model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
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model diagram

Class diagram in package 'model'

model
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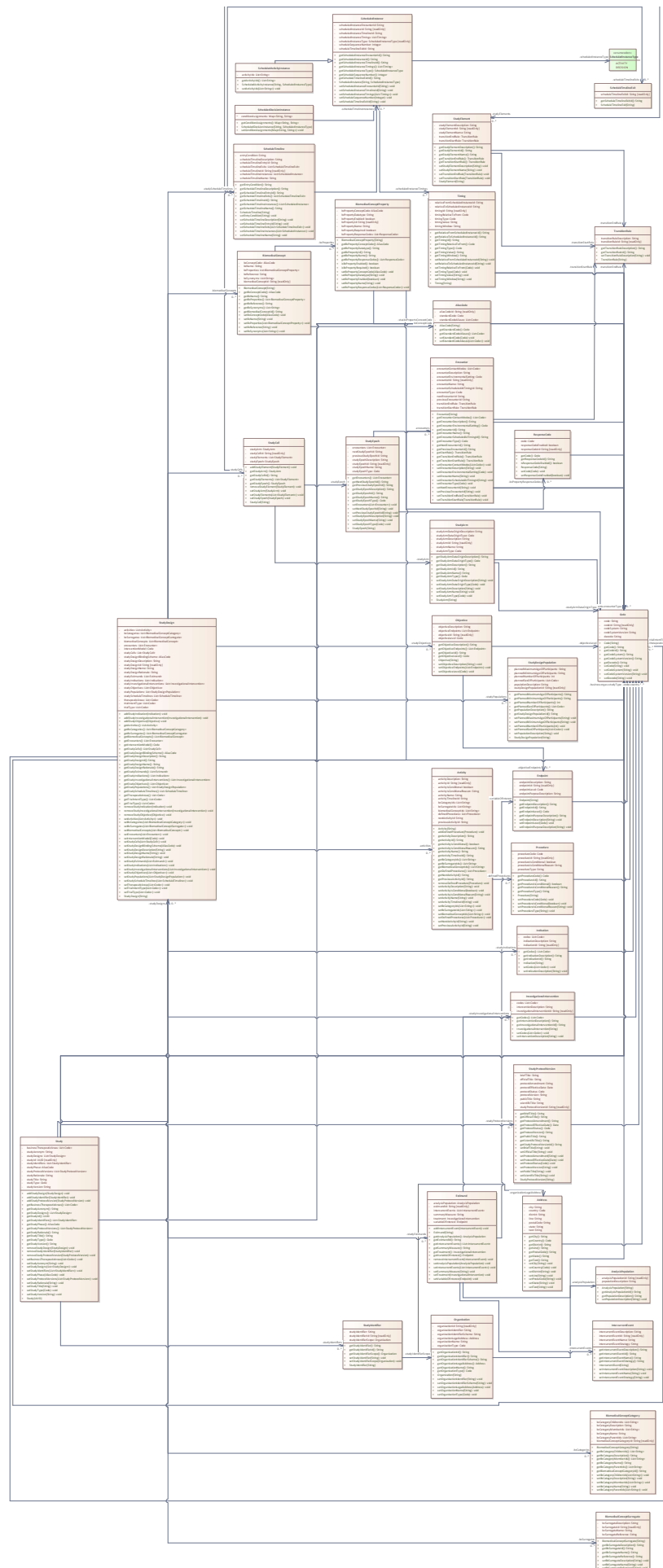
model

Package in package 'DDF'

Figure 1: model

Activity

Class in package 'model'

An action, undertaking, or event, which is anticipated to be performed or observed, or was performed or observed, according to the study protocol during the execution of the study.

Activity
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

activityDescription : String Private

The textual representation of the study activity.

[Is static True. Containment is Not Specified.]

activityId : String Private Const

[Is static True. Containment is Not Specified.]

activityIsConditional : boolean Private

[Is static True. Containment is Not Specified.]

activityIsConditionalReason : String Private

[Is static True. Containment is Not Specified.]

activityName : String Private

The literal identifier (i.e., distinctive designation) of the clinical study activity.

[Is static True. Containment is Not Specified.]

activityTimelineId : String Private

OK, I'm super-struggling with this one here. If we have instances of activities in a ScheduleTimeline that reference activities, then this means that we should have timelines with one Activity, and one ScheduledActvitiyInstance with the same definition that both point to ScheduleTimelines. We also may have an Activity that points to a ScheduleTimeline and a ScheduledActivityInstance that points to same Activity, but to a different ScheduleTimeline. This will likely happen...correct? At the surface it seems so. I'm thinking this won't work and that only ScheduledActivityInstances should ever point to a ScheduleTimeline. Also it's possible for an Activity to be the start of more than one ScheduleTimeline, correct? If so, then this can't be a scalar variable. Hence the association defined (1 to 0..*) between Activity objects and ScheduledActivityInstance objects.

[Is static True. Containment is Not Specified.]

bcCategoryIds : List<String> Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ bcSurrogateIds : List<String> Private

[Is static True. Containment is Not Specified.]

◆ biomedicalConceptIds : List<String> Private

[Is static True. Containment is Not Specified.]

◆ definedProcedures : List<Procedure> Private

[Is static True. Containment is Not Specified.]

◆ nextActivityId : String Private

A system identifier assigned to a study activity that occurs immediately after the current study activity.

[Is static True. Containment is Not Specified.]

◆ previousActivityId : String Private

A system identifier assigned to a study activity that occurs immediately prior to the current study activity.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private definedProcedures (Class) Procedure
    Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity
    Cardinality: [0..*]

OPERATIONS

◆ Activity (activityId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ addDefinedProcedure (procedure : Procedure) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getActivityDescription () : String Public

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getActivityId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getActivityIsConditional () : boolean Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getActivityIsConditionalReason () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getActivityName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getActivityTimelineId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getBcCategoryIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getBcSurrogateIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getBiomedicalConceptIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getDefinedProcedures () : List<Procedure> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getNextActivityId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getPreviousActivityId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 removeDefinedProcedure (procedure : Procedure) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setActivityDescription (description : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

setActivityIsConditional (activityIsConditional : boolean) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setActivityIsConditionalReason (activityIsConditionalReason : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setActivityName (activityName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setActivityTimelineId (activityTimelineId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setBcCategoryIds (bcCategoryIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setBcSurrogateIds (bcSurrogateIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setBiomedicalConceptIds (biomedicalConceptIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setDefinedProcedures (definedProcedures : List<Procedure>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setNextActivityId (nextActivityId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setPreviousActivityId (previousActivityId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Address

Class in package 'model'

Address
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

ATTRIBUTES

🔹 city : String Private

[Is static True. Containment is Not Specified.]

🔹 country : Code Private

[Is static True. Containment is Not Specified.]

🔹 district : String Private

[Is static True. Containment is Not Specified.]

🔹 line : String Private

[Is static True. Containment is Not Specified.]

🔹 postalCode : String Private

[Is static True. Containment is Not Specified.]

🔹 state : String Private

[Is static True. Containment is Not Specified.]

🔹 text : String Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Address   Target: Private country (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Organization   Target: Private organizationLegalAddress (Class) Address

OPERATIONS

🔶 getCity () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getCountry () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getDistrict () : String Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
getLine () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
getPostalCode () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
getState () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
getText () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setCity (city : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setCountry (country : Code) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setDistrict (district : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setLine (line : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setPostalCode (postalCode : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setState (state : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
setText (text : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

AliasCode

Class in package 'model'

An alternative symbol or combination of symbols which is assigned to the members of a collection.

AliasCode
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ATTRIBUTES

aliasCodeId : String Private Const

[Is static True. Containment is Not Specified.]

standardCode : Code Private

[Is static True. Containment is Not Specified.]

standardCodeAliases : List<Code> Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) AliasCode   Target: Private standardCode (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) AliasCode   Target: Private standardCodeAliases (Class) Code
                                                          Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyPhase (Class) AliasCode

Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept   Target: Private bcConceptCode (Class) AliasCode

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private studyDesignBlindingScheme
                                                          (Class) AliasCode

Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty   Target: Private bcPropertyConceptCode (Class)
                                                          AliasCode

OPERATIONS

🔷 AliasCode (aliasCodeId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getStandardCode () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getStandardCodeAliases () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setStandardCode (standardCode : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setStandardCodeAliases (standardCodeAliases : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

AnalysisPopulation

Class in package 'model'

A target study population on which an analysis is performed. These may be represented by the entire study population, a subgroup defined by a particular characteristic measured at baseline, or a principal stratum defined by the occurrence (or non-occurrence, depending on context) of a specific intercurrent event. (ICH E9 R1 Addendum)

AnalysisPopulation
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ATTRIBUTES

🔷 analysisPopulationId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 populationDescription : String Private

The textual representation of the study population for analysis.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private analysisPopulation (Class)
                                                                  AnalysisPopulation

OPERATIONS

AnalysisPopulation (analysisPopulationId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

getAnalysisPopulationId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

getPopulationDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setPopulationDescription (populationDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

BiomedicalConcept

Class in package 'model'

BiomedicalConcept
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

bcConceptCode : AliasCode Private

[Is static True. Containment is Not Specified.]

bcName : String Private

[Is static True. Containment is Not Specified.]

bcProperties : List<BiomedicalConceptProperty> Private

[Is static True. Containment is Not Specified.]

bcReference : String Private

[Is static True. Containment is Not Specified.]

bcSynonyms : List<String> Private

[Is static True. Containment is Not Specified.]

biomedicalConceptId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept   Target: Private bcConceptCode (Class) AliasCode

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✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept   Target: Private bcProperties (Class)
BiomedicalConceptProperty
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private biomedicalConcepts (Class)
BiomedicalConcept
Cardinality: [0..*]

OPERATIONS

◈ BiomedicalConcept (biomedicalConceptId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBcConceptCode () : AliasCode Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBcName () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBcProperties () : List<BiomedicalConceptProperty> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBcReference () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBcSynonyms () : List<String> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getBiomedicalConceptId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ setBcConceptCode (bcConceptCode : AliasCode) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

🔷 setBcName (bcName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setBcProperties (bcProperties : List<BiomedicalConceptProperty>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setBcReference (bcReference : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setBcSynonyms (bcSynonyms : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

BiomedicalConceptCategory

Class in package 'model'

BiomedicalConceptCategory
Version 1.0 Phase 1.0 Proposed
cupke created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

🔷 bcCategoryChildrenIds : List<String> Private

[Is static True. Containment is Not Specified.]

🔷 bcCategoryDescription : String Private

[Is static True. Containment is Not Specified.]

🔷 bcCategoryMemberIds : List<String> Private

[Is static True. Containment is Not Specified.]

🔷 bcCategoryName : String Private

[Is static True. Containment is Not Specified.]

🔷 bcCategoryParentIds : List<String> Private

[Is static True. Containment is Not Specified.]

🔷 biomedicalConceptCategoryId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private bcCategories (Class)
                                                      BiomedicalConceptCategory
                                                      Cardinality: [0..*]

OPERATIONS

◆ BiomedicalConceptCategory (bcCategoryId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategoryChildrenIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategoryDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategoryMemberIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategoryName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategoryParentIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBiomedicalConceptCategoryId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcCategoryChildrenIds (bcCategoryChildrenIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcCategoryDescription (bcCategoryDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcCategoryMemberIds (bcCategoryMemberIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcCategoryName (bcCategoryName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

🔷 setBcCategoryParentIds (bcCategoryParentIds : List<String>) : void Public

                      [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

BiomedicalConceptProperty

Class in package 'model'

BiomedicalConceptProperty
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔷 bcPropertyConceptCode : AliasCode Private

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyDatatype : String Private

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyEnabled : boolean Private

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyId : String Private Const

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyName : String Private

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyRequired : boolean Private

                      [Is static True. Containment is Not Specified.]

🔷 bcPropertyResponseCodes : List<ResponseCode> Private

                      [Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty | Target: Private bcPropertyResponseCodes (Class) ResponseCode
                                                     Cardinality: [0..*]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty | Target: Private bcPropertyConceptCode (Class) AliasCode

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✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept | Target: Private bcProperties (Class) BiomedicalConceptProperty
Cardinality: [0..*]

OPERATIONS

◆ BiomedicalConceptProperty (bcPropertyId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcPropertyConceptCode () : AliasCode Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcPropertyDatatype () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcPropertyId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcPropertyName () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcPropertyResponseCodes () : List<ResponseCode> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ isBcPropertyEnabled () : boolean Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ isBcPropertyRequired () : boolean Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcPropertyConceptCode (bcPropertyConceptCode : AliasCode) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcPropertyDatatype (bcPropertyDatatype : String) : void Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setBcPropertyEnabled (bcPropertyEnabled : boolean) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setBcPropertyName (bcPropertyName : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setBcPropertyResponseCodes (bcPropertyResponseCodes : List<ResponseCode>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

BiomedicalConceptSurrogate

Class in package 'model'

BiomedicalConceptSurrogate
Version 1.0 Phase 1.0 Proposed
cupke created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔹 bcSurrogateDescription : String Private [Is static True. Containment is Not Specified.]
🔹 bcSurrogateId : String Private Const [Is static True. Containment is Not Specified.]
🔹 bcSurrogateName : String Private [Is static True. Containment is Not Specified.]
🔹 bcSurrogateReference : String Private [Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private bcSurrogates (Class) BiomedicalConceptSurrogate
	Cardinality: [0..*]

OPERATIONS

OPERATIONS
🔶 BiomedicalConceptSurrogate (bcSurrogateId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getBcSurrogateDescription () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getBcSurrogateId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getBcSurrogateName () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getBcSurrogateReference () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setBcSurrogateDescription (bcSurrogateDescription : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setBcSurrogateName (bcSurrogateName : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setBcSurrogateReference (bcSurrogateReference : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Code

Class in package 'model'

A symbol or combination of symbols which is assigned to the members of a collection.

Code
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
🔷 code : String Private
The literal value of a code.
[Is static True. Containment is Not Specified.]
🔷 codeId : String Private Const

ATTRIBUTES

[Is static True. Containment is Not Specified.]

🔹 codeSystem : String Private

The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.

[Is static True. Containment is Not Specified.]

🔹 codeSystemVersion : String Private

The version of the code system.

[Is static True. Containment is Not Specified.]

🔹 decode : String Private

Standardized or dictionary-derived human readable text associated with a code.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Objective   Target: Private objectiveLevel (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private trialType (Class) Code
                                                     Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm   Target: Private studyArmType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter   Target: Private encounterContactModes (Class) Code
                                                     Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private businessTherapeuticAreas (Class) Code
                                                     Cardinality: [0..*]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

Target: Private codes (Class) Code
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionModel (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Timing

Target: Private timingType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Timing

Target: Private timingRelativeToFrom (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Address

Target: Private country (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Indication

Target: Private codes (Class) Code
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCode (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) ResponseCode

Target: Private code (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

✏ Association (direction: Source -> Destination)

ASSOCIATIONS	
Source: Public (Class) StudyDesign	Target: Private trialIntentType (Class) Code
	Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) Procedure	Target: Private procedureCode (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch	Target: Private studyEpochType (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) Encounter	Target: Private encounterEnvironmentalSetting (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) AliasCode	Target: Private standardCodeAliases (Class) Code
	Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) Organization	Target: Private organizationType (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) StudyArm	Target: Private studyArmDataOriginType (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private therapeuticAreas (Class) Code
	Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) Encounter	Target: Private encounterType (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesignPopulation	Target: Private plannedSexOfParticipants (Class) Code

ASSOCIATIONS

Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion   Target: Private protocolStatus (Class) Code

OPERATIONS

🔷 Code (codeId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getCode () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getCodeId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getCodeSystem () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getCodeSystemVersion () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getDecode () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setCode (code : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setCodeSystem (codeSystem : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setCodeSystemVersion (codeSystemVersion : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setDecode (decode : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Encounter

Class in package 'model'

Contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual.

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ATTRIBUTES

🔹 encounterContactModes : List<Code> Private

The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).

[Is static True. Containment is Not Specified.]

🔹 encounterDescription : String Private

The textual representation of the protocol-defined clinical encounter.

[Is static True. Containment is Not Specified.]

🔹 encounterEnvironmentalSetting : Code Private

The environment/setting where the event, intervention, or finding occurred.

[Is static True. Containment is Not Specified.]

🔹 encounterId : String Private Const

[Is static True. Containment is Not Specified.]

🔹 encounterName : String Private

The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.

[Is static True. Containment is Not Specified.]

🔹 encounterScheduledAtTimingId : String Private

Ok, so now that we have a better understanding of the ScheduleTimeline, we need to think about what encounters should point to. In this case I believe the only relevent information in a Timing object re: Encounters is the window data which is just a string (could be meaningless). When managing patient protocols, encounters begin with some type of event, not a constraint such as a Timing. Encounters are an umbrella concept for a series of events (px, rx, labs, etc..) that a patient encounters during a provider visit. In patient protocols they often involve diagnoses and claims of "conditions"...not to be confused with conditions associated with ScheduledDecisionInstances. Which makes me think that we might not want to overload the term "condition". Anyway, I won't change this to a collection until we've figured out why the pointer exists.

[Is static True. Containment is Not Specified.]

🔹 encounterType : Code Private

A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an

ATTRIBUTES

assessment or activity is performed.

[Is static True. Containment is Not Specified.]

◆ nextEncounterId : String Private

A system identifier assigned to a clinical encounter that occurs immediately after the current clinical encounter.

[Is static True. Containment is Not Specified.]

◆ previousEncounterId : String Private

A system identifier assigned to a clinical encounter that occurs immediately prior to the current clinical encounter.

[Is static True. Containment is Not Specified.]

◆ transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

◆ transitionStartRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

| Source: Public (Class) Encounter | Target: Private transitionEndRule (Class) TransitionRule |

✎ Association (direction: Source -> Destination)

| Source: Public (Class) Encounter | Target: Private encounterContactModes (Class) Code |
| | Cardinality: [0..*] |

✎ Association (direction: Source -> Destination)

| Source: Public (Class) Encounter | Target: Private transitionStartRule (Class) TransitionRule |

✎ Association (direction: Source -> Destination)

| Source: Public (Class) Encounter | Target: Private encounterEnvironmentalSetting (Class) Code |

✎ Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) Encounter	Target: Private encounterType (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private encounters (Class) Encounter
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch	Target: Private encounters (Class) Encounter
	Cardinality: [0..*]

OPERATIONS

◆ Encounter (encounterId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterContactModes () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterEnvironmentalSetting () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterScheduledAtTimingId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounterType () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getNextEncounterId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

◆ getPreviousEncounterId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStartRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getTransitionEndRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getTransitionStartRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterContactModes (encounterContactModes : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterDescription (encounterDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterEnvironmentalSetting (encounterEnvironmentalSetting : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterName (encounterName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterScheduledAtTimingId (encounterScheduledAtTimingId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setEncounterType (encounterType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setNextEncounterId (nextEncounterId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setPreviousEncounterId (previousEncounterId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setTransitionEndRule (transitionEndRule : TransitionRule) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setTransitionStartRule (transitionStartRule : TransitionRule) : void Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Endpoint

Class in package 'model'

A defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. NOTE: A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined. [After BEST Resource]

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Endpoint
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ATTRIBUTES
🔷 endpointDescription : String Private
The textual representation of the study endpoint.
[Is static True. Containment is Not Specified.]
🔷 endpointId : String Private Const
[Is static True. Containment is Not Specified.]
🔷 endpointLevel : Code Private
A characterization or classification of the study endpoint that determines its category of importance relative to other study endpoints.
[Is static True. Containment is Not Specified.]
🔷 endpointPurposeDescription : String Private
The textual representation of the study endpoint purpose.
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)
Source: Public (Class) Endpoint	Target: Private endpointLevel (Class) Code
✏️ Association (direction: Source -> Destination)
Source: Public (Class) Objective	Target: Private objectiveEndpoints (Class) Endpoint

ASSOCIATIONS	
	Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

OPERATIONS

🔷 Endpoint (endpointId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getEndpointDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getEndpointId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getEndpointLevel () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getEndpointPurposeDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setEndpointDescription (endpointDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setEndpointLevel (endpointLevel : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setEndpointPurposeDescription (endpointPurposeDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Estimand

Class in package 'model'

A precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective. It summarises at a population level what the outcomes would be in the same patients under different treatment conditions being compared. (ICH E9 R1 Addendum)

Estimand
Version 1.0 Phase 1.0 Proposed

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ATTRIBUTES

◆ analysisPopulation : AnalysisPopulation Private

[Is static True. Containment is Not Specified.]

◆ estimandId : String Private Const

[Is static True. Containment is Not Specified.]

◆ intercurrentEvents : List<IntercurrentEvent> Private

[Is static True. Containment is Not Specified.]

◆ summaryMeasure : String Private

A synopsis of the clinical endpoint of interest within the analysis target study population.

[Is static True. Containment is Not Specified.]

◆ treatment : InvestigationalIntervention Private

[Is static True. Containment is Not Specified.]

◆ variableOfInterest : Endpoint Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private intercurrentEvents (Class) IntercurrentEvent
                                                         Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private variableOfInterest (Class) Endpoint

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private analysisPopulation (Class) AnalysisPopulation

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private treatment (Class) InvestigationalIntervention

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private studyEstimands (Class) Estimand
                                                                        Cardinality: [0..*]

OPERATIONS

◈ addIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ Estimand (estimandId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getAnalysisPopulation () : AnalysisPopulation Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getEstimandId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getIntercurrentEvents () : List<IntercurrentEvent> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getSummaryMeasure () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getTreatment () : InvestigationalIntervention Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ getVariableOfInterest () : Endpoint Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ setAnalysisPopulation (analysisPopulation : AnalysisPopulation) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◈ setIntercurrentEvents (intercurrentEvents : List<IntercurrentEvent>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

🔶 setSummaryMeasure (summaryMeasure : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setTreatment (treatment : InvestigationalIntervention) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setVariableOfInterest (variableOfInterest : Endpoint) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Indication

Class in package 'model'

The condition, disease or disorder that the clinical trial is intended to investigate or address.

Indication
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Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

🔷 codes : List<Code> Private

A short sequence of characters that represents the disease indication.

[Is static True. Containment is Not Specified.]

🔷 indicationDescription : String Private

The condition, disease or disorder that the clinical trial is intended to investigate or address.

[Is static True. Containment is Not Specified.]

🔷 indicationId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Indication   Target: Private codes (Class) Code
                                                                                  Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private studyIndications (Class) Indication

ASSOCIATIONS
Cardinality: [0..*]

OPERATIONS

🔶 getCodes () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getIndicationDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getIndicationId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 Indication (indicationId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setCodes (codes : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setIndicationDescription (indicationDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

IntercurrentEvent

Class in package 'model'

An event(s) occurring after treatment initiation that affects either the interpretation or the existence of the measurements associated with the clinical question of interest. (ICH E9 Addendum on Estimands)

IntercurrentEvent
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ATTRIBUTES

🔷 intercurrentEventDescription : String Private

The textual representation of the intercurrent event.

[Is static True. Containment is Not Specified.]

🔷 intercurrentEventId : String Private Const

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ intercurrentEventName : String Private

The literal identifier (i.e., distinctive designation) of the intercurrent event.

[Is static True. Containment is Not Specified.]

◆ intercurrentEventStrategy : String Private

A textual description of the planned strategy to manage and/or mitigate intercurrent events.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private intercurrentEvents (Class) IntercurrentEvent
Cardinality: [0..*]

OPERATIONS

◆ getIntercurrentEventDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getIntercurrentEventId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getIntercurrentEventName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getIntercurrentEventStrategy () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ IntercurrentEvent (intercurrentEventId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setIntercurrentEventDescription (intercurrentEventDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setIntercurrentEventName (intercurrentEventName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setIntercurrentEventStrategy (intercurrentEventStrategy : String) : void Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

InvestigationalIntervention

Class in package 'model'

The drug, device, therapy, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study. [After https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm#5224] (CDISC-Glossary)

InvestigationalIntervention
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔹 codes : List<Code> Private
A short sequence of characters that represents the investigational intervention.
[Is static True. Containment is Not Specified.]
🔹 interventionDescription : String Private
The textual representation of the study intervention.
[Is static True. Containment is Not Specified.]
🔹 investigationalInterventionId : String Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)
Source: Public (Class) InvestigationalIntervention   Target: Private codes (Class) Code
Cardinality: [0..*]
✏️ Association (direction: Source -> Destination)
Source: Public (Class) StudyDesign   Target: Private studyInvestigationalInterventions (Class) InvestigationalIntervention
Cardinality: [0..*]
✏️ Association (direction: Source -> Destination)
Source: Public (Class) Estimand   Target: Private treatment (Class) InvestigationalIntervention

ASSOCIATIONS

OPERATIONS

🔷 getCodes () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getInterventionDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getInvestigationalInterventionId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 InvestigationalIntervention (investigationalInterventionId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setCodes (codes : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setInterventionDescription (interventionDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Objective

Class in package 'model'

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

Objective
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ATTRIBUTES

🔷 objectiveDescription : String Private

The textual representation of the study objective. (BRIDG)

[Is static True. Containment is Not Specified.]

🔷 objectiveEndpoints : List<Endpoint> Private

[Is static True. Containment is Not Specified.]

🔷 objectiveId : String Private Const

ATTRIBUTES

[Is static True. Containment is Not Specified.]

🔷 objectiveLevel : Code Private

A characterization or classification of the study endpoint that determines its category of importance relative to other study objectives.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Objective	Target: Private objectiveLevel (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Objective	Target: Private objectiveEndpoints (Class) Endpoint
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private studyObjectives (Class) Objective
	Cardinality: [0..*]

OPERATIONS

🔶 getObjectiveDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getObjectiveEndpoints () : List<Endpoint> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getObjectiveId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getObjectiveLevel () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 Objective (objectiveId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
◆ setObjectiveDescription (objectiveDescription : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setObjectiveEndpoints (objectiveEndpoints : List<Endpoint>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setObjectiveLevel (objectiveLevel : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Organization

Class in package 'model'

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. (BRIDG)

Organization
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ATTRIBUTES
◆ organizationId : String Private Const
[Is static True. Containment is Not Specified.]
◆ organizationIdentifier : String Private
A unique symbol that establishes identity of the organization. (BRIDG)
[Is static True. Containment is Not Specified.]
◆ organizationIdentifierScheme : String Private
The name of the organization that provides the identifier for the entity.
[Is static True. Containment is Not Specified.]
◆ organizationLegalAddress : Address Private
[Is static True. Containment is Not Specified.]
◆ organizationName : String Private
A non-unique textual identifier for the organization. (BRIDG)
[Is static True. Containment is Not Specified.]
◆ organizationType : Code Private

ATTRIBUTES

A characterization or classification of the 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.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationLegalAddress (Class) Address

✏ Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier

Target: Private studyIdentifierScope (Class) Organization

OPERATIONS

◆ getOrganizationId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getOrganizationIdentifier () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getOrganizationIdentifierScheme () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getOrganizationLegalAddress () : Address Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getOrganizationName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getOrganizationType () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ Organization (organizationId : String) : Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOrganizationIdentifier (organizationIdentifier : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOrganizationLegalAddress (organizationLegalAddress : Address) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOrganizationName (organizationName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOrganizationType (organizationType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Procedure

Class in package 'model'

Any activity performed by manual and/or instrumental means for the purpose of diagnosis, assessment, therapy, prevention, or palliative care.

Procedure
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ATTRIBUTES

🔷 procedureCode : Code Private

A symbol or combination of symbols which is assigned to medical procedure.

[Is static True. Containment is Not Specified.]

🔷 procedureId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 procedureIsConditional : boolean Private

[Is static True. Containment is Not Specified.]

🔷 procedureIsConditionalReason : String Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ procedureType : String Private

A characterization or classification of the study procedure.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Procedure   Target: Private procedureCode (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Activity   Target: Private definedProcedures (Class) Procedure

Cardinality: [0..*]

OPERATIONS

◆ getProcedureCode () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getProcedureId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getProcedureIsConditional () : boolean Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getProcedureIsConditionalReason () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getProcedureType () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ Procedure (procedureId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setProcedureCode (procedureCode : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
🔶 setProcedureIsConditional (procedureIsConditional : boolean) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setProcedureIsConditionalReason (procedureIsConditionalReason : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setProcedureType (procedureType : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ResponseCode

Class in package 'model'

ResponseCode
Version 1.0 Phase 1.0 Proposed
cupke created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔷 code : Code Private
[Is static True. Containment is Not Specified.]
🔷 responseCodeEnabled : boolean Private
[Is static True. Containment is Not Specified.]
🔷 responseCodeId : String Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)
Source: Public (Class) ResponseCode   Target: Private code (Class) Code
✏️ Association (direction: Source -> Destination)
Source: Public (Class) BiomedicalConceptProperty   Target: Private bcPropertyResponseCodes (Class) ResponseCode
Cardinality: [0..*]

OPERATIONS
🔶 getCode () : Code Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getResponseCodeId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 isResponseCodeEnabled () : boolean Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 ResponseCode (responseCodeId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setCode (code : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setResponseCodeEnabled (responseCodeEnabled : boolean) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduledActivityInstance

Class in package 'model'

The ScheduledActivityInstance class is used to extend the ScheduledInstance class with activity-specific information and behaviors needed for the ScheduleTimeline.

ScheduledActivityInstance
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

OUTGOING STRUCTURAL RELATIONSHIPS

⬅ Generalization from ScheduledActivityInstance to ScheduledInstance

[Direction is 'Source -> Destination'.]

ATTRIBUTES

🔷 activityIds : List<String> Private

This is the list of ID references to Activity definitions. There can be 1 or many. This allows for a simpler mechanism for associating non-sequential tasks that have similar constraints to other sequential tasks to be added to the timeline.

[Is static True. Containment is Not Specified.]

OPERATIONS

OPERATIONS

🔶 getActivityIds () : List<String> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 ScheduledActivityInstance (scheduledInstanceId : String , scheduledInstanceType : ScheduledInstanceType) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setActivityIds (activityIds : List<String>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduledDecisionInstance

Class in package 'model'

The ScheduledDecisionInstance class is used to extend the ScheduledInstance class with decision-specific information and behaviors needed for the ScheduleTimeline. Different from other ScheduledInstance extensions, this class will be used for flow-control logic such as branching and looping (cycling).

ScheduledDecisionInstance
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

OUTGOING STRUCTURAL RELATIONSHIPS

⬅ Generalization from ScheduledDecisionInstance to ScheduledInstance

[Direction is 'Source -> Destination'.]

ATTRIBUTES

🔷 conditionAssignments : Map<String, String> Package

This field maps conditions to their associated scheduled instances For example, if you had a generic condition temperature over 99, there may be 2 conditions in the map: {"greater than 99": "123", "less than or equal to 99": "678"} Always state in terms with conditions that are always true The mapping is valid if the condition is true

[Is static True. Containment is Not Specified.]

OPERATIONS

🔶 getConditionAssignments () : Map<String, String> Public

OR conditionAndScheduledInstanceIdAssignments

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 ScheduledDecisionInstance (scheduledInstanceId : String , scheduledInstanceType : ScheduledInstanceType) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
◆ setConditionAssignments (conditionAssignments : Map<String, String>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduledInstance

Class in package 'model'

The ScheduledInstance abstract class is used by ScheduleTimelines to build a sequence of activities and decisions that will define a schedule.

ScheduledInstance
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

INCOMING STRUCTURAL RELATIONSHIPS
➡ Generalization from ScheduledActivityInstance to ScheduledInstance
[Direction is 'Source -> Destination'.]
➡ Generalization from ScheduledDecisionInstance to ScheduledInstance
[Direction is 'Source -> Destination'.]

ATTRIBUTES
◆ scheduledInstanceEncounterId : String Private
I get this now. You do want to know if the instance is part of an encounter. This field points to the encounter that the activity is taking part of.
[Is static True. Containment is Not Specified.]
◆ scheduledInstanceId : String Private Const
[Is static True. Containment is Not Specified.]
◆ scheduledInstanceTimelineId : String Private
This field will have a value if the scheduled instance points to a different timeline
[Is static True. Containment is Not Specified.]
◆ scheduledInstanceTimings : List<Timing> Private
Ok, I'll add this, but it isn't very useful. You're better off starting at a ScheduleTimeline. In this case, you could have an instance pointing to a large number of Timing objects because it has a large number of scheduling constraints. I like the idea of activites not having any Timing references; just decisions because they are selective. If we must, we may want to consider changing this to be directionaly at least...incoming and outgoing?
[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔹 scheduledInstanceType : ScheduledInstanceType Private Const

Possible Values: ACTIVITY, DECISION

[Is static True. Containment is Not Specified.]

🔹 scheduleSequenceNumber : Integer Private

There has been an ask for sequencing of ScheduledInstance in a ScheduleTimeline. In order to do this, the entire ScheduleTimeline must be constructed with all of the necessary ScheduledInstance, Timing and Exit objects. Once this is complete, a some sequencing process can then annotate the ScheduleTimeline's collection of ScheduleInstance objects and update this field. This is a hard field to name, btw. Is scheduleTimelineScheduledInstanceSequenceNumber manageable?

[Is static True. Containment is Not Specified.]

🔹 scheduleTimelineExitId : String Private

In the last version of the model, there was a pointer to an Exit object in the previous version of this class. I'm struggling with this, as the exit is the property of a ScheduleTimeline already. I can understand why we need an entry pointer but not an exit. Is this just a wqy of identifying a final ScheduledInstance in some ScheduleTimeline? Isn't that still the perspective of the timeline? Just trying to name it really shows that I'm trying to point to something that's really something my parent cares about.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduledInstance

Target: Private scheduledInstanceType (Enumeration) ScheduledInstanceType

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduledInstance

Target: Private scheduledInstanceTimings (Class) Timing
Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline

Target: Private scheduleTimelineInstances (Class) ScheduledInstance
Cardinality: [0..*]

OPERATIONS

🔷 getScheduledInstanceEncounterId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

⬦ getScheduledInstanceid () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ getScheduledInstanceTimelineId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ getScheduledInstanceTimings () : List<Timing> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ getScheduledInstanceType () : ScheduledInstanceType Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ getScheduleSequenceNumber () : Integer Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ getScheduleTimelineExitId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ ScheduledInstance (scheduledInstanceId : String , scheduledInstanceType : ScheduledInstanceType) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ setScheduledInstanceEncounterId (scheduledInstanceEncounterId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ setScheduledInstanceTimelineId (scheduledInstanceTimelineId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ setScheduledInstanceTimings (scheduledInstanceTimings : List<Timing>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ setScheduleSequenceNumber (scheduleSequenceNumber : Integer) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬦ setScheduleTimelineExitId (scheduleTimelineExitId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduleTimeline

Class in package 'model'

regarding TimeLine Entry as a new class name. I feel that TimelineEtry is confusing. If there is a timeline entry, then there must be a timeline. Yet, in the diagram, the two concepts are conflated into the TimelineEntry. I suggest keeping ScheduleTimeline and adding entry attribution as a simple condition field.

<div align="right">

ScheduleTimeline

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</div>

ATTRIBUTES

◆ entryCondition : String Private

Here we again place information at two levels: The ScheduledDecisionInstance and The ScheduleTimeline. If the timeline owns all of the instances then it already has a way to get to a condition on a decision. We should ponder this further.

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineDescription : String Private

A textual description of the timeline. There will likely be numerous timelines in a study and this field provides the context for the particular timeline.

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineEntryId : String Private

If the timeline was due to a condition that was met for traversal from a previous timpoint, then we should have a handle to that timepoint.

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineExits : List<ScheduleTimelineExit> Private

This field represents the Exit object associated with the ScheduleTimeline.

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineId : String Private Const

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineInstances : List<ScheduledInstance> Private

At this point, this is an unordered list of instances. We might consider more encapsulation by creating a timepointSequence wrapper.

[Is static True. Containment is Not Specified.]

◆ scheduleTimelineName : String Private

This is field provides a name for the timeline

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline

Target: Private scheduleTimelineExits (Class)
ScheduleTimelineExit
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline

Target: Private scheduleTimelineInstances (Class)
ScheduledInstance
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyScheduleTimelines (Class)
ScheduleTimeline
Cardinality: [0..*]

OPERATIONS

◆ getEntryCondition () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineEntryId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineExits () : List<ScheduleTimelineExit> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineInstances () : List<ScheduledInstance> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getScheduleTimelineName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ ScheduleTimeline (scheduleTimelineId : String) : Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setEntryCondition (entryCondition : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setScheduleTimelineDescription (scheduleTimelineDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setScheduleTimelineEntryId (scheduleTimelineEntryId : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setScheduleTimelineExits (scheduleTimelineScheduleTimelineExits : List<ScheduleTimelineExit>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setScheduleTimelineInstances (scheduleTimelineInstances : List<ScheduledInstance>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setScheduleTimelineName (scheduleTimelineName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduleTimelineExit

Class in package 'model'

Is just Exit intuitive enough in the model as a concept. Does it exist outside of a ScheduleTimeline? If not, then it's maybe a ScheduleTimelineExit or a TimelineExit?

ScheduleTimelineExit
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ATTRIBUTES

🔷 scheduleTimelineExitId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline   Target: Private scheduleTimelineExits (Class) ScheduleTimelineExit

Cardinality: [0..*]

OPERATIONS
◆ getScheduleTimelineExitId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ ScheduleTimelineExit (exitId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Study

Class in package 'model'

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [[http://ClinicalTrials.gov]](CDISC Glossary)

Study
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Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
◆ businessTherapeuticAreas : List<Code> Private
A therapeutic area classification based on the structure and operations of the business unit.
[Is static True. Containment is Not Specified.]
◆ studyAcronym : String Private
[Is static True. Containment is Not Specified.]
◆ studyDesigns : List<StudyDesign> Private
[Is static True. Containment is Not Specified.]
◆ studyId : UUID Private Const
[Is static True. Containment is Not Specified.]
◆ studyIdentifiers : List<StudyIdentifier> Private
[Is static True. Containment is Not Specified.]
◆ studyPhase : AliasCode Private
A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]

ATTRIBUTES
	[Is static True. Containment is Not Specified.]

🔷 studyProtocolVersions : List<StudyProtocolVersion> Private

[Is static True. Containment is Not Specified.]

🔷 studyRationale : String Private

[Is static True. Containment is Not Specified.]

🔷 studyTitle : String Private

The sponsor-defined name of the clinical study.

[Is static True. Containment is Not Specified.]

🔷 studyType : Code Private

The nature of the investigation for which study information is being collected. (AfterÂ clinicaltrials.gov)

[Is static True. Containment is Not Specified.]

🔷 studyVersion : String Private

A plan at a particular point in time for a study.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyPhase (Class) AliasCode

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyIdentifiers (Class)
                                                       StudyIdentifier
                                                            Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private businessTherapeuticAreas (Class)
                                                       Code
                                                            Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyType (Class) Code

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Study	Target: Private studyProtocolVersions (Class) StudyProtocolVersion
	Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) Study	Target: Private studyDesigns (Class) StudyDesign
	Cardinality: [0..*]

OPERATIONS

◆ addStudyDesign (studyDesign : StudyDesign) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ addStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBusinessTherapeuticAreas () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyAcronym () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesigns () : List<StudyDesign> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyId () : UUID Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyIdentifiers () : List<StudyIdentifier> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyPhase () : AliasCode Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

◆ getStudyProtocolVersions () : List<StudyProtocolVersion> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyRationale () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyTitle () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyType () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyVersion () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyDesign (studyDesign : StudyDesign) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyAcronym (studyAcronym : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyDesigns (studyDesigns : List<StudyDesign>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyIdentifiers (studyIdentifiers : List<StudyIdentifier>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyPhase (studyPhase : AliasCode) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyProtocolVersions (studyProtocolVersions : List<StudyProtocolVersion>) : void Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setStudyRationale (studyRationale : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setStudyTitle (studyTitle : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setStudyType (studyType : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setStudyVersion (studyVersion : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 Study (studyId : UUID) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyArm

Class in package 'model'

A planned pathway assigned to the subject as they progress through the study, usually referred to by a name that reflects one or more treatments, exposures, and/or controls included in the path.

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ATTRIBUTES
🔷 studyArmDataOriginDescription : String Private
The textual representation of the study arm data origin.
[Is static True. Containment is Not Specified.]
🔷 studyArmDataOriginType : Code Private
A characterization or classification of the study arm with respect to where the study arm data originates.
[Is static True. Containment is Not Specified.]
🔷 studyArmDescription : String Private
The textual representation of the study arm.
[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 studyArmId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 studyArmName : String Private

The literal identifier (i.e., distinctive designation) of the study arm.

[Is static True. Containment is Not Specified.]

🔷 studyArmType : Code Private

The literal identifier (i.e., distinctive designation) of the study arm type.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm   Target: Private studyArmType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm   Target: Private studyArmDataOriginType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private studyArm (Class) StudyArm

OPERATIONS

🔶 getStudyArmDataOriginDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getStudyArmDataOriginType () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getStudyArmDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getStudyArmId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

⬢ getStudyArmName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ getStudyArmType () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setStudyArmDataOriginDescription (studyArmDataOriginDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setStudyArmDataOriginType (studyArmDataOriginType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setStudyArmDescription (studyArmDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setStudyArmName (studyArmName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setStudyArmType (studyArmType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ StudyArm (studyArmId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyCell

Class in package 'model'

A partitioning of a study arm into individual pieces, which are associated with an epoch and any number of sequential elements within that epoch.

StudyCell
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

🔷 studyArm : StudyArm Private

[Is static True. Containment is Not Specified.]

🔷 studyCellId : String Private Const

ATTRIBUTES

[Is static True. Containment is Not Specified.]

◆ studyElements : List<StudyElement> Private

[Is static True. Containment is Not Specified.]

◆ studyEpoch : StudyEpoch Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyElements (Class) StudyElement
     Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyArm (Class) StudyArm

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyEpoch (Class) StudyEpoch

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyCells (Class) StudyCell
     Cardinality: [0..*]

OPERATIONS

◆ addStudyElement (studyElement : StudyElement) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyArm () : StudyArm Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyCellId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyElements () : List<StudyElement> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
◆ getStudyEpoch () : StudyEpoch Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ removeStudyElement (studyElement : StudyElement) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setStudyArm (studyArm : StudyArm) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setStudyElements (studyElements : List<StudyElement>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setStudyEpoch (studyEpoch : StudyEpoch) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ StudyCell (studyCellId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyDesign

Class in package 'model'

A plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach.

StudyDesign
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
◆ activities : List<Activity> Private
[Is static True. Containment is Not Specified.]
◆ bcCategories : List<BiomedicalConceptCategory> Private
[Is static True. Containment is Not Specified.]
◆ bcSurrogates : List<BiomedicalConceptSurrogate> Private
[Is static True. Containment is Not Specified.]
◆ biomedicalConcepts : List<BiomedicalConcept> Private

ATTRIBUTES

[Is static True. Containment is Not Specified.]

🔹 encounters : List<Encounter> Private

[Is static True. Containment is Not Specified.]

🔹 interventionModel : Code Private

The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov)

[Is static True. Containment is Not Specified.]

🔹 studyCells : List<StudyCell> Private

[Is static True. Containment is Not Specified.]

🔹 studyDesignBlindingScheme : AliasCode Private

[Is static True. Containment is Not Specified.]

🔹 studyDesignDescription : String Private

The textual representation of the study design.

[Is static True. Containment is Not Specified.]

🔹 studyDesignId : String Private Const

[Is static True. Containment is Not Specified.]

🔹 studyDesignName : String Private

The literal identifier (i.e., distinctive designation) of the study design.

[Is static True. Containment is Not Specified.]

🔹 studyDesignRationale : String Private

[Is static True. Containment is Not Specified.]

🔹 studyEstimands : List<Estimand> Private

[Is static True. Containment is Not Specified.]

🔹 studyIndications : List<Indication> Private

[Is static True. Containment is Not Specified.]

🔹 studyInvestigationalInterventions : List<InvestigationalIntervention> Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔹 studyObjectives : List<Objective> Private

[Is static True. Containment is Not Specified.]

🔹 studyPopulations : List<StudyDesignPopulation> Private

[Is static True. Containment is Not Specified.]

🔹 studyScheduleTimelines : List<ScheduleTimeline> Private

This field provides a collection of all of the ScheduleTimeline objects associated with the StudyDesign.

[Is static True. Containment is Not Specified.]

🔹 therapeuticAreas : List<Code> Private

A categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention.

[Is static True. Containment is Not Specified.]

🔹 trialIntentType : List<Code> Private

The planned purpose of the therapy, device, or agent under study in the clinical trial.

[Is static True. Containment is Not Specified.]

🔹 trialType : List<Code> Private

The nature of the interventional study for which information is being collected.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private biomedicalConcepts (Class) BiomedicalConcept
Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private studyPopulations (Class) StudyDesignPopulation
Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private trialType (Class) Code

ASSOCIATIONS
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyCells (Class) StudyCell
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyDesignBlindingScheme (Class) AliasCode

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyEstimands (Class) Estimand
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionModel (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyScheduleTimelines (Class) ScheduleTimeline
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyObjectives (Class) Objective
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private bcCategories (Class) BiomedicalConceptCategory
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyIndications (Class) Indication
Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) StudyDesign	Target: Private trialIntentType (Class) Code
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private bcSurrogates (Class) BiomedicalConceptSurrogate
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private encounters (Class) Encounter
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private therapeuticAreas (Class) Code
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private activities (Class) Activity
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private studyInvestigationalInterventions (Class) InvestigationalIntervention
	Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study	Target: Private studyDesigns (Class) StudyDesign
	Cardinality: [0..*]

OPERATIONS

🔷 addStudyIndication (indication : Indication) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

◆ addStudyObjective (objective : Objective) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getActivities () : List<Activity> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcCategories () : List<BiomedicalConceptCategory> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBcSurrogates () : List<BiomedicalConceptSurrogate> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getBiomedicalConcepts () : List<BiomedicalConcept> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getEncounters () : List<Encounter> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getInterventionModel () : Code Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyCells () : List<StudyCell> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignBlindingScheme () : AliasCode Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignDescription () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignName () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignRationale () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyEstimands () : List<Estimand> Public

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyIndications () : List<Indication> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyObjectives () : List<Objective> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyPopulations () : List<StudyDesignPopulation> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyScheduleTimelines () : List<ScheduleTimeline> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getTherapeuticAreas () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getTrialIntentType () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getTrialType () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyIndication (indication : Indication) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyObjective (objective : Objective) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setActivities (activities : List<Activity>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBcCategories (bcCategories : List<BiomedicalConceptCategory>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

setBcSurrogates (bcSurrogates : List<BiomedicalConceptSurrogate>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setBiomedicalConcepts (biomedicalConcepts : List<BiomedicalConcept>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setEncounters (encounters : List<Encounter>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setInterventionModel (interventionModel : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyCells (studyCells : List<StudyCell>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyDesignBlindingScheme (studyDesignBlindingScheme : AliasCode) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyDesignDescription (studyDesignDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyDesignName (studyDesignName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyDesignRationale (studyDesignRationale : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyEstimands (studyEstimands : List<Estimand>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyIndications (studyIndications : List<Indication>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyInvestigationalInterventions (studyInvestigationalInterventions : List<InvestigationalIntervention>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setStudyObjectives (studyObjectives : List<Objective>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

◆ setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setStudyScheduleTimelines (studyScheduleTimelines : List<ScheduleTimeline>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setTherapeuticAreas (therapeuticAreas : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setTrialIntentType (trialIntentType : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setTrialType (trialType : List<Code>) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ StudyDesign (studyDesignId : String) : Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyDesignPopulation

Class in package 'model'

The population within the general population to which the study results can be generalized.

StudyDesignPopulation
Version 1.0 Phase 1.0 Proposed
cupke created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

◆ plannedMaximumAgeOfParticipants : String Private

[Is static True. Containment is Not Specified.]

◆ plannedMinimumAgeOfParticipants : String Private

[Is static True. Containment is Not Specified.]

◆ plannedNumberOfParticipants : int Private

[Is static True. Containment is Not Specified.]

◆ plannedSexOfParticipants : List<Code> Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ populationDescription : String Private

The textual representation of the study population.

[Is static True. Containment is Not Specified.]

◆ studyDesignPopulationId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesignPopulation

Target: Private plannedSexOfParticipants (Class) Code
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyPopulations (Class) StudyDesignPopulation
Cardinality: [0..*]

OPERATIONS

◆ getPlannedMaximumAgeOfParticipants () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getPlannedMinimumAgeOfParticipants () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getPlannedNumberOfParticipants () : int Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getPlannedSexOfParticipants () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getPopulationDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ getStudyDesignPopulationId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
◆ setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setPlannedNumberOfParticipants (plannedNumberOfParticipants : int) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setPlannedSexOfParticipants (plannedSexOfParticipants : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setPopulationDescription (populationDescription : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ StudyDesignPopulation (uuid : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyElement

Class in package 'model'

A basic building block for time within a clinical study comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element.

<div align="right">StudyElement
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023</div>

ATTRIBUTES
◆ studyElementDescription : String Private The textual representation of the study design element. [Is static True. Containment is Not Specified.]
◆ studyElementId : String Private Const element only attributes - these purely describe an element [Is static True. Containment is Not Specified.]
◆ studyElementName : String Private

ATTRIBUTES

The literal identifier (i.e., distinctive designation) of the study design element.

[Is static True. Containment is Not Specified.]

🔷 transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

🔷 transitionStartRule : TransitionRule Private

all elements point to transition rules

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement   Target: Private transitionStartRule (Class)
                                                        TransitionRule

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement   Target: Private transitionEndRule (Class)
                                                        TransitionRule

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private studyElements (Class)
                                                        StudyElement
                                                           Cardinality: [0..*]

OPERATIONS

🔷 getStudyElementDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getStudyElementId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getStudyElementName () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getTransitionEndRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
🔶 getTransitionStartRule () : TransitionRule Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setStudyElementDescription (studyElementDescription : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setStudyElementName (studyElementName : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTransitionEndRule (transitionEndRule : TransitionRule) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTransitionStartRule (transitionStartRule : TransitionRule) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 StudyElement (studyElementId : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyEpoch

Class in package 'model'

A named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.

StudyEpoch
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔷 encounters : List<Encounter> Private [Is static True. Containment is Not Specified.]
🔷 nextStudyEpochId : String Private A system identifier assigned to the epoch that occurs immediately after the current epoch. [Is static True. Containment is Not Specified.]
🔷 previousStudyEpochId : String Private A system identifier assigned to the epoch that occurs immediately prior to the current epoch. [Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 studyEpochDescription : String Private

The textual representation of the study epoch.

[Is static True. Containment is Not Specified.]

🔷 studyEpochId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 studyEpochName : String Private

The literal identifier (i.e., distinctive designation) of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.

[Is static True. Containment is Not Specified.]

🔷 studyEpochType : Code Private

A characterization or classification of the study epoch, i.e., the named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch   Target: Private studyEpochType (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch   Target: Private encounters (Class) Encounter
                                                                        Cardinality: [0..*]

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private studyEpoch (Class) StudyEpoch

OPERATIONS

🔷 getEncounters () : List<Encounter> Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getNextStudyEpochId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

🔹 getPreviousStudyEpochId () : String Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyEpochDescription () : String Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyEpochId () : String Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyEpochName () : String Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyEpochType () : Code Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setEncounters (encounters : List<Encounter>) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setNextStudyEpochId (nextStudyEpochId : String) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setPreviousStudyEpochId (previousStudyEpochId : String) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setStudyEpochDescription (studyEpochDescription : String) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setStudyEpochName (studyEpochName : String) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setStudyEpochType (studyEpochType : Code) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 StudyEpoch (studyEpochId : String) : Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyIdentifier

Class in package 'model'

A sequence of characters used to identify, name, or characterize the study.

StudyIdentifier
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

🔹 studyIdentifier : String Private

A sequence of characters used to identify, name, or characterize the study.

[Is static True. Containment is Not Specified.]

🔹 studyIdentifierId : String Private Const

[Is static True. Containment is Not Specified.]

🔹 studyIdentifierScope : Organization Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier   Target: Private studyIdentifierScope (Class)
                                                    Organization

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyIdentifiers (Class)
                                                    StudyIdentifier
                                                        Cardinality: [0..*]

OPERATIONS

🔹 getStudyIdentifier () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyIdentifierId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getStudyIdentifierScope () : Organization Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setStudyIdentifier (studyIdentifier : String) : void Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setStudyIdentifierScope (studyIdentifierScope : Organization) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 StudyIdentifier (studyIdentifierId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyProtocolVersion

Class in package 'model'

A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)

StudyProtocolVersion
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔷 briefTitle : String Private
The short descriptive name for the protocol.
[Is static True. Containment is Not Specified.]
🔷 officialTitle : String Private
The formal descriptive name for the protocol.
[Is static True. Containment is Not Specified.]
🔷 protocolAmendment : String Private
A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)
[Is static True. Containment is Not Specified.]
🔷 protocolEffectiveDate : Date Private
The date and time specifying when the protocol amendment takes effect or becomes operative.
[Is static True. Containment is Not Specified.]
🔷 protocolStatus : Code Private
A condition of the protocol at a point in time with respect to its state of readiness for implementation.

ATTRIBUTES

[Is static True. Containment is Not Specified.]

🔹 protocolVersion : String Private

A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)

[Is static True. Containment is Not Specified.]

🔹 publicTitle : String Private

The descriptive name of the protocol that is intended for the lay public, written in easily understood language.

[Is static True. Containment is Not Specified.]

🔹 scientificTitle : String Private

A more extensive descriptive name of the protocol that is intended for medical professionals, written using medical and scientific language.

[Is static True. Containment is Not Specified.]

🔹 studyProtocolVersionId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion   Target: Private protocolStatus (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyProtocolVersions (Class) StudyProtocolVersion
Cardinality: [0..*]

OPERATIONS

🔷 getBriefTitle () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getOfficialTitle () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getProtocolAmendment () : String Public

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getProtocolEffectiveDate () : Date Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getProtocolStatus () : Code Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getProtocolVersion () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getPublicTitle () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getScientificTitle () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getStudyProtocolVersionId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setBriefTitle (briefTitle : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setOfficialTitle (officialTitle : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setProtocolAmendment (protocolAmendment : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setProtocolEffectiveDate (protocolEffectiveDate : Date) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setProtocolStatus (protocolStatus : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setProtocolVersion (protocolVersion : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 setPublicTitle (publicTitle : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
🔷 setScientificTitle (scientificTitle : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 StudyProtocolVersion (studyProtocolVersionId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Timing

Class in package 'model'

The Timing class is used to relate ScheduledInstance objects. In graph, this information would likely sit on relationship that exists between ScheduledInstances. ScheduledInstances have no information regarding their relationships with other ScheduledInstances in a ScheduleTimeline. This is where that information is captured. In a typical GANTT chart, these are the arrows you see between the task boxes that tell us how the work should be sequenced.

Timing
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
🔷 relativeFromScheduledInstanceId : String Private
This field defines the ScheduledInstance object that the timing defines as the anchor. When we define a timing relationship between two ScheduledInstances, one instance is the from and the other is the to in what is essentially a "timing between" constraint.
[Is static True. Containment is Not Specified.]
🔷 relativeToScheduledInstanceId : String Private
This field defines the ScheduledInstance object that has the timing constraint associated with the anchor instance. This is the instance that has the "timingRelativeToFrom" constraint associated with the fromScheduledInstance object.
[Is static True. Containment is Not Specified.]
🔷 timingId : String Private Const
[Is static True. Containment is Not Specified.]
🔷 timingRelativeToFrom : Code Private
Code values that describe the timing relative to the associated timepoint, I believe. Somewhat unsure here. Values are typical of gant task relationship dependencies. They are: StartToStart, StartToEnd, EndToEnd and EndToStart.
[Is static True. Containment is Not Specified.]
🔷 timingType : Code Private

ATTRIBUTES
Code values that describe the type of timing. Valid values include Before, After and Absolute. [Is static True. Containment is Not Specified.]

🔷 timingValue : String Private According to the presentation, the value will be provide further context based on the type of the timing. For example, if the timing type is absolute then maybe something like "first dose, day 0" and if the type is Before it could be "1 day before x". [Is static True. Containment is Not Specified.]

🔷 timingWindow : String Private Defines window of time associated with the timing. We could either define slack or lead time as two variables to ensure consistency however, this can be inferred along with the timingRelativeToFrom value. [Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)

Source: Public (Class) Timing	Target: Private timingType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Timing	Target: Private timingRelativeToFrom (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduledInstance	Target: Private scheduledInstanceTimings (Class) Timing Cardinality: [0..*]

OPERATIONS
🔷 getRelativeFromScheduledInstanceId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getRelativeToScheduledInstanceId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getTimingId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getTimingRelativeToFrom () : Code Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
🔶 getTimingType () : Code Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getTimingValue () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getTimingWindow () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setRelativeFromScheduledInstanceId (relativeFromScheduledInstanceId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setRelativeToScheduledInstanceId (relativeToScheduledInstanceId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTimingRelativeToFrom (timingRelativeToFrom : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTimingType (timingType : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTimingValue (timingValue : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setTimingWindow (timingWindow : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 Timing (timingId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

TransitionRule

Class in package 'model'

A guide that governs the allocation of subjects to operational options at a discrete decision point or branch (e.g., assignment to a particular arm, discontinuation) within a clinical trial plan.

TransitionRule
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES

🔹 transitionRuleDescription : String Private

The textual representation of the transition rule.

[Is static True. Containment is Not Specified.]

🔹 transitionRuleId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)
TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionStartRule (Class)
TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)
TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionEndRule (Class)
TransitionRule

OPERATIONS

🔹 getTransitionRuleDescription () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 getTransitionRuleId () : String Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 setTransitionRuleDescription (transitionRuleDescription : String) : void Public

[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔹 TransitionRule (ruleId : String) : Public

OPERATIONS
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

ScheduledInstanceType

Enumeration in package 'model'

ScheduledInstanceType
Version 1.0 Phase 1.0 Proposed
cupke created on 3/9/2023. Last modified 3/9/2023

ATTRIBUTES
◆ ACTIVITY : Public
[Stereotype is «enum». Is static True. Containment is Not Specified.]
◆ DECISION : Public
[Stereotype is «enum». Is static True. Containment is Not Specified.]

ASSOCIATIONS
✎ Association (direction: Source -> Destination)
Source: Public (Class) ScheduledInstance   Target: Private scheduledInstanceType (Enumeration) ScheduledInstanceType