model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
cupke created on 2/6/2023. Last modified 2/6/2023

model diagram

Class diagram in package 'model'

model
Version 1.0
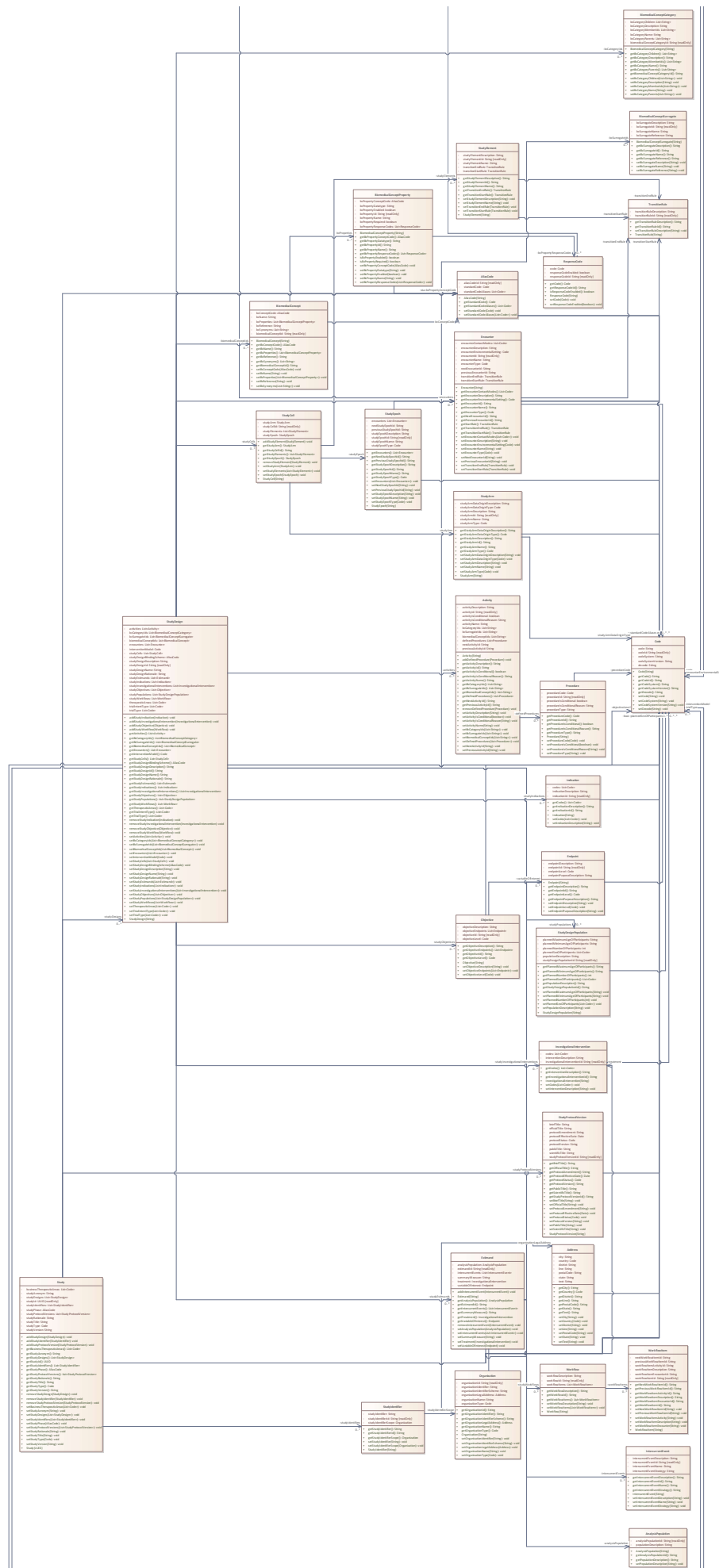cupke created on 2/6/2023. Last modified 2/6/2023

model

Package in package 'DDF'

Figure 1: model

Activity

Class in package 'model'

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

Activity
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
◆ activityDescription : String Private The textual representation of the study activity. [Is static True. Containment is Not Specified.]
◆ activityId : String Private Const [Is static True. Containment is Not Specified.]
◆ activityIsConditional : boolean Private [Is static True. Containment is Not Specified.]
◆ activityIsConditionalReason : String Private [Is static True. Containment is Not Specified.]
◆ activityName : String Private The literal identifier (i.e., distinctive designation) of the clinical study activity. [Is static True. Containment is Not Specified.]
◆ 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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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 2/6/2023. Last modified 2/6/2023

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) Study   Target: Private studyPhase (Class) AliasCode

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

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

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

🔷 getStandardCodeAliases () : List<Code> Public
            [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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

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

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
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
◆ analysisPopulationId : String Private Const
[Is static True. Containment is Not Specified.]
◆ populationDescription : String Private
The textual representation of the study population for analysis.
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✐ Association (direction: Source -> Destination)

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

OPERATIONS
◆ AnalysisPopulation (analysisPopulationId : String) : Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ getAnalysisPopulationId () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ getPopulationDescription () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
◆ setPopulationDescription (populationDescription : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

BiomedicalConcept

Class in package 'model'

BiomedicalConcept
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ATTRIBUTES

◆ bcConceptCode : AliasCode Private

[Is static True. Containment is Not Specified.]

◆ bcName : String Private

[Is static True. Containment is Not Specified.]

◆ bcProperties : List<BiomedicalConceptProperty> Private

[Is static True. Containment is Not Specified.]

◆ bcReference : String Private

[Is static True. Containment is Not Specified.]

◆ bcSynonyms : List<String> Private

[Is static True. Containment is Not Specified.]

◆ biomedicalConceptId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

🖉 Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept

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

🖉 Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept

Target: Private bcConceptCode (Class) AliasCode

🖉 Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) StudyDesign	Target: Private biomedicalConceptIds (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
Version 1.0 Phase 1.0 Proposed
cupke created on 2/6/2023. Last modified 2/6/2023

ATTRIBUTES
◆ bcCategoryChildren : 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.]
◆ bcCategoryParents : 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 bcCategoryIds (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

◆ getBcCategoryChildren () : 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.]

◆ getBcCategoryParents () : 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.]

◆ setBcCategoryChildren (bcCategoryChildren : 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.]

◆ setBcCategoryParents (bcCategoryParents : List<String>) : void Public

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

BiomedicalConceptProperty

Class in package 'model'

BiomedicalConceptProperty
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

◆ bcPropertyConceptCode : AliasCode Private

[Is static True. Containment is Not Specified.]

◆ bcPropertyDatatype : String Private

[Is static True. Containment is Not Specified.]

◆ bcPropertyEnabled : boolean Private

[Is static True. Containment is Not Specified.]

◆ bcPropertyId : String Private Const

[Is static True. Containment is Not Specified.]

◆ bcPropertyName : String Private

[Is static True. Containment is Not Specified.]

◆ bcPropertyRequired : boolean Private

[Is static True. Containment is Not Specified.]

◆ bcPropertyResponseCodes : List<ResponseCode> Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ 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
Version 1.0 Phase 1.0 Proposed
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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 bcSurrogateIds (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

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

> setBcSurrogateDescription (bcSurrogateDescription : String) : void Public
>
> > [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

> setBcSurrogateName (bcSurrogateName : String) : void Public
>
> > [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

> setBcSurrogateReference (bcSurrogateReference : String) : void Public
>
> > [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Code

Class in package 'model'

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

Code
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ATTRIBUTES

> code : String Private
>
> The literal value of a code.
>
> > [Is static True. Containment is Not Specified.]

> codeId : String Private Const
>
> > [Is static True. Containment is Not Specified.]

> codeSystem : String Private
>
> The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.
>
> > [Is static True. Containment is Not Specified.]

> codeSystemVersion : String Private
>
> The version of the code system.
>
> > [Is static True. Containment is Not Specified.]

> decode : String Private

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) Encounter

Target: Private encounterEnvironmentalSetting (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Indication

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Address

Target: Private country (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private interventionModel (Class) Code

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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)

ASSOCIATIONS

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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 encounterEnvironmentalSetting (Class) Code

✏️ Association (direction: Source -> Destination)

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

ASSOCIATIONS	
	TransitionRule

🖊 Association (direction: Source -> Destination)

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

🖊 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 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 2/6/2023. Last modified 2/6/2023

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) Estimand   Target: Private variableOfInterest (Class) Endpoint

---

✏ Association (direction: Source -> Destination)

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

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 2/6/2023. Last modified 2/6/2023

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 variableOfInterest (Class) Endpoint

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

ASSOCIATIONS

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

✏ Association (direction: Source -> Destination)

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

✏ 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

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setAnalysisPopulation (analysisPopulation : AnalysisPopulation) : void Public	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setIntercurrentEvents (intercurrentEvents : List<IntercurrentEvent>) : void Public	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 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 2/6/2023. Last modified 2/6/2023

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 2/6/2023. Last modified 2/6/2023

ATTRIBUTES

ATTRIBUTES

◆ intercurrentEventDescription : String Private

The textual representation of the intercurrent event.

[Is static True. Containment is Not Specified.]

◆ intercurrentEventId : String Private Const

[Is static True. Containment is Not Specified.]

◆ 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 2/6/2023. Last modified 2/6/2023

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) Estimand	Target: Private treatment (Class) InvestigationalIntervention

✏️ Association (direction: Source -> Destination)

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

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.

<div align="right">

Objective
Version 1.0 Phase 1.0 Proposed
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</div>

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 objectiveLevel (Class) Code

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◆ getObjectiveDescription () : String Public

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

◆ getObjectiveEndpoints () : List<Endpoint> Public

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

◆ getObjectiveId () : String Public

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

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

Organization

Class in package 'model'

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

Organization
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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

ATTRIBUTES

	[Is static True. Containment is Not Specified.]

🔷 organizationName : String Private

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

[Is static True. Containment is Not Specified.]

🔷 organizationType : Code Private

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

getOrganizationName () : String Public

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

getOrganizationType () : Code Public

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

Organization (organizationId : String) : Public

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

setOrganizationIdentifier (organizationIdentifier : String) : void Public

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

setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public

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

setOrganizationLegalAddress (organizationLegalAddress : Address) : void Public

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

setOrganizationName (organizationName : String) : void Public

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

setOrganizationType (organizationType : Code) : void Public

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

Procedure

Class in package 'model'

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

Procedure
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

ATTRIBUTES

procedureCode : Code Private

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

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ procedureId : String Private Const

[Is static True. Containment is Not Specified.]

◆ procedureIsConditional : boolean Private

[Is static True. Containment is Not Specified.]

◆ procedureIsConditionalReason : String Private

[Is static True. Containment is Not Specified.]

◆ 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 2/6/2023. Last modified 2/6/2023

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

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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
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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. (After clinicaltrials.gov)

[Is static True. Containment is Not Specified.]

◆ studyVersion : String Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ 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 studyProtocolVersions (Class)
                                                StudyProtocolVersion
                                                Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private businessTherapeuticAreas (Class)
                                                Code
                                                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.

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ATTRIBUTES

🔷 studyArmDataOriginDescription : String Private

The textual representation of the study arm data origin.

[Is static True. Containment is Not Specified.]

🔷 studyArmDataOriginType : Code Private

A characterization or classification of the study arm with respect to where the study arm data originates.

[Is static True. Containment is Not Specified.]

🔷 studyArmDescription : String Private

The textual representation of the study arm.

[Is static True. Containment is Not Specified.]

🔷 studyArmId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 studyArmName : String Private

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

[Is static True. Containment is Not Specified.]

🔷 studyArmType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

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
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Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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 studyElements (Class) StudyElement Cardinality: [0..*]
✎ Association (direction: Source -> Destination) Source: Public (Class) StudyCell Target: Private studyArm (Class) StudyArm
✎ 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.

<div align="right">

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</div>

ATTRIBUTES

◆ activities : List<Activity> Private

[Is static True. Containment is Not Specified.]

◆ bcCategoryIds : List<BiomedicalConceptCategory> Private

[Is static True. Containment is Not Specified.]

◆ bcSurrogateIds : List<BiomedicalConceptSurrogate> Private

[Is static True. Containment is Not Specified.]

◆ biomedicalConceptIds : 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 therapeuticAreas (Class) Code
Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity
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 studyCells (Class) StudyCell
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 bcSurrogateIds (Class) BiomedicalConceptSurrogate
Cardinality: [0..*]

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private interventionModel (Class) Code

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private studyWorkflows (Class) Workflow Cardinality: [0..*]

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.]

🔹 getBcCategoryIds () : List<BiomedicalConceptCategory> Public

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

🔹 getBcSurrogateIds () : List<BiomedicalConceptSurrogate> Public

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

🔹 getBiomedicalConceptIds () : 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.]

⬡ setBcCategoryIds (bcCategoryIds : List<BiomedicalConceptCategory>) : void Public

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

⬡ setBcSurrogateIds (bcSurrogateIds : List<BiomedicalConceptSurrogate>) : void Public

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

⬡ setBiomedicalConceptIds (biomedicalConceptIds : 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.]

StudyDesignPopulation

Class in package 'model'

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

StudyDesignPopulation
Version 1.0 Phase 1.0 Proposed
cupke created on 2/6/2023. Last modified 2/6/2023

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

◆ getPlannedMaximumAgeOfParticipants () : String Public

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

◆ getPlannedMinimumAgeOfParticipants () : String Public

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

◆ getPlannedNumberOfParticipants () : int Public

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

◆ getPlannedSexOfParticipants () : List<Code> Public

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

◆ getPopulationDescription () : String Public

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

◆ getStudyDesignPopulationId () : String Public

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

◆ setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String) : void Public

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

◆ setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String) : void Public

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

◆ setPlannedNumberOfParticipants (plannedNumberOfParticipants : int) : void Public

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

◆ setPlannedSexOfParticipants (plannedSexOfParticipants : List<Code>) : void Public

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

◆ setPopulationDescription (populationDescription : String) : void Public

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

◆ StudyDesignPopulation (uuid : String) : Public

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

StudyElement

Class in package 'model'

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

StudyElement
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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.

StudyEpoch
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

ATTRIBUTES

🔷 encounters : List<Encounter> Private

[Is static True. Containment is Not Specified.]

🔷 nextStudyEpochId : String Private

A system identifier assigned to the epoch that occurs immediately after the current epoch.

[Is static True. Containment is Not Specified.]

🔷 previousStudyEpochId : String Private

A system identifier assigned to the epoch that occurs immediately prior to the current epoch.

[Is static True. Containment is Not Specified.]

🔷 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

ATTRIBUTES

🔷 studyIdentifier : String Private

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

[Is static True. Containment is Not Specified.]

🔷 studyIdentifierId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 studyIdentifierScope : Organization Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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)

StudyProtocolVersion
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

ATTRIBUTES
◆ transitionRuleDescription : String Private The textual representation of the transition rule. [Is static True. Containment is Not Specified.]
◆ transitionRuleId : String Private Const [Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 getTransitionRuleDescription () : String Public

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

🔷 getTransitionRuleId () : String Public

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

🔷 setTransitionRuleDescription (transitionRuleDescription : String) : void Public

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

🔷 TransitionRule (ruleId : String) : Public

[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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 2/6/2023. Last modified 2/6/2023

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.]

OPERATIONS

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