model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
cupke created on 10/19/2022. Last modified 10/19/2022
Alias

model diagram

Class diagram in package 'model'

model
Version 1.0
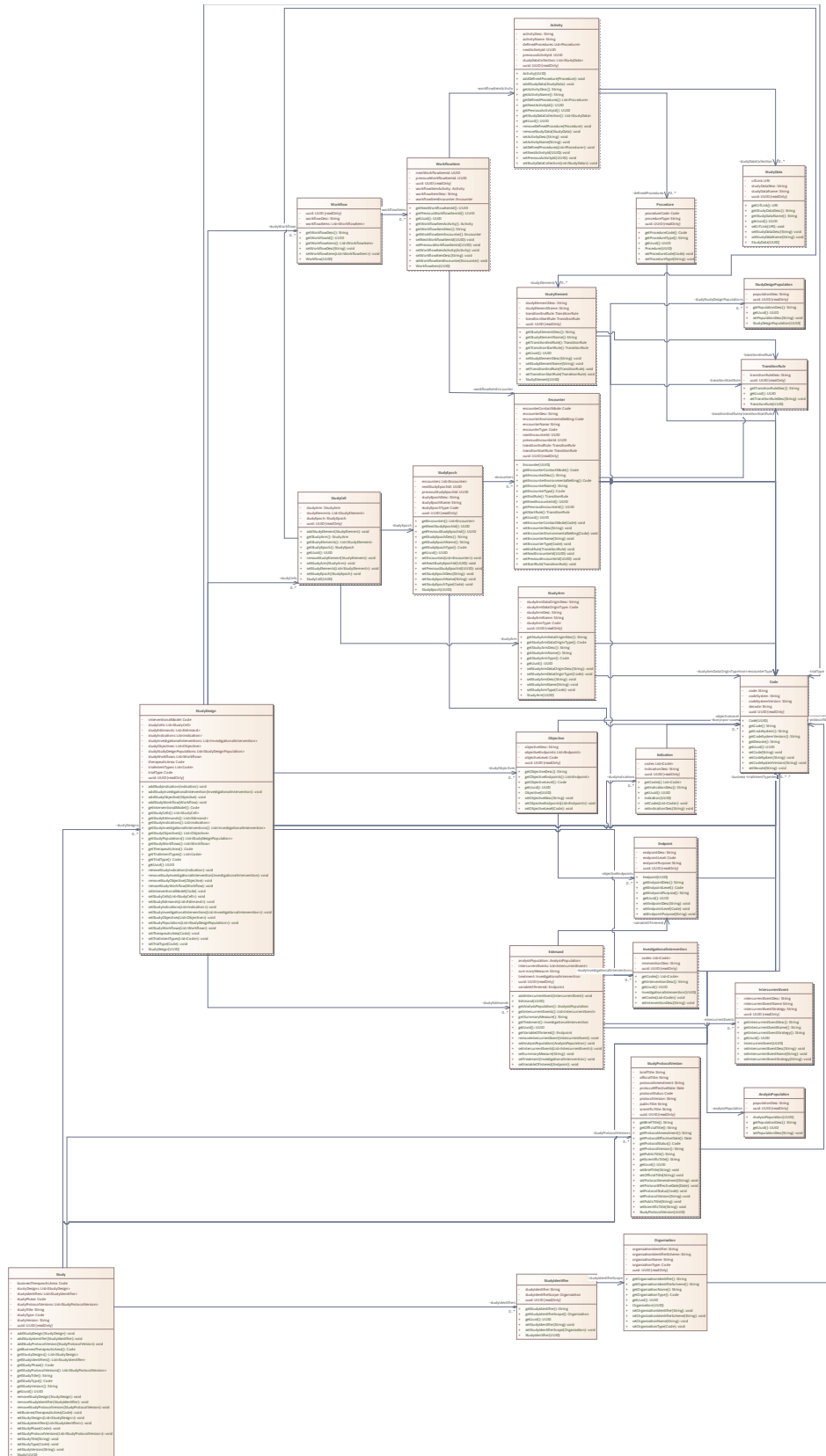cupke created on 10/19/2022. Last modified 10/19/2022

Figure 1: model

Activity

Class in package 'model'

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

Activity
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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..*]

🖉 Association (direction: Source -> Destination)

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

ASSOCIATIONS

✏ 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
[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.]

OPERATIONS

◆ 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
Version 1.0 Phase 1.0 Proposed
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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.]

OPERATIONS

🔷 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
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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.]

🔷 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private interventionalModel (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

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterContactMode (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private therapeuticArea (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Indication

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmDataOriginType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (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.]

OPERATIONS
◆ 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 10/19/2022. Last modified 10/19/2022

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.]

ATTRIBUTES

◆ transitionEndRule : TransitionRule Private

[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) Encounter

Target: Private transitionStartRule (Class) TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class) TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting (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 encounterType (Class) Code

✏ 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

OPERATIONS

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

🔶 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

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

OPERATIONS
◆ 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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.]

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

ASSOCIATIONS

✎ 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 : 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
                    [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
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

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

✏ 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

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
[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 10/19/2022. Last modified 10/19/2022

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)

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.]

OPERATIONS

◆ 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
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

◆ intercurrentEventDesc : String Private
[Is static True. Containment is Not Specified.]

◆ intercurrentEventName : String Private
[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.]

OPERATIONS

◆ 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.]

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)

<div align="right">

InvestigationalIntervention
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</div>

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) Estimand	Target: Private treatment (Class) InvestigationalIntervention

ASSOCIATIONS

✏️ 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.]

🔷 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.

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.]

ATTRIBUTES

◆ uuid : UUID Private Const

[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

◆ 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

</div>

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

OPERATIONS
[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.

<div align="right">

Procedure
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</div>

ATTRIBUTES
◆ procedureCode : Code Private [Is static True. Containment is Not Specified.]
◆ procedureType : String Private [Is static True. Containment is Not Specified.]
◆ uuid : UUID Private Const [Is static True. Containment is Not Specified.]

ASSOCIATIONS

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)

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ATTRIBUTES

🔷 businessTherapeuticArea : Code Private

   [Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ 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 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 studyPhase (Class) Code

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

ASSOCIATIONS

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

✎ Association (direction: Source -> Destination)

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

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.]

◆ getBusinessTherapeuticArea () : 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.]

◆ 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

OPERATIONS

[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.]

🔷 setBusinessTherapeuticArea (businessTherapeuticArea : 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.]

🔷 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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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.]

◆ 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.]

OPERATIONS

◆ 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.]

◆ 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.

StudyCell
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

◆ studyArm : StudyArm Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ 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.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

◆ addStudyElement (studyElement : StudyElement) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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

◆ 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.]

OPERATIONS

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

StudyData

Class in package 'model'

StudyData
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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

[Is static True. Containment is Not Specified.]

🔷 studyEstimands : List<Estimand> Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ 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.]

◆ therapeuticArea : Code Private

[Is static True. Containment is Not Specified.]

◆ trialIntentTypes : List<Code> Private

[Is static True. Containment is Not Specified.]

◆ trialType : 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 interventionalModel (Class) Code

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

✏ Association (direction: Source -> Destination)

ASSOCIATIONS

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

🖊 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 trialIntentTypes (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) StudyDesign	Target: Private studyObjectives (Class) Objective 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 therapeuticArea (Class) Code

🖊 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private studyStudyDesignPopulations (Class) StudyDesignPopulation 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

OPERATIONS

[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.]

🔷 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.]

🔷 getTherapeuticArea () : 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 () : 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

◆ 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.]

◆ 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.]

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

OPERATIONS

◆ 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
Version 1.0 Phase 1.0 Proposed
cupke created on 10/19/2022. Last modified 10/19/2022

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) 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 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

◆ studyElementDesc : String Private

[Is static True. Containment is Not Specified.]

◆ studyElementName : String Private

[Is static True. Containment is Not Specified.]

◆ transitionEndRule : TransitionRule Private

[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

OPERATIONS
[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.]

🔶 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.

StudyEpoch
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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

ATTRIBUTES

[Is static True. Containment is Not Specified.]

◆ studyEpochName : String Private

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

OPERATIONS

🔶 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'

StudyIdentifier
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

🔷 studyIdentifier : String Private

[Is static True. Containment is Not Specified.]

🔷 studyIdentifierScope : Organization Private

[Is static True. Containment is Not Specified.]

🔷 uuid : UUID Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

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)

StudyProtocolVersion
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

ATTRIBUTES

◆ briefTitle : String Private
                          [Is static True. Containment is Not Specified.]

ATTRIBUTES

◆ 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)

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

OPERATIONS

◆ getBriefTitle () : String Public

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

◆ getOfficialTitle () : String Public

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

◆ getProtocolAmendment () : String Public

OPERATIONS

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

◆ getProtocolEffectiveDate () : Date Public

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

◆ getProtocolStatus () : Code Public

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

◆ getProtocolVersion () : String Public

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

◆ getPublicTitle () : String Public

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

◆ getScientificTitle () : String Public

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

◆ 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

[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.]

OPERATIONS
🔷 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 10/19/2022. Last modified 10/19/2022

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)	
Source: Public (Class) Encounter	Target: Private transitionStartRule (Class) TransitionRule
🖊 Association (direction: Source -> Destination)	
Source: Public (Class) Encounter	Target: Private transitionEndRule (Class) TransitionRule
🖊 Association (direction: Source -> Destination)	
Source: Public (Class) StudyElement	Target: Private transitionEndRule (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.]

OPERATIONS

◆ 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'

<div align="right">

Workflow
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

</div>

ATTRIBUTES

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

◆ 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.]

◆ getWorkFlowId () : UUID Public

OPERATIONS

[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.]

🔶 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'

WorkflowItem
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 10/19/2022. Last modified 10/19/2022

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)

ASSOCIATIONS

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

📝 Association (direction: Source -> Destination)

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

📝 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.]

OPERATIONS

◆ 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.]

OPERATIONS

◆ setWorkflowItemEncounter (workflowItemEncounter : Encounter) : void Public

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