

model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
cupke created on 12/13/2022. Last modified 12/13/2022

model diagram

Class diagram in package 'model'

model
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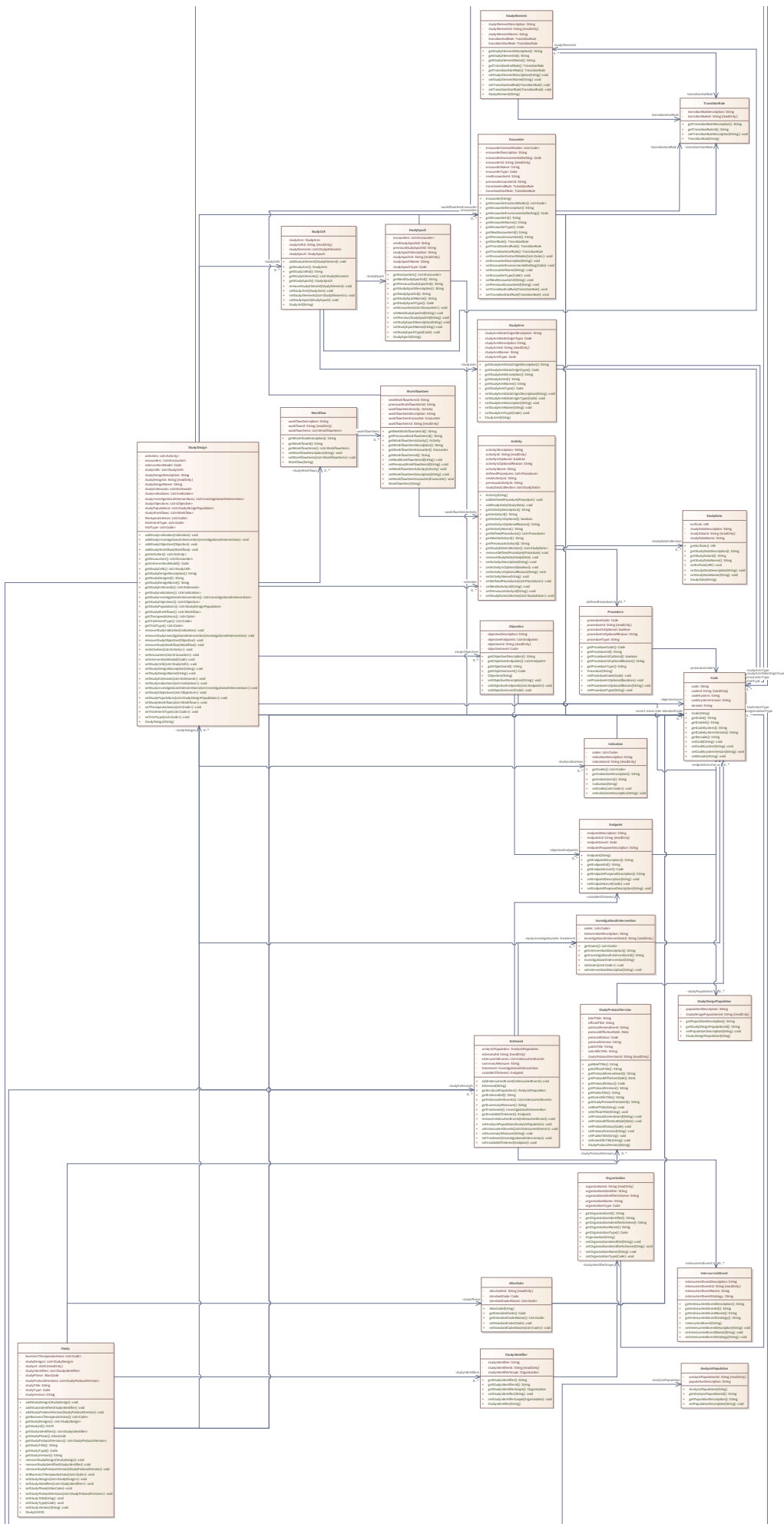


Figure 1: model

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.]
 activityIsOptionalReason : String Private	[Is static True. Containment is Not Specified.]
 activityName : String Private The literal identifier (i.e., distinctive designation) of the clinical study activity.	[Is static True. Containment is Not Specified.]
 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.	

ATTRIBUTES

[Is static True. Containment is Not Specified.]

 studyDataCollection : List<StudyData> Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS
 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private studyDataCollection (Class)
StudyData

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private definedProcedures (Class)
Procedure

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity


Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class)
Activity**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.]

OPERATIONS
 getActivityId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getActivityIsOptional () : boolean Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getActivityIsOptionalReason () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getActivityName () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getDefinedProcedures () : List<Procedure> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getNextActivityId () : 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.]
 setActivityIsOptionalReason (activityIsOptionalReason : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

OPERATIONS

-  **setActivityName (activityName : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **setDefinedProcedures (definedProcedures : List<Procedure>) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **setNextActivityId (nextActivityId : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **setPreviousActivityId (previousActivityId : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **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 standardCodeAliases (Class) Code
Cardinality: [0..*]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyPhase (Class) AliasCode


OPERATIONS

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

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

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

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

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

AnalysisPopulation


Class in package 'model'

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

AnalysisPopulation
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ATTRIBUTES

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

 populationDescription : String Private

ATTRIBUTES

The textual representation of the study population for analysis.

[Is static True. Containment is Not Specified.]


ASSOCIATIONS

 Association (direction: Source -> Destination)


Source: Public (Class) Estimand

Target: Private analysisPopulation (Class)
AnalysisPopulation


OPERATIONS

 AnalysisPopulation (analysisPopulationId : String) : Public


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

 getAnalysisPopulationId () : String Public

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

 getPopulationDescription () : String Public

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

 setPopulationDescription (populationDescription : String) : void Public

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

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.]

ATTRIBUTES

 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.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

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

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private interventionModel (Class) Code

 Association (direction: Source -> Destination)






Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

ASSOCIATIONS		
 Association (direction: Source -> Destination)		
Source: Public (Class) InvestigationalIntervention		Target: Private codes (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) Study		Target: Private businessTherapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private therapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) Study		Target: Private studyType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Indication		Target: Private codes (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) Procedure		Target: Private procedureCode (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Objective		Target: Private objectiveLevel (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 trialType (Class) Code
Cardinality: [0..*]
 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationType (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) Encounter

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


Source: Public (Class) StudyArm

Target: Private studyArmDataOriginType (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.]




OPERATIONS
 <code>getDecode () : String Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setCode (code : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setCodeSystem (codeSystem : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setCodeSystemVersion (codeSystemVersion : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setDecode (decode : String) : void Public</code> [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
 <code>encounterContactModes : List<Code> Private</code> 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.]
 <code>encounterDescription : String Private</code> The textual representation of the protocol-defined clinical encounter. [Is static True. Containment is Not Specified.]
 <code>encounterEnvironmentalSetting : Code Private</code> The environment/setting where the event, intervention, or finding occurred. [Is static True. Containment is Not Specified.]

ATTRIBUTES


 encounterId : String Private Const

[Is static True. Containment is Not Specified.]

 encounterName : String Private

The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.

[Is static True. Containment is Not Specified.]

 encounterType : Code Private


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

[Is static True. Containment is Not Specified.]

 nextEncounterId : String Private


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

[Is static True. Containment is Not Specified.]


 previousEncounterId : String Private

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

[Is static True. Containment is Not Specified.]

 transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

 transitionStartRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting
(Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemEncounter (Class)
Encounter

 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.]

OPERATIONS	
 <code>getEncounterId () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getEncounterName () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getEncounterType () : Code Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getNextEncounterId () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getPreviousEncounterId () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getStartRule () : TransitionRule Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getTransitionEndRule () : TransitionRule Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getTransitionStartRule () : TransitionRule Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setEncounterContactModes (encounterContactModes : List<Code>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setEncounterDescription (encounterDescription : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setEncounterEnvironmentalSetting (encounterEnvironmentalSetting : Code) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setEncounterName (encounterName : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setEncounterType (encounterType : Code) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setNextEncounterId (nextEncounterId : String) : void Public</code>	





OPERATIONS	
	[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.]	
 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
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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) Objective


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

 Association (direction: Source -> Destination)


Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint


OPERATIONS

 Endpoint (endpointId : String) : Public


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

 getEndpointDescription () : String Public

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

 getEndpointId () : String Public


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

 getEndpointLevel () : Code Public


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

 getEndpointPurposeDescription () : String Public


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

 setEndpointDescription (endpointDescription : String) : void Public

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

 setEndpointLevel (endpointLevel : Code) : void Public

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

 setEndpointPurposeDescription (endpointPurposeDescription : String) : void Public

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

Estimand







Class in package 'model'



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

Estimand

Version 1.0 Phase 1.0 Proposed

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ATTRIBUTES	
 analysisPopulation : AnalysisPopulation Private	[Is static True. Containment is Not Specified.]
 estimandId : String Private Const	[Is static True. Containment is Not Specified.]
 intercurrentEvents : List<IntercurrentEvent> Private	[Is static True. Containment is Not Specified.]
 summaryMeasure : String Private A synopsis of the clinical endpoint of interest within the analysis target study population.	[Is static True. Containment is Not Specified.]
 treatment : InvestigationalIntervention Private	[Is static True. Containment is Not Specified.]
 variableOfInterest : Endpoint Private	[Is static True. Containment is Not Specified.]

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

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private treatment (Class)
InvestigationalIntervention

 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.]




OPERATIONS	
 <code>removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setAnalysisPopulation (analysisPopulation : AnalysisPopulation) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setIntercurrentEvents (intercurrentEvents : List<IntercurrentEvent>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setSummaryMeasure (summaryMeasure : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setTreatment (treatment : InvestigationalIntervention) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setVariableOfInterest (variableOfInterest : Endpoint) : void Public</code>	[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	
 <code>codes : List<Code> Private</code>	
A short sequence of characters that represents the disease indication.	[Is static True. Containment is Not Specified.]
 <code>indicationDescription : String Private</code>	
The condition, disease or disorder that the clinical trial is intended to investigate or address.	[Is static True. Containment is Not Specified.]
 <code>indicationId : String Private Const</code>	
	[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Indication


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

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

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


OPERATIONS

 getCodes () : List<Code> Public


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

 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

ATTRIBUTES

 intercurrentEventDescription : String Private

The textual representation of the intercurrent event.

[Is static True. Containment is Not Specified.]

 intercurrentEventId : String Private Const

[Is static True. Containment is Not Specified.]

 intercurrentEventName : String Private

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

[Is static True. Containment is Not Specified.]

 intercurrentEventStrategy : String Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)


Source: Public (Class) Estimand

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

OPERATIONS

 getIntercurrentEventDescription () : String Public

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

 getIntercurrentEventId () : String Public


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

 getIntercurrentEventName () : String Public

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




 getIntercurrentEventStrategy () : String Public

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

 IntercurrentEvent (intercurrentEventId : String) : Public

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

OPERATIONS

-  `setIntercurrentEventDescription (intercurrentEventDescription : String) : void Public`
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  `setIntercurrentEventName (intercurrentEventName : String) : void Public`
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  `setIntercurrentEventStrategy (intercurrentEventStrategy : String) : void Public`
[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]




InvestigationalIntervention

Class in package 'model'



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


InvestigationalIntervention
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Chris Upkes created on 12/13/2022. Last modified 12/13/2022







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)

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

OPERATIONS	
 getCodes () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getInterventionDescription () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getInvestigationalInterventionId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 InvestigationalIntervention (investigationalInterventionId : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setCodes (codes : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setInterventionDescription (interventionDescription : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

Objective


Class in package 'model'

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

Objective

Version 1.0 Phase 1.0 Proposed


Chris Upkes created on 12/13/2022. Last modified 12/13/2022

ATTRIBUTES	
 objectiveDescription : String Private	


ATTRIBUTES

The textual representation of the study objective. (BRIDG)

[Is static True. Containment is Not Specified.]

 objectiveEndpoints : List<Endpoint> Private

[Is static True. Containment is Not Specified.]

 objectiveId : String Private Const

[Is static True. Containment is Not Specified.]

 objectiveLevel : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Objective

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

 Association (direction: Source -> Destination)

Source: Public (Class) Objective


Target: Private objectiveLevel (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

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


OPERATIONS

 getObjectiveDescription () : String Public

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

 getObjectiveEndpoints () : List<Endpoint> Public

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

 getObjectiveId () : String Public

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





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

Organization

Class in package 'model'

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


Organization
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
 <code>organizationId : String Private Const</code> [Is static True. Containment is Not Specified.]
 <code>organizationIdentifier : String Private</code> A unique symbol that establishes identity of the organization. (BRIDG) [Is static True. Containment is Not Specified.]
 <code>organizationIdentifierScheme : String Private</code> The name of the organization that provides the identifier for the entity. [Is static True. Containment is Not Specified.]
 <code>organizationName : String Private</code>

ATTRIBUTES

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

[Is static True. Containment is Not Specified.]

 organizationType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Organization


Target: Private organizationType (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) 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






OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setOrganizationName (organizationName : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setOrganizationType (organizationType : Code) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

Procedure

Class in package 'model'

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

Procedure
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/13/2022. Last modified 12/13/2022

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.]	
 procedureIsOptionalReason : String Private [Is static True. Containment is Not Specified.]	
 procedureType : String Private A characterization or classification of the study procedure. [Is static True. Containment is Not Specified.]	

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Procedure

Target: Private procedureCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Activity


Target: Private definedProcedures (Class)
Procedure

Cardinality: [0..*]


OPERATIONS

 getProcedureCode () : Code Public


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

 getProcedureId () : String Public

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

 getProcedureIsOptional () : boolean Public


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

 getProcedureIsOptionalReason () : String Public


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

 getProcedureType () : String Public


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

 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.]

 setProcedureIsOptionalReason (procedureIsOptionalReason : String) : void Public

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

 setProcedureType (procedureType : String) : void Public

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

OPERATIONS

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. [\[\[http://ClinicalTrials.gov\]\]](http://ClinicalTrials.gov)(CDISC Glossary)

Study

Version 1.0 Phase 1.0 Proposed


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ATTRIBUTES

 businessTherapeuticAreas : List<Code> Private

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

[Is static True. Containment is Not Specified.]

 studyDesigns : List<StudyDesign> Private


[Is static True. Containment is Not Specified.]

 studyId : UUID Private Const

[Is static True. Containment is Not Specified.]


 studyIdentifiers : List<StudyIdentifier> Private

[Is static True. Containment is Not Specified.]


 studyPhase : AliasCode Private

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

[Is static True. Containment is Not Specified.]

 studyProtocolVersions : List<StudyProtocolVersion> Private


[Is static True. Containment is Not Specified.]

 studyTitle : String Private

The sponsor-defined name of the clinical study.


[Is static True. Containment is Not Specified.]

ATTRIBUTES

 studyType : Code Private

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

[Is static True. Containment is Not Specified.]

 studyVersion : String Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyPhase (Class) AliasCode

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)

StudyProtocolVersion

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private businessTherapeuticAreas (Class)

Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

 Association (direction: Source -> Destination)














Source: Public (Class) Study












Target: Private studyIdentifiers (Class)

StudyIdentifier

Cardinality: [0..*]

OPERATIONS

OPERATIONS
 addStudyDesign (studyDesign : StudyDesign) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 addStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getBusinessTherapeuticAreas () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyDesigns () : List<StudyDesign> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyId () : UUID Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyIdentifiers () : List<StudyIdentifier> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyPhase () : AliasCode Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyProtocolVersions () : List<StudyProtocolVersion> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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.]

OPERATIONS	
 <code>removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyDesigns (studyDesigns : List<StudyDesign>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyIdentifiers (studyIdentifiers : List<StudyIdentifier>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyPhase (studyPhase : AliasCode) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyProtocolVersions (studyProtocolVersions : List<StudyProtocolVersion>) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyTitle (studyTitle : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyType (studyType : Code) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyVersion (studyVersion : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>Study (studyId : UUID) : Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyArm

Class in package 'model'


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

StudyArm

ATTRIBUTES
 studyArmDataOriginDescription : String Private


The textual representation of the study arm data origin.

[Is static True. Containment is Not Specified.]

 studyArmDataOriginType : Code Private


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

[Is static True. Containment is Not Specified.]


 studyArmDescription : String Private

The textual representation of the study arm.

[Is static True. Containment is Not Specified.]


 studyArmId : String Private Const

[Is static True. Containment is Not Specified.]

 studyArmName : String Private

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

[Is static True. Containment is Not Specified.]

 studyArmType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS
 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmDataOriginType (Class)
Code
 Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) StudyCell

Target: Private studyArm (Class) StudyArm

OPERATIONS

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

✦ **getStudyArmDataOriginType () : Code Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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

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

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

✦ **getStudyArmType () : Code Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **setStudyArmDataOriginDescription (studyArmDataOriginDescription : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **setStudyArmDataOriginType (studyArmDataOriginType : Code) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **setStudyArmDescription (studyArmDescription : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **setStudyArmName (studyArmName : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **setStudyArmType (studyArmType : Code) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

✦ **StudyArm (studyArmId : String) : Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

StudyCell

Class in package 'model'





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











StudyCell

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ATTRIBUTES	
 studyArm : StudyArm Private	[Is static True. Containment is Not Specified.]
 studyCellId : String Private Const	[Is static True. Containment is Not Specified.]
 studyElements : List<StudyElement> Private	[Is static True. Containment is Not Specified.]
 studyEpoch : StudyEpoch Private	[Is static True. Containment is Not Specified.]

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

OPERATIONS
 addStudyElement (studyElement : StudyElement) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyArm () : StudyArm Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyCellId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyElements () : List<StudyElement> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyEpoch () : StudyEpoch Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 removeStudyElement (studyElement : StudyElement) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyArm (studyArm : StudyArm) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyElements (studyElements : List<StudyElement>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyEpoch (studyEpoch : StudyEpoch) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 StudyCell (studyCellId : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]


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 12/13/2022. Last modified 12/13/2022

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.]

 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.]







OPERATIONS
 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.]











StudyDesign

Class in package 'model'

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

StudyDesign
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ATTRIBUTES
 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

ATTRIBUTES	
	[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.]
 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 studyIndications (Class) Indication
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 interventionModel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private trialIntentType (Class) Code
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 studyInvestigationalInterventions
(Class) InvestigationalIntervention

ASSOCIATIONS

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 trialType (Class) Code

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 studyEstimands (Class) Estimand

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.]

OPERATIONS
 getEncounters () : List<Encounter> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getInterventionModel () : Code Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyCells () : List<StudyCell> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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.]

OPERATIONS
 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.]
 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.]


OPERATIONS	
 setStudyIndications (studyIndications : List<Indication>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyInvestigationalInterventions (studyInvestigationalInterventions : List<InvestigationalIntervention>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyObjectives (studyObjectives : List<Objective>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyWorkflows (studyWorkflows : List<Workflow>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setTherapeuticAreas (therapeuticAreas : List<Code>) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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 12/13/2022. Last modified 12/13/2022

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


ATTRIBUTES	
 studyDesignPopulationId : String Private Const	
[Is static True. Containment is Not Specified.]	
ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyPopulations (Class) 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 12/13/2022. Last modified 12/13/2022


ATTRIBUTES
 studyElementDescription : String Private
The textual representation of the study design element.
[Is static True. Containment is Not Specified.]

ATTRIBUTES

 studyElementId : String Private Const


element only attributes - these purely describe an element

[Is static True. Containment is Not Specified.]


 studyElementName : String Private

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

[Is static True. Containment is Not Specified.]

 transitionEndRule : TransitionRule Private

[Is static True. Containment is Not Specified.]

 transitionStartRule : TransitionRule Private

all elements point to transition rules

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionEndRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyElements (Class)
StudyElement
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.]

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

StudyEpoch

Class in package 'model'

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

StudyEpoch
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/13/2022. Last modified 12/13/2022

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

ATTRIBUTES


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

[Is static True. Containment is Not Specified.]

 previousStudyEpochId : String Private


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

[Is static True. Containment is Not Specified.]


 studyEpochDescription : String Private

The textual representation of the study epoch.

[Is static True. Containment is Not Specified.]

 studyEpochId : String Private Const

[Is static True. Containment is Not Specified.]

 studyEpochName : String Private

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

[Is static True. Containment is Not Specified.]

 studyEpochType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

 Association (direction: Source -> Destination)

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

OPERATIONS
 getEncounters () : List<Encounter> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getNextStudyEpochId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getPreviousStudyEpochId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyEpochDescription () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyEpochId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyEpochName () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyEpochType () : Code Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setEncounters (encounters : List<Encounter>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setNextStudyEpochId (nextStudyEpochId : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setPreviousStudyEpochId (previousStudyEpochId : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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.]

OPERATIONS

 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 12/13/2022. Last modified 12/13/2022

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.]




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

StudyProtocolVersion

Class in package 'model'

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

StudyProtocolVersion
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/13/2022. Last modified 12/13/2022


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.]	

ATTRIBUTES

 protocolEffectiveDate : Date Private


The date and time specifying when the protocol amendment takes effect or becomes operative.

[Is static True. Containment is Not Specified.]

 protocolStatus : Code Private


A condition of the protocol at a point in time with respect to its state of readiness for implementation.

[Is static True. Containment is Not Specified.]

 protocolVersion : String Private


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

[Is static True. Containment is Not Specified.]

 publicTitle : String Private


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

[Is static True. Containment is Not Specified.]

 scientificTitle : String Private

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

[Is static True. Containment is Not Specified.]

 studyProtocolVersionId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code















 Association (direction: Source -> Destination)




Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)
StudyProtocolVersion

Cardinality: [0..*]

OPERATIONS

OPERATIONS	
 getBriefTitle () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getOfficialTitle () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getProtocolAmendment () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getProtocolEffectiveDate () : Date Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getProtocolStatus () : Code Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getProtocolVersion () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getPublicTitle () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getScientificTitle () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyProtocolVersionId () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setBriefTitle (briefTitle : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setOfficialTitle (officialTitle : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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	



OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setProtocolVersion (protocolVersion : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setPublicTitle (publicTitle : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setScientificTitle (scientificTitle : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 StudyProtocolVersion (studyProtocolVersionId : String) : Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]



TransitionRule



Class in package 'model'





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

TransitionRule
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/13/2022. Last modified 12/13/2022

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) Encounter	Target: Private transitionEndRule (Class) TransitionRule
 Association (direction: Source -> Destination)	

ASSOCIATIONS	
Source: Public (Class) StudyElement	Target: Private transitionStartRule (Class) TransitionRule
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyElement	Target: Private transitionEndRule (Class) TransitionRule
 Association (direction: Source -> Destination)	
Source: Public (Class) 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 12/13/2022. Last modified 12/13/2022

ATTRIBUTES	
 workflowDescription : String Private The textual representation of the workflow.	
[Is static True. Containment is Not Specified.]	

ATTRIBUTES

 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 12/13/2022. Last modified 12/13/2022

ATTRIBUTES	
 nextWorkflowItemId : String Private A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item. [Is static True. Containment is Not Specified.]	
 previousWorkflowItemId : String Private A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item. [Is static True. Containment is Not Specified.]	
 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	

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)
WorkflowItem

Cardinality: [0..*]

OPERATIONS

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


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


 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.]

OPERATIONS

WorkflowItem (workflowItemId : String) : Public

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