model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
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model diagram

Class diagram in package 'model'

model
Version 1.0
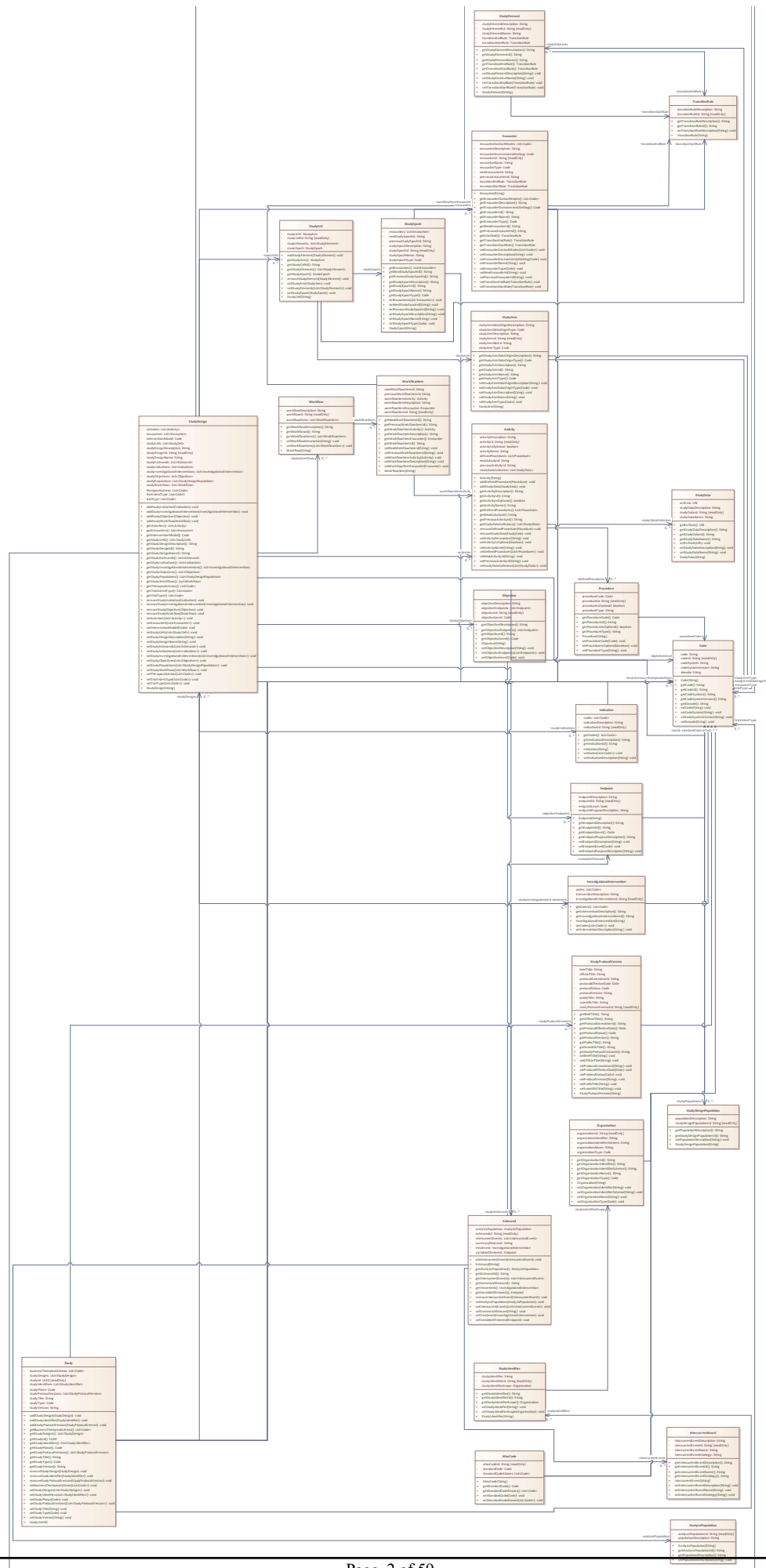cupke created on 11/28/2022. Last modified 11/28/2022

model

Package in package 'DDF'

Figure 1: model

Activity

Class in package 'model'

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

Activity
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
◆ activityDescription : String Private The textual representation of the study activity. [Is static True. Containment is Not Specified.]
◆ activityId : String Private Const [Is static True. Containment is Not Specified.]
◆ activityIsOptional : boolean Private [Is static True. Containment is Not Specified.]
◆ activityName : String Private The literal identifier (i.e., distinctive designation) of the clinical study activity. [Is static True. Containment is Not Specified.]
◆ definedProcedures : List<Procedure> Private [Is static True. Containment is Not Specified.]
◆ nextActivityId : String Private A system identifier assigned to a study activity that occurs immediately after the current study activity. [Is static True. Containment is Not Specified.]
◆ previousActivityId : String Private A system identifier assigned to a study activity that occurs immediately prior to the current study activity. [Is static True. Containment is Not Specified.]
◆ studyDataCollection : List<StudyData> Private

ATTRIBUTES

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class) Activity

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

OPERATIONS

🔶 Activity (activityId : String) : Public

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

🔶 addDefinedProcedure (procedure : Procedure) : void Public

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

🔶 addStudyData (studyData : StudyData) : void Public

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

🔶 getActivityDescription () : String Public

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

🔶 getActivityId () : String Public

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

OPERATIONS

getActivityIsOptional () : boolean 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 () : String Public

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

getPreviousActivityId () : String Public

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

getStudyDataCollection () : List<StudyData> 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.]

setActivityDescription (description : String) : void Public

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

setActivityIsOptional (activityIsOptional : boolean) : 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 : String) : void Public

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

OPERATIONS

🔷 setPreviousActivityId (previousActivityId : String) : 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.]

AliasCode

Class in package 'model'

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

AliasCode
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔷 aliasCodeId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 standardCode : Code Private

[Is static True. Containment is Not Specified.]

🔷 standardCodeAliases : List<Code> Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

OPERATIONS

🔷 AliasCode (aliasCodeId : String) : Public

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

OPERATIONS
⬦ getStandardCode () : Code Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
⬦ getStandardCodeAliases () : List<Code> Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
⬦ setStandardCode (standardCode : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
⬦ setStandardCodeAliases (standardCodeAliases : List<Code>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

AnalysisPopulation

Class in package 'model'

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

AnalysisPopulation
Version 1.0 Phase 1.0 Proposed
cupke created on 11/28/2022. Last modified 11/28/2022

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

ASSOCIATIONS
✎ Association (direction: Source -> Destination)
Source: Public (Class) Estimand   Target: Private analysisPopulation (Class) AnalysisPopulation

OPERATIONS
⬦ AnalysisPopulation (analysisPopulationId : String) : Public

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

🔶 getAnalysisPopulationId () : String Public

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

🔶 getPopulationDescription () : String Public

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

🔶 setPopulationDescription (populationDescription : String) : void Public

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

Code

Class in package 'model'

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

Code
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔶 code : String Private

The literal value of a code.

[Is static True. Containment is Not Specified.]

🔶 codeId : String Private Const

[Is static True. Containment is Not Specified.]

🔶 codeSystem : String Private

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

[Is static True. Containment is Not Specified.]

🔶 codeSystemVersion : String Private

The version of the code system.

[Is static True. Containment is Not Specified.]

🔶 decode : String Private

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

ATTRIBUTES

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionModel (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Indication

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)	
Source: Public (Class) Encounter	Target: Private encounterEnvironmentalSetting (Class) Code

✏ Association (direction: Source -> Destination)	
Source: Public (Class) Organization	Target: Private organizationType (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 businessTherapeuticAreas (Class) Code Cardinality: [0..*]

✏ Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private trialType (Class) Code Cardinality: [0..*]

✏ Association (direction: Source -> Destination)	
Source: Public (Class) AliasCode	Target: Private standardCode (Class) Code

✏ Association (direction: Source -> Destination)	
Source: Public (Class) AliasCode	Target: Private standardCodeAliases (Class) Code Cardinality: [0..*]

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

✏ Association (direction: Source -> Destination)	
Source: Public (Class) Encounter	Target: Private encounterType (Class) Code

ASSOCIATIONS

✏ 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) Procedure   Target: Private procedureCode (Class) Code

✏ Association (direction: Source -> Destination)

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

OPERATIONS

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

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

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

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

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

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

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

🔷 setCodeSystem (codeSystem : String) : void Public

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

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

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

Encounter

Class in package 'model'

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

Encounter
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ATTRIBUTES

encounterContactModes : List<Code> Private

The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).
[Is static True. Containment is Not Specified.]

encounterDescription : String Private

The textual representation of the protocol-defined clinical encounter.
[Is static True. Containment is Not Specified.]

encounterEnvironmentalSetting : Code Private

The environment/setting where the event, intervention, or finding occurred.
[Is static True. Containment is Not Specified.]

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

encounterName : String Private

The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.
[Is static True. Containment is Not Specified.]

ATTRIBUTES

encounterType : Code Private

A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed.

[Is static True. Containment is Not Specified.]

nextEncounterId : String Private

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

[Is static True. Containment is Not Specified.]

previousEncounterId : String Private

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

[Is static True. Containment is Not Specified.]

transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

transitionStartRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class) TransitionRule

Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

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✏ Association (direction: Source -> Destination)

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

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✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

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

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

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

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

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

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

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

OPERATIONS

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

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

⬢ getStartRule () : TransitionRule Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ getTransitionEndRule () : TransitionRule Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ getTransitionStartRule () : TransitionRule Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setEncounterContactModes (encounterContactModes : List<Code>) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setEncounterDescription (encounterDescription : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setEncounterEnvironmentalSetting (encounterEnvironmentalSetting : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setEncounterName (encounterName : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setEncounterType (encounterType : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setNextEncounterId (nextEncounterId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setPreviousEncounterId (previousEncounterId : String) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

⬢ setTransitionEndRule (transitionEndRule : TransitionRule) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS
◆ setTransitionStartRule (transitionStartRule : TransitionRule) : void Public
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

Endpoint

Class in package 'model'

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

Endpoint
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

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

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

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

OPERATIONS

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

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

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

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

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

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

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

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

Estimand

Class in package 'model'

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

Estimand

ATTRIBUTES

◆ analysisPopulation : AnalysisPopulation Private

[Is static True. Containment is Not Specified.]

◆ estimandId : String Private Const

[Is static True. Containment is Not Specified.]

◆ intercurrentEvents : List<IntercurrentEvent> Private

[Is static True. Containment is Not Specified.]

◆ summaryMeasure : String Private

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

[Is static True. Containment is Not Specified.]

◆ treatment : InvestigationalIntervention Private

[Is static True. Containment is Not Specified.]

◆ variableOfInterest : Endpoint Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ 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 analysisPopulation (Class)
                                                   AnalysisPopulation

✎ Association (direction: Source -> Destination)

ASSOCIATIONS

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

✏ Association (direction: Source -> Destination)

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

OPERATIONS

🔶 addIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

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

🔶 Estimand (estimandId : String) : Public

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

🔶 getAnalysisPopulation () : AnalysisPopulation Public

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

🔶 getEstimandId () : String Public

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

🔶 getIntercurrentEvents () : List<IntercurrentEvent> Public

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

🔶 getSummaryMeasure () : String Public

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

🔶 getTreatment () : InvestigationalIntervention Public

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

🔶 getVariableOfInterest () : Endpoint Public

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

🔶 removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

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

🔶 setAnalysisPopulation (analysisPopulation : AnalysisPopulation) : void Public

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

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

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

OPERATIONS

◈ setSummaryMeasure (summaryMeasure : String) : void Public

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

◈ setTreatment (treatment : InvestigationalIntervention) : void Public

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

◈ setVariableOfInterest (variableOfInterest : Endpoint) : void Public

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

Indication

Class in package 'model'

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

Indication
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ATTRIBUTES

◆ codes : List<Code> Private

A short sequence of characters that represents the disease indication.

[Is static True. Containment is Not Specified.]

◆ indicationDescription : String Private

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

[Is static True. Containment is Not Specified.]

◆ indicationId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

🔶 getCodes () : List<Code> Public

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

🔶 getIndicationDescription () : String Public

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

🔶 getIndicationId () : String Public

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

🔶 Indication (indicationId : String) : Public

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

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

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

🔶 setIndicationDescription (indicationDescription : String) : void Public

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

IntercurrentEvent

Class in package 'model'

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

IntercurrentEvent
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔷 intercurrentEventDescription : String Private

The textual representation of the intercurrent event.

[Is static True. Containment is Not Specified.]

🔷 intercurrentEventId : String Private Const

[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 intercurrentEventName : String Private

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

[Is static True. Containment is Not Specified.]

🔷 intercurrentEventStrategy : String Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private intercurrentEvents (Class) IntercurrentEvent

Cardinality: [0..*]

OPERATIONS

🔷 getIntercurrentEventDescription () : String Public

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

🔷 getIntercurrentEventId () : String Public

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

🔷 getIntercurrentEventName () : String Public

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

🔷 getIntercurrentEventStrategy () : String Public

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

🔷 IntercurrentEvent (intercurrentEventId : String) : Public

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

🔷 setIntercurrentEventDescription (intercurrentEventDescription : String) : void Public

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

🔷 setIntercurrentEventName (intercurrentEventName : String) : void Public

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

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

InvestigationalIntervention

Class in package 'model'

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

InvestigationalIntervention
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

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

ASSOCIATIONS
✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private studyInvestigationalInterventions

ASSOCIATIONS
(Class) InvestigationalIntervention Cardinality: [0..*]

OPERATIONS

🔷 getCodes () : List<Code> Public

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

🔷 getInterventionDescription () : String Public

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

🔷 getInvestigationalInterventionId () : String Public

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

🔷 InvestigationalIntervention (investigationalInterventionId : String) : Public

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

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

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

🔷 setInterventionDescription (interventionDescription : String) : void Public

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

Objective

Class in package 'model'

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

Objective
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

🔷 objectiveDescription : String Private

The textual representation of the study objective. (BRIDG)

[Is static True. Containment is Not Specified.]

🔷 objectiveEndpoints : List<Endpoint> Private

[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔹 objectiveId : String Private Const

[Is static True. Containment is Not Specified.]

🔹 objectiveLevel : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

OPERATIONS

🔹 getObjectiveDescription () : String Public

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

🔹 getObjectiveEndpoints () : List<Endpoint> Public

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

🔹 getObjectiveId () : String Public

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

🔹 getObjectiveLevel () : Code Public

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

🔹 Objective (objectiveId : String) : Public

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

OPERATIONS

◆ setObjectiveDescription (objectiveDescription : String) : void Public

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

◆ setObjectiveEndpoints (objectiveEndpoints : List<Endpoint>) : void Public

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

◆ setObjectiveLevel (objectiveLevel : Code) : void Public

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

Organization

Class in package 'model'

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

Organization
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ATTRIBUTES

◆ organizationId : String Private Const

[Is static True. Containment is Not Specified.]

◆ organizationIdentifier : String Private

A unique symbol that establishes identity of the organization. (BRIDG)

[Is static True. Containment is Not Specified.]

◆ organizationIdentifierScheme : String Private

The name of the organization that provides the identifier for the entity.

[Is static True. Containment is Not Specified.]

◆ organizationName : String Private

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

[Is static True. Containment is Not Specified.]

◆ organizationType : Code Private

A characterization or classification of the formalized group of persons or other organizations collected together for a common

ATTRIBUTES

purpose (such as administrative, legal, political) and the infrastructure to carry out that purpose.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◈ getOrganizationId () : String Public

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

◈ getOrganizationIdentifier () : String Public

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

◈ getOrganizationIdentifierScheme () : String Public

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

◈ getOrganizationName () : String Public

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

◈ getOrganizationType () : Code Public

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

◈ Organization (organizationId : String) : Public

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

◈ setOrganizationIdentifier (organizationIdentifier : String) : void Public

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

◈ setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public

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

◈ setOrganizationName (organizationName : String) : void Public

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

🔮 setOrganizationType (organizationType : Code) : void Public

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

Procedure

Class in package 'model'

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

Procedure
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES

🔷 procedureCode : Code Private

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

[Is static True. Containment is Not Specified.]

🔷 procedureId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 procedureIsOptional : boolean Private

[Is static True. Containment is Not Specified.]

🔷 procedureType : String Private

A characterization or classification of the study procedure.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

ASSOCIATIONS

OPERATIONS

getProcedureCode () : Code Public

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

getProcedureId () : String Public

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

getProcedureIsOptional () : boolean Public

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

getProcedureType () : String Public

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

Procedure (procedureId : String) : Public

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

setProcedureCode (procedureCode : Code) : void Public

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

setProcedureIsOptional (procedureIsOptional : boolean) : 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)

Study
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ATTRIBUTES

businessTherapeuticAreas : List<Code> Private

ATTRIBUTES

A therapeutic area classification based on the structure and operations of the business unit.

[Is static True. Containment is Not Specified.]

🔷 studyDesigns : List<StudyDesign> Private

[Is static True. Containment is Not Specified.]

🔷 studyId : UUID Private Const

[Is static True. Containment is Not Specified.]

🔷 studyIdentifiers : List<StudyIdentifier> Private

[Is static True. Containment is Not Specified.]

🔷 studyPhase : Code Private

A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]

[Is static True. Containment is Not Specified.]

🔷 studyProtocolVersions : List<StudyProtocolVersion> Private

[Is static True. Containment is Not Specified.]

🔷 studyTitle : String Private

The sponsor-defined name of the clinical study.

[Is static True. Containment is Not Specified.]

🔷 studyType : Code Private

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

[Is static True. Containment is Not Specified.]

🔷 studyVersion : String Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyIdentifiers (Class)

ASSOCIATIONS

| | StudyIdentifier |
| | Cardinality: [0..*] |

✏️ Association (direction: Source -> Destination)

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

---

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private studyProtocolVersions (Class) StudyProtocolVersion
                                                       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

OPERATIONS

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

⬢ getStudyId () : UUID Public

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

⬢ getStudyIdentifiers () : List<StudyIdentifier> Public

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

⬢ getStudyPhase () : 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.]

⬢ 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.

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

ATTRIBUTES

The textual representation of the study arm.

[Is static True. Containment is Not Specified.]

studyArmId : String Private Const

[Is static True. Containment is Not Specified.]

studyArmName : String Private

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

[Is static True. Containment is Not Specified.]

studyArmType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

OPERATIONS

getStudyArmDataOriginDescription () : String Public

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

getStudyArmDataOriginType () : Code Public

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

getStudyArmDescription () : String Public

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

OPERATIONS

🔷 getStudyArmId () : String Public

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

🔷 getStudyArmName () : String Public

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

🔷 getStudyArmType () : Code Public

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

🔷 setStudyArmDataOriginDescription (studyArmDataOriginDescription : String) : void Public

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

🔷 setStudyArmDataOriginType (studyArmDataOriginType : Code) : void Public

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

🔷 setStudyArmDescription (studyArmDescription : String) : void Public

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

🔷 setStudyArmName (studyArmName : String) : void Public

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

🔷 setStudyArmType (studyArmType : Code) : void Public

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

🔷 StudyArm (studyArmId : String) : Public

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

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.]

ATTRIBUTES

🔹 studyCellId : String Private Const

[Is static True. Containment is Not Specified.]

🔹 studyElements : List<StudyElement> Private

[Is static True. Containment is Not Specified.]

🔹 studyEpoch : StudyEpoch Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 addStudyElement (studyElement : StudyElement) : void Public

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

🔷 getStudyArm () : StudyArm Public

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

🔷 getStudyCellId () : String Public

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

OPERATIONS

⬢ getStudyElements () : List<StudyElement> Public

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

⬢ getStudyEpoch () : StudyEpoch Public

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

⬢ removeStudyElement (studyElement : StudyElement) : void Public

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

⬢ setStudyArm (studyArm : StudyArm) : void Public

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

⬢ setStudyElements (studyElements : List<StudyElement>) : void Public

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

⬢ setStudyEpoch (studyEpoch : StudyEpoch) : void Public

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

⬢ StudyCell (studyCellId : String) : Public

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

StudyData

Class in package 'model'

Data collected in the course of a clinical study.

StudyData
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

◆ ecrfLink : URI Private

The uniform resource locator used to access the digital case report form.

[Is static True. Containment is Not Specified.]

◆ studyDataDescription : String Private

The textual representation of the study data.

[Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 studyDataId : String Private Const

[Is static True. Containment is Not Specified.]

🔷 studyDataName : String Private

The literal identifier (i.e., distinctive designation) for the study data.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Activity

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

OPERATIONS

🔷 getEcrfLink () : URI Public

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

🔷 getStudyDataDescription () : String Public

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

🔷 getStudyDataId () : 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.]

🔷 setEcrfLink (ecrfLink : URI) : void Public

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

🔷 setStudyDataDescription (studyDataDescription : 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 : String) : Public

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

OPERATIONS

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.

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ATTRIBUTES
◆ activities : List<Activity> Private [Is static True. Containment is Not Specified.]
◆ encounters : List<Encounter> Private [Is static True. Containment is Not Specified.]
◆ interventionModel : Code Private The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov) [Is static True. Containment is Not Specified.]
◆ studyCells : List<StudyCell> Private [Is static True. Containment is Not Specified.]
◆ studyDesignDescription : String Private The textual representation of the study design. [Is static True. Containment is Not Specified.]
◆ studyDesignId : String Private Const [Is static True. Containment is Not Specified.]
◆ studyDesignName : String Private The literal identifier (i.e., distinctive designation) of the study design. [Is static True. Containment is Not Specified.]
◆ 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.]

◆ studyPopulations : List<StudyDesignPopulation> Private

[Is static True. Containment is Not Specified.]

◆ studyWorkflows : List<Workflow> Private

[Is static True. Containment is Not Specified.]

◆ therapeuticAreas : List<Code> Private

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

[Is static True. Containment is Not Specified.]

◆ trialIntentType : List<Code> Private

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

[Is static True. Containment is Not Specified.]

◆ trialType : List<Code> Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign	Target: Private studyObjectives (Class) Objective 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.]
🔷 getActivities () : List<Activity> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getEncounters () : List<Encounter> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getInterventionModel () : Code Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔷 getStudyCells () : List<StudyCell> Public

OPERATIONS

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

⬢ getStudyDesignDescription () : String Public

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

⬢ getStudyDesignId () : String Public

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

⬢ getStudyDesignName () : String Public

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

⬢ getStudyEstimands () : List<Estimand> Public

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

⬢ getStudyIndications () : List<Indication> Public

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

⬢ getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public

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

⬢ getStudyObjectives () : List<Objective> Public

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

⬢ getStudyPopulations () : List<StudyDesignPopulation> Public

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

⬢ getStudyWorkflows () : List<Workflow> Public

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

⬢ getTherapeuticAreas () : List<Code> Public

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

⬢ getTrialIntentType () : List<Code> Public

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

⬢ getTrialType () : List<Code> Public

[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.]

OPERATIONS

removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention) : void Public

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

removeStudyObjective (objective : Objective) : void Public

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

removeStudyWorkflow (workflow : Workflow) : void Public

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

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

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

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

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

setInterventionModel (interventionModel : Code) : void Public

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

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

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

setStudyDesignDescription (studyDesignDescription : String) : void Public

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

setStudyDesignName (studyDesignName : String) : void Public

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

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

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

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

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

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

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

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

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

OPERATIONS

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

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

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

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

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

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

StudyDesignPopulation

Class in package 'model'

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

> StudyDesignPopulation
> Version 1.0 Phase 1.0 Proposed
> cupke created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

◆ populationDescription : String Private

The textual representation of the study population.
> [Is static True. Containment is Not Specified.]

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

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

ASSOCIATIONS
StudyDesignPopulation Cardinality: [0..*]

OPERATIONS
🔶 getPopulationDescription () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 getStudyDesignPopulationId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 setPopulationDescription (populationDescription : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
🔶 StudyDesignPopulation (uuid : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyElement

Class in package 'model'

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

StudyElement
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES
🔶 studyElementDescription : String Private The textual representation of the study design element. [Is static True. Containment is Not Specified.]
🔶 studyElementId : String Private Const element only attributes - these purely describe an element [Is static True. Containment is Not Specified.]
🔶 studyElementName : String Private The literal identifier (i.e., distinctive designation) of the study design element. [Is static True. Containment is Not Specified.]

ATTRIBUTES

🔷 transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

🔷 transitionStartRule : TransitionRule Private

all elements point to transition rules

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement   Target: Private 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

🔷 getStudyElementDescription () : String Public

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

🔷 getStudyElementId () : String Public

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

🔷 getStudyElementName () : String Public

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

🔷 getTransitionEndRule () : TransitionRule Public

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

🔷 getTransitionStartRule () : TransitionRule Public

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

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

StudyEpoch

Class in package 'model'

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

StudyEpoch
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

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

ATTRIBUTES

The textual representation of the study epoch.

[Is static True. Containment is Not Specified.]

◆ studyEpochId : String Private Const

[Is static True. Containment is Not Specified.]

◆ studyEpochName : String Private

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

[Is static True. Containment is Not Specified.]

◆ studyEpochType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◆ getEncounters () : List<Encounter> Public

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

◆ getNextStudyEpochId () : String Public

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

◆ getPreviousStudyEpochId () : String Public

OPERATIONS

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

🔷 getStudyEpochDescription () : String Public

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

🔷 getStudyEpochId () : String Public

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

🔷 getStudyEpochName () : String Public

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

🔷 getStudyEpochType () : Code Public

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

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

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

🔷 setNextStudyEpochId (nextStudyEpochId : String) : void Public

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

🔷 setPreviousStudyEpochId (previousStudyEpochId : String) : void Public

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

🔷 setStudyEpochDescription (studyEpochDescription : String) : void Public

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

🔷 setStudyEpochName (studyEpochName : String) : void Public

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

🔷 setStudyEpochType (studyEpochType : Code) : void Public

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

🔷 StudyEpoch (studyEpochId : String) : Public

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

StudyIdentifier

Class in package 'model'

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

StudyIdentifier
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

◆ studyIdentifier : String Private

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

[Is static True. Containment is Not Specified.]

◆ studyIdentifierId : String Private Const

[Is static True. Containment is Not Specified.]

◆ studyIdentifierScope : Organization Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

OPERATIONS

◆ getStudyIdentifier () : String Public

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

◆ getStudyIdentifierId () : String Public

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

◆ getStudyIdentifierScope () : Organization Public

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

◆ setStudyIdentifier (studyIdentifier : String) : void Public

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

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

StudyProtocolVersion

Class in package 'model'

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

<div align="right">

StudyProtocolVersion
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

</div>

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

ATTRIBUTES

🔷 protocolVersion : String Private

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

[Is static True. Containment is Not Specified.]

🔷 publicTitle : String Private

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

[Is static True. Containment is Not Specified.]

🔷 scientificTitle : String Private

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

[Is static True. Containment is Not Specified.]

🔷 studyProtocolVersionId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 getBriefTitle () : String Public

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

🔷 getOfficialTitle () : String Public

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

🔷 getProtocolAmendment () : String Public

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

OPERATIONS

◆ getProtocolEffectiveDate () : Date Public

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

◆ getProtocolStatus () : Code Public

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

◆ getProtocolVersion () : String Public

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

◆ getPublicTitle () : String Public

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

◆ getScientificTitle () : String Public

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

◆ getStudyProtocolVersionId () : String Public

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

◆ setBriefTitle (briefTitle : String) : void Public

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

◆ setOfficialTitle (officialTitle : String) : void Public

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

◆ setProtocolAmendment (protocolAmendment : String) : void Public

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

◆ setProtocolEffectiveDate (protocolEffectiveDate : Date) : void Public

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

◆ setProtocolStatus (protocolStatus : Code) : void Public

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

◆ setProtocolVersion (protocolVersion : String) : void Public

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

◆ setPublicTitle (publicTitle : String) : void Public

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

◆ setScientificTitle (scientificTitle : String) : void Public

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

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

TransitionRule

Class in package 'model'

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

TransitionRule
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

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

🔷 transitionRuleId : String Private Const
[Is static True. Containment is Not Specified.]

ASSOCIATIONS
✏ Association (direction: Source -> Destination)
Source: Public (Class) StudyElement   Target: Private transitionEndRule (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 transitionStartRule (Class) TransitionRule

✏ Association (direction: Source -> Destination)

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

OPERATIONS

🔷 getTransitionRuleDescription () : String Public

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

🔷 getTransitionRuleId () : String Public

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

🔷 setTransitionRuleDescription (transitionRuleDescription : String) : void Public

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

🔷 TransitionRule (ruleId : String) : Public

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

Workflow

Class in package 'model'

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

Workflow
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

🔷 workflowDescription : String Private

The textual representation of the workflow.

　　　　　　[Is static True. Containment is Not Specified.]

🔷 workflowId : String Private Const

　　　　　　[Is static True. Containment is Not Specified.]

🔷 workflowItems : List<WorkflowItem> Private

The textual representation of the workflow item.

　　　　　　[Is static True. Containment is Not Specified.]

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Workflow

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

OPERATIONS

🔷 getWorkflowDescription () : String Public

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

🔷 getWorkflowId () : String Public

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

🔷 getWorkflowItems () : List<WorkflowItem> Public

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

🔷 setWorkflowDescription (workflowDescription : String) : void Public

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

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

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

🔷 Workflow (workFlowUUID : String) : Public

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

WorkflowItem

Class in package 'model'

WorkflowItem
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 11/28/2022. Last modified 11/28/2022

ATTRIBUTES

🔷 nextWorkflowItemId : String Private

ATTRIBUTES

A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item.

[Is static True. Containment is Not Specified.]

◆ previousWorkflowItemId : String Private

A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item.

[Is static True. Containment is Not Specified.]

◆ workflowItemActivity : Activity Private

[Is static True. Containment is Not Specified.]

◆ workflowItemDescription : String Private

The textual representation of the workflow item.

[Is static True. Containment is Not Specified.]

◆ workflowItemEncounter : Encounter Private

[Is static True. Containment is Not Specified.]

◆ workflowItemId : String Private Const

[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 () : String Public

OPERATIONS

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

◈ getPreviousWorkflowItemId () : String Public

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

◈ getWorkflowItemActivity () : Activity Public

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

◈ getWorkflowItemDescription () : String Public

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

◈ getWorkflowItemEncounter () : Encounter Public

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

◈ getWorkflowItemId () : String Public

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

◈ setNextWorkflowItemId (nextWorkflowItemId : String) : void Public

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

◈ setPreviousWorkflowItemId (previousWorkflowItemId : String) : void Public

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

◈ setWorkflowItemActivity (workflowItemActivity : Activity) : void Public

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

◈ setWorkflowItemDescription (workflowItemDescription : String) : void Public

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

◈ setWorkflowItemEncounter (workflowItemEncounter : Encounter) : void Public

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

◈ WorkflowItem (workflowItemId : String) : Public

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