISITDY Map:SDTM IGv3.1.3 = SV.VISITDY Map:SDTM IGv3.1.3 = DA.VISITDY Map:SDTM IGv3.1.3 = FA.VISITDY Map:SDTM IGv3.1.3 = IE.VISITDY Map:SDTM IGv3.1.3 = LB.VISITDY Map:SDTM IGv3.1.3 = MB.VISITDY Map:SDTM IGv3.1.3 = MS.VISITDY Map:SDTM IGv3.1.3 = PC.VISITDY Map:SDTM IGv3.1.3 = TV.VISITDY Map:SDTM IGv3.1.3 = PE.VISITDY Map:SDTM IGv3.1.3 = QS.VISITDY Map:SDTM IGv3.1.3 = TU.VISITDY

Attribute	Notes	Constraints and Tags
duration <i>Class:</i> PlannedActivity <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The intended period of time for the planned activity as defined by the study or experiment.</p> <p>EXAMPLE(S): 6 weeks may be the planned duration for a composite activity that represents the activities occurring during an epoch on arm A.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTR&Rr2 = Maximum duration of treatment Map:CTRRr3 = PlannedActivity.plannedDuration Map:CTRv1.0 = PlannedActivity.duration Map:CTRv1.0 = DefinedActivity.duration Map:FDA HL7 SD SD DSTU2012 = plannedStudy/component4/timePointEventDefinition.effectiveTime Map:LabViewer2.2 = Activity.plannedTimeElapsed Map:LabViewer2.2 = SpecimenCollection.plannedTimeElapsedDescription Map:LabViewer2.2 = plannedTimeElapsedDescription Map:LabViewer2.2 = SpecimenCollection.plannedTimeElapsed Map:LSDAMv2.2.3Plus = PlannedActivity.plannedDuration Map:PSC = Duration.units Map:PSC = Duration.quantity Map:PSCv2.6 = Duration.units Map:PSCv2.6 = StudySegment.cycleLength Map:PSCv2.6 = Duration.quantity Map:SDTM IGv3.1.1 = TE.TEDUR Map:SDTM IGv3.1.2 = TE.TEDUR
repeatFrequencyCode <i>Class:</i> PlannedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the number of occurrences of a planned activity within a given time period.</p> <p>EXAMPLE(S): BID = Two times per day, at unspecified times (does not necessarily imply that these are 12 hours apart) Q12H = Every twelve hours</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRv1.0 = PlannedActivity.repeatFrequencyCode Map:TDM = CyclingRule

Attribute	Notes	Constraints and Tags
repeatFrequencyRatio <i>Class:</i> PlannedActivity <i>Datatype:</i> RTO<INT.NONNEG,PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A ratio representing the number of occurrences of a planned activity within a given time period.</p> <p>EXAMPLE(S): Once per 12 hours 2 times per day</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRv1.0 = PlannedActivity.repeatFrequencyRatio Map:TDM = CyclingRule
repeatQuantityRange <i>Class:</i> PlannedActivity <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many times the planned activity occurs.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the frequency is more than once a day, this is still interpreted per time, e.g. BID for 5 days is 10 repeats.</p>	Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:PSC = Period.repetitions Map:PSCv2.6 = Period.repetitions Map:TDM = CyclingRule
repeatDuration <i>Class:</i> PlannedActivity <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The period of time over which the planned activity is repeated.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from repeatQuantity and repeatFrequencyCode or repeatFrequencyRatio (constraint allows only one). 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 for a domain analysis model.</p>	Map:CTRPv1.0 = PlannedEligibilityCriterion.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedActivity.plannedRangeOfRepetitions Map:CTRPv1.0 = PlannedObservation.plannedRangeOfRepetitions Map:CTRPv1.0 = SubstanceAdministration.plannedRangeOfRepetitions Map:CTRv1.0 = PlannedActivity.repeatDuration Map:TDM = CyclingRule

Attribute	Notes	Constraints and Tags
agentAdministrationCare <i>Class:</i> PlannedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the level of healthcare (care setting) required by the subject based on the nature of the procedure.</p> <p>EXAMPLE(S): Some, but not all, agents given as inpatient All agents given as inpatient All agents given as outpatient</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE 2956638:Therapies. What was the protocol requirement type:
interruptibleIndicator <i>Class:</i> PlannedActivity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the planned activity is interruptable by asynchronous events.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This may only be useful for PlannedSubjectActivityGroups or administrative activities.</p>	Map:HL7SDr1 = TimePointEventDefinition.interruptibleInd

Class: PlannedCompositionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a composite activity and a component activity that comprises it, i.e. parent and child activities where all activities are intended to occur at some point in the context of a particular study or experiment.

EXAMPLE(S):

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

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedCompositionRelationship
- Map:HL7SD = PlannedActivity.precondition1.conjunctionCode
- Map:HL7SD = EligibilityCriterion.Precondition2.conjunctionCode
- Map:LSDAMv2.2.3Plus = PlannedCompositionRelationship
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
PlannedCompositionRelatio	is the component of	PlannedActivity	DESCRIPTION:

Source	Connector	Target	Notes
nship 0..* componentPlannedCompositionRelationship		1 compositePlannedActivity	Each PlannedCompositionRelationship always is the component of one PlannedActivity. Each PlannedActivity might be the parent of one or more PlannedCompositionRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedCompositionRelationship 0..* compositePlannedCompositionRelationship	is the parent of	PlannedActivity 1 componentPlannedActivity	DESCRIPTION: Each PlannedCompositionRelationship always is the parent of one PlannedActivity. Each PlannedActivity might be the component of one or more PlannedCompositionRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
sequenceNumber <i>Class:</i> PlannedCompositionRelationship <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In a course of treatment (a composite activity) that is composed of a chemotherapy activity and a radiotherapy activity, the sequence number indicates which component activity precedes the other.</p>	Map:C3PR = EligibilityCriterion.questionNumber Map:C3PRv2.9 = StratificationCriterion.questionNumber Map:C3PRv2.9 = EligibilityCriteria.questionNumber Map:CTOM = ActivityRelationship.sequenceNumber Map:CTrv1.0 = PlannedCompositionRelationship.sequenceNumber Map:CTrv1.0 = PerformedEligibilityCriterion.displayOrder Map:HL7SD = PlannedStudy.Component2.sequenceNumber Map:LSDAMv2.2.3Plus = PlannedCompositionRelationship.sequenceNumber Map:PSCv2.6 = PlannedActivity.weight Map:SDTM IGv3.1.3 = TA.TAETORD Map:SDTM IGv3.1.3 = SE.TAETORD Map:SDTM IGv3.1.3 = EX.TAETORD

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> PlannedCompositionRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A visit is composed of a physical exam at the beginning <u>of the visit</u>, a drug administration 30 minutes <u>into the visit</u>, and a blood test 2 hours <u>into the visit</u> – the pauseQuantityRange for the physical exam is 0 minutes, 30 minutes for the drug administration and 2 hours for the blood test</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:HL7SD = PlannedStudy.Component2.pauseQuantity Map:Lab = Activity.plannedTimeElapsed Map:LSDAMv2.2.3Plus = PlannedCompositionRelationship.pauseQuantity Map:PSC = PlannedEvent.day Map:PSC = PlannedEvent.units Map:PSC = PlannedEvent.startDay Map:PSCv2.6 = PlannedActivity.day Map:PSCv2.6 = Period.startDay Map:SDTM IGv3.1.1 = EX.EXELTM Map:SDTM IGv3.1.2 = EX.EXELTM Map:SDTM IGv3.1.2 = MB.MBELTM Map:SDTM IGv3.1.2 = PC.PCELTM Map:SDTM IGv3.1.2 = QS.QSELTM Map:SDTM IGv3.1.2 = MS.MSELTM Map:SDTM IGv3.1.2 = EG.EGELTM Map:SDTM IGv3.1.2 = VS.VSELTM Map:SDTM IGv3.1.2 = LB.LBELTM
joinCode <i>Class:</i> PlannedCompositionRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether, and how, a specific activity in a set of parallel activities should come together before subsequent activities can begin.</p> <p>EXAMPLE(S): Wait for this activity to complete before the subsequent activity; Terminate this activity as soon as all parallel "wait" activities are completed (and if this activity hasn't started yet, don't start it at all); Continue this activity after all "wait" activities complete, but don't wait for it to complete before beginning subsequent activities.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PlannedCompositionRelationship.joinCode

Class: PlannedContingentOnRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a planned activity and some criteria to determine if the activity should occur where all activities are intended to occur at some point in the context of a particular study or experiment.

EXAMPLE(S):

Only perform a certain lab test if drug X was administered. (target = another activity)

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)

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))".

OTHER NAME(S):**NOTE(S):**

The criteria may be 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

To evaluate whether the contingency was satisfied, the simple existence of a PerformedActivity (or subclass) related to the DefinedActivity (or subclass) is not enough by itself. The PerformedActivity.statusCode and

PerformedActivity.negativeIndicator must also be checked to ensure that the activity was actually performed.

PerformedActivity.statusCode must be "Completed" and PerformedActivity.negativeIndicator must not be "true".

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedContingentOnRelationship
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
PlannedContingentOnRelationship 0..*	be contingent upon	PlannedCriterionGroup 0..1 prerequisitePlannedCriterionGroup	<p>DESCRIPTION: Each PlannedContingentOnRelationship might be contingent upon one PlannedCriterionGroup. Each PlannedCriterionGroup might be a condition for one or more PlannedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelationship 0..*	be contingent upon	DefinedObservationResult 0..1 prerequisiteDefinedObservationResult	<p>DESCRIPTION: Each PlannedContingentOnRelationship might be contingent upon one DefinedObservationResult.</p>

Source	Connector	Target	Notes
			<p>Each DefinedObservationResult might be a condition for one or more PlannedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelationship 0..* contingentPlannedContingentOnRelationship	be contingent upon	PlannedActivity 0..1 prerequisitePlannedActivity	<p>DESCRIPTION: Each PlannedContingentOnRelationship might be contingent upon one PlannedActivity. Each PlannedActivity might be a condition for one or more PlannedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelationship 0..* prerequisitePlannedContingentOnRelationship	is a condition for	PlannedActivity 1 contingentPlannedActivity	<p>DESCRIPTION: Each PlannedContingentOnRelationship always is a condition for one PlannedActivity. Each PlannedActivity might be contingent upon one or more PlannedContingentOnRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> PlannedContingentOnRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S): OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Constraints and Tags Map:HL7SDr1 = Precondition3.priorityNumber

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> PlannedContingentOnRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): If drug X was administered, perform lab test Y 1 hour afterwards (contingency target = another activity) – the pauseQuantityRange is 1 hour (minimum and maximum bounds of the range are the same)</p> <p>Only perform a substance administration of drug X within 10 minutes if the blood pressure was over some threshold number (target = observation result from another activity that is an observation) – the pauseQuantityRange is 0-10 minutes</p> <p>Only perform a substance administration of drug Y within 10 minutes 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 (target = group of criteria, i.e. "(A and (B or C))" – the pauseQuantityRange is 0-10 minutes</p> <p>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 = "false" and "after the end of" = "true".</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:caAERSv2.2 = PlannedNotification.interval Map:Lab = Activity.plannedTimeElapsed Map:PGx v1.0 = PF.PFELTM Map:PGx v1.0 = BS.BSTPT Map:PGx v1.0 = BS.BSELTM Map:PGx v1.0 = PF.PFTPT Map:PGx v1.0 = PG.PGTPT Map:PSC = PlannedEvent.startDay Map:PSC = PlannedEvent.units Map:PSC = PlannedEvent.day Map:SDTM IGv3.1.1 = EX.EXELTM Map:SDTM IGv3.1.2 = VS.VSELTM Map:SDTM IGv3.1.2 = EG.EGELTM Map:SDTM IGv3.1.2 = PC.PCELTM Map:SDTM IGv3.1.2 = MS.MSELTM Map:SDTM IGv3.1.2 = MB.MBELTM Map:SDTM IGv3.1.2 = EX.EXELTM Map:SDTM IGv3.1.2 = LB.LBELTM Map:SDTM IGv3.1.2 = QS.QSELTM Map:SDTM IGv3.1.3 = VS.VSELTM Map:SDTM IGv3.1.3 = QS.QSELTM Map:SDTM IGv3.1.3 = MS.MSTPT Map:SDTM IGv3.1.3 = PC.PCTPT Map:SDTM IGv3.1.3 = PC.PCELTM Map:SDTM IGv3.1.3 = VS.VSTPT Map:SDTM IGv3.1.3 = EG.EGELTM Map:SDTM IGv3.1.3 = EG.EGTP Map:SDTM IGv3.1.3 = EX.EXELTM Map:SDTM IGv3.1.3 = EX.EXPT Map:SDTM IGv3.1.3 = LB.LBELTM Map:SDTM IGv3.1.3 = LB.LBTPT Map:SDTM IGv3.1.3 = MB.MBELTM Map:SDTM IGv3.1.3 = MB.MBTPT Map:SDTM IGv3.1.3 = MS.MSELTM Map:SDTM IGv3.1.3 = QS.QSTPT

Attribute	Notes	Constraints and Tags
checkpointCode <i>Class:</i> PlannedContingentOnRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the points in the course of an activity when a precondition for the activity is evaluated.</p> <p>EXAMPLE(S) When the checkpointCode for a criterion of a repeatable activity is "end," the criterion is tested only at the end of each repetition of that activity. When the condition holds true, the next repetition is ready for execution.</p> <p>When the checkpointCode is "entry," the criterion is checked at the beginning of each repetition, if any, whereas "beginning" means the criterion is checked only once before the repetition "loop" starts.</p> <p>The checkpointCode "through" is special in that it requires the condition to hold throughout the execution of the activity, even throughout a single execution. As soon as the condition turns false, the activity should receive an interrupt event (see <code>PlannedActivity.interruptibleIndicator</code>) and will eventually terminate.</p> <p>NOTE(S): The checkpointCode specifies when the precondition is to be checked; it is analogous to the various conditional statements and loop constructs in programming languages "while-do" vs. "do-while" or "repeat-until" vs. "loop-exit."</p>	Map:HL7SDr1 = Precondition3.checkpointCode
completionRequiredBeforeStartingIndicator <i>Class:</i> PlannedContingentOnRelationship <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the target activity must have completed prior to starting the source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute may only be used if the target is an activity, not if the target is an observation result or a criterion group.</p>	Map:CTRv1.0 = PlannedContingentOnRelationship.completionRequiredBeforeStartingIndicator Map:TDMv2 = PlannedContingentOnRelationship.completionRequiredBeforeStartingIndicator

Class: PlannedCriterionGroup

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

(A and (B or C)), where A might be an activity, B and C might be 2 different observation results, and the two sets of

parentheses are 2 criterion groups, one inside (a component of) the other.

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTRv1.0 = PlannedCriterionGroup
- Map:TDMv2 = PlannedCriterionGroup

Connectors

Source	Connector	Target	Notes
PlannedCriterionGroupCom positionRelationship 0..* compositePlannedCriterion GroupCompositionRelations hip	be the parent of	PlannedCriterionGroup 0..1 componentPlannedCriterion Group	<p>DESCRIPTION: Each PlannedCriterionGroupCom positionRelationship might be the parent of one PlannedCriterionGroup. Each PlannedCriterionGroup might be the component of one or more PlannedCriterionGroupCom positionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* optionPlannedCriterionGrou pOptionRelationship	is an option that can satisfy	PlannedCriterionGroup 1 choicePlannedCriterionGrou p	<p>DESCRIPTION: Each PlannedCriterionGroupOpti onRelationship always is an option that can satisfy one PlannedCriterionGroup. Each PlannedCriterionGroup might be a choice that has as option one or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* choicePlannedCriterionGrou pOptionRelationship	be a choice that has as option	PlannedCriterionGroup 0..1 optionPlannedCriterionGrou p	<p>DESCRIPTION: Each PlannedCriterionGroupOpti onRelationship might be a choice that has as option one PlannedCriterionGroup. Each</p>

Source	Connector	Target	Notes
			<p>PlannedCriterionGroup might be an option that can satisfy one or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedContingentOnRelati onship 0..* contingentPlannedContinge ntOnRelationship	be contingent upon	PlannedCriterionGroup 0..1 prerequisitePlannedCriterio nGroup	<p>DESCRIPTION:</p> <p>Each PlannedContingentOnRelati onship might be contingent upon one PlannedCriterionGroup.</p> <p>Each PlannedCriterionGroup might be a condition for one or more PlannedContingentOnRelati onship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedRepeatActivityUntil Rule 0..* repeatedPlannedRepeatActi vityUntilRule	be repeated until	PlannedCriterionGroup 0..1 triggeringPlannedCriterionG roup	<p>DESCRIPTION:</p> <p>Each PlannedRepeatActivityUntil Rule might be repeated until one PlannedCriterionGroup.</p> <p>Each PlannedCriterionGroup might trigger the cessation of one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCom positionRelationship 0..* componentPlannedCriterion GroupCompositionRelations hip	is the component of	PlannedCriterionGroup 1 compositePlannedCriterion Group	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupCom positionRelationship always is the component of one PlannedCriterionGroup.</p>

Source	Connector	Target	Notes
			<p>Each PlannedCriterionGroup might be the parent of one or more PlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedCriterionGroupCompositionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedCriterionGroupCompositionRelationship
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
PlannedCriterionGroupCompositionRelationship 0..*	be the parent of	PlannedCriterionGroup 0..1 componentPlannedCriterionGroup	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupCompositionRelationship might be the parent of one PlannedCriterionGroup.</p> <p>Each PlannedCriterionGroup might be the component of one or more PlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			<p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship 0..*	be the parent of	DefinedObservationResult 0..1 componentDefinedObservationResult	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship might be the parent of one DefinedObservationResult. Each DefinedObservationResult might be the component of one or more PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship 0..*	be the parent of	PlannedActivity 0..1 componentPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship might be the parent of one PlannedActivity. Each PlannedActivity might be the component of one or more PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship 0..*	is the component of	PlannedCriterionGroup 1 compositePlannedCriterionGroup	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship always is the component of one PlannedCriterionGroup. Each PlannedCriterionGroup might be the parent of one or more PlannedCriterionGroupCompositePlannedCriterionGroupCompositionRelationship.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
sequenceNumber <i>Class:</i> PlannedCriterionGroupCompositionRelationship <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the relative sequential or temporal ordering of this relationship among other similar relationships having the same source.</p> <p>EXAMPLE(S): In a criterion group that is composed of a substance administration activity and a lab test activity, the sequence number indicates which activity precedes the other.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ActivityRelationship.sequenceNumber Map:CTRv1.0 = PlannedCriterionGroupCompositionRelationship.sequenceNumber

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> PlannedCriterionGroupComposite <i>positionRelationship</i> <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A battery of tests, composed of multiple routine labs that are always ordered together as a group, may be the criterion group for another activity. The tests in the battery may be staggered in time such that test 1 starts <u>right away</u> (i.e. 0 minutes after the start of the battery), test 2 starts <u>10 minutes later</u>, test 3 starts 20 minutes <u>into the battery</u>, etc. – the pauseQuantityRanges would be 0 minutes, 10 minutes and 20 minutes respectively (with minimum and maximum bounds being the same)</p> <p>A glucose tolerance test which is comprised of administering glucose and taking multiple timed blood samples which are then tested for glucose – the timing of each blood sample is the pauseQuantityRange on the relationship between that blood sample collection activity and the composite glucose tolerance test (DefinedCriterionGroup).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed Map:PSC = PlannedEvent.startDay Map:PSC = PlannedEvent.day Map:PSC = PlannedEvent.units

Attribute	Notes	Constraints and Tags
joinCode <i>Class:</i> PlannedCriterionGroupCom positionRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether, and how, a specific activity in a set of parallel activities should come together before subsequent activities can begin.</p> <p>EXAMPLE(S): Wait for this activity to complete before the subsequent activity; Terminate this activity as soon as all parallel "wait" activities are completed (and if this activity hasn't started yet, don't start it at all); Continue this activity after all "wait" activities complete, but don't wait for it to complete before beginning subsequent activities.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PlannedCriterionGroupCompositionRelationship.joinCode

Class: PlannedCriterionGroupOptionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedCriterionGroupOptionRelationship
- Map:TDM = AbstractRule.evaluableExpression
- Map:TDM = TriggeringRule

Connectors

Source	Connector	Target	Notes
PlannedCriterionGroupOpti onRelationship 0..* choicePlannedCriterionGrou pOptionRelationship	be a choice that has as option	DefinedObservationResult 0..1 optionDefinedObservationR esult	DESCRIPTION: Each PlannedCriterionGroupOpti onRelationship might be a choice that has as option one DefinedObservationResult. Each DefinedObservationResult might be an option that can satisfy one or more

Source	Connector	Target	Notes
			<p>PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* optionPlannedCriterionGrou pOptionRelationship	is an option that can satisfy	PlannedCriterionGroup 1 choicePlannedCriterionGrou p	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupOpti onRelationship always is an option that can satisfy one PlannedCriterionGroup.</p> <p>Each PlannedCriterionGroup might be a choice that has as option one or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* choicePlannedCriterionGrou pOptionRelationship	be a choice that has as option	PlannedCriterionGroup 0..1 optionPlannedCriterionGrou p	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupOpti onRelationship might be a choice that has as option one PlannedCriterionGroup.</p> <p>Each PlannedCriterionGroup might be an option that can satisfy one or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedCriterionGroupOpti onRelationship 0..* choicePlannedCriterionGrou pOptionRelationship	be a choice that has as option	PlannedActivity 0..1 optionPlannedActivity	<p>DESCRIPTION:</p> <p>Each PlannedCriterionGroupOpti onRelationship might be a choice that has as option one PlannedActivity. Each PlannedActivity might be an option that can satisfy one</p>

Source	Connector	Target	Notes
			<p>or more PlannedCriterionGroupOpti onRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> PlannedCriterionGroupOpti onRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:CTRv1.0 = PlannedCriterionGroupOptionRelation ship.priorityNumber Map:TDM = AbstractRule.isExclusive

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> PlannedCriterionGroupOpti onRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A pain management criterion group may be comprised of two options, one for substance administration of drug X after waiting 24 hours and one for substance administration of drug Y after waiting 48 hours— the pauseQuantityRange on the 2 option relationships are 24 hours and 48 hours respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed Map:PSC = PlannedEvent.units Map:PSC = PlannedEvent.day Map:PSC = PlannedEvent.startDay

Class: PlannedEligibilityCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context of a particular study that represents a characteristic or requirement intended to be applied to a potential study subject to determine whether or not they may participate in a study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The reason for the PlannedEligibilityCriterion structure is to allow questions defined as agnostic criteria in DefinedEligibilityCriterion, that is, they could be used either as inclusion or exclusion criteria, to be referenced in specific study protocols and allow the inclusion/exclusion distinction to be determined for that study specifically.

Tagged Values:

- Map:CTRPv3.8 = PlannedEligibilityCriterion
- Map:SDTM IGV3.1.3 = TI

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
PlannedEligibilityCriterion 0..* requiringPlannedEligibilityCriterion	requires for eligibility	DefinedEligibilityCriterion Answer 1 requiredDefinedEligibilityCriterionAnswer	DESCRIPTION: Each PlannedEligibilityCriterion always requires for eligibility one DefinedEligibilityCriterion Answer. Each DefinedEligibilityCriterion Answer might be required for eligibility for one or more PlannedEligibilityCriterion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedEligibilityCriterion	specializes	PlannedActivity	DESCRIPTION: Each PlannedEligibilityCriterion always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedEligibilityCriterion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedExclusionCriterion	specializes	PlannedEligibilityCriterion	DESCRIPTION: Each PlannedExclusionCriterion always specializes one PlannedEligibilityCriterion. Each PlannedEligibilityCriterion might be specialized by one PlannedExclusionCriterion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedInclusionCriterion	specializes	PlannedEligibilityCriterion	DESCRIPTION: Each PlannedInclusionCriterion always specializes one PlannedEligibilityCriterion.

Source	Connector	Target	Notes
			<p>Each PlannedEligibilityCriterion might be specialized by one PlannedInclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedExclusionCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context of a particular study that represents a characteristic or requirement intended to be applied to a potential study subject to determine whether they may not participate in a study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The reason for the PlannedEligibilityCriterion structure is to allow questions defined as agnostic criteria in DefinedEligibilityCriterion, that is, they could be used either as inclusion or exclusion criteria, to be referenced in specific study protocols and allow the inclusion/exclusion distinction to be determined for that study specifically.

Tagged Values:

Connectors

Source	Connector	Target	Notes
PlannedExclusionCriterion	specializes	PlannedEligibilityCriterion	<p>DESCRIPTION:</p> <p>Each PlannedExclusionCriterion always specializes one PlannedEligibilityCriterion.</p> <p>Each PlannedEligibilityCriterion might be specialized by one PlannedExclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedExperimentalUnitAllocation

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context 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).

EXAMPLE(S):

randomization, direct assignment based on eligibility criteria, etc.

"Escalating dose cohort studies" enroll subjects in successive arms, i.e., one arm is completely filled before any subjects are enrolled in the next arm. In such a study, allocation depends on which arms have been fully enrolled and which are currently open for enrollment. Note that this example assumes that the experimental unit is the subject (rather than a part of a subject or a group of subjects).

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:SDTM IGv3.1.3 = TA.TABRANCH

Connectors

Source	Connector	Target	Notes
PlannedExperimentalUnitAI location	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedExperimentalUnitAI location always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedExperimentalUnitAI location.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedExperimentalUnitAI locationResult 0..* assignedExperimentalUnitA llocationResult	is an option for	PlannedExperimentalUnitAI location 1 assigningPlannedExperimen talUnitAllocation	<p>DESCRIPTION: Each PlannedExperimentalUnitAI locationResult always is an option for one PlannedExperimentalUnitAI location. Each PlannedExperimentalUnitAI location might assign experimental units to one or more PlannedExperimentalUnitAI locationResult.</p> <p>DEFINITION: This association identifies a relationship between an allocation activity and an option to which experimental units will be assigned.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
PlannedRandomizationBookAllocation	specializes	PlannedExperimentalUnitAl location	<p>DESCRIPTION: Each PlannedRandomizationBook Allocation always specializes one PlannedExperimentalUnitAl location. Each PlannedExperimentalUnitAl location might be specialized by one PlannedRandomizationBook Allocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedExperimentalUnitAllocationResult

Package: Protocol Representation Sub-Domain

DEFINITION:

A possible outcome, of a planned experimental unit allocation activity, which indicates a path to which an experimental unit may be assigned.

EXAMPLE(S):

A randomization activity may assign subjects to one of several drug treatments, a direct assignment may assign subjects to surgery based on a positive response to a preparatory regimen

OTHER NAME(S):

Branch

NOTE(S):

Any evaluation criteria associated with this allocation result is represented by a PlannedContingentOnRelationship related to the PlannedActivity that is linked to this result.

Tagged Values:

- Map:SDTM IGv3.1.3 = TA.TABRANCH

Connectors

Source	Connector	Target	Notes
PlannedExperimentalUnitAl locationResult 0..* assignedExperimentalUnitA llocationResult	is an option for	PlannedExperimentalUnitAl location 1 assigningPlannedExperimentalUnitAllocation	<p>DESCRIPTION: Each PlannedExperimentalUnitAl locationResult always is an option for one PlannedExperimentalUnitAl location. Each PlannedExperimentalUnitAl location might assign experimental units to one or more</p>

Source	Connector	Target	Notes
			<p>PlannedExperimentalUnitAllocationResult</p> <p>DEFINITION: This association identifies a relationship between an allocation activity and an option to which experimental units will be assigned.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedExperimentalUnitAllocationResult 0..* assigningPlannedExperimentalUnitAllocationResult	is an option through which experimental units are assigned to	PlannedActivity 1 assignedPlannedActivity	<p>DESCRIPTION: Each PlannedExperimentalUnitAllocationResult always is an option through which experimental units are assigned to one PlannedActivity. Each PlannedActivity might be the activity executed for one or more PlannedExperimentalUnitAllocationResult.</p> <p>DEFINITION: This association identifies a relationship between an allocation option and the path through which an experimental unit will go if assigned to this option.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
description <i>Class:</i> PlannedExperimentalUnitA1 <i>locationResult</i> <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the experimental unit allocation result.</p> <p>EXAMPLE(S): In SDTM, the TABRANCH variable may contain a description such as "Randomized to Placebo - 5 mg - 10 mg ", "Randomized to Drug A", "Assigned to Rescue on basis of response evaluation".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TA.TABRANCH

Class: PlannedInclusionCriterion

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context of a particular study that represents a characteristic or requirement intended to be applied to a potential study subject to determine whether they may participate in a study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The reason for the PlannedEligibilityCriterion structure is to allow questions defined as agnostic criteria in DefinedEligibilityCriterion, that is, they could be used either as inclusion or exclusion criteria, to be referenced in specific study protocols and allow the inclusion/exclusion distinction to be determined for that study specifically.

Tagged Values:

- Map:CTRPv3.8 = PlannedEligibilityCriterion.inclusionIndicator

Connectors

Source	Connector	Target	Notes
PlannedInclusionCriterion	specializes	PlannedEligibilityCriterion	<p>DESCRIPTION: Each PlannedInclusionCriterion always specializes one PlannedEligibilityCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedNotification

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context of a particular study or experiment that represents the communication of a message to a recipient.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = PlannedNotification

Connectors

Source	Connector	Target	Notes
PlannedNotification	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedNotification always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* receivingNotificationReceiver	be the receiver of	PlannedNotification 0..1 receivedPlannedNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one PlannedNotification. Each PlannedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
studyAccrualThresholdPercent <i>Class:</i> PlannedNotification <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying a percentage of target accrual for a study, which when reached triggers a notification.</p> <p>EXAMPLE(S): 75% or 90% of the target accrual number.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = PlannedNotification.studyThreshold
studySiteAccrualThresholdPercent <i>Class:</i> PlannedNotification <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying a percentage of target accrual at a particular study site, which when reached triggers a notification.</p> <p>EXAMPLE(S): 75% or 90% of the target accrual number.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = PlannedNotification.studySiteThreshold

Class: PlannedOptionRelationship

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a composite activity and an option that can satisfy it, i.e. choice and option activities, where all the activities are intended to occur at some point in the context of a particular study or experiment.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedOptionRelationship
- Map:HL7SD = PlannedActivity.precondition1.conjunctionCode
- Map:HL7SD = EligibilityCriterion.Precondition2.conjunctionCode
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
PlannedOptionRelationship 0..* optionPlannedOptionRelationship	is an option that can satisfy	PlannedActivity 1 choicePlannedActivity	DESCRIPTION: Each PlannedOptionRelationship always is an option that can satisfy one PlannedActivity.

Source	Connector	Target	Notes
			<p>Each PlannedActivity might be a choice that has as option one or more PlannedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedOptionRelationship 0..* choicePlannedOptionRelatio nship	is a choice that has as option 1 optionPlannedActivity	PlannedActivity	<p>DESCRIPTION: Each PlannedOptionRelationship always is a choice that has as option one PlannedActivity. Each PlannedActivity might be an option that can satisfy one or more PlannedOptionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> PlannedOptionRelationship <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:CTRv1.0 = PlannedOptionRelationship.priorityNumber Map:TDM = AbstractRule.isExclusive

Attribute	Notes	Constraints and Tags
pauseQuantityRange <i>Class:</i> PlannedOptionRelationship <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time between when an activity is ready for execution and the actual beginning of the execution.</p> <p>EXAMPLE(S): A pain management activity consists of either administering drug A after waiting 30 minutes or drug B after waiting 60 minutes – the pauseQuantityRanges are 30 minutes and 60 minutes respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The pauseQuantityRange 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 execution" according to the definition above. The pauseQuantityRange counter or timeclock starts then, and when the full amount of time is reached, the activity begins. A pauseQuantityRange 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.</p>	Map:Lab = Activity.plannedTimeElapsed Map:PSC = PlannedEvent.units Map:PSC = PlannedEvent.startDay Map:PSC = PlannedEvent.day Map:SDTM IGv3.1.1 = EX.EXELTM

Class: PlannedRandomizationBookAllocation

Package: Protocol Representation Sub-Domain

DEFINITION:

An activity that is intended to occur at some point in the context 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.

EXAMPLE(S):

A study has two treatment arms, A and B, to which study subjects will be evenly distributed. The first study subject to be randomized received treatment Arm A and that was documented as part of the Randomization Book, the next study subject to be randomized will receive the next open treatment, which is Arm B.

OTHER NAME(S):

NOTE(S):

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 experimental units across those portions of the study. For example, the book entries indicate which arm a given experimental unit, Joe, is assigned to based on the fact that he's the 5th person in stratum group #2.

Tagged Values:

- Map:C3PR = BookRandomization
- Map:C3PRv2.9 = BookRandomization

- Map:CTRRr3 = PlannedRandomizationBookAllocation

Connectors

Source	Connector	Target	Notes
PlannedRandomizationBook Allocation	specializes	PlannedExperimentalUnitAl location	<p>DESCRIPTION: Each PlannedRandomizationBook Allocation always specializes one PlannedExperimentalUnitAl location. Each PlannedExperimentalUnitAl location might be specialized by one PlannedRandomizationBook Allocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RandomizationBookEntry 1..* definedRandomizationBook Entry	is defined by	PlannedRandomizationBook Allocation 1 definingPlannedRandomizationBookAllocation	<p>DESCRIPTION: Each RandomizationBookEntry always is defined by one PlannedRandomizationBook Allocation. Each PlannedRandomizationBook Allocation always defines one or more RandomizationBookEntry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PlannedRepeatActivityUntilRule

Package: Protocol Representation Sub-Domain

DEFINITION:

A relationship between a planned repeating activity and the criteria that may trigger the repeating activity to stop, where all items are intended to occur at some point in the context of a particular study or experiment.

EXAMPLE(S):

Continue repeating kidney dialysis until kidney transplant surgery.

OTHER NAME(S):

NOTE(S):

The criteria may be one of the following:

- another planned activity where the repeating activity stops if this other activity occurs

- a defined observation result where the repeating activity stops if this observation result occurs as a result of a planned observation
- a planned criteria group where the repeating activity stops if this group logically evaluates to true based on its components

Tagged Values:

- Map:CTOM = ActivityRelationship.typeCode
- Map:CTRPv3.8 = ActivityRelationship.typeCode
- Map:CTRv1.0 = PlannedRepeatActivityUntilRule
- Map:TDM = TriggeringRule
- Map:TDM = AbstractRule.evaluableExpression

Connectors

Source	Connector	Target	Notes
PlannedRepeatActivityUntil Rule 0..* repeatedPlannedRepeatActi vityUntilRule	be repeated until	DefinedObservationResult 0..1 triggeringDefinedObservati onResult	<p>DESCRIPTION: Each PlannedRepeatActivityUntil Rule might be repeated until one DefinedObservationResult. Each DefinedObservationResult might trigger the cessation of one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedRepeatActivityUntil Rule 0..* repeatedPlannedRepeatActi vityUntilRule	be repeated until	PlannedCriterionGroup 0..1 triggeringPlannedCriterionG roup	<p>DESCRIPTION: Each PlannedRepeatActivityUntil Rule might be repeated until one PlannedCriterionGroup. Each PlannedCriterionGroup might trigger the cessation of one or more PlannedRepeatActivityUntil Rule.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedRepeatActivityUntil Rule 0..* triggeringPlannedRepeatAct ivityUntilRule	triggers the cessation of	PlannedActivity 1 repeatedPlannedActivity	<p>DESCRIPTION: Each PlannedRepeatActivityUntil Rule always triggers the cessation of one PlannedActivity. Each PlannedActivity might be repeated until one or more</p>

Source	Connector	Target	Notes
			PlannedRepeatActivityUntil Rule. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedRepeatActivityUntil Rule 0..* repeatedPlannedRepeatActivityUntilRule	be repeated until	PlannedActivity 0..1 triggeringPlannedActivity	DESCRIPTION: Each PlannedRepeatActivityUntil Rule might be repeated until one PlannedActivity. Each PlannedActivity might trigger the cessation of one or more PlannedRepeatActivityUntil Rule. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
priorityNumber <i>Class:</i> PlannedRepeatActivityUntil Rule <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A number specifying the relative preference for considering this relationship before other like-typed relationships having the same source activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relationships with lower priorityNumber values are considered before and above those with higher values.</p> <p>The ordering may be a total ordering, in which all priority number are unique, or a partial ordering, in which the same priority may be assigned to more than one relationship. Decimal numbers may be used to insert values between existing priority numbers.</p> <p>For multiple criteria, this specifies which criteria are considered before others.</p> <p>Among alternatives or options that are being chosen by humans, the priorityNumber specifies preference.</p>	Map:HL7SDr1 = Precondition3.priorityNumber
cessationPauseQuantityRange <i>Class:</i> PlannedRepeatActivityUntil Rule <i>Datatype:</i> URG<PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A quantity of time falling within minimum and maximum bounds that specifies the elapsed time after the observed result occurs and before the cessation of repeating the activity.</p> <p>EXAMPLE(S): Stop 20 days after the observed event occurs.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Lab = Activity.plannedTimeElapsed

Attribute	Notes	Constraints and Tags
checkpointCode <i>Class:</i> PlannedRepeatActivityUntil Rule <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the points in the course of an activity when a precondition for the activity is evaluated.</p> <p>EXAMPLE(S) When the checkpointCode for a criterion of a repeatable activity is "end," the criterion is tested only at the end of each repetition of that activity. When the condition holds true, the next repetition is ready for execution.</p> <p>When the checkpointCode is "entry," the criterion is checked at the beginning of each repetition, if any, whereas "beginning" means the criterion is checked only once before the repetition "loop" starts.</p> <p>The checkpointCode "through" is special in that it requires the condition to hold throughout the execution of the activity, even throughout a single execution. As soon as the condition turns false, the activity should receive an interrupt event (see <code>PlannedActivity.interruptibleIndicator</code>) and will eventually terminate.</p> <p>NOTE(S): The checkpointCode specifies when the precondition is to be checked; it is analogous to the various conditional statements and loop constructs in programming languages "while-do" vs. "do-while" or "repeat-until" vs. "loop-exit."</p>	Map:HL7SDr1 = Precondition3.checkpointCode

Class: PlannedStudySite

Package: Protocol Representation Sub-Domain

DEFINITION:

A facility in which study activities are intended to be conducted.

EXAMPLE(S):

The site where the study subject encounter is intended to occur, or the site of the Investigator.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:BRIDGSCC = Model Integrity - Study Versioning
- Map:CTRv1.0 = PlannedStudySite

Connectors

Source	Connector	Target	Notes
PlannedStudySite 0..* performedPlannedStudySite	be a function planned to be performed by	HealthcareFacility 0..1 performingHealthcareFacilit y	DESCRIPTION: Each PlannedStudySite might be a function planned to be performed by one

Source	Connector	Target	Notes
			HealthcareFacility. Each HealthcareFacility might plan to function as one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedStudySite 0..* executingPlannedStudySite	plans to execute	StudyProtocolVersion 1 executesStudyProtocolVersi on	DESCRIPTION: Each PlannedStudySite always plans to execute one StudyProtocolVersion. Each StudyProtocolVersion might be planned to be executed at one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedStudySite 0..* performedPlannedStudySite	be a function planned to be performed by	Organization 0..1 performingOrganization	DESCRIPTION: Each PlannedStudySite might be a function planned to be performed by one Organization. Each Organization might plan to function as one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySitePersonnel 0..* supportsStudySitePersonnel	plan to perform a role for	PlannedStudySite 0..1 supportedPlannedStudySite	DESCRIPTION: Each StudySitePersonnel might plan to perform a role for one PlannedStudySite. Each PlannedStudySite might have a role planned to be performed by one or more StudySitePersonnel. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
duration <i>Class:</i> PlannedStudySite <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The intended period of time for the planned study site's participation in the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:BRIDGSCC = Model Integrity - Study Versioning Map:CTRv1.0 = PlannedStudySite.duration
leadIndicator <i>Class:</i> PlannedStudySite <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the principal administrative organization intended to be responsible for the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Exception: A multi-site study with no single assigned coordination center; in this case, every participating organization can be named as lead organization.</p>	Map:C3PR = StudySite.roleCode Map:CTOM = StudySite.roleCode Map:CTRv1.0 = PlannedStudySite.leadIndicator

Class: PlannedStudySubject

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

10 Adult males, 20 female 6-month old chickens

OTHER NAME(S):

NOTE(S):

Some studies may specify multiple kinds of subjects, each with their own quantity.

Tagged Values:

- Map:CTRv1.0 = PlannedSubject

Connectors

Source	Connector	Target	Notes
PlannedStudySubject 1..* intendedPlannedStudySubject	participates in	StudyProtocolVersion 1 plannedForStudyProtocolVersion	DESCRIPTION: Each PlannedStudySubject always participates in one StudyProtocolVersion. Each StudyProtocolVersion always is participated in by one or more PlannedStudySubject.

Source	Connector	Target	Notes
			<p>DEFINITION: Indicates the types of StudySubjects intended to participate in the StudyProtocolVersion.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): ActualIndicator should be set to 'false' for the Entity that is the subject</p>
PlannedStudySubject 0..* constrainedPlannedStudySubject	be constrained by	DefinedEligibilityCriterion Answer 0..* constrainingDefinedEligibilityCriterion	<p>DESCRIPTION: Each PlannedStudySubject might be constrained by one or more DefinedEligibilityCriterion Answer. Each DefinedEligibilityCriterion Answer might constrain one or more PlannedStudySubject.</p> <p>DEFINITION: Indicates the specific criteria a particular PlannedStudySubject is expected to adhere to.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedStudySubject	specializes	Subject	<p>DESCRIPTION: Each PlannedStudySubject always specializes one Subject. Each Subject might be specialized by one PlannedStudySubject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
quantityRange <i>Class:</i> PlannedStudySubject <i>Datatype:</i> URG<INT.POS> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many of a particular type of subject are planned to be included in the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:FDA HL7 SD SD DSTU2012 = personKind.quantity

Class: PlannedSubjectActivityGroup

Package: Protocol Representation Sub-Domain

DEFINITION:

A collection of activities that are intended to occur or start for the same study or experiment subject at a specific point in the context of a particular study or experiment.

EXAMPLE(S):

Clinic visit during which a physical exam, a blood test, and a substance administration occur

Telephone contact during which temperature, blood pressure and adverse events are reported

Recording multiple observation results in a diary

A treatment strategy that consists of drug administrations with rules for modifying doses

OTHER NAME(S):

visit, time point, study segment, course, treatment strategy, period, cycle

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PlannedSubjectActivityGroup
- Map:SDTM IGv3.1.2 = TE.DOMAIN
- Map:SDTM IGv3.1.2 = TV.DOMAIN
- Map:SDTM IGv3.1.3 = TV

Connectors

Source	Connector	Target	Notes
PlannedSubjectActivityGroup	specializes	PlannedActivity	<p>DESCRIPTION: Each PlannedSubjectActivityGroup always specializes one PlannedActivity. Each PlannedActivity might be specialized by one PlannedSubjectActivityGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
sequenceNumber <i>Class:</i> PlannedSubjectActivityGroup <i>Datatype:</i> INT.NONNEG <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer specifying the order of a visit within a study or experiment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Visit Number</p> <p>NOTE(S): Derived from the sequence number that orders this activity group within a larger activity group: PlannedSubjectActivityGroup [visit, timepoint or other kind of group] > PlannedCompositionRelationship.sequenceNumber > PlannedSubjectActivityGroup [set of planned visits for the study or some other larger activity group]</p>	Map:CDASHv1.1 = EG.VISITNUM Map:CDASHv1.1 = IE.VISITNUM Map:CDASHv1.1 = DA.VISITNUM Map:CDASHv1.1 = LB.VISITNUM Map:CDASHv1.1 = PE.VISITNUM Map:CDASHv1.1 = VS.VISITNUM Map:CTRv1.0 = PlannedSubjectActivityGroup.sequenceNumber Map:PGx v1.0 = PF.VISITNUM Map:PGx v1.0 = BS.VISITNUM Map:PGx v1.0 = PG.VISITNUM Map:PGx v1.0 = SB.VISITNUM Map:PGx v1.0 = BE.VISITNUM Map:SDTM IGv3.1.2 = PE.VISITNUM Map:SDTM IGv3.1.2 = LB.VISITNUM Map:SDTM IGv3.1.2 = PC.PCTPTNUM Map:SDTM IGv3.1.2 = QS.VISITNUM Map:SDTM IGv3.1.2 = FA.VISITNUM Map:SDTM IGv3.1.2 = MB.VISITNUM Map:SDTM IGv3.1.2 = SV.VISITNUM Map:SDTM IGv3.1.2 = TV.VISITNUM Map:SDTM IGv3.1.2 = IE.VISITNUM Map:SDTM IGv3.1.2 = EG.EGTPTNUM Map:SDTM IGv3.1.2 = MS.VISITNUM Map:SDTM IGv3.1.2 = PC.VISITNUM Map:SDTM IGv3.1.2 = MB.MBTPTNUM Map:SDTM IGv3.1.2 = DA.VISITNUM Map:SDTM IGv3.1.2 = MS.MSTPTNUM Map:SDTM IGv3.1.2 = EX.EXPTPTNUM Map:SDTM IGv3.1.2 = EG.VISITNUM Map:SDTM IGv3.1.2 = VS.VISITNUM Map:SDTM IGv3.1.3 = MB.VISITNUM Map:SDTM IGv3.1.3 = TV.VISITNUM Map:SDTM IGv3.1.3 = TU.VISITNUM Map:SDTM IGv3.1.3 = TR.VISITNUM Map:SDTM IGv3.1.3 = SV.VISITNUM Map:SDTM IGv3.1.3 =

Attribute	Notes	Constraints and Tags
		RS.VISITNUM Map:SDTM IGv3.1.3 = RS.VISITNUM Map:SDTM IGv3.1.3 = QS.VISITNUM Map:SDTM IGv3.1.3 = PE.VISITNUM Map:SDTM IGv3.1.3 = MS.VISITNUM Map:SDTM IGv3.1.3 = LB.VISITNUM Map:SDTM IGv3.1.3 = IE.VISITNUM Map:SDTM IGv3.1.3 = FA.VISITNUM Map:SDTM IGv3.1.3 = EG.VISITNUM Map:SDTM IGv3.1.3 = DA.VISITNUM Map:SDTM IGv3.1.3 = VS.VISITNUM Map:SDTM IGv3.1.3 = PC.VISITNUM
targetAccrualNumberRange <i>Class:</i> PlannedSubjectActivityGroup <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: An integer falling within minimum and maximum bounds that specifies how many subjects are to be accrued for the planned subject activity group. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:BRIDGv2.2 = PlannedStudyCell.targetAccrualNumber Map:C3PRv2.9 = Arm.targetAccrualNumber Map:CTRv1.0 = PlannedActivity.targetAccrualNumber Range

Class: RandomizationBookEntry

Package: Protocol Representation Sub-Domain

DEFINITION:

An item/element of a randomization book that can be used to assign an experimental unit to a planned arm or portion of an arm in a study.

EXAMPLE(S):

An entry might be mapping the 5th experimental unit in a given Stratum Group to a particular treatment Arm.

OTHER NAME(S):

NOTE(S):

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 experimental units across those portions of the study. For example, the book entries indicate which arm a given experimental unit, Joe, is assigned to based on the fact that he's the 5th experimental unit in stratum group #2.

Tagged Values:

- Map:C3PRv2.9 = BookRandomizationEntry
- Map:CTRRr3 = RandomizationBookEntry

Connectors

Source	Connector	Target	Notes
RandomizationBookEntry 0..* randomizingRandomizationBookEntry	randomize	StratumGroup 0..1 randomizedStratumGroup	<p>DESCRIPTION: Each RandomizationBookEntry might randomize one StratumGroup. Each StratumGroup might be randomized by one or more RandomizationBookEntry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RandomizationBookEntry 1..* definedRandomizationBookEntry	is defined by	PlannedRandomizationBookAllocation 1 definingPlannedRandomizationBookAllocation	<p>DESCRIPTION: Each RandomizationBookEntry always is defined by one PlannedRandomizationBookAllocation. Each PlannedRandomizationBookAllocation always defines one or more RandomizationBookEntry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
positionNumber <i>Class:</i> RandomizationBookEntry <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 1 . . . 1	<p>DEFINITION: An integer specifying the value of a numerical sequence for a stratum group that should be used to assign an experimental unit to an arm or a portion of an arm.</p> <p>EXAMPLE(S): StratumGroup#: 0; Position: 0; Arm/Portion of Arm: A StratumGroup#: 0; Position: 1; Arm/Portion of Arm: B</p> <p>If 2 experimental units fall in the same Stratum Group i.e. say 0 in the above example, the first will be assigned Arm A because the current position would be 0 and the 2nd would be assigned Arm B since the current position would be incremented by 1 each time an assignment happens.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = BookRandomizationEntry.position Map:C3PRv2.9 = BookRandomizationEntry.position
positionFilledIndicator <i>Class:</i> RandomizationBookEntry <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the position is filled by an experimental unit assignment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = StratumGroup.currentPosition

Class: StratumGroup

Package: Protocol Representation Sub-Domain

DEFINITION:

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 or experimental units to arms on a study.

EXAMPLE(S):

A given study may want to require even distribution of gender and age so stratum groups may be defined as: males under 18, males 18 and over, females under 18, and females 18 and over.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StratificationCriterionAnswerCombination
- Map:C3PRv2.9 = StratumGroup
- Map:CTRPv1.0 = StratumGroup
- Map:CTRPv3.8 = StratumGroup
- Map:CTRr3 = StratumGroup
- Map:CTRv1.0 = StratumGroup

Connectors

Source	Connector	Target	Notes
StratumGroup 1..* characterizedStratumGroup	is characterized by	DefinedStratificationCriteriaOnPermissibleResult 1..* characterizingDefinedStratificationCriterionPermissibleResult	<p>DESCRIPTION: Each StratumGroup always is characterized by one or more DefinedStratificationCriteriaOnPermissibleResult. Each DefinedStratificationCriteriaOnPermissibleResult always characterizes one or more StratumGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StratumGroup 0..* describedStratumGroup	is defined by	StudyProtocolVersion 1 describingStudyProtocolVersion	<p>DESCRIPTION: Each StratumGroup always is defined by one StudyProtocolVersion. Each StudyProtocolVersion might define one or more StratumGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RandomizationBookEntry 0..* randomizingRandomizationBookEntry	randomize	StratumGroup 0..1 randomizedStratumGroup	<p>DESCRIPTION: Each RandomizationBookEntry might randomize one StratumGroup. Each StratumGroup might be randomized by one or more RandomizationBookEntry.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
groupNumber <i>Class:</i> StratumGroup <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer that identifies the stratum group to study personnel, such as the statistician and registrars.</p> <p>EXAMPLE(S): Patient age (years) Stratum A Gender Two-year survival probability Disease Type Treatment Cohort</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p> <p>Text is captured using the originalText attribute of the INT.NONNEG data type.</p>	Map:C3PR = StratumGroup.stratumGroupNumber Map:C3PRv2.9 = StratumGroup.stratumGroupNumber Map:CTRPv1.0 = StratumGroup.groupNumberText Map:CTRPv3.8 = StratumGroup.groupNumberText Map:CTRr3 = StratumGroup.groupNumber Map:CTRv1.0 = StratumGroup.groupNumber
description <i>Class:</i> StratumGroup <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the stratum group.</p> <p>EXAMPLE(S): Primary malignancy, Weight loss severity, Concurrent therapy, Patient age (years), Gleason score, Baseline PSA</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv3.8 = StratumGroup.description

Class: StudyActivity

Package: Protocol Representation Sub-Domain

DEFINITION:

The intention to use a defined activity in the design of a study.

EXAMPLE(S):

If a study's design includes the activity of taking blood pressure, the DefinedActivity for blood pressure is linked to the study via this class.

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:caAERSv2.2 = StudyTherapy
- Map:CTRv1.0 = StudyActivity
- Map:HL7SD = PlannedStudy.Component2
- Map:LSDAMv2.2.3Plus = ActivityCollection.(Protocol)

- Map:SDTM IGV3.1.3 = TE

Connectors

Source	Connector	Target	Notes
StudyActivity 0..* usedStudyActivity	be used by	StudyProtocolVersion 0..1 usingStudyProtocolVersion	<p>DESCRIPTION: Each StudyActivity might be used by one StudyProtocolVersion. Each StudyProtocolVersion might use one or more StudyActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyActivity 0..* usingStudyActivity	uses	DefinedActivity 1 usedDefinedActivity	<p>DESCRIPTION: Each StudyActivity always uses one DefinedActivity. Each DefinedActivity might be used by one or more StudyActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedActivity 0..* usingPlannedActivity	be a use of	StudyActivity 0..1 usedStudyActivity	<p>DESCRIPTION: Each PlannedActivity might be a use of one StudyActivity. Each StudyActivity might be used as one or more PlannedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
studyFocusIndicator <i>Class:</i> StudyActivity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the activity is a key investigational activity for a study.</p> <p>EXAMPLE(S): A study focused on investigating the effectiveness of a drug will flag the substance administration of the drug or a study focused on determining the average blood pressure of a certain population will flag the blood pressure observation.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If a study has study agents, one or more of the study activities will presumably use the agent and have this indicator set to true.</p>	Map:CTRPv1.0 = PlannedEligibilityCriterion.name Map:CTRR = Comparator(s) product name(s) Map:CTRR = Intervention Name Map:CTRv1.0 = StudyActivity.studyFocusIndicator

Class: StudyAgent

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Tamoxifen used in a breast cancer study.

Fish oil used in a heart health study.

Artificial knee joints used in a joint replacement study.

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:caAERSv2.2 = StudyAgent
- Map:CTRPv1.0 = StudyProduct
- Map:CTRRr3 = StudyAgent
- Map:CTRv1.0 = StudyAgent

Connectors

Source	Connector	Target	Notes
StudyAgent 0..* performedStudyAgent	is a function performed by	Product 1 performingProduct	<p>DESCRIPTION: Each StudyAgent always is a function performed by one Product. Each Product might function as one or more StudyAgent.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
StudyAgent 0..* evaluatedStudyAgent	is evaluated by	StudyProtocolVersion 1 evaluatingStudyProtocolVersion	<p>DESCRIPTION: Each StudyAgent always is evaluated by one StudyProtocolVersion. Each StudyProtocolVersion might be evaluating one or more StudyAgent.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
functionCode <i>Class:</i> StudyAgent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying how this agent is used in the study.</p> <p>EXAMPLE(S): lead agent, comparator agent, placebo, active control</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is important to know in multi-agent studies.</p>	Map:CTOM = StudyAgent.investigationalIndicator Map:CTR&Rr2 = IMP Category Map:CTRPv1.0 = StudyProduct.leadProductIndicator Map:CTRR = Comparator Description Map:CTRr3 = StudyAgent.functionCode Map:CTRv1.0 = StudyAgent.functionCode Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=TRT Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=COMPTRT
blindedName <i>Class:</i> StudyAgent <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier of a study agent to be used by participants from whom the identity of the study agent is hidden. This name is assigned within the context of a study so that products which blinded participants should not be able to distinguish between/among have the same blinded name.</p> <p>EXAMPLE(S): In a study for which the study agents are a drug product and a matching placebo, both the active product and the placebo might simply be called "Study Drug." In a study with two different investigational products and their matching placebos, the blinded names might be "Bottle A" and "Bottle B" or "100 mg tablet" and "25 mg tablet."</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:GSK MDRv1.0 = GForge #27182 - Blinded Description for Product functioning as Study Agent

Attribute	Notes	Constraints and Tags
firstInHumanRiskFactorCode <i>Class:</i> StudyAgent <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying the risk factors identified with administering the agent's active substance to humans for the first time in a study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRRr3 = StudyAgent.firstInHumanRiskFactor
firstInHumanIndicator <i>Class:</i> StudyAgent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the first time an active substance of the agent is to be administered to humans in a study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRRr3 = Study.typeCode Map:CTRRr3 = StudyAgent.firstInHumanIndicator
expandedAccessIndicator <i>Class:</i> StudyAgent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the product (drug or device) is available for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled study. Expanded Access is a mechanism that provides non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Study Type - Expanded Access and Has Expanded Access? Map:CTGOV = Has Expanded Access Map:CTRPv1.0 = InterventionalStudyProtocol.expandedAccessIndicator Map:CTRPv1.0 = ObservationalStudyProtocol.expandedAccessIndicator Map:CTRPv1.0 = StudyProtocol.expandedAccessIndicator Map:CTRPv3.8 = StudyIndIde.expandedAccessIndicator Map:CTRR = Expanded access indicator Map:CTRRr3 = StudyAgent.expandedAccessIndicator Map:CTRv1.0 = ExpandedAccessStudyProtocolVersion
substitutionAllowedIndicator <i>Class:</i> StudyAgent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this agent as identified by its active substance is permitted to be substituted by a local brand.</p> <p>EXAMPLE(S): The study protocol may specify the use of Paracetamol which could be substituted locally in the United States with any brand containing acetaminophen, including Tylenol and Panadol.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRRr3 = StudyAgent.substitutionAllowedCode

Attribute	Notes	Constraints and Tags
characteristicModifiedIndicator <i>Class:</i> StudyAgent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the agent's characteristic have been modified from those approved in the marketing authorization in a way that could affect its quality.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Modification may include a change in pharmaceutical form (e.g. over-encapsulation, colour, dilution, re-tabletting for blinding etc.) or removal from the primary packaging and repacking (e.g. removal from a blister and putting in a bottle).</p>	Map:CTRRr3 = StudyAgent.modifiedIndicator
pediatricFormulationIndicator <i>Class:</i> StudyAgent <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the pharmaceutical form of the agent is intended for pediatric usage.</p> <p>EXAMPLE(S): A value of true may indicate that the agent is dissolvable, smaller, or grape flavored to be easily ingested by the pediatric population.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRRr3 = DefinedActivity.categoryCode Map:CTRRr3 = DefinedActivity.subcategoryCode
statusCode <i>Class:</i> StudyAgent <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the agent's association to a study.</p> <p>EXAMPLE(S): pending, active, complete, cancelled</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = StudyAgent.statusCode Map:CTRPv1.0 = StudyProduct.statusCode Map:CTRv1.0 = StudyAgent.statusCode
statusDate <i>Class:</i> StudyAgent <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) on which the status is assigned to the study agent.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = StudyAgent.statusDate Map:CTRPv1.0 = StudyProduct.statusDateRange Map:CTRv1.0 = StudyAgent.statusDate

Class: StudyCondition

Package: Protocol Representation Sub-Domain

DEFINITION:
A condition that is a focus of the study.

EXAMPLE(S):

Acute pain syndrome; Advanced Adenocarcinoma of the Colon and Rectum;
Hot Flashes

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyDisease
- Map:caAERSv2.2 = AbstractStudyDisease
- Map:caAERSv2.2 = DiseaseTerm
- Map:CTRPv1.0 = Conditions or Focus of Study
- Map:CTRPv3.8 = StudyDisease
- Map:CTRR = Condition
- Map:CTRv1.0 = StudyCondition

Connectors

Source	Connector	Target	Notes
StudyCondition 0..*	is the focus of	StudyProtocolVersion 1 focuses onStudyProtocolVersion	<p>DESCRIPTION: Each StudyCondition always is the focus of one StudyProtocolVersion. Each StudyProtocolVersion might focus on one or more StudyCondition.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
code <i>Class:</i> StudyCondition <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the condition that is the focus of the study.</p> <p>EXAMPLE(S): 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = DiseaseTerm Map:C3PRv2.9 = DiseaseTerm.ctepTerm Map:C3PRv2.9 = DiseaseTerm.medraCode Map:C3PRv2.9 = DiseaseTerm.term Map:caAERSv2.2 = AbstractMeddraDomain.whoArtCode Map:caAERSv2.2 = AbstractMeddraDomain.jartCode Map:caAERSv2.2 = AbstractMeddraDomain.version_id Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > MeddraStudyDisease Map:caAERSv2.2 = Condition.name Map:caAERSv2.2 = AbstractMeddraDomain.icd10Code Map:caAERSv2.2 = DiseaseTerm.ctepTerm Map:caAERSv2.2 = AbstractMeddraDomain.hartsCode Map:caAERSv2.2 = AbstractMeddraDomain.meddraTerm Map:caAERSv2.2 = DiseaseTerm.term Map:caAERSv2.2 = AbstractMeddraDomain.icd9Code Map:caAERSv2.2 = AbstractMeddraDomain.costartSymbol Map:caAERSv2.2 = MeddraVersion.name > MeddraStudyDisease Map:caAERSv2.2 = DiseaseTerm.medraCode Map:caAERSv2.2 = AbstractMeddraDomain.icd9CmCode Map:CTOM = Protocol.diseaseCode Map:CTR&Rr2 = MedDRA Code Map:CTR&Rr2 = Medical condition Map:CTR&Rr2 = MedDRA Version Map:CTR&Rr2 = MedDRA EUTCT ID Map:CTR&Rr2 = MedDRA Term Map:CTR&Rr2 = Medical condition in lay language Map:CTR&Rr2 = MedDRA Level Map:CTRPv1.0 = ObservationalStudyProtocol.diseaseCode Map:CTRPv1.0 = InterventionalStudyProtocol.diseaseCode Map:CTRPv1.0 = StudyProtocol.diseaseCode Map:CTRPv3.8 = StudyDisease.diseaseCode Map:CTRRr3 = Study.diseaseCode Map:CTRv1.0 = StudyCondition.code Map:SDTM IGv3.1.2 = TS.TSVAL

Attribute	Notes	Constraints and Tags
		where TSPARMCD=INDIC Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "INDIC" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "INDIC" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "INDIC" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "INDIC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "INDIC"
leadIndicator <i>Class:</i> StudyCondition <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0..1	DEFINITION: Specifies whether this is the primary condition of a study. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = StudyDisease.leadDisease Map:caAERSv2.2 = AbstractStudyDisease.leadDisease Map:CTRPv3.8 = StudyDisease.leadDiseaseIndicator Map:CTRv1.0 = StudyCondition.leadIndicator

Class: StudyLegalSponsor

Package: Protocol Representation Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Government Agency examples: National Cancer Institute (NCI), National Institutes of Health (NIH), National Cancer Research Institute (NCRI)

Private industry examples: pharmaceutical companies

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = StudySponsor
- Map:CTRR = Secondary Sponsor
- Map:CTRv1.0 = StudyLegalSponsor
- Map:HSDBv1.0 = [Lead Organization] .Organization Type

Connectors

Source	Connector	Target	Notes
StudyLegalSponsor 0..* performedStudyLegalSpons or	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvid er	DESCRIPTION: Each StudyLegalSponsor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudyLegalSponsor.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyLegalSponsor 0..* sponsoringStudyLegalSpons or	is responsible for	StudyProtocolVersion 1 sponsoredStudyProtocolVer sion	<p>DESCRIPTION:</p> <p>Each StudyLegalSponsor always is responsible for one StudyProtocolVersion. Each StudyProtocolVersion might be the responsibility of one or more StudyLegalSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyLegalSponsor 0..* performedStudyLegalSpons or	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION:</p> <p>Each StudyLegalSponsor might be a function performed by one Organization. Each Organization might function as one or more StudyLegalSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProtocolDeviation 0..* authorizedPerformedProtoco lDeviation	be authorized by	StudyLegalSponsor 0..1 authorizingStudyLegalSpon sor	<p>DESCRIPTION:</p> <p>Each PerformedProtocolDeviation might be authorized by one StudyLegalSponsor. Each StudyLegalSponsor might authorize one or more PerformedProtocolDeviation .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> StudyLegalSponsor <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether this is the main or principal study legal sponsor.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRR = Sponsor Map:CTRv1.0 = StudyLegalSponsor.primaryIndicator Map:WHO = Primary Sponsor Map:WHO = Secondary Sponsor

Class: StudyObjective

Package: Protocol Representation Sub-Domain

DEFINITION:

A goal that the study is aiming to achieve in terms of a scientific question to be answered by the analysis of data collected during the study.

EXAMPLE(S):

To extend the life of study participants by at least 3 years.

To determine efficacy of Drug X dose 1, dose 2, and dose 3 as measured by the percentage of subjects experiencing headache relief.

To compare overall survival in subjects with [type of cancer] who have received [prior treatment] and who are randomized to treatment with either Combination A+B or single-agent B.

To select a Drug X dose for further evaluation based on comparison of the short-term antiviral activity, safety, and tolerability of different oral doses of Drug X in combination with Drug Y in HIV-1 infected therapy-naïve subjects.

To compare the proportion of subjects developing a rash in subjects administered dermatological precautions (DP) versus subjects administered usual care precautions (UC) during 12 weeks of treatment of Drug X in [disease description] subjects.

To obtain exploratory descriptive information on the relationship of tobacco use, alcohol use and dietary patterns on toxicity and outcomes in males and females.

OTHER NAME(S):

NOTE(S):

StudyProtocolVersion.purposeStatement, StudyProtocolVersion.primaryPurposeTypeCode and StudyObjective may sound similar in meaning but are distinct concepts in BRIDG. StudyProtocolVersion.purposeStatement, which is a broad explanation of why a study is being conducted (e.g. determine efficacy of a drug or procedure), differs from StudyProtocolVersion.primaryPurposeTypeCode which is a classification of the purpose or intent of the study (e.g. Prevention, Treatment, Quality of Life), and that differs from StudyObjective, which describes in a specific and measurable way what the study hopes to accomplish (e.g. extend life of subjects at least 3 years, reduce frequency of symptoms).

Tagged Values:

- Map:CTRPv3.8 = StudyObjective
- Map:CTRR = Objectives
- Map:CTRr3 = StudyObjective
- Map:CTRv1.0 = StudyObjective

Connectors

Source	Connector	Target	Notes
StudyObjective 0..* involvedStudyObjective	is an aim of	StudyProtocolVersion 1 involvingStudyProtocolVersion	<p>DESCRIPTION: Each StudyObjective always is an aim of one StudyProtocolVersion. Each StudyProtocolVersion might aim to achieve one or more StudyObjective.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyOutcomeMeasure 1..* measuringStudyOutcomeMe asure	measures	StudyObjective 1..* measuredStudyObjective	DESCRIPTION: Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is measured by one or more StudyOutcomeMeasure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> StudyObjective <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of study objective.</p> <p>EXAMPLE(S): primary, secondary, tertiary, exploratory</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The examples given are the only allowable concepts for this attribute.</p>	Map:SDTM IGv3.1.1 = TS.TSPARMCD

Attribute	Notes	Constraints and Tags
description <i>Class:</i> StudyObjective <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of the study objective.</p> <p>EXAMPLE(S): The objective of the analysis is to evaluate the efficacy of study treatment versus placebo. The Alzheimer's Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] and the Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) will serve as the primary efficacy instruments. Efficacy will be determined by testing for a statistically significant relationship between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, low dose [54 mg], and high dose [81 mg]).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The example above makes reference to content from more than just the StudyObjective class, rather also from classes closely related to it. However, in prose presentation, this is common practice. See BRIDG GForge Tracker #30649 and #31401.</p>	Map:CTR&Rr2 = Trial main objective Map:CTR&Rr2 = Trial secondary objective Map:CTRPv3.8 = StudyObjective.outline Map:CTRRr3 = StudyObjective.description Map:CTRv1.0 = StudyObjective.description Map:HSDBv1.0 = [Study].Primary Purpose 'Other' value specification Map:HSDBv1.0 = [Study].Primary Purpose Map:SDTM IGv3.1.1 = TS.TSPARMCD Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=OBJPRIM Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=OBJSEC Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OBJSEC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OBJSEC" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "OBJPRIM" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OBJPRIM"

Class: StudyOutcomeMeasure

Package: Protocol Representation Sub-Domain

DEFINITION:

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 that would most specifically answer the hypothesis proposed by the study design.

EXAMPLE(S):

Time to Local Recurrence (TLR), Disease-free Survival (DFS), Survival.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv1.0 = StudyOutcomeMeasure
- Map:CTRPv3.8 = StudyOutcomeMeasure
- Map:CTRRr3 = StudyOutcomeMeasure
- Map:CTRv1.0 = StudyOutcomeMeasure

Connectors

Source	Connector	Target	Notes
StudyOutcomeMeasure 1..* measuringStudyOutcomeMe asure	measures	StudyObjective 1..* measuredStudyObjective	DESCRIPTION: Each StudyOutcomeMeasure always measures one or more StudyObjective. Each StudyObjective always is

Source	Connector	Target	Notes
			<p>measured by one or more StudyOutcomeMeasure.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
name <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A non-unique textual identifier for the study outcome measure.</p> <p>EXAMPLE(S): all-cause mortality</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Outcome Measure Map:CTGOV = Secondary Outcome Measure Map:CTR&Rr2 = Primary end points Map:CTR&Rr2 = Secondary end point Map:CTRPv1.0 = StudyOutcomeMeasure.name Map:CTRPv3.8 = StudyObjective.name Map:CTRPv3.8 = StudyOutcomeMeasure.name Map:CTRr = Outcomes Map:CTRr3 = StudyOutcomeMeasure.name Map:CTRv1.0 = StudyOutcomeMeasure.name Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OUTMSPRI" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "OUTMSPRI" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "OUTMSSEC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OUTMSEXP" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "OUTMSEXP" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OUTMSSEC"

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the kind of study outcome measure.</p> <p>EXAMPLE(S): n/a, safety, efficacy, bio-equivalence, bio-availability, pharmacokinetics, pharmacodynamics</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Study Classification Map:CTGOV = Safety Issue? Map:CTOM = Trial scope Pharmacokinetics Map:CTR&Rr2 = Trial scope Prophylaxis Map:CTR&Rr2 = Trial scope Diagnosis Map:CTR&Rr2 = Trial scope Other Map:CTR&Rr2 = Trial scope Therapy Map:CTR&Rr2 = Trial scope Efficacy Map:CTR&Rr2 = Trial scope Dose response Map:CTR&Rr2 = Trial scope Map:CTR&Rr2 = Trial scope Pharmacogenetic Map:CTR&Rr2 = Trial scope Pharmacodynamics Map:CTR&Rr2 = Trial scope Safety Map:CTR&Rr2 = Trial scope Other specification Map:CTR&Rr2 = Trial scope Bioequivalence Map:CTRPv1.0 = StudyOutcomeMeasure.typeCode Map:CTRPv3.8 = InterventionalStudyProtocol.studyClassificationCode Map:CTRR = Primary Outcome Type Map:CTRRr3 = StudyOutcomeMeasure.typeCode Map:CTRv1.0 = StudyOutcomeMeasure.typeCode Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=TTYPE Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TTYPE" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TTYPE" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TTYPE" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TTYPE" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TTYPE"

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the main or principal study outcome measure.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Primary Outcome Measure Map:CTRPv1.0 = StudyOutcomeMeasure.primaryIndicator Map:CTRPv3.8 = StudyOutcomeMeasure.primaryIndicator Map:CTRR = Primary Outcome Type Map:CTRR = Outcomes Map:CTRr3 = StudyOutcomeMeasure.primaryIndicator Map:CTRv1.0 = StudyOutcomeMeasure.primaryIndicator
exploratoryIndicator <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this study outcome measure is used to evaluate and/or form hypotheses.</p> <p>EXAMPLE(S): A study outcome measure may be marked exploratory if its used to form hypotheses about the intervention outcome(s).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Adapted from NCI Thesaurus, Exploratory Outcome Measure (Code C98724)</p> <p>As per CDISC, study objective can be exploratory (supported by StudyObjective.typeCode) and an outcome measure can also be exploratory independent of the study objective hence this attribute.</p>	Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "OUTMSEXP"
description <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual summary of the study outcome measure used to clarify its meaning, method, or purpose.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv3.8 = StudyOutcomeMeasure.descriptionText Map:CTRr3 = StudyOutcomeMeasure.description

Attribute	Notes	Constraints and Tags
timeFrameText <i>Class:</i> StudyOutcomeMeasure <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Time point(s) at which the study outcome measure is assessed</p> <p>EXAMPLE(S): one year</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Time Frame Map:CTR&Rr2 = Primary end point timepoint Map:CTR&Rr2 = Secondary end point timepoint Map:CTRPv1.0 = StudyOutcomeMeasure.timeframe Map:CTRPv3.8 = StudyOutcomeMeasure.timeFrame Map:CTRR = Outcomes Map:CTRR3 = StudyOutcomeMeasure.timeFrameText Map:CTRv1.0 = StudyOutcomeMeasure.timeFrameText

Class: StudyProtocol

Package: Protocol Representation Sub-Domain

DEFINITION:

A discrete, structured plan (that persists over time) for a study 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.

EXAMPLE(S):

ClinicalTrials.gov study NCT01632332 Vaccine Therapy in Treating Patients With Previously Treated Stage II-III HER2-Positive Breast Cancer. The study protocol includes the elements identified in the NOTE(S) section.

OTHER NAME(S):

NOTE(S):

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. The notion of a study protocol includes (but is not limited to) the design, statistical considerations, activities to test a particular hypothesis or answer a particular question that is the basis of the study, characteristics, specifications, objective(s), background, pre-study/study/post-study portions of the plan (including the design, methodology, statistical considerations, organization). The study protocol may be of any type that involves subjects, including prevention, therapeutic, interventional or observational. Subjects involved in the study protocol may be biological entities (human, animal, specimen, tissue, organ, etc.) or products. The study protocol can be in document form which can be related to other supporting documents, including (but not limited to) informed consent documents, case report forms (CRFs), regulatory and approval documentation, correlative studies, etc. (via the inherited association to DocumentVersionRelationship). That said, it is important to understand that since virtually any change in a study protocol can have significant ramifications in the life cycle of a study, all characteristics (attributes and associations) of a study protocol are captured in the StudyProtocolVersion class. So in fact, the complete notion of a study protocol is represented in BRIDG by the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion and all their associations.

- The StudyProtocol class represents the content of the study protocol which includes characteristics and plan of the study which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the document form of the study protocol and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is the details of the study protocol document that may change over time.

Tagged Values:

- Map:BRIDGSCC = Model Integrity - Study Versioning
- Map:CTRPv3.8 = StudyProtocol
- Map:CTRv1.0 = StudyProtocol

- Map:Statistics v1.0 = StudyProtocol

Connectors

Source	Connector	Target	Notes
StudyProtocol 0..1 planningStudyProtocol	is the plan for	Study 1 plannedStudy	<p>DESCRIPTION: Each StudyProtocol always is the plan for one Study. Each Study might have as plan one StudyProtocol.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolVersion 1..* versioningStudyProtocolVer sion	is a version of	StudyProtocol 1 versionedStudyProtocol	<p>DESCRIPTION: Each StudyProtocolVersion always is a version of one StudyProtocol. Each StudyProtocol always has as a version one or more StudyProtocolVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CompanionStudyRelatio nship 0..* accompañadoCompanionStu dyRelationship	has as a companion	StudyProtocol 1 accompanyingStudyProtocol	<p>DESCRIPTION: Each CompanionStudyRelatio nship always has as a companion one StudyProtocol. Each StudyProtocol might be a companion of one or more CompanionStudyRelatio nship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocument 0..1 representingStudyProtocolD ocument	represents	StudyProtocol 1 representedStudyProtocol	<p>DESCRIPTION: Each StudyProtocolDocument always represents one StudyProtocol. Each StudyProtocol might be represented in one StudyProtocolDocument.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
IntegratedStatisticalAnalysisPlan 0..* integratingIntegratedStatisticalAnalysisPlan	integrates data from	StudyProtocol 1..* integratedStudyProtocol	<p>DESCRIPTION:</p> <p>Each IntegratedStatisticalAnalysisPlan always integrates data from one or more StudyProtocol. Each StudyProtocol might have data integrated from one or more IntegratedStatisticalAnalysisPlan.</p> <p>DEFINITION:</p> <p>Identifies the study protocols whose data is used in the integrated statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySpecificStatisticalAnalysisPlan 0..1 addressingStudySpecificStatisticalAnalysisPlan	addresses the statistical needs of	StudyProtocol 1 addressedStudyProtocol	<p>DESCRIPTION:</p> <p>Each StudySpecificStatisticalAnalysisPlan always addresses the statistical needs of one StudyProtocol. Each StudyProtocol might have statistical needs addressed by one StudySpecificStatisticalAnalysisPlan.</p> <p>DEFINITION:</p> <p>Identifies the study protocol whose data is used in the study specific statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudyProtocolDocument

Package: Protocol Representation Sub-Domain

DEFINITION:

A document that describes a study protocol.

EXAMPLE(S):**OTHER NAME(S):****NOTE(S):**

A study protocol document is one component of the overall concept of a study protocol. The complete notion of the study protocol is represented in BRIDG by the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion and all their associations.

- The StudyProtocol class represents the content of the study protocol which includes characteristics and plan of the study which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the document form of the study protocol and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is the details of the study protocol document that may change over time.

Tagged Values:

- Map:CTRPv3.8 = StudyProtocol.document(Document)
- Map:CTRv1.0 = StudyProtocolDocument

Connectors

Source	Connector	Target	Notes
StudyProtocolDocument	specializes	Document	<p>DESCRIPTION: Each StudyProtocolDocument always specializes one Document. Each Document might be specialized by one StudyProtocolDocument.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocument 0..1 representingStudyProtocolDocument	represents	StudyProtocol 1 representedStudyProtocol	<p>DESCRIPTION: Each StudyProtocolDocument always represents one StudyProtocol. Each StudyProtocol might be represented in one StudyProtocolDocument.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudyProtocolDocumentVersion

Package: Protocol Representation Sub-Domain

DEFINITION:

A variant or snapshot of the study protocol document at a particular point in time.

EXAMPLE(S):

Version 3 of a breast cancer protocol document.

OTHER NAME(S):

Amendment

NOTE(S):

A study protocol document version is one component of the overall concept of a study protocol. The complete notion of the study protocol is represented in BRIDG by the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion and all their associations.

- The StudyProtocol class represents the content of the study protocol which includes characteristics and plan of the study which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the document form of the study protocol and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is the details of the study protocol document that may change over time.

The term "Amendment" needs to be disambiguated since it sometimes refers to the amended version of the protocol (StudyProtocolDocumentVersion) and other times refers to the summary of changes (AmendmentChangeSummaryVersion).

Tagged Values:

- Map:caAERSv2.2 = Study
- Map:CTRv1.0 = StudyProtocolDocumentVersion

Connectors

Source	Connector	Target	Notes
StudyProtocolDocumentVersion 0..1 containingStudyProtocolDocumentVersion	contains	StudyProtocolVersion 1 containedStudyProtocolVersion	<p>DESCRIPTION: Each StudyProtocolDocumentVersion always contains one StudyProtocolVersion. Each StudyProtocolVersion might be the contents of one StudyProtocolDocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocumentVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each StudyProtocolDocumentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StudyProtocolDocumentVersion.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocumentVersionPublicTitle 0..* namingStudyProtocolDocVersionPublicTitle	names	StudyProtocolDocumentVersion 1 namedStudyProtocolDocumentVersion	<p>DESCRIPTION: Each StudyProtocolDocumentVersionPublicTitle always names one StudyProtocolDocumentVersion. Each StudyProtocolDocumentVersion might be named by one or more StudyProtocolDocumentVersionPublicTitle.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
publicDescription <i>Class:</i> StudyProtocolDocumentVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual summary of a document version intended for the general population.</p> <p>EXAMPLE(S): The public description of the August 2012 version of E-3108 is "RATIONALE: Estrogen can cause the growth of breast cancer cells. Hormone therapy using tamoxifen citrate may fight cancer by blocking the use of estrogen by tumor cells.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Study.precisText Map:C3PRv2.9 = StudyVersion.descriptionText Map:caAERSv2.2 = Study.descriptionText Map:CTGOV = Brief Summary Map:CTOM = Protocol.descriptionText Map:CTOM = Protocol.precisText Map:CTRPv1.0 = InterventionalStudyProtocol.publicDescription Map:CTRPv1.0 = ObservationalStudyProtocol.publicDescription Map:CTRPv3.8 = StudyProtocol.publicDescription Map:CTR = Study synopsis Map:CTRr3 = StudyProtocolDocument.publicDescription Map:CTRr3 = Study.briefSummary Map:CRv1.0 = StudyProtocolDocumentVersion.publicDescription Map:FDA HL7 SD SD DSTU2012 = StudyProtocol.text Map:HSDBv1.0 = [Study].Study Public Description Map:LabViewer2.2 = Study.precisText
scientificDescription <i>Class:</i> StudyProtocolDocumentVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual summary of a document version that includes extended scientific or technical information.</p> <p>EXAMPLE(S): Part of the scientific description of the August 2012 version of E-3108 is "OBJECTIVES: Primary -To correlate CYP2D6 score (0 vs 1-2) and progression-free survival (PFS) of patients with metastatic breast cancer treated with tamoxifen citrate."</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Study.descriptionText Map:C3PRv2.9 = StudyVersion.precisText Map:caAERSv2.2 = Study.precisText Map:CTGOV = Detailed Description Map:CTRPv1.0 = StudyProtocol.scientificDescription Map:CTRPv1.0 = ObservationalStudyProtocol.scientific Description Map:CTRPv1.0 = InterventionalStudyProtocol.scientific Description Map:CTRPv3.8 = StudyProtocol.scientificDescription Map:CTRr3 = Study.detailedDescription Map:CRv1.0 = StudyProtocolDocumentVersion.scientific Description Map:HSDBv1.0 = [Study].Study Scientific Description Map:PSCv2.6 = Study.longTitle

Class: StudyProtocolDocumentVersionPublicTitle

Package: Protocol Representation Sub-Domain

DEFINITION:

The title of the document intended for the general population.

EXAMPLE(S):

The official title for E-3108 is "A Phase II Prospective Trial Correlating Progression Free Survival With CYP2D6 Activity in Patients With Metastatic Breast Cancer Treated With Single Agent Tamoxifen" and the public title is "Tamoxifen Citrate in Treating Patients With Metastatic or Recurrent Breast Cancer" for the August 2013 Version.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Vendor1v1.1 = StudyProtocolVersionDocument.publicTitle

Connectors

Source	Connector	Target	Notes
StudyProtocolDocumentVersionPublicTitle 0..* namingStudyProtocolDocVersionPublicTitle	names	StudyProtocolDocumentVersion 1 namedStudyProtocolDocumentVersion	<p>DESCRIPTION: Each StudyProtocolDocumentVersion always names one StudyProtocolDocumentVersion. Each StudyProtocolDocumentVersion might be named by one or more StudyProtocolDocumentVersionPublicTitle.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
name <i>Class:</i> StudyProtocolDocumentVersionPublicTitle <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A textual identifier given to the StudyProtocolVersionDocument.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:dicom = Clinical Trial Context Module - Clinical Trial Protocol Name (0012,0021)</p> <p>Map:dicom = Clinical Trial Subject Module - Clinical Trial Protocol Name (0012,0021)</p> <p>Map:Vendor1v1.1 = StudyProtocolDocumentVersion.publicTitle</p>

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> StudyProtocolDocumentVersionPublicTitle <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of study protocol version document public title.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = StudyProtocolVersionDocument.publicTitle.EN.use

Class: StudyProtocolVersion

Package: Protocol Representation Sub-Domain

DEFINITION:

A variant or snapshot of the study protocol at a particular point in time.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

A change in virtually any aspect of a study protocol can trigger the creation of a new study protocol version. The kinds of changes that can trigger creation of a new study protocol version include (but are not limited to) changes to the design, statistical considerations, activities to test a particular hypothesis or answer a particular question that is the basis of the study, characteristics, specifications, objective(s), background, pre-study/study/post-study portions of the plan (including the design, methodology, statistical considerations, organization), supporting documents such as informed consent documents, case report forms (CRFs), regulatory and approval documentation, correlative studies, etc.

The complete notion of the study protocol is represented in BRIDG by the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion and all their associations.

- The StudyProtocol class represents the content of the study protocol which includes characteristics and plan of the study which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the document form of the study protocol and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is the details of the study protocol document that may change over time.

Tagged Values:

- Map:AE = Study
- Map:C3PRv2.9 = StudyVersion
- Map:C3PRv2.9 = Study
- Map:caAERSv2.2 = Study
- Map:CTRPv1.0 = StudyProtocol
- Map:CTRRr3 = Study
- Map:CTRv1.0 = StudyProtocolVersion
- Map:HL7SD = StudyCharacteristic
- Map:HL7SD = PlannedStudy
- Map:HL7SP = PlannedStudy
- Map:HL7SP = Study
- Map:ICSRr2 = ResearchStudy (in IndividualCaseSafetyReport)
- Map:LabViewer2.2 = Study
- Map:PSCv2.6 = Study
- Map:SDTM IGv3.1.2 = TS.DOMAIN
- Map:SDTM IGv3.1.3 = TS
- Map:Statistics v1.0 = StudyProtocolVersion
- Map:Vendor1v1.1 = StudyProtocolVersion

Connectors

Source	Connector	Target	Notes
StudyProtocolVersion 1..* versioningStudyProtocolVersion	is a version of	StudyProtocol 1 versionedStudyProtocol	<p>DESCRIPTION: Each StudyProtocolVersion always is a version of one StudyProtocol. Each StudyProtocol always has as a version one or more StudyProtocolVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
InterventionalStudyProtocolVersion	specializes	StudyProtocolVersion	<p>DESCRIPTION: Each InterventionalStudyProtocol Version always specializes one StudyProtocolVersion. Each StudyProtocolVersion might be specialized by one InterventionalStudyProtocol Version.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
CompanionStudyRelationship 0..* accompanyingCompanionStudyRelationship	is a companion of	StudyProtocolVersion 1 accompaniedStudyProtocolVersion	<p>DESCRIPTION: Each CompanionStudyRelationship always is a companion of one StudyProtocolVersion. Each StudyProtocolVersion might have as a companion one or more CompanionStudyRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyProtocolDocumentVersion 0..1 containingStudyProtocolDocumentVersion	contains	StudyProtocolVersion 1 containedStudyProtocolVersion	<p>DESCRIPTION: Each StudyProtocolDocumentVersion always contains one StudyProtocolVersion. Each StudyProtocolVersion might be the contents of one</p>

Source	Connector	Target	Notes
			<p>StudyProtocolDocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PlannedStudySubject 1..* intendedPlannedStudySubject	participates in	StudyProtocolVersion 1 plannedForStudyProtocolVersion	<p>DESCRIPTION:</p> <p>Each PlannedStudySubject always participates in one StudyProtocolVersion. Each StudyProtocolVersion always is participated in by one or more PlannedStudySubject.</p> <p>DEFINITION:</p> <p>Indicates the types of StudySubjects intended to participate in the StudyProtocolVersion.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>ActualIndicator should be set to 'false' for the Entity that is the subject</p>
StatisticalAnalysisPlanVersion 0..* addressingStatisticalAnalysisPlanVersion	addresses the statistical needs of	StudyProtocolVersion 1..* addressedStudyProtocolVersion	<p>DESCRIPTION:</p> <p>Each StatisticalAnalysisPlanVersion always addresses the statistical needs of one or more StudyProtocolVersion. Each StudyProtocolVersion might have statistical needs addressed by one or more StatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>Identifies the version of the study protocol that is the basis for a statistical analysis plan version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyOversightAuthority 0..*	oversee	StudyProtocolVersion 0..1	DESCRIPTION: Each

Source	Connector	Target	Notes
overseeingStudyOversightAuthority		overseenStudyProtocolVersion	<p>StudyOversightAuthority might oversee one StudyProtocolVersion. Each StudyProtocolVersion might be overseen by one or more StudyOversightAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyReference 0..* referencingStudyReference	is referenced by	StudyProtocolVersion 1..* referencedStudyProtocolVersion	<p>DESCRIPTION: Each StudyReference always is referenced by one or more StudyProtocolVersion. Each StudyProtocolVersion might refer to one or more StudyReference.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudiedMolecularBiomarkerGroup 0..* studiedStudiedMolecularBiomarkerGroup	is studied by	StudyProtocolVersion 1 studyingStudyProtocolVersion	<p>DESCRIPTION: Each StudiedMolecularBiomarkerGroup always is studied by one StudyProtocolVersion. Each StudyProtocolVersion might be studying one or more StudiedMolecularBiomarkerGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyActivity 0..* usedStudyActivity	be used by	StudyProtocolVersion 0..1 usingStudyProtocolVersion	<p>DESCRIPTION: Each StudyActivity might be used by one StudyProtocolVersion. Each StudyProtocolVersion might use one or more StudyActivity.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyCondition 0..* investigatedStudyCondition	is the focus of	StudyProtocolVersion 1 focuses onStudyProtocolVersion	DESCRIPTION: Each StudyCondition always is the focus of one StudyProtocolVersion. Each StudyProtocolVersion might focus on one or more StudyCondition. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyObjective 0..* involvedStudyObjective	is an aim of	StudyProtocolVersion 1 involvingStudyProtocolVersion	DESCRIPTION: Each StudyObjective always is an aim of one StudyProtocolVersion. Each StudyProtocolVersion might aim to achieve one or more StudyObjective. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PlannedStudySite 0..* executingPlannedStudySite	plans to execute	StudyProtocolVersion 1 executesStudyProtocolVersion	DESCRIPTION: Each PlannedStudySite always plans to execute one StudyProtocolVersion. Each StudyProtocolVersion might be planned to be executed at one or more PlannedStudySite. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyLegalSponsor 0..* sponsoringStudyLegalSponsor	is responsible for	StudyProtocolVersion 1 sponsoredStudyProtocolVersion	DESCRIPTION: Each StudyLegalSponsor always is responsible for one StudyProtocolVersion. Each StudyProtocolVersion might be the responsibility

Source	Connector	Target	Notes
			<p>of one or more StudyLegalSponsor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteProtocolVersionRelationship 0..* executingStudySiteProtocolVersionRelationship	executes	StudyProtocolVersion 1 executedStudyProtocolVersion	<p>DESCRIPTION: Each StudySiteProtocolVersionRelationship always executes one StudyProtocolVersion. Each StudyProtocolVersion might be executed at one or more StudySiteProtocolVersionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ObservationalStudyProtocolVersion	specializes	StudyProtocolVersion	<p>DESCRIPTION: Each ObservationalStudyProtocolVersion always specializes one StudyProtocolVersion. Each StudyProtocolVersion might be specialized by one ObservationalStudyProtocolVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StratumGroup 0..* describedStratumGroup	is defined by	StudyProtocolVersion 1 describingStudyProtocolVersion	<p>DESCRIPTION: Each StratumGroup always is defined by one StudyProtocolVersion. Each StudyProtocolVersion might define one or more StratumGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
Arm 0..* subdividingArm	is a division of	StudyProtocolVersion 1 subdividedStudyProtocolVe rsion	DESCRIPTION: Each Arm always is a division of one StudyProtocolVersion. Each StudyProtocolVersion might be divided into one or more Arm. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyPersonnel 0..* performedStudyPersonnel	perform a role for	StudyProtocolVersion 0..1 performingStudyProtocolVe rsion	DESCRIPTION: Each StudyPersonnel might perform a role for one StudyProtocolVersion. Each StudyProtocolVersion might have a role performed by one or more StudyPersonnel. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyAgent 0..* evaluatedStudyAgent	is evaluated by	StudyProtocolVersion 1 evaluatingStudyProtocolVer sion	DESCRIPTION: Each StudyAgent always is evaluated by one StudyProtocolVersion. Each StudyProtocolVersion might be evaluating one or more StudyAgent. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyResource 0..* usedStudyResource	be used for	StudyProtocolVersion 0..1 usingStudyProtocolVersion	DESCRIPTION: Each StudyResource might be used for one StudyProtocolVersion. Each StudyProtocolVersion might use one or more StudyResource. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedActivity 0..* executedPerformedActivity	execute under	StudyProtocolVersion 0..1 executingStudyProtocolVersion	DESCRIPTION: Each PerformedActivity might execute under one StudyProtocolVersion. Each StudyProtocolVersion might be executed by one or more PerformedActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Epoch 0..* subdividingEpoch	is a division of	StudyProtocolVersion 1 subdividedStudyProtocolVersion	DESCRIPTION: Each Epoch always is a division of one StudyProtocolVersion. Each StudyProtocolVersion might be divided into one or more Epoch. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
acronym <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The non-unique initials or abbreviated name used for identification of the study protocol version.</p> <p>EXAMPLE(S): WHI for Women's Health Initiative</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Acronym Map:CTR&Rr2 = Abbreviated title of trial Map:CTRPv1.0 = ObservationalStudyProtocol.acronym Map:CTRPv1.0 = InterventionalStudyProtocol.acronym Map:CTRPv1.0 = StudyProtocol.acronym Map:CTRPv3.8 = StudyProtocol.acronym Map:CTRR = Acronym Map:CTRRr3 = Study.acronym Map:CTRv1.0 = StudyProtocolVersion.acronym Map:HSDBv1.0 = [Study].Study Acronym Map:Statistics v1.0 = StudyProtocolVersion.acronym Map:WHO = Acronym
mandatoryIndicator <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the modifications contained in the study protocol version must be applied to all sites and subjects or study subjects that want to continue participating in the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = StudyProtocolVersion.mandatoryIndicator Map:PSCv2.6 = Amendment.mandatory Map:Statistics v1.0 = StudyProtocolVersion.mandatoryIndicator
amendmentGracePeriod <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The period of time during which sites can continue to accrue on an existing study protocol version before they are required to switch to the new study protocol version.</p> <p>EXAMPLE(S): 90 days</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = StudyVersion.gracePeriod Map:CTRv1.0 = StudyProtocolVersion.amendmentGracePeriod Map:Statistics v1.0 = StudyProtocolVersion.amendmentGracePeriod

Attribute	Notes	Constraints and Tags
phaseCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a stage in the progression of a therapy from initial experimental use in humans in clinical trials to post-market evaluation.</p> <p>EXAMPLE(S): I, I/II, II, III, N/A</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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. 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 near the time of approval to elicit additional findings. Phase 4: Concurrent with marketing approval, Food and Drug Administration (FDA) may seek agreement from the sponsor to conduct certain post-marketing (phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. Phase 5: Post-marketing surveillance is sometimes referred to as Phase 5.</p>	Map:C3PR = Study.phaseCode Map:C3PRv2.9 = Study.phaseCode Map:caAERSv2.2 = Study.phaseCode Map:CTGOV = Study Design Study Phase Map:CTOM = Protocol.phaseCode Map:CTR&Rr2 = Trial type Therapeutic Confirmatory (Phase III) Map:CTR&Rr2 = Trial type Therapeutic Use (Phase IV) Map:CTR&Rr2 = Trial type Therapeutic Exploratory (Phase II) Map:CTR&Rr2 = Trial type Human pharmacology (Phase I) Map:CTRPv1.0 = InterventionalStudyProtocol.phaseCode Map:CTRPv1.0 = ObservationalStudyProtocol.phaseCode Map:CTRPv1.0 = StudyProtocol.phaseCode Map:CTRPv3.8 = StudyProtocol.phaseCode Map:CTRR = Clinical Trial Phase Map:CTRRr3 = Study.phaseCode Map:CTRRr3 = Study.typeCode Map:CTRv1.0 = StudyProtocolVersion.phaseCode Map:HSDBv1.0 = [Study].Phase Map:LabViewer2.2 = Study.phase Map:SDTM IGv3.1.2 = TS.TSVAL WHERE TSPARMCD=TPHASE Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TPHASE" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TPHASE" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TPHASE" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TPHASE" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TPHASE" Map:Statistics v1.0 = StudyProtocolVersion.phaseCode Map:Vendor1v1.1 = StudyProtocolVersion.phaseCode Map:WHO = Study Type.Phase

Attribute	Notes	Constraints and Tags
primaryPurposeTypeCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of study based upon the intent of the study's activities. A classification of the intent of the study.</p> <p>EXAMPLE(S): 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 studies) explore ways to improve comfort and the quality of life for individuals with a chronic illness.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): StudyProtocolVersion.purposeStatement, StudyProtocolVersion.primaryPurposeTypeCode and StudyObjective may sound similar in meaning but are distinct concepts in BRIDG. StudyProtocolVersion.purposeStatement, which is a broad explanation of why a study is being conducted (e.g. determine efficacy of a drug or procedure), differs from StudyProtocolVersion.primaryPurposeTypeCode which is a classification of the purpose or intent of the study (e.g. Prevention, Treatment, Quality of Life), and that differs from StudyObjective, which describes in a specific and measurable way what the study hopes to accomplish (e.g. extend life of subjects at least 3 years, reduce frequency of symptoms).</p>	Map:C3PR = Study.type Map:C3PRv2.9 = Study.type Map:CTGOV = Intervention Type Map:CTGOV = Study Design Primary Purpose Map:CTOM = Protocol.intentCode Map:CTR&Rr2 = Trial type Bioequivalence Study Map:CTR&Rr2 = Trial type Other specification Map:CTR&Rr2 = Trial type First administration to humans Map:CTR&Rr2 = Trial type Other Map:CTRPv1.0 = StudyProtocol.primaryPurposeCode Map:CTRPv1.0 = ObservationalStudyProtocol.primaryPurposeCode Map:CTRPv1.0 = InterventionalStudyProtocol.primaryPurposeCode Map:CTRPv3.8 = StudyProtocol.primaryPurposeCode Map:CTRPv3.8 = StudyProtocol.primaryPurposeOtherText Map:CTRR = Intervention Type Map:CTRR = Primary Purpose Map:CTRRr3 = Study.primaryPurposeCode Map:CTRv1.0 = StudyProtocolVersion.primaryPurposeCode Map:ICSRr2 = ResearchStudy.code (in IndividualCaseSafetyReport) Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=TINDTP Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "TINDTP" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "TINDTP" Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "TINDTP" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "TINDTP" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "TINDTP" Map:Statistics v1.0 = StudyProtocolVersion.primaryPurposeCode

Attribute	Notes	Constraints and Tags
purposeStatement <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A statement describing the overall intent of the study. This field describes the contribution of this study to product development, treatment strategies, prevention approaches, diagnostic techniques, or patient quality of life, i.e., what knowledge is being contributed from the conduct of this study.</p> <p>EXAMPLE(S): test the efficacy of a particular cancer treatment</p> <p>OTHER NAME(S):</p> <p>NOTE(S): StudyProtocolVersion.purposeStatement, StudyProtocolVersion.primaryPurposeTypeCode and StudyObjective may sound similar in meaning but are distinct concepts in BRIDG. StudyProtocolVersion.purposeStatement, which is an broad explanation of why a study is being conducted (e.g. determine efficacy of a drug or procedure), differs from StudyProtocolVersion.primaryPurposeTypeCode which is a classification of the purpose or intent of the study (e.g. Prevention, Treatment, Quality of Life), and that differs from StudyObjective, which describes in a specific and measurable way what the study hopes to accomplish (e.g. extend life of subjects at least 3 years, reduce frequency of symptoms).</p>	Map:CTRR = Trial Purpose Summary Map:CTRRr3 = Study.purposeStatement Map:CTRv1.0 = StudyProtocolVersion.purposeStatement Map:PRM = Trial Purpose Summary Map:Statistics v1.0 = StudyProtocolVersion.purposeStatement
targetAnatomicSiteCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of a study.</p> <p>EXAMPLE(S): breast, ovary</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CTRPv1.0 = StudyProtocol.targetAnatomicSiteCode Map:CTRPv1.0 = ObservationalStudyProtocol.targetAnatomicSiteCode Map:CTRPv1.0 = InterventionalStudyProtocol.targetAnatomicSiteCode Map:CTRPv3.8 = StudyProtocol.targetAnatomicSiteCode Map:CTRv1.0 = StudyProtocolVersion.targetAnatomicSiteCode Map:Statistics v1.0 = StudyProtocolVersion.targetAnatomicSiteCode

Attribute	Notes	Constraints and Tags
studySchematic <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Diagram which outlines all study epochs, timing of randomization and duration of treatments.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = ObservationalStudyProtocol.studySchematic Map:CTRPv1.0 = StudyProtocol.studySchematic Map:CTRPv1.0 = InterventionalStudyProtocol.studySchematic Map:CTRR = Study schematic/flow chart Map:CTRr3 = Study.studySchematic Map:CTRv1.0 = StudyProtocolVersion.studySchematic Map:Statistics v1.0 = StudyProtocolVersion.studySchematic
designConfigurationCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying how subject or experimental unit exposures to treatment strategies (which may include controls such as no treatment) will be identified, for retrospective studies, or planned, for prospective studies, in order to characterize treatment effects and compare effects of different treatment strategies in the execution of a clinical or pre-clinical study. The configuration will specify whether a subject or experimental unit received or is to receive only one exposure or multiple exposures, and, if multiple exposures, whether those exposures were/are to be simultaneous or in series.</p> <p>EXAMPLE(S): Parallel Group Design, Crossover Design, Factorial Designs, Cohort, Case-control, Case-only, Case-crossover, Ecologic or Community Studies, Family-based</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment.</p>	Map:CTGOV = Intervention Model Map:CTGOV = Study Design Map:CTGOV = Observational Study Model Map:CTRPv1.0 = ObservationalStudyProtocol.studyModelCode Map:CTRPv1.0 = InterventionalStudyProtocol.designConfigurationCode Map:CTRv3.8 = InterventionalStudyProtocol.designConfigurationCode Map:CTRR = Configuration Map:CTRR = Description of study design Map:CTRr3 = ObservationalStudy.studyModelCode Map:CTRr3 = Study.designConfigurationCode Map:CTRv1.0 = StudyProtocolVersion.designConfigurationCode Map:SDTM IGv3.1.3 = TS.TSVCDVER WHERE TSPARMCD = "INTMODEL" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "INTMODEL" Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "INTMODEL" Map:SDTM IGv3.1.3 = TS.TSVALCD WHERE TSPARMCD = "INTMODEL" Map:SDTM IGv3.1.3 = TS.TSVCDREF WHERE TSPARMCD = "INTMODEL" Map:Statistics v1.0 = StudyProtocolVersion.designConfigurationCode Map:WHO = Study Type Study Design Assignment

Attribute	Notes	Constraints and Tags
adaptiveDesignIndicator <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the design of the study is expected to evolve during the execution of the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Adaptive Study Indicator</p> <p>NOTE(S):</p>	Map:CTRv1.0 = StudyProtocolVersion.adaptiveDesignIndicator Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "ADAPT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "ADAPT"
companionCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of ancillary study.</p> <p>EXAMPLE(S): Embedded, Non-Stand-Alone Companion: This study is part of a master study and cannot be executed separately from it nor in association with another master study. The documentation for this kind of companion study is embedded in the protocol of the master study.</p> <p>Non-Embedded, Non-Stand-Alone Companion: This study is documented separately from a master study, but must be performed as part of a master study or as part of several master studies.</p> <p>Non-Embedded, Stand-Alone Companion: This study is a separately documented study that can be performed on its own or as a companion to one or more master studies.</p> <p>Non-Companion/Independent: This study is documented and executed on its own and does not support co-execution with a master study. This kind of study may be a master study with companion studies of its own.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Changes to example codes will require revisiting the RIM-based BRIDG Model.</p>	Map:C3PRv2.9 = Study.companionIndicator Map:C3PRv2.9 = Study.standaloneIndicator Map:CTRv1.0 = StudyProtocolVersion.companionCode Map:Statistics v1.0 = StudyProtocolVersion.companionCode

Attribute	Notes	Constraints and Tags
therapeuticAreaCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the field of knowledge that focuses on research and development of treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual.</p> <p>EXAMPLE(S): eye disease, nervous system disease</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The cardinality is generally 1..1; however, there could be circumstances where it could be 1..*, but since there isn't a clear use case for it, it is defined in the model as 0..1. The BRIDG Work Group invites any use cases for the 1..* cardinality to be brought to the Work Group.</p>	Map:CTRPv3.8 = StudyProtocol.programCodeText Map:CTRRr3 = Study.therapeuticAreaCode Map:Vendor1v1.1 = StudyProtocolVersion.therapeuticAreaCode
studySubjectTypeCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of study subject involved in the study or investigation.</p> <p>EXAMPLE(S): human, rat, mouse, x-ray machine</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is explicitly not meant to represent parts of study subjects that may be studied, such as a human eye, or groups of study subjects such as a herd of cows. It is meant to represent the whole individual that is registered as a study subject.</p>	Map:CTRv1.0 = StudyProtocolVersion.studySubjectTypeCode Map:HL7SP = StudyParticipation_RMIM Map:Statistics v1.0 = StudyProtocolVersion.studySubjectTypeCode

Attribute	Notes	Constraints and Tags
populationDescription <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the subject characteristics, including inclusion and exclusion criteria and describes the population for which the study may be generalized.</p> <p>EXAMPLE(S): A subset of the description of the population to be studied in the August 2012 version of E-3180 is: - "Ages Eligible for Study: 18 Years and older -Genders Eligible for Study: Both Criteria DISEASE CHARACTERISTICS: •Histologically confirmed adenocarcinoma of the breast •Estrogen-receptor and/or progesterone-receptor positive disease •Measurable or non-measurable disease •History of CNS metastasis allowed provided it has been treated (surgery, radiotherapy, or radiosurgery) within the past 4 weeks and does not require medications to control symptoms OTHER NAME(S): NOTE(S): This would include all subgroups as well.</p>	Map:CTGOV = Study Population Description Map:CTR&Rr2 = Population healthy volunteers Map:CTRv1.0 = StudyProtocol.populationDescription Map:CTRv1.0 = InterventionalStudyProtocol.populationDescription Map:CTRv1.0 = ObservationalStudyProtocol.populationDescription Map:CTRv1.0 = ObservationalStudyProtocol.studyPopulationDescription Map:CTRR = Target study population description Map:CTRr3 = Study.populationDescription Map:CTRv1.0 = StudyProtocolVersion.populationDescription Map:Statistics v1.0 = StudyProtocolVersion.populationDescription Map:WHO = Health Condition(s) or Problem(s) Studied
plannedStudySubjectExperience <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A description of what the study subject can expect to experience over the course of the study, including the sequence and duration of activities.</p> <p>EXAMPLE(S): The description, sequence and duration of study epochs, including pre-randomization and post-treatment epochs, therapy withdrawal epochs, and single- and double-blind treatment epochs.</p> <p>OTHER NAME(S): NOTE(S):</p>	Map:CTRR = Planned Subject Participation Experience Map:CTRr3 = Study.plannedStudySubjectExperience Map:CTRv1.0 = StudyProtocolVersion.plannedStudySubjectExperience Map:PRM = Planned Subject Participation Experience (ICH) Map:Statistics v1.0 = StudyProtocolVersion.plannedStudySubjectExperience
plannedSiteNumberRange <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> URG<INT.POS> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many study sites are expected to participate in the conduction of the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Relevant before specific sites have been selected. Can be derived once sites have been selected.</p>	Map:CTRv1.0 = StudyProtocolVersion.plannedSiteNumber

Attribute	Notes	Constraints and Tags
plannedDuration <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The intended period of time for the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTR&Rr2 = PlannedActivity.plannedDuration Map:CTRv1.0 = StudyProtocolVersion.plannedDuration Map:HSDBV1.0 = [Study].Study duration Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=LENGTH Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "LENGTH" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "LENGTH" Map:Statistics v1.0 = StudyProtocolVersion.plannedDuration
plannedInvestigationalExposureQuotient <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> REAL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The number of planned subjects to be exposed to investigational therapy, independent of dose or other factors, divided by the total number of planned subjects.</p> <p>EXAMPLE(S): For the CDISC variable TSVAL where TSPARMCD = "RANDQT", the value might be "0.67"</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "RANDQT" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "RANDQT"

Attribute	Notes	Constraints and Tags
targetAccrualNumberRange <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many study subjects are to be accrued for the study.</p> <p>EXAMPLE(S): The target accrual for the August 2012 version of E-3180 is 240.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): A typical target accrual number (always assumed to be a minimum target) would be targetAccrualNumberRange.IVL<INT>.low, a maximum target accrual would be targetAccrualNumberRange.IVL<INT>.high.</p>	Map:C3PR = Study.targetAccrualNumber Map:C3PRv2.9 = Study.targetAccrualNumber Map:CTGOV = Enrollment Map:CTOM = Protocol.targetAccrualNumber Map:CTR&Rr2 = Population planned numbers in whole trial Map:CTRPv1.0 = StudyProtocol.maximumTargetAccrualNumber Map:CTRPv1.0 = StudyProtocol.targetAccrualNumber Map:CTRPv1.0 = ObservationalStudyProtocol.targetAnatomicSiteCode.targetAccrualNumber Map:CTRPv1.0 = InterventionalStudyProtocol.targetAccrualNumber Map:CTRPv1.0 = InterventionalStudyProtocol.maximumTargetAccrualNumber Map:CTRPv1.0 = ObservationalStudyProtocol.maximumTargetAccrualNumber Map:CTRPv3.8 = StudyProtocol.maximumTargetAccrualNumber Map:CTRPv3.8 = StudyProtocol.targetAccrualNumber Map:CTR = Targeted Accrual Map:CTRr3 = Study.targetAccrualNumberRange Map:CTRv1.0 = StudyProtocolVersion.targetAccrualNumberRange Map:HSDBV1.0 = [Study].Targeted Accrual Map:SDTM IGv3.1.2 = TS.TSVAL where TSPARMCD=PLANSUB Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "PLANSUB" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "PLANSUB" Map:Statistics v1.0 = StudyProtocolVersion.targetAccrualNumberRange Map:WHO = Target Sample Size

Attribute	Notes	Constraints and Tags
periodicTargetAccrualNumber <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> RTO<INT.NONNEG,PQ.TI> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A ratio representing the number of study subjects to be accrued per a specified amount of time.</p> <p>EXAMPLE(S): 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyProtocol.monthlyTargetAccrualNumber Map:CTRPv1.0 = ObservationalStudyProtocol.monthlyTargetAccrualNumber Map:CTRPv1.0 = InterventionalStudyProtocol.monthlyTargetAccrualNumber Map:CTRPv3.8 = StudyProtocol.monthlyTargetAccrualNumber Map:CTRv1.0 = StudyProtocolVersion.periodicTargetAccrualNumber Map:Statistics v1.0 = StudyProtocolVersion.periodicTargetAccrualNumber
accrualReportingMethodCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the technique that is used for reporting study subject accrual data to the study sponsor.</p> <p>EXAMPLE(S): complete, abbreviated</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = ObservationalStudyProtocol.accrualReportingMethodCode Map:CTRPv1.0 = StudyProtocol.accrualReportingMethodCode Map:CTRPv1.0 = InterventionalStudyProtocol.accrualReportingMethodCode Map:CTRPv3.8 = StudyProtocol.accrualReportingMethodCode Map:CTRv1.0 = StudyProtocolVersion.accrualReportingMethodCode Map:Statistics v1.0 = StudyProtocolVersion.accrualReportingMethodCode
responsiblePartyCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of entity who is legally responsible for the execution of the study.</p> <p>EXAMPLE(S): PI, sponsor</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Responsible Party Map:CTRPv1.0 = StudyProtocol.responsiblePartyCode Map:CTRPv1.0 = ObservationalStudyProtocol.responsiblePartyCode Map:CTRPv1.0 = InterventionalStudyProtocol.responsiblePartyCode Map:CTRRr3 = StudyColleague.responsiblePartyIndicator Map:CTRv1.0 = StudyProtocolVersion.responsiblePartyCode Map:Statistics v1.0 = StudyProtocolVersion.responsiblePartyCode

Attribute	Notes	Constraints and Tags
multiInstitutionIndicator <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether a study is designed to be conducted at more than one site concurrently.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p> <p>Derived when StudyProtocolVersion.participatingOrganizationTypeCode = "Multi Center".</p> <p>Traditionally, the domain concept for this attribute is called "Multi-Institutional" indicator, but the intent is to identify whether there will be multiple sites regardless of the source of IRB approval.</p>	Map:C3PR = Study.multiInstitutionIndicator Map:caAERSv2.2 = Study.multiInstitutionIndicator Map:CTOM = Protocol.multiInstitutionIndicator Map:CTR = Multi Institution Indicator Map:CTRv1.0 = StudyProtocolVersion.multiInstitutionIndicator Map:Statistics v1.0 = StudyProtocolVersion.multiInstitutionIndicator
participatingOrganization <i>TypeCode</i> <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of organizations planned to participate as study sites for this study.</p> <p>EXAMPLE(S): Cancer Center, Clinical Center, Consortium, Group, Intergroup, Multi-Center, Network, Single Institution</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyProtocol.participatingOrganizationTypeCode Map:CTRPv1.0 = ObservationalStudyProtocol.participatingOrganizationTypeCode Map:CTRPv1.0 = InterventionalStudyProtocol.participatingOrganizationTypeCode Map:CTRv1.0 = StudyProtocolVersion.participatingOrganizationTypeCode Map:Statistics v1.0 = StudyProtocolVersion.participatingOrganizationTypeCode
participatingLocationCode <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 .. *	<p>DEFINITION: A coded value specifying the locations from which participants will be, are intended to be, or have been recruited for the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): participating countries, participating states</p> <p>NOTE(S):</p>	Map:CTR = Countries of Recruitment Map:CTRr3 = Study.participatingCountryCode Map:CTRv1.0 = StudyProtocolVersion.participatingCountryCode Map:HSDBV1.0 = [Study].location of study Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "FCNTRY" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "FCNTRY" Map:Statistics v1.0 = StudyProtocolVersion.participatingCountryCode Map:WHO = Countries of Recruitment

Attribute	Notes	Constraints and Tags
aeCodingSystem <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> OID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The coding system used for recording adverse events for a study protocol version.</p> <p>EXAMPLE(S): Common Terminology Criteria for Adverse Events (CTC AE)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The AE coding system for the December 2013 version of XYZ is the NCI Common Terminology Criteria for Adverse Events version 4.0 (CTCAE v4.0).</p>	Map:caAERSv2.2 = AETerminology Map:CTRPv1.0 = StudyProtocol.AEcodingSystem Map:CTRPv1.0 = ObservationalStudyProtocol.AECodingSystem Map:CTRPv1.0 = InterventionalStudyProtocol.AECodingSystem Map:CTRv1.0 = StudyProtocolVersion.aeCodingSystem Map:Statistics v1.0 = StudyProtocolVersion.aeCodingSystem
conditionCodingSystem <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> OID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The coding system used for recording conditions that are the focus of a study.</p> <p>EXAMPLE(S): MeSH, ICD-10, SNOMED CT</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = DiseaseTerminology.diseaseCodeTerm Map:CTRv1.0 = StudyProtocolVersion.conditionCodingSystem Map:Statistics v1.0 = StudyProtocolVersion.conditionCodingSystem
delayedRegistryPostingIndicator <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether there is to be a delay in the public disclosure of the study, as permitted by relevant local legislation or regulation.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The study includes a device NOT previously approved or cleared by the US FDA for any use, as specified in US Public Law 110-85, Title VIII, Section 801. Select Yes/No. If "Yes" is selected, full posting of the trial information on ClinicalTrials.gov will be delayed until after the device has been approved or cleared. At that time, it is the registrant's responsibility to change this selection to "No" and release the record for full publication.</p>	Map:CTRPv3.8 = StudyProtocol.delayedpostingIndicator Map:CTRR3 = Study.delayedProtocolPostingIndicator
dataCutoffDate <i>Class:</i> StudyProtocolVersion <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) by which any data collected will be used for analysis.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "DCUTDTC" Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "DCUTDTC"

Class: StudyReference

Package: Protocol Representation Sub-Domain

DEFINITION:

A citation to a publication related to the protocol's background.

EXAMPLE(S):

"Bauman, G.S. et al. (2000). Allelic loss of chromosome 1p and radiotherapy plus chemotherapy in patients with oligodendroglomas. Int J Rad Oncol Biol Phys 48:825-30."

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:CTGOV = References
- Map:CTRr3 = StudyReference
- Map:CTRv1.0 = StudyReference

Connectors

Source	Connector	Target	Notes
StudyReference 0..* referencingStudyReference	is referenced by	StudyProtocolVersion 1..* referencedStudyProtocolVersion	<p>DESCRIPTION: Each StudyReference always is referenced by one or more StudyProtocolVersion. Each StudyProtocolVersion might refer to one or more StudyReference.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
publicationIdentifier <i>Class:</i> StudyReference <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes identity of a publication related to the study protocol background.</p> <p>EXAMPLE(S): 10987815 is the unique PubMed Identifier (PMID) for the citation in MEDLINE.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = MEDLINE Identifier Map:CTRr = Published Results Identifier Map:CTRr3 = StudyReference.publicationIdentifier Map:CTRv1.0 = StudyReference.publicationIdentifier

Attribute	Notes	Constraints and Tags
publicationName <i>Class:</i> StudyReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier specifying the human-readable name of the publication.</p> <p>EXAMPLE(S): MEDLINE is the source for PMID 10987815</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRR = Published Results Title Map:CTRr3 = StudyReference.publicationName Map:CTRv1.0 = StudyReference.publicationName Map:PRM = PublishedResults.title
uniformResourceLocator <i>Class:</i> StudyReference <i>Datatype:</i> TEL.URL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A complete reference to a website (including http://) that is directly relevant to the study.</p> <p>EXAMPLE(S): http://www.alzheimers.org/</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Links URL Map:CTRr3 = StudyReference.universalResourceLocator Map:CTRv1.0 = StudyReference.uniformResourceLocator
citationDescription <i>Class:</i> StudyReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A bibliographical reference in a format acceptable to the publisher of the reference material.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Studies performed in the United States may be required to conform to the National Library of Medicine's MEDLINE format.</p>	Map:CTGOV = Citation Map:CTRR = Published Results Citation Map:CTRr3 = StudyReference.citationDescription Map:CTRv1.0 = StudyReference.citationDescription
linkPageDescription <i>Class:</i> StudyReference <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of the linked page.</p> <p>EXAMPLE(S): If the page being linked is the protocol's home page on the sponsor's Web site, the description might be "This is a link to the study sponsor's web site".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Links Description Map:CTRr3 = StudyReference.linkPageDescription Map:CTRv1.0 = StudyReference.linkPageDescription

Regulatory Sub-Domain

Package «DEPRECATED» in package 'BRIDG Domain Information Model'

The Regulatory sub-domain is intended for those involved in the creation and review of submissions to regulatory authorities. The majority of business requirements come from the regulated product submission (RPS) message specification. It focuses on the documentation required for a product submission to the Food and Drug Administration (FDA).

PLEASE NOTE: This sub-domain has not been updated since BRIDG release 1.0.

Regulatory Sub-Domain

View RG: Regulatory diagram

Class diagram in package 'Regulatory Sub-Domain'

The Regulatory sub-domain is intended for those involved in the creation and review of submissions to regulatory authorities. The majority of business requirements come from the regulated product submission (RPS) message specification. It focuses on the documentation required for a product submission to the Food and Drug Administration (FDA).

View RG: Regulatory

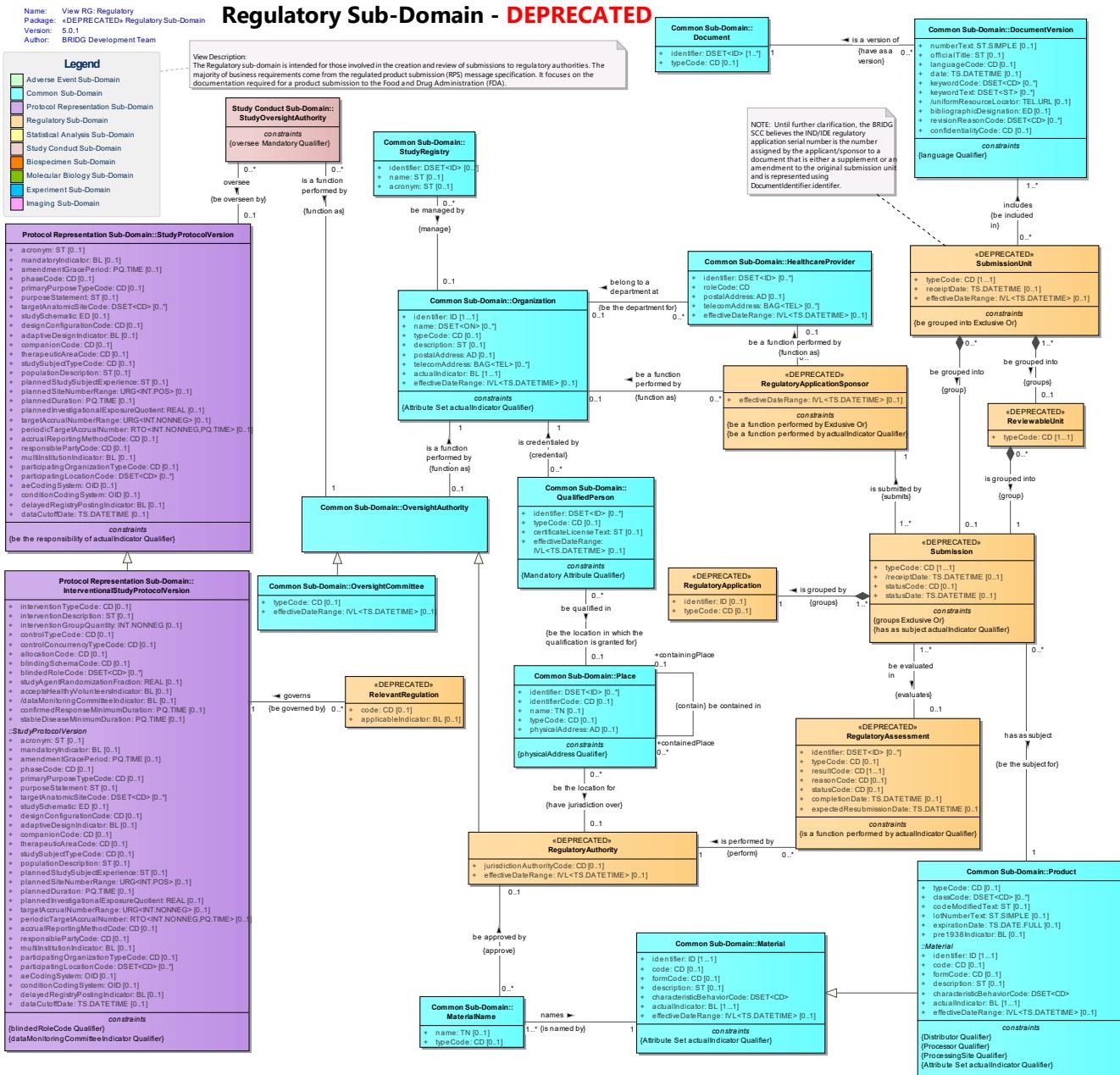


Figure 14: View RG: Regulatory

Class: RegulatoryApplication

Package: Regulatory Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

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.

OTHER NAME(S):

NOTE(S):

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

Tagged Values:

- Map:caAERSv2.2 = InvestigationalNewDrug
- Map:CTRPv3.8 = StudyIndIde
- Map:CTRRr3 = RegulatoryApplication
- Map:CTRv1.0 = RegulatoryApplication
- Map:RPS1 = Application

Connectors

Source	Connector	Target	Notes
Submission 1..* groupedSubmission	is grouped by	RegulatoryApplication 1 groupingRegulatoryApplication	<p>DESCRIPTION: Each Submission always is grouped by one RegulatoryApplication. Each RegulatoryApplication always groups one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> RegulatoryApplication <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A unique symbol that establishes identity of the regulatory application. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = InvestigationalNewDrug.indNumber Map:CTGOV = IND/IDE Number Map:CTGOV = IND/IDE Protocol? Map:CTOM = StudyAgent.investigationalNewDrugI dentifier Map:CTR&Rr2 = PIP Decision number Map:CTRPv1.0 = ObservationalStudyProtocol.indIdeInd icator Map:CTRPv1.0 = StudyProtocol.indIdeIndicator Map:CTRPv3.8 = StudyIndIde.indIdeNumber Map:CTRR = Regulatory Investigational Product Application Identifier Map:CTRR = IND/IDE Protocol (IND/IDE number suffix) Map:CTRr3 = RegulatoryApplication.identifier Map:CTRv1.0 = RegulatoryApplication.identifier Map:HCTv1.0 = MD Anderson Specific Content: Protocol .IND number Map:HSDBv1.0 = [IND/IDE] .Number
typeCode <i>Class:</i> RegulatoryApplication <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the kind of regulatory application. EXAMPLE(S): New Drug Application, 510k, Veterinary New Drug Submission OTHER NAME(S): NOTE(S): Each product type will be supported by a different application type.	Map:CTRPv3.8 = StudyIndIde.indIdeTypeCode Map:CTRR = IND/IDE Indicator Map:CTRr3 = RegulatoryApplication.typeCode Map:CTRv1.0 = RegulatoryApplication.typeCode Map:HSDBv1.0 = [IND/IDE].Type Map:RPS1 = Application.code

Class: RegulatoryApplicationSponsor

Package: Regulatory Sub-Domain

DEFINITION:

An organization or person 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.

EXAMPLE(S):
pharmaceutical company

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = INDHolder
- Map:CTRPv1.0 = RegulatoryApplicationSponsor
- Map:CTRr3 = RegulatoryApplicationSponsor
- Map:CTRv1.0 = RegulatoryApplicationSponsor
- Map:ICSRR2 = holder (in R_Product)
- Map:ICSRR2 = role (in R_Product)

Connectors

Source	Connector	Target	Notes
RegulatoryApplicationSpon sor 0..* performedRegulatoryAppli cationSponsor	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvid er	<p>DESCRIPTION: Each RegulatoryApplicationSpon sor might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more RegulatoryApplicationSpon sor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RegulatoryApplicationSpon sor 0..* performedRegulatoryAppli cationSponsor	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each RegulatoryApplicationSpon sor might be a function performed by one Organization. Each Organization might function as one or more RegulatoryApplicationSpon sor.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Submission 1..* submittedSubmission	is submitted by	RegulatoryApplicationSpon sor 1 submittingRegulatoryAppli cationSponsor	<p>DESCRIPTION: Each Submission always is submitted by one RegulatoryApplicationSpon sor. Each RegulatoryApplicationSpon sor always submits one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> RegulatoryApplicationSponsor <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the regulatory application sponsor is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = RegulatoryApplicationSponsor.effectiveDateRange Map:RPS2 = (New content)

Class: RegulatoryAssessment

Package: Regulatory Sub-Domain

DEFINITION:

An evaluation of a submission by a regulatory body.

EXAMPLE(S):

The FDA evaluates a submission for a new drug or device.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Authorization
- Map:CTRRr3 = RegulatoryAssessment
- Map:CTRv1.0 = RegulatoryAssessment
- Map:ICSRr2 = Approval (in R_Product)

Connectors

Source	Connector	Target	Notes
RegulatoryAssessment 0..* performedRegulatoryAssessment	is performed by	RegulatoryAuthority 1 performingRegulatoryAuthority	<p>DESCRIPTION: Each RegulatoryAssessment always is performed by one RegulatoryAuthority. Each RegulatoryAuthority might perform one or more RegulatoryAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Submission 1..* evaluatedSubmission	be evaluated in	RegulatoryAssessment 0..1 evaluatingRegulatoryAssessment	<p>DESCRIPTION: Each Submission might be evaluated in one RegulatoryAssessment.</p> <p>Each RegulatoryAssessment</p>

Source	Connector	Target	Notes
			<p>always evaluates one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of the regulatory assessment.</p> <p>EXAMPLE(S): New Drug Application (NDA) number, Investigational New Drug (IND) number, Biologic License Application (BLA), Premarket Approval (PMA), 510K</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Authorization.approvalId Map:CTR&Rr2 = Manufacturer authorisation number Map:CTR&Rr2 = Orphan drug number Map:CTR&Rr2 = MA number Map:CTRv1.0 = TherapeuticProduct.identifier Map:CTRr3 = RegulatoryAssessment.identifier Map:CTRv1.0 = RegulatoryAssessment.identifier Map:ICSRr2 = Approval.id (in R_Product)
typeCode <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the approval process used by the regulatory authority.</p> <p>EXAMPLE(S): FDA's Center for Devices and Radiological Health (CDRH) Process, FDA's Center for Drug Evaluation and Research (CDER) Process</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = RegulatoryAssessment.typeCode Map:HSDBV1.0 = [IND/IDE] .Grantor Map:ICSRr2 = Approval.code (in R_Product)

Attribute	Notes	Constraints and Tags
resultCode <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the regulatory designation made by the regulatory authority.</p> <p>EXAMPLE(S): For regular submissions the code can be: approved, not approvable, approvable, complete response or cleared.</p> <p>For expanded access submissions the code can be: Available, No longer available, Temporarily not available, or Approved for marketing.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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".</p> <p>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".</p>	Map:CTGOV = Expanded Access Status Map:CTR&Rr2 = IEC Opinion Given Map:CTR&Rr2 = GMP MP Auth granted Map:CTRPv3.8 = StudyIndIde.expandedAccessStatusCode Map:CTRr = Expanded access indicator Map:CTRr3 = StudyAgent.expandedAccessStatusCode Map:CTRr3 = RegulatoryAssessment.assessmentCode Map:CTRv1.0 = RegulatoryAssessment.resultCode
reasonCode <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the rationale for a regulatory designation.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTR&Rr2 = IEC Opinion not favourable reasons Map:CTR&Rr2 = Reason for no authorisation Map:CTRr3 = RegulatoryAssessment.assessmentReasonCode Map:CTRv1.0 = RegulatoryAssessment.reasonCode
statusCode <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the assessment.</p> <p>EXAMPLE(S): pending, complete</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRr3 = RegulatoryAssessment.statusCode

Attribute	Notes	Constraints and Tags
completionDate <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which this particular assessment is completed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Expanded Access Status Map:CTR&Rr2 = IEC Opinion date Map:CTRR = Expanded access indicator Map:CTRRr3 = RegulatoryAssessment.assessmentDate Map:CTRv1.0 = RegulatoryAssessment.completionDate Map:ICSRr2 = Approval.effectiveTime (in R_Product) Map:ICSRr2 = Author2.time (in R_Product)
expectedResubmissionDate <i>Class:</i> RegulatoryAssessment <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date on which the resubmission of the regulatory application is expected.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Used only when RegulatoryAssessment.statusCode is not complete. Regulatory authorities typically assign a resubmission deadline such as 30 days.</p>	Map:CTRRr3 = RegulatoryAssessment.expectedResubmissionDate

Class: RegulatoryAuthority

Package: Regulatory Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = RegulatoryAuthority
- Map:CTRv1.0 = RegulatoryAuthority
- Map:CTRv3.8 = RegulatoryAuthority
- Map:CTRRr3 = RegulatoryAuthority
- Map:CTRv1.0 = RegulatoryAuthority
- Map:ICSRr2 = territorialAuthority (in R_Product)
- Map:ICSRr2 = Author2 (in R_Product)

Connectors

Source	Connector	Target	Notes
RegulatoryAuthority	specializes	OversightAuthority	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each RegulatoryAuthority always specializes one OversightAuthority. Each OversightAuthority might be specialized by one RegulatoryAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
RegulatoryAssessment 0..* performedRegulatoryAssessment	is performed by	RegulatoryAuthority 1 performingRegulatoryAuthority	<p>DESCRIPTION: Each RegulatoryAssessment always is performed by one RegulatoryAuthority. Each RegulatoryAuthority might perform one or more RegulatoryAssessment.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MaterialName 0..* approvedMaterialName	be approved by	RegulatoryAuthority 0..1 approvingRegulatoryAuthority	<p>DESCRIPTION: Each MaterialName might be approved by one RegulatoryAuthority. Each RegulatoryAuthority might approve one or more MaterialName.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Place 0..* locatingPlace	be the location for	RegulatoryAuthority 0..1 locatedRegulatoryAuthority	<p>DESCRIPTION: Each Place might be the location for one RegulatoryAuthority. Each RegulatoryAuthority might have jurisdiction over one or more Place.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
jurisdictionAuthorityCode <i>Class:</i> RegulatoryAuthority <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the type of governance over which an authority has to make laws and enforce them.</p> <p>EXAMPLE(S): The Food and Drug Administration (FDA) exercises responsibility for pharmacovigilance (<i>jurisdictionAuthorityCode</i>) in the United States (<i>Place.identifierCode</i>).</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTR&Rr2 = SA from NCA Map:CTR&Rr2 = SA (Scientific Advice) from CHMP Map:CTR&Rr2 = SUSAR Reporting to NCAs Map:CTR&Rr2 = SUSAR Reporting to EVCTM Map:CTRPv3.8 = RegulatoryAuthority.jurisdictionCode Map:CTRr3 = RegulatoryAuthority.jurisdictionCode Map:CTRv1.0 = RegulatoryAuthority.jurisdictionAuthorityCode
effectiveDateRange <i>Class:</i> RegulatoryAuthority <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the regulatory authority is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = RegulatoryAuthority.statusCode Map:CTRPv1.0 = RegulatoryAuthority.statusDateRange Map:CTRv1.0 = RegulatoryAuthority.effectiveDateRange

Class: RelevantRegulation

Package: Regulatory Sub-Domain

DEFINITION:

Specifies the jurisdictional law that may be applicable for registering the study to a clinical trial registry.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = (model integrity)
- Map:CTRRv3 = (model integrity)

Connectors

Source	Connector	Target	Notes
RelevantRegulation 0..* governingRelevantRegulation	governs	InterventionalStudyProtocol Version 1 governedInterventionalStudyProtocolVersion	DESCRIPTION: Each RelevantRegulation always governs one InterventionalStudyProtocol Version. Each InterventionalStudyProtocol Version might be governed by one or more RelevantRegulation.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> RelevantRegulation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION:</p> <p>A coded value specifying a regulation that requires the study to be registered.</p> <p>EXAMPLE(S):</p> <p>US Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug and Cosmetic Act: 505, 510(k), 515, 520(m), and 522.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRr3 = Study.applicableRegulationCode
applicableIndicator <i>Class:</i> RelevantRegulation <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION:</p> <p>Specifies whether this study must be registered as required by applicable laws.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>Section 801 Clinical Trial</p> <p>NOTE(S):</p> <p>Under US Public Law 110-85, Title VIII, Section 801, applicable drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Applicable device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance.</p>	Map:CTRPv3.8 = StudyProtocol.section801Indicator Map:CTRPv3.8 = StudyProtocol.FDARegulatedIndicator Map:CTRr3 = Study.applicableClinicalTrialIndicator

Class: ReviewableUnit

Package: Regulatory Sub-Domain

DEFINITION:

A discrete portion of a submission which is used to receive agreement. Once agreement is reached on all units within the submission the submission can then be approved.

EXAMPLE(S):

In a Modular pre-marketing application (PMA) several modules will be sent to the Food and Drug Administration (FDA). Each module will be agreed upon independently of other modules. The FDA then approves the submission based on compilation of all of the modules. These modules are reviewable units.

A veterinary medicine New Animal Drug Application (NADA) (marketing application) is constructed from the Investigational New Animal Drug Application (INADA). In the INADA process the sponsor creates reviewable units. These reviewable units are then compiled to be used as documentation for the marketing application.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = ReviewableUnit
- Map:RPS1 = ReviewableUnit

Connectors

Source	Connector	Target	Notes
ReviewableUnit 0..* groupedReviewableUnit	is grouped into	Submission 1 groupingSubmission	<p>DESCRIPTION: Each ReviewableUnit always is grouped into one Submission. Each Submission might group one or more ReviewableUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubmissionUnit 1..* groupedSubmissionUnit	be grouped into	ReviewableUnit 0..1 groupingReviewableUnit	<p>DESCRIPTION: Each SubmissionUnit might be grouped into one ReviewableUnit. Each ReviewableUnit always groups one or more SubmissionUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> ReviewableUnit <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the kind of reviewable unit.</p> <p>EXAMPLE(S): toxicology, safety, manufacturing, administrative</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = ReviewableUnit.typeCode Map:RPS1 = ReviewableUnit.contents

Class: Submission

Package: Regulatory Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

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

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.

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.

Tagged Values:

- Map:CTRr3 = Submission
- Map:CTRv1.0 = Submission
- Map:ICSRr2 = replacementOf (in R_Product)
- Map:RPS1 = Submission

Connectors

Source	Connector	Target	Notes
Submission 0..* describingSubmission	has as subject	Product 1 describedProduct	<p>DESCRIPTION: Each Submission always has as subject one Product. Each Product might be the subject for one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Submission 1..* groupedSubmission	is grouped by	RegulatoryApplication 1 groupingRegulatoryApplication	<p>DESCRIPTION: Each Submission always is grouped by one RegulatoryApplication. Each RegulatoryApplication always groups one or more Submission.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Submission	is submitted by	RegulatoryApplicationSpon	DESCRIPTION:

Source	Connector	Target	Notes
1..* submittedSubmission		sor 1 submittingRegulatoryApplicationSponsor	Each Submission always is submitted by one RegulatoryApplicationSponsor. Each RegulatoryApplicationSponsor always submits one or more Submission. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Submission 1..* evaluatedSubmission	be evaluated in	RegulatoryAssessment 0..1 evaluatingRegulatoryAssessment	DESCRIPTION: Each Submission might be evaluated in one RegulatoryAssessment. Each RegulatoryAssessment always evaluates one or more Submission. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SubmissionUnit 0..* groupedSubmissionUnit	be grouped into	Submission 0..1 groupingSubmission	DESCRIPTION: Each SubmissionUnit might be grouped into one Submission. Each Submission might group one or more SubmissionUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ReviewableUnit 0..* groupedReviewableUnit	is grouped into	Submission 1 groupingSubmission	DESCRIPTION: Each ReviewableUnit always is grouped into one Submission. Each Submission might group one or more ReviewableUnit. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Source	Connector	Target	Notes

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> Submission <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the kind of submission.</p> <p>EXAMPLE(S): original, supplement, annual report</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRr3 = Submission.typeCode Map:CTRv1.0 = Submission.typeCode Map:RPS1 = Submission.type
receiptDate <i>Class:</i> Submission <i>Datatype:</i> TS.DATETIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the first submission unit is received by the regulatory authority.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the transmission of the first SubmissionUnit to a RegulatoryAuthority. The first transmission is a new SubmissionUnit, Submission and RegulatoryApplication. The first submission of a SubmissionUnit starts a regulatory clock and that is how Submission.receiptDate is derived. Subsequent SubmissionUnits are considered either amendments or supplements to the Submission and/or RegulatoryApplication and the dates for those SubmissionUnits are for tracking purposes and do not set the regulatory time clock.</p>	Map:CTR&Rr2 = NCA Submission Date Map:CTR&Rr2 = IEC Submission Date Map:CTRr3 = Submission.receiptDate Map:CTRv1.0 = Submission.receiptDate Map:RPS1 = Submission.receiptDate
statusCode <i>Class:</i> Submission <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the submission.</p> <p>EXAMPLE(S): active, withdrawn</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Submission Status state transition diagram for further details.</p>	Map:CTR&Rr2 = GMP MP Auth pending Map:CTR&Rr2 = IEC Opinion Status Map:CTRv1.0 = Submission.statusCode Map:ICSRr2 = Approval.statusCode (in R_Product) Map:RPS1 = Submission.status

Attribute	Notes	Constraints and Tags
statusDate <i>Class:</i> Submission <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) on which the status is assigned to the submission.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = Submission.statusDate Map:RPS1 = Submission.status

Class: SubmissionUnit

Package: Regulatory Sub-Domain

DEFINITION:

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

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

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

In the dynamic aspects of the model, a submission unit is one message that may have a collection of many document versions. 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.

Tagged Values:

- Map:CTRRr3 = SubmissionUnit
- Map:CTRv1.0 = SubmissionUnit
- Map:RPS1 = SubmissionUnit

Connectors

Source	Connector	Target	Notes
SubmissionUnit 0..* groupedSubmissionUnit	be grouped into	Submission 0..1 groupingSubmission	<p>DESCRIPTION: Each SubmissionUnit might be grouped into one Submission. Each Submission might group one or more SubmissionUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubmissionUnit 1..* groupedSubmissionUnit	be grouped into	ReviewableUnit 0..1 groupingReviewableUnit	<p>DESCRIPTION: Each SubmissionUnit might be grouped into one ReviewableUnit. Each ReviewableUnit always groups one or more SubmissionUnit.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubmissionUnit 0..* includingSubmissionUnit	includes	DocumentVersion 1..* includedDocumentVersion	<p>DESCRIPTION: Each SubmissionUnit always includes one or more DocumentVersion. Each DocumentVersion might be included in one or more SubmissionUnit.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> SubmissionUnit <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the kind of submission unit.</p> <p>EXAMPLE(S): original, amendment, supplement</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Typically each submission unit type would cause a different regulatory request.</p>	Map:CTRv1.0 = SubmissionUnit.typeCode Map:RPS1 = SubmissionUnit.type
receiptDate <i>Class:</i> SubmissionUnit <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0..1	<p>DEFINITION: The date (and time) on which the submission unit is received by the regulatory authority.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Typically, this date will start a review clock, if applicable. The combination of the typeCode and where the SubmissionUnit was received will determine the deadline for the SubmissionUnit to be reviewed.</p>	Map:CTRv1.0 = SubmissionUnit.receiptDate Map:RPS1 = SubmissionUnit.receiptDate

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> SubmissionUnit <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the submission unit is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = SubmissionUnit.effectiveDateRange Map:RPS1 = ReviewableUnit.status Map:RPS1 = SubmissionUnit.status

Statistical Analysis Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Statistical Analysis Sub-Domain includes concepts describing the planning and performance of the statistical analysis of data collected during clinical trial research and their relationships. This sub-domain will eventually include the semantics for the entire Statistical Analysis lifecycle, but for BRIDG 3.2, only the Statistical Analysis Plan semantics are included.

Statistical Analysis Sub-Domain

View SA: Statistical Analysis diagram

Class diagram in package 'Statistical Analysis Sub-Domain'

View SA: Statistical Analysis

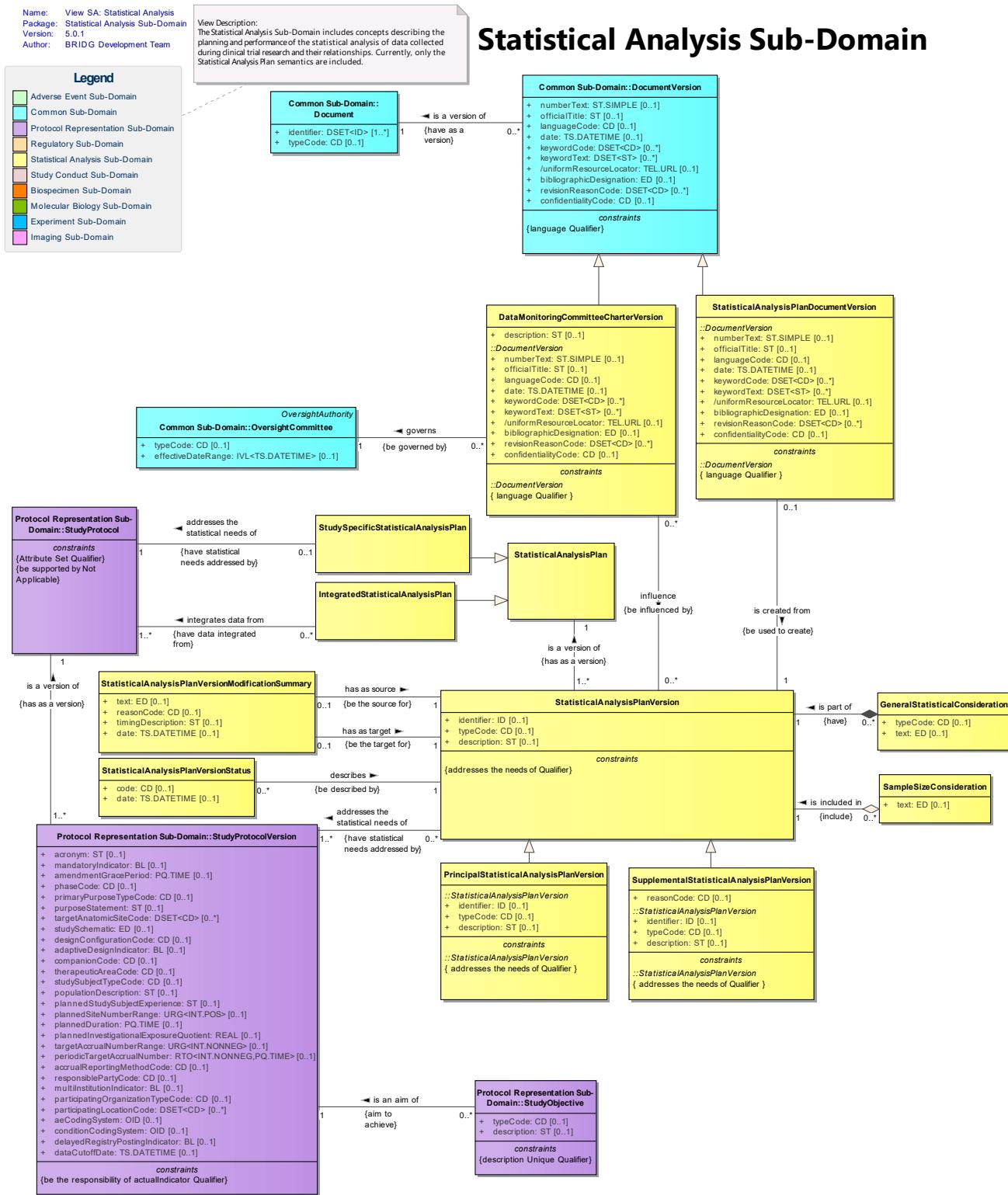


Figure 15: View SA: Statistical Analysis

Class: DataMonitoringCommitteeCharterVersion

Package: Statistical Analysis Sub-Domain

DEFINITION:

A key document that, together with the study protocol and Statistical Analysis Plan (SAP), prospectively defines the study's

Data Monitoring Committee (DMC) infrastructure and, in particular, the DMC's responsibilities; stipulates who sees blinded results and who sees unblinded results; and establishes a method for communication between the DMC and the sponsor.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = DataMonitoringCommitteeCharter

Connectors

Source	Connector	Target	Notes
DataMonitoringCommitteeCharterVersion 0..* influencingDataMonitoringCommitteeCharterVersion	influence	StatisticalAnalysisPlanVersion 0..* influencedStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each DataMonitoringCommitteeCharterVersion might influence one or more StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be influenced by one or more DataMonitoringCommitteeCharterVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DataMonitoringCommitteeCharterVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each DataMonitoringCommitteeCharterVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one DataMonitoringCommitteeCharterVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DataMonitoringCommitteeCharterVersion 0..* governingDataMonitoringCommitteeCharterVersion	governs	OversightCommittee 1 governedOversightCommittee	<p>DESCRIPTION: Each DataMonitoringCommitteeCharterVersion always governs one OversightCommittee. Each OversightCommittee might be governed by one or more</p>

Source	Connector	Target	Notes
			DataMonitoringCommitteeCharterVersion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
description <i>Class:</i> DataMonitoringCommitteeCharterVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A textual explanation of the contents of the data monitoring committee charter.</p> <p>EXAMPLE(S): "Data will be presented via blinded summaries and listings in PDF format, with additional availability of unblinded patient profiles in electronic format. The following is a description of the data to be included in the summaries and listings! If the charter is about meeting schedules, then the description could be "Meetings will be held monthly, beginning 6 weeks after the first subject's first visit."</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = DataMonitoringCommitteeCharter.description

Class: GeneralStatisticalConsideration

Package: Statistical Analysis Sub-Domain

DEFINITION:

Information needed for conducting multiple analyses.

EXAMPLE(S):

Centers within a region with fewer than 3 subjects will be grouped into a pooled center for the region.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 =

Connectors

Source	Connector	Target	Notes
GeneralStatisticalConsideration 0..* containedGeneralStatisticalConsideration	is part of	StatisticalAnalysisPlanVersion 1 containingStatisticalAnalysisPlanVersion	DESCRIPTION: Each GeneralStatisticalConsideration always is part of one StatisticalAnalysisPlanVersion

Source	Connector	Target	Notes
			<p>on. Each StatisticalAnalysisPlanVersion might have one or more GeneralStatisticalConsideration.</p> <p>DEFINITION: Identifies the considerations that inform the detailed design of the analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> GeneralStatisticalConsideration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of general statistical consideration.</p> <p>EXAMPLE(S): subgroup, analysis set, missing data algorithm, derivation algorithm, assessment window, multiple comparison strategy, center pooling</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = GeneralStatisticalConsideration.typeCode
text <i>Class:</i> GeneralStatisticalConsideration <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Textual or media-based representation of the general statistical consideration.</p> <p>EXAMPLE(S): Centers within a region with fewer than 3 subjects will be grouped into a pooled center for the region.</p> <p>Visits will be assigned to assessment windows defined by +/- 7 days from the target visit date as defined in the Time and Events Schedule. If multiple visits fall within an assessment window, the visit closest to the target date will be used. In the case of a tie, the earliest visit date will be used.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = GeneralStatisticalConsideration.text

Class: IntegratedStatisticalAnalysisPlan

Package: Statistical Analysis Sub-Domain

DEFINITION:

A type of statistical analysis plan that is intended to draw conclusions across multiple studies.

EXAMPLE(S):

Plan for integrated analysis of safety data in support of the Integrated Summary of Safety (ISS).

Plan for integrated analysis of efficacy data in support of the Integrated Summary of Effectiveness (ISE).

Plan for multi-study analysis to be presented in a manuscript.

Plan for a meta-analysis of literature studies.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = IntegratedStatisticalAnalysisPlan

Connectors

Source	Connector	Target	Notes
IntegratedStatisticalAnalysis Plan	specializes	StatisticalAnalysisPlan	<p>DESCRIPTION: Each IntegratedStatisticalAnalysis Plan always specializes one StatisticalAnalysisPlan. Each StatisticalAnalysisPlan might be specialized by one IntegratedStatisticalAnalysis Plan.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
IntegratedStatisticalAnalysis Plan 0..* integratingIntegratedStatisticalAnalysisPlan	integrates data from	StudyProtocol 1..* integratedStudyProtocol	<p>DESCRIPTION: Each IntegratedStatisticalAnalysis Plan always integrates data from one or more StudyProtocol. Each StudyProtocol might have data integrated from one or more IntegratedStatisticalAnalysis Plan.</p> <p>DEFINITION: Identifies the study protocols whose data is used in the integrated statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PrincipalStatisticalAnalysisPlanVersion

Package: Statistical Analysis Sub-Domain

DEFINITION:

A type of statistical analysis plan that is the main, comprehensive, pre-specified collection of analyses that support the Clinical Study Report (CSR) or other similar study report.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Analyses that arise after PrincipalStatisticalAnalysisPlanVersion finalization but during preparation of the clinical study report are handled by SupplementalStatisticalAnalysisPlanVersion.

Tagged Values:

- Map:Statistics v1.0 = PrincipalStatisticalAnalysisPlanVersion

Connectors

Source	Connector	Target	Notes
PrincipalStatisticalAnalysisPlanVersion	specializes	StatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each PrincipalStatisticalAnalysisPlanVersion always specializes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be specialized by one PrincipalStatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: SampleSizeConsideration

Package: Statistical Analysis Sub-Domain

DEFINITION:

Information needed for computing the sample size, including any detail not provided in the study protocol.

EXAMPLE(S):

"Approximately 100 patients will be randomized to each of the 3 treatment groups. Previous experience with the oral formulation of xanomeline suggests that this sample size has 90% power to detect a 3.0 mean treatment difference in ADAS-Cog ($p<.05$, two-sided), based on a standard deviation of 6.5. Furthermore, this sample size has 80% power to detect a 0.36 mean treatment difference in CIBIC+ ($p<.05$, two-sided), based on a standard deviation of 0.9."

OTHER NAME(S):

NOTE(S):

InterventionalStudyProtocolVersion.interventionGroupQuantity, Arm.targetAccrualNumberRange, and StudyProtocolVersion.targetAccrualNumberRange are all related to parts of the SampleSizeConsideration that are not yet fully modeled here.

Tagged Values:

- Map:Statistics v1.0 = SampleSizeConsideration

Connectors

Source	Connector	Target	Notes
SampleSizeConsideration 0..*	is included in	StatisticalAnalysisPlanVersion 1 includingStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each SampleSizeConsideration always is included in one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might include one or more SampleSizeConsideration.</p> <p>DEFINITION: Identifies the considerations that inform the calculation of the sample size for a given version of a statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
text <i>Class:</i> SampleSizeConsideration <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A textual or media-based representation of the sample size consideration, including details needed to replicate sample size calculations.</p> <p>EXAMPLE(S): "Approximately 100 patients will be randomized to each of the 3 treatment groups. Previous experience with the oral formulation of xanomeline suggests that this sample size has 90% power to detect a 3.0 mean treatment difference in ADAS-Cog ($p<.05$, two-sided), based on a standard deviation of 6.5. Furthermore, this sample size has 80% power to detect a 0.36 mean treatment difference in CIBIC+ ($p<.05$, two-sided), based on a standard deviation of 0.9."</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Details included could be: difference to be detected, variability, assumptions.</p>	Map:Statistics v1.0 = SampleSizeConsideration.text

Class: StatisticalAnalysisPlan

Package: Statistical Analysis Sub-Domain

DEFINITION:

A plan that encompasses all aspects of statistical activity for a study, including any statistical statements made prior to or at protocol finalization. The Statistical Analysis Plan includes a more technical and detailed elaboration than described in the protocol of the principal features of the analyses, and detailed procedures for executing the statistical analyses of the primary and secondary variables and other data.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The statistical analysis plan evolves during the course of the study.

Tagged Values:

- Map:Statistics v1.0 = StatisticalAnalysisPlan

Connectors

Source	Connector	Target	Notes
StudySpecificStatisticalAnalysisPlan	specializes	StatisticalAnalysisPlan	<p>DESCRIPTION: Each StudySpecificStatisticalAnalysisPlan always specializes one StatisticalAnalysisPlan. Each StatisticalAnalysisPlan might be specialized by one StudySpecificStatisticalAnalysisPlan.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
IntegratedStatisticalAnalysisPlan	specializes	StatisticalAnalysisPlan	<p>DESCRIPTION:</p> <p>Each IntegratedStatisticalAnalysisPlan always specializes one StatisticalAnalysisPlan.</p> <p>Each StatisticalAnalysisPlan might be specialized by one IntegratedStatisticalAnalysisPlan.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanVersion 1..* versioningStatisticalAnalysesPlanVersion	is a version of	StatisticalAnalysisPlan 1 versionedStatisticalAnalysisPlan	<p>DESCRIPTION:</p> <p>Each StatisticalAnalysisPlanVersion always is a version of one StatisticalAnalysisPlan.</p> <p>Each StatisticalAnalysisPlan always has as a version one or more StatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>Identifies the statistical analysis plan that is the basis for a statistical analysis plan version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StatisticalAnalysisPlanDocumentVersion

Package: Statistical Analysis Sub-Domain

DEFINITION:

A representation, conceptually a document, that is created to convey the statistical analysis plan version structured content to human beings.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = StatisticalAnalysisPlanDocumentVersion

Connectors

Source	Connector	Target	Notes
StatisticalAnalysisPlanDocumentVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanDocumentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StatisticalAnalysisPlanDocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanDocumentVersion 0..1 createdStatisticalAnalysisPlanDocumentVersion	is created from	StatisticalAnalysisPlanVersion 1 usedStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanDocumentVersion always is created from one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be used to create one StatisticalAnalysisPlanDocumentVersion.</p> <p>DEFINITION: Identifies the version of a statistical analysis plan that is the basis for a version of a statistical analysis plan document.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StatisticalAnalysisPlanVersion

Package: Statistical Analysis Sub-Domain

DEFINITION:

A point-in-time snapshot of a statistical analysis plan.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

The statistical analysis plan evolves during the course of the study and accordingly the snapshot may address a different issue at varying levels of detail relative to the final plan.

Tagged Values:

- Map:Statistics v1.0 = StatisticalAnalysisPlanVersion

Connectors

Source	Connector	Target	Notes
StatisticalAnalysisPlanVersion 0..* addressingStatisticalAnalysesPlanVersion	addresses the statistical needs of	StudyProtocolVersion 1..* addressedStudyProtocolVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersion always addresses the statistical needs of one or more StudyProtocolVersion. Each StudyProtocolVersion might have statistical needs addressed by one or more StatisticalAnalysisPlanVersion.</p> <p>DEFINITION: Identifies the version of the study protocol that is the basis for a statistical analysis plan version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanVersion 1..* versioningStatisticalAnalysesPlanVersion	is a version of	StatisticalAnalysisPlan 1 versionedStatisticalAnalysisPlan	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersion always is a version of one StatisticalAnalysisPlan. Each StatisticalAnalysisPlan always has as a version one or more StatisticalAnalysisPlanVersion.</p> <p>DEFINITION: Identifies the statistical analysis plan that is the basis for a statistical analysis plan version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DataMonitoringCommitteeChairVersion	influence	StatisticalAnalysisPlanVersion	DESCRIPTION: Each

Source	Connector	Target	Notes
0..* influencingDataMonitoringCommitteeCharterVersion		0..* influencedStatisticalAnalysisPlanVersion	<p>DataMonitoringCommitteeCharterVersion might influence one or more StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be influenced by one or more DataMonitoringCommitteeCharterVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanVersionModificationSummary 0..1 targetStatisticalAnalysisPlanVersionModificationSummary	has as source	StatisticalAnalysisPlanVersion 1 sourceStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersionModificationSummary always has as source one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be the source for one StatisticalAnalysisPlanVersionModificationSummary.</p> <p>DEFINITION: Identifies the changed version of the statistical analysis plan that is used to create a statistical analysis plan version modification summary.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
GeneralStatisticalConsideration 0..* containedGeneralStatisticalConsideration	is part of	StatisticalAnalysisPlanVersion 1 containingStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each GeneralStatisticalConsideration always is part of one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might have one or more GeneralStatisticalConsideration.</p> <p>DEFINITION: Identifies the considerations that inform the detailed design of the analysis plan.</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SampleSizeConsideration 0..* includedSampleSizeConsideration	is included in	StatisticalAnalysisPlanVersion 1 includingStatisticalAnalysisPlanVersion	<p>DESCRIPTION:</p> <p>Each SampleSizeConsideration always is included in one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might include one or more SampleSizeConsideration.</p> <p>DEFINITION:</p> <p>Identifies the considerations that inform the calculation of the sample size for a given version of a statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PrincipalStatisticalAnalysisPlanVersion	specializes	StatisticalAnalysisPlanVersion	<p>DESCRIPTION:</p> <p>Each PrincipalStatisticalAnalysisPlanVersion always specializes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be specialized by one PrincipalStatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanDocumentVersion 0..1 createdStatisticalAnalysisPlanDocumentVersion	is created from	StatisticalAnalysisPlanVersion 1 usedStatisticalAnalysisPlanVersion	<p>DESCRIPTION:</p> <p>Each StatisticalAnalysisPlanDocumentVersion always is created from one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be used to create</p>

Source	Connector	Target	Notes
			<p>one StatisticalAnalysisPlanDocumentVersion.</p> <p>DEFINITION: Identifies the version of a statistical analysis plan that is the basis for a version of a statistical analysis plan document.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SupplementalStatisticalAnalysisPlanVersion	specializes	StatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each SupplementalStatisticalAnalysisPlanVersion always specializes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be specialized by one SupplementalStatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanVersionModificationSummary 0..1 sourceStatisticalAnalysisPlanVersionModificationSummary	has as target	StatisticalAnalysisPlanVersion 1 targetStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersionModificationSummary always has as target one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be the target for one StatisticalAnalysisPlanVersionModificationSummary.</p> <p>DEFINITION: Identifies the original version of the statistical analysis plan that is used to create a statistical analysis plan version modification summary.</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
StatisticalAnalysisPlanVersionStatus 0..* describingStatisticalAnalysisPlanVersionStatus	describes	StatisticalAnalysisPlanVersion 1 describedStatisticalAnalysisPlanVersion	<p>OTHER NAME(S): NOTE(S):</p> <p>DESCRIPTION: Each StatisticalAnalysisPlanVersionStatus always describes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be described by one or more StatisticalAnalysisPlanVersionStatus.</p> <p>DEFINITION: Identifies the statuses at different points in time for a particular version of a statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> StatisticalAnalysisPlanVersion <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes the identity of a version of the statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:Statistics v1.0 = StatisticalAnalysisPlanVersion.version Identifier</p>
typeCode <i>Class:</i> StatisticalAnalysisPlanVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of statistical analysis plan version.</p> <p>EXAMPLE(S): draft, approved</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:Statistics v1.0 = StatisticalAnalysisPlanVersion.version TypeCode</p>

Attribute	Notes	Constraints and Tags
description <i>Class:</i> StatisticalAnalysisPlanVersion <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual explanation of the statistical analysis plan version.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersion.description

Class: StatisticalAnalysisPlanVersionModificationSummary

Package: Statistical Analysis Sub-Domain

DEFINITION:

Information about all changes made between the current and previous version of the statistical analysis plan.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = StatisticalAnalysisPlanVersionModificationSummary

Connectors

Source	Connector	Target	Notes
StatisticalAnalysisPlanVersionModificationSummary 0..1 targetStatisticalAnalysisPlanVersionModificationSummary	has as source	StatisticalAnalysisPlanVersion 1 sourceStatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersionModificationSummary always has as source one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be the source for one StatisticalAnalysisPlanVersionModificationSummary.</p> <p>DEFINITION: Identifies the changed version of the statistical analysis plan that is used to create a statistical analysis plan version modification summary.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StatisticalAnalysisPlanVersionModificationSummary 0..1 sourceStatisticalAnalysisPlan	has as target	StatisticalAnalysisPlanVersion 1 targetStatisticalAnalysisPlan	<p>DESCRIPTION: Each StatisticalAnalysisPlanVersionModificationSummary</p>

Source	Connector	Target	Notes
nVersionModificationSummary		Version	<p>always has as target one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be the target for one StatisticalAnalysisPlanVersionModificationSummary.</p> <p>DEFINITION: Identifies the original version of the statistical analysis plan that is used to create a statistical analysis plan version modification summary.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
text <i>Class:</i> StatisticalAnalysisPlanVersionModificationSummary <i>Datatype:</i> ED <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Textual or media-based summary of the changes.</p> <p>EXAMPLE(S): Distribution assumptions for some analyses were not met, so additional analyses were performed to check robustness of results.</p> <p>Another drug in the class has been approved so additional analyses of a new exploratory endpoint have been added.</p> <p>Site was non-compliant so additional analyses are needed to handle this site's data.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersionModificationSummary.text

Attribute	Notes	Constraints and Tags
reasonCode <i>Class:</i> StatisticalAnalysisPlanVersionModificationSummary <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the motivation, cause, or rationale for the modification.</p> <p>EXAMPLE(S): Request by FDA New information available Change in strategy Error correction Actual analysis differed from planned</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersionModificationSummary.reasonCode
timingDescription <i>Class:</i> StatisticalAnalysisPlanVersionModificationSummary <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Text description of when the modification occurred relative to the study.</p> <p>EXAMPLE(S): Modification made prior to unblinding Modification made prior to first subject's first visit</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersionModificationSummary.timingDescription
date <i>Class:</i> StatisticalAnalysisPlanVersionModificationSummary <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The date (and time) on which the modification took place.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersionModificationSummary.date

Class: StatisticalAnalysisPlanVersionStatus

Package: Statistical Analysis Sub-Domain

DEFINITION:
Describes the state of the statistical analysis plan version.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = (model integrity)

Connectors

Source	Connector	Target	Notes
StatisticalAnalysisPlanVersionStatus 0..*	describes	StatisticalAnalysisPlanVersion 1	DESCRIPTION: Each StatisticalAnalysisPlanVersi

Source	Connector	Target	Notes
describingStatisticalAnalysisPlanVersionStatus		describedStatisticalAnalysisPlanVersion	<p>onStatus always describes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be described by one or more StatisticalAnalysisPlanVersions.</p> <p>DEFINITION: Identifies the statuses at different points in time for a particular version of a statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> StatisticalAnalysisPlanVersionStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the statistical analysis plan version.</p> <p>EXAMPLE(S): active, inactive</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersion.versionStatusCode
date <i>Class:</i> StatisticalAnalysisPlanVersionStatus <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date that the statistical analysis plan version entered the current status.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Statistics v1.0 = StatisticalAnalysisPlanVersion.versionDate

Class: StudySpecificStatisticalAnalysisPlan

Package: Statistical Analysis Sub-Domain

DEFINITION:

A type of statistical analysis plan that is intended to draw conclusions from only one study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = StudySpecificStatisticalAnalysisPlan

Connectors

Source	Connector	Target	Notes
StudySpecificStatisticalAnalysisPlan	specializes	StatisticalAnalysisPlan	<p>DESCRIPTION: Each StudySpecificStatisticalAnalysisPlan always specializes one StatisticalAnalysisPlan. Each StatisticalAnalysisPlan might be specialized by one StudySpecificStatisticalAnalysisPlan.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySpecificStatisticalAnalysisPlan 0..1 addressingStudySpecificStatisticalAnalysisPlan	addresses the statistical needs of	StudyProtocol 1 addressedStudyProtocol	<p>DESCRIPTION: Each StudySpecificStatisticalAnalysisPlan always addresses the statistical needs of one StudyProtocol. Each StudyProtocol might have statistical needs addressed by one StudySpecificStatisticalAnalysisPlan.</p> <p>DEFINITION: Identifies the study protocol whose data is used in the study specific statistical analysis plan.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: SupplementalStatisticalAnalysisPlanVersion

Package: Statistical Analysis Sub-Domain

DEFINITION:

A type of statistical analysis plan version that provides specification for additional analyses not included as part of the principal statistical analysis plan version.

EXAMPLE(S):

Additional analyses during clinical study report preparation,
Response to regulatory request,
Hypothesis generation,
Pre-specified PK analysis plan,

Analysis plan for sub-study or study addendum

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Statistics v1.0 = SupplementalStatisticalAnalysisPlanVersion

Connectors

Source	Connector	Target	Notes
SupplementalStatisticalAnalysisPlanVersion	specializes	StatisticalAnalysisPlanVersion	<p>DESCRIPTION: Each SupplementalStatisticalAnalysisPlanVersion always specializes one StatisticalAnalysisPlanVersion. Each StatisticalAnalysisPlanVersion might be specialized by one SupplementalStatisticalAnalysisPlanVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
reasonCode <i>Class:</i> SupplementalStatisticalAnalysisPlanVersion <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the motivation, cause, or rationale for the supplemental statistical analysis plan.</p> <p>EXAMPLE(S): Additional analyses during clinical study report preparation, Response to regulatory request, Hypothesis generation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This coded concept is extensible, but the examples above cover a large proportion of possible values.</p>	Map:Statistics v1.0 = SupplementalStatisticalAnalysisPlanVersion.reasonCode

Study Conduct Sub-Domain

Package in package 'BRIDG Domain Information Model'

The Study Conduct sub-domain is intended for those involved in the execution of a research study. The majority of business requirements have come from those involved in clinical trials. It focuses on the activities of conducting the study as well as the results from those activities.

[Study Conduct Sub-Domain](#)

View SC: Study Conduct diagram

Class diagram in package 'Study Conduct Sub-Domain'

The Study Conduct sub-domain is intended for those involved in the execution of a research study. The majority of business requirements have come from those involved in clinical trials. It focuses on the activities of conducting the study as well as the results from those activities.

[View SC: Study Conduct](#)

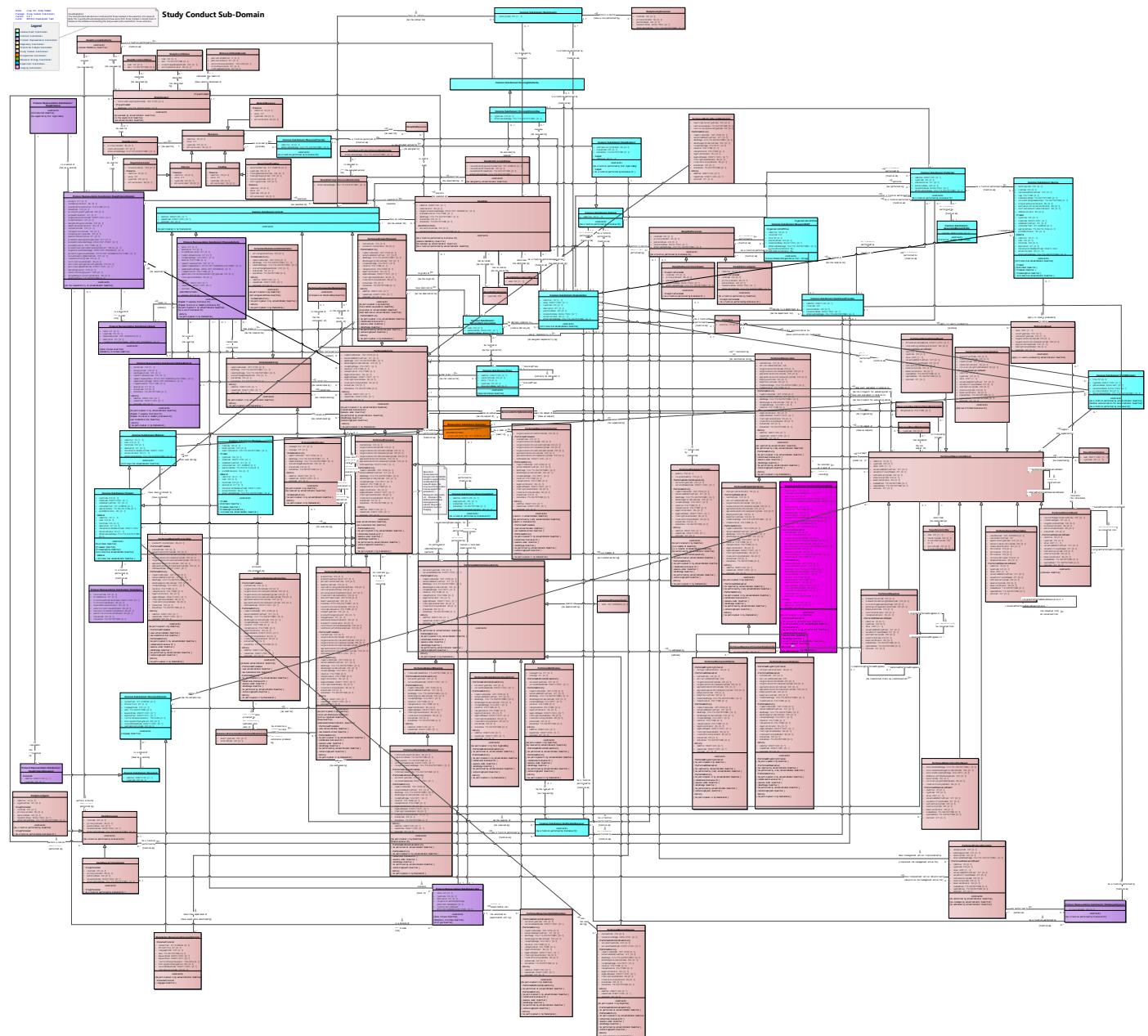


Figure 16: View SC: Study Conduct

Class: AssessedActivityRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between an assessment (performed observation) and the performed activity that the assessment is based on.

EXAMPLE(S):

The act of determining if graft failure occurred involves assessing a stem cell transplant.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:HCTv1.0 = (model integrity)

Connectors

Source	Connector	Target	Notes
AssessedActivityRelationship 0..* assessingAssessedActivityRelationship	has as subject	PerformedActivity 1 assessingPerformedActivity	<p>DESCRIPTION: Each AssessedActivityRelationship always has as subject one PerformedActivity. Each PerformedActivity might be the subject of one or more AssessedActivityRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AssessedActivityRelationship 0..* assessingAssessedActivityRelationship	is the subject of	PerformedObservation 1 assessingPerformedObservation	<p>DESCRIPTION: Each AssessedActivityRelationship always is the subject of one PerformedObservation. Each PerformedObservation might have as subject one or more AssessedActivityRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: AssessedResultRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between an assessment (performed observation) and the results of other performed observations that the assessment is based on.

EXAMPLE(S):

The acts of determining whether an adverse event occurred, determining a diagnosis, or determining a cause of death may each be based on evaluating several test results (PerformedObservation).

A molecular sequence annotation (PerformedObservationResult) may be assessed in an observation activity in an experiment.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = AssessedResultRelationship

- Map:ICSRr2 = Subject10 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = component3 (in IndividualCaseSafetyReport)
- Map:ICSRr2 = SequelTo (in R_Product)
- Map:ICSRr2 = Component2 (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = ActivityItem
- Map:LSDAMv2.2.3Plus = Data.(Finding)
- Map:LSDAMv2.2.3Plus = MolecularSequenceAnnotation.(Finding)
- Map:SDTM IGV3.1.3 = RS.RSLNKGRP

Connectors

Source	Connector	Target	Notes
AssessedResultRelationship 0..* assessingAssessedResultRelationship	is the subject of	PerformedObservation 1 assessingPerformedObservation	<p>DESCRIPTION: Each AssessedResultRelationship always is the subject of one PerformedObservation. Each PerformedObservation might have as subject one or more AssessedResultRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AssessedResultRelationship 0..* assessingAssessedResultRelationship	has as subject	PerformedObservationResult 1 assessedPerformedObservationResult	<p>DESCRIPTION: Each AssessedResultRelationship always has as subject one PerformedObservationResult. Each PerformedObservationResult might be the subject of one or more AssessedResultRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> AssessedResultRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of assessed result relationship.</p> <p>EXAMPLE(S): sequel to, component, cause</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = AssessmentRelationship.typeCode Map:CTRv3.8 = ActivityRelationship.typeCode Map:CTRv1.0 = AssessedResultRelationship.typeCode Map:ICSRr2 = SequelTo.typeCode (in R_Product) Map:ICSRr2 = Component2.typeCode (in IndividualCaseSafetyReport)

Class: Funding

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Funding from pharmaceutical, device or biotechnology companies, the US NIH or the Gates Foundation.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = StudyFundingSponsor
- Map:CTRR = Source(s) of Monetary or Material Support

Connectors

Source	Connector	Target	Notes
Funding	specializes	Resource	<p>DESCRIPTION: Each Funding always specializes one Resource. Each Resource might be specialized by one Funding.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
GovernmentFunding	specializes	Funding	<p>DESCRIPTION: Each GovernmentFunding always specializes one Funding. Each Funding might be specialized by one GovernmentFunding.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes

Class: GovernmentFunding

Package: Study Conduct Sub-Domain

DEFINITION:

Fiscal support from governmental organizations.

EXAMPLE(S):

United States National Institutes of Health (NIH)

OTHER NAME(S):

NOTE(S):

Tagged Values:

Connectors

Source	Connector	Target	Notes
GovernmentFunding	specializes	Funding	<p>DESCRIPTION: Each GovernmentFunding always specializes one Funding. Each Funding might be specialized by one GovernmentFunding.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
serialNumberText <i>Class:</i> GovernmentFunding <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string that represents the six-digit number generally assigned sequentially to a funding mechanism within an institute, center, or division of the United States National Institutes of Health.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.serialNumber Map:CTRPv3.8 = StudyResourcing.serialNumber Map:HSDBv1.0 = [NIH Grant].Serial Number

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> GovernmentFunding <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of application received and processed.</p> <p>EXAMPLE(S): Type 5 (Noncompeting Grant Progress Report) Type 1 (New)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.fundingTypeCode Map:CTRPv1.0 = StudyResourcing.grantTypeCode
fundingMechanismCode <i>Class:</i> GovernmentFunding <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the unique identifier for areas of extramural research activity applied to various funding mechanisms.</p> <p>EXAMPLE(S): R01 (Research Project) U10 (Cooperative Clinical Research Cooperative Agreements)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = ResearchOrganization.fundingMechanism Map:CTRPv1.0 = StudyResourcing.fundingMechanismCode Map:CTRPv3.8 = StudyResourcing.fundingMechanismCode Map:CTRPv3.8 = ResearchOrganization.fundingMechanism Map:HSDBv1.0 = [NIH Grant].Funding Mechanism
fundingCategoryCode <i>Class:</i> GovernmentFunding <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the type of funding provided for a study.</p> <p>EXAMPLE(S): National, Externally Peer-Reviewed, Institutional, Industrial</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is as defined for the NCI Summary 4 Funding requirements.</p>	Map:CTRPv3.8 = StudyResourcing.typeCode Map:HSDBv1.0 = [Summary 4 Funder].Summary 4 Funding Category
nihInstituteCode <i>Class:</i> GovernmentFunding <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A two letter coded value specifying the first major-level subdivision of the organization that supports a grant, contract, or inter-agency agreement. The support may be financial or administrative.</p> <p>EXAMPLE(S): CP2 Division of Cancer Epidemiology and Genetics (NCI) LM National Library of Medicine (NLM)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.nihInstituteCode Map:CTRPv3.8 = StudyResourcing.nihInstituteCode Map:HSDBv1.0 = [NIH Grant].Institute Code

Attribute	Notes	Constraints and Tags
nciProgramCode <i>Class:</i> GovernmentFunding <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the organizational units within the National Cancer Institute (NCI) (divisions, programs and offices) that provide funding.</p> <p>EXAMPLE(S): CTEP (Cancer Therapy Evaluation Program) DTP (Developmental Therapeutics Program) CDP (Cancer Diagnosis Program)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv3.8 = StudyResourcing.nciDivisionProgramCode Map:HSDBv1.0 = [NIH Grant].NCI Division/Program Code

Class: Laboratory

Package: Study Conduct Sub-Domain

DEFINITION:

An organization with the capability and competency to perform scientific research, experiments and measurements.

EXAMPLE(S):

The laboratory that collects the specimen from an experimental unit.

The laboratory that actually performed the test or processed a specimen, and is the source of the corresponding data.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformingLaboratory
- Map:CTRv1.0 = Laboratory
- Map:CTRv1.0 = CollectingLaboratory
- Map:HL7SP = ServiceProvider
- Map:LabViewer2.2 = CentralLaboratory
- Map:LabViewer2.2 = PerformingLaboratory
- Map:LSDAMv2.2.3Plus = Laboratory
- Map:LSDAMv2.2.3Plus = CollectingLaboratory
- Map:PGxv1.0 = BE.BEPARTY

Connectors

Source	Connector	Target	Notes
Laboratory 0..1 performedLaboratory	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each Laboratory might be a function performed by one Organization. Each Organization might function as one Laboratory.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReferenceResult	apply to results produced by	Laboratory	DESCRIPTION:

Source	Connector	Target	Notes
0..* performedReferenceResult		0..1 performingLaboratory	Each ReferenceResult might apply to results produced by one Laboratory. Each Laboratory might produce one or more ReferenceResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SpecimenCollectionProtocol Subject 0..* assignedSpecimenCollection ProtocolSubject	is assigned to	Laboratory 1 assigningLaboratory	DESCRIPTION: Each SpecimenCollectionProtocol Subject always is assigned to one Laboratory. Each Laboratory might be the assigner of one or more SpecimenCollectionProtocol Subject. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S): If the Laboratory is the Performer of the assignment of a Subject to a Protocol, and/or the collector of the informed consent (i.e. the performer of a PerformedSubjectMilestone), then this association from SpecimenCollectionProtocol Subject to Laboratory is redundant and should NOT be used.
Performer 0..* performedPerformer	be a function performed by	Laboratory 0..1 performingLaboratory	DESCRIPTION: Each Performer might be a function performed by one Laboratory. Each Laboratory might function as one or more Performer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProductTransport	assign responsibility to	Laboratory	DESCRIPTION:

Source	Connector	Target	Notes
0..* assigningPerformedProductTransport		0..1 responsibleLaboratory	Each PerformedProductTransport might assign responsibility to one Laboratory. Each Laboratory might be assigned responsibility by one or more PerformedProductTransport. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Laboratory <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A unique symbol that establishes identity of the laboratory. EXAMPLE(S): Clinical Laboratory Improvement Act/Amendment (CLIA) ID OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = Laboratory.identifier Map:HL7SP = Service Provider.id Map:Lab = CentralLaboratory.identifier Map:Lab = PerformingLaboratory.identifier Map:LabViewer2.2 = PerformingLaboratory.identifier Map:LabViewer2.2 = CentralLaboratory.identifier Map:LSDAMv2.2.3Plus = Laboratory.identifier

Class: MaterialResource

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

In kind contributions, donations of study drug, device, etc.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRR = Source(s) of Monetary or Material Support

Connectors

Source	Connector	Target	Notes
MaterialResource	specializes	Resource	DESCRIPTION: Each MaterialResource always specializes one Resource. Each Resource might be specialized by one MaterialResource.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ObservationResultActionTakenRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between an observation result and the actions taken as a result of that outcome.

EXAMPLE(S):

An electrical problem (product investigation result) in a device could result in a recall (product action taken) of the device.

An abnormal lab result triggers a follow-up lab test for further investigation.

Study dose reduced or protocol treatment change due to an adverse event.

OTHER NAME(S):

AdverseEventActionTakenRelationship, ProductActionTakenRelationship

NOTE(S):

Action taken relationship is generally used for "unplanned" activities rather than those already determined in "contingent" relationships in the planned study design.

Tagged Values:

- Map:AE = ActionTaken
- Map:AE = ProductInvestigation.productReturnedIndicator
- Map:AE = ProductInvestigation.remedialActionTaken
- Map:CTRv1.0 = AdverseEventActionTakenRelationship
- Map:CTRv1.0 = ProductActionTakenRelationship
- Map:CTRv1.0 = ObservationResultActionTakenRelationship
- Map:NCI CRF Standard = CDE 2435042v1.2: Protocol Deviation Action Text

Connectors

Source	Connector	Target	Notes
ObservationResultActionTakenRelationship 0..* triggeringObservationResultActionTakenRelationship	triggers	PerformedActivity 1 triggeredPerformedActivity	<p>DESCRIPTION:</p> <p>Each ObservationResultActionTakenRelationship always triggers one PerformedActivity. Each PerformedActivity might be triggered by one or more ObservationResultActionTakenRelationship.</p> <p>DEFINITION:</p> <p>Indicates the PerformedActivity undertaken as a result of an ObservationResult</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
ObservationResultActionTakenRelationship 0..* triggeredObservationResult ActionTakenRelationship	is triggered by	PerformedObservationResult 1 triggeringPerformedObservationResult	DESCRIPTION: Each ObservationResultActionTakenRelationship always is triggered by one PerformedObservationResult. Each PerformedObservationResult might trigger one or more ObservationResultActionTakenRelationship. DEFINITION: Indicates the ObservationResult that causes the initiation of a PerformedActivity EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
delayDuration <i>Class:</i> ObservationResultActionTakenRelationship <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The time delay between an observation result being determined and a resulting performed activity action being taken.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:AE = ActionTaken.delayDuration</p> <p>Map:AE = ProductInvestigation.remedialActionTaken</p> <p>Map:CTOM = AdverseEventTherapy.delayDuration</p> <p>Map:CTOM = AdverseEventTherapy.delayDuration</p> <p>Map:UnitOfMeasureCode</p> <p>Map:CTRv1.0 = ProductActionTakenRelationship.delayDuration</p> <p>Map:CTRv1.0 = ObservationResultActionTakenRelationship.delayDuration</p> <p>Map:CTRv1.0 = AdverseEventActionTakenRelationship.delayDuration</p>

Class: PerformedActivity

Package: Study Conduct Sub-Domain

DEFINITION:
An activity that is successfully or unsuccessfully completed.

EXAMPLE(S):

CBC performed on a specific StudySubject on a given day.

A scheduled blood draw that is missed by a specific ExperimentalUnit on a given day.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = PerformedActivity
- Map:C3PRv2.9 = ScheduledArm
- Map:caAERSv2.2 = CourseDate
- Map:caAERSv2.2 = AdverseEventReportingPeriod
- Map:caAERSv2.2 = TreatmentInformation
- Map:CTRPv3.8 = PerformedActivity
- Map:CTRv1.0 = PerformedActivity
- Map:DICOM = TID 1502 TimePointContext
- Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Include TID 1502 TimePointContext
- Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > Include TID 1502 TimePointContext
- Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Include TID 1502 TimePointContext
- Map:DICOM = TID 1502 TimePointContext > Time Point
- Map:ICSRr2 = productActChoice (in R_Product)
- Map:LabViewer2.2 = Activity
- Map:LSDAMv2.2.3Plus = PerformedMedicalHistoryResult
- Map:LSDAMv2.2.3Plus = PerformedActivity
- Map:PGx v1.0 = BE
- Map:PSCv2.6 = Occurred
- Map:SDTM IGv3.1.2 = SE.DOMAIN
- Map:SDTM IGv3.1.2 = SV.DOMAIN
- Map:SDTM IGv3.1.3 = MH
- Map:SDTM IGv3.1.3 = SV
- Map:SDTM IGv3.1.3 = AE.AECONTRT
- Map:SDTM IGv3.1.3 = SE
- Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY
- Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION
- Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM
- Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS
- Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS
- Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM
- Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES

Connectors

Source	Connector	Target	Notes
PerformedActivity	specializes	Activity	<p>DESCRIPTION: Each PerformedActivity always specializes one Activity. Each Activity might be specialized by one PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	ScheduledActivity 0..1 instantiatedScheduledActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one ScheduledActivity. Each ScheduledActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	PlannedActivity 0..1 instantiatedPlannedActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one PlannedActivity. Each PlannedActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	DefinedActivity 0..1 instantiatedDefinedActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one DefinedActivity. Each DefinedActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* locatedPerformedActivity	take place in	Place 0..1 locatingPlace	<p>DESCRIPTION: Each PerformedActivity might take place in one Place. Each Place might be the location for one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
PerformedActivity 0..* executedPerformedActivity	execute under	StudyProtocolVersion 0..1 executingStudyProtocolVersion	<p>NOTE(S):</p> <p>DESCRIPTION: Each PerformedActivity might execute under one StudyProtocolVersion. Each StudyProtocolVersion might be executed by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* containedPerformedActivity	be contained by	Epoch 0..1 containingEpoch	<p>DESCRIPTION: Each PerformedActivity might be contained by one Epoch. Each Epoch might contain one or more PerformedActivity.</p> <p>DEFINITION: Indicates that a performed but unplanned activity is categorized as part of a particular Epoch.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This cannot be derived by looking at the corresponding planned activity because this association is only used for unplanned activities.</p>
PerformedSubstanceAdministration 0..* startEvaluatedPerformedSubstanceAdministration	have start evaluated in relation to	PerformedActivity 0..1 startRelatedPerformedActivity	<p>DESCRIPTION: Each PerformedSubstanceAdministration might have start evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating the start of one or more PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, CMSTTPT indicates a study event that may be a reference event for the start</p>

Source	Connector	Target	Notes
			<p>of a concomitant medication (PerformedSubstanceAdministration) or SUENTPT might be the reference event for the start of a substance use event (also a PerformedSubstanceAdministration).</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>As per CDISC, any given substance administration can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedSubstanceAdministration and PerformedActivity for evaluating start and end of the administration.</p>
<p>PerformedCompositionRelationship 0..* componentPerformedCompositionRelationship</p>	is the component of	<p>PerformedActivity 1 compositePerformedActivity</p>	<p>DESCRIPTION: Each PerformedCompositionRelationship always is the component of one PerformedActivity. Each PerformedActivity might be the parent of one or more PerformedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
<p>PerformedSubstanceAdministration 0..* endEvaluatedPerformedSubstanceAdministration</p>	have end evaluated in relation to	<p>PerformedActivity 0..1 endRelatedPerformedActivity</p>	<p>DESCRIPTION: Each PerformedSubstanceAdministration might have end evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating the end of one or more PerformedSubstanceAdministration.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>In CDISC SDTM, CMENTPT indicates a study event that may be a reference event for the end of a concomitant medication (PerformedSubstanceAdministration) or SUENTPT might be the reference event for the end of a substance use event (also a PerformedSubstanceAdministration).</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>As per CDISC, any given substance administration can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformeSubstanceAdministration and PerformedActivity for evaluating start and end of the administration.</p>
PerformedCompositionRelationship 0..1 compositePerformedCompositionRelationship	is the parent of	PerformedActivity 1 componentPerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedCompositionRelationship always is the parent of one PerformedActivity. Each PerformedActivity might be the component of one PerformedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport	specializes	PerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedProductTransport</p>

Source	Connector	Target	Notes
			<p>always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ObservationResultActionTakenRelationship 0..* triggeringObservationResultActionTakenRelationship	triggers	PerformedActivity 1 triggeredPerformedActivity	<p>DESCRIPTION: Each ObservationResultActionTakenRelationship always triggers one PerformedActivity. Each PerformedActivity might be triggered by one or more ObservationResultActionTakenRelationship.</p> <p>DEFINITION: Indicates the PerformedActivity undertaken as a result of an ObservationResult</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservationResult 0..* startEvaluatedPerformedObservationResult	have start evaluated in relation to	PerformedActivity 0..1 startRelatedPerformedActivity	<p>DESCRIPTION: Each PerformedObservationResult might have start evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating start of one or more PerformedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, CESTTPT indicates a study event that may be a reference event for the start of a clinical event (PerformedObservationResult).</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			<p>NOTE(S):</p> <p>As per CDISC, any given observation result can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedObservationResult and PerformedActivity for evaluating start and end of the result.</p>
PerformedMedicalRecordAbstraction	specializes	PerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedMedicalRecordAbstraction always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedMedicalRecordAbstraction.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedAdministrativeActivity	specializes	PerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedAdministrativeActivity always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservation 0..* commentingPerformedObservation	be commenting on	PerformedActivity 0..1 commentedPerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedObservation might be commenting on one PerformedActivity. Each PerformedActivity</p>

Source	Connector	Target	Notes
			<p>might be commented on by one or more PerformedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservationResult 0..* endEvaluatedPerformedObservationResult	have end evaluated in relation to	PerformedActivity 0..1 endRelatedPerformedActivity	<p>DESCRIPTION: Each PerformedObservationResult might have end evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timpoint for evaluating end of one or more PerformedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, AEENTPT indicates a study event that may be a reference event for the end of an adverse event, CEENTPT indicates a study event that may be a reference event for the end of a clinical event (PerformedObservationResult) and MHENTPT indicates a study event that may be a reference event for the end of a medical condition (PerformedMedicalConditionResult).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): As per CDISC, any given observation result can have its start evaluated in relation to a performed activities. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedObservationResult and PerformedActivity for</p>

Source	Connector	Target	Notes
			evaluating start and end of the result.
AssessedActivityRelationship 0..* assessingAssessedActivityRelationship	has as subject	PerformedActivity 1 assessedPerformedActivity	<p>DESCRIPTION: Each AssessedActivityRelationship always has as subject one PerformedActivity. Each PerformedActivity might be the subject of one or more AssessedActivityRelationships.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProcedure	specializes	PerformedActivity	<p>DESCRIPTION: Each PerformedProcedure always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedProcedure.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservation	specializes	PerformedActivity	<p>DESCRIPTION: Each PerformedObservation always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedObservation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
EvaluatedActivityRelationship 0..* evaluatingEvaluatedActivityRelationship	evaluates	PerformedActivity 1 evaluatedPerformedActivity	<p>DESCRIPTION: Each EvaluatedActivityRelationship always evaluates one PerformedActivity. Each PerformedActivity might be evaluated by one or more EvaluatedActivityRelationships</p>

Source	Connector	Target	Notes
			<p>hip.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
repetitionNumber <i>Class:</i> PerformedActivity <i>Datatype:</i> INT.POS <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer that identifies the particular occurrence of a repeating activity. The first repetition is defined as '1'.</p> <p>EXAMPLE(S): A PlannedActivity might have a repeatQuantity of 4 which would result in 4 ScheduledActivity and PerformedActivity with repetitionNumbers of 1, 2, 3, and 4 respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from ScheduledActivity.repetitionNumber.</p>	<p>Map:caAERSv2.2 = AdverseEventReportingPeriod.cycleNumber</p> <p>Map:caAERSv2.2 = TreatmentInformation.totalCourses</p> <p>Map:caAERSv2.2 = CourseDate.number</p> <p>Map:CTrv1.0 = PerformedActivity.repetitionNumber</p> <p>Map:HCTv1.0 = CDE 2763975:Therapies.What is the number of systemic/intrathecal therapy cycles administered?</p> <p>Map:HCTv1.0 = CDE 3060732:Therapies.What is the reason for the number of cycles missing value?</p> <p>Map:HCTv1.0 = CDE 3060718:Therapies.What was the number of cycles for the therapeutic procedure?</p> <p>Map:HCTv1.0 = CDE 2954036:Therapy Doses.Specify the number of days of radiation therapy</p> <p>Map:LSDAMv2.2.3Plus = PerformedActivity.repetitionNumber</p> <p>Map:NCI CRF Standard = CDE 2072v4.1: Treatment Current Course Number</p> <p>Map:NCI CRF Standard = CDE 2732184v1.0: Protocol Course Number Count</p> <p>Map:NCI CRF Standard = CDE 62590v3.0: Agent Course Count</p> <p>Map:NCI CRF Standard = CDE 62676v3.0: Prior Chemotherapy Regimen Number</p> <p>Map:NCI CRF Standard = CDE 2744948v1.0: Treatment Cycle Number</p> <p>Map:PGx v1.0 = PF.PFREPNUM</p>

Attribute	Notes	Constraints and Tags
nameCodeModifiedText <i>Class:</i> PerformedActivity <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A character string that is a revision of the original text of the activity designation to enable the coding of the text.</p> <p>EXAMPLE(S): If the originalText is "apendectomy", the valueCodeModifiedText could be changed to "appendectomy", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p> <p>This attribute accommodates cases where the original text for identifying what is the activity is captured as DefinedActivity.nameCode(CD).originalText, but is unencodable as is, and requires modification to enable encoding, then the code can be captured as DefinedActivity.nameCode(CD).code.</p>	Map:SDTM IGv3.1.3 = MH.MHMODIFY

Attribute	Notes	Constraints and Tags
dateRange <i>Class:</i> PerformedActivity <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span when this activity began and ended.</p> <p>EXAMPLE(S): The date and time when a sample is taken from the subject.</p> <p>A dose of chemotherapy is given on June 12th starting at 9am and finishing at 12pm.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Whether administrative or preparatory activities are included in this time frame is up to whoever is defining the activity - this time frame is all that matters when the activity occurred.</p> <p>The date range is an interval (IVL) data type, meaning it has a beginning (low) and end (high) values. It is also a datetime (TS.DATETIME) data type, meaning the beginning date and the end date can have uncertain values (e.g., a range). For example, if a subject was diagnosed with leukemia sometime in 2009 and that subject had a transplant (substance administration) sometime in 2010. We can surmise that the subject must have had a preparative regimen sometime between those times. Therefore the preparative regimen activity would have a beginning (low) date range of between 2009-01-01 and 2009-12-31; and an ending (high) date range of between 2010-01-01 and 2010-12-31. The precise data type mappings would be:</p> <p>IVL<TS.DATETIME>.low.uncertainRange.low = 2009-01-01 IVL<TS.DATETIME>.low.uncertainRange.high = 2009-12-31 IVL<TS.DATETIME>.high.uncertainRange.low = 2010-01-01 IVL<TS.DATETIME>.high.uncertainRange.high = 2010-12-31</p> <p>[Note that times are left out of the example to keep it as simple as possible.]</p>	Map:AE = Device.dateDeviceReturnedToManufacturer Map:AE = ProductInvestigation.investigationDate Map:AE = AdverseEvent.baselineDate Map:AIM v4 rv48 = AnnotationCollection.dateTime Map:AIM v4 rv48 = AnnotationEntity.dateTime Map:C3PRv2.9 = StudySubjectConsentVersion.informedConsentSignedDate Map:C3PRv2.9 = ScheduledEpoch.offEpochDate Map:C3PRv2.9 = ScheduledArm.startDate Map:C3PRv2.9 = ScheduledEpoch.startDate Map:C3PRv2.9 = ScheduledNotification.dateSent Map:C3PRv2.9 = StudyParticipantDiseaseHistory.diagnosisDate Map:caAERSv2.2 = StudyParticipantPriorTherapy.endDate Map:caAERSv2.2 = StudyParticipantPriorTherapy.startDate Map:caAERSv2.2 = MedicalDevice.implantedDate Map:caAERSv2.2 = ConcomitantMedication.startDate Map:caAERSv2.2 = AdverseEventResponseDescription.eventTreatmentTime Map:caAERSv2.2 = AdverseEventResponseDescription.reducedDate Map:caAERSv2.2 = AdverseEventResponseDescription.dateRemovedFromProtocol Map:caAERSv2.2 = CM.CMENTIM Map:caAERSv2.2 = ConcomitantMedication.endDate Map:caAERSv2.2 = StudyParticipantAssignment.firstCourseDate Map:caAERSv2.2 = ReportingPeriodReviewComment Map:caAERSv2.2 = DiseaseHistory.diagnosticDate Map:caAERSv2.2 = SurgeryIntervention.interventionDate Map:caAERSv2.2 = TreatmentInformation.firstCourseDate Map:caAERSv2.2 = StudyParticipantConcomitantMedication.startDate Map:caAERSv2.2 = AdverseEvent.gradedDate

Attribute	Notes	Constraints and Tags
		Map:caAERSv2.2 = StudyParticipantConcomitantMedication.endDate Map:caAERSv2.2 = AdverseEventResponseDescription.statusDate Map:caAERSv2.2 = Lab.labDate Map:caAERSv2.2 = AdverseEventReportingPeriod.startDate Map:caAERSv2.2 = AdverseEventReportingPeriod.endDate Map:caAERSv2.2 = LabValue.date Map:caAERSv2.2 = CourseDate.date Map:caAERSv2.2 = MedicalDevice.explantedDate Map:caAERSv2.2 = RadiationIntervention.lastTreatmentDate Map:CDASHv1.1 = EX.EXSTTIM Map:CDASHv1.1 = VS.VSTIM Map:CDASHv1.1 = PE.PEDAT Map:CDASHv1.1 = VS.VSDAT Map:CDASHv1.1 = DA.DADAT Map:CDASHv1.1 = CM.CMSTTIM Map:CDASHv1.1 = MH.MHDATA Map:CDASHv1.1 = LB.LBTIM Map:CDASHv1.1 = CM.CMSTDAT Map:CDASHv1.1 = EX.EXSTDAT Map:CDASHv1.1 = DM.DMDAT Map:CDASHv1.1 = EX.EXENDAT Map:CDASHv1.1 = SU.SUSTDAT Map:CDASHv1.1 = EX.EXENTIM Map:CDASHv1.1 = EG.EGDAT Map:CDASHv1.1 = SU.SUENDAT Map:CDASHv1.1 = DS.DSSTTIM Map:CDASHv1.1 = CM.CMENTIM Map:CDASHv1.1 = DS.DSSTDAT Map:CDASHv1.1 = CM.CMENDAT Map:CDASHv1.1 = EG.EGTIM Map:CDASHv1.1 = PE.PETIM Map:CDASHv1.1 = LB.LBDAT Map:CTGOV = Record Verification Date Map:CTOM = Procedure.startDate Map:CTOM = StudyParticipantAssignment.enrollmentAge Map:CTOM = QualitativeEvaluation.evaluationDate Map:CTOM = FemaleReproductiveCharacteristic.menopauseStartDate Map:CTOM = Diagnosis.evaluationDate Map:CTOM = DiseaseResponse.evaluationDate Map:CTOM = LesionEvaluation.evaluationDate Map:CTOM = Radiation.stopDate

Attribute	Notes	Constraints and Tags
		Map:CTOM = Assessment.evaluationDate Map:CTOM = AdverseEventTherapy.treatmentDate Map:CTOM = DeathSummary.evaluationDate Map:CTOM = SubstanceAdministration.stopDate Map:CTOM = Radiation.startDate Map:CTOM = SpecimenAcquisition.startDate Map:CTOM = Activity.startDate Map:CTOM = Procedure.stopDate Map:CTOM = Activity.stopDate Map:CTOM = SpecimenAcquisition.stopDate Map:CTOM = Surgery.stopDate Map:CTOM = Surgery.startDate Map:CTOM = Imaging.stopDate Map:CTOM = Imaging.startDate Map:CTOM = SubstanceAdministration.startDate Map:CTRPv1.0 = StudyProtocol.recordVerificationDate Map:CTRPv1.0 = InterventionalStudyProtocol.recordVerificationDate Map:CTRPv1.0 = ObservationalStudyProtocol.recordVerificationDate Map:CTRPv3.8 = PerformedActivity.actualDateRange Map:CTRv1.0 = PerformedActivity.dateRange Map:DICOM = General Study Module - Study Date (0008,0020) Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Study Time (0008,0030) Map:DICOM = General Study Module - Study Time (0008,0030) Map:DICOM = Study Level Keys for the Patient Root Query/Retrieve Information Model - Study Date (0008,0020) Map:HCTv1.0 = CDE 2705511:Occurrences.Product infusion begin time: Map:HCTv1.0 = CDE 2931627:Therapies.Date radiation therapy stopped: Map:HCTv1.0 = CDE 3006893:Occurrences.Sample (specimen) collection date. Map:HCTv1.0 = CDE 2770838:Occurrences.What was the date of the subsequent HSCT? Map:HCTv1.0 = CDE 2794409:Therapies.What was the end date the immunosuppressive agents

Attribute	Notes	Constraints and Tags
		were administered to treat or prevent GVHD? Map:HCTv1.0 = CDE 2866078:Occurrences.Date platelets $\geq 20 \times 10^9/L$: Map:HCTv1.0 = CDE 2866490:Occurrences.Thawing process begin date: Map:HCTv1.0 = CDE 3057653:Therapies.Specify the date retinoid therapy was started: Map:HCTv1.0 = CDE 2786643:Occurrences.Thawing process begin time: Map:HCTv1.0 = CDE 2931619:Therapies.Date radiation therapy started: Map:HCTv1.0 = CDE 3124175:Occurrences.Date cytogenetic status established: Map:HCTv1.0 = CDE 2775861:Occurrences.What date was an initial platelet count greater than or equal to $50 \times 10^9/L$ achieved? Map:HCTv1.0 = CDE 2707802:Occurrences.Product infusion end time: Map:HCTv1.0 = CDE 2744513:Therapies.Specify date systemic/intrathecal therapy started: Map:HCTv1.0 = CDE 2970253:Occurrences.If necessary, please validate the recurrent/progressive disease status date response. Map:HCTv1.0 = CDE 2957536:Occurrences.Date of secondary malignancy: Map:HCTv1.0 = CDE 2750705:Therapy Results.Date response to line of therapy established: Map:HCTv1.0 = CDE 2866764:Occurrences.What assessment date determined that CR has not been achieved from the HSCT? Map:HCTv1.0 = CDE 3163960:Therapies.Erythrocyte transfusion date: Map:HCTv1.0 = CDE 2866508:Occurrences.Date the current disease status was established: Map:HCTv1.0 = MD Anderson Specific Content: Transplant.Day of infusion. Map:HCTv1.0 = CDE 2866737:Medical Records and Forms.Clinical Data Form Today's Date Map:HCTv1.0 = CDE 2774708:Therapies.Time of receipt of

Attribute	Notes	Constraints and Tags
		<p>product: Map:HCTv1.0 = CDE 2797546:Occurrences.Date first discharged from hospital post-HSCT: Map:HCTv1.0 = CDE 3005937:Occurrences.Evaluation Date: Map:HCTv1.0 = CDE 2866424:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.Date of the most recent previous HSCT: Map:HCTv1.0 = CDE 2866949:Occurrences.Date the relapse / progression was first seen by clinical / hematological method: Map:HCTv1.0 = CDE 3061478:Therapies.Specify the date other treatment was started: Map:HCTv1.0 = CDE 2866710:Diagnosis.What is the diagnosis date of the new malignancy, lymphoproliferative or myeloproliferative disorder that occurred? Map:HCTv1.0 = CDE 2774075:Numbers.How many subsequent days of collection? Map:HCTv1.0 = CDE 2866380:Occurrences.If initial platelets have not recovered to >20 x 10^9/L since HSCT, what was the date of last assessment? Map:HCTv1.0 = CDE 2875783:Therapies.Preparative regimen begin date: Map:HCTv1.0 = CDE 2866523:Therapies.Date of DCI: Map:HCTv1.0 = CDE 2594448:Therapies.What was the start date for the velafermin administration? Map:HCTv1.0 = CDE 2960535:Therapies.When did therapy stop? Map:HCTv1.0 = CDE 2866433:Occurrences.Specify the date the clinical / hematologic CR was achieved: Map:HCTv1.0 = CDE 2866483:Therapies.Specify the date for the first course of each agent administered: Map:HCTv1.0 = CDE 2594446:Therapies.Specify the start date of the KGF administration: Map:HCTv1.0 = CDE 2794460:Occurrences.Actual date of follow-up: Map:HCTv1.0 = CDE 2960313:Therapies.When did the preparative regimen medication start? Map:HCTv1.0 = CDE </p>

Attribute	Notes	Constraints and Tags
		<p>2866144:Occurrences.If absolute neutrophil count of $0.5 \times 10^9/L$ has not been achieved, what was the date of last assessment?</p> <p>Map:HCTv1.0 = CDE 2770403:Lab Results.What was the date of the clinical or hematologic evidence?</p> <p>Map:HCTv1.0 = CDE 2866494:Lab Results.Date of decline in ANC to less than 500/mm³ for 3 days or more:</p> <p>Map:HCTv1.0 = CDE 2770388:Lab Results.What was the date of the molecular analysis?</p> <p>Map:HCTv1.0 = CDE 2866059:Lab Results.Date of product analysis:</p> <p>Map:HCTv1.0 = CDE 2821465:Disease Response.What was the date of best response?</p> <p>Map:HCTv1.0 = CDE 2860472:Therapies.What date did the systemic therapy end?</p> <p>Map:HCTv1.0 = CDE 2866527:Diagnosis.Date of diagnosis of chronic GVHD</p> <p>Map:HCTv1.0 = CDE 2866035:Therapies.Date of receipt of product at your facility:</p> <p>Map:HCTv1.0 = CDE 2866443:Occurrences.Date the cytogenetic complete remission was determined via conventional cytogenetics:</p> <p>Map:HCTv1.0 = CDE 3019234:Therapies.What date did the radiation therapy end?</p> <p>Map:HCTv1.0 = CDE 3018891:Therapies.Radiation therapy administered begin date:</p> <p>Map:HCTv1.0 = CDE 2798743:Diagnosis.Specify the year the diagnosis was made:</p> <p>Map:HCTv1.0 = CDE 2750854:Therapy Results.Date of relapse following the therapeutic procedure:</p> <p>Map:HCTv1.0 = CDE 2866131:Occurrences.Date the original disease status was determined:</p> <p>Map:HCTv1.0 = CDE 2771948:Therapies.Date of last leukapheresis:</p> <p>Map:HCTv1.0 = CDE 2965140:Procedures.Date of excisional biopsy / surgical procedure performed:</p> <p>Map:HCTv1.0 = CDE 2866037:Procedures.Date of multiple product infusion</p> <p>Map:HCTv1.0 = CDE 3163964:Therapies.Platelet transfusion date:</p>

Attribute	Notes	Constraints and Tags
		Map:HCTv1.0 = CDE 2953206:Techniques.Date of consent to donate research blood samples: Map:HCTv1.0 = CDE 2866133:Occurrences.What date was the relapse/progression detected by a molecular method? Map:HCTv1.0 = CDE 2947020:Involvement and Extent of Disease.Date of progression: Map:HCTv1.0 = CDE 2980873:Therapies.Date of orthopedic surgery Map:HCTv1.0 = CDE 3082352:Therapies.What was the last date chemotherapy was administered? Map:HCTv1.0 = CDE 2978753:Occurrences.Date of post therapy disease relapse/progression Map:HCTv1.0 = CDE 2979195:Therapies.What was the date of the last chemotherapy cycle? Map:HCTv1.0 = CDE 2866485:Lab Results.Date of ANC recovery: Map:HCTv1.0 = CDE 2936575:Disease Response.Specify the date complete remission was achieved: Map:HCTv1.0 = CDE 2866435:Occurrences.Date the molecular complete remission was determined: Map:HCTv1.0 = CDE 2943067:Diagnosis.What was the date of MDS / MPS transformation? Map:HCTv1.0 = CDE 2861238:Occurrences.When was the disease assessment type used to assess the disease? Map:HCTv1.0 = CDE 2866139:Occurrences.What date was the relapse/progression detected by a clinical/hematological method? Map:HCTv1.0 = CDE 2786663:Occurrences.Thawing process end time: Map:HCTv1.0 = CDE 2951782:Diagnosis.What was the date of the PET assessment? Map:HCTv1.0 = CDE 2771864:Therapies.If the apheresis for the DCI source was done at a different time other than for the collection of PBSC used for the allogeneic HSCT, what was the date of apheresis? Map:HCTv1.0 = CDE 2953241:Techniques.Date of consent to submit research data: Map:HCTv1.0 = CDE 2866951:Occurrences.First date seen that detected the relapse / progression

Attribute	Notes	Constraints and Tags
		<p>by cytogenetic / FISH method: Map:HCTv1.0 = CDE 2744515:Therapies.Specify date systemic/intrathecal therapy ended: Map:HCTv1.0 = CDE 2866462:Occurrences.Date of the current molecular assessment used to assess the disease status. Map:HCTv1.0 = CDE 2771946:Therapies.Date of first leukapheresis: Map:HCTv1.0 = CDE 2866947:Occurrences.Date the relapse / progression was first seen by molecular method: Map:HCTv1.0 = CDE 2866135:Occurrences.What date was the relapse/progression detected by a cytogenetic/FISH method? Map:HCTv1.0 = CDE 2866938:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.Date of hematopoietic stem cell transplantation (HSCT) for which this form is being completed: Map:HCTv1.0 = CDE 2866746:Diagnosis.What was the date of diagnosis of the primary disease for which the hematopoietic stem cell transplantation was performed? Map:HCTv1.0 = CDE 2866504:Occurrences.Date of current clinical / hematologic assessment used to assess the disease status Map:HCTv1.0 = CDE 2866487:Activity.Date storage started: Map:HCTv1.0 = CDE 2866437:Occurrences.Date the cytogenetic complete remission was determined via FISH: Map:HCTv1.0 = CDE 2782523:Lab Results.What was the date of the cytogenetic analysis? Map:HCTv1.0 = CDE 2986174:Occurrences.If necessary, please validate the sample collection date response. Map:HCTv1.0 = CDE 2947021:Occurrences.Date of relapse: Map:HCTv1.0 = CDE 2760949:Disease, Disorder or Finding.Date of the disease status evaluation: Map:HCTv1.0 = CDE 3061335:Therapies.What date was immunotherapy administered? Map:HCTv1.0 = CDE 2953362:Lab Results.Date the histologic transformation occurred: Map:HCTv1.0 = CDE 2866759:Occurrences.Survival </p>

Attribute	Notes	Constraints and Tags
		status:latest follow-up date Map:HCTv1.0 = CDE 2866525:Occurrences.Date of the latest cytogenetic / FISH assessment: Map:HCTv1.0 = CDE 2860466:Therapies.What date did the systemic therapy begin? Map:HCTv1.0 = CDE 2964208:Therapies.Specify the date the first chemotherapy cycle began Map:HCTv1.0 = CDE 2944110:Occurrences.What date did the disease relapse or progress? Map:HCTv1.0 = CDE 2866766:Therapies.Date of product collection: Map:HCTv1.0 = CDE 3115646:Therapies.Date of previous HSCT: Map:HCTv1.0 = CDE 2954767:Therapies.What date was the surgical procedure performed? Map:HCTv1.0 = MD Anderson Specific Content: Product.Number of days cell product was in culture Map:HCTv1.0 = CDE 2932795:Diagnosis.Date of diagnosis: Map:HCTv1.0 = CDE 2866414:Occurrences.First date of 3 consecutive labs initial ANC recovery >= to 0.5×10^9 was achieved: Map:HCTv1.0 = CDE 2936618:Occurrences.Date the disease status was established: Map:HCTv1.0 = CDE 2960533:Therapies.When did the therapy start? Map:HCTv1.0 = CDE 2866534:Diagnosis.If the MDS subtype is AML, date of MDS diagnosis: Map:HCTv1.0 = CDE 2770410:Occurrences.What is the documented date of the stable, mixed chimerism? Map:ICSRr2 = InvestigativeEvent.effectiveTime (in IndividualCaseSafetyReport) Map:ICSRr2 = ProductEvent.effectiveTime (in R_Product) Map:ICSRr2 = RelatedInvestigation.effectiveTime (in IndividualCaseSafetyReport) Map:ICSRr2 = SpecimenCollectionProcess.effectiveTime (in R_Specimen universal) Map:ICSRr2 = TransportationEvent.effectiveTime (in R_Product) Map:Lab = Activity.actualStartTime

Attribute	Notes	Constraints and Tags
		Map:Lab = LabResult.testPerformedDateTime Map:Lab = Activity.actualEndDateTime Map:LabViewer2.2 = SpecimenCollection.actualStartDateTi me Map:LabViewer2.2 = Activity.actualStartTime Map:LabViewer2.2 = Activity.actualEndDateTime Map:LabViewer2.2 = LaboratoryResult.testPerformedDateTime Map:LabViewer2.2 = SpecimenCollection.actualEndDateTi me Map:LSDAMv2.2.3Plus = PerformedActivity.actualDateRange Map:NCI CRF Standard = CDE 2003580v3.0: Lab Collection Time Map:NCI CRF Standard = CDE 3028746v1.0: Intervention Occurrence End Date Map:NCI CRF Standard = CDE 2004170v3.0: Evaluation Date Map:NCI CRF Standard = CDE 2004139v3.0: Stop Time Map:NCI CRF Standard = CDE 3028744v1.0: Intervention Occurrence Begin Date Map:NCI CRF Standard = CDE 62739v3.0: Current Stage Complete Assessment Date Map:NCI CRF Standard = CDE 2003745v5.0: Form Completion Date Map:NCI CRF Standard = CDE 2992v4.0: Treatment Reporting Period End Date Map:NCI CRF Standard = CDE 2004004v3.0: Sample Collection Date Map:NCI CRF Standard = CDE 2179659v2.0: Patient Relevant Medical History Date Map:NCI CRF Standard = CDE 65167v3.0: Last Treatment Date Map:NCI CRF Standard = CDE 2004095v3.0: Start Time Map:NCI CRF Standard = CDE 3008897v1.0: Case Report Form Review Date Map:NCI CRF Standard = CDE 2003745v5.0: Form Completion Date Map:NCI CRF Standard = CDE 2746541v1.0: Participant Enrollment Date Map:NCI CRF Standard = CDE 64166v3.0: Form Amended Complete Date Map:NCI CRF Standard = CDE 2171v4.0: Patient Registration Date

Attribute	Notes	Constraints and Tags
		Map:NCI CRF Standard = CDE 2993v4.0: Treatment Reporting Period Begin Dat Map:PGx v1.0 = BE.BEENDTC Map:PGx v1.0 = PG.PGDTC Map:PGx v1.0 = SB.SBDTC Map:PGx v1.0 = PF.PFDTC Map:PGx v1.0 = BE.BEDUR Map:PGx v1.0 = BE.BESTDT Map:PGx v1.0 = BE.BEDTC Map:PGx v1.0 = BS.BSDTC Map:PGx v1.0 = PF.PFRFTDTC Map:PSC = VitalSign.measureTime Map:PSC = ScheduledEventState.occurred Map:PSC = StudyParticipantAssignment.startDate Map:PSC = Occurred.date Map:PSCv2.6 = AdverseEvent.detectionDate Map:SDTM IGv3.1.1 = EG.EGDTC Map:SDTM IGv3.1.1 = LB.LBDTC Map:SDTM IGv3.1.1 = SV.SVSTDTC Map:SDTM IGv3.1.1 = EX.EXSTDTC Map:SDTM IGv3.1.1 = SV.SVENDTC Map:SDTM IGv3.1.1 = CM.CMENDTC Map:SDTM IGv3.1.1 = DS.DSDTC Map:SDTM IGv3.1.1 = IE.IEDTC Map:SDTM IGv3.1.1 = DA.DADTC Map:SDTM IGv3.1.1 = VS.VSDTC Map:SDTM IGv3.1.1 = QS.QSDTC Map:SDTM IGv3.1.1 = DS.DSSTDTC Map:SDTM IGv3.1.1 = CM.CMSTDTC Map:SDTM IGv3.1.1 = PE.PEDTC Map:SDTM IGv3.1.1 = LB.LBENDTC Map:SDTM IGv3.1.1 = SU.SUENDTC Map:SDTM IGv3.1.1 = CO.CODTC Map:SDTM IGv3.1.1 = MH.MHDTC Map:SDTM IGv3.1.1 = SE.SESTDTC Map:SDTM IGv3.1.1 = SU.SUSTDTC Map:SDTM IGv3.1.1 = DM.DMDTC Map:SDTM IGv3.1.1 = EX.EXENDTC Map:SDTM IGv3.1.1 = SE.SEENDTC Map:SDTM IGv3.1.1 = SC.SCDTC Map:SDTM IGv3.1.2 = CE.CESTTPT Map:SDTM IGv3.1.2 = PP.PPRFTDTC Map:SDTM IGv3.1.2 = CE.CEENRPT Map:SDTM IGv3.1.2 = CM.CMSTRF Map:SDTM IGv3.1.2 =

Attribute	Notes	Constraints and Tags
		QS.QSRFTDTC Map:SDTM IGv3.1.2 = CM.CMENRTPT Map:SDTM IGv3.1.2 = CE.CESTRF Map:SDTM IGv3.1.2 = VS.VSRFTDTC Map:SDTM IGv3.1.2 = PC.PCDTC Map:SDTM IGv3.1.2 = IE.IEDTC Map:SDTM IGv3.1.2 = MB.MBRFTDTC Map:SDTM IGv3.1.2 = FA.FADTC Map:SDTM IGv3.1.2 = SU.SUENTPT Map:SDTM IGv3.1.2 = SV.SVSTDTC Map:SDTM IGv3.1.2 = CM.CMSTDTC Map:SDTM IGv3.1.2 = CE.CESTRTPT Map:SDTM IGv3.1.2 = EG.EGRFTDTC Map:SDTM IGv3.1.2 = SU.SUSTRF Map:SDTM IGv3.1.2 = PE.PEDTC Map:SDTM IGv3.1.2 = PP.PPDTCTC Map:SDTM IGv3.1.2 = LB.LBDTC Map:SDTM IGv3.1.2 = MB.MBDTC Map:SDTM IGv3.1.2 = CE.CEENTPT Map:SDTM IGv3.1.2 = VS.VSDTC Map:SDTM IGv3.1.2 = SU.SUENRTPT Map:SDTM IGv3.1.2 = SU.SUSENDTC Map:SDTM IGv3.1.2 = LB.LBENDTC Map:SDTM IGv3.1.2 = CE.CEENRF Map:SDTM IGv3.1.2 = SE.SEENDTC Map:SDTM IGv3.1.2 = DM.DMDTC Map:SDTM IGv3.1.2 = CM.CMSTRTP Map:SDTM IGv3.1.2 = SU.SUENRF Map:SDTM IGv3.1.2 = PC.PCRFTDTC Map:SDTM IGv3.1.2 = MH.MHDTCTC Map:SDTM IGv3.1.2 = CM.CMSTTPT Map:SDTM IGv3.1.2 = SU.SUSTTPT Map:SDTM IGv3.1.2 = CM.CMENTPT Map:SDTM IGv3.1.2 = QS.QSDTC Map:SDTM IGv3.1.2 = CO.CODTC Map:SDTM IGv3.1.2 = CM.CMENDTC Map:SDTM IGv3.1.2 = PC.PCENDTC Map:SDTM IGv3.1.2 = SV.SVENDTC Map:SDTM IGv3.1.2 = DS.DSSTDTC Map:SDTM IGv3.1.2 = CM.CMENRF Map:SDTM IGv3.1.2 = DA.DADTC Map:SDTM IGv3.1.2 = LB.LBRFTDTC

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = SU.SUSTDTC Map:SDTM IGv3.1.2 = MS.MSDTC Map:SDTM IGv3.1.2 = EG.EGDTC Map:SDTM IGv3.1.2 = SE.SESTDTC Map:SDTM IGv3.1.2 = SC.SCDTC Map:SDTM IGv3.1.2 = EX.EXSTDTC Map:SDTM IGv3.1.2 = EX.EXENDTC Map:SDTM IGv3.1.2 = CE.CEDTC Map:SDTM IGv3.1.2 = SU.SUSTRPT Map:SDTM IGv3.1.3 = DM.RFXENDTC Map:SDTM IGv3.1.3 = DM.RFXSTDTC Map:SDTM IGv3.1.3 = DM.RFPENDTC Map:SDTM IGv3.1.3 = DM.DMDTC Map:SDTM IGv3.1.3 = DA.DADTC Map:SDTM IGv3.1.3 = CO.CODTC Map:SDTM IGv3.1.3 = CM.CMSTTPT Map:SDTM IGv3.1.3 = CM.CMSTDTC Map:SDTM IGv3.1.3 = CM.CMENTPT Map:SDTM IGv3.1.3 = CM.CMENDTC Map:SDTM IGv3.1.3 = CE.CEENTPT Map:SDTM IGv3.1.3 = EG.EGDTC Map:SDTM IGv3.1.3 = CE.CEDTC Map:SDTM IGv3.1.3 = AE.AEENTPT Map:SDTM IGv3.1.3 = CE.CESTTPT Map:SDTM IGv3.1.3 = MS.MSDTC Map:SDTM IGv3.1.3 = SU.SUSTDTC Map:SDTM IGv3.1.3 = PC.PCRFTDTC Map:SDTM IGv3.1.3 = PC.PCENDTC Map:SDTM IGv3.1.3 = SV.SVSTDTC Map:SDTM IGv3.1.3 = PC.PCDTC Map:SDTM IGv3.1.3 = LB.LBRFTDTC Map:SDTM IGv3.1.3 = DS.DSDTC Map:SDTM IGv3.1.3 = SE.SESTDTC Map:SDTM IGv3.1.3 = MB.MBRFTDTC Map:SDTM IGv3.1.3 = LB.LBDTC Map:SDTM IGv3.1.3 = SV.SVENDTC Map:SDTM IGv3.1.3 = SU.SUSTTPT Map:SDTM IGv3.1.3 = SU.SUENTPT Map:SDTM IGv3.1.3 = MH.MHSTDTC Map:SDTM IGv3.1.3 = MH.MHDTC Map:SDTM IGv3.1.3 =

Attribute	Notes	Constraints and Tags
		MH.MHENDTC Map:SDTM IGv3.1.3 = MH.MHENTPT Map:SDTM IGv3.1.3 = SU.SUENDTC Map:SDTM IGv3.1.3 = VS.VSRFTDTC Map:SDTM IGv3.1.3 = QS.QSRFTDTC Map:SDTM IGv3.1.3 = LB.LBENDTC Map:SDTM IGv3.1.3 = DS.DSSTDTC Map:SDTM IGv3.1.3 = RS.RSDTC Map:SDTM IGv3.1.3 = QS.QSDTC Map:SDTM IGv3.1.3 = EG.EGRFTDTC Map:SDTM IGv3.1.3 = EX.EXENDTC Map:SDTM IGv3.1.3 = PE.PEDTC Map:SDTM IGv3.1.3 = EX.EXSTDTC Map:SDTM IGv3.1.3 = MB.MBDTC Map:SDTM IGv3.1.3 = VS.VSDTC Map:SDTM IGv3.1.3 = FA.FADTC Map:SDTM IGv3.1.3 = TU.TUDTC Map:SDTM IGv3.1.3 = SC.SCDTC Map:SDTM IGv3.1.3 = TR.TRDTC Map:SDTM IGv3.1.3 = SE.SEENDTC Map:SDTM IGv3.1.3 = IE.IEDTC Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE IMMUNOTHERAPY STARTED FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE OTHER TREATMENT STARTED Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE RADIATION STARTED FLAG Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - DATE OF DIAGNOSIS Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - DATE OF DIAGNOSIS FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE THERAPY INITIATED FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE OF FIRST SURGICAL PROCEDURE Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE HORMONE THERAPY STARTED

Attribute	Notes	Constraints and Tags
		Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE RADIATION STARTED Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE IMMUNOTHERAPY STARTED Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - RADIATION Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE CHEMOTHERAPY STARTED Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE CHEMOTHERAPY STARTED FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE OTHER TREATMENT STARTED FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE HORMONE THERAPY STARTED FLAG Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - DATE OF FIRST SURGICAL PROCEDURE FLAG Map:WHO = Date of Registration in Primary Registry Map:WHO = Date of First Enrollment

Attribute	Notes	Constraints and Tags
dateRangeValidationCode <i>Class:</i> PerformedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the degree of authoritativeness or certitude of the date of the activity</p> <p>EXAMPLE(S): date estimated date greater than 100 days - day is correct date known date less than 100 days - date is correct date previously reported</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The concept of "date unknown" is captured by a nullFlavor of "UNK" on the dateRange attribute, rather than a code in this attribute.</p>	Map:HCTv1.0 = CDE 2794432:Therapies.If necessary, please validate the final date of immunosuppressant administration response. Map:HCTv1.0 = CDE 2978136:Therapies.If necessary, please validate the chemotherapy administered date response. Map:HCTv1.0 = CDE 2946356:Occurrences.If necessary, please validate the disease status date response. Map:HCTv1.0 = CDE 2775863:Occurrences.If necessary, please validate the date of platelets greater than or equal to $50 \times 10^9/L$ response. Map:HCTv1.0 = CDE 2980833:Therapies.If necessary, please validate the orthopedic surgery date response. Map:HCTv1.0 = CDE 3133870:Diagnosis.If necessary, please validate the diagnosis date response. Map:HCTv1.0 = CDE 2979213:Therapies.If necessary, please validate the last chemotherapy cycle date response. Map:HCTv1.0 = CDE 3071475:Quality of Life.If necessary, please validate the vineland adaptive behavior date response. Map:HCTv1.0 = CDE 2991134:Occurrences.If necessary, please validate the evaluation date response. Map:HCTv1.0 = CDE 3162397:Occurrences.If necessary, please validate the last contact date response Map:HCTv1.0 = CDE 2775854:Occurrences.If necessary, please validate the date of platelets greater than or equal to $20 \times 10^9/L$ response. Map:HCTv1.0 = CDE 2821467:Disease Response.If necessary, please validate the best response date value.

Attribute	Notes	Constraints and Tags
studyDayRange <i>Class:</i> PerformedActivity <i>Datatype:</i> IVL<INT> <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The relative timing for a performed activity expressed as the number of days offset from the study-defined reference activity (e.g., date of registration, start of treatment) for this particular experimental unit.</p> <p>EXAMPLE(S): Day 1, Days 10-20</p> <p>OTHER NAME(S): Study Day</p> <p>NOTE(S): Derived from the dateRange of this activity minus the dateRange of the reference activity + 1. The study-defined reference activity can be different from study to study. The study day for a date after this reference activity is a positive integer calculated as the difference in the two dates + 1. The study day for dates before the reference activity is a negative integer calculated as the difference between the two dates. Note that this means there is no "Day 0."</p>	Map:CTRv1.0 = PerformedActivity.studyDayRange Map:PGx v1.0 = PF.PFDY Map:PGx v1.0 = BE.BESTDY Map:PGx v1.0 = BE.BEENDY Map:PGx v1.0 = BS.BSDY Map:PGx v1.0 = PG.PGDY Map:SDTM IGv3.1.2 = MH.MHDY Map:SDTM IGv3.1.2 = AE.AEENDY Map:SDTM IGv3.1.2 = EG.EGDY Map:SDTM IGv3.1.2 = CE.CEDY Map:SDTM IGv3.1.2 = LB.LBDY Map:SDTM IGv3.1.2 = PE.PEDY Map:SDTM IGv3.1.2 = IE.IEDY Map:SDTM IGv3.1.2 = DA.DADY Map:SDTM IGv3.1.2 = SV.SVENDY Map:SDTM IGv3.1.2 = SU.SUSTDY Map:SDTM IGv3.1.2 = QS.QSDY Map:SDTM IGv3.1.2 = EX.EXENDY Map:SDTM IGv3.1.2 = PC.PCDY Map:SDTM IGv3.1.2 = CM.CMENDY Map:SDTM IGv3.1.2 = VS.VSDY Map:SDTM IGv3.1.2 = SU.SUENDY Map:SDTM IGv3.1.2 = FA.FADY Map:SDTM IGv3.1.2 = DM.DMDY Map:SDTM IGv3.1.2 = EX.EXSTDY Map:SDTM IGv3.1.2 = AE.AESTDY Map:SDTM IGv3.1.2 = MB.MBDY Map:SDTM IGv3.1.2 = MS.MSDY Map:SDTM IGv3.1.2 = DS.DSSTDY Map:SDTM IGv3.1.2 = CM.CMSTDY Map:SDTM IGv3.1.2 = SC.SCDY Map:SDTM IGv3.1.2 = SV.SVSTDY Map:SDTM IGv3.1.3 = CE.CEENDTC Map:SDTM IGv3.1.3 = CE.CEDY Map:SDTM IGv3.1.3 = MH.MHSSTDTC Map:SDTM IGv3.1.3 = FA.FADY Map:SDTM IGv3.1.3 = TR.TRDY Map:SDTM IGv3.1.3 = SV.SVSTDY Map:SDTM IGv3.1.3 = SV.SVENDY Map:SDTM IGv3.1.3 = SU.SUSTDY Map:SDTM IGv3.1.3 = SU.SUENDY Map:SDTM IGv3.1.3 = SC.SCDY Map:SDTM IGv3.1.3 = RS.RSDY Map:SDTM IGv3.1.3 = QS.QSDY Map:SDTM IGv3.1.3 = PE.PEDY Map:SDTM IGv3.1.3 = MS.MSDY Map:SDTM IGv3.1.3 = MH.MHDY Map:SDTM IGv3.1.3 = MB.MBDY Map:SDTM IGv3.1.3 = MH.MHENDTC Map:SDTM IGv3.1.3 = IE.IEDY Map:SDTM IGv3.1.3 = CE.CESTDTC Map:SDTM IGv3.1.3 = EX.EXSTDY Map:SDTM IGv3.1.3 = EX.EXENDY Map:SDTM IGv3.1.3 = EG.VISITDY

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = EG.EGDY Map:SDTM IGv3.1.3 = DS.DSSTDY Map:SDTM IGv3.1.3 = DM.DMDY Map:SDTM IGv3.1.3 = DA.DADY Map:SDTM IGv3.1.3 = CM.CMSTDY Map:SDTM IGv3.1.3 = CM.CMENDY Map:SDTM IGv3.1.3 = PC.PCDY Map:SDTM IGv3.1.3 = VS.VSDY Map:SDTM IGv3.1.3 = TU.TUDY Map:SDTM IGv3.1.3 = LB.LBDY

Attribute	Notes	Constraints and Tags
duration <i>Class:</i> PerformedActivity <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time over which the activity is performed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the notion of duration in the IVL (width) portion of the dateRange attribute.</p>	AE:Exclude = True Map:caAERSv2.2 = CourseAgent.durationAndSchedule Map:CDASHv1.1 = SU.SUCDUR Map:CDASHv1.1 = SU.SUCDURU Map:CTOM = Radiation.durationUnitOfMeasureCode Map:CTOM = Surgery.durationUnitOfMeasureCode Map:CTOM = SubstanceAdministration.durationUnitOfMeasureCode Map:CTOM = Procedure.durationValue Map:CTOM = Procedure.durationUnitOfMeasureCode Map:CTOM = SubstanceAdministration.durationValue Map:CTOM = Activity.durationValue Map:CTOM = SpecimenAcquisition.durationUnitOfMeasureCode Map:CTOM = Imaging.durationValue Map:CTOM = Radiation.durationValue Map:CTOM = Activity.durationUnitOfMeasureCode Map:CTOM = Surgery.durationValue Map:CTOM = SpecimenAcquisition.durationValue Map:CTOM = Imaging.durationUnitOfMeasureCode Map:CTRPv3.8 = PerformedActivity.actualDuration Map:CTRv1.0 = PerformedActivity.duration Map:LSDAMv2.2.3Plus = PerformedActivity.actualDuration Map:SDTM IGv3.1.1 = CM.CMDUR Map:SDTM IGv3.1.1 = EX.EXDUR Map:SDTM IGv3.1.1 = SU.SUDUR Map:SDTM IGv3.1.2 = SU.SUDUR Map:SDTM IGv3.1.2 = EX.EXDUR Map:SDTM IGv3.1.2 = CM.CMDUR Map:SDTM IGv3.1.3 = SU.SUDUR Map:SDTM IGv3.1.3 = CM.CMDUR Map:SDTM IGv3.1.3 = EX.EXDUR

Attribute	Notes	Constraints and Tags
delayDuration <i>Class:</i> PerformedActivity <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time that an action is delayed relative to an original schedule.</p> <p>EXAMPLE(S): If a substance administration is delayed 2 days as a result of an adverse event, then the delayDuration is 2 days.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing the dates of the scheduled activity with the corresponding performed activity.</p>	AE:Exclude = True Map:caAERSv2.2 = CourseAgent.administrationDelayAmount Map:caAERSv2.2 = CourseAgent.administrationDelayUnits Map:caAERSv2.2 = AdverseEventResponseDescription.daysNotGiven Map:CTRv1.0 = PerformedActivity.delayDuration Map:LSDAMv2.2.3Plus = PerformedActivity.delayDuration

Attribute	Notes	Constraints and Tags
negationIndicator <i>Class:</i> PerformedActivity <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether an activity did not occur.</p> <p>EXAMPLE(S): If a subject did not take aspirin in the previous week, the negationIndicator = "true".</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If it is important to capture the fact that a particular activity did not occur, then this attribute is used, often along with negationReason.</p>	Map:AE = ProductInvestigation.investigationPerformedIndicator Map:AE = PerformedObservationResult.negationIndicator Map:CDASHv1.1 = VS.VSSTAT Map:CTRv1.0 = PerformedActivity.negationIndicator Map:HCTv1.0 = CDE 3073228:Lab Results.What is the reason for the DRB4 alleles missing value? Map:HCTv1.0 = CDE 3073224:Lab Results.What is the reason for the DRB1 alleles missing value? Map:HCTv1.0 = CDE 3073243:Lab Results.What is the reason for the DPA1 alleles missing value? Map:HCTv1.0 = CDE 3073237:Lab Results.What is the reason for the DRB5 alleles missing value? Map:HCTv1.0 = CDE 2686182:Lab Results.For the systemic lupus erythematosus, what was the ANA test result? Map:HCTv1.0 = CDE 2760277:Lab Results.Did laboratory procedure test for nucleated red blood cells? Map:HCTv1.0 = CDE 2689329:Lab Results.For systemic lupus, erythematosus, what was the total complement test result? Map:HCTv1.0 = CDE 2760378:Specimen Characteristics.Was the cell viability tested? Map:HCTv1.0 = CDE 3073235:Lab Results.What is the reason for the DQB1 alleles missing value? Map:HCTv1.0 = CDE 2749880:Lab Results.For the polyarteritis nodosa, classical or microscopic, what was the laboratory procedure type? Map:HCTv1.0 = CDE 2695060:Lab Results.If FDA licensed nucleic acid amplification test (NAT) for human immunodeficiency virus(HIV)-1 performed; specify results Map:HCTv1.0 = CDE 2691365:Lab Results.For the polymyositis-dermatomyositis, were the biopsy results typical of the disease? Map:HCTv1.0 = CDE 3073220:Lab Results.What is the reason for the B alleles missing value? Map:HCTv1.0 = CDE 2691376:Lab Results.For the

Attribute	Notes	Constraints and Tags
		<p>polymyositis-dermatomyositis, were the EMG results typical of the disease?</p> <p>Map:HCTv1.0 = CDE 2749876:Lab Results.For the wegener granulomatosis, what was the result of the laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 3073239:Lab Results.What is the reason for the DQA1 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 3098936:Individuals.What is the reason for the missing number of pregnancies?</p> <p>Map:HCTv1.0 = CDE 2691374:Lab Results.For the dermatomyositis, was there a rash present that was typical of the disease?</p> <p>Map:HCTv1.0 = CDE 2760308:Lab Results.Did laboratory procedure test for CD3 + cells?</p> <p>Map:HCTv1.0 = CDE 2769662:Procedures.Did this donor have a central line placed?</p> <p>Map:HCTv1.0 = CDE 2686188:Lab Results.For the systemic lupus erythematosus, what was the ds DNA test result?</p> <p>Map:HCTv1.0 = CDE 2689324:Lab Results.For the systemic lupus erythematosus (SLE), what was the C4 test result?</p> <p>Map:HCTv1.0 = CDE 2749870:Lab Results.For the antiphospholipid syndrome, what was the result of the laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 2682913:Lab Results.For the systemic lupus erythematosus, what was the test results at diagnosis for the other antibody?</p> <p>Map:HCTv1.0 = CDE 2775132:Therapies.Was a particular post hematopoietic stem cell transplant therapy administered?</p> <p>Map:HCTv1.0 = CDE 3073218:Lab Results.What is the reason for the A alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2760376:Lab Results.Did laboratory procedure test for CD4 + cells?</p> <p>Map:HCTv1.0 = CDE 2760292:Lab Results.Did the laboratory procedure test for CD34+ cells?</p> <p>Map:HCTv1.0 = CDE 3073222:Lab Results.What is the reason for the C alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2681691:Chronic or Associated Diseases and Exposures.What was the recipient's test results for the presence</p>

Attribute	Notes	Constraints and Tags
		<p>of CMV-antibodies?(Chronic)</p> <p>Map:HCTv1.0 = CDE 3073226:Lab Results.What is the reason for the DRB3 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2682755:Therapies.Was imatinib mesylate given for pre-transplant therapy for the other acute leukemia anytime prior to the start of the preparative regimen?</p> <p>Map:HCTv1.0 = CDE 2772013:Procedures.Was the donor tested for sickle cell anemia?</p> <p>Map:HCTv1.0 = CDE 2686194:Lab Results.For the systemic lupus erythematosus, what was the C3 test result?</p> <p>Map:HCTv1.0 = CDE 2748995:Techniques.Was a particular tumor cell detection method used after purging?</p> <p>Map:HCTv1.0 = CDE 2760131:Lab Results.Did laboratory procedure test for mononucleated cells?</p> <p>Map:HCTv1.0 = CDE 2760264:Lab Results.Did laboratory procedure test for nucleated cells?</p> <p>Map:LSDAMv2.2.3Plus = PerformedActivity.missedIndicator</p> <p>Map:NCI CRF Standard = CDE 2838523v1.0: Laboratory Specimen Collection Status Indicator</p> <p>Map:NCI CRF Standard = CDE 2179986v1.0: Concomitant Medication Use Ind-3</p> <p>Map:PGx v1.0 = PG.PGSTAT</p> <p>Map:PGx v1.0 = PF.PFSTAT</p> <p>Map:PGx v1.0 = BS.BSSTAT</p> <p>Map:SDTM IGv3.1.1 = EG.EGSTAT</p> <p>Map:SDTM IGv3.1.1 = CM.CMSTAT</p> <p>Map:SDTM IGv3.1.1 = DA.DASTAT</p> <p>Map:SDTM IGv3.1.1 = VS.VSSTAT</p> <p>Map:SDTM IGv3.1.1 = QS.QSSTAT</p> <p>Map:SDTM IGv3.1.1 = SC.SCSTAT</p> <p>Map:SDTM IGv3.1.1 = SU.SUSTAT</p> <p>Map:SDTM IGv3.1.1 = LB.LBSTAT</p> <p>Map:SDTM IGv3.1.1 = MH.MHSTAT</p> <p>Map:SDTM IGv3.1.1 = PE.PESTAT</p> <p>Map:SDTM IGv3.1.2 = EG.EGSTAT</p> <p>Map:SDTM IGv3.1.2 = CE.CESTAT</p> <p>Map:SDTM IGv3.1.2 = MS.MSSTAT</p> <p>Map:SDTM IGv3.1.2 = PC.PCSTAT</p> <p>Map:SDTM IGv3.1.2 = MB.MBSTAT</p> <p>Map:SDTM IGv3.1.2 = PP.PPSTAT</p> <p>Map:SDTM IGv3.1.2 = QS.QSSTAT</p> <p>Map:SDTM IGv3.1.2 = FA.FASTAT</p> <p>Map:SDTM IGv3.1.2 = MH.MHSTAT</p> <p>Map:SDTM IGv3.1.2 = PE.PESTAT</p> <p>Map:SDTM IGv3.1.2 = VS.VSSTAT</p>

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.2 = CM.CMSTAT Map:SDTM IGv3.1.2 = DA.DASTAT Map:SDTM IGv3.1.2 = LB.LBSTAT Map:SDTM IGv3.1.2 = SU.SUSTAT Map:SDTM IGv3.1.2 = SC.SCSTAT Map:SDTM IGv3.1.3 = PE.PESTAT Map:SDTM IGv3.1.3 = SU.SUSTAT Map:SDTM IGv3.1.3 = SC.SCSTAT Map:SDTM IGv3.1.3 = RS.RSSTAT Map:SDTM IGv3.1.3 = QS.QSSTAT Map:SDTM IGv3.1.3 = TR.TRSTAT Map:SDTM IGv3.1.3 = PC.PCSTAT Map:SDTM IGv3.1.3 = MS.MSSTAT Map:SDTM IGv3.1.3 = MH.MHOCCUR Map:SDTM IGv3.1.3 = LB.LBSTAT Map:SDTM IGv3.1.3 = FA.FASTAT Map:SDTM IGv3.1.3 = EG.EGSTAT Map:SDTM IGv3.1.3 = DA.DASTAT Map:SDTM IGv3.1.3 = VS.VSSTAT Map:SDTM IGv3.1.3 = CM.CMSTAT Map:SDTM IGv3.1.3 = MB.MBSTAT

Attribute	Notes	Constraints and Tags
negationReason <i>Class:</i> PerformedActivity <i>Datatype:</i> DSET<SC> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: The text and/or code that describes why an activity did not occur.</p> <p>EXAMPLE(S): forgot to ask, sample lost</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = ProductInvestigation.notEvaluatedBy ManufacturerExplanation Map:CTRPv3.8 = PerformedSubjectMilestone.missedReason Map:CTRv1.0 = PerformedActivity.negationReason Map:HCTv1.0 = CDE 2646256:Treatment/Off-treatment Reasons.Reasons for treatment discontinuation Map:HCTv1.0 = CDE 2556195:Therapy Results.Specify reason Map:HCTv1.0 = CDE 2764241:Therapies.What is the reason for the systemic/intrathecal number of cycles missing value? Map:HCTv1.0 = CDE 2775605:Therapies.Specify the reason this HSCT was canceled: Map:HCTv1.0 = CDE 2949994:Therapies.What is the reason for the systemic therapy cycle administered missing value? Map:HCTv1.0 = CDE 2963889:Disease, Disorder or Finding.Specify reason status was not assessed: Map:HCTv1.0 = CDE 2964380:Therapy Doses.What is the reason for the number of chemotherapy cycles missing values? Map:HCTv1.0 = CDE 3124485:Disease Response.What is the reason for the missing disease status? Map:HCTv1.0 = CDE 2775548:Therapies.Specify the reason the HSCT was not performed: Map:LSDAMv2.2.3Plus = PerformedActivity.missedReason Map:PGx v1.0 = PG.PGREASND Map:PGx v1.0 = PF.PFREASND Map:PGx v1.0 = BS.BSREASND Map:PSC = Canceled Map:SDTM IGv3.1.1 = EG.EGREASND Map:SDTM IGv3.1.1 = CM.CMREASND Map:SDTM IGv3.1.1 = QS.QSREASND Map:SDTM IGv3.1.1 = DA.DAREASND Map:SDTM IGv3.1.1 = PE.PEREASND Map:SDTM IGv3.1.1 = LB.LBREASND Map:SDTM IGv3.1.1 = MH.MHREASND

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.1 = SC.SCREASND Map:SDTM IGv3.1.1 = VS.VSREASND Map:SDTM IGv3.1.1 = SU.SUREASND Map:SDTM IGv3.1.2 = PP.PPREASND Map:SDTM IGv3.1.2 = FA.FAREASND Map:SDTM IGv3.1.2 = QS.QSREASND Map:SDTM IGv3.1.2 = PC.PCREASND Map:SDTM IGv3.1.2 = MS.MSREASND Map:SDTM IGv3.1.2 = SC.SCREASND Map:SDTM IGv3.1.2 = MB.MBREASND Map:SDTM IGv3.1.2 = EG.EGREASND Map:SDTM IGv3.1.2 = VS.VSREASND Map:SDTM IGv3.1.2 = LB.LBREASND Map:SDTM IGv3.1.2 = MH.MHREASND Map:SDTM IGv3.1.2 = SU.SUREASND Map:SDTM IGv3.1.2 = DA.DAREASND Map:SDTM IGv3.1.2 = CE.CEREASND Map:SDTM IGv3.1.2 = PE.PEREASND Map:SDTM IGv3.1.2 = CM.CMREASND Map:SDTM IGv3.1.3 = TR.TRREASND Map:SDTM IGv3.1.3 = PE.PEREASND Map:SDTM IGv3.1.3 = QS.QSREASND Map:SDTM IGv3.1.3 = RS.RSREASND Map:SDTM IGv3.1.3 = PC.PCREASND Map:SDTM IGv3.1.3 = SU.SUREASND Map:SDTM IGv3.1.3 = FA.FAREASND Map:SDTM IGv3.1.3 = VS.VSREASND Map:SDTM IGv3.1.3 = SC.SCREASND Map:SDTM IGv3.1.3 = MS.MSREASND Map:SDTM IGv3.1.3 = MH.MHREASND Map:SDTM IGv3.1.3 =

Attribute	Notes	Constraints and Tags
		LB.LBREASND Map:SDTM IGv3.1.3 = EG.EGREASND Map:SDTM IGv3.1.3 = DA.DAREASND Map:SDTM IGv3.1.3 = CM.CMREASND Map:SDTM IGv3.1.3 = CE.CEREASND Map:SDTM IGv3.1.3 = MB.MBREASND Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - REASON FOR NO SURGERY OF PRIMARY SITE
fastingStatusIndicator <i>Class:</i> PerformedActivity <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the participant had been abstaining from eating when the activity was performed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the presence of a PerformedObservation (e.g. "Was the subject fasting when the specimen collection was performed?") and associated PerformedObservationResult.value (constrained to a BL with value of "true") related to a PerformedActivity. The PerformedObservation would be related to the PerformedActivity by both being components of the same composite activity such as a visit (DefinedSubjectActivityGroup or PlannedSubjectActivityGroup).</p>	Map:CDASHv1.1 = LB.LBCOND Map:CTRv1.0 = PerformedActivity.fastingStatusIndicator Map:Lab = SpecimenCollection.fastingStatus Map:LabViewer2.2 = SpecimenCollection.fastingStatusIndicator Map:LSDAMv2.2.3Plus = PerformedSpecimenCollection.fastingStatusIndicator Map:SDTM IGv3.1.1 = LB.LBFAST Map:SDTM IGv3.1.2 = LB.LBFAST Map:SDTM IGv3.1.2 = PC.PCFAST Map:SDTM IGv3.1.3 = PC.PCFAST Map:SDTM IGv3.1.3 = LB.LBFAST
medicalHistoryIndicator <i>Class:</i> PerformedActivity <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the activity is considered part of the historical record of a subject, that is, it did not occur within the bounds of the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing the date range of the activity (PerformedActivity.dateRange) with the subject participation in the study (PerformedStudySubjectMilestone.studyReferenceDateRange). If the date is within the study participation date range then this indicator will be "false". Note that this means that this indicator will be derived differently for each study.</p>	Map:HCTv1.0 = CDE 2676441:Comorbid Conditions.Is there a history of mechanical ventilation?

Attribute	Notes	Constraints and Tags
statusCode <i>Class:</i> PerformedActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of a performed activity.</p> <p>EXAMPLE(S): For a lab test, this would be the condition or stage in the lifecycle of the test (e.g., "completed", "canceled", etc.).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Performed Activity Status state transition diagram for further details.</p>	Map:AE = PerformedActivity.ongoingPerformanceIndicator Map:AE = ProductInvestigation.manufacturerEvaluationStatus Map:CTOM = ClinicalResult.statusCode Map:CTOM = Histopathology.statusCode Map:CTOM = Observation.statusCode Map:CTRPv1.0 = SubstanceAdministration.statusCode Map:CTRPv1.0 = Activity.statusCode Map:CTRPv3.8 = Activity.statusCode Map:CTRv1.0 = PerformedActivity.statusCode Map:HL7SD = EligibilityCriterion.statusCode Map:ICSRr2 = RelatedInvestigation.statusCode (in IndividualCaseSafetyReport) Map:ICSRr2 = InvestigativeEvent.statusCode (in IndividualCaseSafetyReport) Map:Lab = LabTest.status Map:LabViewer2.2 = LaboratoryTest.status Map:LSDAMv2.2.3Plus = PerformedActivity.statusCode Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - TREATMENT STATUS
statusDate <i>Class:</i> PerformedActivity <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the status is assigned to the activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = Activity.statusDateRange Map:CTRPv1.0 = SubstanceAdministration.statusDateRange Map:CTRPv3.8 = Activity.statusDateRange Map:CTRv1.0 = PerformedActivity.statusDate Map:LabViewer2.2 = Study.startDate Map:LSDAMv2.2.3Plus = PerformedActivity.statusDate

Class: PerformedAdministrativeActivity

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action within the context of a given study or experiment that is not directly related to the overarching hypothesis evaluation or testing, but is nonetheless essential to the efficient and/or effective coordination and execution of the study or experiment.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = PerformedAdministrativeActivity
- Map:CTRv1.0 = PerformedAdministrativeActivity
- Map:HL7SP = RegistrationEvent
- Map:LSDAMv2.2.3Plus = PerformedAdministrativeActivity

Connectors

Source	Connector	Target	Notes
PerformedAdministrativeActivity	specializes	PerformedActivity	<p>DESCRIPTION: Each PerformedAdministrativeActivity always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedAdministrativeActivity 0..* performedPerformedAdministrativeActivity	be performed at	StudySite 0..1 performingStudySite	<p>DESCRIPTION: Each PerformedAdministrativeActivity might be performed at one StudySite. Each StudySite might perform one or more PerformedAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This association has been deprecated since StudySite can be the subject of an administrative activity via Subject to Organization association and can be a performer of an activity via the Performer to Organization association.</p>
PerformedMaterialStorage	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedMaterialStorage always specializes one</p>

Source	Connector	Target	Notes
			PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedMaterialStorage. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedStudyAdministrativeActivity	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedStudyAdministrativeActivity always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedStudyAdministrativeActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedStudyAgentTransfer	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedStudyAgentTransfer always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedStudyAgentTransfer. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedSubjectMilestone	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedSubjectMilestone always specializes one PerformedAdministrativeActivity.

Source	Connector	Target	Notes
			tivity. Each PerformedAdministrativeActivity might be specialized by one PerformedSubjectMilestone. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProgressCount	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedProgressCount always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedProgressCount. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedNotification	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedNotification always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedNotification. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedSpecimenMove	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedSpecimenMove always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedSpecimenMove.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedExperimentalUnitAllocation	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedExperimentalUnitAllocation always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedExperimentalUnitAllocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
varianceTypeCode <i>Class:</i> PerformedAdministrativeActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of variance.</p> <p>EXAMPLE(S): early / late occurrence of an act, higher / lower amount transferred</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PerformedAdministrativeActivity.varianceTypeCode Map:LSDAMv2.2.3Plus = PerformedAdministrativeActivity.varianceTypeCode Map:SDTM IGv3.1.1 = (New content - variance type needed for RIM mapping)
varianceReasonCode <i>Class:</i> PerformedAdministrativeActivity <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying why what occurred is different from what was expected.</p> <p>EXAMPLE(S): Subject received early treatment because of vacation plans.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = StudyParticipantAssignment.eligibility WaiverReasonText Map:CTRv1.0 = PerformedAdministrativeActivity.varianceReason Map:LSDAMv2.2.3Plus = PerformedAdministrativeActivity.varianceReason Map:SDTM IGv3.1.1 = DS.DSTERM

Class: PerformedClinicalInterpretation

Package: Study Conduct Sub-Domain

DEFINITION:

An assessment which involves determining the meaning of one or more other observation results.

EXAMPLE(S):

The results of a white blood cell count may be interpreted as constituting a grade 2 toxicity.

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:CTRv1.0 = PerformedClinicalInterpretation
- Map:HCTv1.0 = CDE 2871889:Disease, Disorder or Finding.Was there a history of clinically significant fungal infection?

Connectors

Source	Connector	Target	Notes
PerformedClinicalInterpretation	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedClinicalInterpretation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedClinicalInterpretation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AdverseEventSeriousness	specializes	PerformedClinicalInterpretation	<p>DESCRIPTION: Each AdverseEventSeriousness always specializes one PerformedClinicalInterpretation. Each PerformedClinicalInterpretation might be specialized by one or more AdverseEventSeriousness.</p> <p>DEFINITION: Specifies the degree or extent of the consequence suffered by the subject.</p> <p>EXAMPLE(S): resulted in death, required hospitalization, was life threatening</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
			While often not reported as a separate observation, seriousness codes are technically the result of assessing the subject and the adverse event they are experiencing. The association to the AdverseEvent should theoretically be derivable via the following path: AdverseEventSeriousness > PerformedObservation [assess seriousness] > AssessedResultRelationship > AdverseEvent. However, since this information is often not available, AdverseEventSeriousness has been modeled as both a subclass of PerformedClinicalInterpretation and as having an association directly to the AdverseEvent class.

Attributes

Attribute	Notes	Constraints and Tags
toxicityTermCode <i>Class:</i> PerformedClinicalInterpretation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the degree to which a substance is able to damage an exposed organism.</p> <p>EXAMPLE(S): hypocalcaemia</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Similar to CTC Term (short name), e.g., the National Cancer Institute's Common Toxicity Criteria terminology.</p>	Map:CTRv1.0 = PerformedClinicalInterpretation.toxicityTermCode Map:SDTM IGv3.1.1 = LB.LBTOX Map:SDTM IGv3.1.2 = LB.LBTOX Map:SDTM IGv3.1.3 = LB.LBTOX

Attribute	Notes	Constraints and Tags
toxicityGradeCode <i>Class:</i> PerformedClinicalInterpretation <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the numeric grade for the toxicity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedClinicalInterpretation.value(ANY=>CD).code WHERE PerformedObservationResult > PerformedObservation > DefinedObservation > DefinedObservationResult.typeCode = "toxicity grade code"</p> <p>Similar to Common Toxicity Criteria Toxicity Grade</p>	Map:CTRv1.0 = PerformedClinicalInterpretation.toxicityGradeCode Map:SDTM IGv3.1.1 = LB.LBTOXGR Map:SDTM IGv3.1.2 = LB.LBTOXGR Map:SDTM IGv3.1.3 = LB.LBTOXGR
severityCode <i>Class:</i> PerformedClinicalInterpretation <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the intensity of the interpreted event.</p> <p>EXAMPLE(S): Moderate could be used to describe acne.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedClinicalInterpretation.value(ANY=>CD).code WHERE PerformedClinicalInterpretation > PerformedObservation > DefinedObservation.nameCode = "assess severity".</p>	Map:CTRv1.0 = PerformedClinicalInterpretation.severityCode Map:HCTv1.0 = CDE 2962140:Disease, Disorder or Finding.What was the sensitivity of the CNS tumor to chemotherapy? Map:SDTM IGv3.1.1 = PE.PESEV Map:SDTM IGv3.1.2 = CE.CESEV Map:SDTM IGv3.1.3 = CE.CESEV
abnormalIndicator <i>Class:</i> PerformedClinicalInterpretation <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether an interpreted event is abnormal.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedClinicalInterpretation.value(ANY=>CD).code WHERE PerformedObservationResult.typeCode = "assess abnormality".</p>	Map:CTOM = ClinicalResult.normalAbnormalIndicator Map:CTRv1.0 = PerformedClinicalInterpretation.abnormalIndicator Map:NCI CRF Standard = CDE 2841229v1.0: Test Result Reference Object Range Flag Indicator

Attribute	Notes	Constraints and Tags
clinicallySignificantIndicator <i>Class:</i> PerformedClinicalInterpretation <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether a subject's clinical condition is important based on judgment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from $\text{PerformedClinicalInterpretation.value(ANY=>BL)}$ WHERE $\text{PerformedClinicalInterpretation} > \text{PerformedObservation}$ > $\text{DefinedObservation.nameCode} = \text{"assess clinical significance"}$.</p>	Map:CDASHv1.1 = EG.EGCLSIG Map:CDASHv1.1 = PE.PECLSIG Map:CDASHv1.1 = LB.LBCLSIG Map:CDASHv1.1 = VS.VSCLSIG Map:CTOM = ClinicalResult.significanceIndicator Map:CTRv1.0 = PerformedClinicalInterpretation.clinicallySignificantIndicator Map:SDTM IGv3.1.2 = LB.SUPPLB.QNAM=LBCLSIG Map:SDTM IGv3.1.2 = EG.SUPPEG.QNAM=EGCLSIG Map:SDTM IGv3.1.2 = PE.SUPPPE.QNAM=PECLSIG Map:SDTM IGv3.1.2 = VS.SUPPPVS.QNAM=VSCLSIG

Class: PerformedClinicalResult

Package: Study Conduct Sub-Domain

DEFINITION:

A result of a clinical observation, i.e. from an examination, test or direct observation performed on the experimental unit.

EXAMPLE(S):

The performed observation of "WBC count" would be associated to a clinical result called "WBC result" in which the results of the observation (7500 WBCs) would be stored.

OTHER NAME(S):

NOTE(S):

There is an association between the observation that has the original data (and the original units) and the observation in which the data elements have been converted into standardized units.

If further use case are discovered it may be necessary to move the recursive relationship up to PerformedObservationResult.

Tagged Values:

- Map:caAERSv2.2 = LabValue
- Map:CTRv1.0 = PerformedClinicalResult
- Map:LabViewer2.2 = LaboratoryResult
- Map:LSDAMv2.2.3Plus = PerformedClinicalResult

Connectors

Source	Connector	Target	Notes
PerformedClinicalResult 0..1 originalPerformedClinicalResult	be converted into	PerformedClinicalResult 0..* convertedPerformedClinicalResult	<p>DESCRIPTION: Each [original] PerformedClinicalResult might be converted into one or more [converted] PerformedClinicalResult. Each [converted] PerformedClinicalResult might be converted from one [original] PerformedClinicalResult.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedClinicalResult 0..* referencingPerformedClinic alResult	reference	ReferenceResult 0..* referencedReferenceResult	DESCRIPTION: Each PerformedClinicalResult might reference one or more ReferenceResult. Each ReferenceResult might be referenced by one or more PerformedClinicalResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedClinicalResult	specializes	PerformedObservationResul t	DESCRIPTION: Each PerformedClinicalResult always specializes one PerformedObservationResul t. Each PerformedObservationResul t might be specialized by one PerformedClinicalResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedClinicalResult 0..1 originalPerformedClinicalR esult	be converted into	PerformedClinicalResult 0..* convertedPerformedClinical Result	DESCRIPTION: Each [original] PerformedClinicalResult might be converted into one or more [converted] PerformedClinicalResult. Each [converted] PerformedClinicalResult might be converted from one [original] PerformedClinicalResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Source	Connector	Target	Notes

Attributes

Attribute	Notes	Constraints and Tags
normalRangeComparison Code <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the relationship of a value to a normal range or reference range of values.</p> <p>EXAMPLE(S): high, low, within normal range, outside normal range</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing PerformedObservationResult.value to the ReferenceResult.value.</p>	Map:CDASHv1.1 = LB.LBNRIND Map:CTRv1.0 = PerformedClinicalResult.normalRangeComparisonCode Map:LSDAMv2.2.3Plus = PerformedClinicalResult.normalRangeComparisonCode Map:SDTM IGv3.1.1 = LB.LBNRIND Map:SDTM IGv3.1.1 = EG.EGNRIND Map:SDTM IGv3.1.1 = VS.VSNRIND Map:SDTM IGv3.1.2 = LB.LBNRIND Map:SDTM IGv3.1.3 = LB.LBNRIND
infectiousAgent <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> ST <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The name of the specific microbe that the test is intended to identify.</p> <p>EXAMPLE(S): streptococcus pneumoniae, staphylococcus aureus</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedObservation directly or indirectly linked to DefinedActivity.nameCode(CD).originaltext.</p>	Map:caAERSv2.2 = Lab.infectiousAgent Map:CTRv1.0 = PerformedClinicalResult.infectiousAgent Map:LSDAMv2.2.3Plus = PerformedClinicalResult.infectiousAgent

Attribute	Notes	Constraints and Tags
targetBiomarkerCode <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying a variation in cellular or biochemical components or processes, structures, or functions that is objectively measurable in a biological system and that characterizes normal biologic processes, pathogenic processes, an organism's state of health or disease, likelihood of developing a disease, prognosis, or response to a particular therapeutic intervention. This is the focus of an observation.</p> <p>EXAMPLE(S): Biomarkers include but are not limited to such phenotypic parameters as specific enzyme or hormone concentration, specific gene phenotype, presence or absence of biological substance.</p> <p>For an observation with a nameCode of "Determine the Allele for the HLA-A Locus on Chromosome 6", the observation result might have a targetBiomarkerCode of "HLA-A" and a value of "HLA-A*01:01:01" (the specific allele)</p> <p>For an observation with a nameCode of "Determine the variant nucleotide for Single Nucleotide Polymorphism RS110789", the observation result might have a targetBiomarkerCode of "Rs110789" and a value of "C" (cytosine, the specific nucleotide that is variant)</p> <p>OTHER NAME(S): Genetic Marker</p> <p>NOTE(S): There is no associated 'approach' for a Biomarker, as there is for an anatomic site. In the context of Bone Marrow Transplantation, the bodily substance that is collected to determine the Biomarker (the HLA Alleles) is typically blood or saliva. Thus, the thing that is collected is the typeCode of the Material that is collected via a PerformedSpecimenCollection.</p> <p>The attribute 'targetBiomarkerCode' was chosen as inclusive of 'targetGeneticMarkerCode', which is more specific to the Bone Marrow Transplantation domain. However, the Life Sciences Domain Analysis Model is using Biomarker as the focus of their Genomic Analysis, and thus this broader definition was chosen to facilitate that alignment.</p>	Map:HCTv1.0 = CDE 2695256:Lab Results.1st A antigen specificity:

Attribute	Notes	Constraints and Tags
biomarkerIndicator <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether a result is considered a biomarker.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is based on a result as stated in the NCI Thesaurus for Biomarker: A variation in cellular or biochemical components or processes, structures, or functions that is objectively measurable in a biological system and that characterizes normal biologic processes, pathogenic processes, an organism's state of health or disease, likelihood of developing a disease, prognosis, or response to a particular therapeutic intervention. Biomarkers include but not limited to such phenotypic parameters as specific enzyme or hormone concentration, specific gene phenotype, presence or absence of biological substances.</p>	Map:CTOM = ClinicalResult.biomarkerIndicator Map:CTRv1.0 = PerformedClinicalResult.biomarkerIndicator Map:LSDAMv2.2.3Plus = PerformedClinicalResult.biomarkerIndicator
asCollectedIndicator <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the observation is represented in the units or values as originally collected.</p> <p>EXAMPLE(S): A performing lab may have completed the observation or lab test using conventional units, but the sponsor may wish to have the test reported in SI units. This flag will be set to "true" on the lab test that has the original units, and "false" on the lab test in which the units that are different than the lab test's original units.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PerformedClinicalResult.asCollectedIndicator Map:LSDAMv2.2.3Plus = PerformedClinicalResult.asCollectedIndicator Map:SDTM IGv3.1.1 = LB.LBORRES

Attribute	Notes	Constraints and Tags
statusCode <i>Class:</i> PerformedClinicalResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the reported result.</p> <p>EXAMPLE(S): preliminary, final, corrected</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PerformedClinicalResult.statusCode Map:HCTv1.0 = CDE 2952889:Lab Results.What was the status of the serum free light chains (kappa) finding? Map:HCTv1.0 = CDE 2866061:Lab Results.What was the status of the cerebrospinal fluid total protein finding? Map:HCTv1.0 = CDE 2970731:Lab Results.What was the status of the TRK expression finding? Map:HCTv1.0 = CDE 2986015:Lab Results.What was the low stroma histology type? Map:HCTv1.0 = CDE 2861065:Lab Results.What was the status of the serum albumin finding? Map:HCTv1.0 = CDE 2861054:Lab Results.What was the status of the serum beta 2 microglobulin finding? Map:HCTv1.0 = CDE 2970736:Lab Results.What was the status of the expression of proto-oncogenes finding? Map:HCTv1.0 = CDE 2934447:Lab Results.What was the status of the blasts in bone marrow finding? Map:HCTv1.0 = CDE 2861133:Lab Results.What was the status of the plasma cells in bone marrow from an unknown source finding? Map:HCTv1.0 = CDE 2863877:Lab Results.What was the status of the serum ferritin finding? Map:HCTv1.0 = CDE 2957563:Lab Results.HER2 IHC Status Map:HCTv1.0 = CDE 2952919:Lab Results.What was the status of the serum free light chains lambda finding? Map:HCTv1.0 = CDE 2863186:Lab Results.What was the status of the hematocrit finding? Map:HCTv1.0 = CDE 2953864:Lab Results.What was the status of the lactate dehydrogenase finding? Map:HCTv1.0 = CDE 2940075:Lab Results.What was the status of the neutrophil finding? Map:HCTv1.0 = CDE 3061547:Lab Results.What was the status of the serum alpha-fetoprotein finding? Map:HCTv1.0 = CDE 2952875:Lab Results.What was the status of the urinary monoclonal light chain finding? Map:HCTv1.0 = CDE 2963402:Lab Results.What was the status of the lymphocytes present in bone marrow

Attribute	Notes	Constraints and Tags
		<p>finding?</p> <p>Map:HCTv1.0 = CDE 2963488:Lab Results.What was the status of the prolymphocytes finding?</p> <p>Map:HCTv1.0 = CDE 2970537:Lab Results.What was the status of the N-myc amplification finding?</p> <p>Map:HCTv1.0 = CDE 2860929:Lab Results.What was the status of the blood blast count finding?</p> <p>Map:HCTv1.0 = CDE 2860841:Lab Results.What was the status of the platelet finding?</p> <p>Map:HCTv1.0 = CDE 2982913:Lab Results.What was the status of the uncorrected reticulocyte finding?</p> <p>Map:HCTv1.0 = CDE 3019776:Lab Results.What was the status of the modal chromosome number finding?</p> <p>Map:HCTv1.0 = CDE 2884436:Lab Results.What was the status of the lymphocytes finding?</p> <p>Map:HCTv1.0 = CDE 2954073:Lab Results.What was the status of the serum immunologic finding?</p> <p>Map:HCTv1.0 = CDE 2895879:Lab Results.What was the status of the eosinophil finding?</p> <p>Map:HCTv1.0 = CDE 3061552:Lab Results.What was the status of the serum beta-human chorionic gonadotropin finding?</p> <p>Map:HCTv1.0 = CDE 2969525:Lab Results.What was the status of the vanillyl mandelic acid finding?</p> <p>Map:HCTv1.0 = CDE 2967117:Lab Results.What was the status of the homovanillic acid finding?</p> <p>Map:HCTv1.0 = CDE 2953017:Lab Results.What was the status of the serum monoclonal M protein finding?</p> <p>Map:HCTv1.0 = CDE 2974094:Lab Results.What was the status of the gamma-enolase finding?</p> <p>Map:HCTv1.0 = CDE 2897741:Lab Results.What was the status of the basophil finding?</p> <p>Map:Lab = LabResult.reportedResultStatus</p> <p>Map:LabViewer2.2 = LaboratoryResult.reportedResultStatus</p> <p>Map:LSDAMv2.2.3Plus = PerformedClinicalResult.reportedResultStatusCode</p>

Class: PerformedCompositionRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

A relationship between a composite activity and a component activity that comprises it, i.e. parent and child activities where all activities have occurred in the context of a particular study or experiment.

EXAMPLE(S):

An unplanned substance administration occurs as part of a planned encounter.

A planned substance administration occurs as part of an encounter that is different than the one in which it was originally planned.

An unplanned encounter contains a number of activities.

OTHER NAME(S):

NOTE(S):

Particularly relevant when one or both of the activities are not planned as the composition relationship can't be established using the normal PlannedCompositionRelationship or DefinedCompositionRelationship.

Tagged Values:

- Map:AIM v4 rv48 = ImageAnnotation.imageAnnotationCollection(ImageAnnotationCollection)
- Map:CTRv1.0 = PerformedActivity.contained(PerformedActivity)

Connectors

Source	Connector	Target	Notes
PerformedCompositionRelationship 0..* componentPerformedCompositionRelationship	is the component of	PerformedActivity 1 compositePerformedActivity	<p>DESCRIPTION: Each PerformedCompositionRelationship always is the component of one PerformedActivity. Each PerformedActivity might be the parent of one or more PerformedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedCompositionRelationship 0..1 compositePerformedCompositionRelationship	is the parent of	PerformedActivity 1 componentPerformedActivity	<p>DESCRIPTION: Each PerformedCompositionRelationship always is the parent of one PerformedActivity. Each PerformedActivity might be the component of one PerformedCompositionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedDiagnosis

Package: Study Conduct Sub-Domain

DEFINITION:

The identification of a disease or illness by examining the signs and symptoms.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = DiseaseHistory
- Map:caAERSv2.2 = StudyParticipantDiseaseHistory
- Map:caAERSv2.2 = DiseaseHistory
- Map:CTRv1.0 = PerformedDiagnosis
- Map:HCTv1.0 = CDE 2962088:Involvement and Extent of Disease.Specify other co-existing phakomatosis:
- Map:LSDAMv2.2.3Plus = PerformedDiagnosis

Connectors

Source	Connector	Target	Notes
PerformedDiagnosis	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedDiagnosis always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedDiagnosis 0..* convertedPerformedDiagnos is	be converted from	PerformedDiagnosis 0..1 originalPerformedDiagnosis	<p>DESCRIPTION: Each [converted] PerformedDiagnosis might be converted from one [original] PerformedDiagnosis. Each [original] PerformedDiagnosis might be converted into one or more [converted] PerformedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PerformedDiagnosis 0..1 transformingPerformedDiagnosis	be transformed into	PerformedDiagnosis 0..1 transformedPerformedDiagnosis	<p>DESCRIPTION: Each PerformedDiagnosis might be transformed into one PerformedDiagnosis. Each PerformedDiagnosis might be transformed from one PerformedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedDiagnosisProcedureRelationship 0..* addressingPerformedDiagnosisProcedureRelationship	addresses	PerformedDiagnosis 1 addressedPerformedDiagnosis	<p>DESCRIPTION: Each PerformedDiagnosisProcedureRelationship always addresses one PerformedDiagnosis. Each PerformedDiagnosis might be addressed by one or more PerformedDiagnosisProcedureRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedDiagnosis 0..* convertedPerformedDiagnoses	be converted from	PerformedDiagnosis 0..1 originalPerformedDiagnosis	<p>DESCRIPTION: Each [converted] PerformedDiagnosis might be converted from one [original] PerformedDiagnosis. Each [original] PerformedDiagnosis might be converted into one or more [converted] PerformedDiagnosis.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedDiagnosis 0..1 transformingPerformedDiagnosis	be transformed into	PerformedDiagnosis 0..1 transformedPerformedDiagnosis	<p>DESCRIPTION: Each PerformedDiagnosis might be transformed into one PerformedDiagnosis. Each PerformedDiagnosis might be transformed from one PerformedDiagnosis.</p>

Source	Connector	Target	Notes
			one PerformedDiagnosis. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
diseaseStatusCode <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the amount of disease present in a subject.</p> <p>EXAMPLE(S): metastatic and disease-free (cancer-specific examples)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = Diagnosis.diseaseStatusCode Map:CTRv1.0 = PerformedDiagnosis.diseaseStatusCode Map:HCTv1.0 = CDE 2980437:Disease Response.What was testicular neoplasm the best response type? Map:HCTv1.0 = CDE 2971700:Disease Response.Specify the disease status: Map:HCTv1.0 = CDE 3073181:Disease Response.What is the status of Acute Lymphoblastic Leukemia ? Map:HCTv1.0 = CDE 3008778:Disease Response.Specify the best response of autonomic neuropathy: Map:HCTv1.0 = CDE 2688824:Disease Response.At the time of transplantation, what was the status of the JMML? Map:HCTv1.0 = CDE 2688964:Disease Response.What was the status of the other malignancy at the time of transplantation? Map:HCTv1.0 = CDE 3124457:Disease Response.Specify the disease status: Map:HCTv1.0 = CDE 2685079:Disease Response.What was the status of the hodgkin lymphoma at the time of transplantation? Map:HCTv1.0 = CDE 3045387:Disease Response.What was the best non-bone response? Map:HCTv1.0 = CDE 3009333:Disease, Disorder or Finding.Specify the status of this system: Map:HCTv1.0 = CDE 58250//:Therapy Results.Did the patient achieve a complete response according to clinical/ hematologic criteria Map:HCTv1.0 = CDE 2970628:Involvement and Extent of Disease.What was the breast carcinoma status? Map:HCTv1.0 = CDE 3045394:Disease Response.What was the best bone response? Map:HCTv1.0 = CDE 2677716:Involvement and Extent of Disease.Main cause of death: Other,specify Map:HCTv1.0 = CDE 2680980:Outcome of Therapy.Maximum grade of Acute

Attribute	Notes	Constraints and Tags
		<p>Graft Versus Host Disease after this DCI?</p> <p>Map:HCTv1.0 = CDE</p> <p>3009221:Disease Response.Specify the best renal response:</p> <p>Map:HCTv1.0 = CDE</p> <p>2936606:Disease, Disorder or Finding.What is the disease status?</p> <p>Map:HCTv1.0 = CDE</p> <p>3072091:Disease Response.What is the disease status of AML prior to the prep regimen?</p> <p>Map:HCTv1.0 = CDE</p> <p>2947820:Disease, Disorder or Finding.What was the plasma cell disorder disease status?</p> <p>Map:HCTv1.0 = CDE</p> <p>2685098:Disease Response.What was the status of the other acute leukemia at the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>3008113:Disease Response.Specify the best cardiac response:</p> <p>Map:HCTv1.0 = CDE</p> <p>2675153:Chronic Myelogenous Leukemia (CML): Part 1 of 2.If the CML was in hematologic complete remission, what was the disease status before treatment?</p> <p>Map:HCTv1.0 = CDE</p> <p>2003853:Quality of Life.Performance Status (Karnofsky)</p> <p>Map:HCTv1.0 = CDE</p> <p>2962154:Disease, Disorder or Finding.What was the CNS disease status?</p> <p>Map:HCTv1.0 = CDE</p> <p>2965947:Disease, Disorder or Finding.What is the status of the original disease?</p> <p>Map:HCTv1.0 = CDE</p> <p>2685083:Disease Response.What was the status of the non-hodgkin's lymphoma at the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>3009297:Disease Response.Specify other system best response:</p> <p>Map:HCTv1.0 = CDE</p> <p>3008833:Disease Response.Specify the best response of peripheral neuropathy:</p> <p>Map:HCTv1.0 = CDE</p> <p>3130146:Disease Response.What was the chronic lymphocytic leukemia status?</p> <p>Map:HCTv1.0 = CDE</p> <p>2688889:Disease Response.What was the status of the other leukemia at the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p>

Attribute	Notes	Constraints and Tags
		<p>2950554:Disease Response.What was the best response to HSCT? Map:HCTv1.0 = CDE</p> <p>3008793:Disease, Disorder or Finding.Specify the status of autonomic neuropathy: Map:HCTv1.0 = CDE</p> <p>2970355:Disease Response.What was breast cancer best response? Map:HCTv1.0 = CDE</p> <p>2939779:Disease, Disorder or Finding.What was the status of the myelofibrosis? Map:HCTv1.0 = CDE</p> <p>2686057:Myelodysplastic or Myeloproliferative Disease Classification at Diagnosis.If the MDS/MPS/CMMML was treated with chemotherapy, what was the disease status at the time of transplantation? Map:HCTv1.0 = CDE</p> <p>2954551:Disease Response.What was the best response of the CNS neoplasm? Map:HCTv1.0 = CDE</p> <p>2677309:Involvement and Extent of Disease.Specify other main cause of death: Map:HCTv1.0 = CDE</p> <p>2936640:Disease Response.What was the best response of myelodysplastic/myeloproliferative disease to HSCT? Map:HCTv1.0 = CDE</p> <p>3029363:Disease Response.What is the Chronic Lymphocytic Leukemia best response type? Map:HCTv1.0 = CDE</p> <p>2685094:Disease Response.What was the status of the acute lymphoblastic leukemia (ALL) at the time of transplantation? Map:HCTv1.0 = CDE</p> <p>3008835:Disease, Disorder or Finding.Specify the status of peripheral neuropathy: Map:HCTv1.0 = CDE</p> <p>2984453:Disease Response.What was the testicular germ cell cancer best response? Map:HCTv1.0 = CDE</p> <p>2750703:Disease Response.Best response to line of therapy: Map:HCTv1.0 = CDE</p> <p>3008178:Disease Response.Specify the best hepatic response: Map:HCTv1.0 = CDE</p> <p>2685090:Disease Response.What was the status of the acute myelogenous leukemia (AML) or acute nonlymphocytic leukemia (ANLL) at</p>

Attribute	Notes	Constraints and Tags
		<p>the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>2950694:Disease Response.What was the best response of the lymphoma to HSCT ?</p> <p>Map:HCTv1.0 = CDE</p> <p>2180158:Quality of Life.Performance Status (Lansky)</p> <p>Map:HCTv1.0 = CDE</p> <p>2957272:Disease, Disorder or Finding.What was the status of lymphoma?</p> <p>Map:HCTv1.0 = CDE</p> <p>2674599:Disease Response.What was the status of MDS/MPS/CMMI at transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>3124484:Disease Response.What was the status of myelodysplastic/myeloproliferative disease?</p> <p>Map:HCTv1.0 = CDE</p> <p>2939802:Disease, Disorder or Finding.What was the status of the chronic myelogenous leukemia?</p> <p>Map:HCTv1.0 = CDE</p> <p>3076261:Disease Response.What was the disease status?</p> <p>Map:HCTv1.0 = CDE</p> <p>2688951:Disease Response.What was the status of the breast cancer at the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>2691339:Disease Response.What was the plasma cell disorder status at transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>2939328:Disease Response.Specify cytogenetic remission:</p> <p>Map:HCTv1.0 = CDE</p> <p>2676471:Chronic Myelogenous Leukemia (CML): Part 1 of 2.What was the phase of the CML at the time of transplantation?</p> <p>Map:HCTv1.0 = CDE</p> <p>2770757:Disease Response.What was the recipient's disease status?</p> <p>Map:HCTv1.0 = CDE</p> <p>2986871:Disease, Disorder or Finding.What was the disease status?_</p> <p>Map:HCTv1.0 = CDE</p> <p>3057354:Disease, Disorder or Finding.Specify current neurologic status:</p> <p>Map:HCTv1.0 = CDE</p> <p>2770281:Disease Response.What is the status of the original disease?</p> <p>Map:HCTv1.0 = CDE</p> <p>3009205:Disease Response.Specify the best hematologic response:</p> <p>Map:LSDAMv2.2.3Plus =</p>

Attribute	Notes	Constraints and Tags
		PerformedDiagnosis.diseaseStatusCode Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.lymphNodeStage Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.distantMetastasisStage Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - AJCC EDITION NUMBER Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS METS AT DX-BONE Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - CLINICAL T Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS METS AT DX Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS METS AT DX-LIVER Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS LYMPH NODES Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS EXTENSION Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS METS AT DX-BRAIN Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - PATHOLOGIC STAGE GROUP Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - PATHOLOGIC M Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - PATHOLOGIC N Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - PATHOLOGIC T Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - CLINICAL STAGE GROUP Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - CLINICAL N Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA

Attribute	Notes	Constraints and Tags
		COLLECTION SYSTEM - CS METS AT DX-CS METS AT DX-LUNG Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - CLINICAL M
diseaseStatusMissingReasonCode <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying why a disease status is missing.</p> <p>EXAMPLE(S): "the sample was damaged" is a reason code within the "unevaluable" classification.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The distinctions between unevaluable, missing reason and not assessed, will be made in the hierarchy of the reason codes and need not be made as distinct attributes, since they are mutually exclusive.</p> <p>This value should only be populated if PerformedDiagnosis.diseaseStatusCode is null.</p>	Map:HCTv1.0 = CDE 2974029:Disease Response.Specify reason disease status was unevaluable: Map:HCTv1.0 = CDE 2740336:Occurrences.If necessary, please validate the clinical and or hematologic CR date response:
clinicalStageDescriptorCode <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the prefix or suffix, used in conjunction with AJCC clinical TNM designations, that denotes special circumstances that may affect the staging and analysis of the data and is based on the clinical T, N, and M values prior to treatment.</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 0 = None 1 = E (Extranodal, lymphomas only) 2 = S (Spleen, lymphomas only) 3 = M (Multiple primary tumors in a single site) 5 = E & S (Extranodal and spleen, lymphomas only) 9 = Unknown, not stated in patient record</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The descriptors are adjuncts to and do not change the stage group (which is captured in diseaseStatusCode).</p>	Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - CLINICAL STAGE (PREFIX/SUFFIX) DESCRIPTOR

Attribute	Notes	Constraints and Tags
pathologicStageDescriptor Code <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the prefix or suffix, used in conjunction with AJCC clinical TNM designations, that denotes special circumstances that may affect the staging and analysis of the data and is based on the pathologic T, N, and M values after completion of surgical treatment.</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 0 = None 1 = E (Extranodal, lymphomas only) 2 = S (Spleen, lymphomas only) 3 = M (Multiple primary tumors in a single site) 4 = Y (Classification during or after initial multimodality therapy)—pathologic staging only 5 = E & S (Extranodal and spleen, lymphomas only) 6 = M & Y (Multiple primary tumors and initial multimodality therapy) 9 = Unknown, not stated in patient record</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The descriptors are adjuncts to and do not change the stage group.</p>	Map:SEER 2015 = SECTION V STAGE OF DISEASE AT DIAGNOSIS - PATHOLOGIC STAGE (PREFIX/SUFFIX) DESCRIPTOR
bodySystemCode <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomical structure that consists of organs and organ subclasses responsible for certain body functions.</p> <p>EXAMPLE(S): gastrointestinal system, urinary system, hematopoietic system</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE 3082348:Involvement and Extent of Disease.What was the site of extranodal involvement? Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - PRIMARY SITE
recurrenceIndicator <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether this is a reappearance of the existing disease.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = Diagnosis.recurrenceIndicator Map:CTRv1.0 = PerformedDiagnosis.recurrenceIndicator Map:LSDAMv2.2.3Plus = PerformedDiagnosis.recurrenceIndicator

Attribute	Notes	Constraints and Tags
acceptedIndicator <i>Class:</i> PerformedDiagnosis <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether, when more than one independent assessor provides an evaluation, this disease assessment is considered the accepted one among the several assessments provided .</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is theoretically derived from an assessment activity that looks at all evaluations and identifies the accepted one.</p>	Map:SDTM IGv3.1.3 = RS.RSACPTFL

Class: PerformedDiagnosisProcedureRelationship

Package: Study Conduct Sub-Domain

DEFINITION:
Specifies the link between a diagnosis and the procedure performed to address it.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:HCTv1.0 = CDE 2974177:Diagnosis.What was the primary CNS disease for which the HSCT was performed?

Connectors

Source	Connector	Target	Notes
PerformedDiagnosisProcedureRelationship 0..* addressingPerformedDiagnosisProcedureRelationship	addresses	PerformedDiagnosis 1 addressedPerformedDiagnos is	<p>DESCRIPTION: Each PerformedDiagnosisProcedureRelationship always addresses one PerformedDiagnosis. Each PerformedDiagnosis might be addressed by one or more PerformedDiagnosisProcedureRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedDiagnosisProcedureRelationship 0..* addressedPerformedDiagnosisProcedureRelationship	is addressed by	PerformedProcedure 1 addressingPerformedProced ure	<p>DESCRIPTION: Each PerformedDiagnosisProcedureRelationship always is addressed by one</p>

Source	Connector	Target	Notes
			<p>PerformedProcedure. Each PerformedProcedure might address one or more PerformedDiagnosisProcedureRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> PerformedDiagnosisProcedureRelationship <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether this is the main or principal diagnosis addressed by a procedure.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:HCTv1.0 = CDE 2974177:Diagnosis.What was the primary CNS disease for which the HSCT was performed?</p>

Class: PerformedEligibilityCriterion

Package: Study Conduct Sub-Domain

DEFINITION:

One of a set of conditions that a study subject must meet in order to participate in a study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedEligibilityCriterion
- Map:SDTM IGv3.1.2 = IE.DOMAIN
- Map:SDTM IGv3.1.3 = IE

Connectors

Source	Connector	Target	Notes
PerformedEligibilityCriterion	specializes	PerformedObservation	<p>DESCRIPTION: Each PerformedEligibilityCriterion always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedEligibilityCriterion.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedExclusionCriterion	specializes	PerformedEligibilityCriterion	DESCRIPTION: Each PerformedExclusionCriterion always specializes one PerformedEligibilityCriterion. Each PerformedEligibilityCriterion might be specialized by one PerformedExclusionCriterion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedInclusionCriterion	specializes	PerformedEligibilityCriterion	DESCRIPTION: Each PerformedInclusionCriterion always specializes one PerformedEligibilityCriterion. Each PerformedEligibilityCriterion might be specialized by one PerformedInclusionCriterion. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
notApplicableIndicator <i>Class:</i> PerformedEligibilityCriterion <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the specific eligibility criterion is not applicable to this participant.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = EligibilityCriterion.notApplicableIndicator Map:CTRv1.0 = PerformedEligibilityCriterion.notApplicableIndicator

Class: PerformedExclusionCriterion

Package: Study Conduct Sub-Domain

DEFINITION:

A characteristic or requirement that disqualifies a subject from participation in a study.

EXAMPLE(S):

pregnancy

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = ExclusionEligibilityCriterion
- Map:CTRv1.0 = PerformedExclusionCriterion

Connectors

Source	Connector	Target	Notes
PerformedExclusionCriterion	specializes	PerformedEligibilityCriterion	<p>DESCRIPTION: Each PerformedExclusionCriterion always specializes one PerformedEligibilityCriterion. Each PerformedEligibilityCriterion might be specialized by one PerformedExclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedExperimentalUnitAllocation

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action 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).

EXAMPLE(S):

Mrs. Smith is assigned to Arm A.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:NCI CRF Standard = CDE 2454528v1.0: Protocol Arm Assignment Text

Connectors

Source	Connector	Target	Notes
PerformedExperimentalUnitAllocation 0..* assigningPerformedExperimentalUnitAllocation	assign an experimental unit to	Arm 0..1 assignedArm	<p>DESCRIPTION: Each PerformedExperimentalUnitAllocation might assign an experimental unit to one Arm. Each Arm might be assigned an experimental unit by one or more PerformedExperimentalUnitAllocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedExperimentalUnitAllocation	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedExperimentalUnitAllocation always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedExperimentalUnitAllocation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedHistopathologyResult

Package: Study Conduct Sub-Domain

DEFINITION:

The findings from a microscopic study of characteristic tissue abnormalities by employing various cytochemical and immunocytochemical stains.

EXAMPLE(S):

HER-2 positive primary breast cancer, adenocarcinoma of the colon

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedHistopathology
- Map:LSDAMv2.2.3Plus = PerformedHistopathology

Connectors

Source	Connector	Target	Notes
PerformedHistopathologyResult	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedHistopathology always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedHistopathology.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
differentiationGradeCode <i>Class:</i> PerformedHistopathologyResult <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the degree of cellular differentiation in a tissue sample.</p> <p>EXAMPLE(S): A brain tumor could be grade 3</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = HistopathologyGrade.gradeCodeSystem Map:CTOM = HistopathologyGrade.gradeCode Map:CTRv1.0 = PerformedHistopathology.differentiationGradeCode Map:LSDAMv2.2.3Plus = PerformedHistopathology.differentiationGradeCode Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - GRADE, DIFFERENTIATION OR CELL INDICATOR
involvedSurgicalMarginIndicator <i>Class:</i> PerformedHistopathologyResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the margins of surgical resection are infiltrated by the abnormal tissue.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = Histopathology.involvedSurgicalMarginIndicator Map:CTRv1.0 = PerformedHistopathology.involvedSurgicalMarginIndicator Map:LSDAMv2.2.3Plus = PerformedHistopathology.involvedSurgicalMarginIndicator

Class: PerformedInclusionCriterion

Package: Study Conduct Sub-Domain

DEFINITION:
A characteristic or requirement that a subject must meet to participate in a study.

EXAMPLE(S):
Must be over the age of 18

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = InclusionEligibilityCriterion
- Map:CTRv1.0 = PerformedInclusionCriterion

Connectors

Source	Connector	Target	Notes
PerformedInclusionCriterion	specializes	PerformedEligibilityCriterion	<p>DESCRIPTION: Each PerformedInclusionCriterion always specializes one PerformedEligibilityCriterion. Each PerformedEligibilityCriterion might be specialized by one PerformedInclusionCriterion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: PerformedLesionDescription

Package: Study Conduct Sub-Domain

DEFINITION:

A characterization of the extent of any localized or abnormal change in the structure of part of an organ or tissue.

EXAMPLE(S):

Typically provided as a set of two measurements (two longest perpendicular measurements) and/or volume measurement.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedLesionDescription
- Map:LSDAMv2.2.3Plus = PerformedLesionDescription

Connectors

Source	Connector	Target	Notes
PerformedLesionDescription	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedLesionDescription always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by</p>

Source	Connector	Target	Notes
			<p>one PerformedLesionDescription.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedLesionDescription 0..* convertedPerformedLesionDescription	be converted from	PerformedLesionDescription 0..1 originalPerformedLesionDescription	<p>DESCRIPTION: Each [converted] PerformedLesionDescription might be converted from one [original] PerformedLesionDescription. Each [original] PerformedLesionDescription might be converted into one or more [converted] PerformedLesionDescription.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedLesionDescription 0..* convertedPerformedLesionDescription	be converted from	PerformedLesionDescription 0..1 originalPerformedLesionDescription	<p>DESCRIPTION: Each [converted] PerformedLesionDescription might be converted from one [original] PerformedLesionDescription. Each [original] PerformedLesionDescription might be converted into one or more [converted] PerformedLesionDescription.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
lesionNumber <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The integer assigned to a lesion for a subject.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Once a lesion number is designated for a specific lesion that number may not change or re-used to denote a different lesion.</p>	Map:CTOM = LesionDescription.evaluationNumber Map:CTOM = LesionDescription.lesionNumber Map:CTRv1.0 = PerformedLesionDescription.lesionNumber Map:LSDAMv2.2.3Plus = PerformedLesionDescription.lesionNumber Map:SDTM IGv3.1.3 = TU.TULNKID Map:SDTM IGv3.1.3 = TR.TRLNKID Map:SDTM IGv3.1.3 = RS.RSLNKID
lesionIdentifierText <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A human-readable text label used for tracking a finding or feature, potentially across multiple observations, over time, where this label is unique among other findings or features for the same subject. [Adapted from DICOM Tracking ID (0062,0020)]</p> <p>EXAMPLE(S): T01, NT02, T04.2, T02/T03, NEW01 [Adopted from CDISC SDTM's TU.TULNKID examples]</p> <p>OTHER NAME(S): Lesion Number Tracking Identifier Link ID (TU.TULNKID)</p> <p>NOTE(S): Once a lesion identifier text is designated for a specific lesion that identifier text may not change or be re-used to denote a different lesion for the same subject. Note there is no expectation that lesion identifier texts are unique across all subjects.</p>	Map:AIM v4 rv48 = AnnotationEntity.name Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Tracking Identifier Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Tracking Identifier Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > Tracking Identifier
appearanceTypeCode <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the appearance of a superficial lesion.</p> <p>EXAMPLE(S): flat, nodular</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = LesionDescription.appearanceTypeCode Map:CTRv1.0 = PerformedLesionDescription.appearanceTypeCode Map:LSDAMv2.2.3Plus = PerformedLesionDescription.appearanceTypeCode

Attribute	Notes	Constraints and Tags
contactAnatomicSiteCode <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the anatomic site (single) in contact with the lesion. EXAMPLE(S): OTHER NAME(S): NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.	Map:CTOM = LesionDescription.contactAnatomicSiteCodeSystem Map:CTOM = LesionDescription.contactAnatomicSiteCode Map:CTRv1.0 = PerformedLesionDescription.contactAnatomicSiteCode Map:LSDAMv2.2.3Plus = PerformedLesionDescription.contactAnatomicSiteCode
measurableIndicator <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether a lesion or site of disease is measurable. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTOM = LesionDescription.measurableIndicator Map:CTRv1.0 = PerformedLesionDescription.measurableIndicator Map:HCTv1.0 = CDE 2978313:Tumor Measurements.Was the primary neoplasm size known? Map:LSDAMv2.2.3Plus = PerformedLesionDescription.measurableIndicator Map:SDTM IGv3.1.3 = TR.TRORRES
xDimension <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The measurement of a lesion or location in the 'X' (first or length) dimension. EXAMPLE(S): OTHER NAME(S): NOTE(S): This is the longest measurement or largest value if only one measurement is captured.	Map:CTOM = LesionDescription.xaDimension Map:CTRv1.0 = PerformedLesionDescription.xDimension Map:LSDAMv2.2.3Plus = PerformedLesionDescription.xDimension Map:SDTM IGv3.1.3 = TR.TRSTRESU Map:SDTM IGv3.1.3 = TR.TRSTRESN Map:SDTM IGv3.1.3 = TR.TRORRESU Map:SDTM IGv3.1.3 = TR.TRORRES Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS TUMOR SIZE

Attribute	Notes	Constraints and Tags
yDimension <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The measurement of a lesion in the 'Y' (second or width) dimension.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = LesionDescription.yaDimension Map:CTRv1.0 = PerformedLesionDescription.yDimension Map:LSDAMv2.2.3Plus = PerformedLesionDescription.yDimension Map:SDTM IGv3.1.3 = TR.TRSTRESU Map:SDTM IGv3.1.3 = TR.TRSTRESN Map:SDTM IGv3.1.3 = TR.TRORRESU Map:SDTM IGv3.1.3 = TR.TRORRES
zDimension <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The measurement of a lesion in the 'Z' (third) dimension.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = LesionDescription.zaDimension Map:CTRv1.0 = PerformedLesionDescription.zDimension Map:LSDAMv2.2.3Plus = PerformedLesionDescription.zDimension Map:SDTM IGv3.1.3 = TR.TRSTRESU Map:SDTM IGv3.1.3 = TR.TRSTRESN Map:SDTM IGv3.1.3 = TR.TRORRESU Map:SDTM IGv3.1.3 = TR.TRORRES
dimensionProduct <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The result or product of multiplying dimensions (2 or 3) of a site or specimen.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from multiplying at least two (2) of the following: PerformedLesionDescription.xDimension, PerformedLesionDescription.yDimension, PerformedLesionDescription.zDimension.</p>	Map:CTOM = LesionDescription.dimensionProduct Map:CTRv1.0 = PerformedLesionDescription.dimensionProduct Map:HCTv1.0 = CDE 3104035:Involvement and Extent of Disease.Specify the size of the largest lymph nodal mass: Map:HCTv1.0 = CDE 2978340:Tumor Measurements.What is the value of the primary neoplasm size specimen measurement? Map:HCTv1.0 = CDE 2963625:Surgical Margin Measurements.Size of residual tumor after surgery: Map:LSDAMv2.2.3Plus = PerformedLesionDescription.dimensionProduct

Attribute	Notes	Constraints and Tags
acceptedIndicator <i>Class:</i> PerformedLesionDescription <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether, when more than one independent assessor provides an evaluation, this lesion assessment is considered the accepted one among the several assessments provided .</p> <p>EXAMPLE(S): OTHER NAME(S):</p> <p>NOTE(S): This attribute is theoretically derived from an assessment activity that looks at all evaluations and identifies the accepted one.</p>	Map:SDTM IGv3.1.3 = TU.TUACPTFL Map:SDTM IGv3.1.3 = TR.TRACPTFL

Class: PerformedMaterialProcessStep

Package: Study Conduct Sub-Domain

DEFINITION:

The completed act of processing a material.

EXAMPLE(S):

freezing, thawing, spinning, embedding, dividing, aliquot, adding additives or growth factors

OTHER NAME(S):

product manipulation

NOTE(S):

Material process may be performed on any kind of material, such as a specimen, nanomaterial, or biologic. The result of the process may a similar or different kind of material, for instance a specimen may be the result of a specimen processing step (e.g., aliquot or division of a specimen), or alternatively a blood product has anticoagulants added to it to preserve the product. Other processing steps, such as adding growth factor to induce cell growth, may be performed on the blood product.

Note that PerformedMaterialProcessStep inherits two associations that perhaps should be mutually exclusive - 1) the association between a PerformedProcedure and a Product that it uses, and 2) the association between an Activity and an ExperimentalActivityItem that it uses.

Question for SMEs: Should this be made a constraint on this class, or even on a higher level superclass?

Tagged Values:

- Map:LSDAMv2.2.3Plus = PerformedSpecimenSpun
- Map:LSDAMv2.2.3Plus = PerformedSpecimenThaw
- Map:LSDAMv2.2.3Plus = PerformedSpecimenFixed
- Map:LSDAMv2.2.3Plus = PerformedSpecimenFrozen
- Map:LSDAMv2.2.3Plus = PerformedMaterialProcessStep
- Map:LSDAMv2.2.3Plus = PerformedSpecimenEmbedded
- Map:LSDAMv2.2.3Plus = PerformedSpecimenEmbedded.embeddingMediumType

Connectors

Source	Connector	Target	Notes
PerformedMaterialProcessStep	specializes	PerformedProcedure	<p>DESCRIPTION: Each PerformedMaterialProcessStep always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedMaterialProcessStep.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Material 0..* producedMaterial	have been produced by	PerformedMaterialProcessStep 0..1 producingPerformedMaterialProcessStep	<p>DESCRIPTION: Each Material might have been produced by one PerformedMaterialProcessStep. Each PerformedMaterialProcessStep might have produced one or more Material.</p> <p>DEFINITION: Indicates that material was produced by a process step.</p> <p>EXAMPLE(S): A blood product has anticoagulants added to it to preserve the product A blood product has growth factor added to it to induce cell growth</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
standardTimeIndicator <i>Class:</i> PerformedMaterialProcessStep <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether the time of the process step is specified using standard (as opposed to daylight savings) time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the location and date are known, this data is derivable.</p>	<p>Map:HCTv1.0 = CDE 2786645:Occurrences.Is the thawing begin time standard time or daylight savings time?</p> <p>Map:HCTv1.0 = CDE 2786665:Occurrences.Is the thawing end time standard time or daylight savings time?</p>

Class: PerformedMaterialStorage

Package: Study Conduct Sub-Domain

DEFINITION:
The completed action of safekeeping harvested material in a depository.

EXAMPLE(S):
refrigeration, cryopreservation, dehydration

OTHER NAME(S):

NOTE(S):

There is a difference between the act of changing the state of material, which is represented by PerformedMaterialProcessStep, and the act of maintaining state of the material by storing it, which is represented by PerformedMaterialStorage.

Tagged Values:

Connectors

Source	Connector	Target	Notes
PerformedMaterialStorage	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedMaterialStorage always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedMaterialStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedMaterialStorage 0..* usingPerformedMaterialStorage	use	Product 0..* usedProduct	<p>DESCRIPTION: Each PerformedMaterialStorage might use one or more Product. Each Product might be used during one or more PerformedMaterialStorage.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> PerformedMaterialStorage <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the technique that is used to store the material.</p> <p>EXAMPLE(S): liquid nitrogen vapor phase electric freezer</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE 2786006:Activity.Specify the storage method used for the cord blood unit:
temperatureRange <i>Class:</i> PerformedMaterialStorage <i>Datatype:</i> URG<PQ> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The thermal reading at which the storage unit was set.</p> <p>EXAMPLE(S): >= -80 degrees celsius -135 to -80 degrees celsius -150 to -135 degrees celsius < -150 degrees celsius</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE:2786019:Activity.What is the temperature in celsius during storage?

Class: PerformedMedicalConditionResult

Package: Study Conduct Sub-Domain

DEFINITION:

Any sign, symptom, disease, or other medical occurrence.

EXAMPLE(S):

death, back pain, headache, pulmonary embolism, heart attack, pregnancy, flu, broken bone, menstrual period, depression

OTHER NAME(S):

Clinical Events

Medical History

NOTE(S):

This condition may have been recalled by the subject or a caregiver or provided in their medical record.

Tagged Values:

- Map:caAERSv2.2 = StudyParticipantPreExistingCondition
- Map:CTRv1.0 = PerformedMedicalConditionResult
- Map:NCI CRF Standard = MedicalHistory
- Map:SDTM IGV3.1.3 = CE

Connectors

Source	Connector	Target	Notes
PerformedMedicalConditionResult	specializes	PerformedObservationResult	<p>DESCRIPTION: Each PerformedMedicalConditionResult always specializes one PerformedObservationResult. Each</p>

Source	Connector	Target	Notes
			<p>PerformedObservationResult might be specialized by one PerformedMedicalConditionResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubstanceAdministration 0..* addressingPerformedSubstanceAdministration	address	PerformedMedicalConditionResult 0..* addressedPerformedMedicalConditionResult	<p>DESCRIPTION: Each PerformedSubstanceAdministration might address one or more PerformedMedicalConditionResult. Each PerformedMedicalConditionResult might be addressed by one or more PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
occurrenceDateRange <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span in which the medical condition began and ended.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Onset date, resolution date, duration.</p> <p>NOTE(S): These may be partial dates or durations (duration is the width property of the IVL<TS> datatype).</p> <p>A condition may be considered to have ended when a subject returns to their baseline state.</p>	Map:CDASHv1.1 = MH.MHENDAT Map:CDASHv1.1 = MH.MHSTDAT Map:CTRv1.0 = PerformedMedicalConditionResult.occurrenceDateRange Map:HCTv1.0 = CDE 2871898:Occurrences.Date fungal infection occurred Map:HCTv1.0 = CDE 2787854:Adverse Events.Date engraftment syndrome occurred: Map:HCTv1.0 = CDE 2960491:Adverse Events.Date of graft failure: Map:LSDAMv2.2.3Plus = PerformedMedicalHistoryResult.occurrenceDateRange Map:NCI CRF Standard = CDE 2736881v1.0: Personal Medical History Ongoing Indicator Map:SDTM IGv3.1.1 = MH.MHENDTC Map:SDTM IGv3.1.1 = MH.MHSTDTC Map:SDTM IGv3.1.2 = CE.CEENDTC Map:SDTM IGv3.1.2 = MH.MHENRF Map:SDTM IGv3.1.2 = CE.CESTDTC Map:SDTM IGv3.1.2 = MH.MHSTDTC Map:SDTM IGv3.1.2 = MH.MHENRTPT Map:SDTM IGv3.1.2 = MH.MHENDTC
occurrenceDateRangeValidationCode <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the degree of authoritativeness or certitude of the occurrence date.</p> <p>EXAMPLE(S): "date estimated" "date > 100 days, date is correct" "date < 100 days, date is correct"</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The concept of "date unknown" is captured by a nullFlavor of "UNK" on the dateRange attribute, rather than a code in this attribute. A patient might have recovered from neutrophil in the past, but isn't sure of the exact date and state "I think it was in January of 2005". This would be recorded with an occurrenceDateRange of "January 2005" and an uncertainOccuranceDateCode of "estimated".</p>	Map:HCTv1.0 = CDE 2795658:Lab Results.If necessary, please validate the neutrophil recovery date response.

Attribute	Notes	Constraints and Tags
occurrenceStudyDayRange <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> IVL<INT> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The relative timing for a medical condition expressed as the number of days offset from the study-defined reference activity (e.g., date of registration, start of treatment) for this particular experimental unit.</p> <p>EXAMPLE(S): Day 1, Days 10-20</p> <p>OTHER NAME(S): Study Day</p> <p>NOTE(S): Derived from the occurrenceDateRange of this medical condition result minus the dateRange of the reference activity + 1.</p> <p>The study-defined reference activity can be different from study to study. The study day for a date after this reference activity is a positive integer calculated as the difference in the two dates + 1. The study day for dates before the reference activity is a negative integer calculated as the difference between the two dates. Note that this means there is no "Day 0."</p>	Map:SDTM IGv3.1.3 = MH.MHDY
endRelativeToReferenceCode <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the end of the medical condition event with respect to the sponsor-defined reference period.</p> <p>EXAMPLE(S): before, during, during/after, after</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing PerformedSubstanceAdministration.dateRange(IVL<TS.DATETIME>).high and PerformedStudySubjectMilestone.studyReferenceDateRange.</p> <p>Sponsors should define the reference period in the study metadata.</p> <p>This may be populated when a start date is not collected.</p>	Map:CTRv1.0 = PerformedMedicalConditionResult.endRelativeToReferenceCode Map:LSDAMv2.2.3Plus = PerformedMedicalHistoryResult.endRelativeToReferenceCode Map:SDTM IGv3.1.1 = MH.MHENRF

Attribute	Notes	Constraints and Tags
severityCode <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the intensity of the condition.</p> <p>EXAMPLE(S): Moderate could be used to describe acne.</p> <p>Values of: none,mild or trivial,moderate or severe,valve replacement,unknown could be used for a aorta valvular insufficiency</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from <code>PerformedClinicalInterpretation.value(ANY=>CD) WHERE PerformedClinicalInterpretation > PerformedObservation [severity assessment] > DefinedObservation.nameCode = "assess severity" AND PerformedObservation [severity assessment] > AssessedResultRelationship > PerformedMedicalConditionResult</code></p>	Map:HCTv1.0 = CDE 3021198:Diagnosis.Specify the severity of the valvular insufficiency:
clinicallySignificantIndicator <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether a subject's clinical condition is important based on judgment.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from <code>PerformedClinicalInterpretation.value(ANY=>BL) WHERE PerformedClinicalInterpretation > PerformedObservation > DefinedObservation.nameCode = "assess clinical significance".</code></p>	Map:HCTv1.0 = CDE 2759600:Diagnosis.Was there a coexisting significant hemorrhage?
medicalHistoryIndicator <i>Class:</i> PerformedMedicalConditionResult <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the condition is considered part of the historical record of a subject, that is, it did not occur within the bounds of the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the medical history indicator on the activity <code>(PerformedActivity.medicalHistoryIndicator)</code> which produced this result.</p>	Map:CTRv1.0 = PerformedMedicalConditionResult.medicalHistoryIndicator Map:SDTM IGv3.1.2 = MH.DOMAIN

Class: PerformedMedicalRecordAbstraction

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of extracting relevant healthcare information for a given patient from the document(s) provided by

healthcare professionals.

EXAMPLE(S):

The collection of data for patient #7034 from a participating registry contributing data to the Surveillance, Epidemiology, and End Results (SEER) Program at the U.S. National Cancer Institute (NCI)

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:SEER 2015 = SECTION II INFORMATION SOURCE

Connectors

Source	Connector	Target	Notes
PerformedMedicalRecordAbstraction	specializes	PerformedActivity	<p>DESCRIPTION: Each PerformedMedicalRecordAbstraction always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedMedicalRecordAbstraction.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
reportingSourceTypeCode <i>Class:</i> PerformedMedicalRecordAbstraction <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of medical record that provided the best information when abstracting the relevant healthcare data.</p> <p>EXAMPLE(S): 1 = Hospital inpatient; Managed health plans with comprehensive, unified medical records (new code definition effective with diagnosis on or after 1/1/2006) 2 = Radiation Treatment Centers or Medical Oncology Centers (hospital affiliated or independent) (effective with diagnosis on or after 1/1/2006) 3 = Laboratory Only (hospital affiliated or independent) 4 = Physician's Office/Private Medical Practitioner (LMD) 5 = Nursing/Convalescent Home / Hospice 6 = Autopsy Only 7 = Death Certificate Only 8 = Other hospital outpatient units/surgery centers (effective with diagnosis on or after 1/1/2006)</p> <p>OTHER NAME(S): Type of Reporting Source (NCI SEER)</p> <p>NOTE(S): This is not necessarily the original document that identified the case; rather, it is the source that provided the best information.</p>	Map:SEER 2015 = SECTION II INFORMATION SOURCE - TYPE OF REPORTING SOURCE
lastFollowUpDate <i>Class:</i> PerformedMedicalRecordAbstraction <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the records for this subject were last updated.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - DATE OF LAST FOLLOW UP OR DEATH FLAG Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - DATE OF LAST FOLLOW UP OR OF DEATH

Attribute	Notes	Constraints and Tags
lastFollowUpSourceTypeCode <i>Class:</i> PerformedMedicalRecordAbstraction <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0..1	<p>DEFINITION: A coded value specifying the kind of medical record that provided the latest vital status information about this person.</p> <p>EXAMPLE(S): For the U.S. National Cancer Institute (NCI) Surveillance, Epidemiology, and End Results (SEER) program: 1 = "Autopsy Only" or "Death Certificate Only" case 2 = Active follow up case 3 = In situ cancer of the cervix uteri only 4 = San Francisco-Oakland only: Case not originally in active follow up, but in active follow up now"</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - TYPE OF FOLLOW UP

Class: PerformedNotification

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action within the context of a given study that represents the communication of a message to a recipient.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = ScheduledNotification

Connectors

Source	Connector	Target	Notes
PerformedNotification	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedNotification always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..*	be the receiver of	PerformedNotification 0..1	DESCRIPTION: Each NotificationReceiver

Source	Connector	Target	Notes
receivingNotificationReceiver		receivedPerformedNotification	<p>might be the receiver of one PerformedNotification.</p> <p>Each PerformedNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
messageTitle <i>Class:</i> PerformedNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>The subject of the notification.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = ScheduledNotification.title
message <i>Class:</i> PerformedNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>The actual text that was included in the notification.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = ScheduledNotification.message Map:caAERSv2.2 = NotificationBodyContent.content

Class: PerformedObservation

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of observing, monitoring, measuring or otherwise qualitatively or quantitatively gathering data or information about one or more aspects of a subject.

EXAMPLE(S):

lab test, taking vital signs, physical exam, specimen quality review, obtaining DNA sequence, genotyping a genetic variant, measuring the pH of a solution

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AIM v4 rv48 = ImagingObservationEntity
- Map:AIM v4 rv48 = ImagingObservationCharacteristic
- Map:AIM v4 rv48 = ImageAnnotationCollection
- Map:AIM v4 rv48 = ImageAnnotation
- Map:AIM v4 rv48 = CalculationEntity
- Map:AIM v4 rv48 = InferenceEntity

- Map:caAERSv2.2 = Lab
- Map:CTRPv3.8 = PerformedObservation
- Map:CTRv1.0 = PerformedStudyObservation
- Map:CTRv1.0 = PerformedObservation
- Map:DICOM = TID 1500 MeasurementReport > Imaging Measurements > Include TID 1410 PlanarROIMeasurements
- Map:DICOM = TID 1500 MeasurementReport > Qualitative Evaluations
- Map:DICOM = TID 1419 ROIMeasurements
- Map:DICOM = TID 1500 MeasurementReport > Imaging Measurements > Include TID 1501 MeasurementGroup
- Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group
- Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > Include TID 1419 ROIMeasurements
- Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Include TID 300 Measurement
- Map:DICOM = TID 1501 MeasurementGroup > Measurement Group
- Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Include TID 1419 ROIMeasurements
- Map:DICOM = TID 1500 MeasurementReport > Imaging Measurements > Include TID 1411 VolumetricROIMeasurements
- Map:DICOM = TID 1500 MeasurementReport
- Map:DICOM = TID 300 Measurement
- Map:ICSRr2 = ObservationEvent (in IndividualCaseSafetyReport)
- Map:ICSRr2 = RelatedInvestigation (in IndividualCaseSafetyReport)
- Map:ICSRr2 = InvestigativeEvent (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Subject7 (in IndividualCaseSafetyReport)
- Map:LabViewer2.2 = LaboratoryTest
- Map:LSDAMv2.2.3Plus = PerformedSpecimenQualityReview
- Map:LSDAMv2.2.3Plus = PerformedObservation
- Map:PGx v1.0 = BS
- Map:SDTM IGv3.1.2 = EG.DOMAIN
- Map:SDTM IGv3.1.2 = MH.DOMAIN
- Map:SDTM IGv3.1.2 = PC.DOMAIN
- Map:SDTM IGv3.1.2 = CE.DOMAIN
- Map:SDTM IGv3.1.2 = LB.DOMAIN
- Map:SDTM IGv3.1.2 = QS.DOMAIN
- Map:SDTM IGv3.1.2 = FA.DOMAIN
- Map:SDTM IGv3.1.2 = VS.DOMAIN
- Map:SDTM IGv3.1.2 = MS.DOMAIN
- Map:SDTM IGv3.1.2 = CO.DOMAIN
- Map:SDTM IGv3.1.2 = PE.DOMAIN
- Map:SDTM IGv3.1.2 = PP.DOMAIN
- Map:SDTM IGv3.1.2 = MB.DOMAIN
- Map:SDTM IGv3.1.2 = SC.DOMAIN
- Map:SDTM IGv3.1.3 = FA
- Map:SDTM IGv3.1.3 = SC
- Map:SDTM IGv3.1.3 = QS
- Map:SDTM IGv3.1.3 = PE
- Map:SDTM IGv3.1.3 = PC
- Map:SDTM IGv3.1.3 = MS
- Map:SDTM IGv3.1.3 = CO
- Map:SDTM IGv3.1.3 = LB
- Map:SDTM IGv3.1.3 = EG
- Map:SDTM IGv3.1.3 = TR
- Map:SDTM IGv3.1.3 = MB
- Map:SDTM IGv3.1.3 = TU
- Map:SDTM IGv3.1.3 = VS
- Map:SDTM IGv3.1.3 = RS
- Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group

Connectors

Source	Connector	Target	Notes
PerformedObservation	be recorded as a result of	PerformedObservationResul	DESCRIPTION:

Source	Connector	Target	Notes
0..* recordedPerformedObservation		t 0..1 triggeringPerformedObservationResult	Each PerformedObservation might be recorded as a result of one PerformedObservationResult. Each PerformedObservationResult might result in recording one or more PerformedObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservation 0..* commentingPerformedObservation	be commenting on	PerformedActivity 0..1 commentedPerformedActivity	DESCRIPTION: Each PerformedObservation might be commenting on one PerformedActivity. Each PerformedActivity might be commented on by one or more PerformedObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservation	specializes	PerformedActivity	DESCRIPTION: Each PerformedObservation always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservation 0..* commentingPerformedObservation	be commenting on	SafetyReportVersion 0..1 commentedSafetyReportVersion	DESCRIPTION: Each PerformedObservation might be commenting on one SafetyReportVersion. Each SafetyReportVersion might be commented on by one or more PerformedObservation. DEFINITION:

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservationResult 0..* resultedPerformedObservationResult	is a result of	PerformedObservation 1 producingPerformedObservation	DESCRIPTION: Each PerformedObservationResult always is a result of one PerformedObservation. Each PerformedObservation might result in one or more PerformedObservationResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdverseEventOutcomeAssessment	specializes	PerformedObservation	DESCRIPTION: Each AdverseEventOutcomeAssessment always specializes one PerformedObservation. Each PerformedObservation might be specialized by one AdverseEventOutcomeAssessment. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
CausalAssessment	specializes	PerformedObservation	DESCRIPTION: Each CausalAssessment always specializes one PerformedObservation. Each PerformedObservation might be specialized by one CausalAssessment. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AssessedResultRelationship 0..*	is the subject of	PerformedObservation 1	DESCRIPTION: Each

Source	Connector	Target	Notes
assessedAssessedResultRelationship		assessingPerformedObservation	AssessedResultRelationship always is the subject of one PerformedObservation. Each PerformedObservation might have as subject one or more AssessedResultRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProductInvestigation	specializes	PerformedObservation	DESCRIPTION: Each PerformedProductInvestigation always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedProductInvestigation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AssessedActivityRelationship 0..* assessedAssessedActivityRelationship	is the subject of	PerformedObservation 1 assessingPerformedObservation	DESCRIPTION: Each AssessedActivityRelationship always is the subject of one PerformedObservation. Each PerformedObservation might have as subject one or more AssessedActivityRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedEligibilityCriterion	specializes	PerformedObservation	DESCRIPTION: Each PerformedEligibilityCriterion always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedEligibilityCriterion

Source	Connector	Target	Notes
			n. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedGeneticObservation	specializes	PerformedObservation	DESCRIPTION: Each PerformedGeneticObservation always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedGeneticObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedImagingStudy	specializes	PerformedObservation	DESCRIPTION: Each PerformedImagingStudy always specializes one PerformedObservation. Each PerformedObservation might be specialized by one PerformedImagingStudy. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the technique used to perform the observation.</p> <p>EXAMPLE(S): Arterial puncture, sphygmomanometry (for blood pressure measurement)</p> <p>Global introspection, algorithm, bayesian (for Adverse Event causality)</p> <p>Estrogen Receptor Assay, Progesterone Receptor Assay, p53 Assay (for clinical result assay)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = CausalAssessment.methodCode Map:AE = PerformedProductInvestigation.evaluationMethodCode Map:CDASHv1.1 = EG.EGMETHOD Map:CTOM = ClinicalResult.meansVitalStatusObtainedCode Map:CTOM = ClinicalResult.labTechniqueCode Map:CTOM = LesionDescription.methodCode Map:CTOM = ClinicalResult.assayMethodCode Map:CTRPv3.8 = PerformedObservation.methodCode Map:CTRv1.0 = PerformedObservation.methodCode Map:DICOM = TID 300 Measurement > \$Measurement parameter > Measurement Method Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Measurement Method Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter > Measurement Method Map:DICOM = TID 1419 ROIMeasurements > Measurement Group > Measurement Method Map:HCTv1.0 = CDE 2630451:Procedures.Specify test and method for test performed on other infectious disease marker: Map:HCTv1.0 = CDE 2775544:Techniques.What tumor cell detection method was used ? Map:HCTv1.0 = CDE 2861466:Procedures.What type of cytogenetic analysis was the disease assessed by? Map:HCTv1.0 = CDE 3020053:Procedures.Specify other mental process development testing clinical assessment tool: Map:HCTv1.0 = CDE 2778231:Techniques.Specify other tumor cell detection method used prior to HCST Map:HCTv1.0 = CDE 2780165:Lab Results.Chimerism study method type: Map:HCTv1.0 = CDE 2985297:Lab Results.Specify the chimerism laboratory procedure method type: Map:HCTv1.0 = CDE 3179398:Lab Results.First fungal infection confirmed laboratory procedure name: Map:HCTv1.0 = CDE 3057363:Lab Results.Specify the method used to assess left ventricle performance:

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 3057325:Procedures.What clinical assessment test tool was used to determine mental development: Map:HCTv1.0 = CDE 2963400:Lab Results.What type of neoplastic cell detection method was performed? Map:HCTv1.0 = CDE 2861233:Procedures.What method was used to assess the disease? Map:HCTv1.0 = CDE 2767307:Techniques.Specify the other tumor cells detection method Map:HCTv1.0 = CDE 3009669:Lab Results.Specify the index used to report the value: Map:HCTv1.0 = CDE 2760530:Specimen Characteristics.Which method of testing cell viability was used? Map:HCTv1.0 = CDE 3179410:Lab Results.Second fungal infection confirmed laboratory procedure name: Map:HCTv1.0 = CDE 2749589:Involvement and Extent of Disease.What was the systemic lupus erythematosus (SLE) biopsy type? Map:HCTv1.0 = CDE 2974160:Lab Results.Specify other paroxysmal nocturnal hemoglobinuria test: Map:HCTv1.0 = CDE 3179414:Lab Results.Third fungal infection confirmed laboratory procedure name: Map:HCTv1.0 = CDE 2974158:Lab Results.What paroxysmal nocturnal hemoglobinuria test was used? Map:HCTv1.0 = CDE 2974019:Procedures.Which method(s) were used to evaluate the status? Map:HCTv1.0 = CDE 2978298:Tumor Measurements.What was the primary neoplasm size assessment method? Map:HCTv1.0 = CDE 2749395:Involvement and Extent of Disease.What was the systemic sclerosis biopsy type? Map:HCTv1.0 = CDE 3031335:Procedures.Specify disease or disorder assessment method: Map:HCTv1.0 = CDE 2785787:Specimen Characteristics.Specify cell specimen viable laboratory procedure: Map:HCTv1.0 = CDE 2778929:Techniques.What kind of method was used to detect tumor cells after purging? Map:ICSRr2 = CausalityAssessment.methodCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = </p>

Attribute	Notes	Constraints and Tags
		PerformedObservation.methodCode Map:PGx v1.0 = PG.PGMETHOD Map:PGx v1.0 = BS.BSMETHOD Map:PGx v1.0 = PF.PFMETHOD Map:SDTM IGv3.1.2 = MB.MBMETHOD Map:SDTM IGv3.1.2 = PC.PCMETHOD Map:SDTM IGv3.1.2 = MS.MSMETHOD Map:SDTM IGv3.1.2 = LB.LBMETHOD Map:SDTM IGv3.1.2 = CM.CMPRESP Map:SDTM IGv3.1.2 = PE.PEMETHOD Map:SDTM IGv3.1.2 = EG.EGMETHOD Map:SDTM IGv3.1.2 = CE.CEPRESP Map:SDTM IGv3.1.2 = MH.MHPRESP Map:SDTM IGv3.1.3 = MB.MBMETHOD Map:SDTM IGv3.1.3 = TU.TUMETHOD Map:SDTM IGv3.1.3 = TR.TRMETHOD Map:SDTM IGv3.1.3 = PE.PEMETHOD Map:SDTM IGv3.1.3 = MS.MSMETHOD Map:SDTM IGv3.1.3 = LB.LBMETHOD Map:SDTM IGv3.1.3 = EG.EGMETHOD Map:SDTM IGv3.1.3 = PC.PCMETHOD Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS METS EVAL Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - DIAGNOSTIC CONFIRMATION Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS TUMOR SIZE/EXT EVAL Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS LYMPH NODES EVAL

Attribute	Notes	Constraints and Tags
derivationMethodCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the technique used to calculate a measured value.</p> <p>EXAMPLE(S): mean, maximum of set</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map: DICOM = TID 300 Measurement > \$Measurement parameter > Derivation
targetAnatomicSiteCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of the observation.</p> <p>EXAMPLE(S): Lower intestine for a colonoscopy observation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The target site of the result may be different than the target site of the activity (PerformedObservation) that generated it. For example, a chest x-ray (observation) has the target site of chest while the result might show an infiltration in the left lower lobe of the lung (target site of result), or a dermatological exam may check the skin across the whole body (target site of observation) while the result might identify a rash on the right leg (target site of result).</p> <p>Neither target anatomic site nor approach anatomic site is necessarily required or relevant for certain observations, however if either or both are present then the distinction between them is that the approach site is where the measurement or observation is performed and the target site is what is ultimately being evaluated. The target site is often implicit in the definition of the observation itself.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions</p>	Map: CTOM = Imaging.anatomicSiteCodeSystem Map: CTOM = Imaging.anatomicSiteCode Map: CTRv3.8 = PerformedObservation.targetSiteCode Map: CTRv1.0 = PerformedObservation.targetAnatomicSiteCode Map: DICOM = General Series Module - Body Part Examined (0018,0015) Map: LSDAMv2.2.3Plus = PerformedObservation.targetAnatomicSiteCode Map: SDTM IGv3.1.2 = FA.FALOC Map: SDTM IGv3.1.2 = PE.PELOC Map: SDTM IGv3.1.3 = VS.VSLOC Map: SDTM IGv3.1.3 = PE.PELOC Map: SDTM IGv3.1.3 = FA.FALOC

Attribute	Notes	Constraints and Tags
targetAnatomicSiteLateralityCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for an observation.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CTRV1.0 = PerformedObservation.targetAnatomicSiteLateralityCode Map:LSDAMv2.2.3Plus = PerformedObservation.targetAnatomicSiteLateralityCode Map:SDTM IGv3.1.3 = VS.VSLOC Map:SDTM IGv3.1.3 = FA.FALOC
approachAnatomicSiteCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomic location or access point for an observation.</p> <p>EXAMPLE(S): Anus for a colonoscopy observation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Neither target anatomic site nor approach anatomic site is necessarily required or relevant for certain observations, however if either or both are present then the distinction between them is that the approach site is the access point for the measurement or observation and the target site is what is ultimately being evaluated.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CDASHv1.1 = VS.VSLOC Map:CTRV1.0 = PerformedObservation.approachAnatomicSiteCode Map:SDTM IGv3.1.2 = FA.FALOC Map:SDTM IGv3.1.2 = EG.EGLOC Map:SDTM IGv3.1.2 = VS.VSLOC Map:SDTM IGv3.1.3 = VS.VSLOC Map:SDTM IGv3.1.3 = FA.FALOC Map:SDTM IGv3.1.3 = EG.EGLOC

Attribute	Notes	Constraints and Tags
approachAnatomicSiteLateralityCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is an access point for a observation.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CDASHv1.1 = VS.VSLOC Map:CTRv1.0 = PerformedObservation.approachAnatomicSiteLateralityCode Map:SDTM IGv3.1.2 = EG.EGLOC Map:SDTM IGv3.1.2 = VS.VSLOC Map:SDTM IGv3.1.2 = FA.FALOC Map:SDTM IGv3.1.3 = VS.VSLOC Map:SDTM IGv3.1.3 = FA.FALOC
bodySystemCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomical structure that consists of organs and organ subclasses responsible for certain body functions.</p> <p>EXAMPLE(S): gastrointestinal system, urinary system, hematopoietic system</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PerformedObservationResult.bodySystemCode Map:LSDAMv2.2.3Plus = PerformedObservationResult.bodySystemCode Map:NCI CRF Standard = CDE 3192450v1.0: Physical Examination Criteria Category Map:NCI CRF Standard = CDE 2182671v1.0: Other Body System/Site Text Map:NCI CRF Standard = CDE 3192540v1.0: Medical History Review of Systems Criteria Category Map:SDTM IGv3.1.1 = PE.PEBODSYS Map:SDTM IGv3.1.2 = PE.PEBODSYS Map:SDTM IGv3.1.3 = PE.PEBODSYS

Attribute	Notes	Constraints and Tags
bodyPositionCode <i>Class:</i> PerformedObservation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the 3-dimensional spatial orientation of a subject during a particular observation.</p> <p>EXAMPLE(S): supine, trendelenburg, standing</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:CDASHv1.1 = VS.VSPOS Map:CDASHv1.1 = EG.EGPOS Map:CTOM = ClinicalResult.bodyPositionCode Map:CTRV1.0 = PerformedObservation.bodyPositionCode Map:DICOM = General Series Module - Patient Position (0018,5100) Map:LSDAMv2.2.3Plus = PerformedObservation.bodyPositionCode Map:SDTM IGv3.1.1 = EG.EGPOS Map:SDTM IGv3.1.1 = VS.VSPOS Map:SDTM IGv3.1.2 = VS.VSPOS Map:SDTM IGv3.1.2 = EG.EGPOS Map:SDTM IGv3.1.3 = VS.VSPOS Map:SDTM IGv3.1.3 = EG.EGPOS
focalDateRange <i>Class:</i> PerformedObservation <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The time period in which the observation result is held to be true.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from DefinedObservation.focalDateRange alone (i.e., directly from simple date ranges like 1990-1999) or from evaluating the expression in DefinedObservation.focalDateRange (which references a date that is now known).</p>	Map:CTOM = DiseaseResponse.progressionDate Map:CTOM = Diagnosis.confirmationDate Map:CTRV1.0 = PerformedObservation.focalDateRange Map:ICSR2 = CausalityAssessment.effectiveTime (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = PerformedObservation.focalDateRange Map:NCI CRF Standard = CDE 2006851v4.0: Adverse Event Final Assessment Date Map:NCI CRF Standard = CDE 2744943v1.0: Adverse Event Begin Assessment Date Map:SDTM IGv3.1.2 = PC.PCEVLINT
focalDuration <i>Class:</i> PerformedObservation <i>Datatype:</i> PQ.TIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The quantity of time in which the observation result is held to be true.</p> <p>EXAMPLE(S): 2 months is the focalDuration for a question such as "Have you smoked in the last 2 months?".</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedObservation.focalDateRange.</p>	AE:Exclude = True Map:CTOM = DiseaseResponse.progressionPeriod Map:CTOM = DiseaseResponse.progressionPeriodUnitOfMeasureCode Map:CTRV1.0 = PerformedObservation.focalDuration Map:LSDAMv2.2.3Plus = PerformedObservation.focalDuration Map:SDTM IGv3.1.1 = QS.QSEVLINT

Class: PerformedObservationResult

Package: Study Conduct Sub-Domain

DEFINITION:

The data or finding obtained by observing, monitoring, measuring or otherwise qualitatively or quantitatively recording one or more aspects of a subject, experimental unit, system, or process.

EXAMPLE(S):

A blood chemistry result
 A diagnosis of breast cancer
 A pregnancy test result
 A blood pressure measurement
 Identification of nausea as an adverse event
 The conclusion of an adverse event outcome assessment
 The finding from an experiment
 The data used as input to an experiment
 Data produced by computation
 An image annotation
 The reformatting, transformation, semantic/syntactic normalization or downloading of data from public resources
 A cell count
 Neoplastic cellularity

OTHER NAME(S):

Data
 Data Acquisition Result
 Finding

NOTE(S):*Tagged Values:*

- Map:AIM v4 rv48 = CalculationResult
- Map:C3PRv2.9 = SubjectEligibilityAnswer
- Map:CTRPv3.8 = PerformedObservationResult
- Map:CTRPv3.8 = ObservationResult
- Map:CTRv1.0 = PerformedObservationResult
- Map:HCTv1.0 = CDE 2769634:Adverse Events.Specify other most likely cause of the adverse event:
- Map:ICSRr2 = InvestigationCharacteristic (in IndividualCaseSafetyReport)
- Map:ICSRr2 = Characteristics (in R_Product)
- Map:LSDAMv2.2.3Plus = PerformedSpecimenReviewResult
- Map:LSDAMv2.2.3Plus = Data
- Map:LSDAMv2.2.3Plus = Finding
- Map:LSDAMv2.2.3Plus = ImageAnnotation
- Map:LSDAMv2.2.3Plus = PerformedObservationResult
- Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging

Connectors

Source	Connector	Target	Notes
PerformedObservationResult 0..* resultedPerformedObservationResult	is a result of	PerformedObservation 1 producingPerformedObservation	<p>DESCRIPTION: Each PerformedObservationResult always is a result of one PerformedObservation. Each PerformedObservation might result in one or more PerformedObservationResults.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
PerformedObservationResult 0..* startEvaluatedPerformedObservationResult	have start evaluated in relation to	PerformedActivity 0..1 startRelatedPerformedActivity	<p>DESCRIPTION: Each PerformedObservationResult might have start evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating start of one or more PerformedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, CESTTPT indicates a study event that may be a reference event for the start of a clinical event (PerformedObservationResult).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): As per CDISC, any given observation result can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedObservationResult and PerformedActivity for evaluating start and end of the result.</p>
PerformedObservationResult 0..* endEvaluatedPerformedObservationResult	have end evaluated in relation to	PerformedActivity 0..1 endRelatedPerformedActivity	<p>DESCRIPTION: Each PerformedObservationResult might have end evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating end of one or more PerformedObservationResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, AEENTPT indicates a study</p>

Source	Connector	Target	Notes
			<p>event that may be a reference event for the end of an adverse event, CEENTPT indicates a study event that may be a reference event for the end of a clinical event (PerformedObservationResult) and MHENTPT indicates a study event that may be a reference event for the end of a medical condition (PerformedMedicalConditionResult).</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>As per CDISC, any given observation result can have its start evaluated in relation to a performed activities. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedObservationResult and PerformedActivity for evaluating start and end of the result.</p>
PerformedObservationResult 0..* establishingPerformedObservationResult	establish	Biomarker 0..* establishedBiomarker	<p>DESCRIPTION:</p> <p>Each PerformedObservationResult might establish one or more Biomarker. Each Biomarker might be established by one or more PerformedObservationResults.</p> <p>DEFINITION:</p> <p>Identifies the finding that results in the identification of a biomarker.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservationResult 0..* inferredPerformedObservationResult	be inferred from	PerformedObservationResult 0..1 infersPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each PerformedObservationResult might be inferred from one PerformedObservationResult</p>

Source	Connector	Target	Notes
			t. Each PerformedObservationResult might infer one or more PerformedObservationResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedGeneticInterpretation	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedGeneticInterpretation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedGeneticInterpretation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProductProblemDiscovery	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedProductProblemDiscovery always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProductProblemDiscovery. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProcedure 0..* recordedPerformedProcedure	be recorded as a result of	PerformedObservationResult 0..1 triggeringPerformedObservationResult	DESCRIPTION: Each PerformedProcedure might be recorded as a result of one PerformedObservationResult. Each

Source	Connector	Target	Notes
			PerformedObservationResult might result in recording one or more PerformedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedObservation 0..* recordedPerformedObservation	be recorded as a result of	PerformedObservationResult 0..1 triggeringPerformedObservationResult	DESCRIPTION: Each PerformedObservation might be recorded as a result of one PerformedObservationResult. Each PerformedObservationResult might result in recording one or more PerformedObservation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedGeneticObservationResult	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedGeneticObservationResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedGeneticObservationResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
EvaluatedResultRelationship 0..* evaluatingEvaluatedResultRelationship	evaluates	PerformedObservationResult 1 evaluatedPerformedObservationResult	DESCRIPTION: Each EvaluatedResultRelationship always evaluates one PerformedObservationResult. Each PerformedObservationResult might be evaluated by one

Source	Connector	Target	Notes
			or more EvaluatedResultRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedLesionDescription	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedLesionDescription always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedLesionDescription. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedClinicalInterpretation	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedClinicalInterpretation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedClinicalInterpretation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdverseEventOutcomeResult	specializes	PerformedObservationResult	DESCRIPTION: Each AdverseEventOutcomeResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one

Source	Connector	Target	Notes
			AdverseEventOutcomeResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProductInvestigationResult	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedProductInvestigationResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProductInvestigationResult. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
ResultClassification 0..* classifyingResultClassification	classifies	PerformedObservationResult 1 classifiedPerformedObservationResult	DESCRIPTION: Each ResultClassification always classifies one PerformedObservationResult. Each PerformedObservationResult might be classified by one or more ResultClassification. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedDiagnosis	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedDiagnosis always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedDiagnosis. DEFINITION:

Source	Connector	Target	Notes
			<p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
TargetAnatomicSite 0..* describingTargetAnatomicSite	described	PerformedObservationResult 1 describedPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each TargetAnatomicSite always described one PerformedObservationResult. Each PerformedObservationResult might be described by one or more TargetAnatomicSite.</p> <p>DEFINITION:</p> <p>Indicates result being described by a particular site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Biomarker 0..* basingBiomarker	be based on	PerformedObservationResult 0..* basedPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each Biomarker might be based on one or more PerformedObservationResult. Each PerformedObservationResult might be the basis of one or more Biomarker.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>An image annotation might be the basis for a biomarker.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
MolecularSequenceAnnotation	specializes	PerformedObservationResult	<p>DESCRIPTION:</p> <p>Each MolecularSequenceAnnotation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one MolecularSequenceAnnotation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
ReportVersion 0..* describingReportVersion	describe	PerformedObservationResult 0..* describedPerformedObservationResult	DESCRIPTION: Each ReportVersion might describe one or more PerformedObservationResult. Each PerformedObservationResult might be described by one or more ReportVersion. DEFINITION: EXAMPLE(S): surgical pathology report describes observations about a specimen collection group OTHER NAME(S): NOTE(S):
ObservationResultActionTakenRelationship 0..* triggeredObservationResultActionTakenRelationship	is triggered by	PerformedObservationResult 1 triggeringPerformedObservationResult	DESCRIPTION: Each ObservationResultActionTakenRelationship always is triggered by one PerformedObservationResult. Each PerformedObservationResult might trigger one or more ObservationResultActionTakenRelationship. DEFINITION: Indicates the ObservationResult that causes the initiation of a PerformedActivity EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedMedicalConditionResult	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedMedicalConditionResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedMedicalConditionResult.

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
AssessedResultRelationship 0..* assessingAssessedResultRelationship	has as subject	PerformedObservationResult 1 assessedPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each AssessedResultRelationship always has as subject one PerformedObservationResult. Each PerformedObservationResult might be the subject of one or more AssessedResultRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedClinicalResult	specializes	PerformedObservationResult	<p>DESCRIPTION:</p> <p>Each PerformedClinicalResult always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedClinicalResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
DocumentVersion 0..* containingDocumentVersion	contain	PerformedObservationResult 0..* containedPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each DocumentVersion might contain one or more PerformedObservationResult. Each PerformedObservationResult might be the contents for one or more DocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>A finding might be</p>

Source	Connector	Target	Notes
			<p>published in a scientific journal.</p> <p>A data set produced by a computational process might be circulated as a document.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProtocolDeviation	specializes	PerformedObservationResult	<p>DESCRIPTION:</p> <p>Each PerformedProtocolDeviation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProtocolDeviation.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PointOfContact 0..* supportingPointOfContact	support	PerformedObservationResult 0..* supportedPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each PointOfContact might support one or more PerformedObservationResult. Each PerformedObservationResult might be supported by one or more PointOfContact.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedObservationResult 0..* inferredPerformedObservationResult	be inferred from	PerformedObservationResult 0..1 infersPerformedObservationResult	<p>DESCRIPTION:</p> <p>Each PerformedObservationResult might be inferred from one PerformedObservationResult. Each PerformedObservationResult might infer one or more PerformedObservationResult.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):
AdverseEvent	specializes	PerformedObservationResult	DESCRIPTION: Each AdverseEvent always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one AdverseEvent. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedHistopathologyResult	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedHistopathology always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedHistopathology. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> PerformedObservationResult <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The unique symbol that establishes identity of the observation result.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AIM v4 rv48 = Entity.uniqueIdentifier Map:CDASHv1.1 = SU.SUNCF Map:CDASHv1.1 = EX.EXYN Map:CDASHv1.1 = EX.EXDOSADJ Map:CDASHv1.1 = CM.CMAENO Map:CDASHv1.1 = EG.EGREFID Map:CDASHv1.1 = EX.EXTRTCMP Map:CDASHv1.1 = CM.CMMHNO Map:CTOM = Imaging.imageIdentifier Map:CTOM = Imaging.identifier Map:CTRv1.0 = PerformedObservationResult.identifier Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Tracking Unique Identifier Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > Tracking Unique Identifier Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > Tracking Unique Identifier Map:ICSRr2 = DefectReference.id (in IndividualCaseSafetyReport) Map:ICSRr2 = AdverseEventAssessment.id (in IndividualCaseSafetyReport) Map:ICSRr2 = ProductDefectAssessment.id (in IndividualCaseSafetyReport) Map:ICSRr2 = ObservationEvent.id (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = PerformedObservationResult.identifier Map:LSDAMv2.2.3Plus = PerformedImaging.imageIdentifier Map:LSDAMv2.2.3Plus = ImageAnnotation.uniqueIdentifier Map:SDTM IGv3.1.2 = DV.DVREFID Map:SDTM IGv3.1.2 = CE.CEREFID Map:SDTM IGv3.1.2 = MH.MHREFID Map:SDTM IGv3.1.2 = EG.EGREFID Map:SDTM IGv3.1.3 = CE.CEREFID Map:SDTM IGv3.1.3 = MH.MHREFID Map:SDTM IGv3.1.3 = EG.EGREFID Map:SDTM IGv3.1.3 = DV.DVREFID Map:SDTM IGv3.1.3 = TU.TUREFID

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> PerformedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of observation result.</p> <p>EXAMPLE(S): A single blood pressure observation has two results, typeCode = "systolic" and typeCode = "diastolic".</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ClinicalResult.value Map:CTRPv3.8 = ObservationResult.typeCode Map:CTRv1.0 = PerformedObservationResult.typeCode Map:ICSRr2 = ObservationEvent.code (in IndividualCaseSafetyReport) Map:ICSRr2 = InvestigationCharacteristic.code (in IndividualCaseSafetyReport) Map:ICSRr2 = Characteristics.code (in R_Product) Map:ICSRr2 = AdverseEventAssessment.code (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = PerformedObservationResult.typeCode Map:LSDAMv2.2.3Plus = ImageAnnotation.type

Attribute	Notes	Constraints and Tags
value <i>Class:</i> PerformedObservationResult <i>Datatype:</i> ANY <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: Data or information that is determined by an act of observation.</p> <p>EXAMPLE(S): The result of a lab test, physical finding, self-reported symptom.</p> <p>The adverse event term code.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Animal.overallStateOfHealthCode Map:AE = Assessment.textInterpretation Map:AE = ProductObservation.value Map:AE = AdverseEvent.adverseEventTermCode Map:AE = InvestigativeSubject.gestationPeriod Map:AE = AdverseEvent.reactionText Map:AE = Person.numberOfSiblings Map:AE = ProductInvestigation.evaluationResultCode Map:AE = Assessment.codedInterpretation Map:AIM v4 rv48 = CalculationData.value Map:AIM v4 rv48 = InferenceEntity.typeCode Map:AIM v4 rv48 = CalculationResult.unitOfMeasure Map:AIM v4 rv48 = ImagingObservationCharacteristic.typeCode Map:AIM v4 rv48 = ImagingObservationEntity.typeCode Map:C3PR = StratificationCriterionPermissibleAnswer.permissibleAnswer Map:C3PRv2.9 = SubjectEligibilityAnswer.answerText Map:C3PRv2.9 = DiseaseHistory.otherPrimaryDiseaseCode Map:C3PRv2.9 = AdverseEvent.verbatim Map:C3PRv2.9 = SubjectStratificationAnswer Map:caAERSv2.2 = PreExistingCondition.meddraLowLevelTerm > StudyParticipantPreExistingCondition Map:caAERSv2.2 = Ctc.name > AdverseEventCtcTerm Map:caAERSv2.2 = StudyParticipantDiseaseHistory.otherPrimaryDisease Map:caAERSv2.2 = AbstractMeddraDomain.icd10Code Map:caAERSv2.2 = AbstractMeddraDomain.costartSymbol Map:caAERSv2.2 = AdverseEventResponseDescription.eventAbate Map:caAERSv2.2 = AdverseEventResponseDescription.eventDescription Map:caAERSv2.2 = LabValue.value Map:caAERSv2.2 =

Attribute	Notes	Constraints and Tags
		<p>AdverseEventResponseDescription.studyDrugInterrupted Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > AdverseEvent Map:caAERSv2.2 = AbstractMeddraDomain.icd9CmCode Map:caAERSv2.2 = CtcTerm.ctepCode > AdverseEvent Map:caAERSv2.2 = DiseaseHistory.otherPrimaryDisease Map:caAERSv2.2 = Lab.units Map:caAERSv2.2 = SAEReportPreExistingCondition.other Map:caAERSv2.2 = PreExistingCondition.meddraLowLevelTermCode > SAEReportPreExistingCondition Map:caAERSv2.2 = AbstractMeddraDomain.whoArtCode Map:caAERSv2.2 = CtcTerm.select > AdverseEventCtcTerm Map:caAERSv2.2 = PreExistingCondition.meddraLowLevelTermCode > StudyParticipantPreExistingCondition Map:caAERSv2.2 = AdverseEventResponseDescription.presentStatus Map:caAERSv2.2 = PreExistingCondition.meddraLowLevelTerm > SAEReportPreExistingCondition Map:caAERSv2.2 = AbstractMeddraDomain.jartCode Map:caAERSv2.2 = ParticipantHistory.weight Map:caAERSv2.2 = CtcTerm.term > AdverseEventCtcTerm Map:caAERSv2.2 = PreExistingCondition.text > StudyParticipantPreExistingCondition Map:caAERSv2.2 = ParticipantHistory.baselinePerformanceStatus Map:caAERSv2.2 = ParticipantHistory.height Map:caAERSv2.2 = MeddraVersion.name > AdverseEventMeddraLowLevelTerm Map:caAERSv2.2 = AbstractMeddraDomain.meddraTerm Map:caAERSv2.2 = StudyParticipantPreExistingCondition.other Map:caAERSv2.2 = AbstractMeddraDomain.meddraCode > AdverseEventMeddraLowLevelTerm Map:caAERSv2.2 = MeddraVersion.name > AdverseEvent</p>

Attribute	Notes	Constraints and Tags
		Map:caAERSv2.2 = StudyParticipantAssignment.performance Map:caAERSv2.2 = PreExistingCondition.text > SAEReportPreExistingCondition Map:caAERSv2.2 = AbstractMeddraDomain.version_id Map:caAERSv2.2 = AdverseEvent > AbstractAdverseEventTerm Map:caAERSv2.2 = AdverseEventResponseDescription.causeOfDeath Map:caAERSv2.2 = DiseaseHistory > AbstractStudyDisease Map:caAERSv2.2 = AbstractMeddraDomain.icd9Code Map:caAERSv2.2 = AbstractMeddraDomain.hartsCode Map:CDASHv1.1 = LB.LBORRES Map:CDASHv1.1 = MH.MHOCCUR Map:CDASHv1.1 = DS.DSDECOD Map:CDASHv1.1 = SC.SCPERF Map:CDASHv1.1 = DS.DSTERM Map:CDASHv1.1 = LB.LBORRESU Map:CDASHv1.1 = DV.DVTERM Map:CDASHv1.1 = DV.DVDECOD Map:CDASHv1.1 = AE.AETERM Map:CDASHv1.1 = MH.MHTERM Map:CDASHv1.1 = VS.VSORRESU Map:CDASHv1.1 = PE.PEPPERF Map:CDASHv1.1 = MH.MHCTRL Map:CDASHv1.1 = CM.CMYN Map:CDASHv1.1 = SC.SCORRES Map:CDASHv1.1 = CM.CMOCCUR Map:CDASHv1.1 = AE.AEYN Map:CDASHv1.1 = MH.MHYN Map:CDASHv1.1 = EG.EGPERF Map:CDASHv1.1 = AE.AEOCCUR Map:CDASHv1.1 = PE.PEDESC Map:CDASHv1.1 = AE.AEOUT Map:CDASHv1.1 = EG.EGORRES Map:CDASHv1.1 = DV.DVYN Map:CDASHv1.1 = PE.PERES Map:CDASHv1.1 = VS.VSORRES Map:CTOM = CancerStage.stageCodeSystem Map:CTOM = QualitativeEvaluation.menstrualIndicator Map:CTOM = QualitativeEvaluation.menstrualPatternTypeCode Map:CTOM = QualitativeEvaluation.anamResultAccuracyPercent Map:CTOM = AdverseEvent.outcomeCode Map:CTOM = FemaleReproductiveCharacteristic.firstLiveBirthAge

Attribute	Notes	Constraints and Tags
		Map:CTOM = Specimen.volumeUnitOfMeasureCode Map:CTOM = QualitativeEvaluation.performanceStatusCode Map:CTOM = Person.householdIncomeCode Map:CTOM = Person.employmentStatusCode Map:CTOM = QualitativeEvaluation.painIndexCode Map:CTOM = DeathSummary.deathCauseCode Map:CTOM = Specimen.volume Map:CTOM = DeathSummary.deathCauseText Map:CTOM = QualitativeEvaluation.painIndexCode System Map:CTOM = DiseaseResponse.responseCodeSystem Map:CTOM = LesionEvaluation.evaluationCode Map:CTOM = Diagnosis.diseaseDiagnosisCodeSystem Map:CTOM = FemaleReproductiveCharacteristic.abortionIndicator Map:CTOM = DiseaseResponse.responseCode Map:CTOM = FemaleReproductiveCharacteristic.liveBirthCount Map:CTOM = ParticipantEligibilityAnswer.answerText Map:CTOM = QualitativeEvaluation.survivalStatusDescriptionText Map:CTOM = ClinicalResult.valueUnitOfMeasureCode Map:CTOM = AdverseEvent.descriptionText Map:CTOM = Participant.householdIncomeCode Map:CTOM = CancerStage.stageCode Map:CTOM = ClinicalResult.value Map:CTOM = Participant.employmentStatusCode Map:CTOM = Participant.employmentStatusOtherText Map:CTOM = QualitativeEvaluation.performanceStatusCodeSystem Map:CTOM = QualitativeEvaluation.survivalStatusCode

Attribute	Notes	Constraints and Tags
		Map:CTOM = Diagnosis.diseaseDiagnosisCode Map:CTOM = DiseaseResponse.courseDispositionCode Map:CTOM = Neoplasm.cellTypeCode Map:CTOM = FemaleReproductiveCharacteristic.menopauseAge Map:CTOM = FemaleReproductiveCharacteristic.stillBirthCount Map:CTOM = Histopathology.grossExamResultCode Map:CTRPv3.8 = ObservationResult.resultText Map:CTRPv3.8 = ObservationResult.resultCode Map:CTRPv3.8 = ObservationResult.resultQuantity Map:CTRPv3.8 = ObservationResult.resultIndicator Map:CTRv1.0 = PerformedObservationResult.categoryCode Map:CTRv1.0 = PerformedObservationResult.value Map:DICOM = TID 1410 PlanarROIMeasurements > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 1500 MeasurementReport > Qualitative Evaluations > (unconstrained name/value pair) Map:DICOM = TID 1411 VolumetricROIMeasurements > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > \$QualitativeEvaluation Map:DICOM = TID 300 Measurement > \$Measurement parameter Map:HCTv1.0 = CDE 2685348:Diagnosis.Specify the other type of plasma cell disorder: Map:HCTv1.0 = CDE 3103994:Biological Process.What was the sensitivity of the lymphoma to chemotherapy? Map:HCTv1.0 = CDE 2695347:Lab Results.Second DQ antigen specificity: Map:HCTv1.0 = CDE 2693507:Lab Results.Number of B antigens provided:

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2953097:Lab Results.Serum Calcium Unit of Measure</p> <p>Map:HCTv1.0 = CDE 2738971:Disease, Disorder or Finding.Specify other predisposing condition:</p> <p>Map:HCTv1.0 = CDE 3158590:Medical Records and Forms.What is the indication for CIBMTR recipient ID (CRID) assignment?</p> <p>Map:HCTv1.0 = CDE 2964760:Lab Results.What is the status of B-cell engraftment?</p> <p>Map:HCTv1.0 = CDE 2760831:Diagnosis.Specify the other hematologic diagnosis:</p> <p>Map:HCTv1.0 = CDE 3128022:Diagnosis.Specify other autoimmune disease:</p> <p>Map:HCTv1.0 = CDE 2953026:Lab Results.What is the serum M protein unit of measure?</p> <p>Map:HCTv1.0 = CDE 3017713:Molecular Abnormality.What was the outcome of the cytogenetic analysis?</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Recipient.Recipient body surface area (m²)</p> <p>Map:HCTv1.0 = CDE 3128020:Disease, Disorder or Finding.What was the chronic lymphocytic leukemia histology type?</p> <p>Map:HCTv1.0 = CDE 2649435:Diagnosis.What was the subtype of the non-hodgkin lymphoma diffuse, large B-cell lymphoma?</p> <p>Map:HCTv1.0 = CDE 2967344:Individuals.Number affected:</p> <p>Map:HCTv1.0 = CDE 2771985:Lab Results.Total value of mesenchymal cells:</p> <p>Map:HCTv1.0 = CDE 2787461:Diagnosis.What is the primary disease for which the HSCT was performed?</p> <p>Map:HCTv1.0 = CDE 2760286:Lab Results.Total value of CD34+ cells:</p> <p>Map:HCTv1.0 = CDE 2729902:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the results:</p> <p>Map:HCTv1.0 = CDE 2955919:Lab Results.Specify cell line:</p> <p>Map:HCTv1.0 = CDE 2760790:Diagnosis.Specify the other gastrointestinal diagnosis:</p> <p>Map:HCTv1.0 = CDE 2936204:Abnormal Cell.Were</p>

Attribute	Notes	Constraints and Tags
		<p>cytogenetic abnormalities present at diagnosis?</p> <p>Map:HCTv1.0 = CDE 2861069:Lab Results.What is the unit of measure for serum albumin?</p> <p>Map:HCTv1.0 = CDE 2695343:Lab Results.First DQ antigen specificity:</p> <p>Map:HCTv1.0 = CDE 3061542:Medical Imaging.What were the results of the image studies performed?</p> <p>Map:HCTv1.0 = CDE 2692300:Diagnosis.Specify the other juvenile idiopathic arthritis:</p> <p>Map:HCTv1.0 = CDE 2695025:Lab Results.Test results of infectious disease marker for human T-Lymphotropic virus antibody (Anti-HTLV I / II):</p> <p>Map:HCTv1.0 = CDE 2964762:Lab Results.What is the status of myeloid engraftment?</p> <p>Map:HCTv1.0 = CDE 2967327:Individuals.Are other family members known to have neuroblastoma or ganglioneuroma?</p> <p>Map:HCTv1.0 = CDE 2953024:Lab Results.What is the value of serum monoclonal M protein?</p> <p>Map:HCTv1.0 = CDE 2815349:Disease, Disorder or Finding.How many prior HSCTs have been done?</p> <p>Map:HCTv1.0 = CDE 2704184:Lab Results.Second DQA1* allele designations:</p> <p>Map:HCTv1.0 = CDE 2688923:Diagnosis.What was the classification of plasma cell disorders?</p> <p>Map:HCTv1.0 = CDE 2695088:Lab Results.Test results of infectious disease marker for syphilis using serologic testing for syphilis(STS)</p> <p>Map:HCTv1.0 = CDE 2760760:Diagnosis.What is the gastrointestinal diagnosis type?</p> <p>Map:HCTv1.0 = CDE 3008133:Disease, Disorder or Finding.Specify the cardiac status:</p> <p>Map:HCTv1.0 = CDE 2676555:Involvement and Extent of Disease.What was the stage of the breast cancer at diagnosis?</p> <p>Map:HCTv1.0 = CDE 3179224:Lab Results.Does the recipient have clinical significant zygomycosis fungal infection history?</p> <p>Map:HCTv1.0 = CDE 3028430:Lab Results.What is the value of the enzyme evaluated for activity level?</p> <p>Map:HCTv1.0 = CDE</p>

Attribute	Notes	Constraints and Tags
		<p>2786671:Activity.Was the primary container (e.g.,cord blood unit bag) intact upon thawing?</p> <p>Map:HCTv1.0 = CDE 2950619:Lab Results.Specify monoclonal immunoglobulin result:</p> <p>Map:HCTv1.0 = CDE 2760374:Lab Results.CD4+ cells exponent value:</p> <p>Map:HCTv1.0 = CDE 2950698:Lab Results.What is the lymphoma histology type?</p> <p>Map:HCTv1.0 = CDE 2695021:Lab Results.Test results of infectious disease marker for hepatitis C virus (HCV) antibody (Anti-HCV)</p> <p>Map:HCTv1.0 = CDE 2760306:Lab Results.CD3+ cells exponent value:</p> <p>Map:HCTv1.0 = CDE 2793785:Quality of Life.What was the Karnofsky / Lansky score?</p> <p>Map:HCTv1.0 = CDE 2704175:Lab Results.First DQA1* allele designations:</p> <p>Map:HCTv1.0 = CDE 3181148:Lab Results.Specify neutrophils one decimal place billion per liter value:</p> <p>Map:HCTv1.0 = CDE 2695275:Lab Results.First B antigen specificity:</p> <p>Map:HCTv1.0 = CDE 2797618:Outcome of Therapy.List the maximum severity of acute graft versus host disease skin involvement:</p> <p>Map:HCTv1.0 = CDE 2749843:Lab Results.For the systemic sclerosis, what was the result of the laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 3086814:Lab Results.What is the oxygen saturation level percentage?</p> <p>Map:HCTv1.0 = CDE 2871885:Procedures.What is the cm H₂O value of the cerebrospinal fluid closing pressure:</p> <p>Map:HCTv1.0 = CDE 2780726:Lab Results.Chimerism study total number of donor cells:</p> <p>Map:HCTv1.0 = CDE 2744521:Techniques.Specify portion manipulated:</p> <p>Map:HCTv1.0 = CDE 2785867:Activity.Was the cord blood unit completely frozen when it arrived at your center?</p> <p>Map:HCTv1.0 = CDE 2760540:Diagnosis.Specify the other CNS / psychiatric diagnosis:</p> <p>Map:HCTv1.0 = CDE 2686104:Diagnosis.Specify the other hemoglobinopathy:</p> <p>Map:HCTv1.0 = CDE 2985301:Lab Results.Specify the chimerism</p>

Attribute	Notes	Constraints and Tags
		laboratory procedure cell type: Map:HCTv1.0 = CDE 3115777:Lab Results.What was the serum alpha-fetoprotein value? Map:HCTv1.0 = CDE 2953272:Individuals.Specify other health insurance: Map:HCTv1.0 = CDE 2965430:Symptoms.Did chronic diarrhea occur ? Map:HCTv1.0 = CDE 3073243:Lab Results.What is the reason for the DPA1 alleles missing value? Map:HCTv1.0 = CDE 2897746:Lab Results.What is the percent of basophils? Map:HCTv1.0 = CDE 2952892:Lab Results.Serum free light chains (kappa): Map:HCTv1.0 = CDE 2780118:Lab Results.What is the value of hemoglobin? Map:HCTv1.0 = CDE 2682630:Diagnosis.What was the W.H.O classification of the acute myelogenous leukemia (AML) or acute nonlymphocytic leukemia (ANLL)? Map:HCTv1.0 = CDE 2782552:Adverse Events.Specify the other hematopoietic stem cell infusion adverse event type Map:HCTv1.0 = CDE 2793799:Diagnosis.Diagnosis of chronic GVHD was based on: Map:HCTv1.0 = CDE 2799093:Lab Results.What is the unit of measure for platelets? Map:HCTv1.0 = CDE 3118470:Medical Records and Forms.Search result: Map:HCTv1.0 = CDE 2005035:Lab Results.Hemoglobin Map:HCTv1.0 = CDE 2954522:Involvement and Extent of Disease.Specify the lymphoma stage of organ involvement: Map:HCTv1.0 = CDE 3073233:Lab Results.What is the reason for the DRB5 alleles missing value? Map:HCTv1.0 = CDE 2686182:Lab Results.For the systemic lupus erythematosus, what was the ANA test result? Map:HCTv1.0 = CDE 2974091:Involvement and Extent of Disease.Specify the Evans Stage: Map:HCTv1.0 = CDE 2760898:Diagnosis.Specify the other pulmonary diagnosis: Map:HCTv1.0 = CDE 3123937:Lab

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		<p>Results.What is the eosinophils percentage value? Map:HCTv1.0 = CDE 2861067:Lab Results.Serum albumin value: Map:HCTv1.0 = CDE 2974113:Disease, Disorder or Finding.What was the aplastic anemia etiology? Map:HCTv1.0 = CDE 3020044:Disease, Disorder or Finding.What is the central nervous system abnormality type? Map:HCTv1.0 = CDE 2686200:Lab Results.What was the CPK test result? Map:HCTv1.0 = CDE 2952921:Lab Results.What is the value of serum creatinine? Map:HCTv1.0 = CDE 2760127:Lab Results.Total value of mononucleated cells: Map:HCTv1.0 = CDE 2932807:Disease, Disorder or Finding.Specify prior disease: Map:HCTv1.0 = CDE 2971688:Lab Results.Specify level and units: Map:HCTv1.0 = CDE 2003853:Pre-Preparative Regimen.Performance Status Map:HCTv1.0 = CDE 2675085:Diagnosis.Specify the type of acute lymphoblastic leukemia (ALL): Map:HCTv1.0 = CDE 2558043:Disease Response.What was the recipient's survival status at latest follow-up? Map:HCTv1.0 = CDE 2802770:Lab Results.Specify cluster of differentiation type: Map:HCTv1.0 = CDE 2775872:Lab Results.What is the value of WBC: Map:HCTv1.0 = CDE 2871881:Lab Results.What is the cm H2O value of the cerebrospinal fluid opening pressure: Map:HCTv1.0 = CDE 2695297:Lab Results.Second C antigen specificity: Map:HCTv1.0 = CDE 2694887:Lab Results.First DPB1* allele designations: Map:HCTv1.0 = CDE 2695029:Lab Results.Test results of infectious disease marker for human immunodeficiency virus(HIV)-1 p24 antigen: Map:HCTv1.0 = CDE 2952923:Lab Results.Serum free light chains (lambda): Map:HCTv1.0 = CDE 2770355:Lab Results.Was the disease detected by molecular analysis? Map:HCTv1.0 = CDE</p>

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		<p>2729065:Adverse Events.If the donor died as a result of the collection, specify the cause of death: Map:HCTv1.0 = CDE 2729161:Lab Results.Total volume of product: Map:HCTv1.0 = CDE</p> <p>2798687:Chronic or Associated Diseases and Exposures.How many years did the recipient smoke cigarettes? Map:HCTv1.0 = CDE</p> <p>2760532:Diagnosis.What is the CNS / psychiatric diagnosis type? Map:HCTv1.0 = CDE</p> <p>2797534:Diagnosis.Specify the clinical sign, symptom or evaluation used to diagnose liver toxicity: Map:HCTv1.0 = CDE 2799091:Lab Results.What is the value of platelets? 0 Map:HCTv1.0 = CDE</p> <p>2760473:Diagnosis.Specify the chromosome abnormality: Map:HCTv1.0 = CDE 2965920:Lab Results.What is the IgA level? Map:HCTv1.0 = CDE 2967232:Lab Results.What is the value of homovanillic acid? Map:HCTv1.0 = CDE 2802820:Lab Results.What is the value of the cluster of differentiation? Map:HCTv1.0 = CDE</p> <p>3158540:Therapies.Specify other indication for cellular therapy: Map:HCTv1.0 = CDE</p> <p>2739534:Adverse Events.What type of Adverse Events were associated with the stem cell infusion? Map:HCTv1.0 = CDE 2974108:Lab Results.What was the gamma-enolase value ? Map:HCTv1.0 = CDE 2936025:Lab Results.Results of cytogenetic testing: Map:HCTv1.0 = CDE 2693554:Lab Results.First C* allele designations: Map:HCTv1.0 = CDE</p> <p>2785810:Involvement and Extent of Disease.What was the maximum extent of chronic GVHD during this period? Map:HCTv1.0 = CDE 2952877:Lab Results.Urinary monoclonal light chains: Map:HCTv1.0 = CDE</p> <p>2494701:Pre-Preparative Regimen.Which scale was used to measure/report the functional status? Map:HCTv1.0 = CDE 2634620:Lab Results.Hepatitis A antibody status Map:HCTv1.0 = CDE 2704246:Lab Results.First DP antigen specificity:</p>

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2974069:Invvolvement and Extent of Disease.What is the Pediatric Oncology Group Stage?</p> <p>Map:HCTv1.0 = CDE 2950911:Lab Results.Is the histology a transformation from CLL?</p> <p>Map:HCTv1.0 = CDE 3073235:Lab Results.What is the reason for the DQB1 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2939332:Organ Measurements.What was the spleen size?</p> <p>Map:HCTv1.0 = CDE 3010717:Diagnosis.What is the inheritance of immune deficiency?</p> <p>Map:HCTv1.0 = CDE 2679790:Disease, Disorder or Finding.Specify the other inherited platelet abnormalities:</p> <p>Map:HCTv1.0 = CDE 2760808:Diagnosis.Specify the other genitourinary diagnosis:</p> <p>Map:HCTv1.0 = CDE 3086799:Lab Results.What is the value of serum IgG?</p> <p>Map:HCTv1.0 = CDE 2686171:Diagnosis.Specify the other autoimmune cytopenia:</p> <p>Map:HCTv1.0 = CDE 2951827:Diagnosis.What was the result of the PET assessment?</p> <p>Map:HCTv1.0 = CDE 3181250:Lab Results.Specify drug level:</p> <p>Map:HCTv1.0 = CDE 2704199:Lab Results.Number of DP antigens provided:</p> <p>Map:HCTv1.0 = CDE 3076040:Lab Results.What is the percentage of monocytes?</p> <p>Map:HCTv1.0 = CDE 2748995:Techniques.Was a particular tumor cell detection method used after purging?</p> <p>Map:HCTv1.0 = CDE 2695328:Lab Results.Number of DQ antigens provided:</p> <p>Map:HCTv1.0 = CDE 2773882:Lab Results.CD8+ cells exponent value:</p> <p>Map:HCTv1.0 = CDE 2756919:Lab Results.What is the value of the immunoglobulin test?</p> <p>Map:HCTv1.0 = CDE 3024868:Disease, Disorder or Finding.Were the exam results normal or abnormal?</p> <p>Map:HCTv1.0 = CDE 2675091:Diagnosis.Specify the type of other acute leukemia:</p> <p>Map:HCTv1.0 = CDE 2953262:Individuals.Specify the type</p>

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		<p>of health insurance:</p> <p>Map:HCTv1.0 = CDE 2875642:Individuals.Weight</p> <p>Map:HCTv1.0 = CDE 2967294:Anatomic Sites.Number of tumors present:</p> <p>Map:HCTv1.0 = CDE 2689280:Involvement and Extent of Disease.What was the International Staging System for Myeloma Stage?</p> <p>Map:HCTv1.0 = CDE 2784429:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 1st organism with name(s):</p> <p>Map:HCTv1.0 = CDE 2986435:Disease, Disorder or Finding.What was the prognosis type of seminoma?</p> <p>Map:HCTv1.0 = CDE 2951780:Lab Results.Heavy chain</p> <p>Map:HCTv1.0 = CDE 2760372:Lab Results.Total value of CD4+ cells:</p> <p>Map:HCTv1.0 = CDE 3136597:Biological Process.What was the sensitivity of the disease to chemotherapy?</p> <p>Map:HCTv1.0 = CDE 2953285:Affiliation Type.Is the person enrolled in school?</p> <p>Map:HCTv1.0 = CDE 2952925:Lab Results.What is the unit of measure for serum immunoglobulin light chain lambda?</p> <p>Map:HCTv1.0 = CDE 2769602:Adverse Events.Specify other illness cause of the adverse event:</p> <p>Map:HCTv1.0 = CDE 2760382:Lab Results.When the colony-forming units (CFU) were assessed, what was the total number of CFU-GM counted?</p> <p>Map:HCTv1.0 = CDE 2957553:Lab Results.Specify abnormality:</p> <p>Map:HCTv1.0 = CDE 2801066:Diagnosis.Specify the diagnosis of liver toxicity by the type of clinical signs, symptoms or evaluation:</p> <p>Map:HCTv1.0 = CDE 3061152:Lab Results.What is the percentage of hematocrit?</p> <p>Map:HCTv1.0 = CDE 2798679:Property or Attribute.Have you smoked cigarettes within the past year?</p> <p>Map:HCTv1.0 = CDE 2950700:Lab Results.Specify the lymphoma histology:</p> <p>Map:HCTv1.0 = CDE 2780721:Lab Results.Chimerism study total cells</p>

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		<p>examined:</p> <p>Map:HCTv1.0 = CDE 2991013:Lab Results.What is the unit of measure for leukocyte enzyme activity level?</p> <p>Map:HCTv1.0 = CDE 2964752:Lab Results.What is the status of T-cell engraftment?</p> <p>Map:HCTv1.0 = CDE 2953022:Specimen Characteristics.Specify the size of the largest neoplasm mass:</p> <p>Map:HCTv1.0 = CDE 2695256:Lab Results.1st A antigen specificity:</p> <p>Map:HCTv1.0 = CDE 2737648:Disease, Disorder or Finding.What was the cause of the therapy related AML?</p> <p>Map:HCTv1.0 = CDE 2679802:Diagnosis.Specify the type of autoimmune disease:</p> <p>Map:HCTv1.0 = CDE 2002710:Chronic or Associated Diseases and Exposures.Specify other</p> <p>Map:HCTv1.0 = CDE 2695078:Lab Results.Test results of infectious disease marker for Anti-HIV 1 and anti-HIV 2 (antibodies to Human Immunodeficiency Viruses):</p> <p>Map:HCTv1.0 = CDE 2963361:Lab Results.Was the diagnostic image positive for CNS tumor?</p> <p>Map:HCTv1.0 = CDE 2705046:Lab Results.First DRB3* allele designations:</p> <p>Map:HCTv1.0 = CDE 2679527:Diagnosis.Specify the type of other solid tumor:</p> <p>Map:HCTv1.0 = CDE 2950614:Lab Results.What was the status of the serum immunofixation finding?</p> <p>Map:HCTv1.0 = CDE 2798745:Occurrences.Specify the other malignancy(ies):</p> <p>Map:HCTv1.0 = CDE 2859803:Lab Results.Plasma cells in blood percentage value:</p> <p>Map:HCTv1.0 = CDE 2704143:Lab Results.Second DRB5 * allele designations:</p> <p>Map:HCTv1.0 = CDE 3128032:Symptoms.What were the chronic lymphocytic leukemia symptoms?</p> <p>Map:HCTv1.0 = CDE 2695323:Lab Results.Second DR antigen specificity:</p> <p>Map:HCTv1.0 = CDE 2760303:Lab Results.Total value of CD3+ cells:</p> <p>Map:HCTv1.0 = CDE 3086802:Units of Measure.What is the unit of measure for serum IgG?</p>

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2789977:Personal attributes.Donor's blood type and Rh factor: Map:HCTv1.0 = CDE 2686163:Diagnosis.Specify the other autoimmune neurological disorder: Map:HCTv1.0 = MD Anderson Specific Content: Product.Transgene % Map:HCTv1.0 = CDE 2860221:Lab Results.Absolute number of plasma cells in blood value: Map:HCTv1.0 = CDE 2180456:Lab Results.Hepatitis B surface antibody Status Map:HCTv1.0 = CDE 3123936:Disease, Disorder or Finding.What is the result of the audiometric test assessed at the speech threshold for 2000 hertz? Map:HCTv1.0 = CDE 2986478:Disease, Disorder or Finding.Specify testicular non-seminomatous germ cell tumor prognosis: Map:HCTv1.0 = CDE 3179200:Lab Results.Does the recipient have clinical significant aspergillus fungal infection history? Map:HCTv1.0 = CDE 2974120:Disease, Disorder or Finding.Specify viral hepatitis type: Map:HCTv1.0 = CDE 2704135:Lab Results.DR51 specificity present? Map:HCTv1.0 = CDE 2181363:Diagnosis.Durie-Salmon Stage Map:HCTv1.0 = CDE 2695284:Lab Results.Second B antigen specificity: Map:HCTv1.0 = CDE 2952899:Lab Results.What is the unit of measure for serum immunoglobulin light chain, Kappa? Map:HCTv1.0 = CDE 2965922:Lab Results.What is the IgE level? Map:HCTv1.0 = CDE 2772026:Disease, Disorder or Finding.Specify genetic disease: Map:HCTv1.0 = CDE 2784431:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 2nd organism with name(s): Map:HCTv1.0 = CDE 2677074:Disease, Disorder or Finding.If the breast cancer was in the state of relapse at the time of transplantation, what was the sensitivity to chemotherapy? Map:HCTv1.0 = CDE 2770702:Biological Process.Specify</p>

Attribute	Notes	Constraints and Tags
		<p>the etiology of the other organism: Map:HCTv1.0 = CDE 2689272:Diagnosis.What was the classification of the immune deficiency? Map:HCTv1.0 = CDE 3009207:Disease, Disorder or Finding.Specify the hematologic status: Map:HCTv1.0 = CDE 3073220:Lab Results.What is the reason for the B alleles missing value? Map:HCTv1.0 = CDE 2749839:Lab Results.Were tumor cells detected in collected cells, before purging prior to HSCT? Map:HCTv1.0 = CDE 2694901:Lab Results.Second DPB1* allele designations: Map:HCTv1.0 = CDE 2691376:Lab Results.For the polymyositis-dermatomyositis, were the EMG results typical of the disease? Map:HCTv1.0 = CDE 2760129:Lab Results.Mononucleated cells exponent value: Map:HCTv1.0 = CDE 3010917:Diagnosis.What is the type of Batten disease? Map:HCTv1.0 = CDE 2676557:Diagnosis.Was the breast cancer inflammatory or non-inflammatory? Map:HCTv1.0 = CDE 2795420:Lab Results.Did the recipient recover and maintain ANC greater than or equal to 500/mmE3 following the decline? Map:HCTv1.0 = CDE 2815530:Individuals.What is the combined houseould gross annual income? Map:HCTv1.0 = CDE 3117210:Lab Results.Specify the testicular cancer stage: Map:HCTv1.0 = CDE 2756925:Lab Results.What is the unit of measure for the Ig test? Map:HCTv1.0 = CDE 2693547:Lab Results.Second B* allele designations: Map:HCTv1.0 = CDE 2969090:Lab Results.What is the value of vanillylmandelic acid measurement? Map:HCTv1.0 = CDE 2782608:Lab Results.What is the unit of measure for AST (SGOT)? Map:HCTv1.0 = CDE 2677067:Disease Response.Specify the type of complete remission of the breast cancer at the time of transplantation:</p>

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2769598:Adverse Events.What is the most likely cause of the adverse event?</p> <p>Map:HCTv1.0 = CDE 2760860:Diagnosis.What is the liver diagnosis type?</p> <p>Map:HCTv1.0 = CDE 2782511:Symptoms.Specify the symptoms of engraftment syndrome:</p> <p>Map:HCTv1.0 = CDE 2963549:Lab Results.Did hypercalcemia occur?</p> <p>Map:HCTv1.0 = CDE 2738465:Disease, Disorder or Finding.What was the cause of the therapy-related MDS/MPS?</p> <p>Map:HCTv1.0 = CDE 64516//:Lab Results.Provide DNA Index of Leukemic Cells</p> <p>Map:HCTv1.0 = CDE 2693524:Lab Results.First A* allele designations:</p> <p>Map:HCTv1.0 = CDE 2969591:Involvement and Extent of Disease.What was the stage of breast cancer at diagnosis?</p> <p>Map:HCTv1.0 = CDE 2784433:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 3rd organism with name(s):</p> <p>Map:HCTv1.0 = CDE 2979356:Diagnosis.Specify the ratio of HER2 signals to 17 centromere signals:</p> <p>Map:HCTv1.0 = CDE 2685380:Diagnosis.Specify the other type of leukemia:</p> <p>Map:HCTv1.0 = CDE 2780171:Lab Results.Chimerism study cell type:</p> <p>Map:HCTv1.0 = CDE 3179231:Lab Results.Does the recipient have clinical significant rhizopus fungal infection history?</p> <p>Map:HCTv1.0 = CDE 3028423:Lab Results.Indicate the enzyme that was evaluated for activity level:</p> <p>Map:HCTv1.0 = CDE 2682913:Lab Results.For the systemic lupus erythematosus, what was the test results at diagnosis for the other antibody?</p> <p>Map:HCTv1.0 = CDE 2815190:Personal attributes.What is the person's retirement income status?</p> <p>Map:HCTv1.0 = CDE 2816459:Behavior.What is the average number of packs of cigarettes smoked per day?</p> <p>Map:HCTv1.0 = CDE 2771987:Lab Results.Mesenchymal cells exponent value:</p>

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		<p>Map:HCTv1.0 = CDE 2689329:Lab Results.For systemic lupus, erythematosus, what was the total complement test result?</p> <p>Map:HCTv1.0 = CDE 3179295:Lab Results.Does the recipient have clinical significant zygomycota fungal infection history?</p> <p>Map:HCTv1.0 = CDE 3104029:Lab Results.ER % cells stained positive:</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.CD19%</p> <p>Map:HCTv1.0 = CDE 2964425:Diagnosis.Specify the histological diagnosis of resected tissue</p> <p>Map:HCTv1.0 = CDE 2983177:Lab Results.Specify the proliferative index value:</p> <p>Map:HCTv1.0 = CDE 2784437:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 5th organism with name(s):</p> <p>Map:HCTv1.0 = CDE 2704139:Lab Results.First DRB5 * allele designations:</p> <p>Map:HCTv1.0 = CDE 2875701:Physical Description of Individuals.What is the dosing body weight unit of measure?</p> <p>Map:HCTv1.0 = CDE 2695308:Lab Results.First DR antigen specificity:</p> <p>Map:HCTv1.0 = CDE 2962097:Disease, Disorder or Finding.Was there a family history of cancer in first degree relatives under 40 years of age?</p> <p>Map:HCTv1.0 = CDE 2749801:Lab Results.Were tumor cells detected in bone marrow, in the interval between last systemic therapy and collection prior to HSCT?</p> <p>Map:HCTv1.0 = CDE 2180578:Disease, Disorder or Finding.Left Ventricular Ejection Fraction at Rest</p> <p>Map:HCTv1.0 = CDE 2860225:Lab Results.Absolute number of plasma cells in blood unit of measure:</p> <p>Map:HCTv1.0 = CDE 2693528:Lab Results.Second A* allele designations:</p> <p>Map:HCTv1.0 = CDE 2978596:Lab Results.Specify estrogen receptor assay results:</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.Regulatory T cells</p> <p>Map:HCTv1.0 = CDE 2760290:Lab Results.CD34+ cells exponent value:</p> <p>Map:HCTv1.0 = CDE</p>

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		<p>2769017:Involvement and Extent of Disease.Primary cause of death: Map:HCTv1.0 = CDE 2866117:Lab Results.Cerebrospinal fluid(CSF) total protein value: Map:HCTv1.0 = MD Anderson Specific Content: Product.Hematopoietic stem cells Map:HCTv1.0 = CDE 2182896:Chronic or Associated Diseases and Exposures.Have you smoked at least 100 cigarettes in your entire life? Map:HCTv1.0 = CDE 2968377:Individuals.What was the other genetic disorder in the first degree relative? Map:HCTv1.0 = MD Anderson Specific Content: Product.Mesenchymal cells Map:HCTv1.0 = CDE 2954716:Outcome of Therapy.Specify the sensitivity of myeloma to chemotherapy: Map:HCTv1.0 = CDE 2749870:Lab Results.For the antiphospholipid syndrome, what was the result of the laboratory procedure? Map:HCTv1.0 = CDE 2704223:Lab Results.Second DPA1* allele designations: Map:HCTv1.0 = CDE 2705050:Lab Results.Second DRB3* allele designations: Map:HCTv1.0 = CDE 2693560:Lab Results.Second C* allele designations: Map:HCTv1.0 = CDE 2760378:Specimen Characteristics.Was the cell viability tested? Map:HCTv1.0 = CDE 2986573:Outcome of Therapy.Indicate the sensitivity of the testicular carcinoma to any platinum-containing chemotherapeutic agent administered: Map:HCTv1.0 = CDE 2695096:Lab Results.Test results of infectious disease marker for west nile virus (WNV) using nucleic acid amplification test (NAT) Map:HCTv1.0 = CDE 2691365:Lab Results.For the polymyositis-dermatomyositis, were the biopsy results typical of the disease? Map:HCTv1.0 = CDE 2804619:Data Source.Is the data reported on this form based on contact with the physician? Map:HCTv1.0 = CDE 2802822:Lab Results.What is the unit of measure for </p>

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		<p>the cluster of differentiation?</p> <p>Map:HCTv1.0 = CDE 3073228:Lab Results.What is the reason for the DRB4 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2986315:Lab Results.Specify malignant testicular germ cell tumor histology:</p> <p>Map:HCTv1.0 = CDE 2797508:Involvement and Extent of Disease.Specify any other non-infectious pulmonary abnormalities that developed:</p> <p>Map:HCTv1.0 = CDE 3188446:Diagnosis.Specify the enzyme deficiency:</p> <p>Map:HCTv1.0 = CDE 2434914:Eligibility.Menopausal status</p> <p>Map:HCTv1.0 = CDE 2737130:Disease, Disorder or Finding.What was the clinically significant co-existing disease or organ impairment?</p> <p>Map:HCTv1.0 = CDE 2784435:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 4th organism with name(s):</p> <p>Map:HCTv1.0 = CDE 2769114:Involvement and Extent of Disease.Contributing cause of death:</p> <p>Map:HCTv1.0 = CDE 2630453:Lab Results.Specify test results for test performed on other infectious disease marker</p> <p>Map:HCTv1.0 = CDE 2749841:Lab Results.For the systemic sclerosis, what was the laboratory procedure type?</p> <p>Map:HCTv1.0 = CDE 3031295:Lab Results.What is the value of urinary monoclonal light chains?</p> <p>Map:HCTv1.0 = CDE 3073237:Lab Results.What is the reason for the DPB1 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2695304:Lab Results.Number of DR antigens provided</p> <p>Map:HCTv1.0 = CDE 2514317:Diagnosis.CML Lineage</p> <p>Map:HCTv1.0 = CDE 2704098:Lab Results.Bw4 specificity present?</p> <p>Map:HCTv1.0 = CDE 2685162:Diagnosis.Specify the other histiocytic disorder:</p> <p>Map:HCTv1.0 = CDE 2676358:Therapies.Did graft failure occur?</p> <p>Map:HCTv1.0 = CDE 2986513:Outcome of Therapy.What was the sensitivity of the testicular carcinoma to chemotherapy?</p>

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		<p>Map:HCTv1.0 = CDE 2739683:Therapy Results.Was a complete remission (CR) ever achieved in response to the HSCT?</p> <p>Map:HCTv1.0 = CDE 2695074:Procedures.Was FDA licensed nucleic acid amplification test (NAT) for hepatitis C virus performed; specify results</p> <p>Map:HCTv1.0 = CDE 2704125:Lab Results.Second DRB4* allele designations:</p> <p>Map:HCTv1.0 = CDE 3061554:Lab Results.Serum beta-human chorionic gonadotropin value:</p> <p>Map:HCTv1.0 = CDE 2677079:Diagnosis.What was the classification of the other malignancy?</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Transplant.Total number of cells infused</p> <p>Map:HCTv1.0 = CDE 2603692:Outcome of Therapy.What was the maximum Grade of acute graft versus host disease</p> <p>Map:HCTv1.0 = CDE 3030987:Lab Results.What is the value of serum free light chains lambda?</p> <p>Map:HCTv1.0 = CDE 2795147:Lab Results.What is the percentage of neutrophils?</p> <p>Map:HCTv1.0 = CDE 2679800:Diagnosis.Specify the other inherited disorder of metabolism:</p> <p>Map:HCTv1.0 = CDE 2815058:Personal attributes.Is the person an adult or emancipated minor?</p> <p>Map:HCTv1.0 = CDE 2974122:Disease, Disorder or Finding.Specify other aplastic anemia etiology:</p> <p>Map:HCTv1.0 = CDE 2939877:Diagnosis.Specify the number of phases experienced:</p> <p>Map:HCTv1.0 = CDE 2775874:Lab Results.What is the unit of measure for WBC?</p> <p>Map:HCTv1.0 = CDE 2760821:Diagnosis.What is the hematologic diagnostic type?</p> <p>Map:HCTv1.0 = CDE 3126069:Procedures.What was the visual eye acuity snellen fraction numerator?</p> <p>Map:HCTv1.0 = CDE 3181117:Lab Results.Specify paroxysmal nocturnal hemoglobinuria results:</p> <p>Map:HCTv1.0 = CDE 2798766:Lab Results.What is the LDH lab value?</p> <p>Map:HCTv1.0 = CDE 3009223:Disease, Disorder or</p>

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		<p>Finding.Specify the renal status: Map:HCTv1.0 = CDE 3141318:Lab Results.Specify test sensitivity to cross-linking agents test results: Map:HCTv1.0 = CDE 2002838:Procedures.Total number of axillary lymph nodes examined Map:HCTv1.0 = CDE 2685168:Diagnosis.What was the classification of the inherited disorders of metabolism / osteopetrosis? Map:HCTv1.0 = CDE 2986133:Lab Results.What is the value of leukocyte enzyme activity level? Map:HCTv1.0 = MD Anderson Specific Content: Product.CD3% Map:HCTv1.0 = CDE 2760804:Diagnosis.What is the genitourinary diagnosis type? Map:HCTv1.0 = CDE 2685158:Diagnosis.What was the classification of the histiocytic disorder? Map:HCTv1.0 = CDE 2688790:Diagnosis.What was the classification of the chronic myelogenous leukemia (Philadelphia chromosome+, Ph+, t(9;22)(q34;q11), or variant OR bcrabl+)? Map:HCTv1.0 = CDE 2594609:Lab Results.Was the lymphoma or lymphoproliferative disease EBV positive? Map:HCTv1.0 = CDE 2935457:Disease Response.Specify the degree of disease response to treatment(s): Map:HCTv1.0 = CDE 2737638:Disease, Disorder or Finding.Specify the other type of clinically significant comorbidity: Map:HCTv1.0 = CDE 2688882:Diagnosis.What is the classification of the other leukemia? Map:HCTv1.0 = CDE 2911999:Diagnosis.What was the classification of the aplastic anemia? Map:HCTv1.0 = CDE 2749826:Lab Results.Were tumor cells detected in circulating blood cells prior to HSCT? Map:HCTv1.0 = CDE 2760905:Diagnosis.Specify the other diagnosis: Map:HCTv1.0 = CDE 2895871:Disease, Disorder or Finding.What type of the cell origin of the new malignancy is it? Map:HCTv1.0 = CDE 2685390:Diagnosis.Specify the other constitutional anemia: Map:HCTv1.0 = CDE 2538920:Units </p>

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		of Measure.Height Unit of Measure UCUM Code Map:HCTv1.0 = CDE 2693568:Lab Results.Test results of infectious disease marker for hepatitis B virus (HBV) surface antigen(HBsAg) Map:HCTv1.0 = CDE 3050012:Techniques.Specify portion of cells cryopreserved prior to infusion Map:HCTv1.0 = CDE 2965306:Disease, Disorder or Finding.What is the cause of disease type ? Map:HCTv1.0 = CDE 2769129:Involvement and Extent of Disease.Specify contributing cause of death: Map:HCTv1.0 = CDE 2685046:Disease Response.If there was a relapse of hodgkin lymphoma at the time of transplantation, what was the sensitivity to chemotherapy? Map:HCTv1.0 = CDE 2760451:Diagnosis.What is the chromosome abnormality diagnosis type? Map:HCTv1.0 = CDE 2939856:Disease, Disorder or Finding.How many blast phases occurred? Map:HCTv1.0 = CDE 2704262:Therapy Doses.Was the entire volume of product infused? Map:HCTv1.0 = CDE 2686194:Lab Results.For the systemic lupus erythematosus, what was the C3 test result? Map:HCTv1.0 = CDE 2798645:Personal attributes.What is the blood type and Rh factor? Map:HCTv1.0 = CDE 3021261:Quality of Life.What is the value of the mental process development assessment score? Map:HCTv1.0 = CDE 3124170:Lab Results.Did any cytogenetic or molecular testing for BCR/ABL or Ph+ show a positive result? Map:HCTv1.0 = CDE 3212384:Lab Results.Were donor cells present as determined by non-quantitative means? Map:HCTv1.0 = CDE 2760281:Diagnosis.What is the cardiovascular diagnosis type? Map:HCTv1.0 = CDE 2939337:Lab Results.Specify which type of cytogenetic and or molecular abnormalities showed a positive result: Map:HCTv1.0 = CDE 2675089:Diagnosis.What was the

Attribute	Notes	Constraints and Tags
		<p>W.H.O. classification of the other acute leukemia?</p> <p>Map:HCTv1.0 = CDE 2677061:Disease, Disorder or Finding.If the breast cancer was in the state of relapse at the time of transplantation, what was the number of the relapse?</p> <p>Map:HCTv1.0 = CDE 2729172:Lab Results.What was the unit of measure for the total volume of the product being analyzed?</p> <p>Map:HCTv1.0 = CDE 2977753:Lab Results.Specify the histologic findings by Shimada classification:</p> <p>Map:HCTv1.0 = CDE 2867504:Lab Results.Serum creatinine 2 decimal place value:</p> <p>Map:HCTv1.0 = CDE 2784439:Lab Results.For the bacterial or fungal infection cultures performed prior to infusion, specify the 6th organism with name(s):</p> <p>Map:HCTv1.0 = CDE 3024910:Disease, Disorder or Finding.What is the percentage of ejection fraction?</p> <p>Map:HCTv1.0 = CDE 2634596:Lab Results.Hepatitis B - DNA status</p> <p>Map:HCTv1.0 = CDE 2749876:Lab Results.For the wegener granulomatosis, what was the result of the laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 3135354:Organ Measurements.Specify the spleen size below costal margin in centimeters:</p> <p>Map:HCTv1.0 = CDE 2769651:Individuals.What is the number of pregnancies?</p> <p>Map:HCTv1.0 = CDE 2967358:Individuals.Is there a family history of other genetic diseases in first-degree blood relatives?</p> <p>Map:HCTv1.0 = CDE 2965488:Lab Results.What is the mitogen proliferation response?</p> <p>Map:HCTv1.0 = CDE 2760234:Lab Results.Total value of nucleated cells:</p> <p>Map:HCTv1.0 = CDE 3057303:Quality of Life.What was the Vineland adaptive behavior scales value?</p> <p>Map:HCTv1.0 = CDE 2782521:Lab Results.Was the disease detected by cytogenetic analysis?</p> <p>Map:HCTv1.0 = CDE 3028432:Lab Results.What is the unit of measure for enzyme evaluated for activity level?</p> <p>Map:HCTv1.0 = CDE 3181189:Lab Results.Specify reticulocytes one decimal place billion per liter value:</p>

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		<p>Map:HCTv1.0 = CDE 2681691:Chronic or Associated Diseases and Exposures.What was the recipient's test results for the presence of CMV-antibodies?(Chronic)</p> <p>Map:HCTv1.0 = CDE 2760261:Lab Results.Nucleated cells exponent value:</p> <p>Map:HCTv1.0 = CDE 2768641:Outcome of Therapy.Specify the other HSCT related main cause(s) of death:</p> <p>Map:HCTv1.0 = CDE 2797645:Outcome of Therapy.List the maximum severity of the acute graft versus host disease upper intestinal tract involvement:</p> <p>Map:HCTv1.0 = CDE 2760294:Diagnosis.Specify the other cardiovascular diagnosis:</p> <p>Map:HCTv1.0 = CDE 2685066:Diagnosis.Specify the type of other B-cell lymphoma:</p> <p>Map:HCTv1.0 = CDE 2646370:Lab Results.PgR % cells stained positive</p> <p>Map:HCTv1.0 = CDE 2965492:Lab Results.What is the natural killer cell function?</p> <p>Map:HCTv1.0 = CDE 2679566:Disease, Disorder or Finding.What was the classification of the platelet disorder?</p> <p>Map:HCTv1.0 = CDE 2494565:Diagnosis.What was the primary disease for which the HSCT was performed?</p> <p>Map:HCTv1.0 = CDE 2787346:Disease, Disorder or Finding.Specify the result of the diagnosis based on evidence from the biopsy (histology):</p> <p>Map:HCTv1.0 = CDE 2871879:Lab Results.Was the cerebrospinal fluid opening pressure known?</p> <p>Map:HCTv1.0 = CDE 2965208:Lab Results.What is the percentage of lymphocytes?</p> <p>Map:HCTv1.0 = CDE 2676535:Biological Process.If there was a relapse of non-hodgkin lymphoma at the time of transplantation, what was the sensitivity to chemotherapy?</p> <p>Map:HCTv1.0 = CDE 2797722:Involvement and Extent of Disease.Specify the other non-infectious liver toxicity:</p> <p>Map:HCTv1.0 = CDE 2686127:Diagnosis.Specify the other immune deficiency:</p> <p>Map:HCTv1.0 = CDE</p>

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		<p>2760867:Diagnosis.Specify the other liver disease diagnosis: Map:HCTv1.0 = CDE 2861046:Lab Results.What is the percent of blasts in blood?</p> <p>Map:HCTv1.0 = CDE 2962060:Involvement and Extent of Disease.What was the extent stage of the CNS tumor?</p> <p>Map:HCTv1.0 = CDE 3030985:Lab Results.What is the value of serum free light chains (kappa): Map:HCTv1.0 = CDE 2002839:Lab Results.Number of positive axillary lymph nodes</p> <p>Map:HCTv1.0 = CDE 2695060:Lab Results.If FDA licensed nucleic acid amplification test (NAT) for human immunodeficiency virus(HIV)-1 performed; specify results Map:HCTv1.0 = CDE 3008193:Disease, Disorder or Finding.Specify the hepatic status: Map:HCTv1.0 = CDE 2771967:Lab Results.NK cells exponent value: Map:HCTv1.0 = CDE 2681693:Pre-Preparative Regimen.What was the donor test results for the presence of CMV-antibodies? Map:HCTv1.0 = CDE 3123697:Disease, Disorder or Finding.What were the results for the tympanometry assessment? Map:HCTv1.0 = CDE 2180758:Disease, Disorder or Finding.Shortening Fraction Map:HCTv1.0 = CDE 2969596:Diagnosis.Specify breast cancer histology: Map:HCTv1.0 = CDE 2961440:Lab Results.What is the stroma-rich histology? Map:HCTv1.0 = CDE 2965903:Lab Results.What is the IgM level? Map:HCTv1.0 = CDE 3057316:Lab Results.What is the value of the cerebrospinal fluid total protein measurement? Map:HCTv1.0 = CDE 2950916:Lab Results.Immunochemical Type Map:HCTv1.0 = CDE 2686188:Lab Results.For the systemic lupus erythematosus, what was the ds DNA test result? Map:HCTv1.0 = CDE 2626962:Procedures.Number of metaphases examined Map:HCTv1.0 = CDE 2693564:Lab Results.First DRB1* allele designations:</p>

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		<p>Map:HCTv1.0 = MD Anderson Specific Content: Product.Fresh product</p> <p>Map:HCTv1.0 = CDE 2873940:Diagnostic or Prognostic Factor.Test results of infectious disease marker for Epstein-Barr antibody:</p> <p>Map:HCTv1.0 = CDE 2681996:Therapies.Was KGF (palifermin, Kepivance) started or is there a plan to use it?</p> <p>Map:HCTv1.0 = CDE 2982953:Lab Results.What is the percentage of the percent of cells positive for neuroblastoma?</p> <p>Map:HCTv1.0 = CDE 2861060:Lab Results.Serum beta 2-microglobulin unit of measure:</p> <p>Map:HCTv1.0 = CDE 3204062:Individuals.What adjusted body weight was used?</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.CD56%</p> <p>Map:HCTv1.0 = CDE 3031315:Lab Results.What is the unit of measure for urinary monoclonal light chains?</p> <p>Map:HCTv1.0 = CDE 2939876:Disease, Disorder or Finding.Specify the number of blast phases:</p> <p>Map:HCTv1.0 = CDE 2974055:Involvement and Extent of Disease.Specify the International Neuroblastoma Staging System disease stage:</p> <p>Map:HCTv1.0 = CDE 3081978:Diagnosis.What was the subtype for which the HSCT was performed?</p> <p>Map:HCTv1.0 = CDE 2658051:Lab Results.Light Chain Involved</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.Effector T cells</p> <p>Map:HCTv1.0 = CDE 2694875:Lab Results.First DQB1* allele designations:</p> <p>Map:HCTv1.0 = CDE 2738448:Diagnosis.What was the MDS or myeloproliferative disease classification?</p> <p>Map:HCTv1.0 = CDE 2795891:Outcome of Therapy.Overall severity of chronic GVHD:</p> <p>Map:HCTv1.0 = CDE 2681619:Pre-Preparative Regimen.What was the recipient's test results for the presence of CMV-antibodies?</p> <p>Map:HCTv1.0 = CDE</p>

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		<p>2962099:Disease, Disorder or Finding.What was the family history of cancer in first degree relatives under 40 years of age?</p> <p>Map:HCTv1.0 = CDE 2780733:Lab Results.Chimerism study total number of host cells:</p> <p>Map:HCTv1.0 = CDE 2971761:Lab Results.Were any other molecular abnormalities present?</p> <p>Map:HCTv1.0 = CDE 2974177:Diagnosis.What was the primary CNS disease for which the HSCT was performed?</p> <p>Map:HCTv1.0 = CDE 2954746:Therapies.At what point in the disease course was the HSCT performed?</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Recipient.Recipient weight (kg)</p> <p>Map:HCTv1.0 = CDE 2936194:Lab Results.Specify BCR/ABL or other molecular tests results:</p> <p>Map:HCTv1.0 = MD Anderson Specific Content: Product.CD4%</p> <p>Map:HCTv1.0 = CDE 2785785:Activity.Were the secondary containers (e.g., insulated shipping containers and unit cassette) intact when they arrived at your center?</p> <p>Map:HCTv1.0 = CDE 62732//:Therapy Results.Has residual primary tumor been detected (after resection)?</p> <p>Map:HCTv1.0 = CDE 2861058:Lab Results.Serum beta 2 microglobulin value:</p> <p>Map:HCTv1.0 = CDE 2982573:Lab Results.What was the result of the bone marrow laboratory procedure?</p> <p>Map:HCTv1.0 = CDE 2963521:Lab Results.Leukemia cell type:</p> <p>Map:HCTv1.0 = CDE 2861157:Lab Results.What is the percent of blasts in the bone marrow?</p> <p>Map:HCTv1.0 = CDE 2682005:Therapies.As part of a toxicity modifying regimen, was FGF (velafermin) started or is there a plan to use it?</p> <p>Map:HCTv1.0 = CDE 2780738:Lab Results.Chimerism study percent of donor cells:</p> <p>Map:HCTv1.0 = CDE 2682797:Chronic Myelogenous Leukemia (CML): Part 1 of 2.At the time of transplantation, what was the number of the status of the CML?</p> <p>Map:HCTv1.0 = CDE 2676483:Diagnosis.Specify the type of</p>

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		<p>hodgkin lymphoma: Map:HCTv1.0 = CDE 2730798:Lab Results.When the colony-forming units (CFU) were assessed, what was the total number of colonies counted? Map:HCTv1.0 = CDE 2689324:Lab Results.For the systemic lupus erythematosus (SLE), what was the C4 test result? Map:HCTv1.0 = CDE 2965899:Lab Results.What is the IgG level? Map:HCTv1.0 = CDE 2693511:Lab Results.Number of C antigens provided: Map:HCTv1.0 = CDE 2952509:Lab Results.Was the monoclonal band type present? Map:HCTv1.0 = CDE 3158516:Medical Records and Forms.Specify other indication for CIBMTR recipient ID (CRID) assignment: Map:HCTv1.0 = CDE 2952507:Lab Results.Which monoclonal bands were present? Map:HCTv1.0 = CDE 2771962:Lab Results.Total value of NK cells: Map:HCTv1.0 = CDE 2798800:Lab Results.What is the unit of measure for serum creatinine? Map:HCTv1.0 = CDE 2967337:Individuals.Specify the family member(s) diagnosed with neuroblastoma or ganglioneuroma: Map:HCTv1.0 = CDE 2867502:Lab Results.Serum creatinine: Map:HCTv1.0 = CDE 2780745:Lab Results.Chimerism study percent of host cells: Map:HCTv1.0 = CDE 3129551:Involvement and Extent of Disease.What was the Binet stage? Map:HCTv1.0 = CDE 3031376:Disease, Disorder or Finding.What is the result of the method used to assess disease? Map:HCTv1.0 = CDE 2677072:Disease, Disorder or Finding.If the breast cancer was in the state of relapse at the time of transplantation, was the cancer local or metastatic? Map:HCTv1.0 = CDE 2797633:Outcome of Therapy.List the maximum severity of the acute graft versus host disease lower intestinal tract involvement: Map:HCTv1.0 = CDE 2794427:Specimen Characteristics.Percent Cells Viable: Map:HCTv1.0 = CDE 58265 /:Lab</p>

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		<p>Results.Marrow Cellularity Status Map:HCTv1.0 = CDE 2695266:Lab Results.2nd A antigen specificity Map:HCTv1.0 = CDE 2860911:Lab Results.What is the value of plasma cells in bone marrow aspirate? Map:HCTv1.0 = CDE 2693502:Lab Results.Number of A antigens provided: Map:HCTv1.0 = CDE 2775909:Lab Results.What is the unit of measure for hemoglobin? Map:HCTv1.0 = CDE 2962101:Disease, Disorder or Finding.Specify the family history of cancer in first degree relatives under 40 years of age: Map:HCTv1.0 = CDE 2704158:Lab Results.DR53 specificity present? Map:HCTv1.0 = CDE 2686055:DONOR'.For an HLA-mismatched related donor, what was the degree of mismatch: Map:HCTv1.0 = CDE 2686147:Diagnosis.Specify the other arthritis: Map:HCTv1.0 = CDE 2686111:Diagnosis.Specify the other SCID: Map:HCTv1.0 = CDE 2935895:Molecular Abnormality.Specify the Philadelphia chromosome positive metaphases value (%): Map:HCTv1.0 = CDE 2798928:Lab Results.What is the hemoglobin lab value? Map:HCTv1.0 = MD Anderson Specific Content: Product.Frozen product Map:HCTv1.0 = CDE 2691374:Lab Results.For the dermatomyositis, was there a rash present that was typical of the disease? Map:HCTv1.0 = CDE 2760279:Lab Results.Total value of nucleated red blood cells: Map:HCTv1.0 = CDE 3123938:Disease, Disorder or Finding.What is the result of the audiometric test assessed at the speech threshold for 500 hertz? Map:HCTv1.0 = CDE 2965477:Lab Results.What is the status of B-cell function? Map:HCTv1.0 = CDE 2798924:Lab Results.What is the lymphocytes lab value? Map:HCTv1.0 = CDE 2769109:Involvement and Extent of Disease.Specify primary cause of</p>

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		<p>death: Map:HCTv1.0 = CDE 2971763:Lab Results.Specify other molecular abnormality: Map:HCTv1.0 = CDE 2797671:Outcome of Therapy.List the maximum severity of acute graft versus host disease liver involvement: Map:HCTv1.0 = CDE 2861135:Lab Results.What was the percentage of plasma cells in bone marrow from the unknown source? Map:HCTv1.0 = CDE 3017711:Molecular Abnormality.Were cytogenetics tested? Map:HCTv1.0 = CDE 2686173:Diagnosis.Specify the other autoimmune bowel disorder: Map:HCTv1.0 = CDE 2968379:Individuals.Specify other genetic disease: Map:HCTv1.0 = CDE 3030931:Lab Results.What is the value of platelets? Map:HCTv1.0 = CDE 3073218:Lab Results.What is the reason for the A alleles missing value? Map:HCTv1.0 = CDE 3061213:Adverse Events.What is the percentage of body surface area affected by skin rash due to engraftment syndrome? Map:HCTv1.0 = CDE 2866119:Lab Results.What is the unit of measure for the cerebrospinal fluid total protein: Map:HCTv1.0 = CDE 2728988:Adverse Events.Specify the life-threatening complications that the donor experienced during or after the collection: Map:HCTv1.0 = CDE 2704252:Lab Results.Second DP antigen specificity: Map:HCTv1.0 = CDE 3179207:Lab Results.Does the recipient have clinical significant fusarium fungal infection history? Map:HCTv1.0 = CDE 2630200:Units of Measure.Weight Unit of Measure UCUM Code Map:HCTv1.0 = CDE 2860890:Lab Results.What is the percentage of plasma cells in bone marrow biopsy? Map:HCTv1.0 = CDE 2874163:Individuals.Height Map:HCTv1.0 = CDE 2685070:Diagnosis.Specify the other T / NK cell lymphoma: Map:HCTv1.0 = CDE 2967342:Individuals.Specify relationship: Map:HCTv1.0 = CDE 2685309:Diagnosis.Specify the type of</p>

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		other connective tissue disease: Map:HCTv1.0 = CDE 2724626:Diagnosis.Primary cancer type Map:HCTv1.0 = CDE 2704210:Lab Results.First DPA1* allele designations: Map:HCTv1.0 = CDE 2986313:Lab Results.What was the histology type of the malignant testicular germ cell tumor? Map:HCTv1.0 = CDE 2970552:Lab Results.Were proto-oncogenes detected? Map:HCTv1.0 = CDE 3158627:Therapies.What is the indication for cellular therapy? Map:HCTv1.0 = CDE 2798697:Occurrences.Which malignancy(ies) occurred? Map:HCTv1.0 = CDE 2181361:Diagnosis.Durie-Salmon Sub-stage Map:HCTv1.0 = CDE 2704151:Lab Results.DR52 specificity present? Map:HCTv1.0 = CDE 2738883:Disease, Disorder or Finding.Specify predisposing condition: Map:HCTv1.0 = CDE 2860212:Lab Results.What was the status of the monocyte finding? Map:HCTv1.0 = CDE 3028428:Lab Results.Specify the other disease enzyme evaluated for activity level Map:HCTv1.0 = CDE 3126070:Procedures.What was the visual eye acuity snellen fraction denominator? Map:HCTv1.0 = CDE 2760660:Diagnosis.What is the endocrine disorder diagnosis type? Map:HCTv1.0 = CDE 2689395:Diagnosis.Specify the other vasculitis: Map:HCTv1.0 = CDE 3141228:Quality of Life.Lansky Performance Status Score Map:HCTv1.0 = CDE 2798756:Lab Results.What is the value of serum glutamic oxaloacetic transferase? Map:HCTv1.0 = CDE 2704121:Lab Results.First DRB4* allele designations: Map:HCTv1.0 = CDE 2677117:Biological Process.If there was a relapse of the other malignancy, what was the sensitivity to chemotherapy? Map:HCTv1.0 = CDE 2793779:Diagnosis.What was the type

Attribute	Notes	Constraints and Tags
		of chronic GVHD onset? Map:HCTv1.0 = CDE 58208 /:Diagnosis.Rai Stage Classification Map:HCTv1.0 = CDE 3105041:Disease-Disorder Classification.What was the classification of hematologic disorder? Map:HCTv1.0 = MD Anderson Specific Content: Product.CD8% Map:HCTv1.0 = CDE 2963407:Lab Results.What is the value of lymphocytes present in bone marrow? Map:HCTv1.0 = CDE 2863881:Lab Results.What is the value of serum ferritin? Map:HCTv1.0 = CDE 2798778:Lab Results.What is the unit of measure for LDH? Map:HCTv1.0 = CDE 2695291:Lab Results.First C antigen specificity Map:HCTv1.0 = CDE 2957357:UML DEFAULT CD.Progesterone Receptor status Map:HCTv1.0 = CDE 3212372:Lab Results.Were host cells present as determined by non-quantitative means? Map:HCTv1.0 = CDE 2965215:Chronic or Associated Diseases and Exposures.Was maternal engraftment present? Map:HCTv1.0 = CDE 2685061:Diagnosis.Specify the type of non-hodgkin lymphoma: Map:HCTv1.0 = CDE 2597018:Lab Results.Lactate Dehydrogenase Map:HCTv1.0 = CDE 2970589:Lab Results.Specify copy number: Map:HCTv1.0 = CDE 2693543:Lab Results.First B* allele designations: Map:HCTv1.0 = CDE 2963374:Lab Results.Was any tumor present in the biopsy? Map:HCTv1.0 = CDE 2962086:Involvement and Extent of Disease.What was the history of co-existing phakomatosis? Map:HCTv1.0 = CDE 3128021:Disease, Disorder or Finding.Specify the Chronic Lymphocytic Leukemia histology: Map:HCTv1.0 = CDE 2772153:Lab Results.Total value of CD8+ cells: Map:HCTv1.0 = CDE 2946347:Involvement and Extent of Disease.What kind of disease present? Map:HCTv1.0 = CDE 2967346:Individuals.Number unknown: Map:HCTv1.0 = CDE 2695092:Lab Results.Test results of infectious

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		<p>disease marker for cytomegalovirus(CMV) antibody (IgG or total): Map:HCTv1.0 = CDE 2940579:Diagnosis.Specify which accelerated phase symptoms were present: Map:HCTv1.0 = CDE 2785801:Lab Results.When the colony-forming units were assessed, was there growth? Map:HCTv1.0 = CDE 2912001:Diagnosis.What was the classification of the congenital abnormalities of erythrocyte differentiation or function? Map:HCTv1.0 = CDE 2760894:Diagnosis.What is the pulmonary diagnosis type? Map:HCTv1.0 = CDE 3073239:Lab Results.What is the reason for the DQA1 alleles missing value? Map:HCTv1.0 = CDE 2760071:Diagnosis.Specify the other autoimmune disease diagnosis: Map:HCTv1.0 = CDE 2694945:Lab Results.Test results of infectious disease marker for hepatitis B virus (HBV) core antibody (Anti HBc) Map:HCTv1.0 = CDE 3021221:Diagnosis.Specify the valvular insufficiency type: Map:HCTv1.0 = CDE 2953095:Lab Results.What is the value of serum calcium? Map:HCTv1.0 = CDE 2704108:Lab Results.Bw6 specificity present? Map:HCTv1.0 = CDE 2685385:Diagnosis.Specify the other acquired cytopenic syndrome: Map:HCTv1.0 = MD Anderson Specific Content: Product.CAR% Map:HCTv1.0 = CDE 2932805:Disease, Disorder or Finding.What was the prior disease? Map:HCTv1.0 = CDE 2980333:Involvement and Extent of Disease.Specify the recurrent disease present in another site: Map:HCTv1.0 = CDE 2782626:Lab Results.What is the unit of measure for total serum bilirubin? Map:HCTv1.0 = CDE 2954687:Symptoms.Specify the systemic symptoms: Map:HCTv1.0 = MD Anderson Specific Content: Product.NK cells Map:HCTv1.0 = CDE 3073222:Lab Results.What is the reason for the C alleles missing value? Map:HCTv1.0 = CDE 2760275:Lab Results.Nucleated red blood cells </p>

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		<p>exponent value:</p> <p>Map:HCTv1.0 = CDE 2693570:Lab Results.Second DRB1* allele designations:</p> <p>Map:HCTv1.0 = CDE 2782624:Lab Results.What is the value of total serum bilirubin?</p> <p>Map:HCTv1.0 = CDE 3073224:Lab Results.What is the reason for the DRB1 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 3073226:Lab Results.What is the reason for the DRB3 alleles missing value?</p> <p>Map:HCTv1.0 = CDE 2969621:Lab Results.Was the biopsy site positive for neuroblastoma?</p> <p>Map:HCTv1.0 = CDE 2950100:Disease, Disorder or Finding.What kind of clinical features were presented ?</p> <p>Map:HCTv1.0 = CDE 2694882:Lab Results.Second DQB1* allele designations:</p> <p>Map:HCTv1.0 = CDE 2691627:Disease Response.If the plasma cell disorder was treated, what was the number of the response?</p> <p>Map:HCTv1.0 = CDE 2770662:Biological Process.Specify the etiology of the other virus:</p> <p>Map:HCTv1.0 = CDE 2798684:Property or Attribute.Have you smoked cigarettes prior to but not during the past year?</p> <p>Map:HCTv1.0 = CDE 2965468:Lab Results.What is the status of T-cell function?</p> <p>Map:HCTv1.0 = CDE 2969619:Eligibility.Specify the patient's age at menopause:</p> <p>Map:HCTv1.0 = CDE 2760665:Diagnosis.Specify the other endocrine diagnosis:</p> <p>Map:HCTv1.0 = CDE 3098936:Individuals.What is the reason for the missing number of pregnancies?</p> <p>Map:HL7SP = VerificationEvent.value</p> <p>Map:ICSRr2 = Characteristics.value (in R_Product)</p> <p>Map:ICSRr2 = AdverseEventAssessment.text (in IndividualCaseSafetyReport)</p> <p>Map:ICSRr2 = ObservationEvent.value (in IndividualCaseSafetyReport)</p> <p>Map:ICSRr2 = InvestigationCharacteristic.value (in IndividualCaseSafetyReport)</p> <p>Map:Lab =</p>

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		LabResult.numericPrecision Map:Lab = LabResult.textResult Map:Lab = LabResult.numericResult Map:Lab = LaboratoryResult.numericResult Map:Lab = LabResult.referenceTextList Map:LabViewer2.2 = LabResultUnitOfMeasure.code Map:LabViewer2.2 = LaboratoryResult.numericPrecision Map:LabViewer2.2 = LaboratoryResult.textResult Map:LSDAMv2.2.3Plus = PerformedLesionDescription.lymphaticInvasion Map:LSDAMv2.2.3Plus = PerformedLesionDescription.perineuralInvasion Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.numberLymphNodesInvolved Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.numberLymphNodesExamined Map:LSDAMv2.2.3Plus = PerformedObservationResult.result Map:LSDAMv2.2.3Plus = PerformedLesionDescription.venousInvasion Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.primaryTumorStage Map:NCI CRF Standard = CDE 2538246v1.0: MedDRA Adverse Event Code Map:NCI CRF Standard = CDE 2201348v1.0: Adverse Event Suspected Other Attribution Text Name Map:NCI CRF Standard = CDE 2902378v1.0: Prostate Carcinoma Whitmore-Jewett System Stage Map:NCI CRF Standard = CDE 2848650v1.0: Binet Staging System Stage Map:NCI CRF Standard = CDE 3419395v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Pathologic Regional Lymph Node N Stage Map:NCI CRF Standard = CDE 323v3.0: Common Toxicity Criteria Adverse Event Term Type Map:NCI CRF Standard = CDE 3241064v1.0: Laboratory Test Result Character Value Map:NCI CRF Standard = CDE 2787947v1.0: Laboratory Test Result Unit of Measure Unified Code for

Attribute	Notes	Constraints and Tags
		Units of Measure Code Map:NCI CRF Standard = CDE 3125302v1.1: Common Terminology Criteria for Adverse Events Version 4.0 Low Level Term Name Map:NCI CRF Standard = CDE 2003874v3.0: Medical History Description Map:NCI CRF Standard = CDE 2902396v1.0: CML Disease Phase Category Map:NCI CRF Standard = CDE 2435038v1.0: Protocol Deviation Description Text Map:NCI CRF Standard = CDE 58208v3.0: CLL Leukemia RAI Stage Map:NCI CRF Standard = CDE 3419389v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Clinical Regional Lymph Node N Stage Map:NCI CRF Standard = CDE 2183360v2.0: Laboratory Test Result Numeric Value Map:NCI CRF Standard = CDE 2179892v1.0: Adverse Event Cancer Treatment Related Type Map:NCI CRF Standard = CDE 3133353v1.0: Common Terminology Criteria for Adverse Events Version 4.0 Mapped Low Level Term MedDRA Code Map:NCI CRF Standard = CDE 3419391v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Clinical Distant Metastasis M Stage Map:NCI CRF Standard = CDE 2902402v1.0: Lymphoma B-Symptoms Medical Record Documented Indicator Map:NCI CRF Standard = CDE 3192550v1.0: Medical History Review of Systems Finding Type Map:NCI CRF Standard = CDE 3419406v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Pathologic Distant Metastasis M Stage Map:NCI CRF Standard = CDE 2689280v1.0: Plasma Cell Myeloma International Staging System for Myeloma Stage Map:NCI CRF Standard = CDE 2004106v3.0: Dose Limiting Toxicity Ind Map:NCI CRF Standard = CDE 3419407v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Group Stage Map:NCI CRF Standard = CDE

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		<p>2902417v1.0: Lymphoma Ann Arbor Staging System Stage Map:NCI CRF Standard = CDE</p> <p>2902390v1.0: Pediatric Lymphoid Cancer St. Jude Stage Map:NCI CRF Standard = CDE</p> <p>2746517v1.0: Adverse Event Outcome Type Map:NCI CRF Standard = CDE</p> <p>2181363v1.0: Myeloma Diagnosis Stage Map:NCI CRF Standard = CDE</p> <p>3419387v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Clinical Tumor T Stage Map:NCI CRF Standard = CDE</p> <p>2201880v1.0: Patient Abnormal Physical Examination Specify Map:NCI CRF Standard = CDE</p> <p>2902443v1.0: Hodgkin's Lymphoma Modified Ann Arbor Staging System Stage Map:NCI CRF Standard = CDE</p> <p>3419393v1.0: Breast Cancer American Joint Committee on Cancer (AJCC) Edition 7 Pathologic Tumor T Stage Map:NCI CRF Standard = CDE</p> <p>3116943v1.0: Gynecologic Tumor Grouping FIGO 2009 Cervical Carcinoma Stage Map:NCI CRF Standard = CDE</p> <p>2188132v1.0: Adverse Event Verbatim Term Text Map:NCI CRF Standard = CDE</p> <p>3192455v1.0: Physical Examination Finding Type Map:PGx v1.0 = BS.BSORRES Map:PGx v1.0 = BS.BSSTRESC Map:PGx v1.0 = BS.BSSTRESU Map:PGx v1.0 = PG.PGORRES Map:PGx v1.0 = PG.PGORRESU Map:PGx v1.0 = PG.PGSTRESC Map:PGx v1.0 = PG.PGSTRESN Map:PGx v1.0 = BS.BSORRESU Map:PGx v1.0 = PF.PFRESCAT Map:PGx v1.0 = PG.PGSTRESU Map:PGx v1.0 = PF.PFORRES Map:PGx v1.0 = PF.PFORRESU Map:PGx v1.0 = BS.BSSTRESN Map:PGx v1.0 = PF.PFSTRESC Map:PGx v1.0 = PF.PFSTRESN Map:PGx v1.0 = PF.PFSTRESU Map:SDTM IGv3.1.1 = AE.AESLIFE Map:SDTM IGv3.1.1 = VS.VSORRES Map:SDTM IGv3.1.1 = AE.AESOD Map:SDTM IGv3.1.1 = VS.VSLOINC Map:SDTM IGv3.1.1 = EG.EGORRES Map:SDTM IGv3.1.1 = IE.IESTRESC Map:SDTM IGv3.1.1 =</p>

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		PE.PESTRESU Map:SDTM IGv3.1.1 = PE.PESTRESN Map:SDTM IGv3.1.1 = QS.QSORRESU Map:SDTM IGv3.1.1 = QS.QSSTRESPC Map:SDTM IGv3.1.1 = PE.PEORRESU Map:SDTM IGv3.1.1 = MH.MHOCCUR Map:SDTM IGv3.1.1 = IE.IEORRES Map:SDTM IGv3.1.1 = VS.VSSTRESPC Map:SDTM IGv3.1.1 = AE.AEREL Map:SDTM IGv3.1.1 = LB.LBSTRRESPC Map:SDTM IGv3.1.1 = CM.CMOCCUR Map:SDTM IGv3.1.1 = EG.EGSTRESPC Map:SDTM IGv3.1.1 = SC.SCORRESPC Map:SDTM IGv3.1.1 = AE.AESCONG Map:SDTM IGv3.1.1 = EG.EGLOINC Map:SDTM IGv3.1.1 = LB.LBSTRRESPC Map:SDTM IGv3.1.1 = TS.TSVAL Map:SDTM IGv3.1.1 = VS.VSSTRESPC Map:SDTM IGv3.1.1 = PE.PESTRESPC Map:SDTM IGv3.1.1 = AE.AESCAN Map:SDTM IGv3.1.1 = AE.AESMIE Map:SDTM IGv3.1.1 = LB.LBORRESPC Map:SDTM IGv3.1.1 = MH.MHDECOD Map:SDTM IGv3.1.1 = AE.AESDISAB Map:SDTM IGv3.1.1 = DV.DVDECOD Map:SDTM IGv3.1.1 = LB.LBLOINC Map:SDTM IGv3.1.1 = DS.DSTERM Map:SDTM IGv3.1.1 = AE.AETERM Map:SDTM IGv3.1.1 = VS.VSORRESPC Map:SDTM IGv3.1.1 = EG.EGSTRESPC Map:SDTM IGv3.1.1 = SC.SCORRESPC Map:SDTM IGv3.1.1 = SC.SCSTRESPC Map:SDTM IGv3.1.1 = AE.AEOUT Map:SDTM IGv3.1.1 = EG.EGORRESPC Map:SDTM IGv3.1.1 = EG.EGSTRESPC Map:SDTM IGv3.1.1 = LB.LBORRESPC

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		Map:SDTM IGv3.1.1 = LB.LBSTRES Map:SDTM IGv3.1.1 = SC.SCSTRESN Map:SDTM IGv3.1.1 = VS.VSSTRESN Map:SDTM IGv3.1.1 = MH.MHTERM Map:SDTM IGv3.1.1 = AE.AERELNST Map:SDTM IGv3.1.1 = SC.SCSTRES Map:SDTM IGv3.1.1 = PE.PEORRES Map:SDTM IGv3.1.1 = QS.QSORRES Map:SDTM IGv3.1.1 = QS.QSSTRESU Map:SDTM IGv3.1.1 = QS.QSSTRESN Map:SDTM IGv3.1.1 = AE.AESDTH Map:SDTM IGv3.1.1 = AE.AEDECOD Map:SDTM IGv3.1.2 = PE.PEORRES Map:SDTM IGv3.1.2 = LB.LBSTRESU Map:SDTM IGv3.1.2 = DS.DSDECOD Map:SDTM IGv3.1.2 = QS.QSSTRESU Map:SDTM IGv3.1.2 = MS.MSORRES Map:SDTM IGv3.1.2 = FA.FASTRESN Map:SDTM IGv3.1.2 = MS.MSRESCAT Map:SDTM IGv3.1.2 = LB.LBSTRESN Map:SDTM IGv3.1.2 = SC.SCSTRES Map:SDTM IGv3.1.2 = MB.MBRESCAT Map:SDTM IGv3.1.2 = QS.QSORRES Map:SDTM IGv3.1.2 = MS.MSSTRESN Map:SDTM IGv3.1.2 = LB.LBORRESU Map:SDTM IGv3.1.2 = MH.MHOCCUR Map:SDTM IGv3.1.2 = SC.SCSTRESN Map:SDTM IGv3.1.2 = PC.PCSTRESN Map:SDTM IGv3.1.2 = DV.DVDECOD Map:SDTM IGv3.1.2 = MB.MBORRESU Map:SDTM IGv3.1.2 = EG.EGORRES Map:SDTM IGv3.1.2 = FA.FASTRESU

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		Map:SDTM IGv3.1.2 = VS.VSSTRESP Map:SDTM IGv3.1.2 = PE.PESTRESP Map:SDTM IGv3.1.2 = DS.DSTERM Map:SDTM IGv3.1.2 = MB.MBORRES Map:SDTM IGv3.1.2 = CE.CEDECOD Map:SDTM IGv3.1.2 = SC.SCORRES Map:SDTM IGv3.1.2 = SC.SCORRESU Map:SDTM IGv3.1.2 = IE.IESTRESP Map:SDTM IGv3.1.2 = PP.PPORIES Map:SDTM IGv3.1.2 = MB.MBSTRRESU Map:SDTM IGv3.1.2 = SU.SUOCCUR Map:SDTM IGv3.1.2 = QS.QSORRESU Map:SDTM IGv3.1.2 = PC.PCORIES Map:SDTM IGv3.1.2 = PP.PPORIES Map:SDTM IGv3.1.2 = EG.EGSTRESP Map:SDTM IGv3.1.2 = PP.PPSTRESP Map:SDTM IGv3.1.2 = PC.PCSTRESP Map:SDTM IGv3.1.2 = MB.MBSTRRESP Map:SDTM IGv3.1.2 = PC.PCSTRESP Map:SDTM IGv3.1.2 = MH.MHDECOD Map:SDTM IGv3.1.2 = FA.FAORRESU Map:SDTM IGv3.1.2 = PP.PPSTRESP Map:SDTM IGv3.1.2 = QS.QSSTRESP Map:SDTM IGv3.1.2 = MS.MSSTRRESP Map:SDTM IGv3.1.2 = EG.EGORRESP Map:SDTM IGv3.1.2 = MB.MBSTRRESP Map:SDTM IGv3.1.2 = SC.SCSTRESP Map:SDTM IGv3.1.2 = FA.FAOBJ Map:SDTM IGv3.1.2 = MS.MSSTRRESP Map:SDTM IGv3.1.2 = AE.AEOUT Map:SDTM IGv3.1.2 = CM.CMOCCUR Map:SDTM IGv3.1.2 = EG.EGFXN Map:SDTM IGv3.1.2 = CE.CETERM Map:SDTM IGv3.1.2 = VS.VSORRES Map:SDTM IGv3.1.2 =

Attribute	Notes	Constraints and Tags
		QS.QSSTRESN Map:SDTM IGv3.1.2 = CE.CEOCCUR Map:SDTM IGv3.1.2 = MS.MSORRESU Map:SDTM IGv3.1.2 = DV.DVTERM Map:SDTM IGv3.1.2 = FA.FAORRES Map:SDTM IGv3.1.2 = MH.MHTERM Map:SDTM IGv3.1.2 = PE.PEORRESU Map:SDTM IGv3.1.2 = LB.LBSTRDESC Map:SDTM IGv3.1.2 = PP.PPSTRESN Map:SDTM IGv3.1.2 = VS.VSORRESU Map:SDTM IGv3.1.2 = AE.AETERM Map:SDTM IGv3.1.2 = FA.FASTRESC Map:SDTM IGv3.1.2 = AE.AEDECOD Map:SDTM IGv3.1.2 = PC.PCORRES Map:SDTM IGv3.1.2 = VS.VSSTRESN Map:SDTM IGv3.1.2 = EG.EGSTRESN Map:SDTM IGv3.1.2 = VS.VSSTRESU Map:SDTM IGv3.1.2 = EG.EGSTRESU Map:SDTM IGv3.1.2 = LB.LBORRES Map:SDTM IGv3.1.3 = QS.QSSTRESU Map:SDTM IGv3.1.3 = QS.QSSTRESN Map:SDTM IGv3.1.3 = QS.QSSTRESC Map:SDTM IGv3.1.3 = PC.PCSTRESC Map:SDTM IGv3.1.3 = QS.QSORRESU Map:SDTM IGv3.1.3 = PE.PEORRES Map:SDTM IGv3.1.3 = QS.QSORRES Map:SDTM IGv3.1.3 = PE.PESTRESC Map:SDTM IGv3.1.3 = PE.PEORRESU Map:SDTM IGv3.1.3 = SC.SCSTRESN Map:SDTM IGv3.1.3 = PC.PCSTRESU Map:SDTM IGv3.1.3 = PC.PCSTRESN Map:SDTM IGv3.1.3 = TR.TRORRES Map:SDTM IGv3.1.3 = PC.PCORRESU

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = VS.VSSTRESU Map:SDTM IGv3.1.3 = VS.VSSTRESN Map:SDTM IGv3.1.3 = VS.VSSTRESC Map:SDTM IGv3.1.3 = VS.VSORRESU Map:SDTM IGv3.1.3 = VS.VSORRES Map:SDTM IGv3.1.3 = SC.SCORRESU Map:SDTM IGv3.1.3 = TR.TRSTRES Map:SDTM IGv3.1.3 = RS.RSORRES Map:SDTM IGv3.1.3 = SU.SUSTAT Map:SDTM IGv3.1.3 = SU.SUOCCUR Map:SDTM IGv3.1.3 = SC.SCSTRESU Map:SDTM IGv3.1.3 = SC.SCSTRES Map:SDTM IGv3.1.3 = TU.TUORRES Map:SDTM IGv3.1.3 = SC.SCORRES Map:SDTM IGv3.1.3 = RS.RSSTRES Map:SDTM IGv3.1.3 = TU.TUSTRES Map:SDTM IGv3.1.3 = CM.CMSTAT Map:SDTM IGv3.1.3 = FA.FASTRESU Map:SDTM IGv3.1.3 = FA.FASTRESN Map:SDTM IGv3.1.3 = FA.FASTRES Map:SDTM IGv3.1.3 = FA.FAORRESU Map:SDTM IGv3.1.3 = FA.FAORRES Map:SDTM IGv3.1.3 = FA.FAOBJ Map:SDTM IGv3.1.3 = EG.EGSTRESU Map:SDTM IGv3.1.3 = EG.EGSTRES Map:SDTM IGv3.1.3 = EG.EGORRES Map:SDTM IGv3.1.3 = IE.IEORRES Map:SDTM IGv3.1.3 = DV.DVDECOD Map:SDTM IGv3.1.3 = EG.EGSTRESN Map:SDTM IGv3.1.3 = CE.CETERM Map:SDTM IGv3.1.3 = CE.CESTAT Map:SDTM IGv3.1.3 = CE.CEOCCUR Map:SDTM IGv3.1.3 = PC.PCORRES Map:SDTM IGv3.1.3 = CE.CEDECOD Map:SDTM IGv3.1.3 = AE.AEDECOD

Attribute	Notes	Constraints and Tags
		Map:SDTM IGv3.1.3 = AE.AEOUT Map:SDTM IGv3.1.3 = AE.AETERM Map:SDTM IGv3.1.3 = AE.AEPTCD Map:SDTM IGv3.1.3 = DV.DVTERM Map:SDTM IGv3.1.3 = MH.MHDECOD Map:SDTM IGv3.1.3 = MS.MSRESCAT Map:SDTM IGv3.1.3 = MS.MSORRESU Map:SDTM IGv3.1.3 = MS.MSSTRESC Map:SDTM IGv3.1.3 = EG.EGORRESU Map:SDTM IGv3.1.3 = IE.IESTRESC Map:SDTM IGv3.1.3 = MH.MHTERM Map:SDTM IGv3.1.3 = MS.MSSTRESN Map:SDTM IGv3.1.3 = MS.MSSTRESU Map:SDTM IGv3.1.3 = MH.MHOCCUR Map:SDTM IGv3.1.3 = MS.MSORRES Map:SDTM IGv3.1.3 = MB.MBSTRESU Map:SDTM IGv3.1.3 = LB.LBSTRESU Map:SDTM IGv3.1.3 = LB.LBORRES Map:SDTM IGv3.1.3 = LB.LBORRESU Map:SDTM IGv3.1.3 = LB.LBSTRDESC Map:SDTM IGv3.1.3 = MH.MHSTAT Map:SDTM IGv3.1.3 = LB.LBSTRRESN Map:SDTM IGv3.1.3 = MB.MBSTRRESN Map:SDTM IGv3.1.3 = MB.MBORTRES Map:SDTM IGv3.1.3 = MB.MBORTRESU Map:SDTM IGv3.1.3 = MB.MBRESCAT Map:SDTM IGv3.1.3 = MB.MBSTRDESC Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS SITE-SPECIFIC FACTORS 1 - 25 Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - IMMUNOTHERAPY Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - SURGICAL PROCEDURE OF OTHER SITE Map:SEER 2015 = SECTION VII

Attribute	Notes	Constraints and Tags
		FIRST COURSE OF THERAPY - SURGERY OF PRIMARY SITE Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - CHEMOTHERAPY Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - HORMONE THERAPY Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - SCOPE OF REGIONAL LYMPH NODE SURGERY Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - HEMATOLOGIC TRANSPLANT AND ENDOCRINE PROCEDURES Map:SEER 2015 = SECTION VII FIRST COURSE OF THERAPY - OTHER THERAPY Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - ICD CODE REVISION USED FOR CAUSE OF DEATH Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - UNDERLYING CAUSE OF DEATH Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Date Active Followup Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Flag Active Followup Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Date Presumed Alive Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Flag Presumed Alive Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Mos Presumed Alive Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS SITE-SPECIFIC FACTORS 1 - 25 Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - HISTOLOGIC TYPE ICD-O-3 Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Mos Active Followup Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - TYPE OF REPORTING

Attribute	Notes	Constraints and Tags
		SOURCE/SEQUENCE NUMBER INTERFIELD REVIEW Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - SEQUENCE NUMBER-CENTRAL Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - MORPHOLOGY Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - BEHAVIOR CODE Map:SEER 2015 = SECTION VIII FOLLOW UP INFORMATION - SURVIVAL DATA ITEMS - Surv-Date DX Recode Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - HISTOLOGY/BEHAVIOR INTERFIELD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - AGE/SITE/HISTOLOGY INTERFIELD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - SEQUENCE NUMBER/DIAGNOSTIC CONFIRMATION INTERFIELD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - SITE/HISTOLOGY/LATERALITY/S EQUENCE INTERRECORD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - SURGERY/DIAGNOSTIC CONFIRMATION INTERFIELD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - SITE/TYPE INTERFIELD REVIEW Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - LEUKEMIA OR LYMPHOMA/DIAGNOSTIC CONFIRMATION INTERFIELD REVIEW Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - REGIONAL NODES EXAMINED Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - OVER-RIDE FLAG FOR SITE/BEHAVIOR (IF39) Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - OVER-RIDE FLAG FOR SITE/EOD/DIAGNOSIS DATE

Attribute	Notes	Constraints and Tags
		<p>(IF40) Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - OVER-RIDE FLAG FOR SITE/LATERALITY/EOD (IF41) Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - OVER-RIDE FLAG FOR SITE/LATERALITY/MORPHOLOG Y (IF42) Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - GRADE PATH VALUE Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - GRADE PATH SYSTEM Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - LYMPH-VASCULAR INVASION Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - CS TUMOR SIZE Map:SEER 2015 = SECTION VI COLLABORATIVE STAGE DATA COLLECTION SYSTEM - REGIONAL NODES POSITIVE Map:SEER 2015 = SECTION IX ADMINISTRATIVE CODES - SEQUENCE NUMBER/ILL-DEFINED SITE INTERFIELD REVIEW </p>

Attribute	Notes	Constraints and Tags
valueCodeModifiedText <i>Class:</i> PerformedObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A character string that is a revision of the original text observation result to enable the coding of the text.</p> <p>EXAMPLE(S): If the originalText is "hedache", the valueCodeModifiedText could be changed to "headache", so that the text can be successfully coded.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): In the context of BRIDG, text modification occurs a single time for a given instance of originalText.</p>	Map:CTRPv3.8 = ObservationResult.resultCodeModifiedText Map:CTRv1.0 = PerformedObservationResult.valueCodeModifiedText Map:LSDAMv2.2.3Plus = PerformedObservationResult.resultCodeModifiedText Map:SDTM IGv3.1.1 = MH.MHMODIFY Map:SDTM IGv3.1.1 = PE.PEMODIFY Map:SDTM IGv3.1.1 = AE.AEMODIFY Map:SDTM IGv3.1.2 = AE.AEMODIFY Map:SDTM IGv3.1.2 = PE.PEMODIFY Map:SDTM IGv3.1.2 = MH.MHMODIFY Map:SDTM IGv3.1.3 = PE.PEMODIFY Map:SDTM IGv3.1.3 = MH.MHMODIFY Map:SDTM IGv3.1.3 = AE.AEMODIFY

Attribute	Notes	Constraints and Tags
valueNullFlavorReason <i>Class:</i> PerformedObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The text and/or code that describes why no result was provided.</p> <p>EXAMPLE(S): Subject refused to answer question.</p> <p>Error message returned by equipment to explain why the device was unable to produce a result.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This value should only be populated if PerformedObservationResult.value is null.</p>	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = PerformedObservationResult.valueNullFlavorReason Map:HCTv1.0 = CDE 2953093:Lab Results.What was the status of the serum calcium finding? Map:HCTv1.0 = CDE 3030971:Lab Results.What was the reason for the laboratory procedure specimen source missing value? Map:HCTv1.0 = CDE 2798802:Lab Results.What is the reason for the serum creatinine missing value? Map:HCTv1.0 = CDE 2974128:Disease, Disorder or Finding.What is the reason for the aplastic anemia etiology missing value? Map:HCTv1.0 = CDE 2816461:Behavior.What is the reason for the cigarette average daily pack use missing value? Map:HCTv1.0 = CDE 2773885:Lab Results.Did laboratory procedure test for CD8+cells? Map:HCTv1.0 = CDE 3024912:Data Source.What is the reason for the ejection fraction missing value? Map:HCTv1.0 = CDE 2775883:Lab Results.What is the reason for the neutrophils missing value? Map:HCTv1.0 = CDE 3020350:Quality of Life.What is the reason for the mental process development assessment score missing value? Map:HCTv1.0 = CDE 3085846:Quality of Life.What is the Vineland Adaptive Behavior Scales performance type? Map:HCTv1.0 = CDE 3024947:Quality of Life.What is the mental development testing score type? Map:HCTv1.0 = CDE 2799095:Lab Results.What is the reason for the platelets missing value? Map:HCTv1.0 = CDE 2978413:Tumor Measurements.What is the reason for the primary neoplasm size missing value? Map:HCTv1.0 = CDE 3181147:Lab Results.What is the reason for the drug level missing value? Map:HCTv1.0 = CDE 3057314:Data Source.If necessary, specify the reason for the missing visual acuity value: Map:HCTv1.0 = CDE 2775889:Lab Results.What is the reason for the lymphocytes missing value?

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2974126:Disease, Disorder or Finding.What is the reason for the viral hepatitis type missing value?</p> <p>Map:HCTv1.0 = CDE 2771977:Lab Results.What is the reason for the NK cells missing value?</p> <p>Map:HCTv1.0 = CDE 2730853:Lab Results.When the colony-forming units were assessed, was the total number of colonies unknown?</p> <p>Map:HCTv1.0 = CDE 2802830:Lab Results.What is the reason for the cluster of differentiation missing value?</p> <p>Map:HCTv1.0 = CDE 3024908:Lab Results.What is the reason for the oxygen saturation percentage level missing value?</p> <p>Map:HCTv1.0 = CDE 2780747:Lab Results.What is the reason for the chimerism study percent of host cells missing value?</p> <p>Map:HCTv1.0 = CDE 2965152:Disease Response.What was the reason the best response to disease not assessed?</p> <p>Map:HCTv1.0 = CDE 2798786:Lab Results.What is the reason for the lactate dehydrogenase missing value?</p> <p>Map:HCTv1.0 = CDE 2782628:Lab Results.What is the reason for the total serum bilirubin missing value?</p> <p>Map:HCTv1.0 = CDE 3024914:Data Source.What is the reason for the shortening fraction result missing value?</p> <p>Map:HCTv1.0 = CDE 2771989:Lab Results.What is the reason for the mesenchymal cells missing value?</p> <p>Map:HCTv1.0 = CDE 2775920:Lab Results.What is the reason for the hematocrit missing value?</p> <p>Map:HCTv1.0 = CDE 2780740:Lab Results.What is the reason for the chimerism study percent of donor cells missing value?</p> <p>Map:HCTv1.0 = CDE 2756923:Lab Results.What is the reason for the immunoglobulin missing value?</p> <p>Map:HCTv1.0 = CDE 2782618:Lab Results.What is the reason for the Serum Glutamic Oxaloacetic Transferase missing value?</p> <p>Map:HCTv1.0 = CDE 2775911:Lab Results.What is the reason for the hemoglobin missing value?</p> <p>Map:HCTv1.0 = CDE 3057305:Quality of Life.What is the reason for the Vineland adaptive behavior scales score missing value?</p>

Attribute	Notes	Constraints and Tags
		Map:HCTv1.0 = CDE 2798689:Chronic or Associated Diseases and Exposures.What is the reason for the smoking duration missing value? Map:HCTv1.0 = CDE 2775876:Lab Results.What is the reason for the WBC missing value? Map:HCTv1.0 = CDE 2760398:Lab Results.When the colony-forming units were assessed, was the total number of CFU-GM unknown? Map:SDTM IGv3.1.3 = SU.SUREASND Map:SDTM IGv3.1.3 = CE.CEREASND Map:SDTM IGv3.1.3 = CM.CMREASND Map:SDTM IGv3.1.3 = MH.MHREASND
confidentialityCode <i>Class:</i> PerformedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the degree of privacy applicable for the observation result.</p> <p>EXAMPLE(S): Do not reveal to study sponsor.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ClinicalResult.confidentialityCode Map:CTOM = LesionDescription.confidentialityCode Map:CTOM = Histopathology.confidentialityCode Map:CTOM = Observation.confidentialityCode Map:CTRv1.0 = PerformedObservationResult.confidentialityCode Map:ICSRr2 = InvestigativeEvent.confidentialityCode (in IndividualCaseSafetyReport) Map:ICSRr2 = RelatedInvestigation.confidentialityCode (in IndividualCaseSafetyReport) Map:LSDAMv2.2.3Plus = PerformedObservationResult.confidentialityCode

Attribute	Notes	Constraints and Tags
uncertaintyCode <i>Class:</i> PerformedObservationResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying whether and to what degree this evaluation or observation has been asserted to be in doubt in any way.</p> <p>EXAMPLE(S): A patient might have had a cholecystectomy procedure in the past, but isn't sure what the outcome was.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	AE:Exclude = True Map:CTOM = Observation.uncertaintyCode Map:CTOM = ClinicalResult.uncertaintyCode Map:CTOM = LesionDescription.uncertaintyCode Map:CTOM = Histopathology.uncertaintyCode Map:CTRv1.0 = PerformedObservationResult.uncertaintyCode Map:HCTv1.0 = CDE 2695060:Lab Results.If FDA licensed nucleic acid amplification test (NAT) for human immunodeficiency virus(HIV)-1 performed; specify results Map:LSDAMv2.2.3Plus = PerformedObservationResult.uncertaintyCode
baselineIndicator <i>Class:</i> PerformedObservationResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the result is a starting point to which other results may be compared.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = AdverseEventReportingPeriod.isBaseline Map:CTRv1.0 = PerformedObservationResult.baselineIndicator Map:LSDAMv2.2.3Plus = PerformedObservationResult.baselineIndicator Map:PGx v1.0 = PF.PFBLFL Map:PGx v1.0 = BS.BSBLFL Map:SDTM IGv3.1.2 = QS.QSBLFL Map:SDTM IGv3.1.2 = EG.EGBLFL Map:SDTM IGv3.1.2 = VS.VSBLFL Map:SDTM IGv3.1.2 = FA.FABLFL Map:SDTM IGv3.1.2 = LB.LBBLFL Map:SDTM IGv3.1.2 = MS.MSBLFL Map:SDTM IGv3.1.2 = MB.MBBFLFL Map:SDTM IGv3.1.3 = FA.FABLFL Map:SDTM IGv3.1.3 = EG.EGBLFL Map:SDTM IGv3.1.3 = LB.LBBLFL Map:SDTM IGv3.1.3 = VS.VSBLFL Map:SDTM IGv3.1.3 = MB.MBBFLFL Map:SDTM IGv3.1.3 = MS.MSBLFL Map:SDTM IGv3.1.3 = QS.QSBLFL

Attribute	Notes	Constraints and Tags
createdDate <i>Class:</i> PerformedObservationResult <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the result is created.</p> <p>EXAMPLE(S): A computational process runs for 3 days and generates data periodically in output files (resulting in a one-to-many relationship between the processing activity and the multiple resulting files).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The createdDate of results is distinct from reportedDate which represents the date on which results were reported to the requestor (usually a physician or similar entity) and distinct from the dateRange of the PerformedObservation which represents the time period during which the activity occurred.</p>	Map:caAERSv2.2 = Outcome.date Map:CTRv1.0 = AdverseEventSeriousness.date Map:LSDAMv2.2.3Plus = MolecularSequenceAnnotation.date Map:LSDAMv2.2.3Plus = Data.creationDate
reportedDate <i>Class:</i> PerformedObservationResult <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the result is reported.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:AE = Reporter.initialReporterIndicator Map:CTOM = LesionDescription.reportingDate Map:CTOM = ClinicalResult.reportingDate Map:CTOM = Observation.reportingDate Map:CTOM = Histopathology.reportingDate Map:CTRv1.0 = PerformedObservationResult.reportedDate Map:LSDAMv2.2.3Plus = PerformedObservationResult.reportedDate Map:NCI CRF Standard = CDE 2435009v1.1: Protocol Deviation Notification Date

Attribute	Notes	Constraints and Tags
comment <i>Class:</i> PerformedObservationResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Additional description of the observation result.</p> <p>EXAMPLE(S): Comments from the investigator regarding the condition of the specimen or any other observation.</p> <p>Comments in addition to the specimen condition from the central or performing laboratory describing the specimen.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = ReportingPeriodReviewComment Map:caAERSv2.2 = AdverseEvent.comments Map:caAERSv2.2 = ReportReviewComment Map:CTOM = DiseaseResponse.commentText Map:CTOM = HistopathologyGrade.commentText Map:CTRv1.0 = PerformedObservationResult.comment Map:ICSRr2 = Characteristics.text (in R_Product) Map:Lab = LabResult.referenceRangeComments Map:LSDAMv2.2.3Plus = PerformedObservationResult.comment Map:NCI CRF Standard = CDE 797v5.0: Research Comments Text Map:SDTM IGv3.1.1 = CO.COVAL Map:SDTM IGv3.1.2 = CO.COVAL Map:SDTM IGv3.1.3 = CO.COVAL

Class: PerformedProcedure

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action whose immediate and primary intention is the alteration of the physical or mental condition of the subject, study subject or experimental unit.

EXAMPLE(S):

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, counseling, etc.

OTHER NAME(S):

NOTE(S):

The documented use cases from life sciences are limited to procedure and observations. Use cases for other kinds of activities in life sciences are needed to support this relationship at the Activity level. In the next release, this relationship will have to be re-assessed.

Tagged Values:

- Map:AE = Intervention
- Map:caAERSv2.2 = TreatmentAssignment
- Map:caAERSv2.2 = StudyParticipantPriorTherapy
- Map:caAERSv2.2 = RadiationIntervention
- Map:caAERSv2.2 = SurgeryIntervention
- Map:CTRv1.0 = PerformedProcedure
- Map:ICSRr2 = Procedure (in A_ProductReportingRelevantInformation)
- Map:ICSRr2 = ProductUseReference (in IndividualCaseSafetyReport)
- Map:LSDAMv2.2.3Plus = PerformedProcedure

Connectors

Source	Connector	Target	Notes
PerformedProcedure 0..*	be recorded as a result of	PerformedObservationResult	DESCRIPTION: Each PerformedProcedure

Source	Connector	Target	Notes
recordedPerformedProcedure		0..1 triggeringPerformedObservationResult	might be recorded as a result of one PerformedObservationResult. Each PerformedObservationResult might result in recording one or more PerformedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProcedure 0..* usingPerformedProcedure	use	Product 0..* usedProduct	DESCRIPTION: Each PerformedProcedure might use one or more Product. Each Product might be used during one or more PerformedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProcedure	specializes	PerformedActivity	DESCRIPTION: Each PerformedProcedure always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedProcedure. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
SafetyReportVersion 0..* reportingSafetyReportVersion	report as prior therapies	PerformedProcedure 0..* reportedPerformedProcedure	DESCRIPTION: Each SafetyReportVersion might report as prior therapies one or more PerformedProcedure. Each PerformedProcedure might be reported as a prior therapy in one or more SafetyReportVersion. DEFINITION: EXAMPLE(S):

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
PerformedSubstanceExtraction	specializes	PerformedProcedure	DESCRIPTION: Each PerformedSubstanceExtraction always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSubstanceExtraction. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedSpecimenCollection	specializes	PerformedProcedure	DESCRIPTION: Each PerformedSpecimenCollection always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSpecimenCollection. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedDiagnosisProcedureRelationship 0..* addressedPerformedDiagnosisProcedureRelationship	is addressed by	PerformedProcedure 1 addressingPerformedProcedure	DESCRIPTION: Each PerformedDiagnosisProcedureRelationship always is addressed by one PerformedProcedure. Each PerformedProcedure might address one or more PerformedDiagnosisProcedureRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedMaterialProcessSt	specializes	PerformedProcedure	DESCRIPTION:

Source	Connector	Target	Notes
ep			<p>Each PerformedMaterialProcessStep always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedMaterialProcessStep.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubstanceAdministration	specializes	PerformedProcedure	<p>DESCRIPTION:</p> <p>Each PerformedSubstanceAdministration always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the technique that is used to perform the procedure.</p> <p>EXAMPLE(S): Finger stick, veni puncture, Abdominal/ ascites effusion, Biopsy, Bronchial alveolar lavage (BAL) (for specimen collection) Capillary electrophoresis and HPLC (for In Vitro Characterization) Cell counting, flow cytometry (for In Vivo Characterization) Open, laparoscopic (for cholecystectomy)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = RadiationIntervention.administration Map:CTOM = SpecimenAcquisition.methodCode Map:CTRv1.0 = PerformedProcedure.methodCode Map:HCTv1.0 = CDE 2790003:Tissue Banking.Specify other thaw method: Map:HCTv1.0 = CDE 2789998:Tissue Banking.What method was used to thaw the product? Map:HCTv1.0 = CDE 2748813:Therapies.Specify the other malignant cell removal method: Map:Lab = SpecimenCollection.method Map:LabViewer2.2 = SpecimenCollection.method Map:LabViewer2.2 = SpecimenCollection.type Map:LSDAMv2.2.3Plus = PerformedSpecimenFixed.fixationType Map:LSDAMv2.2.3Plus = PerformedProcedure.methodCode Map:LSDAMv2.2.3Plus = InvitroCharacterization.assayType Map:SDTM IGv3.1.1 = LB.LBMETHOD Map:SDTM IGv3.1.1 = EG.EGMETHOD

Attribute	Notes	Constraints and Tags
targetAnatomicSiteCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of a procedure.</p> <p>EXAMPLE(S): Kidney (or a nephrectomy)</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Multiple contiguous sites within the same organ system may be referenced.</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:AE = Intervention.targetSite Map:caAERSv2.2 = Lab.site Map:CTOM = Procedure.anatomicSiteCodeSystem Map:CTOM = Surgery.anatomicSiteCode Map:CTOM = SpecimenAcquisition.anatomicSiteCodeSystem Map:CTOM = Radiation.anatomicSiteCode Map:CTOM = Surgery.anatomicSiteCodeSystem Map:CTOM = Radiation.anatomicSiteCodeSystem Map:CTOM = SpecimenAcquisition.anatomicSiteCode Map:CTOM = Procedure.anatomicSiteCode Map:CTrv1.0 = PerformedProcedure.targetAnatomicSiteCode Map:HCTv1.0 = CDE 2980893:Anatomic Sites.Site of orthopedic surgery Map:HCTv1.0 = CDE 2954787:Therapies.Specify other surgery site(s) Map:HCTv1.0 = CDE 64160//:Anatomic Sites.Site of Biopsy Map:HCTv1.0 = CDE 2957282:Therapies.What is the site of radiation therapy? Map:HCTv1.0 = CDE 2952974:Therapies.What was the radiation field? Map:HCTv1.0 = CDE 2980936:Anatomic Sites.Specify the other site of orthopedic surgery Map:LSDAMv2.2.3Plus = PerformedProcedure.targetAnatomicSiteCode Map:PGx v1.0 = BE.BELOC Map:PGx v1.0 = BS.BSANTRREG Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.2 = MB.MBLOC Map:SDTM IGv3.1.3 = MB.MBLOC

Attribute	Notes	Constraints and Tags
targetAnatomicSiteConditionCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the state of the target anatomic site.</p> <p>EXAMPLE(S): The subject's left arm was bruised where the IV was inserted.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = SpecimenAcquisition.siteConditionCode Map:CTRv1.0 = PerformedProcedure.targetAnatomicSiteConditionCode Map:LSDAMv2.2.3Plus = PerformedProcedure.targetAnatomicSiteConditionCode
targetAnatomicSiteLateralityCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for a procedure.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CTRv1.0 = PerformedProcedure.targetAnatomicSiteLateralityCode Map:LSDAMv2.2.3Plus = PerformedProcedure.targetAnatomicSiteLateralityCode Map:PGx v1.0 = BE.BELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.2 = MB.MBLOC Map:SDTM IGv3.1.3 = TU.TULAT
targetAnatomicSiteDirectionalityCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the directional portion of the anatomic site that is a target site for a procedure.</p> <p>EXAMPLE(S): upper, interior</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute complements the target anatomic site code and target anatomic site laterality code.</p>	Map:SDTM IGv3.1.3 = TU.TUDIR

Attribute	Notes	Constraints and Tags
approachAnatomicSiteCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the anatomic location or access point for a procedure.</p> <p>EXAMPLE(S): Arm for an injection, trans-abdominal for a nephrectomy.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:AE = Intervention.approachSite Map:CDASHv1.1 = EX.EXLOC Map:CTRv1.0 = PerformedProcedure.approachAnatomicSiteCode Map:HCTv1.0 = CDE 2416537:Therapy Doses.Radiation Field Map:HCTv1.0 = CDE 2769668:Anatomic Sites.Specify the other site of the central line placement: Map:HCTv1.0 = CDE 2769666:Anatomic Sites.What is the anatomic site of the central venous access catheter? Map:LSDAMv2.2.3Plus = PerformedProcedure.approachAnatomicSiteCode Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.2 = EX.EXLOC Map:SDTM IGv3.1.3 = EX.EXLOC
approachAnatomicSiteLateralityCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is an access point for a procedure.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute was deprecated in BRIDG 3.1 but undeprecated in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:CDASHv1.1 = EX.EXLOC Map:CTRv1.0 = PerformedProcedure.approachAnatomicSiteLateralityCode Map:LSDAMv2.2.3Plus = PerformedProcedure.approachAnatomicSiteLateralityCode Map:PGx v1.0 = BE.BELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.2 = EX.EXLOC
nonReasonCode <i>Class:</i> PerformedProcedure <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying the motivation, cause or rationale that is explicitly NOT why an activity occurred.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE 2750712:Therapies.Did a particular reason for the non-myeloablative / reduced intensity preparative regimen occur?

Class: PerformedProductTransport

Package: Study Conduct Sub-Domain

DEFINITION:

A completed action of transporting a product between a point of origin and a point of destination.

EXAMPLE(S):

Delivery of drugs from the manufacturer to a medical facility.

OTHER NAME(S):**NOTE(S):***Tagged Values:*

- Map:CTRv1.0 = PerformedProductTransport
- Map:ICSRr2 = TransportationEvent (in R_Product)
- Map:ICSRr2 = Origin (in R_Product)
- Map:ICSRr2 = Destination (in R_Product)

Connectors

Source	Connector	Target	Notes
PerformedProductTransport	specializes	PerformedActivity	<p>DESCRIPTION: Each PerformedProductTransport always specializes one PerformedActivity. Each PerformedActivity might be specialized by one PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* destinedPerformedProductT ransport	have destination	ServiceDeliveryLocation 0..1 destinationServiceDeliveryL ocation	<p>DESCRIPTION: Each PerformedProductTransport might have destination one ServiceDeliveryLocation. Each ServiceDeliveryLocation might be the destination for one or more PerformedProductTransport.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* usingPerformedProductTran sport	use	Product 0..* usedProduct	<p>DESCRIPTION: Each PerformedProductTransport might use one or more Product. Each Product might be used during one or more PerformedProductTransport.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProductTransport 0..* originatedPerformedProductTransport	originate at	ServiceDeliveryLocation 0..1 originServiceDeliveryLocation	<p>DESCRIPTION: Each PerformedProductTransport might originate at one ServiceDeliveryLocation. Each ServiceDeliveryLocation might be the origin of one or more PerformedProductTransport.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>
PerformedProductTransport 0..* assigningPerformedProductTransport	assign responsibility to	Laboratory 0..1 responsibleLaboratory	<p>DESCRIPTION: Each PerformedProductTransport might assign responsibility to one Laboratory. Each Laboratory might be assigned responsibility by one or more PerformedProductTransport.</p> <p>DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
methodCode <i>Class:</i> PerformedProductTransport <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the technique that is used to transport the product.</p> <p>EXAMPLE(S): frozen gel pack room temperature per transplant center request</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE 2785775:Activity.Specify the shipping environment of the product(s): Map:HCTv1.0 = CDE 2785777:Activity.Specify shipping environment:

Attribute	Notes	Constraints and Tags
standardTimeIndicator <i>Class:</i> PerformedProductTransport <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the time of the product transport is specified using standard (as opposed to daylight savings) time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the location and date are known, this data is derivable.</p>	Map:HCTv1.0 = CDE 2774729:Therapies.Is time of receipt of product standard time or daylight savings time?

Class: PerformedProgressCount

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of determining the total number of an item in a project.

EXAMPLE(S):

The number of subjects that have completed the screening process in a study; the number of study sites that have received their site initiation visit.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Vendor1v1.1 = ProgressCount

Connectors

Source	Connector	Target	Notes
PerformedProgressCount	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedProgressCount always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedProgressCount.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
count <i>Class:</i> PerformedProgressCount <i>Datatype:</i> INT.NONNEG <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The number of items being counted. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:Vendor1v1.1 = StudyOverallStatus.sitesConfirmed Map:Vendor1v1.1 = StudyOverallStatus.countriesActual Map:Vendor1v1.1 = StudyOverallStatus.sitesActual Map:Vendor1v1.1 = ProgressCount.count

Class: PerformedProtocolDeviation

Package: Study Conduct Sub-Domain

DEFINITION:

A designation of an event as a variation from process or procedures defined in a study protocol.

EXAMPLE(S):

Study subject not withdrawn as per protocol, excluded concomitant medication, treatment deviation.

OTHER NAME(S):

NOTE(S):

Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety.

Tagged Values:

- Map:CTRv1.0 = PerformedProtocolDeviation
- Map:NCI CRF Standard = ProtocolDeviation
- Map:SDTM IGv3.1.2 = DV.DOMAIN
- Map:SDTM IGv3.1.3 = DV

Connectors

Source	Connector	Target	Notes
PerformedProtocolDeviation 0..* authorizedPerformedProtocolDeviation	be authorized by	StudyLegalSponsor 0..1 authorizingStudyLegalSponsor	DESCRIPTION: Each PerformedProtocolDeviation might be authorized by one StudyLegalSponsor. Each StudyLegalSponsor might authorize one or more PerformedProtocolDeviation. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProtocolDeviation 0..* implementedPerformedProtocolDeviation	have management action implemented by	StudySitePersonnel 0..1 implementingStudySitePersonnel	DESCRIPTION: Each PerformedProtocolDeviation might have management action implemented by one StudySitePersonnel. Each StudySitePersonnel might implement the management action for one or more

Source	Connector	Target	Notes
			PerformedProtocolDeviation . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProtocolDeviation	specializes	PerformedObservationResult	DESCRIPTION: Each PerformedProtocolDeviation always specializes one PerformedObservationResult. Each PerformedObservationResult might be specialized by one PerformedProtocolDeviation . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProtocolDeviation 0..* managedPerformedProtocol Deviation	have management action determined by	StudyResearchCoordinator 0..1 managingStudyResearchCoordinator	DESCRIPTION: Each PerformedProtocolDeviation might have management action determined by one StudyResearchCoordinator. Each StudyResearchCoordinator might determine the management action for one or more PerformedProtocolDeviation . DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
categoryCode <i>Class:</i> PerformedProtocolDeviation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying a classification of protocol deviation. EXAMPLE(S): Concomitant Medications, Data Integrity Compromised, Eligibility not checked, Eligibility waiver, Informed Consent, Other specify, Study Procedures, Treatment [NCI CRF Standard examples] OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = PerformedProtocolDeviation.categoryCode Map:NCI CRF Standard = CDE 2740419v1.0: Protocol Deviation Other Category Descriptive Text Map:NCI CRF Standard = CDE 2740412v1.0: Protocol Deviation Category Map:SDTM IGv3.1.1 = DV.DVCAT Map:SDTM IGv3.1.2 = DV.DVCAT Map:SDTM IGv3.1.3 = DV.DVCAT
subcategoryCode <i>Class:</i> PerformedProtocolDeviation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying a subdivision within a larger category of a protocol deviation. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRv1.0 = PerformedProtocolDeviation.subcategoryCode Map:SDTM IGv3.1.2 = DV.DVSCAT Map:SDTM IGv3.1.3 = DV.DVSCAT
severityCode <i>Class:</i> PerformedProtocolDeviation <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the intensity of a protocol deviation. EXAMPLE(S): major, moderate, minor OTHER NAME(S): NOTE(S):	Map:NCI CRF Standard = CDE 2740401v1.0: Protocol Deviation Severity Type
occurrenceDateRange <i>Class:</i> PerformedProtocolDeviation <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date and time span specifying when the protocol deviation began and ended. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CDASHv1.1 = DV.DVENTIM Map:CDASHv1.1 = DV.DVSTDAT Map:CDASHv1.1 = DV.DVSTTIM Map:CDASHv1.1 = DV.DVENDAT Map:CTRv1.0 = PerformedProtocolDeviation.occurrenceDateRange Map:NCI CRF Standard = CDE 2434998v1.0: Protocol Deviation Occurrence Date Map:SDTM IGv3.1.1 = DV.DVSTDTC Map:SDTM IGv3.1.1 = DV.DVENDTC Map:SDTM IGv3.1.2 = DV.DVENDTC Map:SDTM IGv3.1.2 = DV.DVSTDTC Map:SDTM IGv3.1.3 = DV.DVSTDTC Map:SDTM IGv3.1.3 = DV.DVENDTC

Class: PerformedSpecimenCollection

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of gathering samples that may be used for subsequent analysis.

EXAMPLE(S):

blood draw

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedSpecimenCollection
- Map:ICSRr2 = SpecimenCollectionProcess (in R_Specimen universal)
- Map:LabViewer2.2 = SpecimenCollection
- Map:LSDAMv2.2.3Plus = PerformedSpecimenCollection

Connectors

Source	Connector	Target	Notes
PerformedSpecimenCollection	specializes	PerformedProcedure	<p>DESCRIPTION: Each PerformedSpecimenCollection always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSpecimenCollection.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenCollectionGroup 0..1 producedSpecimenCollectio nGroup	be a result of	PerformedSpecimenCollecti on 0..1 producingPerformedSpecim enCollection	<p>DESCRIPTION: Each SpecimenCollectionGroup might be a result of one PerformedSpecimenCollection. Each PerformedSpecimenCollection might result in one SpecimenCollectionGroup.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Specimen 0..* producedSpecimen	be a result of	PerformedSpecimenCollecti on 0..1	<p>DESCRIPTION: Each Specimen might be a result of one</p>

Source	Connector	Target	Notes
		producingPerformedSpecimenCollection	<p>PerformedSpecimenCollection. Each PerformedSpecimenCollection might result in one or more Specimen.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
targetAnatomicSitePortionCode <i>Class:</i> PerformedSpecimenCollection <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the arrangement or apportionment of the body (or a paired organ) that is a target site for a procedure.</p> <p>EXAMPLE(S): entire, single, segment, many</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:SDTM IGv3.1.3 = TU.TUPORTOT</p>

Class: PerformedStudyAdministrativeActivity

Package: Study Conduct Sub-Domain

DEFINITION:

The completed study level administrative activity that is independent of a study subject.

EXAMPLE(S):

IRB Approval, site enrollment, FDA audit

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = PerformedStudyAdministrativeActivity
- Map:HL7SP = Study.evaluation

Connectors

Source	Connector	Target	Notes
PerformedStudyAdministrativeActivity	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedStudyAdministrativeActivity always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one</p>

Source	Connector	Target	Notes
			PerformedStudyAdministrativeActivity. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: PerformedStudyAgentTransfer

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action in which an authorized party at a designated study site dispenses or receives a study agent to/from a study subject.

EXAMPLE(S):

StudySubject receives a bottle of pills.

OTHER NAME(S):

NOTE(S):

Original units can be derived from the translation attribute of the PQ data type on PerformedStudyAgentTransfer.quantity.

The term "study agent" only pertains within the context of a given study. To make this explicit in BRIDG it was determined that the StudyAgent class would only be used to connect Product to StudyProtocolVersion. All activity-related classes would be associated directly to Product to avoid the issues of activities that may cross study boundaries. To determine if a given activity uses a study agent one need only compare the product used in the activity with the list of products associated to StudyAgent for a given StudyProtocolVersion. It should be noted that this determination could be different for different studies and could evolve over the course of a given study.

Tagged Values:

- Map:CTRv1.0 = PerformedStudyAgentTransfer
- Map:SDTM IGV3.1.2 = DA.DOMAIN
- Map:SDTM IGV3.1.3 = DA

Connectors

Source	Connector	Target	Notes
PerformedStudyAgentTransfer	specializes	PerformedAdministrativeActivity	DESCRIPTION: Each PerformedStudyAgentTransfer always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedStudyAgentTransfer. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
PerformedStudyAgentTransfer 0..* transferringPerformedStudyAgentTransfer	is a transfer of	Product 1 transferredProduct	<p>NOTE(S):</p> <p>DESCRIPTION: Each PerformedStudyAgentTransfer always is a transfer of one Product. Each Product might be transferred during one or more PerformedStudyAgentTransfer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedStudyAgentTransfer 0..* authorizedPerformedStudyAgentTransfer	be authorized by	StudySiteResearchCoordinator 0..1 authorizingStudySiteResearchCoordinator	<p>DESCRIPTION: Each PerformedStudyAgentTransfer might be authorized by one StudySiteResearchCoordinator. Each StudySiteResearchCoordinator might authorize one or more PerformedStudyAgentTransfer.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
quantity <i>Class:</i> PerformedStudyAgentTransfer <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The amount and unit of study agent transferred in standard or canonical units.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = PerformedStudyAgentTransfer.quantity Map:SDTM IGv3.1.1 = DA.DASTRESC Map:SDTM IGv3.1.1 = DA.DAORRESU Map:SDTM IGv3.1.1 = DA.DAORRES Map:SDTM IGv3.1.2 = DA.DASTRESU Map:SDTM IGv3.1.2 = DA.DASTRESN Map:SDTM IGv3.1.3 = DA.DASTRESU Map:SDTM IGv3.1.3 = DA.DASTRESN
originalQuantity <i>Class:</i> PerformedStudyAgentTransfer <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The amount and unit of study agent transferred in original units.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Original units can be derived from the translation attribute of the PQ data type PerformedStudyAgentTransfer.quantity.</p>	Map:CDASHv1.1 = DA.DAORRESU Map:CDASHv1.1 = DA.DAORRES Map:CTRv1.0 = PerformedStudyAgentTransfer.originalQuantity Map:SDTM IGv3.1.1 = DA.DAORRESU Map:SDTM IGv3.1.1 = DA.DAORRES Map:SDTM IGv3.1.2 = DA.DAORRESU Map:SDTM IGv3.1.2 = DA.DAORRES Map:SDTM IGv3.1.3 = DA.DAORRESU Map:SDTM IGv3.1.3 = DA.DAORRES

Class: PerformedStudySubjectMilestone

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action which marks a common administrative landmark for a study subject in the course of a study.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = ScheduledEpoch
- Map:CTRPv3.8 = PerformedSubjectMilestone
- Map:CTRv1.0 = PerformedStudySubjectMilestone
- Map:LabViewer2.2 = SubjectAssignment
- Map:NCI CRF Standard = Enrollment
- Map:NCI CRF Standard = Registration
- Map:SDTM IGv3.1.2 = DS.DOMAIN

- Map:SDTM IGV3.1.3 = DS

Connectors

Source	Connector	Target	Notes
PerformedStudySubjectMilestone	specializes	PerformedSubjectMilestone	<p>DESCRIPTION: Each PerformedStudySubjectMilestone always specializes one PerformedSubjectMilestone.</p> <p>Each PerformedSubjectMilestone might be specialized by one PerformedStudySubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
informedConsentIndicator <i>Class:</i> PerformedStudySubjectMilestone <i>Datatype:</i> BL <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the study subject gave official consent by signing the official consent form.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from the existence of PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "obtain informed consent".</p>	Map:HCTv1.0 = CDE 2532667:Recipient Identification.Consented for Research? Map:HCTv1.0 = CDE 2630147:Recipient Identification.Consent for CIBMTR related specimen repository
registrationDate <i>Class:</i> PerformedStudySubjectMilestone <i>Datatype:</i> TS.DATETIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) the subject has been registered to the study assuming they have finished screening and have been found eligible.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "register subject".</p>	Map:C3PRv2.9 = StudySubject.startDate Map:caAERSv2.2 = StudyParticipantAssignment.startDate Map:CTRPv1.0 = PerformedStudySubjectMilestone.registrationDate Map:CTRPv3.8 = PerformedSubjectMilestone.registrationDate Map:CTRv1.0 = PerformedStudySubjectMilestone.registrationDate Map:LabViewer2.2 = SubjectAssignment.onStudyDate Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone.registrationDate

Attribute	Notes	Constraints and Tags
offStudyDate <i>Class:</i> PerformedStudySubjectMilestone <i>Datatype:</i> TS.DATETIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) when the study subject is removed from the study.</p> <p>EXAMPLE(S): The subject is not being followed and will not be retreated.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "remove subject from study".</p>	Map:C3PR = StudySubject.offStudyDate Map:C3PRv2.9 = StudySubject.offStudyDate Map:CTOM = StudyParticipantAssignment.offStudyDate Map:CTRv1.0 = PerformedStudySubjectMilestone.offStudyDate Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone.offStudyDate
offStudyReasonCode <i>Class:</i> PerformedStudySubjectMilestone <i>Datatype:</i> DSET<CD> <i>Derived:</i> True <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A coded value specifying why the subject is removed from a study.</p> <p>EXAMPLE(S): patient died</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedStudySubjectMilestone.reasonCode WHERE PerformedActivity > DefinedActivity.nameCode = "remove subject from study".</p>	Map:C3PR = StudySubject.offStudyReasonText Map:C3PRv2.9 = StudySubject.offStudyReasonText Map:CTOM = StudyParticipantAssignment.offStudyReasonOtherText Map:CTOM = StudyParticipantAssignment.offStudyReasonCode Map:CTRv1.0 = PerformedStudySubjectMilestone.offStudyReasonCode Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone.offStudyReasonCode
studyReferenceDateRange <i>Class:</i> PerformedStudySubjectMilestone <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span used to indicate the start and end of the study for a subject.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived in two parts: The start date is derived from PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "first intake of agent" (or other study-specific milestone). The end date is derived from PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "last intake of agent" (or other study-specific milestone).</p> <p>These dates are required for all randomized subjects; null for screen failures (if screen failures are submitted).</p>	Map:C3PR = StudySubject.startDate Map:CTRv1.0 = PerformedStudySubjectMilestone.studyReferenceDateRange Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone.studyReferenceDateRange Map:SDTM IGv3.1.1 = DM.RFSTDTC Map:SDTM IGv3.1.1 = DM.RFENDTC Map:SDTM IGv3.1.2 = MH.MHENTPT Map:SDTM IGv3.1.2 = AE.AEENTPT Map:SDTM IGv3.1.2 = DM.RFSTDTC Map:SDTM IGv3.1.2 = DM.RFENDTC Map:SDTM IGv3.1.3 = DM.RFSTDTC Map:SDTM IGv3.1.3 = DM.RFENDTC

Class: PerformedSubjectMilestone

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action which marks a common administrative landmark for a subject in the course of a study.

EXAMPLE(S):

obtain informed consent, verify eligibility criteria, enroll, registration to a study, randomize, assignment to a treatment arm, start of on-study period, complete study visits, end of on-study period, exit study, break treatment blind, premature withdrawal, assignment to a specimen collection protocol at a collection laboratory

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone

Connectors

Source	Connector	Target	Notes
PerformedSubjectMilestone	specializes	PerformedAdministrativeActivity	<p>DESCRIPTION: Each PerformedSubjectMilestone always specializes one PerformedAdministrativeActivity. Each PerformedAdministrativeActivity might be specialized by one PerformedSubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubjectMilestone 0..* usingPerformedStudySubjectMilestone	use	DocumentVersion 0..1 usedDocumentVersion	<p>DESCRIPTION: Each PerformedSubjectMilestone might use one DocumentVersion. Each DocumentVersion might be used for one or more PerformedSubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SpecimenCollectionProtocolSubject 0..1 registeredSpecimenCollectionProtocolSubject	be registered by	PerformedSubjectMilestone 0..1 registeringPerformedSubjectMilestone	<p>DESCRIPTION: Each SpecimenCollectionProtocolSubject might be registered by one</p>

Source	Connector	Target	Notes
			<p>PerformedSubjectMilestone. Each PerformedSubjectMilestone might register one SpecimenCollectionProtocol Subject.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): If the CollectingLaboratory is the Performer of the assignment of a Subject to a Protocol, and/or the collector of the informed consent (i.e. the performer of a PerformedSubjectMilestone) , then the association from SpecimenCollectionProtocol Subject to CollectingLaboratory is redundant and should NOT be used.</p>
PerformedStudySubjectMilestone	specializes	PerformedSubjectMilestone	<p>DESCRIPTION: Each PerformedStudySubjectMilestone always specializes one PerformedSubjectMilestone. Each PerformedSubjectMilestone might be specialized by one PerformedStudySubjectMilestone.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
informedConsentDate <i>Class:</i> PerformedSubjectMilestone <i>Datatype:</i> TS.DATETIME <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) the study subject gives official consent by signing the official consent form.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from PerformedStudySubjectMilestone.dateRange WHERE PerformedActivity > DefinedActivity.nameCode = "obtain informed consent".</p>	Map:C3PR = StudySubject.informedConsentSignedDate Map:CTOM = StudyParticipantAssignment.informedConsentFormSignedDate Map:CTRPv3.8 = PerformedSubjectMilestone.informedConsentDate Map:CTRv1.0 = PerformedStudySubjectMilestone.informedConsentDate Map:LabViewer2.2 = SubjectAssignment.informedConsentFormSignedDate Map:LSDAMv2.2.3Plus = PerformedStudySubjectMilestone.informedConsentDate Map:SDTM IGv3.1.3 = DM.RFICDTC

Class: PerformedSubstanceAdministration

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of applying, introducing or otherwise giving medications or other substances to the subject or experimental unit.

EXAMPLE(S):

An experimental unit who receives methotrexate as part of chemotherapy, radiation therapy,

For a SubstanceAdministration, targetAnatomicSiteCode = coronary artery, approachAnatomicSiteCode = groin, routeOfAdministrationCode = intra-arterial.

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AE = Intervention
 - Map:caAERSv2.2 = StudyParticipantPriorTherapy
 - Map:caAERSv2.2 = StudyParticipantConcomitantMedication
 - Map:CTRv1.0 = PerformedSubstanceAdministration
 - Map:HCTv1.0 = CDE 2934704:Therapies.Were tyrosine kinase inhibitors administered?
 - Map:HCTv1.0 = CDE 3040303:Therapies.Was another radioisotope administered?
 - Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration
 - Map:SDTM_IGv3.1.2 = SU.DOMAIN
 - Map:SDTM_IGv3.1.2 = EX.DOMAIN
 - Map:SDTM_IGv3.1.2 = CM.DOMAIN
 - Map:SDTM_IGv3.1.3 = SU
 - Map:SDTM_IGv3.1.3 = EX
 - Map:SDTM_IGv3.1.3 = CM

Connectors

Source	Connector	Target	Notes
PerformedSubstanceAdministration 0..*	have start evaluated in relation to	PerformedActivity 0..1 startRelatedPerformedActivity	DESCRIPTION: Each PerformedSubstanceAdministration

Source	Connector	Target	Notes
startEvaluatedPerformedSubstanceAdministration		ty	<p>stration might have start evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating the start of one or more PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S): In CDISC SDTM, CMSTTP indicates a study event that may be a reference event for the start of a concomitant medication (PerformedSubstanceAdministration) or SUENTPT might be the reference event for the start of a substance use event (also a PerformedSubstanceAdministration).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): As per CDISC, any given substance administration can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedSubstanceAdministration and PerformedActivity for evaluating start and end of the administration.</p>
PerformedSubstanceAdministration 0..* endEvaluatedPerformedSubstanceAdministration	have end evaluated in relation to	PerformedActivity 0..1 endRelatedPerformedActivity	<p>DESCRIPTION:</p> <p>Each PerformedSubstanceAdministration might have end evaluated in relation to one PerformedActivity. Each PerformedActivity might be the timepoint for evaluating the end of one or more PerformedSubstanceAdministration.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			<p>EXAMPLE(S): In CDISC SDTM, CMENTPT indicates a study event that may be a reference event for the end of a concomitant medication (PerformedSubstanceAdministration) or SUENTPT might be the reference event for the end of a substance use event (also a PerformedSubstanceAdministration).</p> <p>OTHER NAME(S):</p> <p>NOTE(S): As per CDISC, any given substance administration can have its start evaluated in relation to a performed activity. Likewise it can also have its end evaluated in relation to a performed activity. The two performed activities need not necessarily be the same in both cases, thus there are two distinct associations between PerformedSubstanceAdministration and PerformedActivity for evaluating start and end of the administration.</p>
PerformedSubstanceAdministration 0..* addressingPerformedSubstanceAdministration	address	PerformedMedicalConditionResult 0..* addressedPerformedMedicalConditionResult	<p>DESCRIPTION: Each PerformedSubstanceAdministration might address one or more PerformedMedicalConditionResult. Each PerformedMedicalConditionResult might be addressed by one or more PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubstanceAdministration	specializes	PerformedProcedure	<p>DESCRIPTION: Each PerformedSubstanceAdministration always specializes</p>

Source	Connector	Target	Notes
			<p>one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubstanceExtractionAdministrationRelationship 0..* producedSubstanceExtractionAdministrationRelationship	be producing a substance later used in	PerformedSubstanceAdministration 0..1 usingPerformedSubstanceAdministration	<p>DESCRIPTION: Each SubstanceExtractionAdministrationRelationship might be producing a substance later used in one PerformedSubstanceAdministration. Each PerformedSubstanceAdministration might be using a substance produced by one or more SubstanceExtractionAdministrationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
productDose <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The quantity of a substance or medication used in a substance administration.</p> <p>EXAMPLE(S): 5 mg</p> <p>OTHER NAME(S):</p> <p>NOTE(S): DefinedSubstanceAdministration.productDose can contain a dose expressed in absolute or relative terms (e.g., mg or mg/kg). ScheduledSubstanceAdministration.activeIngredientDose and PerformedSubstanceAdministration.productDose must contain a dose expressed in absolute terms (e.g., mg). If the DefinedSubstanceAdministration.productDose was expressed in relative terms (e.g., mg/kg), then the absolute dose must have been calculated using one or more observed factors as identified by the DefinedExpressionVariableRelationship.</p>	Map:caAERSv2.2 = AdverseEventResponseDescription.reducedDose Map:caAERSv2.2 = RadiationIntervention.dosage Map:caAERSv2.2 = Dose.amount Map:caAERSv2.2 = Dose.unit Map:caAERSv2.2 = RadiationIntervention.dosageUnit Map:CDASHv1.1 = EX.EXVOLT Map:CDASHv1.1 = EX.EXVOLTU Map:CTOM = SubstanceAdministration.singleDoseUnitOfMeasureCode Map:CTOM = Radiation.doseUnitOfMeasureCode Map:CTOM = SubstanceAdministration.singleDose Map:CTOM = StudyParticipantAssignment.studyAge Map:CTOM = Radiation.dose Map:CTOM = StudyParticipantAssignment.studyAge Map:CTOM = UnitDoseLevelUnitOfMeasureCode Map:CTOM = Radiation.dose Map:HCTv1.0 = CDE 3108427:Therapies.What is the dose value of the preparative regimen medication? Map:HCTv1.0 = CDE 2729014:Therapies.For the allogeneic blood transfusion, specify the number of units: Map:HCTv1.0 = CDE 2738560:Therapy Doses.Total volume of product plus additives infused: Map:HCTv1.0 = CDE 2180757:Therapies.RT Dose per Fraction Map:HCTv1.0 = CDE 2954034:Therapy Doses.Dose per fraction unit of measure: Map:HCTv1.0 = CDE 2729000:Therapies.For the autologous blood transfusion, specify the number of units: Map:HCTv1.0 = CDE 2954032:Therapy Doses.Dose per fraction: Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.dose Map:NCI CRF Standard = CDE 2182728v2.0: Agent Dose Map:NCI CRF Standard = CDE 3028750v1.0: Intervention Potency Unit of Measure for Unified Code for Units of Measure Code

Attribute	Notes	Constraints and Tags
productDoseDescription <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The textual representation of dosing amounts or a range of dosing information used in a substance administration.</p> <p>EXAMPLE(S): 200-400</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is used for more complex dosages such as scaling and tapering doses, uncertain dosage ranges, differing morning and evening doses and other instructions that can't be expressed with a simple PQ.</p>	Map:CTOM = SubstanceAdministration.descriptionText Map:CTRv1.0 = PerformedSubstanceAdministration.productDoseDescription Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.doseDescription

Attribute	Notes	Constraints and Tags
periodProductDoseTotal <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The total of all doses of treatment in a given period of time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The given period of time is defined in dosePeriodCode.</p> <p>This attribute, periodProductDoseTotal, is not necessarily derivable since the dose may be provided as a string (in productDoseDescription).</p>	Map:caAERSv2.2 = Dose.amount Map:caAERSv2.2 = RadiationIntervention.fractionNumber Map:caAERSv2.2 = Dose.units Map:CTOM = SubstanceAdministration.totalDose Map:CTOM = SubstanceAdministration.totalDoseUnitOfMeasureCode Map:CTrv1.0 = PerformedSubstanceAdministration.periodProductDoseTotal Map:HCTv1.0 = CDE 2962200:Therapies.Specify interstitial irradiation/brachytherapy total dose: Map:HCTv1.0 = CDE 2953815:Therapies.Total dose unit of measure: Map:HCTv1.0 = CDE 3181110:Therapies.Therapeutic procedure administered milligram daily dose: Map:HCTv1.0 = CDE 2721441:Therapies.Total Dose Map:HCTv1.0 = CDE 2960635:Therapies.Specify local cranial radiation total dose: Map:HCTv1.0 = CDE 2964435:Therapies.Radiation therapy field radioactive instillation total dose Map:HCTv1.0 = CDE 2980940:Therapies.What was the radiation total dose? Map:HCTv1.0 = CDE 2960649:Therapies.Specify gamma knife and/or radiosurgery radiation total dose: Map:HCTv1.0 = CDE 2960642:Therapies.Specify craniospinal radiation total dose: Map:HCTv1.0 = CDE 3086792:Therapies.Specify total dose: Map:HCTv1.0 = CDE 2960770:Therapies.Specify the total radiation dose administered to another site: Map:HCTv1.0 = CDE 2960298:Therapies.What was the preparative regimen total milligram dose? Map:HCTv1.0 = CDE 2960618:Therapies.Specify whole brain radiation total dose: Map:HCTv1.0 = CDE 2960768:Therapies.Specify local spinal radiation total dose: Map:HCTv1.0 = CDE 2979333:Therapies.Local-regional radiation therapy total dose: Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.pe

Attribute	Notes	Constraints and Tags
		riodDoseTotal
dosePeriodCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the period during which the dose total is administered.</p> <p>EXAMPLE(S): daily, course</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The dose total is defined in periodProductDoseTotal and/or periodActiveIngredientDoseTotal.</p>	Map:caAERSv2.2 = CourseAgent>totalDoseAdministered ThisCourse>Dose Map:CTRv1.0 = PerformedSubstanceAdministration.dosePeriodCode Map:HCTv1.0 = CDE 2635420:Therapy Doses.Was the radiation therapy fractionated Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.dosePeriodCode
periodActiveIngredientDo seTotal <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The total amount of active ingredient in all doses of treatment in a given period of time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The given period of time is defined in dosePeriodCode.</p> <p>Derived by multiplying PerformedSubstanceAdministration.periodProductDoseTotal (the composite product that was administered) with the ProductRelationship.quantity (a ratio) for the component product that is the active ingredient (where ProductRelationship.activeIngredientIndicator = "true").</p>	Map:caAERSv2.2 = Dose.amount Map:caAERSv2.2 = Dose.units Map:caAERSv2.2 = RadiationIntervention.fractionNumber Map:CDASHv1.1 = CM.CMDOSTOT Map:CTOM = SubstanceAdministration.totalDoseUnitOfMeasureCode Map:CTOM = SubstanceAdministration.totalDose Map:CTRv1.0 = PerformedSubstanceAdministration.periodActiveIngredientDoseTotal Map:SDTM IGv3.1.1 = SU.SUDOSTOT Map:SDTM IGv3.1.1 = EX.EXDOSTOT Map:SDTM IGv3.1.1 = CM.CMDOSTOT Map:SDTM IGv3.1.2 = EX.EXDOSTOT Map:SDTM IGv3.1.2 = CM.CMDOSTOT Map:SDTM IGv3.1.2 = SU.SUDOSTOT Map:SDTM IGv3.1.3 = SU.SUDOSTOT Map:SDTM IGv3.1.3 = CM.CMDOSTOT Map:SDTM IGv3.1.3 = EX.EXDOSTOT Map:SDTM IGv3.1.3 = EX.EXDOSTXT Map:SDTM IGv3.1.3 = EX.EXDOSU

Attribute	Notes	Constraints and Tags
activeIngredientDose <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The quantity of active ingredients used in a substance administration.</p> <p>EXAMPLE(S): 5 mg</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived by multiplying the PerformedSubstanceAdministration.productDose (the composite product that was administered) with the ProductRelationship.quantity (a ratio) for the component product that is the active ingredient (where ProductRelationship.activeIngredientIndicator = "true").</p>	Map:caAERSv2.2 = AdverseEventResponseDescription.reducedDose Map:caAERSv2.2 = RadiationIntervention.dosage Map:caAERSv2.2 = Dose.amount Map:caAERSv2.2 = RadiationIntervention.dosageUnit Map:caAERSv2.2 = Dose.unit Map:CDASHv1.1 = CM.CMDOSU Map:CDASHv1.1 = SU.SUDOSU Map:CDASHv1.1 = EX.EXDOSU Map:CDASHv1.1 = EX.EXDSTXT Map:CTOM = SubstanceAdministration.singleDoseUnitOfMeasureCode Map:CTOM = StudyParticipantAssignment.studyAge ntDoseLevel Map:CTOM = StudyParticipantAssignment.studyAge ntDoseLevelUnitOfMeasureCode Map:CTOM = SubstanceAdministration.singleDose Map:CTRv1.0 = PerformedSubstanceAdministration.ac tiveIngredientDose Map:SDTM IGv3.1.1 = CM.CMDOSE Map:SDTM IGv3.1.1 = EX.EXDOSU Map:SDTM IGv3.1.1 = SU.SUDOSE Map:SDTM IGv3.1.1 = EX.EXDOSE Map:SDTM IGv3.1.1 = CM.CMDOSU Map:SDTM IGv3.1.1 = SU.SUDOSU Map:SDTM IGv3.1.2 = SU.SUDOSE Map:SDTM IGv3.1.2 = EX.EXDOSU Map:SDTM IGv3.1.2 = CM.CMDOSE Map:SDTM IGv3.1.2 = EX.EXDOSE Map:SDTM IGv3.1.2 = SU.SUDOSU Map:SDTM IGv3.1.2 = CM.CMDOSU Map:SDTM IGv3.1.3 = SU.SUDOSU Map:SDTM IGv3.1.3 = CM.CMDOSE Map:SDTM IGv3.1.3 = EX.EXDOSE Map:SDTM IGv3.1.3 = EX.EXDOSU Map:SDTM IGv3.1.3 = SU.SUDOSE Map:SDTM IGv3.1.3 = CM.CMDOSE

Attribute	Notes	Constraints and Tags
activeIngredientDoseDescription <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The textual representation of active ingredients in the dosing amounts or a range of dosing information used in a substance administration.</p> <p>EXAMPLE(S): 200-400</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is used for more complex dosages such as scaling and tapering doses, uncertain dosage ranges, differing morning and evening doses and other instructions that can't be expressed with a simple PQ.</p>	Map:CDASHv1.1 = SU.SUDSTXT Map:CDASHv1.1 = EX.EXDSTXT Map:CDASHv1.1 = CM.CMDSTXT Map:CTOM = SubstanceAdministration.descriptionText Map:CTRv1.0 = PerformedSubstanceAdministration.activeIngredientDoseDescription Map:SDTM IGv3.1.1 = SU.SUDOSTXT Map:SDTM IGv3.1.1 = CM.CMDOXTXT Map:SDTM IGv3.1.1 = EX.EXDOSTXT Map:SDTM IGv3.1.2 = CM.CMDOXTXT Map:SDTM IGv3.1.2 = SU.SUDOSTXT Map:SDTM IGv3.1.2 = EX.EXDOSTXT Map:SDTM IGv3.1.3 = SU.SUDOSTXT Map:SDTM IGv3.1.3 = CM.CMDOXTXT
treatmentVehicleQuantity <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The quantity and units of treatment vehicle used.</p> <p>EXAMPLE(S): 10 milligrams, 2 milliliters</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived by multiplying the PerformedSubstanceAdministration.productDose (the composite product that was administered) with the ProductRelationship.quantity (a ratio) for the component product that is the active ingredient (where ProductRelationship.activeIngredientIndicator = "false").</p>	Map:CTRv1.0 = SubstanceAdministration.treatmentVehicleVolume Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.treatmentVehicleVolume Map:NCI CRF Standard = CDE 2871633v1.0: Agent Administration Drug Vehicle Total Volume Number Map:SDTM IGv3.1.2 = EX.EXVAMT Map:SDTM IGv3.1.2 = EX.EXVAMTU Map:SDTM IGv3.1.3 = EX.EXVAMTU Map:SDTM IGv3.1.3 = EX.EXVAMT
distinctProductCount <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The number of products (resulting from different collections) used for this substance administration.</p> <p>EXAMPLE(S): If blood is taken from 2 people (two donations from one of them), this would be counted as 3 different collections.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is a count of distinct donations, typically used for stem cell transplants.</p>	Map:HCTv1.0 = CDE 3010760:DONOR!.What is the number of hematopoietic stem cell products that resulted from different collection methods or episodes and or mobilization techniques? Map:HCTv1.0 = CDE 2693395:Procedures.Were multiple products infused?

Attribute	Notes	Constraints and Tags
doseFrequencyCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying how often doses are administered.</p> <p>EXAMPLE(S): BID, TID, QID</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is needed in order to capture multiple substance administrations in one act, rather than each time a patient swallows a pill, for example "The patient took med X 3 times a day for 10 days starting on June 9th".</p>	Map:caAERSv2.2 = CourseAgent.durationAndSchedule Map:CDASHv1.1 = EX.EXDOSFRQ Map:CDASHv1.1 = SU.SUDOSFRQ Map:CDASHv1.1 = CM.CMDOSFRQ Map:CTOM = SubstanceAdministration.doseFrequencyText Map:CTOM = SubstanceAdministration.doseFrequencyCode Map:CTRv1.0 = PerformedSubstanceAdministration.doseFrequencyCode Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.doseFrequencyCode Map:NCI CRF Standard = CDE 2003322v4.0: Administration Schedule Term Name Map:SDTM IGv3.1.1 = EX.EXDOSFRQ Map:SDTM IGv3.1.1 = CM.CMDOSFRQ Map:SDTM IGv3.1.1 = SU.SUDOSFRQ Map:SDTM IGv3.1.2 = CM.CMDOSFRQ Map:SDTM IGv3.1.2 = EX.EXDOSFRQ Map:SDTM IGv3.1.2 = SU.SUDOSFRQ Map:SDTM IGv3.1.3 = SU.SUDOSFRQ Map:SDTM IGv3.1.3 = CM.CMDOSFRQ Map:SDTM IGv3.1.3 = EX.EXDOSFRQ
flowRate <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> RTO<PQ,PQ.TIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A ratio specifying the speed with which the substance is introduced into the subject.</p> <p>EXAMPLE(S): 100 mL/h 1 g/d 40 mmol/h</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = EX.EXFLRTU Map:CDASHv1.1 = EX.EXFLRT Map:CTRv1.0 = PerformedSubstanceAdministration.flowRate Map:FDA HL7 SD SD DSTU2012 = PlannedSubjectActivity/SubstanceAdministration.rateQuantity Map:NCI CRF Standard = CDE 2475888v1.0: Infusion Flow Rate Number

Attribute	Notes	Constraints and Tags
routeOfAdministrationCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the physiological path or method of introducing the substance into or onto the subject.</p> <p>EXAMPLE(S): oral, intravenous, swallow, oral rinse, oral topical application, chew, oral dissolve, oral inhalation</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Route is more than just approach site. It deals with how the body will actually absorb/receive the drug. The approach site might be "mouth", but from a route code perspective, this could include: swallow, oral rinse, oral topical application, chew, oral dissolve, oral inhalation (via intermittent flow or rebreather mask). The effect of the drug could vary depending on the route even if the body site happens to be the same.</p>	Map:caAERSv2.2 = Dose.route Map:CDASHv1.1 = EX.EXROUTE Map:CDASHv1.1 = CM.CMROUTE Map:CTOM = SubstanceAdministration.routeCode Map:CTRv1.0 = PerformedSubstanceAdministration.routeOfAdministrationCode Map:HCTv1.0 = CDE 2960396:Therapies.What was the route of administration for the preparative regimen drugs? Map:HCTv1.0 = CDE 2698088:Therapy Doses.Specify the route of product infusion: Map:HCTv1.0 = MD Anderson Specific Content: Transplant.Intravenous administration Map:HCTv1.0 = CDE 2780200:Therapy Doses.Specify route of infusion: Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.routeOfAdministrationCode Map:NCI CRF Standard = CDE 2003586v6.0: Access Route of Administration Text Code Map:SDTM IGv3.1.1 = EX.EXROUTE Map:SDTM IGv3.1.1 = CM.CMROUTE Map:SDTM IGv3.1.1 = SU.SUROUTE Map:SDTM IGv3.1.2 = CM.CMROUTE Map:SDTM IGv3.1.2 = EX.EXROUTE Map:SDTM IGv3.1.2 = SU.SUROUTE Map:SDTM IGv3.1.3 = SU.SUROUTE Map:SDTM IGv3.1.3 = CM.CMROUTE Map:SDTM IGv3.1.3 = EX.EXROUTE
interruptionDuration <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The period of time during which a substance administration is interrupted.</p> <p>EXAMPLE(S): An infusion started at 12:15pm and ended at 2:37pm, but there was an interruption of 17 minutes.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = EX.EXINTRP Map:CDASHv1.1 = EX.EXINTRPU Map:CTRv1.0 = PerformedSubstanceAdministration.interruptionDuration

Attribute	Notes	Constraints and Tags
changeTypeCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A coded value specifying the modification of the substance administration in relation to the previous substance administration. EXAMPLE(S): Agent Added, Agent Dose Decreased, Agent Dose Increased OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = CourseAgent.agentAdjustment Map:CTOM = SubstanceAdministration.doseChangeCode Map:CTRv1.0 = PerformedSubstanceAdministration.changeTypeCode Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.changeTypeCode
plannedChangeIndicator <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether a change in the substance administration in relation to the previous substance administration is planned or not. EXAMPLE(S): True = planned, False = unplanned OTHER NAME(S): NOTE(S):	Map:CTOM = SubstanceAdministration.doseChangeIndicatorCode Map:CTOM = DiseaseResponse.doseChangeIndicatorCode Map:CTRv1.0 = PerformedSubstanceAdministration.plannedChangeIndicator Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.plannedChangeIndicator
changeReason <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The rationale for changing the substance administration in relation to the previous substance administration. EXAMPLE(S): Dose reduced due to hematologic toxicity OTHER NAME(S): NOTE(S):	Map:CDASHv1.1 = EX.EXADJ Map:CTRv1.0 = PerformedSubstanceAdministration.changeReason Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.changeReason Map:SDTM IGv3.1.1 = EX.EXADJ Map:SDTM IGv3.1.2 = EX.EXADJ Map:SDTM IGv3.1.3 = EX.EXADJ
substanceUnknownIndicator <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the substance administered was not known. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:HCTv1.0 = CDE 2974124:Therapies.What is the reason for the drug induced drug missing value?
standardTimeIndicator <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the time of the substance administration is specified using standard (as opposed to daylight savings) time. EXAMPLE(S): OTHER NAME(S): NOTE(S): If the location and date are known, this data is derivable.	Map:HCTv1.0 = CDE 2713225:Occurrences.Is it the standard time or daylight savings time? Map:HCTv1.0 = CDE 2713223:Occurrences.Is it the standard time or daylight savings time?

Attribute	Notes	Constraints and Tags
startRelativeToReferenceCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying when this event started with respect to the sponsor-defined reference period.</p> <p>EXAMPLE(S): Medications that are ongoing at the end of the reference period should have a value of "during/after" for this variable.</p> <p>Before, during, during/after, after</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing PerformedSubstanceAdministration.dateRange(I VL<TS.DATETIME).low and PerformedStudySubjectMilestone.studyReferenceDateRange.</p> <p>Sponsors should define the reference period in the study metadata.</p> <p>This may be populated when a start date is not collected.</p>	Map:CTRv1.0 = PerformedSubstanceAdministration.startRelativeToReferenceCode Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.startRelativeToReferenceCode Map:SDTM IGv3.1.1 = CM.CMSTRF Map:SDTM IGv3.1.1 = SU.SUSTRF Map:SDTM IGv3.1.3 = SU.SUSTRF Map:SDTM IGv3.1.3 = CM.CMSTRF
endRelativeToReferenceCode <i>Class:</i> PerformedSubstanceAdministration <i>Datatype:</i> CD <i>Derived:</i> True <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying when this event ended with respect to the sponsor-defined reference period.</p> <p>EXAMPLE(S): before, during, during/after, after</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Derived from comparing PerformedSubstanceAdministration.dateRange(I VL<TS.DATETIME>).high and PerformedStudySubjectMilestone.studyReferenceDateRange.</p> <p>Sponsors should define the reference period in the study metadata.</p> <p>This may be populated when a start date is not collected.</p>	Map:CTRv1.0 = PerformedSubstanceAdministration.endRelativeToReferenceCode Map:LSDAMv2.2.3Plus = PerformedSubstanceAdministration.endRelativeToReferenceCode Map:SDTM IGv3.1.1 = SU.SUENRF Map:SDTM IGv3.1.1 = CM.CMENRF Map:SDTM IGv3.1.3 = SU.SUENRF Map:SDTM IGv3.1.3 = CM.CMENRF

Class: PerformedSubstanceExtraction

Package: Study Conduct Sub-Domain

DEFINITION:

The completed action of extracting something from an associated study subject for the purpose of the extracted product to be administered to a subject.

EXAMPLE(S):

A donor giving Bone Marrow Stem Cells for a Stem Cell Transplant

OTHER NAME(S):

NOTE(S):

The study subject could be the same for the extraction and the intended administration.

This is different than a PerformedSpecimenCollection, in that the intent is different: This is a donation.

Tagged Values:

Connectors

Source	Connector	Target	Notes
PerformedSubstanceExtraction	specializes	PerformedProcedure	<p>DESCRIPTION: Each PerformedSubstanceExtraction always specializes one PerformedProcedure. Each PerformedProcedure might be specialized by one PerformedSubstanceExtraction.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedSubstanceExtraction 0..* producingPerformedSubstanceExtraction	produces	Biologic 1 producedBiologic	<p>DESCRIPTION: Each PerformedSubstanceExtraction always produces one Biologic. Each Biologic might be produced by one or more PerformedSubstanceExtraction.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubstanceExtractionAdministrationRelationship 0..1 usedSubstanceExtractionAdministrationRelationship	uses a substance produced by	PerformedSubstanceExtraction 1 producingPerformedSubstanceExtraction	<p>DESCRIPTION: Each SubstanceExtractionAdministrationRelationship always uses a substance produced by one PerformedSubstanceExtraction. Each PerformedSubstanceExtraction might be producing a substance later used in one SubstanceExtractionAdministrationRelationship.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: ReferenceResult

Package: Study Conduct Sub-Domain

DEFINITION:

The possible or expected results that can be obtained by observing, monitoring, measuring or otherwise qualitatively or quantitatively recording one or more aspects of physiologic or psychologic processes.

EXAMPLE(S):

The normal range for a systolic blood pressure reading is 110-130 for adult males:

ReferenceResult.referenceTypeCode = normal range

ReferenceResult.valueTypeCode = systolic blood pressure

ReferenceResult.value(ANY=>IVL<PQ>) = 110-130 mm[Hg]

ReferenceResult.populationScopeCode = adult males

The limit of quantitation for a PK assay, concentration of drug XYZ is 2-60 nanograms/ml for adult women as processed by Acme Labs:

ReferenceResult.referenceTypeCode = limit of quantitation

ReferenceResult.valueTypeCode = PK assay, concentration of drug XYZ

ReferenceResult.value(ANY=>IVL<PQ>) = 2-60 nanograms/ml

ReferenceResult > PerformingLaboratory > Laboratory > Organization.name = Acme Labs

The normal range for a hemoglobin concentration measurement on an adult female performed by Acme Labs is 12.1 to 15.1 g/dL:

ReferenceResult.referenceTypeCode = normal range

ReferenceResult.valueTypeCode = hemoglobin concentration measurement

ReferenceResult.value(ANY=>IVL<PQ>) = 12.1 to 15.1 g/dL

ReferenceResult.populationScopeCode = adult females

ReferenceResult > PerformingLaboratory > Laboratory > Organization.name = Acme Labs

The normal range for a fasting blood glucose measurement on an adult performed by Acme Labs is 3.6 to 5.8 mmol/L:

ReferenceResult.referenceTypeCode = normal range

ReferenceResult.valueTypeCode = blood glucose measurement

ReferenceResult.value(ANY=>IVL<PQ>) = 3.6 to 5.8 mmol/L

ReferenceResult.populationScopeCode = adult

ReferenceResult.fastingStatusIndicator = true

ReferenceResult > PerformingLaboratory > Laboratory > Organization.name = Acme Labs

OTHER NAME(S):

Normal range, reference range, limit of quantitation, clinical concern range, data checking range, alert range

NOTE(S):

The context of a reference result may include any combination of the following: the performing lab, the performing device, and the population to which the reference value pertains. The context may also omit any of those aspects as well.

Tagged Values:

- Map:BRIDGSCC = Model Integrity
- Map:CTRv1.0 = ReferenceResult

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
ReferenceResult 0..* performedReferenceResult	apply to results produced by	Device 0..1 performingDevice	<p>DESCRIPTION: Each ReferenceResult might apply to results produced by one Device. Each Device might produce one or more ReferenceResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReferenceResult 0..* performedReferenceResult	apply to results produced by	Laboratory 0..1 performingLaboratory	<p>DESCRIPTION: Each ReferenceResult might apply to results produced by one Laboratory. Each Laboratory might produce one or more ReferenceResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedClinicalResult 0..* referencingPerformedClinic alResult	reference	ReferenceResult 0..* referencedReferenceResult	<p>DESCRIPTION: Each PerformedClinicalResult might reference one or more ReferenceResult. Each ReferenceResult might be referenced by one or more PerformedClinicalResult.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
value <i>Class:</i> ReferenceResult <i>Datatype:</i> ANY <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A reference for some measurement that a physician or other health professional can use to interpret a set of results for a particular experimental unit.</p> <p>EXAMPLE(S): For systolic blood pressure, ReferenceResult.value(ANY) would be constrained to IVL<PQ> and would = 110-130 mm[Hg]</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = LB.LBORNRI Map:CDASHv1.1 = LB.LBORNRL Map:CTOM = ClinicalResult.labReferenceRangeCode Map:CTRv1.0 = ReferenceResult.value Map:HCTv1.0 = CDE 2953266:LabResults.upper limit of normal for kappa free light chain: Map:HCTv1.0 = CDE 2953111:LabResults.What is the upper limit of normal value of AST (SGOT)? Map:HCTv1.0 = CDE 2963544:LabResults.What is the upper limit of normal value of beta-2-microglobulin protein? Map:HCTv1.0 = CDE 2597015:LabResults.Lactate Dehydrogenase ULN Map:HCTv1.0 = CDE 2953866:LabResults.LDH Upper Limit of Normal Unit of Measure Map:HCTv1.0 = CDE 2953113:LabResults.What is the upper limit of normal value of total serum bilirubin? Map:HCTv1.0 = CDE 2953277:LabResults.Unit of measure: lambda Map:HCTv1.0 = CDE 2953268:LabResults.Upper limit of normal for lambda free light chain: Map:HCTv1.0 = CDE 2953270:LabResults.Unit of measure: kappa Map:HCTv1.0 = CDE 2954096:LabResults.Specify the serum immunoglobulin lower limit of normal value: Map:HCTv1.0 = CDE 2953117:LabResults.What is the upper limit of normal value of serum creatinine? Map:HCTv1.0 = CDE 2953862:LabResults.Serum Creatinine Upper Limit of Normal Map:HCTv1.0 = CDE 2954133:LabResults.Serum Immunoglobulin Upper Limit of Normal Map:Lab = LabResult.referenceTextList Map:Lab = LabResult.referenceRangeLow Map:Lab = LabResult.referenceRangeHigh Map:Lab = LaboratoryResult.referenceTextList Map:LabViewer2.2 = LaboratoryResult.referenceRangeLow Map:LabViewer2.2 = LaboratoryResult.referenceRangeHigh Map:NCI CRF Standard = CDE 2841212v1.0: Test Result High Test Reference Range Number Map:NCI CRF Standard = CDE

Attribute	Notes	Constraints and Tags
		2841221v1.0: Test Result Low Test Reference Range Number Map:SDTM IGv3.1.1 = LB.LBSTNRLO Map:SDTM IGv3.1.1 = LB.LBORNRL Map:SDTM IGv3.1.1 = LB.LBSTNRNC Map:SDTM IGv3.1.1 = LB.LBORNRI Map:SDTM IGv3.1.1 = LB.LBSTNRHI Map:SDTM IGv3.1.2 = LB.LBSTNRHI Map:SDTM IGv3.1.2 = LB.LBORNRI Map:SDTM IGv3.1.2 = PC.PCLLOQ Map:SDTM IGv3.1.2 = LB.LBSTNRLO Map:SDTM IGv3.1.2 = LB.LBORNRL Map:SDTM IGv3.1.2 = LB.LBSTNRNC Map:SDTM IGv3.1.3 = PC.PCLLOQ Map:SDTM IGv3.1.3 = LB.LBORNRI Map:SDTM IGv3.1.3 = LB.LBSTNRLO Map:SDTM IGv3.1.3 = LB.LBSTNRNC Map:SDTM IGv3.1.3 = LB.LBSTNRHI Map:SDTM IGv3.1.3 = LB.LBSTNRLO
valueTypeCode <i>Class:</i> ReferenceResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of clinical result to which this reference result must be associated.</p> <p>EXAMPLE(S): For a blood pressure measurement, the valueTypeCode may be systolic or diastolic.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTOM = ClinicalResult.value Map:CTRv1.0 = ReferenceResult.valueTypeCode

Attribute	Notes	Constraints and Tags
referenceTypeCode <i>Class:</i> ReferenceResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the kind of reference, i.e. how it is to be used or what its purpose is.</p> <p>EXAMPLE(S): normal range limit of quantitation clinical concern range data checking range alert range</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = ReferenceResult.referenceTypeCode Map:SDTM IGv3.1.2 = LB.LBSTNRLO Map:SDTM IGv3.1.2 = LB.LBSTNRC Map:SDTM IGv3.1.2 = LB.LBORNHI Map:SDTM IGv3.1.2 = PC.PCLLOQ Map:SDTM IGv3.1.2 = LB.LBSTNRHI Map:SDTM IGv3.1.2 = LB.LBORNLO
targetAnatomicSiteCode <i>Class:</i> ReferenceResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0..1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of a reference result.</p> <p>EXAMPLE(S): Arm for skin rash</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:CTOM = LesionDescription.contactAnatomicSiteCode Map:CTOM = LesionDescription.contactAnatomicSiteCodeSystem Map:CTRv1.0 = ReferenceResult.targetAnatomicSiteCode Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = EX.EXLOC
targetAnatomicSiteLateralityCode <i>Class:</i> ReferenceResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0..1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for a result.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute is deprecated in BRIDG 3.1 since the only source use case for splitting out laterality from anatomic site comes from CTOM. All other source models had these concepts combined in one attribute. Therefore it was determined to combine these attributes to match the majority of use cases.</p>	Map:CTRv1.0 = ReferenceResult.targetAnatomicSiteLateralityCode Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = AE.AELOC

Attribute	Notes	Constraints and Tags
populationScopeCode <i>Class:</i> ReferenceResult <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the type of subjects to which this reference result applies. EXAMPLE(S): adult males adult females minor males minor females OTHER NAME(S): NOTE(S):	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = ReferenceResult.populationScopeCode
fastingStatusIndicator <i>Class:</i> ReferenceResult <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Specifies whether the result applies to when the subject had been abstaining from eating when the specimen was obtained. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:BRIDGSCC = Model Integrity Map:CTRv1.0 = ReferenceResult.fastingStatusIndicator
comment <i>Class:</i> ReferenceResult <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: Additional description of the reference result. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTOM = DiseaseResponse.commentText Map:CTRv1.0 = ReferenceResult.comment Map:Lab = LabResult.referenceRangeComments Map:LabViewer2.2 = LaboratoryResult.referenceRangeComment Map:SDTM IGv3.1.1 = CO.COVAL

Class: ReferenceToStudyResults

Package: Study Conduct Sub-Domain

DEFINITION:

A citation in an external publication that refers to results of this study.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

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

"Inbound" references, could be to interim or final results, not a reference from this study to other studies.

Tagged Values:

- Map:CTRv1.0 = ReferenceToStudyResults

Connectors

Source	Connector	Target	Notes
ReferenceToStudyResults	references the results of	StudyConduct	DESCRIPTION:

Source	Connector	Target	Notes
0..* referencingReferenceToStudyResults		1 referencedStudyConduct	<p>Each ReferenceToStudyResults always references the results of one StudyConduct. Each StudyConduct might have results referenced in one or more ReferenceToStudyResults.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
publicationIdentifier <i>Class:</i> ReferenceToStudyResults <i>Datatype:</i> II <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes identity to a publication that cites this study's results.</p> <p>EXAMPLE(S): 10987815 is the unique PubMed Identifier (PMID) for the citation in MEDLINE.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = MEDLINE Identifier Map:CTRv1.0 = ReferenceToStudyResults.publicationIdentifier
publicationName <i>Class:</i> ReferenceToStudyResults <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A non-unique textual identifier specifying the source of the publication identifier.</p> <p>EXAMPLE(S): MEDLINE is the source for PMID 10987815</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = ReferenceToStudyResults.publicationName Map:PRM = PublishedResults.title
uniformResourceLocator <i>Class:</i> ReferenceToStudyResults <i>Datatype:</i> TEL.URL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A complete reference to a website (including http://) that is directly relevant to the study.</p> <p>EXAMPLE(S): http://www.alzheimers.org/</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Links URL Map:CTRv1.0 = ReferenceToStudyResults.uniformResourceLocator

Attribute	Notes	Constraints and Tags
citationDescription <i>Class:</i> ReferenceToStudyResults <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A bibliographical reference in a format acceptable to the registration authority. EXAMPLE(S): OTHER NAME(S): NOTE(S): Studies performed in the United States may be required to conform to the National Library of Medicine's MEDLINE format.	Map:CTGOV = Citation Map:CTRv1.0 = ReferenceToStudyResults.citationDescription
linkPageDescription <i>Class:</i> ReferenceToStudyResults <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The textual representation of the linked page. EXAMPLE(S): 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. OTHER NAME(S): NOTE(S):	Map:CTGOV = Links Description Map:CTRv1.0 = ReferenceToStudyResults.linkPageDescription

Class: RegistrationCenter

Package: Study Conduct Sub-Domain

DEFINITION:

The service of recording subject participation on a study. The service may include allocation to an Arm or a portion of an Arm (when secondary allocations may occur).

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = RegistrationCenter

Connectors

Source	Connector	Target	Notes
RegistrationCenter	specializes	Service	<p>DESCRIPTION: Each RegistrationCenter always specializes one Service. Each Service might be specialized by one RegistrationCenter.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> RegistrationCenter <i>Datatype:</i> TEL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of a registration center.</p> <p>EXAMPLE(S): The phone number to call to request that a subject be registered and randomized on a study.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = PhoneCallRandomization.phoneNumber Map:C3PRv2.9 = PhoneCallRandomization.phoneNumber Map:CTRv1.0 = RegistrationCenter.telecomAddress

Class: Resource

Package: Study Conduct Sub-Domain

DEFINITION:

Items necessary to support a research study.

EXAMPLE(S):

Funding, material, labor, service

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv1.0 = StudyResourcing
- Map:CTRr3 = Resource
- Map:CTRv1.0 = Resource
- Map:Vendor1v1.1 = Resource

Connectors

Source	Connector	Target	Notes
Resource 1..* providedResource	be provided by	ResourceProvider 0..1 providingResourceProvider	<p>DESCRIPTION: Each Resource might be provided by one ResourceProvider. Each ResourceProvider always provides one or more Resource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Service	specializes	Resource	DESCRIPTION: Each Service always specializes one Resource.

Source	Connector	Target	Notes
			Each Resource might be specialized by one Service. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteResource 0..* usingStudySiteResource	uses	Resource 1 usedResource	DESCRIPTION: Each StudySiteResource always uses one Resource. Each Resource might be used for one or more StudySiteResource. EXAMPLE(S): OTHER NAME(S): NOTE(S): DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyResource 0..* usingStudyResource	uses	Resource 1 usedResource	DESCRIPTION: Each StudyResource always uses one Resource. Each Resource might be used for one or more StudyResource. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Funding	specializes	Resource	DESCRIPTION: Each Funding always specializes one Resource. Each Resource might be specialized by one Funding. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
MaterialResource	specializes	Resource	DESCRIPTION:

Source	Connector	Target	Notes
			<p>Each MaterialResource always specializes one Resource. Each Resource might be specialized by one MaterialResource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> Resource <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A unique symbol that establishes identity of the resource.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.1 = Resource.identifier
name <i>Class:</i> Resource <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A textual identifier given to the resource.</p> <p>EXAMPLE(S): MRI Machine 1</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = Clinical Trial Context Module - Clinical Trial Coordinating Center Name (0012,0060) Map:Vendor1v1.1 = Resource.identifier
typeCode <i>Class:</i> Resource <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the kind of resource.</p> <p>EXAMPLE(S): For Services: Institutional Review Board (IRB) Data Safety Monitoring Board (DSMB) Data Coordinating Center For Government Funding: Type 5 (Noncompeting Grant Progress Report) Type 1 (New)</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = BookRandomization Map:C3PR = StudyCoordinatingCenter Map:caAERSv2.2 = StudyCoordinatingCenter Map:CTR&Rr2 = Trial has data monitoring committee Map:CTRPv3.8 = OrganizationFunctionalRole.functionCode Map:CTRRr3 = Service.typeCode Map:CTRv1.0 = Service.typeCode Map:Vendor1v1.1 = Resource.typeCode

Attribute	Notes	Constraints and Tags
activeIndicator <i>Class:</i> Resource <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether the resource is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.activeIndicator Map:CTRv1.0 = Resource.activeIndicator Map:Vendor1v1.1 = Resource.activeIndicator

Class: ResultClassification

Package: Study Conduct Sub-Domain

DEFINITION:

A category describing the result as distinguished by anatomical or physiological system, etiology, or purpose.

EXAMPLE(S):

Blood and lymphatic system disorders
Cardiac disorders
Congenital, familial and genetic disorders
Infections and infestations
Injury, poisoning and procedural complications
Investigations
Social circumstances
Surgical and medical procedures

OTHER NAME(S):

System Organ Class
Body System
Low Level Term
High Level Term
High Level Group Term

NOTE(S):

Examples provided here are a sampling from the values for MedDRA System Organ Class.

Tagged Values:

- Map:SDTM IGv3.1.3 = AE.AEBDSYCD

Connectors

Source	Connector	Target	Notes
ResultClassification 0..* classifyingResultClassification	classifies	PerformedObservationResult 1 classifiedPerformedObservationResult	<p>DESCRIPTION: Each ResultClassification always classifies one PerformedObservationResult. Each PerformedObservationResult might be classified by one or more ResultClassification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
code <i>Class:</i> ResultClassification <i>Datatype:</i> DSET<CD> <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the category of the result as distinguished by anatomical or physiological system, etiology, or purpose</p> <p>EXAMPLE(S): Blood and lymphatic system disorders; Cardiac disorders; Congenital, familial and genetic disorders; Ear and labyrinth disorders; Endocrine disorders; Eye disorders; Gastrointestinal disorders; General disorders and administration site conditions; Hepatobiliary disorders; Immune system disorders; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (incl cysts and polyps); Nervous system disorders; Pregnancy, puerperium and perinatal conditions; Psychiatric disorders; Renal and urinary disorders; Reproductive system and breast disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous tissue disorders; Social circumstances; Surgical and medical procedures; Vascular disorders</p> <p>OTHER NAME(S): Body System System Organ Class High Level Term High Level Group Term Low Level Term</p> <p>NOTE(S): Examples provided here are from the values for MedDRA System Organ Class.</p>	Map:HCTv1.0 = CDE 2797538:Involvement and Extent of Disease.Specify the type of organ impairment /disorder: Map:HCTv1.0 = CDE 2797573:Involvement and Extent of Disease.Specify the other organ impairment / disorder: Map:HCTv1.0 = CDE 2749891:Involvement and Extent of Disease.For the polymyositis-dermatomyositis, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 3129555:Involvement and Extent of Disease.Was there extramedullary and / or extranodal involvement? Map:HCTv1.0 = CDE 2750113:Involvement and Extent of Disease.For the polyarteritis nodosa, classical or microscopic, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 2750535:Involvement and Extent of Disease.For the psoriatic arthritis / psoriasis, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 2686142:Involvement and Extent of Disease.For the psoriatic arthritis / psoriasis specify the other involvement: Map:HCTv1.0 = CDE 2748902:Involvement and Extent of Disease.For the systemic sclerosis, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 2749918:Involvement and Extent of Disease.For the antiphospholipid syndrome, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 2953469:Involvement and Extent of Disease.Specify the lymphoma organ involved: Map:HCTv1.0 = CDE 2674903:Involvement and Extent of Disease.Specify the other involvement for sjogren syndrome: Map:HCTv1.0 = CDE 2749605:Involvement and Extent of Disease.For the sjogren syndrome, what was the involved organ or clinical problem? Map:HCTv1.0 = CDE 2749929:Involvement and Extent of Disease.Specify the other type of antiphospholipid syndrome involvement:

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2749969:Involvement and Extent of Disease.For the wegener granulomatosis, what was the involved organ or clinical problem?</p> <p>Map:HCTv1.0 = CDE 2750646:Involvement and Extent of Disease.Specify the type of wegener granulomatosis involvement:</p> <p>Map:HCTv1.0 = CDE 2685212:Involvement and Extent of Disease.Specify the other involvement of the systemic sclerosis:</p> <p>Map:HCTv1.0 = CDE 2749007:Involvement and Extent of Disease.For the systemic lupus erythematosus (SLE), what was the involved organ or clinical problem?</p> <p>Map:HCTv1.0 = CDE 2750141:Involvement and Extent of Disease.For the rheumatoid arthritis, what was the involved organ or clinical problem?</p> <p>Map:HCTv1.0 = CDE 2750124:Involvement and Extent of Disease.Specify the type of polyarteritis nodosa, classical or microscopic, involvement:</p> <p>Map:HCTv1.0 = CDE 2750529:Involvement and Extent of Disease.Specify the type of rheumatoid arthritis involvement:</p> <p>Map:HCTv1.0 = CDE 2749904:Involvement and Extent of Disease.Specify the type of polymyositis-dermatomyositis involvement:</p> <p>Map:HCTv1.0 = CDE 2749585:Involvement and Extent of Disease.Specify the type of systemic lupus erythematosus (SLE) involvement:</p> <p>Map:HCTv1.0 = CDE 3082350:Involvement and Extent of Disease.Specify the site of extranodal involvement:</p> <p>Map:HCTv1.0 = CDE 2686158:Involvement and Extent of Disease.For the multiple sclerosis, specify the other involvement:</p> <p>Map:HCTv1.0 = CDE 2749910:Involvement and Extent of Disease.For the multiple sclerosis, what was the involved organ or clinical problem?</p> <p>Map:NCI CRF Standard = CDE 2943864v1.0: MedDRA System Organ Class (SOC)</p> <p>Map:SDTM IGv3.1.1 = MH.MHBODSYS</p> <p>Map:SDTM IGv3.1.1 =</p>

Attribute	Notes	Constraints and Tags
		AE.AEBODSYS Map:SDTM IGv3.1.2 = CE.CEBODSYS Map:SDTM IGv3.1.2 = AE.AEBODSYS Map:SDTM IGv3.1.2 = MH.MHBODSYS Map:SDTM IGv3.1.3 = AE.AESOC Map:SDTM IGv3.1.3 = CE.CEBODSYS Map:SDTM IGv3.1.3 = AE.AESOCCD Map:SDTM IGv3.1.3 = AE.AELLTCD Map:SDTM IGv3.1.3 = AE.AELLT Map:SDTM IGv3.1.3 = AE.AEHTLCD Map:SDTM IGv3.1.3 = AE.AEHLGTC Map:SDTM IGv3.1.3 = AE.AEHLGT Map:SDTM IGv3.1.3 = AE.AEBODSYS Map:SDTM IGv3.1.3 = AE.AEBDSYCD Map:SDTM IGv3.1.3 = MH.MHBODSYS Map:SDTM IGv3.1.3 = AE.AEHLT
typeCode <i>Class:</i> ResultClassification <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	DEFINITION: A coded value specifying the kind of classification. EXAMPLE(S): body system low level term high level term high level group term sponsor's primary system organ class sponsor's secondary system organ class OTHER NAME(S): NOTE(S):	Map:SDTM IGv3.1.3 = AE.AEBDSYCD

Class: ScheduledActivity

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:PSCv2.6 = Canceled
- Map:PSCv2.6 = Conditional
- Map:PSCv2.6 = NotApplicable
- Map:PSCv2.6 = Scheduled
- Map:PSCv2.6 = ScheduledStudySegment
- Map:PSCv2.6 = ScheduledActivity
- Map:PSCv2.6 = Missed

Connectors

Source	Connector	Target	Notes
ScheduledActivity 0..* instantiatingScheduledActivity	instantiates	PlannedActivity 1 instantiatedPlannedActivity	<p>DESCRIPTION: Each ScheduledActivity always instantiates one PlannedActivity. Each PlannedActivity might be instantiated by one or more ScheduledActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ScheduledActivity	specializes	Activity	<p>DESCRIPTION: Each ScheduledActivity always specializes one Activity. Each Activity might be specialized by one ScheduledActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedActivity 0..* instantiatingPerformedActivity	instantiate	ScheduledActivity 0..1 instantiatedScheduledActivity	<p>DESCRIPTION: Each PerformedActivity might instantiate one ScheduledActivity. Each ScheduledActivity might be instantiated by one or more PerformedActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ScheduledNotification	specializes	ScheduledActivity	<p>DESCRIPTION: Each ScheduledNotification always specializes one ScheduledActivity. Each</p>

Source	Connector	Target	Notes
			<p>ScheduledActivity might be specialized by one ScheduledNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ScheduledSubstanceAdministration	specializes	ScheduledActivity	<p>DESCRIPTION: Each ScheduledSubstanceAdministration always specializes one ScheduledActivity. Each ScheduledActivity might be specialized by one ScheduledSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
repetitionNumber <i>Class:</i> ScheduledActivity <i>Datatype:</i> INT.POS <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer that identifies the particular occurrence of a repeating activity. The first repetition is defined as '1'.</p> <p>EXAMPLE(S): A PlannedActivity might have a repeatQuantity of 4 which would result in 4 ScheduledActivity with repetitionNumbers of 1, 2, 3, and 4 respectively.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The ScheduledActivity will repeat at least the minimum number of times and at most, the maximum number of times as defined in PlannedActivity.repeatQuantity.</p>	Map:PSC = Period.repetitions Map:PSCv2.6 = ScheduledActivity.repetitionNumber

Attribute	Notes	Constraints and Tags
dateRange <i>Class:</i> ScheduledActivity <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: The date and time span specifying when the activity is scheduled to begin and end.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = ScheduledNotification.scheduledOn Map:HCTv1.0 = CDE 2866945:Therapies.If this HSCT was postponed, what is the new estimated date? Map:HCTv1.0 = CDE 3158501:Therapies.Scheduled infusion date: Map:NCI CRF Standard = CDE 657v3.0: Treatment Projected Begin Date Map:PRM = Period.startDay Map:PSC = ScheduledEventState.scheduled Map:PSC = Scheduled.date Map:PSC = ScheduledEvent.date/idealDate Map:PSCv2.6 = ScheduledStudySegment.startDate
idealDateRange <i>Class:</i> ScheduledActivity <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span specifying when the activity was originally scheduled to begin and end.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This would be the date and time span based on applying the study or experiment calendar to a specific subject.</p>	Map:PSCv2.6 = ScheduledActivity.idealDate
statusChangeReasonCode <i>Class:</i> ScheduledActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying why the status has changed.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PSCv2.6 = ScheduledActivityState.reason
statusCode <i>Class:</i> ScheduledActivity <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in a lifecycle of a scheduled activity.</p> <p>EXAMPLE(S): For a lab test, this would be the condition or stage in the lifecycle of the test (e.g., "scheduled", "canceled", "performed").</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Scheduled Activity Status state transition diagram for further details.</p>	Map:PSC = ScheduledEventState

Attribute	Notes	Constraints and Tags
statusDate <i>Class:</i> ScheduledActivity <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the status is assigned to the activity.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:PSC = ScheduledEventState.canceled

Class: ScheduledNotification

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:caAERSv2.2 = ScheduledEmailNotification
- Map:caAERSv2.2 = ScheduledNotification

Connectors

Source	Connector	Target	Notes
ScheduledNotification	specializes	ScheduledActivity	<p>DESCRIPTION: Each ScheduledNotification always specializes one ScheduledActivity. Each ScheduledActivity might be specialized by one ScheduledNotification.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
NotificationReceiver 0..* receivingNotificationReceiver	be the receiver of	ScheduledNotification 0..1 receivedScheduledNotification	<p>DESCRIPTION: Each NotificationReceiver might be the receiver of one ScheduledNotification. Each ScheduledNotification might be received by one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
messageTitle <i>Class:</i> ScheduledNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The subject of the notification.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = ScheduledEmailNotification.subject
message <i>Class:</i> ScheduledNotification <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The actual text scheduled to be included in the notification.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This may mean that message variables have been replaced with actual data.</p>	Map:caAERSv2.2 = ScheduledEmailNotification.body

Class: ScheduledSubstanceAdministration

Package: Study Conduct Sub-Domain

DEFINITION:

An activity of applying, introducing or otherwise giving medications or other substances to a subject or experimental unit that is anticipated to occur at some time in the future.

EXAMPLE(S):

Administration of methotrexate as part of chemotherapy.

OTHER NAME(S):

NOTE(S):

Tagged Values:

Connectors

Source	Connector	Target	Notes
ScheduledSubstanceAdministration	specializes	ScheduledActivity	<p>DESCRIPTION: Each ScheduledSubstanceAdministration always specializes one ScheduledActivity. Each ScheduledActivity might be specialized by one ScheduledSubstanceAdministration.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
activeIngredientDose <i>Class:</i> ScheduledSubstanceAdministration <i>Datatype:</i> PQ <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The quantity of active ingredient anticipated to be administered.</p> <p>EXAMPLE(S): 5 mg</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is intended to be a subject-specific quantity.</p> <p>DefinedSubstanceAdministration.productDose can contain a dose expressed in absolute or relative terms (e.g., mg or mg/kg). ScheduledSubstanceAdministration.activeIngredientDose and PerformedSubstanceAdministration.productDose must contain a dose expressed in absolute terms (e.g., mg). If the DefinedSubstanceAdministration.productDose was expressed in relative terms (e.g., mg/kg), then the absolute dose must have been calculated using one or more observed factors as identified by the DefinedDoseExpressionVariableRelationship.</p>	Map:CDASHv1.1 = EX.EXPDOSEU Map:CDASHv1.1 = EX.EXPDOSE Map:CTRPv3.8 = PlannedSubstanceAdministration.dose

Class: Service

Package: Study Conduct Sub-Domain

DEFINITION:

Labor support for research.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRRr3 = Service
- Map:CTRv1.0 = Service

Connectors

Source	Connector	Target	Notes
Service	specializes	Resource	<p>DESCRIPTION: Each Service always specializes one Resource. Each Resource might be</p>

Source	Connector	Target	Notes
			specialized by one Service. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
RegistrationCenter	specializes	Service	DESCRIPTION: Each RegistrationCenter always specializes one Service. Each Service might be specialized by one RegistrationCenter. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Class: StudyConduct

Package: Study Conduct Sub-Domain

DEFINITION:

An ongoing and/or past performance of a formal investigation as specified in a study protocol.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

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. The notion of a study protocol includes (but is not limited to) the design, statistical considerations, activities to test a particular hypothesis or answer a particular question that is the basis of the study, characteristics, specifications, objective(s), background, pre-study/study/post-study portions of the plan (including the design, methodology, statistical considerations, organization). The study may be of any type that involves subjects, including prevention, therapeutic, interventional or observational. Subjects involved in the study protocol may be biological entities (human, animal, specimen, tissue, organ, etc.) or products. The study protocol is related to other supporting documents, including (but not limited to) informed consent documents, case report forms (CRFs), regulatory and approval documentation, correlative studies, etc. (via the inherited association to DocumentVersionRelationship). The complete notion of the study protocol is represented in BRIDG by the classes StudyProtocol, StudyProtocolVersion, StudyProtocolDocument, StudyProtocolDocumentVersion, StudyConduct and all their associations.

- The StudyProtocol class represents the content of the study protocol which includes characteristics and plan of the study which can be distilled into or abstracted from a version of the study protocol document and can exist even before the information is put into document form.
- The StudyProtocolVersion class represents the details of the study protocol that may change over time.
- The StudyProtocolDocument class represents the document form of the study protocol and is a grouping of the various study protocol document versions.
- The StudyProtocolDocumentVersion class represents the document form of the study protocol version and is the details of the study protocol document that may change over time.
- The StudyConduct class represents the execution of a study based on a study protocol definition which includes the scheduled and performed activities that are subject-specific as well as study-level and site-level activities.

Tagged Values:

- Map:caAERSv2.2 = Study
- Map:CTRv1.0 = StudyExecution
- Map:Vendor1v1.1 = StudyExecution

Connectors

Source	Connector	Target	Notes
StudyConduct	specializes	ProjectConduct	<p>DESCRIPTION: Each StudyConduct always specializes one ProjectState. Each ProjectState might be specialized by one StudyConduct.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyOverallStatus 0..* describingStudyOverallStat us	describes	StudyConduct 1 describedStudyConduct	<p>DESCRIPTION: Each StudyOverallStatus always describes one StudyConduct. Each StudyConduct might be described by one or more StudyOverallStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
ReferenceToStudyResults 0..* referencingReferenceToStud yResults	references the results of	StudyConduct 1 referencedStudyConduct	<p>DESCRIPTION: Each ReferenceToStudyResults always references the results of one StudyConduct. Each StudyConduct might have results referenced in one or more ReferenceToStudyResults.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySite 0..* executingStudySite	execute	StudyConduct 0..1 executedStudyConduct	<p>DESCRIPTION: Each StudySite might execute one StudyConduct. Each StudyConduct might be executed at one or more StudySite.</p>

Source	Connector	Target	Notes
			<p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyOversightAuthority 0..* overseeingStudyOversightAuthority	oversee	StudyConduct 0..1 overseenStudyConduct	<p>DESCRIPTION: Each StudyOversightAuthority might oversee one StudyConduct. Each StudyConduct might be overseen by one or more StudyOversightAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyResource 0..* usedStudyResource	be used for	StudyConduct 0..1 usingStudyConduct	<p>DESCRIPTION: Each StudyResource might be used for one StudyConduct. Each StudyConduct might use one or more StudyResource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performingStudyPersonnel	perform a role for	StudyConduct 0..1 performedStudyConduct	<p>DESCRIPTION: Each StudyPersonnel might perform a role for one StudyConduct. Each StudyConduct might have a role performed by one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyRecruitmentStatus 0..* describingStudyRecruitmentStatus	describes	StudyConduct 1 describedStudyConduct	<p>DESCRIPTION: Each StudyRecruitmentStatus always describes one</p>

Source	Connector	Target	Notes
			<p>StudyConduct. Each StudyConduct might be described by one or more StudyRecruitmentStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
enrolledStudySubjectNumber <i>Class:</i> StudyConduct <i>Datatype:</i> INT.POS <i>Derived:</i> True <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: An integer specifying the quantity of study subjects enrolled in the study at the current time.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This can be derived by counting the number of enrolled subjects.</p>	<p>Map:CTRv1.0 = StudyRecruitmentStatus.enrolledSubjectNumber</p> <p>Map:SDTM IGv3.1.3 = TS.TSVALNF WHERE TSPARMCD = "ACTSUB"</p> <p>Map:SDTM IGv3.1.3 = TS.TSVAL WHERE TSPARMCD = "ACTSUB"</p> <p>Map:Vendor1v1.1 = StudyExecution.enrolledStudySubject Number</p>

Class: StudyCountryPersonnel

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Study Country Investigator, Study Country Research Coordinator

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:Vendor1v1.1 = StudySitePersonnel

Connectors

Source	Connector	Target	Notes
StudyCountryPersonnel 0..* performingStudyCountryPersonnel	perform a role for	StudyCountry 0..1 performedStudyCountry	<p>DESCRIPTION: Each StudyCountryPersonnel might perform a role for one StudyCountry. Each StudyCountry might have a role performed by one or more StudyCountryPersonnel.</p> <p>DEFINITION:</p>

Source	Connector	Target	Notes
			EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
roleCode <i>Class:</i> StudyCountryPersonnel <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: The coded value specifying a type of responsibility of the study country personnel. EXAMPLE(S): Principal Investigator, Sub Investigator, Facility Contact Backup OTHER NAME(S): NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Site Investigator" and primaryIndicator ="true".	Map:C3PRv2.9 = StudyPersonnel.roleCode Map:C3PRv2.9 = StudyInvestigator.roleCode Map:C3PRv2.9 = RoleBasedRecipient.role Map:caAERSv2.2 = StudyPersonnel.roleCode Map:caAERSv2.2 = RoleBasedRecipient.role Map:CTGOV = Facility Contact Backup Map:CTRPv1.0 = StudySiteInvestigator.roleCode Map:CTRPv1.0 = StudyParticipationContact.roleCode Map:CTRPv3.8 = StudySiteContact.roleCode Map:CTR = Site Representative/Investigator Map:CTRv1.0 = StudySitePersonnel.roleCode Map:SDTM IGv3.1.3 = EG.EGEVAL Map:SDTM IGv3.1.3 = TU.TUEVAL Map:SDTM IGv3.1.3 = FA.FAEVAL Map:SDTM IGv3.1.3 = PE.PEEVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = TR.TREVAL
primaryIndicator <i>Class:</i> StudyCountryPersonnel <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether this is the main or principal study country personnel. EXAMPLE(S): OTHER NAME(S): NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Site Investigator" and primaryIndicator ="true".	Map:CTRPv1.0 = StudyParticipationContact.primaryIndicator Map:CTRPv1.0 = StudySiteInvestigator.primaryIndicator Map:CTRPv3.8 = StudySiteContact.primaryIndicator Map:CTRv1.0 = StudySitePersonnel.primaryIndicator

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> StudyCountryPersonnel <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A contact point used to send physical forms of communication to the study country personnel. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = Address.zip > SiteResearchStaff Map:caAERSv2.2 = Address.city > SiteResearchStaff Map:caAERSv2.2 = Address.country > SiteResearchStaff Map:caAERSv2.2 = Address.street > SiteResearchStaff Map:caAERSv2.2 = Address.state > SiteResearchStaff Map:CTRPv1.0 = StudyParticipationContact.postalAddress Map:CTRPv1.0 = StudySiteInvestigator.postalAddress Map:CTRPv3.8 = StudySiteContact.postalAddress Map:CTRr3 = StudySiteContact.postalAddress Map:CTRv1.0 = StudySitePersonnel.postalAddress
telecomAddress <i>Class:</i> StudyCountryPersonnel <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of a study country personnel. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:CTGOV = Facility Contact - Email Map:CTGOV = Facility Contact - Phone Map:CTGOV = Facility Contact - Ext Map:CTRPv1.0 = StudySiteInvestigator.telecomAddress Map:CTRPv1.0 = StudyParticipationContact.telecomAddress Map:CTRPv3.8 = StudySiteContact.telecomAddress Map:CTRv1.0 = StudySitePersonnel.telecomAddress Map:HCTv1.0 = CDE 2517550:UML DEFAULT CD.Person Email Address Map:NCI CRF Standard = CDE 2661012v3.0: Clinical Research Associate Person Fax Number Map:NCI CRF Standard = CDE 2661003v1.0: Clinical Research Associate Person Telephone Number

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudyCountryPersonnel <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the study country personnel is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = HealthcareSiteInvestigator.statusCode Map:C3PR = HealthcareSiteInvestigator.statusDate Map:C3PRv2.9 = StudyPersonnel.statusCode Map:C3PRv2.9 = StudyPersonnel.statusDate Map:C3PRv2.9 = StudyInvestigator.statusCode Map:C3PRv2.9 = StudyInvestigator.statusDate Map:caAERSv2.2 = StudyPersonnel.endDate Map:caAERSv2.2 = StudyPersonnel.startDate Map:CTRPv1.0 = StudyParticipationContact.statusCode Map:CTRPv1.0 = StudyParticipationContact.statusDateRange Map:CTRPv1.0 = StudySiteInvestigator.statusCode Map:CTRPv1.0 = StudySiteInvestigator.statusDateRange Map:CTRPv3.8 = FunctionalRole.statusDateRange Map:CTRv1.0 = StudySitePersonnel.effectiveDateRange

Class: StudyInvestigator

Package: Study Conduct Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyInvestigator
- Map:caAERSv2.2 = StudyInvestigator
- Map:CTRPv1.0 = StudyInvestigator
- Map:CTRPv3.8 = StudyInvestigator
- Map:CTRr3 = StudyInvestigator
- Map:CTRv1.0 = StudyInvestigator
- Map:HL7SP = Investigator

Connectors

Source	Connector	Target	Notes
StudyInvestigator	specializes	StudyPersonnel	DESCRIPTION: Each StudyInvestigator

Source	Connector	Target	Notes
			<p>always specializes one StudyPersonnel. Each StudyPersonnel might be specialized by one StudyInvestigator.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> StudyInvestigator <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A unique symbol that establishes identity of the study investigator.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = Investigator.ncIIdentifier Map:CDASHv1.1 = DM.INVID Map:CTRPv1.0 = StudyInvestigator.id Map:CTRv1.0 = StudyInvestigator.identifier Map:HL7SP = Investigator.id Map:SDTM IGv3.1.1 = DM.INVID Map:SDTM IGv3.1.2 = DM.INVID
signatureText <i>Class:</i> StudyInvestigator <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The signed name of the investigator who is responsible for completing a form or report for a clinical study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): 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.</p>	Map:C3PR = StudyInvestigator.signatureIndicator Map:C3PR = StudyInvestigator.signatureText Map:caAERSv2.2 = StudyInvestigator.signatureText Map:CTOM = StudyInvestigator.signatureText Map:CTOM = StudyInvestigator.signatureIndicator Map:CTRPv1.0 = StudyInvestigator.signatureText Map:CTRv1.0 = StudyInvestigator.signatureText Map:NCI CRF Standard = CDE 58320v5.0: Investigator Signature Text

Class: StudyOverallStatus

Package: Study Conduct Sub-Domain

DEFINITION:
Describes the comprehensive state of the study.

EXAMPLE(S):

OTHER NAME(S):

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

Tagged Values:

- Map:CTRPv1.0 = StudyOverallStatus
- Map:CTRPv3.8 = StudyOverallStatus
- Map:CTRr3 = StudyOverallStatus
- Map:CTRv1.0 = StudyOverallStatus
- Map:HL7SP = Study.subjectOf1
- Map:Vendor1v1.1 = StudyOverallStatus

Connectors

Source	Connector	Target	Notes
StudyOverallStatus 0..* describingStudyOverallStat us	describes	StudyConduct 1 describedStudyConduct	<p>DESCRIPTION: Each StudyOverallStatus always describes one StudyConduct. Each StudyConduct might be described by one or more StudyOverallStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> StudyOverallStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the study as a whole.</p> <p>EXAMPLE(S): 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.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Study Overall Status state transition diagram for further details.</p> <p>The overall status of a study may overlap with the study site status and accrual status. This overlap needs to be clearly differentiated. (See tracker issue 29398). A proposed solution is to eliminate the study recruitment status codes and adopt the CTRP values for study status code.</p>	Map:C3PRv2.9 = Study.coordinatingCenterStudyStatus Map:caAERSv2.2 = Study.status Map:CTRPv1.0 = StudyOverallStatus.statusCode Map:CTRPv3.8 = StudyOverallStatus.statusCode Map:CTRr = Trial Status Map:CTRr3 = StudyOverallStatus.statusCode Map:CTRv1.0 = StudyOverallStatus.code Map:HSDBv1.0 = [Study status].Current Trial Status Map:Vendor1v1.1 = StudyOverallStatus.code

Attribute	Notes	Constraints and Tags
date <i>Class:</i> StudyOverallStatus <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the overall status of the study is assigned.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Study Start Date Map:CTGOV = Anticipated Study Completion Date Map:CTGOV = Actual Primary Completion Date Map:CTGOV = Anticipated Primary Completion Date Map:CTGOV = Actual Study Completion Date Map:CTRPv1.0 = InterventionalStudyProtocol.statusDate Map:CTRPv1.0 = ObservationalStudyProtocol.primaryCompletionDate Map:CTRPv1.0 = InterventionalStudyProtocol.primaryCompletionDate Map:CTRPv1.0 = StudyOverallStatus.statusDate Map:CTRPv1.0 = StudyProtocol.primaryCompletionDate Map:CTRPv1.0 = StudyProtocol.startDate Map:CTRPv1.0 = ObservationalStudyProtocol.startDate Map:CTRPv3.8 = StudyOverallStatus.statusDate Map:CTRPv3.8 = StudyProtocol.primaryCompletionDate Map:CTRPv3.8 = StudyProtocol.startDate Map:CTRR = Primary Completion Date (estimated or actual) Map:CTRR = Completion date, estimated or actual Map:CTRr3 = StudyOverallStatus.statusDate Map:CTRv1.0 = StudyOverallStatus.date Map:HSDBv1.0 = [Study status].Study Start Date Map:HSDBv1.0 = [Study status].temporary closure start date Map:HSDBv1.0 = [Study status].Primary Completion Date Map:HSDBv1.0 = [Study status].Current Trial Status Date Map:Vendor1v1.1 = StudyOverallStatus.date

Attribute	Notes	Constraints and Tags
studyStoppedReasonCode <i>Class:</i> StudyOverallStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying why the study has been halted or terminated (for suspended, terminated or withdrawn studies).</p> <p>EXAMPLE(S): 1=Accrual Goal Met, 2=Closed due to toxicity, 3=Closed due to lack of study progress, 4=Temporarily closed per study design.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): These codes are typically assigned locally.</p>	Map:CTGOV = Why Study Stopped Map:CTRPv1.0 = StudyOverallStatus.studyStoppedReasonCode Map:CTRPv3.8 = StudyOverallStatus.studyStoppedReasonCode Map:CTRRr3 = StudyOverallStatus.studyStoppedReasonCode Map:CTRv1.0 = StudyOverallStatus.studyStoppedReasonCode Map:HSDBv1.0 = [Study status] .Why Study Stopped? Map:HSDBv1.0 = [Study status] .temporary closure status Map:Vendor1v1.1 = StudyOverallStatus.studyStoppedReasonCode

Attribute	Notes	Constraints and Tags
anticipatedIndicator <i>Class:</i> StudyOverallStatus <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether the overall status of the study is an estimate. EXAMPLE(S): OTHER NAME(S): NOTE(S): BRIDG SCC has made the decision to add an anticipatedIndicator until we learn the business rules of how the overall study status could be derived.	Map:CTRPv1.0 = ObservationalStudyProtocol.startDateTypeCode Map:CTRPv1.0 = InterventionalStudyProtocol.startDateTypeCode Map:CTRPv1.0 = StudyProtocol.primaryCompletionDateTypeCode Map:CTRPv1.0 = ObservationalStudyProtocol.primaryCompletionDateTypeCode Map:CTRPv1.0 = StudyProtocol.startDateTypeCode Map:CTRPv1.0 = InterventionalStudyProtocol.primaryCompletionDateTypeCode Map:CTRPv1.0 = StudyOverallStatus.anticipatedIndicator Map:CTRPv3.8 = StudyProtocol.primaryCompletionDateTypeCode Map:CTRPv3.8 = StudyOverallStatus.statusTypeCode Map:CTRPv3.8 = StudyProtocol.startDateTypeCode Map:CTRR = Completion date, estimated or actual Map:CTRR = Primary Completion Date (estimated or actual) Map:CTRr3 = StudyOverallStatus.anticipatedIndicator Map:CTRv1.0 = StudyOverallStatus.anticipatedIndicator Map:HSDBv1.0 = [Study status].Primary Completion Date Type Map:HSDBv1.0 = [Study status].Study Start Date Type Map:Vendor1v1.0 = StudyOverallStatus.anticipatedIndicator
comment <i>Class:</i> StudyOverallStatus <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Additional description of the overall status of the study. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = StudyOverallStatus.commentText Map:CTRPv3.8 = StudyOverallStatus.commentText Map:CTRr3 = StudyOverallStatus.comment Map:CTRv1.0 = StudyOverallStatus.comment Map:Vendor1v1.1 = StudyOverallStatus.comment

Class: StudyOversightAuthority

Package: Study Conduct Sub-Domain

DEFINITION:

An organization with monitoring, regulatory, or supervisory authority over biomedical research at the local, regional, national, or international level for a particular study.

EXAMPLE(S):

NCI, FDA, IRB, etc.

OTHER NAME(S):**NOTE(S):**

An NCI sponsored study is monitored by the NCI (or its designate) and required to meet federal regulations per the FDA. Participating sites must comply with their governing IRB requirements and institutional policy. Each of these study oversight authorities (NCI, FDA, IRB) is responsible for different aspects of the study.

Tagged Values:

- Map:CTGOV = Data Monitoring Committee?
- Map:CTGOV = FDA Regulated Intervention?
- Map:CTRPv1.0 = InterventionalStudyProtocol.FDAregulatedIndicator
- Map:CTRPv3.8 = StudyRegulatoryAuthority
- Map:CTRv1.0 = StudyOversightAuthority
- Map:HSDBv1.0 = [Lead Organization] .Organization Type

Connectors

Source	Connector	Target	Notes
StudyOversightAuthority 0..* overseeingStudyOversightAuthority	oversee	StudyProtocolVersion 0..1 overseenStudyProtocolVersion	<p>DESCRIPTION: Each StudyOversightAuthority might oversee one StudyProtocolVersion. Each StudyProtocolVersion might be overseen by one or more StudyOversightAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyOversightAuthority 0..* overseeingStudyOversightAuthority	oversee	StudyConduct 0..1 overseenStudyConduct	<p>DESCRIPTION: Each StudyOversightAuthority might oversee one StudyConduct. Each StudyConduct might be overseen by one or more StudyOversightAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyOversightAuthority 0..* performedStudyOversightAuthority	is a function performed by	OversightAuthority 1 performingOversightAuthority	<p>DESCRIPTION: Each StudyOversightAuthority always is a function</p>

Source	Connector	Target	Notes
			<p>performed by one OversightAuthority. Each OversightAuthority might function as one or more StudyOversightAuthority.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudyPersonnel

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Study Principal Investigator, Coordinating Investigator, Study Director, Study Chair, Public Queries, Scientific Queries, Scientific Leadership

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyPersonnel
- Map:CTGOV = Coordinating investigator
- Map:CTRPv3.8 = StudyContact
- Map:CTRr3 = StudyColleague
- Map:CTRv1.0 = StudyPersonnel
- Map:Vendor1v1.1 = StudyPersonnel

Connectors

Source	Connector	Target	Notes
StudyPersonnel 0..* performedStudyPersonnel	be a function performed by	ResearchStaff 0..1 performingResearchStaff	<p>DESCRIPTION: Each StudyPersonnel might be a function performed by one ResearchStaff. Each ResearchStaff might function as one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performedStudyPersonnel	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvid	<p>DESCRIPTION: Each StudyPersonnel might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
		er	<p>one HealthcareProvider. Each HealthcareProvider might function as one or more StudyPersonnel.</p> <p>DEFINITION: Indicates that the StudyPersonnel role is being fulfilled by a HealthcareProvider</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performingStudyPersonnel	perform a role for	StudyConduct 0..1 performedStudyConduct	<p>DESCRIPTION: Each StudyPersonnel might perform a role for one StudyConduct. Each StudyConduct might have a role performed by one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyPersonnel 0..* performedStudyPersonnel	perform a role for	StudyProtocolVersion 0..1 performingStudyProtocolVersion	<p>DESCRIPTION: Each StudyPersonnel might perform a role for one StudyProtocolVersion. Each StudyProtocolVersion might have a role performed by one or more StudyPersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyInvestigator	specializes	StudyPersonnel	<p>DESCRIPTION: Each StudyInvestigator always specializes one StudyPersonnel. Each StudyPersonnel might be specialized by one StudyInvestigator.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p>

Source	Connector	Target	Notes
			OTHER NAME(S): NOTE(S):
Study 0..1 participatedStudy	be participated in by	StudyPersonnel 0..* participatingStudyPersonnel	DESCRIPTION: Each Study might be participated in by one or more StudyPersonnel. Each StudyPersonnel might participate in one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	StudyPersonnel 0..1 performingStudyPersonnel	DESCRIPTION: Each NotificationReceiver might be a function performed by one StudyPersonnel. Each StudyPersonnel might function as one or more NotificationReceiver. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudyResearchCoordinator	specializes	StudyPersonnel	DESCRIPTION: Each StudyResearchCoordinator always specializes one StudyPersonnel. Each StudyPersonnel might be specialized by one StudyResearchCoordinator. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
roleCode <i>Class:</i> StudyPersonnel <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the type of responsibility of the study personnel.</p> <p>EXAMPLE(S): Study Principal Investigator, Coordinating Investigator, Study Director, Study Chair, Public Queries, Scientific Queries, Scientific Leadership, Registrar, Study Coordinator.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Investigator" and primaryIndicator ="true".</p>	Map:C3PR = StudyInvestigator.roleCode Map:C3PR = StudyPersonnel.roleCode Map:C3PRv2.9 = StudyPersonnel.roleCode Map:C3PRv2.9 = RoleBasedRecipient.role Map:C3PRv2.9 = StudyInvestigator.roleCode Map:caAERSv2.2 = StudyInvestigator.roleCode Map:caAERSv2.2 = RoleBasedRecipient.role Map:CTGOV = Overall Study Officials - Official's Role Map:CTGOV = Overall Study Officials Map:CTGOV = Central Contact Backup Map:CTGOV = Central Contact Map:CTOM = StudyInvestigator.responsibilityRoleCode Map:CTR&Rr2 = Further information contact name Map:CTRPv1.0 = StudyInvestigator.roleCode Map:CTRPv1.0 = StudyContact.roleCode Map:CTRPv3.8 = StudyContact.roleCode Map:CTRR = Responsible Contact Person Map:CTRRr3 = StudyColleague.roleCode Map:CTRv1.0 = StudyPersonnel.roleCode Map:FDA HL7 SD SD DSTU2012 = plannedStudy/performer.functionCode Map:HL7SP = Investigator.code Map:HSDBV1.0 = [IND/IDE] .Holder Type Map:SDTM IGv3.1.3 = TU.TUEVAL Map:SDTM IGv3.1.3 = TR.TREVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = PE.PEEVAL Map:SDTM IGv3.1.3 = EG.EGEVAL Map:SDTM IGv3.1.3 = FA.FAEVAL Map:Vendor1v1.1 = StudyPersonnel.roleCode Map:WHO = Contact for Public Queries - type Map:WHO = Contact for Scientific Queries - type Map:WHO = Contact for Scientific Queries Map:WHO = Contact for Public Queries

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> StudyPersonnel <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the main or principal study personnel.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Investigator" and primaryIndicator ="true".</p>	Map:CTRPv1.0 = StudyContact.primaryIndicator Map:CTRPv1.0 = StudyInvestigator.primaryIndicator Map:CTRv1.0 = StudyPersonnel.primaryIndicator Map:Vendor1v1.1 = StudyPersonnel.primaryIndicator

Attribute	Notes	Constraints and Tags
postalAddress <i>Class:</i> StudyPersonnel <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A contact point used to send physical forms of communication to the study personnel.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Responsible Party - Contact Information Map:CTR&Rr2 = Investigator Street Address Map:CTR&Rr2 = Further information contact Post Code Map:CTR&Rr2 = Further information contact Town/City Map:CTR&Rr2 = Contact point for further information on the trial Street Address Map:CTR&Rr2 = Investigator Country Map:CTR&Rr2 = Further information contact Country Map:CTR&Rr2 = Investigator Post Code Map:CTR&Rr2 = Investigator Town/City Map:CTRPv1.0 = StudyContact.postalAddress Map:CTRPv1.0 = StudyInvestigator.postalAddress Map:CTRPv3.8 = StudyContact.postalAddress Map:CTRR = Responsible Contact Person Map:CTRRr3 = StudyColleague.postalAddress Map:CTRv1.0 = StudyPersonnel.postalAddress Map:HSDBv1.0 = [Principal Investigator] .Zip/Postal code Map:HSDBv1.0 = [Principal Investigator] .Street Address Map:HSDBv1.0 = [Principal Investigator] .State/Province Map:HSDBv1.0 = [Principal Investigator] .Country Map:HSDBv1.0 = [Principal Investigator] .City Map:Vendor1v1.1 = StudyPersonnel.postalAddress Map:WHO = Contact for Public Queries - country Map:WHO = Contact for Scientific Queries - zip Map:WHO = Contact for Scientific Queries - address Map:WHO = Contact for Public Queries - city Map:WHO = Contact for Scientific Queries - country Map:WHO = Contact for Scientific Queries - city Map:WHO = Contact for Public Queries - address Map:WHO = Contact for Public Queries - zip

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> StudyPersonnel <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of the study personnel.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:CTGOV = Responsible Party - Contact Information Map:CTGOV = Central Contact - Phone Map:CTGOV = Central Contact - Email Map:CTGOV = Central Contact - Ext Map:CTR&Rr2 = Further information contact E-mail Map:CTR&Rr2 = Further information contact Telephone Map:CTR&Rr2 = Investigator Fax Map:CTR&Rr2 = Investigator Email Map:CTR&Rr2 = Investigator Telephone Map:CTR&Rr2 = Further information contact Fax Map:CTRPv1.0 = StudyInvestigator.telecomAddress Map:CTRPv1.0 = StudyContact.telecomAddress Map:CTRPv3.8 = StudyContact.telecomAddress Map:CTRR = Responsible Contact Person Map:CTRRr3 = StudyColleague.telecomAddress Map:CTRv1.0 = StudyPersonnel.telecomAddress Map:HSDBv1.0 = [Principal Investigator] .FAX Map:HSDBv1.0 = [Principal Investigator] .URL Map:HSDBv1.0 = [Principal Investigator] .TTY Map:HSDBv1.0 = [Principal Investigator] .Email Address Map:HSDBv1.0 = [Principal Investigator] .Phone Map:Vendor1v1.1 = StudyPersonnel.telecomAddress Map:WHO = Contact for Public Queries - email Map:WHO = Contact for Public Queries - telephone Map:WHO = Contact for Scientific Queries - email Map:WHO = Contact for Scientific Queries - telephone

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudyPersonnel <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the study personnel is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = StudyInvestigator.statusCode Map:C3PRv2.9 = StudyPersonnel.statusDate Map:C3PRv2.9 = StudyInvestigator.statusCode Map:C3PRv2.9 = StudyPersonnel.statusCode Map:C3PRv2.9 = StudyInvestigator.statusCode Map:caAERSv2.2 = StudyInvestigator.startDate Map:caAERSv2.2 = StudyInvestigator.endDate Map:CTOM = StudyInvestigator.statusCode Map:CTRPv1.0 = StudyInvestigator.statusDateRange Map:CTRPv1.0 = StudyInvestigator.statusCode Map:CTRPv1.0 = StudyContact.statusCode Map:CTRPv1.0 = StudyContact.statusDateRange Map:CTRPv3.8 = FunctionalRole.statusCode Map:CTRv1.0 = StudyPersonnel.effectiveDateRange Map:HL7SP = Investigator.statusCode Map:Vendor1v1.1 = StudyPersonnel.effectiveDateRange

Class: StudyRecruitmentStatus

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Not Yet Recruiting, Recruiting, etc

OTHER NAME(S):

NOTE(S):

A study must complete all of the requirements to allow subject recruitment - statuses include Not Yet Recruiting, Recruiting, etc. and the status changes are determined by the sponsor. If study XYZ is in Recruiting status, participating sites, after completing the necessary regulatory requirements, may recruit and enroll subjects.

Tagged Values:

- Map:CTRPv1.0 = StudyRecruitmentStatus
- Map:CTRPv3.8 = StudyRecruitmentStatus
- Map:CTRRr3 = StudyRecruitmentStatus
- Map:CTRv1.0 = StudyRecruitmentStatus
- Map:HL7SP = Study.subjectOf2

Connectors

Source	Connector	Target	Notes
StudyRecruitmentStatus	describes	StudyConduct	DESCRIPTION:

Source	Connector	Target	Notes
0..* describingStudyRecruitmentStatus		1 describedStudyConduct	Each StudyRecruitmentStatus always describes one StudyConduct. Each StudyConduct might be described by one or more StudyRecruitmentStatus. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> StudyRecruitmentStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the phase in the lifecycle of recruitment for the study. EXAMPLE(S): Not yet recruiting; recruiting; enrolling by invitation; active, not recruiting; completed; suspended; terminated; withdrawn. OTHER NAME(S): NOTE(S): The recruitment status of a study may overlap with the study site status and accrual status. This overlap needs to be clearly differentiated. (See tracker issue 29398). A proposed solution is to eliminate the study recruitment status codes and adopt the CTRP values for study status code.	Map:CTGOV = Recruitment Status Map:CTGOV = Overall Recruitment Status Map:CTRPv1.0 = StudyRecruitmentStatus.statusCode Map:CTRPv3.8 = StudyRecruitmentStatus.statusCode Map:CTR = Recruitment Status Map:CTRr3 = StudyRecruitmentStatus.statusCode Map:CTRv1.0 = StudyRecruitmentStatus.code Map:WHO = Recruitment Status
date <i>Class:</i> StudyRecruitmentStatus <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the recruitment status is assigned. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTRPv1.0 = StudyRecruitmentStatus.statusDate Map:CTRPv3.8 = StudyRecruitmentStatus.statusDate Map:CTRv1.0 = StudyRecruitmentStatus.date

Class: StudyResearchCoordinator

Package: Study Conduct Sub-Domain

DEFINITION:

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.

EXAMPLE(S):

OTHER NAME(S):

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

study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse

NOTE(S):

The Study Research Coordinator for study XYZ may review medical records to determine if a particular patient may be eligible for the study. If so, he will notify the investigator for further review. The Coordinator may ensure eligibility is validated, register the subject, ensure the patient is managed per the protocol, collect and submit the subject study data, and respond to data queries.

Tagged Values:

- Map:CTRRr3 = StudyResearchCoordinator

Connectors

Source	Connector	Target	Notes
StudyResearchCoordinator	specializes	StudyPersonnel	<p>DESCRIPTION: Each StudyResearchCoordinator always specializes one StudyPersonnel. Each StudyPersonnel might be specialized by one StudyResearchCoordinator.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedProtocolDeviation 0..* managedPerformedProtocol Deviation	have management action determined by	StudyResearchCoordinator 0..1 managingStudyResearchCoordinator	<p>DESCRIPTION: Each PerformedProtocolDeviation might have management action determined by one StudyResearchCoordinator. Each StudyResearchCoordinator might determine the management action for one or more PerformedProtocolDeviation .</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudyResource

Package: Study Conduct Sub-Domain

DEFINITION:

The association between a resource and the study on which it is used.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PR = StudyOrganization
- Map:C3PRv2.9 = StudyCoordinatingCenter
- Map:C3PRv2.9 = StudyFundingSponsor
- Map:caAERSv2.2 = StudyCoordinatingCenter
- Map:caAERSv2.2 = StudyFundingSponsor
- Map:CTRPv3.8 = StudyResourcing
- Map:CTRr3 = StudyResource
- Map:CTRv1.0 = StudyResource

Connectors

Source	Connector	Target	Notes
StudyResource 0..* usedStudyResource	be used for	StudyConduct 0..1 usingStudyConduct	<p>DESCRIPTION: Each StudyResource might be used for one StudyConduct. Each StudyConduct might use one or more StudyResource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyResource 0..* usingStudyResource	uses	Resource 1 usedResource	<p>DESCRIPTION: Each StudyResource always uses one Resource. Each Resource might be used for one or more StudyResource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudyResource 0..* usedStudyResource	be used for	StudyProtocolVersion 0..1 usingStudyProtocolVersion	<p>DESCRIPTION: Each StudyResource might be used for one StudyProtocolVersion. Each StudyProtocolVersion might use one or more StudyResource.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> StudyResource <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether this is the main or principal study resource.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This distinguishes between an organization that is the primary funder vs. a funder who provides less money for a study.</p>	Map:CTRPv1.0 = StudyResourceProvider.primaryIndicator Map:CTRv1.0 = StudyResource.primaryIndicator
inactiveComment <i>Class:</i> StudyResource <i>Datatype:</i> ST <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Additional description why the resource is no longer active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.inactiveCommentText Map:CTRPv3.8 = StudyResourcing.inactiveCommentText
effectiveDateRange <i>Class:</i> StudyResource <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the study resource is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRPv1.0 = StudyResourcing.activeIndicator Map:CTRPv3.8 = StudyResourcing.activeIndicator Map:CTRv1.0 = StudyResource.effectiveDateRange Map:HL7SP = Service Provider.effectiveTime

Class: StudySite

Package: Study Conduct Sub-Domain

DEFINITION:

A facility in which study activities are conducted.

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyOrganization
- Map:C3PRv2.9 = StudySite
- Map:caAERSv2.2 = StudySite
- Map:caAERSv2.2 = StudyOrganization
- Map:CTGOV = Facility

- Map:CTRPv1.0 = StudyParticipation
- Map:CTRPv3.8 = OrganizationFunctionalRole.functionCode
- Map:CTRPv3.8 = StudySiteOverallStatus
- Map:CTRPv3.8 = StudySite
- Map:CTRr3 = StudySite
- Map:CTRv1.0 = StudySite
- Map:DICOM = Clinical Trial Context Module
- Map:HL7SP = StudySite
- Map:HL7SP = SubjectProtectionApproval
- Map:HL7SP = Study.performer1
- Map:HSDBv1.0 = [Lead Organization].Organization Type
- Map:LabViewer2.2 = StudySite
- Map:PSC = StudySite
- Map:PSCv2.6 = StudySite

Connectors

Source	Connector	Target	Notes
StudySite 0..* executingStudySite	execute	StudyConduct 0..1 executedStudyConduct	<p>DESCRIPTION: Each StudySite might execute one StudyConduct. Each StudyConduct might be executed at one or more StudySite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySite 0..* performedStudySite	be a function performed by	Organization 0..1 performingOrganization	<p>DESCRIPTION: Each StudySite might be a function performed by one Organization. Each Organization might function as one or more StudySite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySite 0..* performedStudySite	be a function performed by	HealthcareFacility 0..1 performingHealthcareFacilit y	<p>DESCRIPTION: Each StudySite might be a function performed by one HealthcareFacility. Each HealthcareFacility might function as one or more StudySite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
StudySite 0..* managedStudySite	be managed by	StudyCountry 0..1 managingStudyCountry	<p>DESCRIPTION: Each StudySite might be managed by one StudyCountry. Each StudyCountry might manage one or more StudySite.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
Activity 0..* hasContextActivity	have as context	StudySite 0..1 contextForStudySite	<p>DESCRIPTION: Each Activity might have as context one StudySite. Each StudySite might be the context for one or more Activity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteRelationship 0..* sourceStudySiteRelationship	has as target	StudySite 1 targetStudySite	<p>DESCRIPTION: Each StudySiteRelationship always has as target one StudySite. Each StudySite might be the target for one or more StudySiteRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteRelationship 0..* targetStudySiteRelationship	has as source	StudySite 1 sourceStudySite	<p>DESCRIPTION: Each StudySiteRelationship always has as source one StudySite. Each StudySite might be the source for one or more StudySiteRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):
StudySiteResource 0..* usedStudySiteResource	is used at	StudySite 1 usingStudySite	DESCRIPTION: Each StudySiteResource always is used at one StudySite. Each StudySite might use one or more StudySiteResource. DEFINITION: Indicates resources intended to be or actually consumed by a particular study site. EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteProtocolVersionRelationship 0..* executedStudySiteProtocolVersionRelationship	is executed at	StudySite 1 executingStudySite	DESCRIPTION: Each StudySiteProtocolVersionRelationship always is executed at one StudySite. Each StudySite might execute one or more StudySiteProtocolVersionRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySitePersonnel 0..* performingStudySitePersonnel	perform a role for	StudySite 0..1 performedStudySite	DESCRIPTION: Each StudySitePersonnel might perform a role for one StudySite. Each StudySite might have a role performed by one or more StudySitePersonnel. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteRecruitmentStatus 0..* describingStudySiteRecruitmentStatus	describes	StudySite 1 describedStudySite	DESCRIPTION: Each StudySiteRecruitmentStatus always describes one StudySite. Each StudySite might be described by one or more

Source	Connector	Target	Notes
			<p>StudySiteRecruitmentStatus.</p> <p>DEFINITION: Indicates the point-in-time recruitment status of a study from the perspective of the study site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
OversightCommittee 0..* overseeingOversightCommittee	oversee	StudySite 0..* overseenStudySite	<p>DESCRIPTION: Each OversightCommittee might oversee one or more StudySite. Each StudySite might be overseen by one or more OversightCommittee.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedAdministrativeActivity 0..* performedPerformedAdministrativeActivity	be performed at	StudySite 0..1 performingStudySite	<p>DESCRIPTION: Each PerformedAdministrativeActivity might be performed at one StudySite. Each StudySite might perform one or more PerformedAdministrativeActivity.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This association has been deprecated since StudySite can be the subject of an administrative activity via Subject to Organization association and can be a performer of an activity via the Performer to Organization association.</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> StudySite <i>Datatype:</i> DSET<ID> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A unique symbol that establishes identity of the study site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CDASHv1.1 = DM.SITEID Map:CTRPv3.8 = StudySite.localStudyProtocolIdentifier Map:CTRv1.0 = StudySite.identifier Map:DICOM = Clinical Trial Context Module - Clinical Trial Site ID (0012,0030) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Site ID (0012,0030) Map:HL7SP = StudySite.id Map:SDTM IGv3.1.1 = DM.SITEID Map:SDTM IGv3.1.2 = DM.SITEID Map:SDTM IGv3.1.3 = DM.SITEID
leadIndicator <i>Class:</i> StudySite <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: Specifies whether this is the principal administrative organization responsible for the study.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Exception: A multi-site study with no single assigned coordination center; in this case, every participating organization can be named as lead organization.</p>	Map:C3PR = StudySite.roleCode Map:CTOM = StudySite.roleCode Map:CTRv1.0 = StudySite.leadIndicator
targetAccrualNumberRange <i>Class:</i> StudySite <i>Datatype:</i> URG<INT.NONNEG> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: An integer falling within minimum and maximum bounds that specifies how many experimental units are needed for enrollment at this site.</p> <p>EXAMPLE(S): The Mill Valley Clinic study site has determined their site accrual target for study XYZ to be 15 accruals.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = StudySite.targetAccrualNumber Map:C3PRv2.9 = StudySite.targetAccrualNumber Map:CTOM = StudySite.targetAccrualNumber Map:CTR&Rr2 = Population planned numbers in MS Map:CTR&Rr2 = Population planned numbers in EEA Map:CTRPv1.0 = StudyParticipation.targetAccrualNumber Map:CTRPv3.8 = StudySite.targetAccrualNumber Map:CTRr3 = StudySite.targetAccrualNumberRange Map:CTRv1.0 = StudySite.targetAccrualNumberRange

Attribute	Notes	Constraints and Tags
plannedDuration <i>Class:</i> StudySite <i>Datatype:</i> PQ.TIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The intended period of time for the study site's participation in the study. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:CTR&Rr2 = Estimated trial duration in MS months Map:CTR&Rr2 = Estimated trial duration worldwide days Map:CTR&Rr2 = Estimated trial duration in MS years Map:CTR&Rr2 = Estimated trial duration in MS days Map:CTR&Rr2 = Estimated trial duration worldwide years Map:CTR&Rr2 = Estimated trial duration worldwide months Map:CTR&Rr3 = Study.duration Map:CTRv1.0 = StudySite.plannedDuration
dateRange <i>Class:</i> StudySite <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date and time span specifying when the site's participation in the study begins and ends. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PR = StudySite.startDate Map:C3PR = StudySite.endDate Map:CTGOV = StudySite.startDate Map:CTOM = StudySite.stopDate Map:CTRv1.0 = StudyParticipation.dateRange Map:CTRv1.0 = StudySite.dateRange
statusCode <i>Class:</i> StudySite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: A coded value specifying the phase in the lifecycle of the study site. EXAMPLE(S): 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. OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = SiteStatusHistory.siteStudyStatus Map:caAERSv2.2 = StudySite.statusCode Map:CTOM = StudySite.statusCode Map:CTRv1.0 = StudyParticipation.statusCode Map:CTRv3.8 = StudySite.(StudySiteOverallStatus) Map:CTRv3.8 = FunctionalRole.statusCode Map:CTRv3.8 = StudySiteOverallStatus.statusCode Map:CTRv1.0 = StudySite.statusCode
statusDate <i>Class:</i> StudySite <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	DEFINITION: The date (and time) on which the status is assigned to the study site. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:C3PRv2.9 = SiteStatusHistory.startDate Map:CTOM = StudySite.irbApprovalDate Map:CTRv1.0 = StudyParticipation.statusDateRange Map:CTRv3.8 = StudySiteOverallStatus.statusCode Map:CTRv3.8 = FunctionalRole.statusDateRange Map:CTRv3.8 = StudySite.accrualDateRange Map:CTRv1.0 = StudySite.statusCode

Attribute	Notes	Constraints and Tags
accrualStatusCode <i>Class:</i> StudySite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of a participating site relative to the enrollment of additional experimental units in the given study.</p> <p>EXAMPLE(S): Open to accrual Closed to accrual Temporarily closed to accrual Pending accrual</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Study Site Accrual Status state transition diagram for further details.</p> <p>The accrual status of a study site may overlap with the overall status of the study and study site status. This overlap needs to be clearly differentiated. (See tracker issue 29398). A proposed solution is to eliminate the study site accrual status codes and adopt the CTRP values for study site status code.</p>	Map:CTRv1.0 = StudySite.accrualStatusCode
accrualStatusDate <i>Class:</i> StudySite <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the accrual status is established.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTRv1.0 = StudySite.accrualStatusDate

Class: StudySiteInvestigator

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudyInvestigator
- Map:CTGOV = Investigators (at the protocol location)
- Map:CTRv1.0 = StudySiteInvestigator
- Map:CTRv3.8 = StudySiteInvestigator
- Map:CTRv1.0 = StudySiteInvestigator
- Map:HL7SP = Study.performer3

Connectors

Source	Connector	Target	Notes
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Source	Connector	Target	Notes
StudySiteInvestigator	specializes	StudySitePersonnel	<p>DESCRIPTION: Each StudySiteInvestigator always specializes one StudySitePersonnel. Each StudySitePersonnel might be specialized by one StudySiteInvestigator.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
identifier <i>Class:</i> StudySiteInvestigator <i>Datatype:</i> ID <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A unique symbol that establishes identity of the study site investigator.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Open issue: Need to know if this is actually an identifier specifically assigned to an investigator specific to a particular study and site.</p>	Map:CTRv1.0 = StudySiteInvestigator.identifier Map:SDTM IGv3.1.3 = DM.INVID

Class: StudySiteOversightStatus

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

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

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = StudySiteOversightStatus
- Map:PSCv2.6 = AmendmentApproval

Connectors

Source	Connector	Target	Notes
StudySiteOversightStatus 0..* assignedStudySiteOversight Status	be assigned by	OversightCommittee 0..1 assigningOversightCommittee	<p>DESCRIPTION: Each StudySiteOversightStatus might be assigned by one OversightCommittee. Each OversightCommittee might</p>

Source	Connector	Target	Notes
			<p>assign one or more StudySiteOversightStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteOversightStatus 0..* describingStudySiteOversightStatus	describes	StudySiteProtocolVersionRelationship 1 describedStudySiteProtocolVersionRelationship	<p>DESCRIPTION: Each StudySiteOversightStatus always describes one StudySiteProtocolVersionRelationship. Each StudySiteProtocolVersionRelationship might be described by one or more StudySiteOversightStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
reviewBoardApprovalNumberText <i>Class:</i> StudySiteOversightStatus <i>Datatype:</i> ST.SIMPLE <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A character string that is assigned by the review board upon approval of the protocol.</p> <p>EXAMPLE(S): 12-001234, 4-05, or any string defined by the review board.</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:CTGOV = Board Approval Number Map:CTRPv3.8 = StudySite.reviewBoardApprovalNumber Map:CTRR = IRB Approval Number Map:CTRv1.0 = StudySiteOversightStatus.reviewBoardApprovalNumberText Map:DICOM = Clinical Trial Context Module - Clinical Trial Protocol Ethics Committee Approval Number (0012,0082) Map:DICOM = Clinical Trial Subject Module - Clinical Trial Protocol Ethics Committee Approval Number (0012,0082) Map:HCTv1.0 = MD Anderson Specific Content: Protocol .NIH-OBA Number Map:HCTv1.0 = MD Anderson Specific Content: Protocol .IBC number Map:HCTv1.0 = MD Anderson Specific Content: Protocol .IRB number Map:HSDBv1.0 = [IRB].IRB number
reviewBoardProcessCode <i>Class:</i> StudySiteOversightStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of the review board process.</p> <p>EXAMPLE(S): request not submitted; submitted, pending; submitted, approved; submitted, exempt; submitted, denied; submission not required</p> <p>OTHER NAME(S):</p> <p>NOTE(S): Please refer to the Review Board Process Status state transition diagram for further details.</p>	Map:CTGOV = Board Approval Status Map:CTRPv3.8 = StudySite.reviewBoardApprovalStatusCode Map:CTRR = IRB Review/Approval Status Map:CTRv1.0 = StudySiteOversightStatus.reviewBoardProcessCode Map:HSDBv1.0 = [IRB].IRB review type
reviewBoardProcessDate <i>Class:</i> StudySiteOversightStatus <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the Institutional Review Board (IRB) determined the status of this study protocol for execution at this site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Review Board Approval Date</p> <p>NOTE(S):</p>	Map:C3PR = StudySite.irbApprovalDate Map:C3PRv2.9 = StudySiteStudyVersion.irbApprovalDate Map:CTOM = StudySite.irbApprovalDate Map:CTRv1.0 = StudySiteOversightStatus.reviewBoardProcessDate Map:HSDBv1.0 = [IRB].IRB approval date Map:PSCv2.6 = AmendmentApproval.date

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudySiteOversightStatus <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: The date and time span specifying when the review board's oversight status (process code) begins and ends.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S): Ethics Committee Approval Effectiveness Start and End Date</p> <p>NOTE(S):</p>	Map:DICOM = Clinical Trial Context Module - Ethics Committee Approval Effectiveness Start Date (0012,0086) Map:DICOM = Clinical Trial Context Module - Ethics Committee Approval Effectiveness End Date (0012,0087)

Class: StudySitePersonnel

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Study Site Investigator, Study Site Research Coordinator

OTHER NAME(S):

NOTE(S):

roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Site Investigator" and primaryIndicator = "true".

Tagged Values:

- Map:C3PRv2.9 = StudyPersonnel
- Map:caAERSv2.2 = StudyPersonnel
- Map:CTGOV = Facility Contact
- Map:CTRPv1.0 = StudyParticipationContact
- Map:CTRPv3.8 = StudySiteContact
- Map:CTRRr3 = StudySiteContact
- Map:CTRv1.0 = StudySitePersonnel
- Map:HL7SP = Study.performer3
- Map:Vendor1v1.1 = StudySitePersonnel

Connectors

Source	Connector	Target	Notes
StudySitePersonnel 0..* performedStudySitePersonnel	be a function performed by	ResearchStaff 0..1 performingResearchStaff	<p>DESCRIPTION: Each StudySitePersonnel might be a function performed by one ResearchStaff. Each ResearchStaff might function as one or more StudySitePersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Source	Connector	Target	Notes
StudySitePersonnel 0..* supportsStudySitePersonnel	plan to perform a role for	PlannedStudySite 0..1 supportedPlannedStudySite	<p>DESCRIPTION: Each StudySitePersonnel might plan to perform a role for one PlannedStudySite. Each PlannedStudySite might have a role planned to be performed by one or more StudySitePersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySitePersonnel 0..* performingStudySitePersonnel	perform a role for	StudySite 0..1 performedStudySite	<p>DESCRIPTION: Each StudySitePersonnel might perform a role for one StudySite. Each StudySite might have a role performed by one or more StudySitePersonnel.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySitePersonnel 0..* performedStudySitePersonnel	be a function performed by	HealthcareProvider 0..1 performingHealthcareProvider	<p>DESCRIPTION: Each StudySitePersonnel might be a function performed by one HealthcareProvider. Each HealthcareProvider might function as one or more StudySitePersonnel.</p> <p>DEFINITION: Indicates that the StudySitePersonnel role is being fulfilled by a HealthcareProvider.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteResearchCoordinator	specializes	StudySitePersonnel	<p>DESCRIPTION: Each StudySiteResearchCoordinator always specializes one StudySitePersonnel. Each StudySitePersonnel might be specialized by one</p>

Source	Connector	Target	Notes
			StudySiteResearchCoordinator. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
Study 0..1 participatedStudy	be participated in by	StudySitePersonnel 0..* participatingStudySitePersonnel	DESCRIPTION: Each Study might be participated in by one or more StudySitePersonnel. Each StudySitePersonnel might participate in one Study. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteInvestigator	specializes	StudySitePersonnel	DESCRIPTION: Each StudySiteInvestigator always specializes one StudySitePersonnel. Each StudySitePersonnel might be specialized by one StudySiteInvestigator. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
PerformedProtocolDeviation 0..* implementedPerformedProtocolDeviation	have management action implemented by	StudySitePersonnel 0..1 implementingStudySitePersonnel	DESCRIPTION: Each PerformedProtocolDeviation might have management action implemented by one StudySitePersonnel. Each StudySitePersonnel might implement the management action for one or more PerformedProtocolDeviation. DEFINITION: EXAMPLE(S): OTHER NAME(S):

Source	Connector	Target	Notes
NotificationReceiver 0..* performedNotificationReceiver	be a function performed by	StudySitePersonnel 0..1 performingStudySitePersonnel	<p>NOTE(S):</p> <p>DESCRIPTION: Each NotificationReceiver might be a function performed by one StudySitePersonnel. Each StudySitePersonnel might function as one or more NotificationReceiver.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
roleCode <i>Class:</i> StudySitePersonnel <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: The coded value specifying a type of responsibility of the study site personnel.</p> <p>EXAMPLE(S): Principal Investigator, Sub Investigator, Facility Contact Backup</p> <p>OTHER NAME(S):</p> <p>NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Site Investigator" and primaryIndicator ="true".</p>	Map:C3PRv2.9 = StudyPersonnel.roleCode Map:C3PRv2.9 = StudyInvestigator.roleCode Map:C3PRv2.9 = RoleBasedRecipient.role Map:caAERSv2.2 = StudyPersonnel.roleCode Map:caAERSv2.2 = RoleBasedRecipient.role Map:CTGOV = Facility Contact Backup Map:CTRPv1.0 = StudySiteInvestigator.roleCode Map:CTRPv1.0 = StudyParticipationContact.roleCode Map:CTRPv3.8 = StudySiteContact.roleCode Map:CTR = Site Representative/Investigator Map:CTRv1.0 = StudySitePersonnel.roleCode Map:SDTM IGv3.1.3 = FA.FAEVAL Map:SDTM IGv3.1.3 = EG.EGEVAL Map:SDTM IGv3.1.3 = PE.PEEVAL Map:SDTM IGv3.1.3 = RS.RSEVAL Map:SDTM IGv3.1.3 = TR.TREVAL Map:SDTM IGv3.1.3 = TU.TUEVAL Map:Vendor1v1.1 = StudySitePersonnel.roleCode

Attribute	Notes	Constraints and Tags
primaryIndicator <i>Class:</i> StudySitePersonnel <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: Specifies whether this is the main or principal study site personnel. EXAMPLE(S): OTHER NAME(S): NOTE(S): roleCode and primaryIndicator are redundant attributes when roleCode = "Principal Site Investigator" and primaryIndicator = "true".	Map:CTRPv1.0 = StudyParticipationContact.primaryIndicator Map:CTRPv1.0 = StudySiteInvestigator.primaryIndicator Map:CTRPv3.8 = StudySiteContact.primaryIndicator Map:CTRv1.0 = StudySitePersonnel.primaryIndicator Map:Vendor1v1.1 = StudySitePersonnel.primaryIndicator
postalAddress <i>Class:</i> StudySitePersonnel <i>Datatype:</i> AD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	DEFINITION: A contact point used to send physical forms of communication to the study site personnel. EXAMPLE(S): OTHER NAME(S): NOTE(S):	Map:caAERSv2.2 = Address.zip > SiteResearchStaff Map:caAERSv2.2 = Address.city > SiteResearchStaff Map:caAERSv2.2 = Address.country > SiteResearchStaff Map:caAERSv2.2 = Address.street > SiteResearchStaff Map:caAERSv2.2 = Address.state > SiteResearchStaff Map:CTRPv1.0 = StudyParticipationContact.postalAddress Map:CTRPv1.0 = StudySiteInvestigator.postalAddress Map:CTRPv3.8 = StudySiteContact.postalAddress Map:CTRr3 = StudySiteContact.postalAddress Map:CTRv1.0 = StudySitePersonnel.postalAddress Map:Vendor1v1.1 = StudySitePersonnel.postalAddress

Attribute	Notes	Constraints and Tags
telecomAddress <i>Class:</i> StudySitePersonnel <i>Datatype:</i> BAG<TEL> <i>Derived:</i> False <i>Cardinality:</i> 0 . . *	<p>DEFINITION: A sequence of digits or characters used to identify a particular telephone, fax, or email of a study site personnel.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:caAERSv2.2 = ContactMechanismBasedRecipient.address Map:CTGOV = Facility Contact - Email Map:CTGOV = Facility Contact - Phone Map:CTGOV = Facility Contact - Ext Map:CTRPv1.0 = StudySiteInvestigator.telecomAddress Map:CTRPv1.0 = StudyParticipationContact.telecomAddress Map:CTRPv3.8 = StudySiteContact.telecomAddress Map:CTRv1.0 = StudySitePersonnel.telecomAddress Map:HCTv1.0 = CDE 2517550:UML DEFAULT CD.Person Email Address Map:NCI CRF Standard = CDE 2661012v3.0: Clinical Research Associate Person Fax Number Map:NCI CRF Standard = CDE 2661003v1.0: Clinical Research Associate Person Telephone Number Map:Vendor1v1.1 = StudySitePersonnel.telecomAddress

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudySitePersonnel <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span for when the study site personnel is active.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PR = HealthcareSiteInvestigator.statusCode Map:C3PR = HealthcareSiteInvestigator.statusDate Map:C3PRv2.9 = StudyPersonnel.statusCode Map:C3PRv2.9 = StudyPersonnel.statusDate Map:C3PRv2.9 = StudyInvestigator.statusCode Map:C3PRv2.9 = StudyInvestigator.statusDate Map:caAERSv2.2 = StudyPersonnel.endDate Map:caAERSv2.2 = StudyPersonnel.startDate Map:CTRPv1.0 = StudyParticipationContact.statusCode Map:CTRPv1.0 = StudyParticipationContact.statusDateRange Map:CTRPv1.0 = StudySiteInvestigator.statusCode Map:CTRPv1.0 = StudySiteInvestigator.statusDateRange Map:CTRPv3.8 = FunctionalRole.statusDateRange Map:CTRv1.0 = StudySitePersonnel.effectiveDateRange Map:Vendor1v1.1 = StudySitePersonnel.effectiveDateRange

Class: StudySiteProtocolVersionRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between a study site and a version of the study protocol used or available for use at that site.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Even if a study site's IRB has not reviewed the study protocol version, if there is a new version for the study protocol, then there is the potential for a relationship between the site and the version. The dateRange is specified only if the version is approved for this site by the IRB and activated at the site. Retroactive approval means that the dateRange does not have to be on or after the IRB approval date.

Tagged Values:

- Map:C3PRv2.9 = StudySiteStudyVersion
- Map:CTRv1.0 = StudySiteProtocolVersionRelationship

Connectors

Source	Connector	Target	Notes
StudySiteProtocolVersionRelationship	is executed at	StudySite 1	DESCRIPTION: Each

Source	Connector	Target	Notes
0..* executedStudySiteProtocol VersionRelationship		executingStudySite	StudySiteProtocolVersionR elationship always is executed at one StudySite. Each StudySite might execute one or more StudySiteProtocolVersionR elationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteProtocolVersionR elationship 0..* executingStudySiteProtocol VersionRelationship	executes	StudyProtocolVersion 1 executedStudyProtocolVersi on	DESCRIPTION: Each StudySiteProtocolVersionR elationship always executes one StudyProtocolVersion. Each StudyProtocolVersion might be executed at one or more StudySiteProtocolVersionR elationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySubjectProtocolVersio nRelationship 0..* assignedStudySubjectProtoc olVersionRelationship	is assigned to	StudySiteProtocolVersionR elationship 1 assigningStudySiteProtocol VersionRelationship	DESCRIPTION: Each StudySubjectProtocolVersio nRelationship always is assigned to one StudySiteProtocolVersionR elationship. Each StudySiteProtocolVersionR elationship might be the assigned version for one or more StudySubjectProtocolVersio nRelationship. DEFINITION: EXAMPLE(S): OTHER NAME(S): NOTE(S):
StudySiteOversightStatus 0..* describingStudySiteOversig htStatus	describes	StudySiteProtocolVersionR elationship 1 describedStudySiteProtocol	DESCRIPTION: Each StudySiteOversightStatus always describes one

Source	Connector	Target	Notes
		VersionRelationship	<p>StudySiteProtocolVersionRelationship. Each StudySiteProtocolVersionRelationship might be described by one or more StudySiteOversightStatus.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudySiteProtocolVersionRelationship <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION:</p> <p>The date and time span specifying when the relationship between a study site and study protocol version begins and ends.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = StudySiteStudyVersion.startDate Map:C3PRv2.9 = StudySiteStudyVersion.endDate Map:CTRv1.0 = StudySiteProtocolVersionRelationship.effectiveDateRange

Class: StudySiteRecruitmentStatus

Package: Study Conduct Sub-Domain

DEFINITION:

The point-in-time expression of the progress of finding and enrolling study subjects into a study for a particular study site.

EXAMPLE(S):

Not yet recruiting, Recruiting, Completed, Suspended, Terminated

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRPv3.8 = StudySiteAccrualStatus
- Map:CTRv1.0 = StudySiteRecruitmentStatus

Connectors

Source	Connector	Target	Notes
StudySiteRecruitmentStatus 0..* describingStudySiteRecruitmentStatus	describes	StudySite 1 describedStudySite	<p>DESCRIPTION:</p> <p>Each StudySiteRecruitmentStatus always describes one StudySite. Each StudySite might be described by one or more StudySiteRecruitmentStatus.</p>

Source	Connector	Target	Notes
			<p>DEFINITION: Indicates the point-in-time recruitment status of a study from the perspective of the study site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
code <i>Class:</i> StudySiteRecruitmentStatus <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 . . 1	<p>DEFINITION: A coded value specifying the phase in the lifecycle of recruitment for the study site.</p> <p>EXAMPLE(S): Not yet recruiting; recruiting; enrolling by invitation; active, not recruiting; completed; suspended; terminated; withdrawn.</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The recruitment status of a study may overlap with the study site status and accrual status. This overlap needs to be clearly differentiated. (See tracker issue 29398).</p>	Map:C3PRv2.9 = SiteStatusHistory.siteStudyStatus Map:CTRPv1.0 = StudySiteAccrualStatus.statusCode Map:CTRPv3.8 = StudySiteAccrualStatus.statusCode Map:CTRv1.0 = StudySiteRecruitmentStatus.code
date <i>Class:</i> StudySiteRecruitmentStatus <i>Datatype:</i> TS.DATETIME <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date (and time) on which the study site recruitment status is assigned.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = SiteStatusHistory.startDate Map:CTRPv1.0 = StudySiteAccrualStatus.statusCode Map:CTRPv3.8 = StudySiteAccrualStatus.statusDate Map:CTRv1.0 = StudySiteRecruitmentStatus.date

Class: StudySiteRelationship

Package: Study Conduct Sub-Domain

DEFINITION:
Specifies the link between one study site and another.

EXAMPLE(S):
The parent-child relationship between one study site and another where study-specific resources, such as study agents, or services are provided by one site to the other.

OTHER NAME(S):

NOTE(S):

- Tagged Values:**
- Map:Vendor1v1.0 = SiteRelationship

Connectors

Source	Connector	Target	Notes
StudySiteRelationship 0..* sourceStudySiteRelationship	has as target	StudySite 1 targetStudySite	<p>DESCRIPTION: Each StudySiteRelationship always has as target one StudySite. Each StudySite might be the target for one or more StudySiteRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteRelationship 0..* targetStudySiteRelationship	has as source	StudySite 1 sourceStudySite	<p>DESCRIPTION: Each StudySiteRelationship always has as source one StudySite. Each StudySite might be the source for one or more StudySiteRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
typeCode <i>Class:</i> StudySiteRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1 .. 1	<p>DEFINITION: A coded value specifying the kind of study site relationship.</p> <p>EXAMPLE(S): provides study agent for is the parent of</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:Vendor1v1.0 = SiteRelationship.typeCode

Class: StudySiteResearchCoordinator

Package: Study Conduct Sub-Domain

DEFINITION:

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

EXAMPLE(S):

Study Site Research Coordinator John Smith is responsible for registering subjects and managing the appropriate records for

study XYZ at Mill Valley Clinic.

OTHER NAME(S):

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

study coordinator, research coordinator, clinical coordinator, research nurse, protocol nurse.

NOTE(S):

Tagged Values:

Connectors

Source	Connector	Target	Notes
StudySiteResearchCoordinator	specializes	StudySitePersonnel	<p>DESCRIPTION: Each StudySiteResearchCoordinator always specializes one StudySitePersonnel. Each StudySitePersonnel might be specialized by one StudySiteResearchCoordinator.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
PerformedStudyAgentTransfer 0..* authorizedPerformedStudyAgentTransfer	be authorized by	StudySiteResearchCoordinator 0..1 authorizingStudySiteResearchCoordinator	<p>DESCRIPTION: Each PerformedStudyAgentTransfer might be authorized by one StudySiteResearchCoordinator. Each StudySiteResearchCoordinator might authorize one or more PerformedStudyAgentTransfers.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudySiteResource

Package: Study Conduct Sub-Domain

DEFINITION:

The association between a resource and the study site on which it is used.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map: CTRv1.0 = StudySite.used(StudyResource)

Connectors

Source	Connector	Target	Notes
StudySiteResource 0..* usedStudySiteResource	is used at	StudySite 1 usingStudySite	<p>DESCRIPTION: Each StudySiteResource always is used at one StudySite. Each StudySite might use one or more StudySiteResource.</p> <p>DEFINITION: Indicates resources intended to be or actually consumed by a particular study site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySiteResource 0..* usingStudySiteResource	uses	Resource 1 usedResource	<p>DESCRIPTION: Each StudySiteResource always uses one Resource. Each Resource might be used for one or more StudySiteResource.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p> <p>DEFINITION: EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudySubjectExperienceDocumentVersion

Package: Study Conduct Sub-Domain

DEFINITION:

A document capturing the actual end-to-end (or beginning to point-in-time) experience of a single study subject within the context of a particular study

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:CTRv1.0 = StudySubjectExperienceDocumentVersion

Connectors

Source	Connector	Target	Notes
StudySubjectExperienceDocumentVersion	specializes	DocumentVersion	<p>DESCRIPTION: Each StudySubjectExperienceDocumentVersion always specializes one DocumentVersion. Each DocumentVersion might be specialized by one StudySubjectExperienceDocumentVersion.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySubjectExperienceDocumentVersion 0..* describingStudySubjectExperienceDocumentVersion	describes experience of	StudySubject 1 describedStudySubject	<p>DESCRIPTION: Each StudySubjectExperienceDocumentVersion always describes experience of one StudySubject. Each StudySubject might have experience described by one or more StudySubjectExperienceDocumentVersion.</p> <p>DEFINITION: Indicates the subject whose experience is recounted in the study subject experience document.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Class: StudySubjectProtocolVersionRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between a study subject and a version of the study protocol at a site.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:C3PRv2.9 = StudySubjectStudyVersion
- Map:caAERSv2.2 = StudyParticipantAssignment
- Map:CTRv1.0 = StudySubjectProtocolVersionRelationship
- Map:ICSRr2 = Subject12 (in IndividualCaseSafetyReport)

Connectors

Source	Connector	Target	Notes
StudySubjectProtocolVersionRelationship 0..* assignedStudySubjectProtocolVersionRelationship	is the assigned version for	StudySubject 1 assigningStudySubject	<p>DESCRIPTION: Each StudySubjectProtocolVersionRelationship always is the assigned version for one StudySubject. Each StudySubject might be assigned to one or more StudySubjectProtocolVersionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
StudySubjectProtocolVersionRelationship 0..* assignedStudySubjectProtocolVersionRelationship	is assigned to	StudySiteProtocolVersionRelationship 1 assigningStudySiteProtocolVersionRelationship	<p>DESCRIPTION: Each StudySubjectProtocolVersionRelationship always is assigned to one StudySiteProtocolVersionRelationship. Each StudySiteProtocolVersionRelationship might be the assigned version for one or more StudySubjectProtocolVersionRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
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Attribute	Notes	Constraints and Tags
effectiveDateRange <i>Class:</i> StudySubjectProtocolVersionRelationship <i>Datatype:</i> IVL<TS.DATETIME> <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: The date and time span specifying when the relationship between a study subject and study protocol version begins and ends.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:C3PRv2.9 = StudySubjectStudyVersion Map:CTRv1.0 = StudySubjectProtocolVersionRelationship.effectiveDateRange

Class: SubstanceExtractionAdministrationRelationship

Package: Study Conduct Sub-Domain

DEFINITION:

Specifies the link between an extraction (performed substance extraction) of a biologic product and the administration (performed substance administration) of that biologic product.

EXAMPLE(S):

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:HCTv1.0 = CDE 2761889:DONOR'.Autologous HSCT?

Connectors

Source	Connector	Target	Notes
SubstanceExtractionAdministrationRelationship 0..1 usedSubstanceExtractionAdministrationRelationship	uses a substance produced by	PerformedSubstanceExtraction 1 producingPerformedSubstanceExtraction	<p>DESCRIPTION: Each SubstanceExtractionAdministrationRelationship always uses a substance produced by one PerformedSubstanceExtraction. Each PerformedSubstanceExtraction might be producing a substance later used in one SubstanceExtractionAdministrationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>
SubstanceExtractionAdministrationRelationship 0..* producedSubstanceExtractionAdministrationRelationship	be producing a substance later used in	PerformedSubstanceAdministration 0..1 usingPerformedSubstanceAdministration	<p>DESCRIPTION: Each SubstanceExtractionAdministrationRelationship might be producing a substance later used in one PerformedSubstanceAdministration</p>

Source	Connector	Target	Notes
			<p>stration. Each PerformedSubstanceAdministration might be using a substance produced by one or more SubstanceExtractionAdministrationRelationship.</p> <p>DEFINITION:</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>

Attributes

Attribute	Notes	Constraints and Tags
donorTypeCode <i>Class:</i> SubstanceExtractionAdministrationRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the kind of donor that is used.</p> <p>EXAMPLE(S): Syngeneic, HLA-identical sibling, HLA-matched other relative, HLA-mismatched relative, Unrelated donor</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	<p>Map:HCTv1.0 = CDE 2675075:DONOR!.What type of donor was used for this hematopoietic stem cell transplant?</p> <p>Map:HCTv1.0 = CDE 2897753:Anatomic Structure, System, or Substance.Specify tissue donor type:</p> <p>Map:HCTv1.0 = CDE 2675073:Hematopoietic Stem Cell Transplant (HSCT) : Part 1 of 4.If there has been more than one hematopoietic stem cell transplantation, what was the type of the most recent previous hematopoietic stem cell transplantation?</p> <p>Map:HCTv1.0 = CDE 2730905:Therapy Doses.Was a particular hematopoietic stem cell source used?</p> <p>Map:HCTv1.0 = CDE 2889035:Anatomic Structure, System, or Substance.What kind of non-NMDP donor type is it?</p> <p>Map:HCTv1.0 = CDE 2730901:Therapy Doses.What source was used for the hematopoietic stem cell transplantation?</p>

Attribute	Notes	Constraints and Tags
relationCode <i>Class:</i> SubstanceExtractionAdministrationRelationship <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the self-relationship of the source to the target.</p> <p>EXAMPLE(S): Autologous (self), Allogeneic-related, Allogeneic Unrelated</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This is not a familial relationship.</p>	Map:HCTv1.0 = CDE 2957417:Techniques.What was the HSC source for the last HSCT? Map:HCTv1.0 = CDE 2815342:Therapies.What is the subsequent HSCT transplant type? Map:HCTv1.0 = CDE 2957396:Therapy Doses.What was (were) the prior HSC source(s)? Map:HCTv1.0 = MD Anderson Specific Content: Product.Autologous product Map:HCTv1.0 = MD Anderson Specific Content: Product.Allogeneic Map:HCTv1.0 = CDE 2761889:DONOR!.Autologous HSCT? Map:HCTv1.0 = CDE 2771526:Therapies.What was the HSC source?

Class: TargetAnatomicSite

Package: Study Conduct Sub-Domain

DEFINITION:

An anatomic location that is the focus of an observation result.

EXAMPLE(S):

brainstem, spinal cord for a lesion
arm for skin rash

OTHER NAME(S):

NOTE(S):

Tagged Values:

- Map:AIM v4 rv48 = ImagingPhysicalEntity

Connectors

Source	Connector	Target	Notes
TargetAnatomicSite 0..* describingTargetAnatomicSite	described	PerformedObservationResult 1 describedPerformedObservationResult	<p>DESCRIPTION: Each TargetAnatomicSite always described one PerformedObservationResult. Each PerformedObservationResult might be described by one or more TargetAnatomicSite.</p> <p>DEFINITION: Indicates result being described by a particular site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p>

Source	Connector	Target	Notes
			NOTE(S):

Attributes

Attribute	Notes	Constraints and Tags

Attribute	Notes	Constraints and Tags
code <i>Class:</i> TargetAnatomicSite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 1...1	<p>DEFINITION: A coded value specifying the anatomic location that is the focus of an observation result.</p> <p>EXAMPLE(S): arm for skin rash. brain stem or spinal cord for a lesion</p> <p>OTHER NAME(S):</p> <p>NOTE(S): The target site of the result may be different than the target site of the activity (PerformedObservation) that generated it. For example, a chest x-ray (observation) has the target site of chest while the result might show an infiltration in the left lower lobe of the lung (target site of result), or a dermatological exam may check the skin across the whole body (target site of observation) while the result might identify a rash on the right leg (target site of result).</p> <p>Sources that capture anatomic site and laterality separately should map both to this attribute. For implementation models based on BRIDG where site and laterality are captured separately, you may wish to capture both concepts as a post-coordinated code structure or as multiple code repetitions.</p>	Map:AE = AdverseEvent.bodyLocation Map:AIM v4 rv48 = ImagingPhysicalEntity.typeCode Map:C3PRv2.9 = DiseaseHistory.otherPrimaryDiseaseSiteCode Map:C3PRv2.9 = ICD9DiseaseSite.name Map:C3PRv2.9 = ICD9DiseaseSite Map:C3PRv2.9 = ICD9DiseaseSite.code Map:caAERSv2.2 = AnatomicSite.name > StudyParticipationDiseaseHistory Map:caAERSv2.2 = DiseaseHistory.otherPrimaryDiseaseSite Map:caAERSv2.2 = MetastaticDiseaseSite Map:caAERSv2.2 = AnatomicSite.name > DiseaseHistory Map:caAERSv2.2 = MetastaticDiseaseSite.otherSite > DiseaseHistory Map:caAERSv2.2 = MetastaticDiseaseSite > DiseaseHistory Map:caAERSv2.2 = MetastaticDiseaseSite.otherSite > StudyParticipantDiseaseHistory Map:caAERSv2.2 = StudyParticipantDiseaseHistory.otherPrimaryDiseaseSite Map:CTOM = Diagnosis.primaryAnatomicSiteCodeSystem Map:CTOM = Diagnosis.primaryAnatomicSiteLateralityCode Map:CTOM = Diagnosis.primaryAnatomicSiteCode Map:CTOM = LesionDescription.anatomicSiteCode Map:CTOM = LesionDescription.anatomicSiteCodeSystem Map:CTRv1.0 = PerformedObservationResult.targetAnatomicSiteCode Map:DICOM = TID 300 Measurement > \$Measurement parameter > Finding Site Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter > Finding Site Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Finding Site Map:DICOM = Measurement Group > Finding Site > Measurement Group >

Attribute	Notes	Constraints and Tags
		<p>Finding Site Map:HCTv1.0 = CDE 3133376:Involvement and Extent of Disease.What is the disease involvement site name? Map:HCTv1.0 = CDE 2970615:Involvement and Extent of Disease.Specify other sites: Map:HCTv1.0 = CDE 3031379:Anatomic Sites.Specify the known site(s) of disease progression / recurrence: Map:HCTv1.0 = CDE 2970440:Lab Results.What tissues were analyzed? Map:HCTv1.0 = CDE 2978277:Anatomic Sites.Specify site(s) of relapse/progression: Map:HCTv1.0 = CDE 2962064:Anatomic Sites.What was the primary CNS tumor site ? Map:HCTv1.0 = CDE 2961431:Involvement and Extent of Disease.Specify metastasis anatomic site: Map:HCTv1.0 = CDE 3005935:Involvement and Extent of Disease.Specify amyloidosis other system response: Map:HCTv1.0 = CDE 3057312:Anatomic Sites.On what eye was the examination performed? Map:HCTv1.0 = CDE 2969634:Involvement and Extent of Disease.Specify other metastasis lymph nodes: Map:HCTv1.0 = CDE 2986153:Anatomic Sites.Specify site of extra-gonadal germ cell tumor: Map:HCTv1.0 = CDE 2739572:Disease, Disorder or Finding.Specify other extramedullary disease site Map:HCTv1.0 = CDE 65154 /:Involvement and Extent of Disease.Site of Involvement Map:HCTv1.0 = CDE 2967296:Anatomic Sites.Specify other site: Map:HCTv1.0 = CDE 2739560:Disease, Disorder or Finding.Specify extramedullary disease site type: Map:HCTv1.0 = CDE 2787385:Anatomic Sites.Specify the biopsy site used to indicate the diagnostic evidence: Map:HCTv1.0 = CDE 2793731:Anatomic Sites.Specify the other site of the organ involvement: Map:HCTv1.0 = CDE 2003987:Anatomic Sites.Body Site </p>

Attribute	Notes	Constraints and Tags
		<p>Map:HCTv1.0 = CDE 2974004:Disease Response.Specify other site: Map:HCTv1.0 = CDE 2987033:Anatomic Sites.What was the site of the extragonadal germ cell metastases? Map:HCTv1.0 = CDE 2970480:Lab Results.Specify other tissue: Map:HCTv1.0 = CDE 3020048:Disease, Disorder or Finding.Specify location of the central nervous system abnormalities: Map:HCTv1.0 = CDE 2969616:Lab Results.What biopsy site was positive for neuroblastoma? Map:HCTv1.0 = CDE 2986193:Anatomic Sites.Specify tumor site: Map:HCTv1.0 = CDE 2971708:Disease Response.Which site? Map:HCTv1.0 = CDE 3061535:Diagnosis.Specify the site of metastasis: Map:HCTv1.0 = CDE 2987074:Anatomic Sites.Specify other site extra-gonadal metastases present: Map:HCTv1.0 = CDE 3124482:Anatomic Sites.Specify other site: Map:HCTv1.0 = CDE 2970680:Anatomic Sites.What was the site of disease involvement? Map:HCTv1.0 = CDE 3082348:Involvement and Extent of Disease.What was the site of extranodal involvement? Map:HCTv1.0 = CDE 3086004:Anatomic Sites.Specify the site(s) of primary tumors(s): Map:HCTv1.0 = CDE 2969639:Lab Results.What was the other biopsy site positive for neuroblastoma? Map:HCTv1.0 = CDE 2787340:Anatomic Sites.What is the biopsy site used to indicate the diagnostic evidence: Map:HCTv1.0 = CDE 2967298:Diagnosis.What was the site of metastasis? Map:HCTv1.0 = CDE 2793699:Anatomic Sites.Specify the site of the organ involvement: Map:HCTv1.0 = CDE 2952465:Anatomic Sites.Extranodal involvement anatomic site specify: Map:HCTv1.0 = CDE 2871915:Disease, Disorder or Finding.First infectious disorder site: Map:HCTv1.0 = CDE</p>

Attribute	Notes	Constraints and Tags
		<p>2760031:Diagnosis.What is the hemorrhage site? Map:HCTv1.0 = CDE</p> <p>2934832:Anatomic Sites.Select the infection organism site: Map:HCTv1.0 = CDE</p> <p>2970368:Lab Results.Specify the tissue analyzed: Map:HCTv1.0 = CDE</p> <p>2969632:Anatomic Sites.Which sites did the metastasis lymph nodes present? Map:HCTv1.0 = CDE</p> <p>2873907:Disease, Disorder or Finding.Second infectious disorder site: Map:HCTv1.0 = CDE</p> <p>2760980:Disease, Disorder or Finding.Specify site(s) of active leukemia: Map:HCTv1.0 = CDE</p> <p>3009313:Anatomic Sites.Specify other organ system assessed for status: Map:HCTv1.0 = CDE</p> <p>61294//:Anatomic Sites.Other specify Map:HCTv1.0 = CDE</p> <p>2761018:Disease, Disorder or Finding.Specify the location of active leukemia in the patient: Map:HCTv1.0 = CDE</p> <p>2760036:Diagnosis.Indicate the site the hemorrhage occurred: Map:HCTv1.0 = CDE</p> <p>2767//P:Anatomic Sites.Is the primary site or tumor bed involved Map:HCTv1.0 = CDE</p> <p>2969604:Anatomic Sites.What was the location of the breast cancer? Map:HCTv1.0 = CDE</p> <p>2962066:Anatomic Sites.Specify other primary CNS tumor site: Map:HCTv1.0 = CDE</p> <p>2873912:Disease, Disorder or Finding.Third infectious disorder site: Map:HCTv1.0 = CDE</p> <p>3124480:Anatomic Sites.Which sites of neuroblastoma were involved? Map:LSDAMv2.2.3Plus = PerformedObservationResult.targetAnatomicSiteCode Map:LSDAMv2.2.3Plus = PerformedPathologicalStaging.metastasisSite Map:SDTM IGv3.1.1 = AE.AELOC Map:SDTM IGv3.1.1 = PE.PELOC Map:SDTM IGv3.1.1 = VS.VSLOC Map:SDTM IGv3.1.1 = EX.EXLOC Map:SDTM IGv3.1.2 = PE.PELOC Map:SDTM IGv3.1.2 = FA.FALOC Map:SDTM IGv3.1.2 = AE.AELOC Map:SDTM IGv3.1.3 = AE.AELOC Map:SDTM IGv3.1.3 = FA.FALOC</p>

Attribute	Notes	Constraints and Tags
lateralityCode <i>Class:</i> TargetAnatomicSite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the side of the body (or a paired organ) that is a target site for an observation result.</p> <p>EXAMPLE(S): bilateral, left, right</p> <p>OTHER NAME(S):</p> <p>NOTE(S): A PerformedObservationResult.targetAnatomicSiteLateralityCode attribute was deprecated in BRIDG 3.1 but added back as TargetAnatomicSite.lateralityCode in 4.0 since source use cases for separate laterality include SDTM and CTOM. This change ensures that users of the BRIDG model are not bound to a particular kind of vocabulary, such as pre- or post-coordinated vocabularies. Collapsing laterality into the target site code is an implementation option.</p>	Map:SDTM IGv3.1.3 = PE.PELOC Map:SDTM IGv3.1.3 = TU.TULOC Map:AIM v4 rv48 = ImagingPhysicalEntityCharacteristic.typeCode Map:CTRv1.0 = PerformedObservationResult.targetAnatomicSiteLateralityCode Map:DICOM = TID 300 Measurement > \$Measurement parameter > Finding Site > Laterality Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Finding Site > Laterality Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter > Finding Site > Laterality Map:DICOM = TID 1419 ROIMeasurements > Measurement Group > Finding Site > Laterality Map:LSDAMv2.2.3Plus = PerformedObservationResult.targetAnatomicSiteLateralityCode Map:SDTM IGv3.1.3 = TU.TULAT Map:SDTM IGv3.1.3 = FA.FALOC Map:SEER 2015 = SECTION IV DESCRIPTION OF THIS NEOPLASM - LATERALITY
directionalityCode <i>Class:</i> TargetAnatomicSite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 . . 1	<p>DEFINITION: A coded value specifying the directional portion of the anatomic site that is a target of the observation result.</p> <p>EXAMPLE(S): upper, interior</p> <p>OTHER NAME(S):</p> <p>NOTE(S): This attribute complements the target anatomic site code and target anatomic site laterality code.</p>	Map:DICOM = TID 300 Measurement > \$Measurement parameter > Finding Site > Topographical modifier Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Finding Site > Topographical modifier Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter > Finding Site > Topographical modifier Map:DICOM = TID 1419 ROIMeasurements > Measurement Group > Finding Site > Topographical modifier Map:SDTM IGv3.1.3 = TU.TUDIR

Attribute	Notes	Constraints and Tags
portionCode <i>Class:</i> TargetAnatomicSite <i>Datatype:</i> CD <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: A coded value specifying the arrangement or apportionment of the body (or a paired organ) that is a target site for an observation result.</p> <p>EXAMPLE(S): entire, single, segment, many</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:DICOM = TID 300 Measurement > \$Measurement parameter > Finding Site > Topographical modifier Map:DICOM = TID 1501 MeasurementGroup > Measurement Group > Finding Site > Topographical modifier Map:DICOM = TID 1419 ROIMeasurements > \$Measurement parameter > Finding Site > Topographical modifier Map:DICOM = TID 1419 ROIMeasurements > Measurement Group > Finding Site > Topographical modifier Map:SDTM IGv3.1.3 = TU.TUPORTOT
primaryIndicator <i>Class:</i> TargetAnatomicSite <i>Datatype:</i> BL <i>Derived:</i> False <i>Cardinality:</i> 0 .. 1	<p>DEFINITION: Specifies whether this is the main or principal site.</p> <p>EXAMPLE(S):</p> <p>OTHER NAME(S):</p> <p>NOTE(S):</p>	Map:HCTv1.0 = CDE :2962064:Anatomic Sites.What was the primary CNS tumor site ?

Additional Focused Views

Package in package 'BRIDG Domain Information Model'

Additional Focused Views: Release 4.1 introduces additional focused views, which are small diagrams that contain a narrowly-scoped view of a particular area of BRIDG such as Product, Organization, and BiologicEntity.

Additional Focused Views

Activities diagram

Class diagram in package 'Additional Focused Views'

Activities

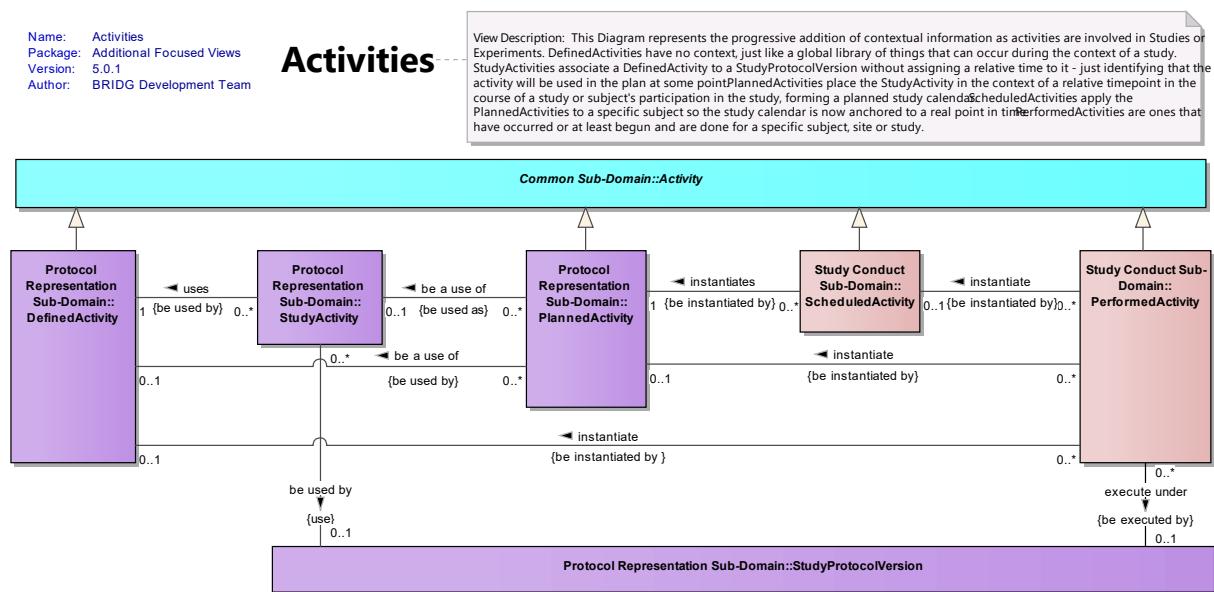


Figure 17: Activities

Adverse Events diagram

Class diagram in package 'Additional Focused Views'

Adverse Events

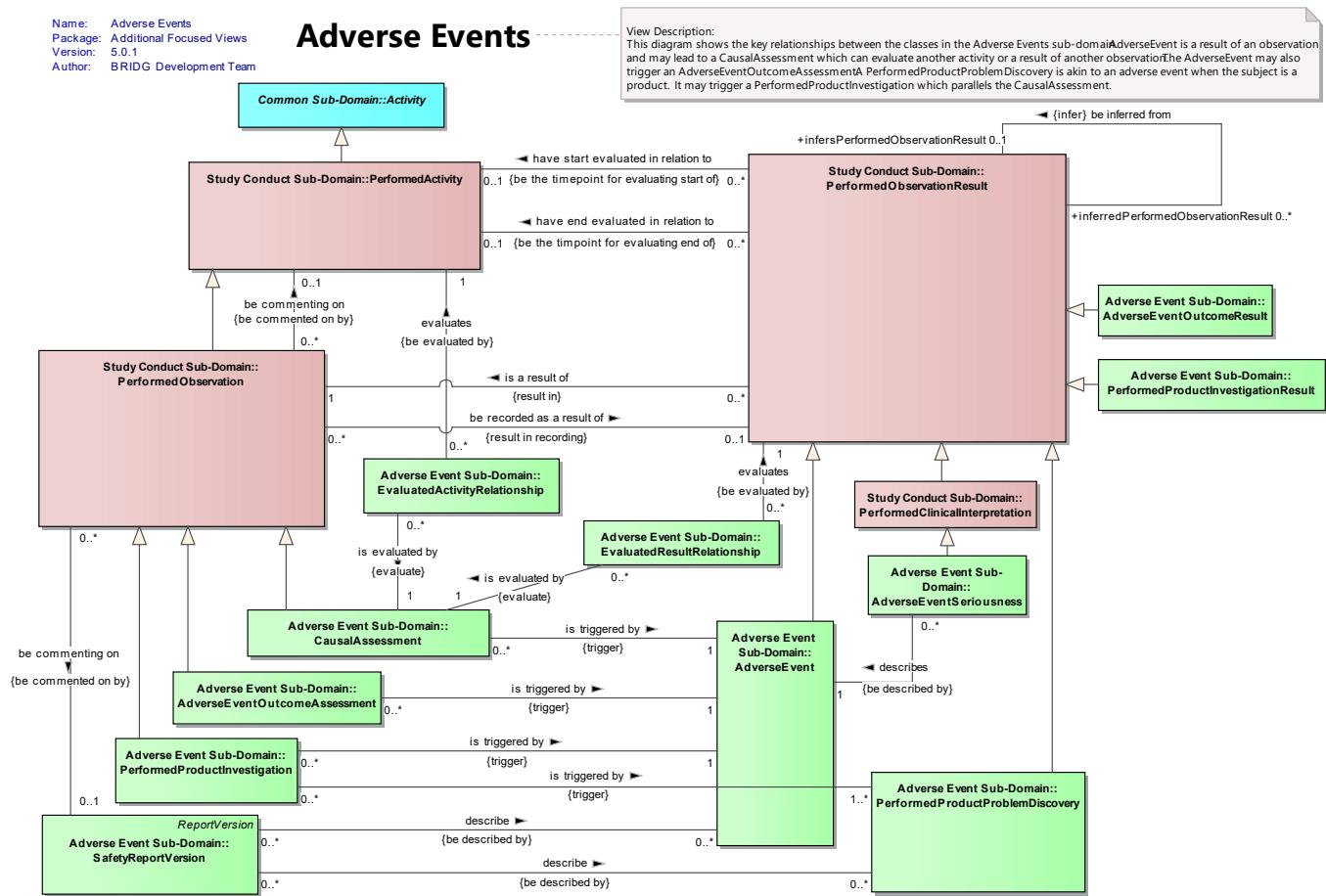


Figure 18: Adverse Events

BiologicEntity and Related Classes diagram

Class diagram in package 'Additional Focused Views'

BiologicEntity and Related Classes

Name: BiologicEntity and Related Classes
 Package: Additional Focused Views
 Version: 5.0.1
 Author: BRIDG Development Team

BiologicEntity and Related Classes

View Description:

This diagram shows the key classes associated with BiologicEntity and the nature of the relationships, including the Person and Animal subclasses and how parts and groups of BiologicEntities are represented.

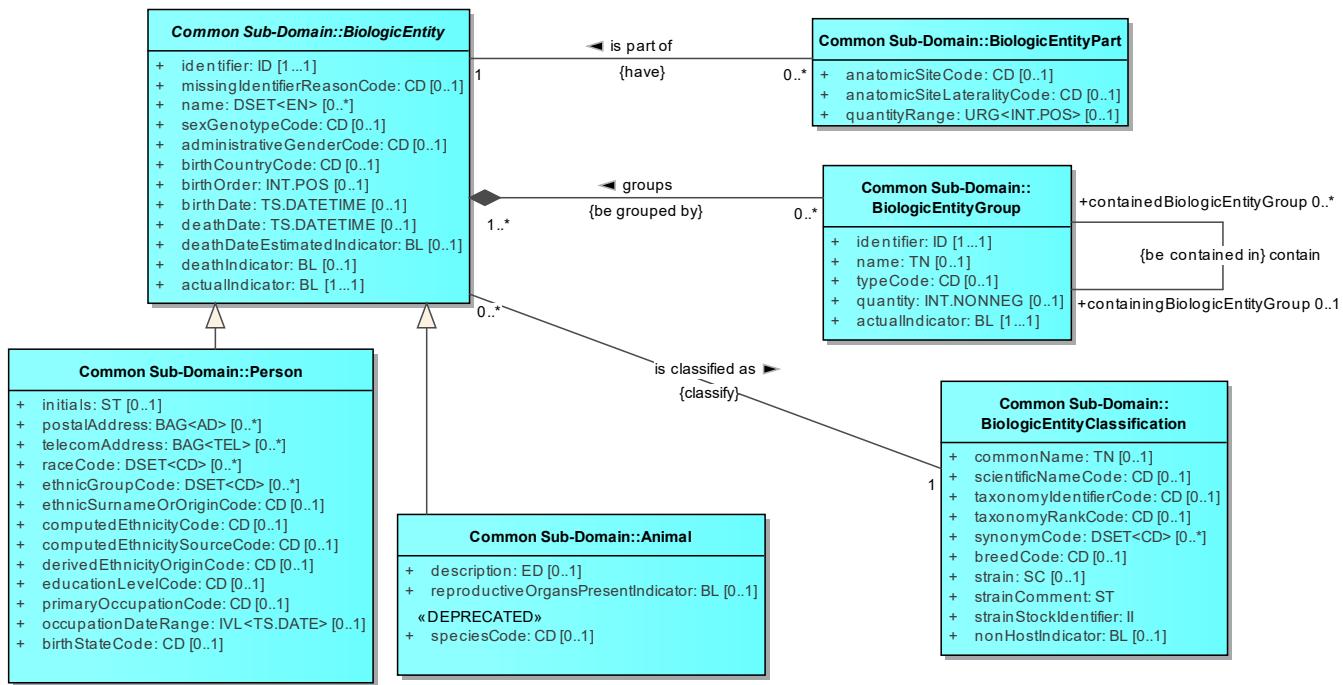


Figure 19: BiologicEntity and Related Classes

ClinicalTrials.gov diagram

Class diagram in package 'Additional Focused Views'

ClinicalTrials.gov

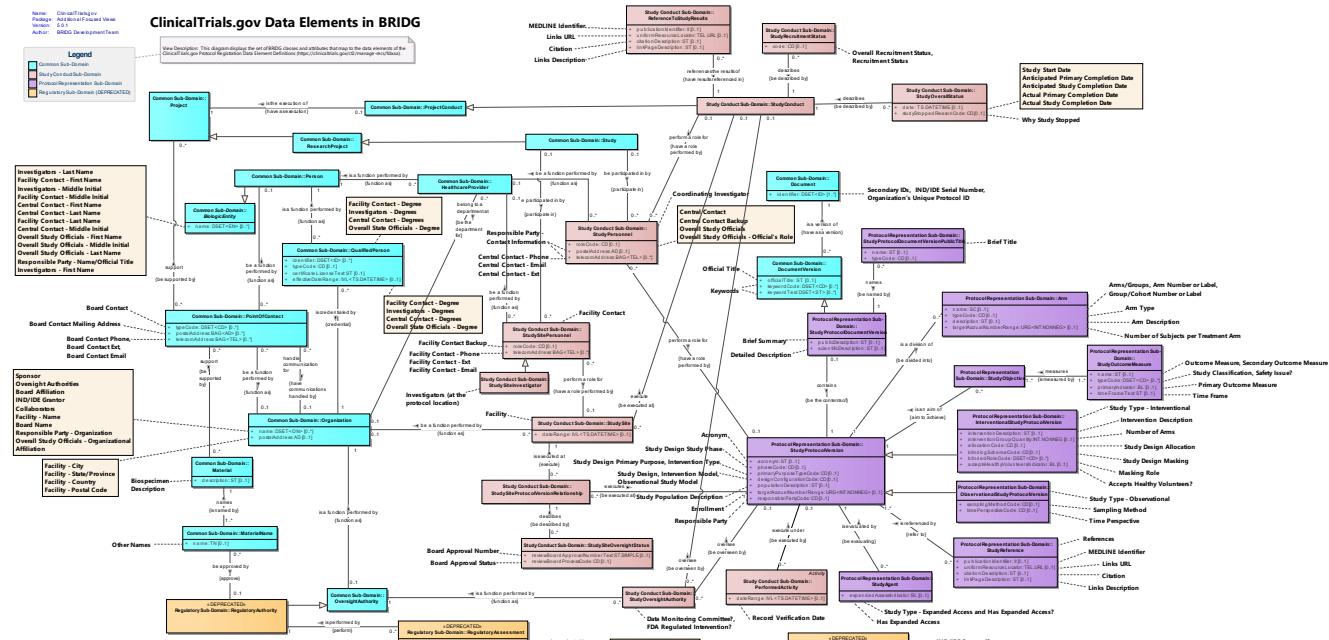


Figure 20: ClinicalTrials.gov

Oncology View diagram

Class diagram in package 'Additional Focused Views'

Oncology View

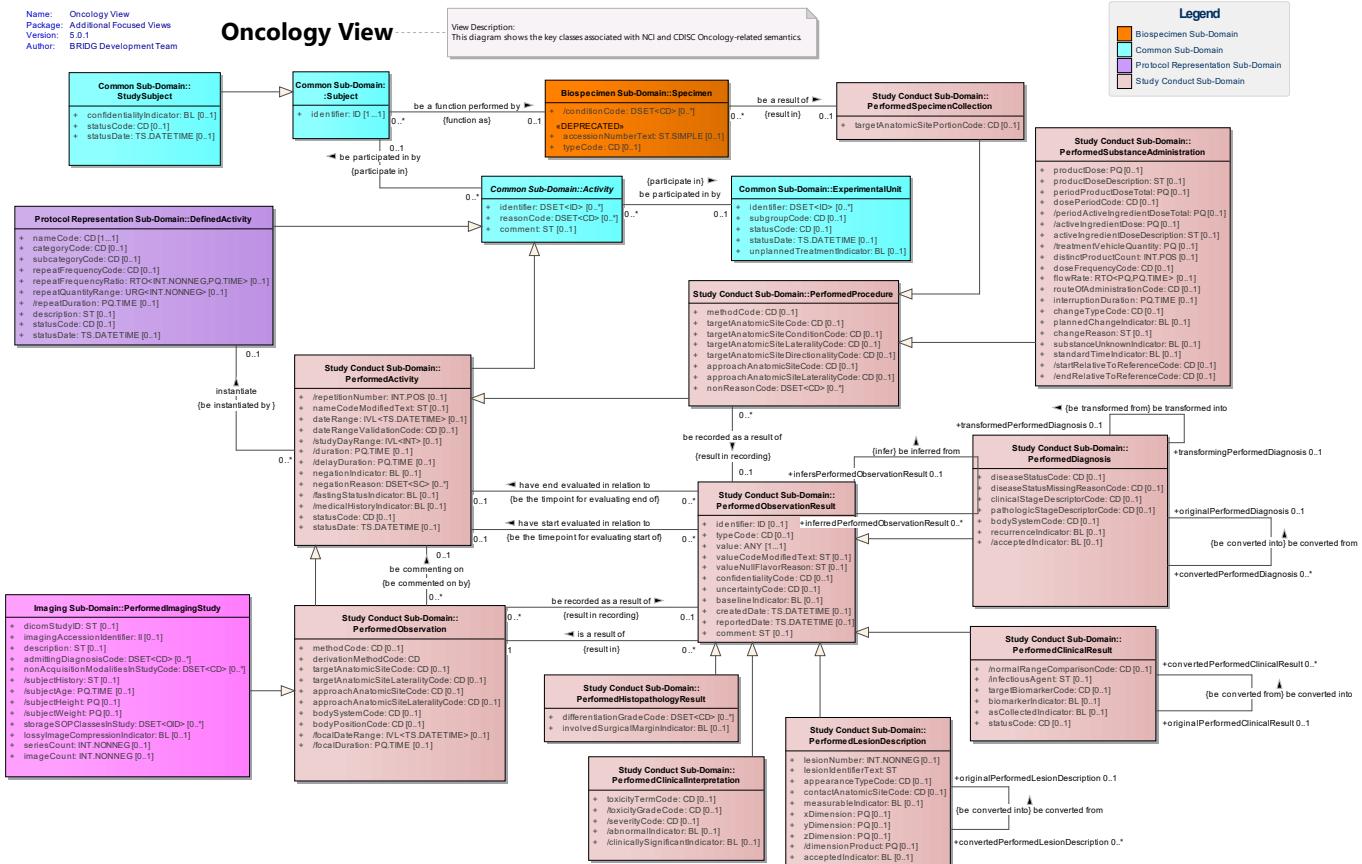


Figure 21: Oncology View

Organization diagram

Class diagram in package 'Additional Focused Views'

Organization

Name: Organization
Package: Additional Focused Views
Version: 5.0.1
Author: BRIDG Development Team

Organization

View Description:
This view shows the concepts that represent the primary organizations involved in basic, pre-clinical, clinical, and translational research and associated regulatory artifacts.

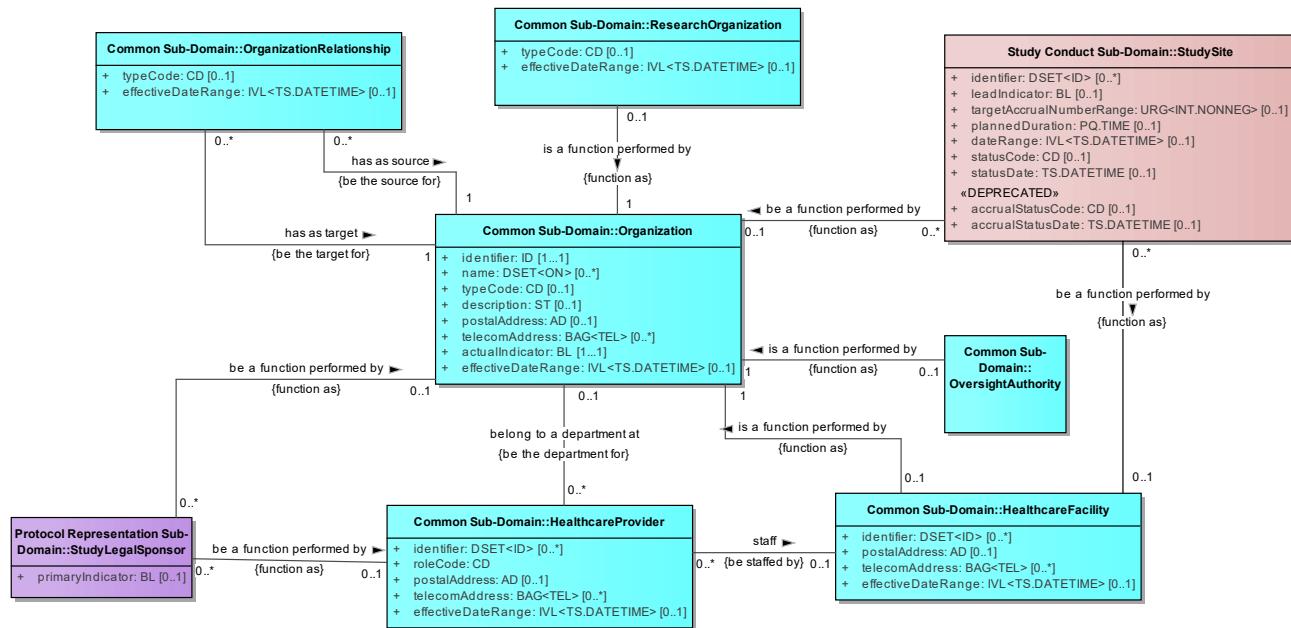


Figure 22: Organization

Organization-Related Classes - no attributes diagram

Class diagram in package 'Additional Focused Views'

Organization-Related Classes - no attributes

Name: Organization-Related Classes - no attributes
Package: Additional Focused Views
Version: 5.0.1
Author: BRIDG Development Team

Organization-Related Classes - no attributes

View Description:
This diagram shows the functions that Organizations can perform in the context of clinical research and life science experiments, and translational research in general also depicts how some kinds of people functions are related to Organizations. Note that, for simplicity sake, this diagram omits all attributes in any of these classes, though many of the classes actually do contain attributes.

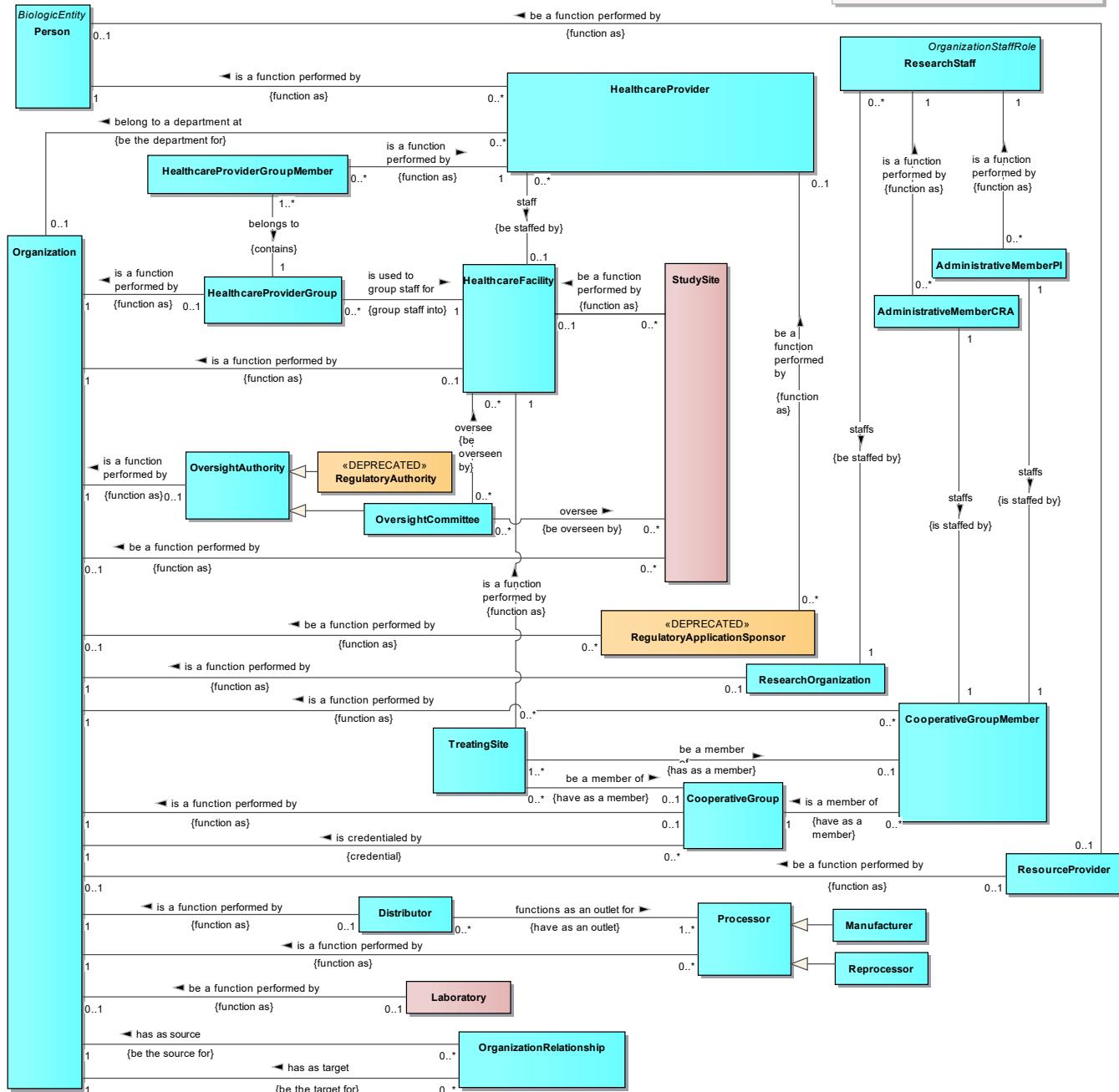


Figure 23: Organization-Related Classes - no attributes

Observations and Results diagram

Class diagram in package 'Additional Focused Views'

Observations and Results

Name: Observations and Results
Package: Additional Focused Views
Version: 5.0.1
Author: BRIDG Development Team

Observations and Results

View Description:
This diagram shows the variety of relationships around PerformedObservation and PerformedObservationResult, aside from the extensive subclass relationships.

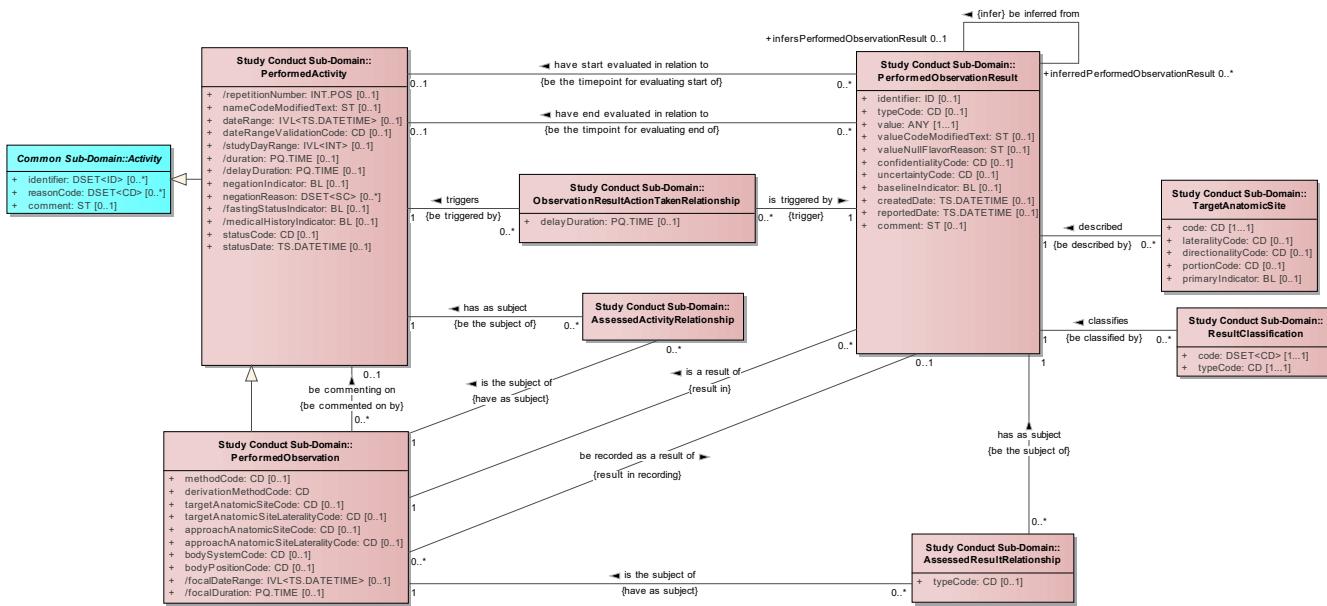


Figure 24: Observations and Results

Participant Registration diagram

Class diagram in package 'Additional Focused Views'

Participant Registration

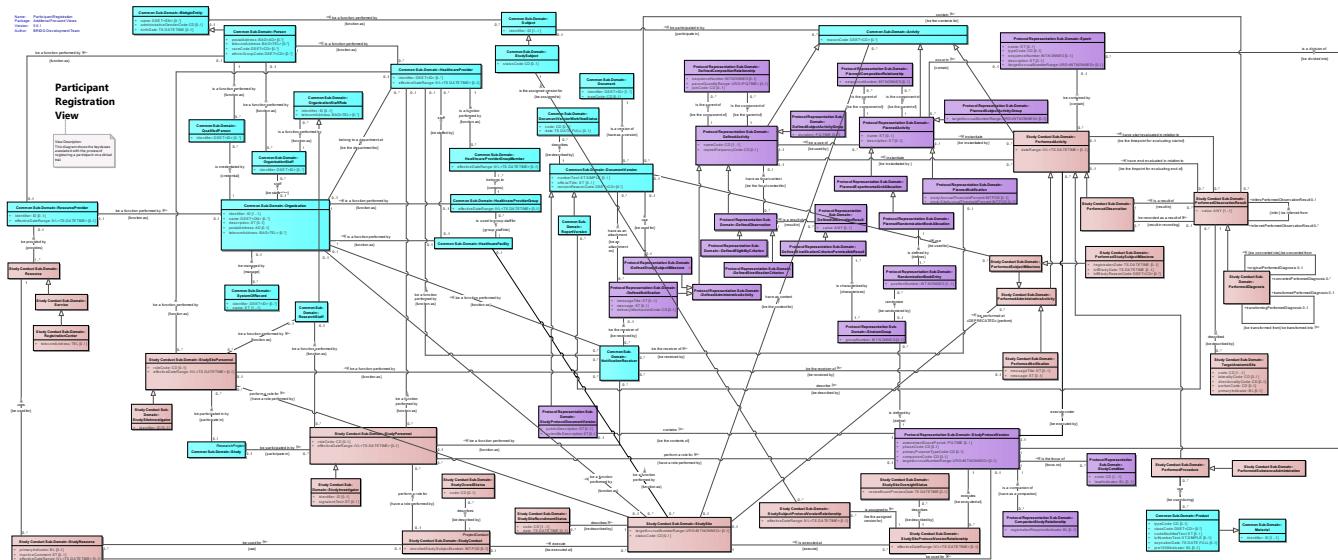


Figure 25: Participant Registration

Performer diagram

Class diagram in package 'Additional Focused Views'

Performer

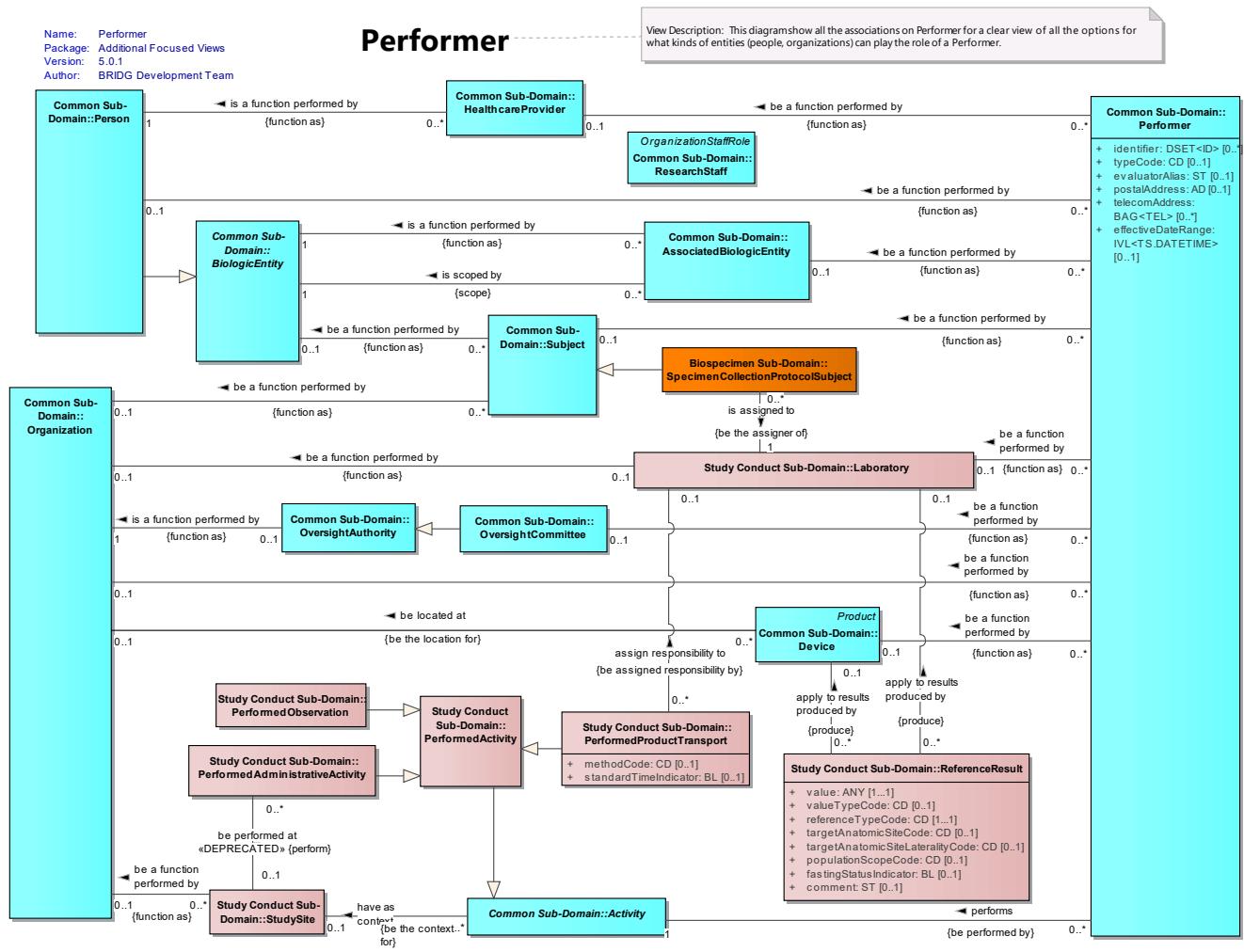


Figure 26: Performer

Product diagram

Class diagram in package 'Additional Focused Views'

Product

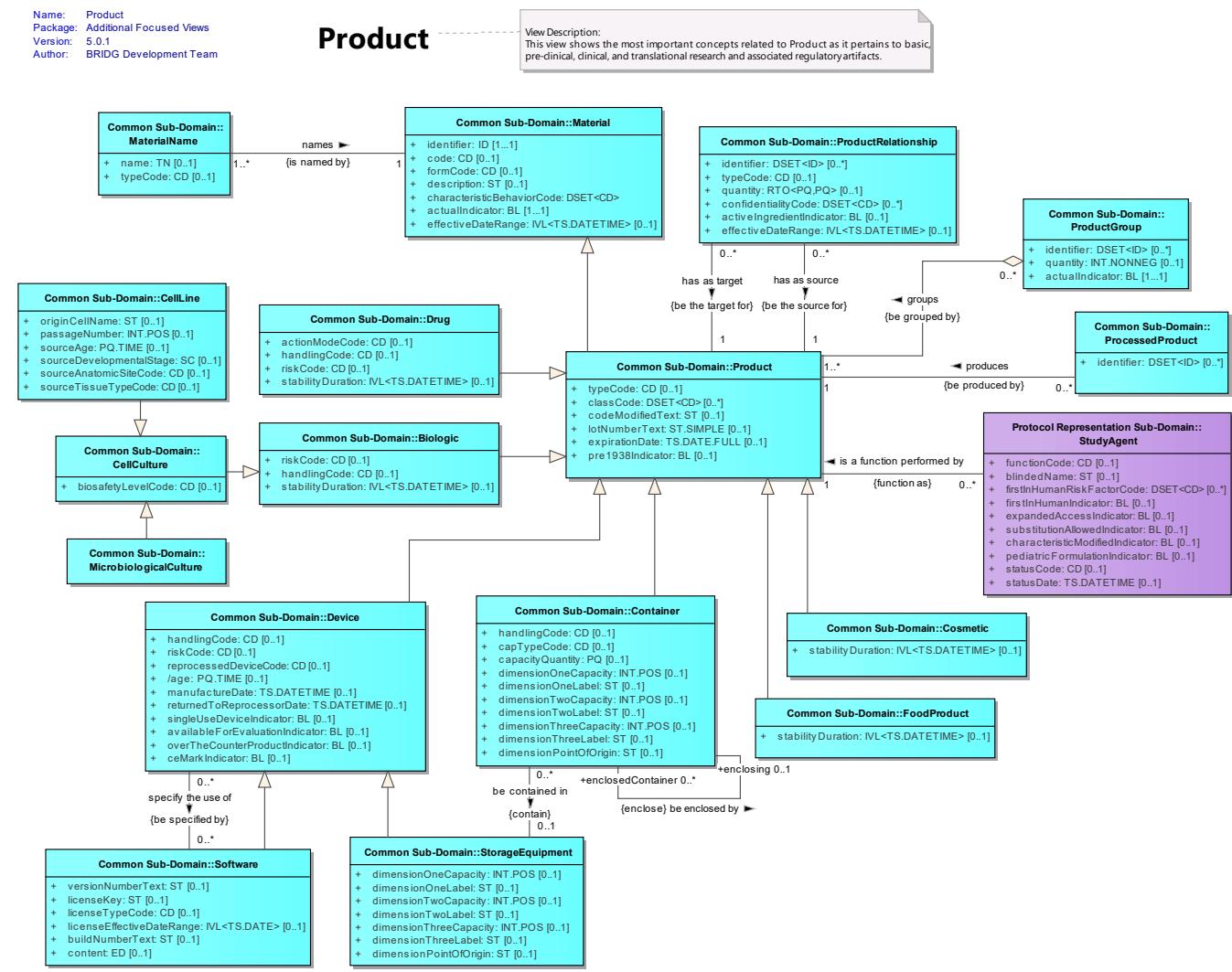


Figure 27: Product

SDTM 3.1.3 View diagram

Class diagram in package 'Additional Focused Views'

Need view description here.

SDTM 3.1.3 View

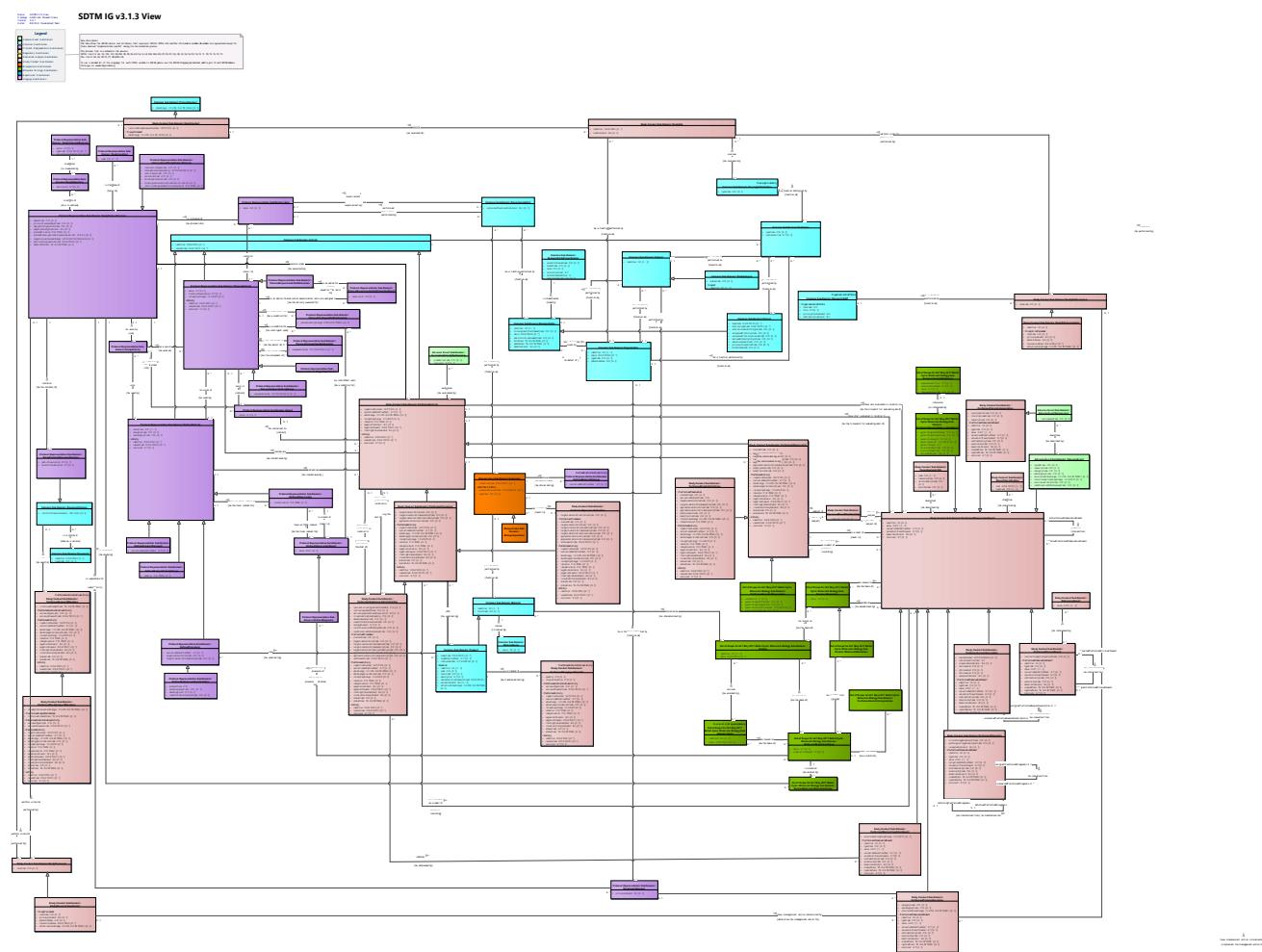


Figure 28: SDTM 3.1.3 View

SDTM Exposure (EX) Domain View diagram

Class diagram in package 'Additional Focused Views'

SDTM Exposure (EX) Domain View

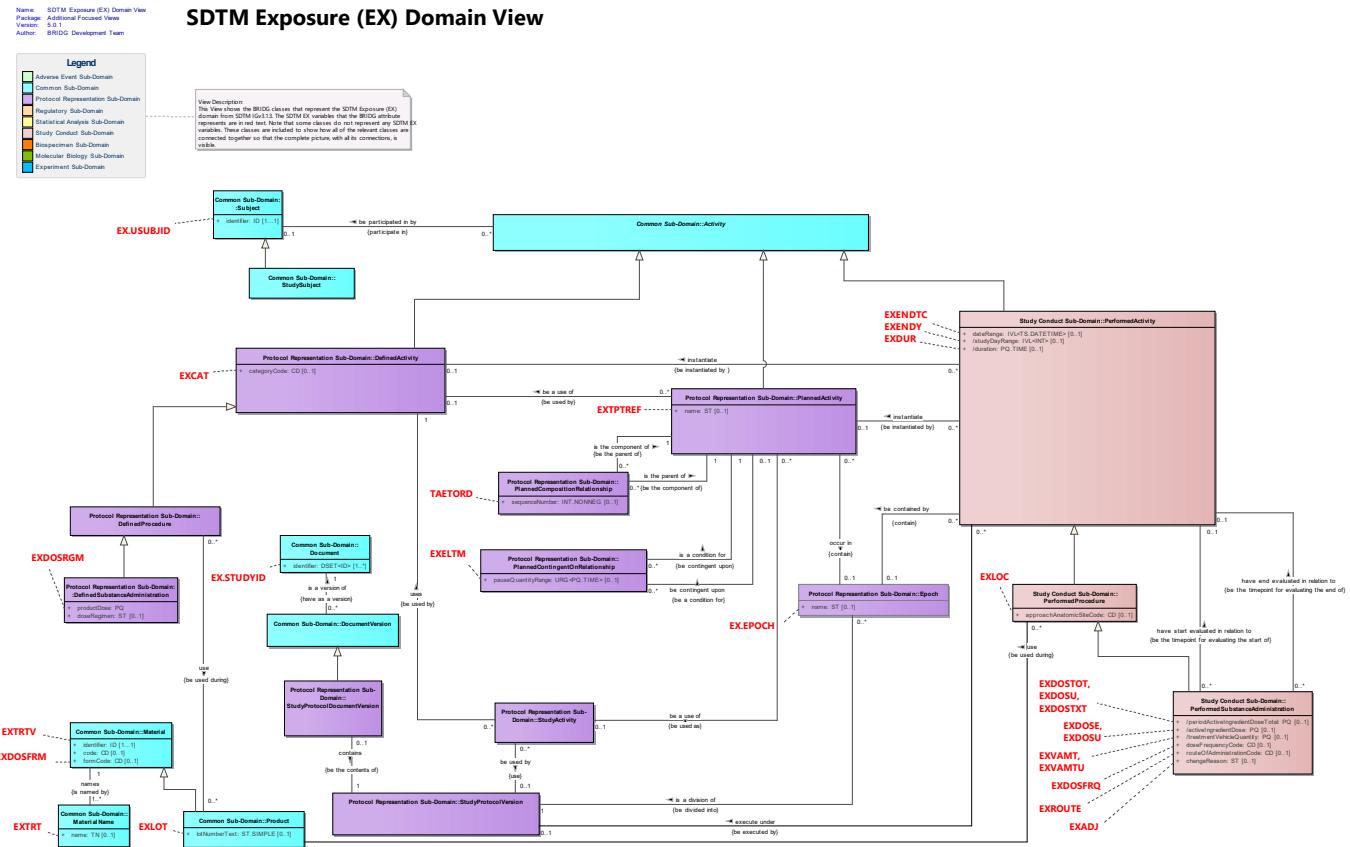


Figure 29: SDTM Exposure (EX) Domain View

SDTM Disease Response (RS) Domain View diagram

Class diagram in package 'Additional Focused Views'

SDTM Disease Response (RS) Domain View

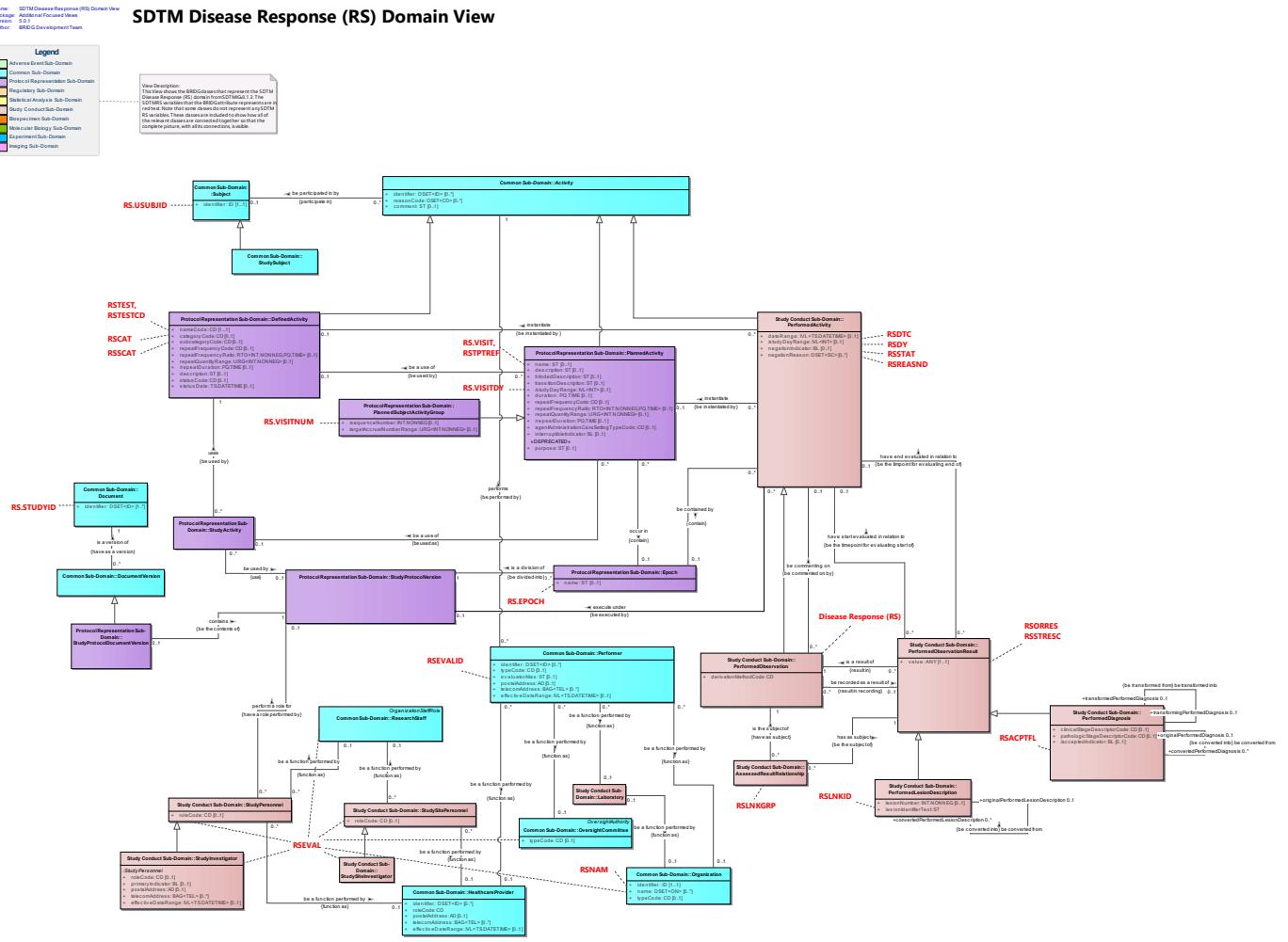


Figure 30: SDTM Disease Response (RS) Domain View

SDTM Vital Signs (VS) View diagram

Class diagram in package 'Additional Focused Views'

SDTM Vital Signs (VS) View

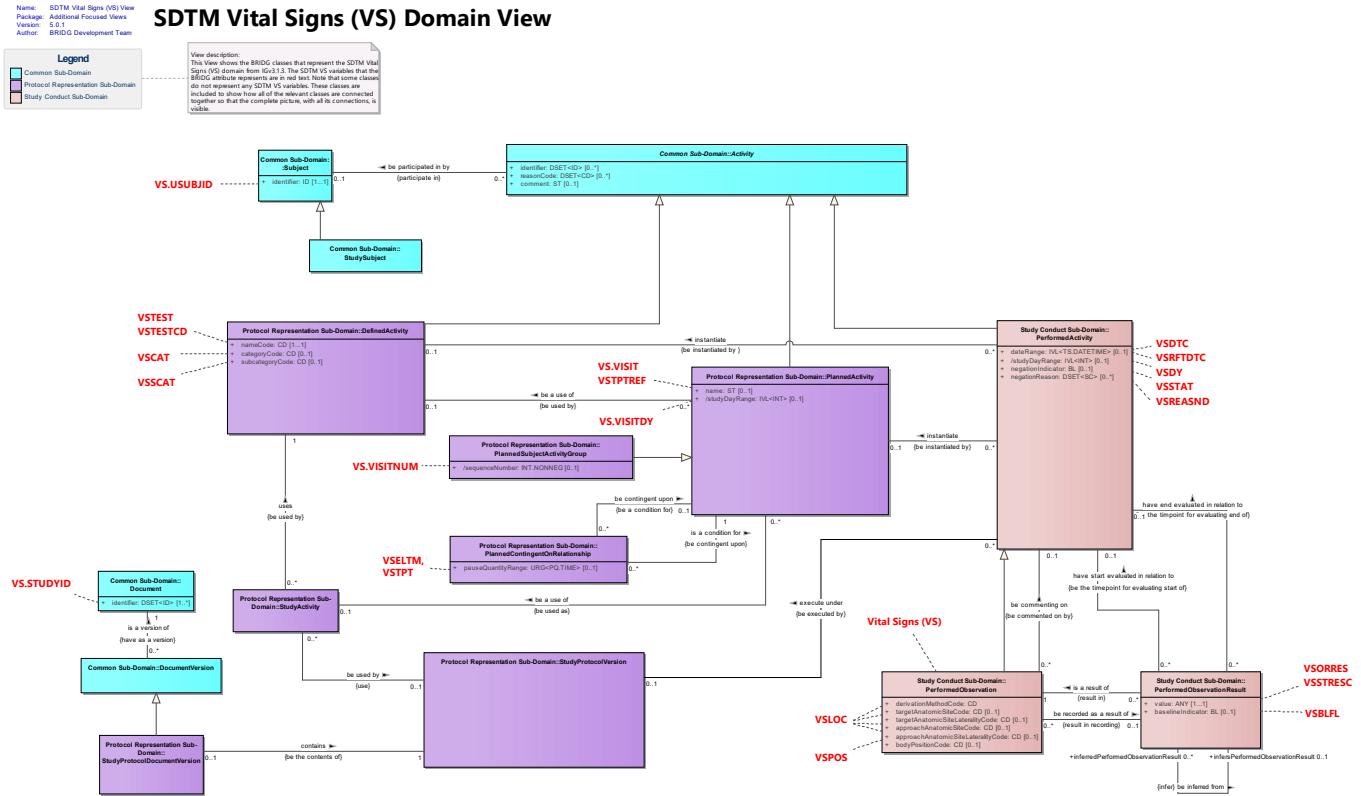
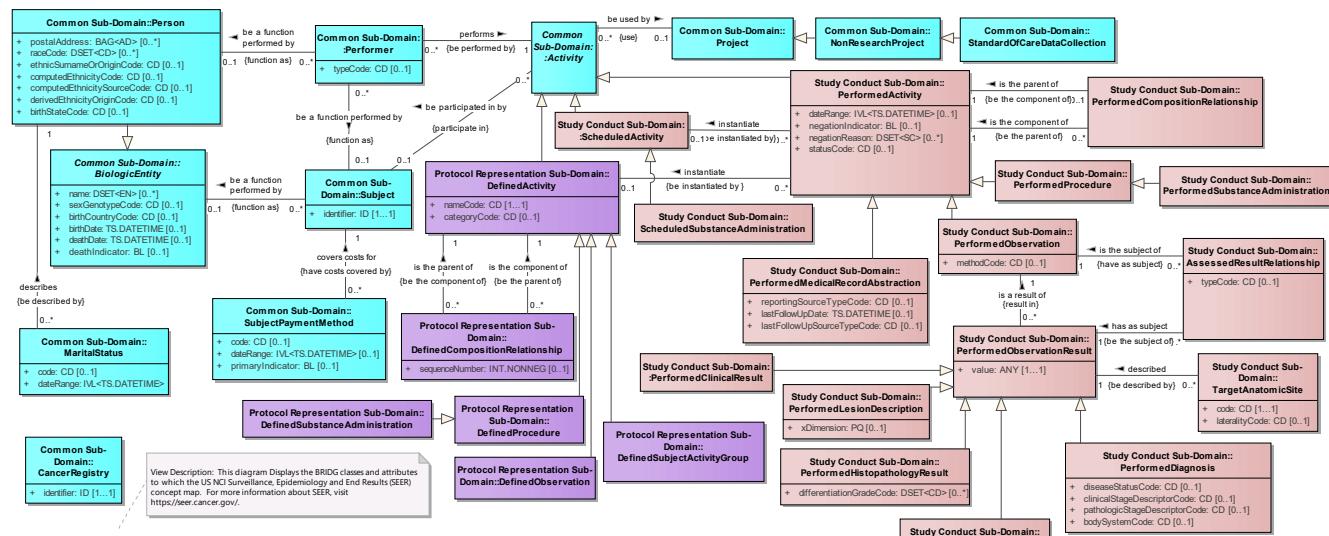


Figure 31: SDTM Vital Signs (VS) View

SEER View diagram

Class diagram in package 'Additional Focused Views'

SEER View



US NCI Surveillance, Epidemiology and End Results (SEER) Concepts in BRIDG 5.0Plus

Figure 32: SEER View

StudySite and StudySubject diagram

Class diagram in package 'Additional Focused Views'

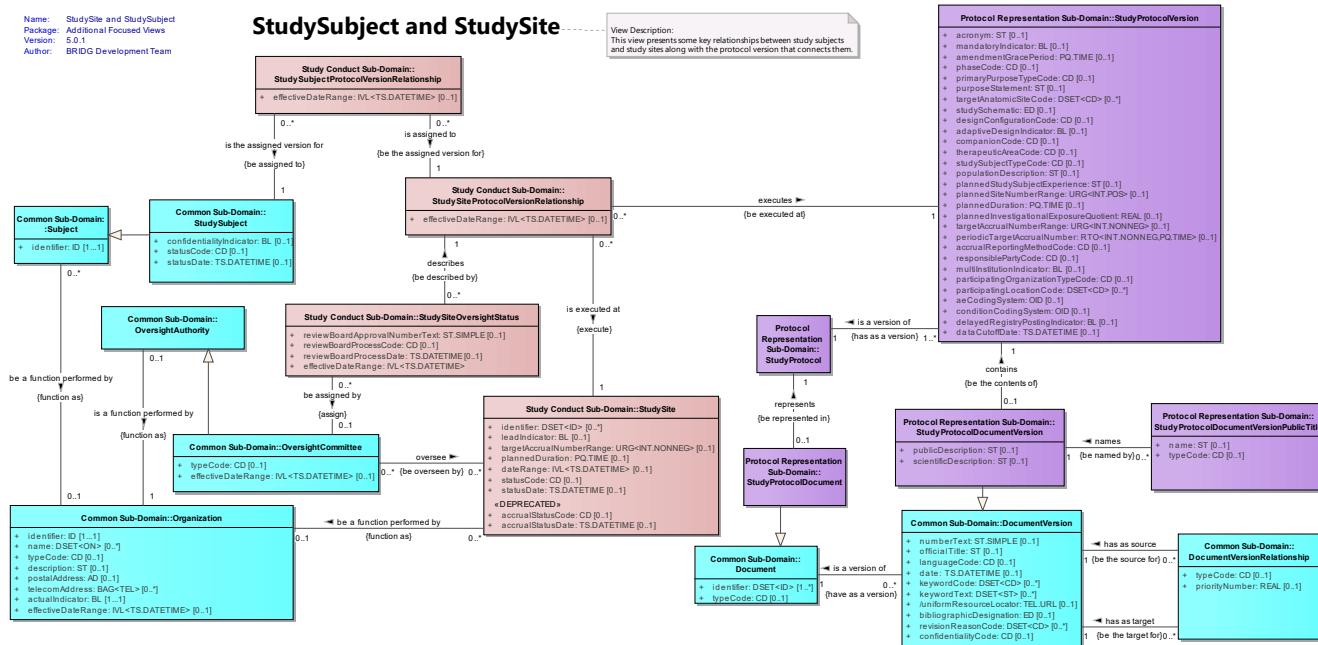


Figure 33: StudySite and StudySubject

Subject and ExperimentalUnit Comparison diagram

Class diagram in package 'Additional Focused Views'

Subject and ExperimentalUnit Comparison

Name: Subject and ExperimentalUnit Comparison
 Package: Additional Focused Views
 Version: 5.0.1
 Author: BRIDG Development Team

Subject and ExperimentalUnit Comparison

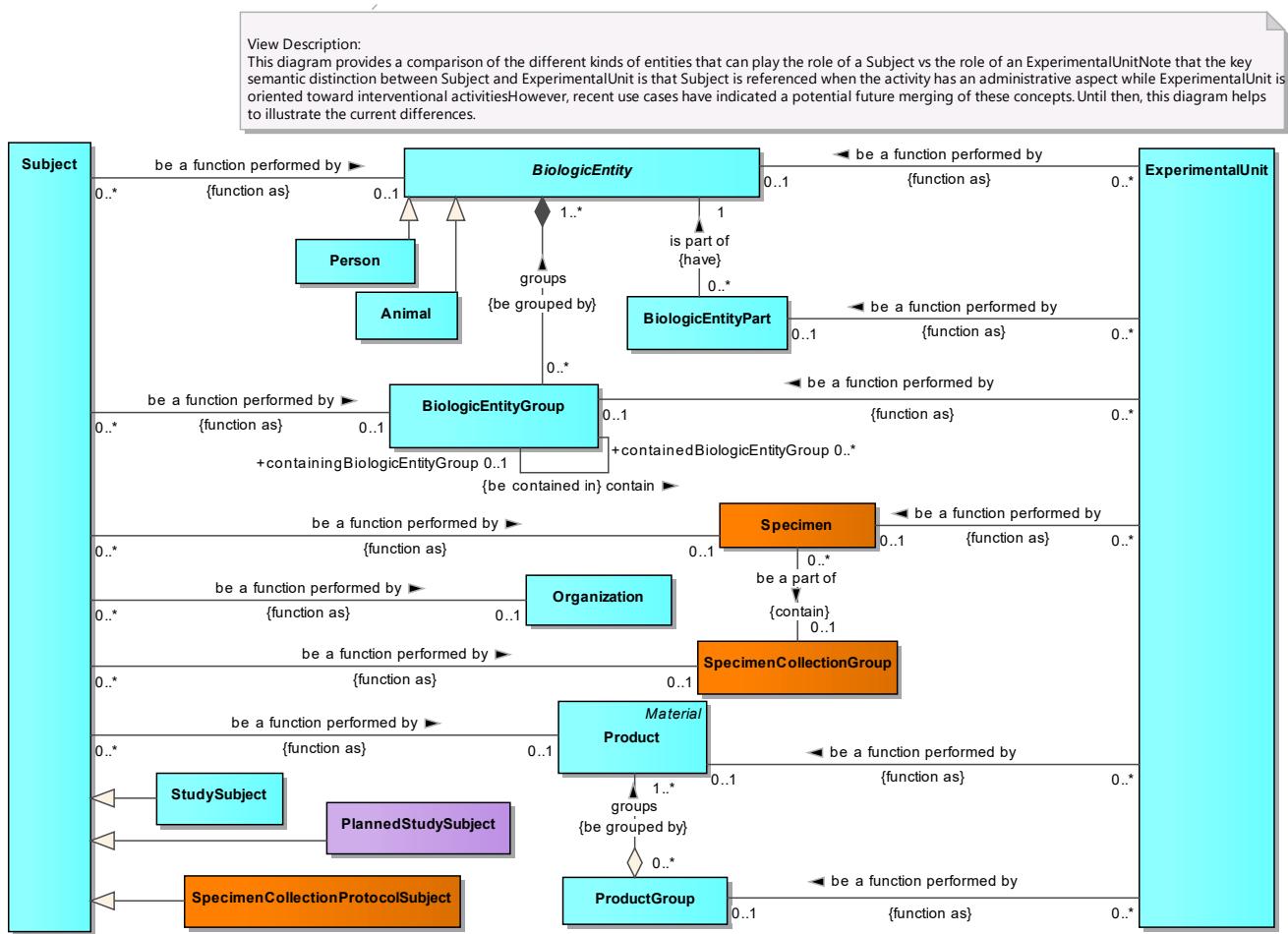


Figure 34: Subject and ExperimentalUnit Comparison