model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
cupke created on 11/1/2022. Last modified 11/1/2022

model diagram

Class diagram in package 'model'

model
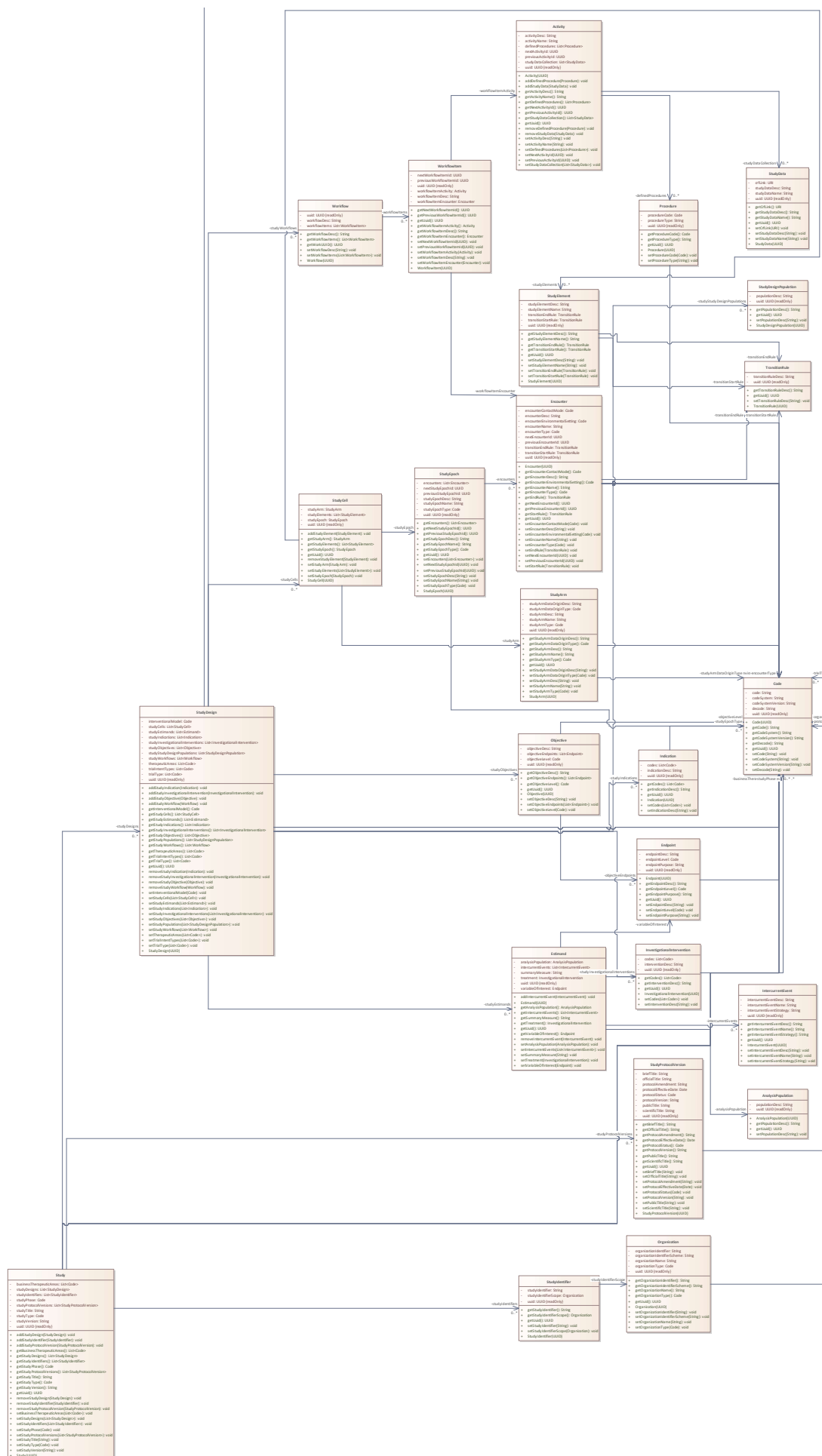Version 1.0
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model

Package in package 'DDF'

Figure 1: model

Activity

Class in package 'model'

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

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Activity
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</div>

ATTRIBUTES
◆ activityDesc : String Private [Is static True. Containment is Not Specified.]
◆ activityName : String Private [Is static True. Containment is Not Specified.]
◆ definedProcedures : List<Procedure> Private [Is static True. Containment is Not Specified.]
◆ nextActivityId : UUID Private [Is static True. Containment is Not Specified.]
◆ previousActivityId : UUID Private [Is static True. Containment is Not Specified.]
◆ studyDataCollection : List<StudyData> Private [Is static True. Containment is Not Specified.]
◆ uuid : UUID Private Const [Is static True. Containment is Not Specified.]

ASSOCIATIONS
✎ Association (direction: Source -> Destination) Source: Public (Class) Activity   Target: Private studyDataCollection (Class) StudyData   Cardinality: [0..*]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class) Activity

OPERATIONS

🔶 Activity (activityId : UUID) : 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.]

🔶 addStudyData (studyData : StudyData) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getActivityDesc () : 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.]

🔶 getDefinedProcedures () : List<Procedure> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getNextActivityId () : UUID Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getPreviousActivityId () : UUID Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getStudyDataCollection () : List<StudyData> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 getUuid () : UUID Public

OPERATIONS	
	[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.]
🔷 removeStudyData (studyData : StudyData) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setActivityDesc (description : 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.]
🔷 setDefinedProcedures (definedProcedures : List<Procedure>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setNextActivityId (nextActivityId : UUID) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setPreviousActivityId (previousActivityId : UUID) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setStudyDataCollection (studyDataCollection : List<StudyData>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

AnalysisPopulation

Class in package 'model'

AnalysisPopulation
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ATTRIBUTES	
🔷 populationDesc : String Private	[Is static True. Containment is Not Specified.]
🔷 uuid : UUID Private Const	[Is static True. Containment is Not Specified.]

ASSOCIATIONS

🖊 Association (direction: Source -> Destination)

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

OPERATIONS

🔶 AnalysisPopulation (uuid : UUID) : Public

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

🔶 getPopulationDesc () : String Public

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

🔶 getUuid () : UUID Public

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

🔶 setPopulationDesc (populationDesc : String) : void Public

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

Code

Class in package 'model'

Code
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔷 code : String Private

[Is static True. Containment is Not Specified.]

🔷 codeSystem : String Private

[Is static True. Containment is Not Specified.]

🔷 codeSystemVersion : String Private

[Is static True. Containment is Not Specified.]

🔷 decode : String Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Study

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionalModel (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyPhase (Class) Code

✏ Association (direction: Source -> Destination)

ASSOCIATIONS

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint	Target: Private endpointLevel (Class) Code

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

◈ Code (codeId : UUID) : 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.]

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

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

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

◈ getUuid () : UUID 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.]

OPERATIONS

Encounter

Class in package 'model'

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

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ATTRIBUTES

🔹 encounterContactMode : Code Private	
	[Is static True. Containment is Not Specified.]
🔹 encounterDesc : String Private	
	[Is static True. Containment is Not Specified.]
🔹 encounterEnvironmentalSetting : Code Private	
	[Is static True. Containment is Not Specified.]
🔹 encounterName : String Private	
	[Is static True. Containment is Not Specified.]
🔹 encounterType : Code Private	
	[Is static True. Containment is Not Specified.]
🔹 nextEncounterId : UUID Private	
	[Is static True. Containment is Not Specified.]
🔹 previousEncounterId : UUID Private	
	[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.]
🔹 uuid : UUID Private Const	

ATTRIBUTES

[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 encounterType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterContactMode (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class) TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class) TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemEncounter (Class) Encounter

OPERATIONS

🔷 Encounter (encounterId : UUID) : Public

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

OPERATIONS

getEncounterContactMode () : Code Public

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

getEncounterDesc () : 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.]

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.]

getEndRule () : TransitionRule Public

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

getNextEncounterId () : UUID Public

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

getPreviousEncounterId () : UUID 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.]

getUuid () : UUID Public

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

setEncounterContactMode (encounterContactMode : Code) : void Public

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

setEncounterDesc (encounterDesc : 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

OPERATIONS
[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.]

🔶 setEndRule (endTransitionRule : TransitionRule) : void Public

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

🔶 setNextEncounterId (nextEncounterId : UUID) : void Public

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

🔶 setPreviousEncounterId (previousEncounterId : UUID) : void Public

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

🔶 setStartRule (startTransitionRule : 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
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ATTRIBUTES

🔷 endpointDesc : String Private

[Is static True. Containment is Not Specified.]

🔷 endpointLevel : Code Private

[Is static True. Containment is Not Specified.]

🔷 endpointPurpose : String Private

[Is static True. Containment is Not Specified.]

🔷 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ATTRIBUTES

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint   Target: Private endpointLevel (Class) Code

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✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 Endpoint (endpointId : UUID) : Public
                    [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getEndpointDesc () : 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.]

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

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

🔷 setEndpointDesc (endpointDesc : 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.]

🔷 setEndpointPurpose (endpointPurpose : String) : void Public

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

Estimand

Class in package 'model'

Estimand
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
🔹 analysisPopulation : AnalysisPopulation Private
[Is static True. Containment is Not Specified.]
🔹 intercurrentEvents : List<IntercurrentEvent> Private
[Is static True. Containment is Not Specified.]
🔹 summaryMeasure : String Private
[Is static True. Containment is Not Specified.]
🔹 treatment : InvestigationalIntervention Private
[Is static True. Containment is Not Specified.]
🔹 uuid : UUID Private Const
[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 treatment (Class) InvestigationalIntervention
✏️ Association (direction: Source -> Destination)
Source: Public (Class) Estimand   Target: Private analysisPopulation (Class) AnalysisPopulation

ASSOCIATIONS

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

Source: Public (Class) 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 : UUID) : 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.]

◆ 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.]

◆ getUuid () : UUID 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
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ATTRIBUTES
⬡ codes : List<Code> Private
[Is static True. Containment is Not Specified.]
⬡ indicationDesc : String Private
[Is static True. Containment is Not Specified.]
⬡ uuid : UUID Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✎ Association (direction: Source -> Destination)

ASSOCIATIONS	
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.]

◈ getIndicationDesc () : String Public

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

◈ getUuid () : UUID Public

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

◈ Indication (indicationId : UUID) : 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.]

◈ setIndicationDesc (indicationDesc : String) : void Public

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

IntercurrentEvent

Class in package 'model'

IntercurrentEvent
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

◈ intercurrentEventDesc : String Private

[Is static True. Containment is Not Specified.]

◈ intercurrentEventName : String Private

ATTRIBUTES

[Is static True. Containment is Not Specified.]

🔹 intercurrentEventStrategy : String Private

[Is static True. Containment is Not Specified.]

🔹 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

OPERATIONS

🔹 getIntercurrentEventDesc () : 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.]

🔹 getUuid () : UUID Public

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

🔹 IntercurrentEvent (intercurrentEventId : UUID) : Public

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

🔹 setIntercurrentEventDesc (intercurrentEventDesc : 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 (strategy : String) : void Public

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

OPERATIONS

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
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ATTRIBUTES
◆ codes : List<Code> Private
[Is static True. Containment is Not Specified.]
◆ interventionDesc : String Private
[Is static True. Containment is Not Specified.]
◆ uuid : UUID Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

OPERATIONS
🔷 getCodes () : List<Code> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getInterventionDesc () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 InvestigationalIntervention (investigationalInterventionId : UUID) : 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.]
🔷 setInterventionDesc (interventionDesc : 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.

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Objective
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ATTRIBUTES
🔷 objectiveDesc : String Private
[Is static True. Containment is Not Specified.]
🔷 objectiveEndpoints : List<Endpoint> Private
[Is static True. Containment is Not Specified.]
🔷 objectiveLevel : Code Private
[Is static True. Containment is Not Specified.]
🔷 uuid : UUID Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◆ getObjectiveDesc () : 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.]

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

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

◆ Objective (objectiveId : UUID) : Public
                        [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setObjectiveDesc (objectiveDesc : 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)

<div align="right">

Organization
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ATTRIBUTES
🔷 organizationIdentifier : String Private
[Is static True. Containment is Not Specified.]
🔷 organizationIdentifierScheme : String Private
[Is static True. Containment is Not Specified.]
🔷 organizationName : String Private
[Is static True. Containment is Not Specified.]
🔷 organizationType : Code Private
[Is static True. Containment is Not Specified.]
🔷 uuid : UUID Private Const
[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) StudyIdentifier   Target: Private studyIdentifierScope (Class) Organization

OPERATIONS

🔷 getOrganizationIdentifier () : String Public

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

OPERATIONS
🔷 getOrganizationIdentifierScheme () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getOrganizationName () : String Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getOrganizationType () : Code Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 Organization (organizationId : UUID) : 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.]
🔷 setOrganizationName (organizationName : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 setOrganizationType (organizationType : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Procedure

Class in package 'model'

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

Procedure
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ATTRIBUTES
🔷 procedureCode : Code Private
[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 procedureType : String Private

[Is static True. Containment is Not Specified.]

🔷 uuid : UUID Private Const

[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.]

🔷 getProcedureType () : String Public

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

🔷 getUuid () : UUID Public

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

🔷 Procedure (procedureId : UUID) : 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.]

🔷 setProcedureType (procedureType : String) : 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)

<div align="right">

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ATTRIBUTES
◆ businessTherapeuticAreas : List<Code> Private [Is static True. Containment is Not Specified.]
◆ studyDesigns : List<StudyDesign> Private [Is static True. Containment is Not Specified.]
◆ studyIdentifiers : List<StudyIdentifier> Private [Is static True. Containment is Not Specified.]
◆ studyPhase : Code Private [Is static True. Containment is Not Specified.]
◆ studyProtocolVersions : List<StudyProtocolVersion> Private [Is static True. Containment is Not Specified.]
◆ studyTitle : String Private [Is static True. Containment is Not Specified.]
◆ studyType : Code Private [Is static True. Containment is Not Specified.]
◆ studyVersion : String Private [Is static True. Containment is Not Specified.]
◆ uuid : UUID Private Const [Is static True. Containment is Not Specified.]

ASSOCIATIONS
✎ Association (direction: Source -> Destination)

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

ASSOCIATIONS

✎ 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 studyPhase (Class) Code

✎ 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 studyType (Class) Code

✎ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 addStudyDesign (studyDesign : StudyDesign) : void Public
    [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 addStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public
    [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public
    [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔷 getBusinessTherapeuticAreas () : List<Code> Public
    [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.]

OPERATIONS

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

◆ getStudyPhase () : Code 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.]

◆ 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.]

◆ getUuid () : UUID Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyDesign (studyDesign : StudyDesign) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code>) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

◆ 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.]

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

StudyArm

Class in package 'model'

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

StudyArm
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ATTRIBUTES
◆ studyArmDataOriginDesc : String Private
[Is static True. Containment is Not Specified.]
◆ studyArmDataOriginType : Code Private
[Is static True. Containment is Not Specified.]
◆ studyArmDesc : String Private
[Is static True. Containment is Not Specified.]
◆ studyArmName : String Private
[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ studyArmType : Code Private

[Is static True. Containment is Not Specified.]

◆ uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◆ getStudyArmDataOriginDesc () : 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.]

◆ getStudyArmDesc () : 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.]

◆ getUuid () : UUID Public

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

OPERATIONS
⬥ setStudyArmDataOriginDesc (studyArmDataOriginDesc : 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.]
⬥ setStudyArmDesc (studyArmDesc : 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 : UUID) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyCell

Class in package 'model'

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

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ATTRIBUTES
⬥ studyArm : StudyArm Private [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.]
⬥ uuid : UUID Private Const [Is static True. Containment is Not Specified.]

ATTRIBUTES

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)

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.]

🔶 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.]

🔶 getUuid () : UUID 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.]

OPERATIONS

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 : UUID) : Public

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

StudyData

Class in package 'model'

StudyData
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ATTRIBUTES

crfLink : URI Private

[Is static True. Containment is Not Specified.]

studyDataDesc : String Private

[Is static True. Containment is Not Specified.]

studyDataName : String Private

[Is static True. Containment is Not Specified.]

uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Activity   Target: Private studyDataCollection (Class)
                                                         StudyData
                                                             Cardinality: [0..*]

OPERATIONS

◆ getCrfLink () : URI Public

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

◆ getStudyDataDesc () : String Public

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

◆ getStudyDataName () : String Public

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

◆ getUuid () : UUID Public

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

◆ setCrfLink (crfLink : URI) : void Public

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

◆ setStudyDataDesc (studyDataDesc : String) : void Public

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

◆ setStudyDataName (studyDataName : String) : void Public

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

◆ StudyData (studyDataId : UUID) : Public

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

StudyDesign

Class in package 'model'

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

StudyDesign
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ATTRIBUTES

◆ interventionalModel : Code Private

[Is static True. Containment is Not Specified.]

◆ studyCells : List<StudyCell> Private

ATTRIBUTES

[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.]

🔹 studyStudyDesignPopulations : 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

[Is static True. Containment is Not Specified.]

🔹 trialIntentTypes : List<Code> Private

[Is static True. Containment is Not Specified.]

🔹 trialType : List<Code> Private

[Is static True. Containment is Not Specified.]

🔹 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) StudyDesign

Target: Private studyObjectives (Class) Objective

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 studyWorkflows (Class) Workflow

Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionalModel (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 studyEstimands (Class) Estimand

Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyStudyDesignPopulations (Class) StudyDesignPopulation

Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private trialIntentTypes (Class) Code

Cardinality: [0..*]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study | Target: Private 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.]

🔷 getInterventionalModel () : 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.]

🔷 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.]

OPERATIONS

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.]

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

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

getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

removeStudyIndication (indication : Indication) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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

removeStudyWorkflow (workflow : Workflow) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

setInterventionalModel (interventionalModel : 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.]

setStudyEstimands (studyEstimands : List<Estimand>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

🔹 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.]

🔹 setTrialIntentTypes (trialIntentTypes : 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 : UUID) : Public

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

StudyDesignPopulation

Class in package 'model'

StudyDesignPopulation
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ATTRIBUTES

🔹 populationDesc : String Private

[Is static True. Containment is Not Specified.]

🔹 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ATTRIBUTES

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 getPopulationDesc () : String Public

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

🔷 getUuid () : UUID Public

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

🔷 setPopulationDesc (populationDesc : String) : void Public

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

🔷 StudyDesignPopulation (uuid : UUID) : 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 11/1/2022. Last modified 11/1/2022

ATTRIBUTES

🔷 studyElementDesc : String Private

[Is static True. Containment is Not Specified.]

🔷 studyElementName : String Private

[Is static True. Containment is Not Specified.]

🔷 transitionEndRule : TransitionRule Private

ATTRIBUTES	
	[Is static True. Containment is Not Specified.]
🔷 transitionStartRule : TransitionRule Private	
	[Is static True. Containment is Not Specified.]
🔷 uuid : UUID Private Const	
	[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionEndRule (Class) TransitionRule

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionStartRule (Class) TransitionRule

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

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

OPERATIONS

🔷 getStudyElementDesc () : 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.]

🔷 getUuid () : UUID Public

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

OPERATIONS
◆ setStudyElementDesc (studyElementDesc : 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 : UUID) : 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.

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ATTRIBUTES
◆ encounters : List<Encounter> Private
[Is static True. Containment is Not Specified.]
◆ nextStudyEpochId : UUID Private
[Is static True. Containment is Not Specified.]
◆ previousStudyEpochId : UUID Private
[Is static True. Containment is Not Specified.]
◆ studyEpochDesc : String Private
[Is static True. Containment is Not Specified.]
◆ studyEpochName : String Private

ATTRIBUTES

	[Is static True. Containment is Not Specified.]

🔹 studyEpochType : Code Private

[Is static True. Containment is Not Specified.]

🔹 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 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 () : UUID Public

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

🔹 getPreviousStudyEpochId () : UUID Public

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

🔹 getStudyEpochDesc () : 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

OPERATIONS

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

◆ getUuid () : UUID 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 : UUID) : void Public

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

◆ setPreviousStudyEpochId (previousStudyEpochId : UUID) : void Public

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

◆ setStudyEpochDesc (studyEpochDesc : 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 : UUID) : Public

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

StudyIdentifier

Class in package 'model'

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ATTRIBUTES

◆ studyIdentifier : String Private

[Is static True. Containment is Not Specified.]

◆ studyIdentifierScope : Organization Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier

Target: Private studyIdentifierScope (Class) Organization

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyIdentifiers (Class) StudyIdentifier

Cardinality: [0..*]

OPERATIONS

◆ getStudyIdentifier () : String Public

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

◆ getStudyIdentifierScope () : Organization Public

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

◆ getUuid () : UUID 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 : UUID) : Public

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

StudyProtocolVersion

Class in package 'model'

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

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ATTRIBUTES

briefTitle : String Private

[Is static True. Containment is Not Specified.]

officialTitle : String Private

[Is static True. Containment is Not Specified.]

protocolAmendment : String Private

[Is static True. Containment is Not Specified.]

protocolEffectiveDate : Date Private

[Is static True. Containment is Not Specified.]

protocolStatus : Code Private

[Is static True. Containment is Not Specified.]

protocolVersion : String Private

[Is static True. Containment is Not Specified.]

publicTitle : String Private

[Is static True. Containment is Not Specified.]

scientificTitle : String Private

[Is static True. Containment is Not Specified.]

uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

ASSOCIATIONS

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.]

◆ getUuid () : UUID Public

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

◆ setBriefTitle (briefTitle : String) : void Public

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

◆ setOfficialTitle (officialTitle : String) : void Public

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

◆ setProtocolAmendment (protocolAmendment : String) : void Public

OPERATIONS
[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 : UUID) : 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 11/1/2022. Last modified 11/1/2022

ATTRIBUTES
🔷 transitionRuleDesc : String Private   [Is static True. Containment is Not Specified.]
🔷 uuid : UUID Private Const   [Is static True. Containment is Not Specified.]

ASSOCIATIONS
🖊 Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

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

🔶 getUuid () : UUID Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 setTransitionRuleDesc (transitionRuleDesc : String) : void Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

🔶 TransitionRule (ruleId : UUID) : Public
> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Workflow

Class in package 'model'

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ATTRIBUTES

🔷 uuid : UUID Private Const
> [Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 workflowDesc : String Private

[Is static True. Containment is Not Specified.]

🔷 workflowItems : List<WorkflowItem> Private

[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

🔶 getWorkflowDesc () : 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.]

🔶 getWorkUUID () : UUID Public

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

🔶 setWorkflowDesc (workflowDesc : String) : void Public

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

🔶 setWorkflowItems (workflowItems : List<WorkflowItem>) : void Public

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

🔶 Workflow (workFlowUUID : UUID) : Public

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

WorkflowItem

Class in package 'model'

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WorkflowItem

Version 1.0 Phase 1.0 Proposed

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ATTRIBUTES

◆ nextWorkflowItemId : UUID Private

[Is static True. Containment is Not Specified.]

◆ previousWorkflowItemId : UUID Private

[Is static True. Containment is Not Specified.]

◆ uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

◆ workflowItemActivity : Activity Private

[Is static True. Containment is Not Specified.]

◆ workflowItemDesc : String Private

[Is static True. Containment is Not Specified.]

◆ workflowItemEncounter : Encounter Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem	Target: Private workflowItemEncounter (Class) Encounter

✏ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem	Target: Private workflowItemActivity (Class) Activity

✏ Association (direction: Source -> Destination)

Source: Public (Class) Workflow	Target: Private workflowItems (Class) WorkflowItem Cardinality: [0..*]

OPERATIONS

🔶 getNextWorkflowItemId () : UUID Public

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

🔶 getPreviousWorkflowItemId () : UUID Public

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

🔶 getUuid () : UUID Public

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

🔶 getWorkflowItemActivity () : Activity Public

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

🔶 getWorkflowItemDesc () : String Public

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

🔶 getWorkflowItemEncounter () : Encounter Public

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

🔶 setNextWorkflowItemId (nextWorkflowItemId : UUID) : void Public

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

🔶 setPreviousWorkflowItemId (previousWorkflowItemId : UUID) : void Public

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

🔶 setWorkflowItemActivity (workflowItemActivity : Activity) : void Public

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

🔶 setWorkflowItemDesc (workflowItemDesc : String) : void Public

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

🔶 setWorkflowItemEncounter (workflowItemEncounter : Encounter) : void Public

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

🔶 WorkflowItem (workflowItemId : UUID) : Public

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