

model

Package in package 'DDF'

model

Version 1.0 Phase 1.0 Proposed

cupke created on 2/7/2023. Last modified 2/7/2023

model diagram

Class diagram in package 'model'

model

Version 1.0

cupke created on 2/7/2023. Last modified 2/7/2023

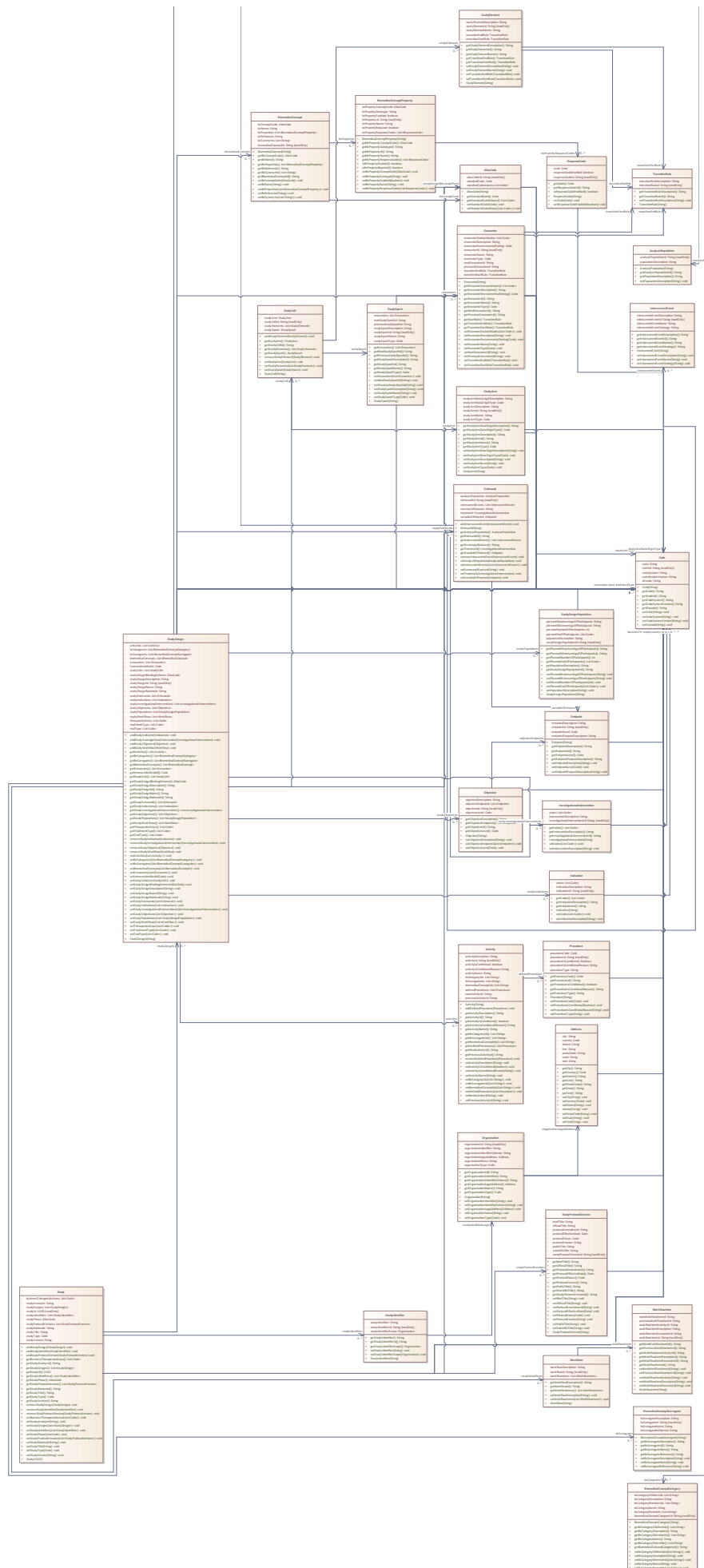


Figure 1: model

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

Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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.]
 bcCategoryIds : List<String> Private	[Is static True. Containment is Not Specified.]
 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	


ATTRIBUTES

[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















[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.]

OPERATIONS	
 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.]
 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.]
 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.]
 setBcCategoryIds (bcCategoryIds : List<String>) : void Public	

OPERATIONS	
	[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
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 cupke created on 2/7/2023. Last modified 2/7/2023

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.]	

ATTRIBUTES

 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


[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.]

OPERATIONS	
 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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) BiomedicalConceptProperty

Target: Private bcPropertyConceptCode (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) Study

Target: Private studyPhase (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

OPERATIONS


[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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cupke created on 2/7/2023. Last modified 2/7/2023

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.]

OPERATIONS

BiomedicalConcept

Class in package 'model'

BiomedicalConcept
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cupke created on 2/7/2023. Last modified 2/7/2023

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
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConcept	Target: Private bcProperties (Class) BiomedicalConceptProperty Cardinality: [0..*]
 Association (direction: Source -> Destination)	

ASSOCIATIONS

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.]

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

OPERATIONS

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


BiomedicalConceptCategory

Class in package 'model'

BiomedicalConceptCategory
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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.]








OPERATIONS
 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.]
 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
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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 bcPropertyConceptCode (Class) AliasCode
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConceptProperty	Target: Private bcPropertyResponseCodes (Class) ResponseCode Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConcept	Target: Private bcProperties (Class) BiomedicalConceptProperty Cardinality: [0..*]

OPERATIONS

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 [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
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cupke created on 2/7/2023. Last modified 2/7/2023





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

 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.]






OPERATIONS
 <code>getBcSurrogateReference () : String Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setBcSurrogateDescription (bcSurrogateDescription : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setBcSurrogateName (bcSurrogateName : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setBcSurrogateReference (bcSurrogateReference : String) : void Public</code> [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
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Chris Upkes created on 2/7/2023. Last modified 2/7/2023

ATTRIBUTES
 <code>code : String Private</code> The literal value of a code. [Is static True. Containment is Not Specified.]
 <code>codeId : String Private Const</code> [Is static True. Containment is Not Specified.]
 <code>codeSystem : String Private</code> The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes. [Is static True. Containment is Not Specified.]
 <code>codeSystemVersion : String Private</code> The version of the code system. [Is static True. Containment is Not Specified.]
 <code>decode : String Private</code>

ATTRIBUTES

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) StudyArm

Target: Private studyArmDataOriginType (Class)
Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

 Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

 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 interventionModel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

 Association (direction: Source -> Destination)

ASSOCIATIONS	
Source: Public (Class) StudyDesignPopulation	Target: Private plannedSexOfParticipants (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) AliasCode	Target: Private standardCode (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private trialType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) Encounter	Target: Private encounterEnvironmentalSetting (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyEpoch	Target: Private studyEpochType (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) AliasCode	Target: Private standardCodeAliases (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) Procedure	Target: Private procedureCode (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) ResponseCode	Target: Private code (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyProtocolVersion	Target: Private protocolStatus (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) Study	Target: Private businessTherapeuticAreas (Class) Code

ASSOCIATIONS

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private therapeuticAreas (Class) Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (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) Objective

Target: Private objectiveLevel (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.]




OPERATIONS
 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.


Encounter
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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


ATTRIBUTES

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.]

 encounterType : Code Private


A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an 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 encounterContactModes (Class)
Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting
(Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch


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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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.]

OPERATIONS	
 getEncounterName () : 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.]
 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.]
 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.]

OPERATIONS

 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 [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]

Endpoint
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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

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
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

Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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 analysisPopulation (Class) AnalysisPopulation
 Association (direction: Source -> Destination)	
Source: Public (Class) Estimand	Target: Private intercurrentEvents (Class) IntercurrentEvent Cardinality: [0..*]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private treatment (Class)
InvestigationalIntervention

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand


Target: Private variableOfInterest (Class) Endpoint

 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.]




OPERATIONS
 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.]
 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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

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

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

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 2/7/2023. Last modified 2/7/2023


ATTRIBUTES

 intercurrentEventDescription : String Private

ATTRIBUTES

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.]

 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.]

OPERATIONS

	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 [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 2/7/2023. Last modified 2/7/2023

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)

ASSOCIATIONS

Source: Public (Class) StudyDesign

Target: Private studyInvestigationalInterventions
(Class) InvestigationalIntervention
Cardinality: [0..*] Association (direction: Source -> Destination)

Source: Public (Class) Estimand


Target: Private treatment (Class)
InvestigationalIntervention**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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023

ATTRIBUTES objectiveDescription : String Private


ATTRIBUTES

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

[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 objectiveEndpoints (Class)
Endpoint

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code


 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.]





OPERATIONS
 <code>getObjectiveLevel () : Code Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>Objective (objectiveId : String) : Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setObjectiveDescription (objectiveDescription : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setObjectiveEndpoints (objectiveEndpoints : List<Endpoint>) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setObjectiveLevel (objectiveLevel : Code) : void Public</code> [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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023


ATTRIBUTES
 <code>organizationId : String Private Const</code> [Is static True. Containment is Not Specified.]
 <code>organizationIdentifier : String Private</code> A unique symbol that establishes identity of the organization. (BRIDG) [Is static True. Containment is Not Specified.]
 <code>organizationIdentifierScheme : String Private</code> The name of the organization that provides the identifier for the entity. [Is static True. Containment is Not Specified.]
 <code>organizationLegalAddress : Address Private</code> [Is static True. Containment is Not Specified.]

ATTRIBUTES

 organizationName : String Private

A non-unique textual identifier for the organization. (BRIDG)

[Is static True. Containment is Not Specified.]

 organizationType : Code Private

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 organizationType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationLegalAddress (Class)
Address

 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.]



OPERATIONS
 <code>getOrganizationName () : String Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getOrganizationType () : Code Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>Organization (organizationId : String) : Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationIdentifier (organizationIdentifier : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationLegalAddress (organizationLegalAddress : Address) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationName (organizationName : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationType (organizationType : Code) : void Public</code> [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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023






ATTRIBUTES
 <code>procedureCode : Code Private</code> A symbol or combination of symbols which is assigned to medical procedure. [Is static True. Containment is Not Specified.]
 <code>procedureId : String Private Const</code>

ATTRIBUTES	
	[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.]
 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.]

OPERATIONS




-  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.]
-  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 2/7/2023. Last modified 2/7/2023

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)


ASSOCIATIONS

Source: Public (Class) BiomedicalConceptProperty


Target: Private bcPropertyResponseCodes (Class)
ResponseCode

Cardinality: [0..*]


OPERATIONS

 getCode () : Code Public


[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.]

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

Version 1.0 Phase 1.0 Proposed








Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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.]

ATTRIBUTES	
 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]	[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

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..*]

 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

 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..*]

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

OPERATIONS	
	[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.]	
 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.]	







OPERATIONS
 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 [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.

StudyArm
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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.]	
 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 studyArmDataOriginType (Class) Code	
 Association (direction: Source -> Destination) Source: Public (Class) StudyArm Target: Private studyArmType (Class) Code	

ASSOCIATIONS

 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.]

 **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.]

OPERATIONS

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 2/7/2023. Last modified 2/7/2023

ATTRIBUTES

 studyArm : StudyArm Private	[Is static True. Containment is Not Specified.]
 studyCellId : String Private Const	[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 studyEpoch (Class) StudyEpoch
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyCell	Target: Private studyArm (Class) StudyArm
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyCell	Target: Private studyElements (Class) StudyElement Cardinality: [0..*]
 Association (direction: Source -> Destination)	

ASSOCIATIONS

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.]

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 2/7/2023. Last modified 2/7/2023

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	[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	

ATTRIBUTES	
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.]
 studyObjectives : List<Objective> Private	[Is static True. Containment is Not Specified.]
 studyPopulations : List<StudyDesignPopulation> Private	[Is static True. Containment is Not Specified.]
 studyWorkflows : List<Workflow> Private	[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

ASSOCIATIONS		
 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 studyCells (Class) StudyCell Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private studyIndications (Class) Indication 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 studyObjectives (Class) Objective Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialType (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..*]

ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyWorkflows (Class) Workflow 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 therapeuticAreas (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 studyPopulations (Class) StudyDesignPopulation Cardinality: [0..*]
 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 encounters (Class) Encounter Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyDesignBlindingScheme (Class) AliasCode

ASSOCIATIONS


 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.]

 addStudyObjective (objective : Objective) : void Public

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

 addStudyWorkflow (workflow : Workflow) : 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.]

OPERATIONS	
 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	[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.]
 getStudyWorkflows () : List<Workflow> 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	







OPERATIONS	
	[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.]	
 removeStudyWorkflow (workflow : Workflow) : 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.]	
 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.]	

OPERATIONS
 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.]
 setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyWorkflows (studyWorkflows : List<Workflow>) : 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.]

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 2/7/2023. Last modified 2/7/2023

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.]
 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

OPERATIONS	
 <code>getPlannedMaximumAgeOfParticipants () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getPlannedMinimumAgeOfParticipants () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getPlannedNumberOfParticipants () : int Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getPlannedSexOfParticipants () : List<Code> Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getPopulationDescription () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getStudyDesignPopulationId () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setPlannedNumberOfParticipants (plannedNumberOfParticipants : int) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setPlannedSexOfParticipants (plannedSexOfParticipants : List<Code>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setPopulationDescription (populationDescription : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>StudyDesignPopulation (uuid : String) : Public</code>	[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.

StudyElement

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 2/7/2023. Last modified 2/7/2023

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 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	

ASSOCIATIONS

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.]

✦ **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.

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.]
 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)	

ASSOCIATIONS


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.] 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.]

OPERATIONS

-  **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
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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)

ASSOCIATIONS


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**

[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)

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ATTRIBUTES **briefTitle : String Private**

The short descriptive name for the protocol.

[Is static True. Containment is Not Specified.]

 **officialTitle : String Private**

ATTRIBUTES

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.

[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


ASSOCIATIONS

 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


[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.]



OPERATIONS
 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.]
 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.]

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
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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) 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

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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


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

Workflow

Class in package 'model'


The operational aspect of a work procedure: how tasks are structured, who performs them, what their relative order is, how they are synchronized, how information flows to support the tasks and how tasks are being tracked.

Workflow


ATTRIBUTES workflowDescription : String Private

The textual representation of the workflow.

[Is static True. Containment is Not Specified.]

 workflowId : String Private Const

[Is static True. Containment is Not Specified.]

 workflowItems : List<WorkflowItem> Private

The textual representation of the workflow item.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)
WorkflowItem


Cardinality: [0..*]

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

Target: Private studyWorkflows (Class) Workflow


Cardinality: [0..*]

OPERATIONS getWorkflowDescription () : String Public


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

 getWorkflowId () : String Public

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



 getWorkflowItems () : List<WorkflowItem> Public

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

 setWorkflowDescription (workflowDescription : String) : void Public

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

OPERATIONS







-  **setWorkflowItems (workflowItems : List<WorkflowItem>) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **Workflow (workFlowUUID : String) : Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

WorkflowItem

Class in package 'model'

WorkflowItem
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ATTRIBUTES

-  **nextWorkflowItemId : String Private**
 A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item.
 [Is static True. Containment is Not Specified.]
-  **previousWorkflowItemId : String Private**
 A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item.
 [Is static True. Containment is Not Specified.]
-  **workflowItemActivityId : String Private**
 [Is static True. Containment is Not Specified.]
-  **workflowItemDescription : String Private**
 The textual representation of the workflow item.
 [Is static True. Containment is Not Specified.]
-  **workflowItemEncounterId : String Private**
 [Is static True. Containment is Not Specified.]
-  **workflowItemId : String Private Const**
 [Is static True. Containment is Not Specified.]

ASSOCIATIONS

-  **Association (direction: Source -> Destination)**

ASSOCIATIONS

Source: Public (Class) Workflow

Target: Private workflowItems (Class)
WorkflowItem

Cardinality: [0..*]

OPERATIONS

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

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

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

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

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

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

setNextWorkflowItemId (nextWorkflowItemId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setPreviousWorkflowItemId (previousWorkflowItemId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setWorkflowItemActivity (workflowItemActivityId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setWorkflowItemDescription (workflowItemDescription : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setWorkflowItemEncounter (workflowItemEncounterId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

WorkflowItem (workflowItemId : String) : Public

OPERATIONS

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