

model

Package in package 'DDF'

model
Version 1.0 Phase 1.0 Proposed
cupke created on 12/14/2022. Last modified 12/14/2022

model diagram

Class diagram in package 'model'

model
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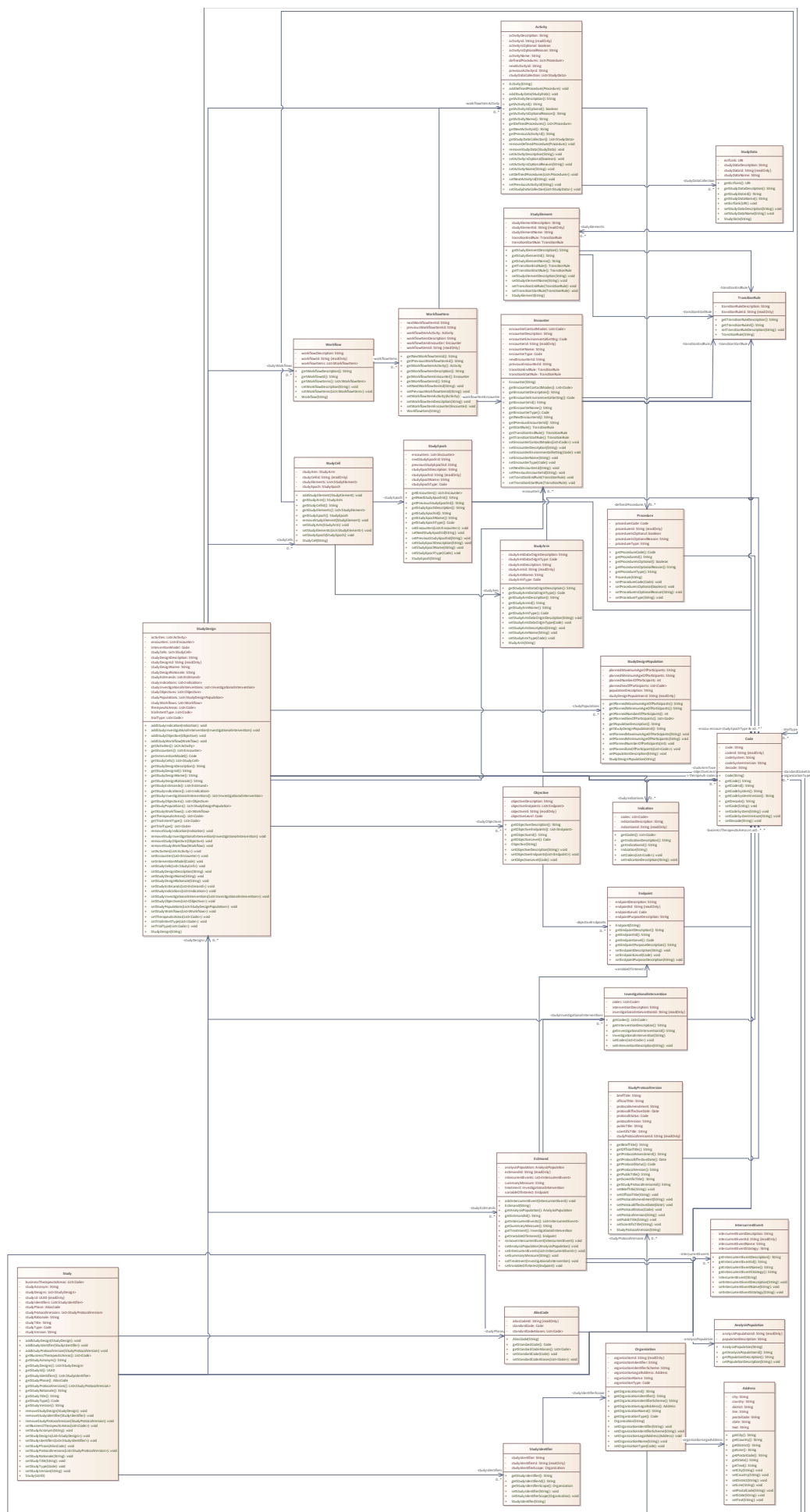


Figure 1: model

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 definedProcedures (Class)
Procedure

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private studyDataCollection (Class)
StudyData

Cardinality: [0..*]

 Association (direction: Source -> Destination)


Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class)
Activity
 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity
Cardinality: [0..*]**OPERATIONS**
 Activity (activityId : String) : Public


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

 addDefinedProcedure (procedure : Procedure) : void Public














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



 addStudyData (studyData : StudyData) : void Public

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

 getActivityDescription () : String Public

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







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.]


Address

Class in package 'model'

Address
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ATTRIBUTES	
 city : String Private	[Is static True. Containment is Not Specified.]
 country : String Private	[Is static True. Containment is Not Specified.]
 district : String Private	[Is static True. Containment is Not Specified.]
 line : String Private	[Is static True. Containment is Not Specified.]
 postalCode : String Private	[Is static True. Containment is Not Specified.]
 state : String Private	[Is static True. Containment is Not Specified.]

ATTRIBUTES

 text : String Private

[Is static True. Containment is Not Specified.]


ASSOCIATIONS

 Association (direction: Source -> Destination)


Source: Public (Class) Organization

Target: Private organizationLegalAddress (Class)
Address


OPERATIONS

 getCity () : String Public


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

 getCountry () : String Public


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

 getDistrict () : String Public


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

 getLine () : String Public


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

 getPostalCode () : String Public


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

 getState () : String Public


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

 getText () : String Public

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

 setCity (city : String) : void Public

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

 setCountry (country : String) : void Public

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

OPERATIONS	
 setDistrict (district : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setLine (line : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPostalCode (postalCode : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setState (state : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setText (text : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

AliasCode

Class in package 'model'


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

AliasCode

Version 1.0 Phase 1.0 Proposed

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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


Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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) Study

Target: Private studyType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterContactModes (Class)
Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCodeAliases (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 businessTherapeuticAreas (Class)
Code

Cardinality: [0..*]

ASSOCIATIONS		
 Association (direction: Source -> Destination)		
Source: Public (Class) Objective		Target: Private objectiveLevel (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyProtocolVersion		Target: Private protocolStatus (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesignPopulation		Target: Private plannedSexOfParticipants (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyEpoch		Target: Private studyEpochType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Endpoint		Target: Private endpointLevel (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyArm		Target: Private studyArmDataOriginType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private interventionModel (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Procedure		Target: Private procedureCode (Class) Code

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (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 studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

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

 Association (direction: Source -> Destination)

Source: Public (Class) Indication

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

 Association (direction: Source -> Destination)

Source: Public (Class) Organization


Target: Private organizationType (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) AliasCode

Target: Private standardCode (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.]



OPERATIONS
 getCodeSystem () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getCodeSystemVersion () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getDecode () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setCode (code : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setCodeSystem (codeSystem : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setCodeSystemVersion (codeSystemVersion : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setDecode (decode : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]









Encounter

Class in package 'model'

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

Encounter
Version 1.0 Phase 1.0 Proposed
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ATTRIBUTES
 encounterContactModes : List<Code> Private The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device). [Is static True. Containment is Not Specified.]
 encounterDescription : String Private The textual representation of the protocol-defined clinical encounter.

ATTRIBUTES	
	[Is static True. Containment is Not Specified.]
 encounterEnvironmentalSetting : Code Private The environment/setting where the event, intervention, or finding occurred.	[Is static True. Containment is Not Specified.]
 encounterId : String Private Const	[Is static True. Containment is Not Specified.]
 encounterName : String Private The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.	[Is static True. Containment is Not Specified.]
 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 encounterContactModes (Class) Code Cardinality: [0..*]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting
(Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch


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

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemEncounter (Class)
Encounter















OPERATIONS






 Encounter (encounterId : 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.]

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




OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setEncounterType (encounterType : Code) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setNextEncounterId (nextEncounterId : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPreviousEncounterId (previousEncounterId : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setTransitionEndRule (transitionEndRule : TransitionRule) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setTransitionStartRule (transitionStartRule : TransitionRule) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

Endpoint

Class in package 'model'


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

Endpoint
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

ATTRIBUTES

[Is static True. Containment is Not Specified.]

 endpointPurposeDescription : String Private

The textual representation of the study endpoint purpose.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand


Target: Private variableOfInterest (Class) Endpoint

 Association (direction: Source -> Destination)


Source: Public (Class) Objective

Target: Private objectiveEndpoints (Class)
Endpoint


Cardinality: [0..*]

OPERATIONS Endpoint (endpointId : String) : Public


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

 getEndpointDescription () : String Public

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

 getEndpointId () : String Public


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

 getEndpointLevel () : Code Public



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

 getEndpointPurposeDescription () : String Public

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

 setEndpointDescription (endpointDescription : String) : void Public

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







OPERATIONS
 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

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private treatment (Class)
InvestigationalIntervention

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private analysisPopulation (Class)
AnalysisPopulation

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

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

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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


OPERATIONS

 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


OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getTreatment () : InvestigationalIntervention Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getVariableOfInterest () : Endpoint Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <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.]

ATTRIBUTES

 indicationDescription : String Private

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

[Is static True. Containment is Not Specified.]

 indicationId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Indication

Target: Private codes (Class) Code

Cardinality: [0..*]


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyIndications (Class) Indication

Cardinality: [0..*]


OPERATIONS

 getCodes () : List<Code> Public


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

 getIndicationDescription () : String Public

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

 getIndicationId () : String Public


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

 Indication (indicationId : String) : Public

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

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

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

 setIndicationDescription (indicationDescription : String) : void Public

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

IntercurrentEvent





Class in package 'model'


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




IntercurrentEvent


Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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	




OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getIntercurrentEventStrategy () : String Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 <code>IntercurrentEvent (intercurrentEventId : String) : Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 <code>setIntercurrentEventDescription (intercurrentEventDescription : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 <code>setIntercurrentEventName (intercurrentEventName : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 <code>setIntercurrentEventStrategy (intercurrentEventStrategy : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

InvestigationalIntervention

Class in package 'model'

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

InvestigationalIntervention
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

Target: Private codes (Class) Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private treatment (Class)

InvestigationalIntervention

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

Target: Private studyInvestigationalInterventions


(Class) InvestigationalIntervention

Cardinality: [0..*]

OPERATIONS

 getCodes () : List<Code> Public


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

 getInterventionDescription () : String Public

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

 getInvestigationalInterventionId () : String Public


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

 InvestigationalIntervention (investigationalInterventionId : String) : Public

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

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

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

 setInterventionDescription (interventionDescription : String) : void Public

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

Objective


Class in package 'model'

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

Objective


Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 12/14/2022. Last modified 12/14/2022


ATTRIBUTES
 objectiveDescription : String Private

The textual representation of the study objective. (BRIDG)


[Is static True. Containment is Not Specified.]

 objectiveEndpoints : List<Endpoint> Private

[Is static True. Containment is Not Specified.]

 objectiveId : String Private Const

[Is static True. Containment is Not Specified.]

 objectiveLevel : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS
 Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveEndpoints (Class) Endpoint


Cardinality: [0..*]

 Association (direction: Source -> Destination)








Source: Public (Class) StudyDesign

Target: Private studyObjectives (Class) Objective

Cardinality: [0..*]

OPERATIONS
 getObjectiveDescription () : String Public

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



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

Organization


Class in package 'model'

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

Organization
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

ATTRIBUTES
 organizationId : String Private Const [Is static True. Containment is Not Specified.]
 organizationIdentifier : String Private A unique symbol that establishes identity of the organization. (BRIDG) [Is static True. Containment is Not Specified.]

ATTRIBUTES


 organizationIdentifierScheme : String Private

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

[Is static True. Containment is Not Specified.]

 organizationLegalAddress : Address Private

[Is static True. Containment is Not Specified.]

 organizationName : String Private

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

[Is static True. Containment is Not Specified.]

 organizationType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationLegalAddress (Class)
Address

 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.]

OPERATIONS	
 <code>getOrganizationIdentifierScheme () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getOrganizationLegalAddress () : Address Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getOrganizationName () : String Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>getOrganizationType () : Code Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>Organization (organizationId : String) : Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationIdentifier (organizationIdentifier : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationLegalAddress (organizationLegalAddress : Address) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationName (organizationName : String) : void Public</code>	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setOrganizationType (organizationType : Code) : void Public</code>	[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 12/14/2022. Last modified 12/14/2022


ATTRIBUTES

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.]



OPERATIONS
 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.]











Study

Class in package 'model'

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [[<http://ClinicalTrials.gov>]](CDISC Glossary)

Study
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

ATTRIBUTES	
 studyDesigns : List<StudyDesign> Private	[Is static True. Containment is Not Specified.]
 studyId : UUID Private Const	[Is static True. Containment is Not Specified.]
 studyIdentifiers : List<StudyIdentifier> Private	[Is static True. Containment is Not Specified.]
 studyPhase : AliasCode Private A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	[Is static True. Containment is Not Specified.]
 studyProtocolVersions : List<StudyProtocolVersion> Private	[Is static True. Containment is Not Specified.]
 studyRationale : String Private	[Is static True. Containment is Not Specified.]
 studyTitle : String Private The sponsor-defined name of the clinical study.	[Is static True. Containment is Not Specified.]
 studyType : Code Private The nature of the investigation for which study information is being collected. (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)	

ASSOCIATIONS

Source: Public (Class) Study

Target: Private studyType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)
StudyProtocolVersion

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyIdentifiers (Class)
StudyIdentifier

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private businessTherapeuticAreas (Class)
Code


Cardinality: [0..*]

 Association (direction: Source -> Destination)


Source: Public (Class) Study

Target: Private studyPhase (Class) AliasCode

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.]

OPERATIONS	
 getStudyAcronym () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyDesigns () : List<StudyDesign> Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyId () : UUID Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyIdentifiers () : List<StudyIdentifier> Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyPhase () : AliasCode Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyProtocolVersions () : List<StudyProtocolVersion> Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyRationale () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyTitle () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyType () : Code Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyVersion () : String Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 removeStudyDesign (studyDesign : StudyDesign) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code>) : void Public	

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyAcronym (studyAcronym : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyDesigns (studyDesigns : List<StudyDesign>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyIdentifiers (studyIdentifiers : List<StudyIdentifier>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyPhase (studyPhase : AliasCode) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyProtocolVersions (studyProtocolVersions : List<StudyProtocolVersion>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyRationale (studyRationale : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyTitle (studyTitle : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyType (studyType : Code) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyVersion (studyVersion : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 Study (studyId : UUID) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

StudyArm

Class in package 'model'

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


StudyArm
Version 1.0 Phase 1.0 Proposed

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 studyArmDataOriginType (Class)
Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyArm (Class) StudyArm

ASSOCIATIONS

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

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

OPERATIONS
 addStudyElement (studyElement : StudyElement) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getStudyArm () : StudyArm Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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 12/14/2022. Last modified 12/14/2022


ATTRIBUTES

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
 <code>setStudyDataDescription (studyDataDescription : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>setStudyDataName (studyDataName : String) : void Public</code> [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 <code>StudyData (studyDataId : String) : Public</code> [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
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

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.]
 studyDesignRationale : String Private	[Is static True. Containment is Not Specified.]
 studyEstimands : List<Estimand> Private	[Is static True. Containment is Not Specified.]
 studyIndications : List<Indication> Private	[Is static True. Containment is Not Specified.]
 studyInvestigationalInterventions : List<InvestigationalIntervention> Private	[Is static True. Containment is Not Specified.]
 studyObjectives : List<Objective> Private	[Is static True. Containment is Not Specified.]
 studyPopulations : List<StudyDesignPopulation> Private	[Is static True. Containment is Not Specified.]
 studyWorkflows : List<Workflow> Private	[Is static True. Containment is Not Specified.]
 therapeuticAreas : List<Code> Private A categorization of a disease, disorder, or other condition based on common characteristics and often associated with a medical specialty focusing on research and development of specific therapeutic interventions for the purpose of treatment and prevention.	[Is static True. Containment is Not Specified.]
 trialIntentType : List<Code> Private The planned purpose of the therapy, device, or agent under study in the clinical trial.	[Is static True. Containment is Not Specified.]
 trialType : List<Code> Private	

ATTRIBUTES

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 studyCells (Class) StudyCell

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private encounters (Class) Encounter

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private therapeuticAreas (Class) Code

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 trialType (Class) Code

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyIndications (Class) Indication

Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyObjectives (Class) Objective

Cardinality: [0..*]

ASSOCIATIONS

 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 studyInvestigationalInterventions
(Class) InvestigationalIntervention
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 studyEstimands (Class) Estimand
Cardinality: [0..*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private activities (Class) Activity
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

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getActivities () : List<Activity> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getEncounters () : List<Encounter> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getInterventionModel () : Code Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyCells () : List<StudyCell> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyDesignDescription () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyDesignId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyDesignName () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyDesignRationale () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyEstimands () : List<Estimand> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyIndications () : List<Indication> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyObjectives () : List<Objective> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyPopulations () : List<StudyDesignPopulation> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

OPERATIONS
 getStudyWorkflows () : List<Workflow> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getTherapeuticAreas () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getTrialIntentType () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getTrialType () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 removeStudyIndication (indication : Indication) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 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.]







OPERATIONS	
 setStudyDesignName (studyDesignName : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyDesignRationale (studyDesignRationale : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyEstimands (studyEstimands : List<Estimand>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyIndications (studyIndications : List<Indication>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyInvestigationalInterventions (studyInvestigationalInterventions : List<InvestigationalIntervention>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyObjectives (studyObjectives : List<Objective>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setStudyWorkflows (studyWorkflows : List<Workflow>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setTherapeuticAreas (therapeuticAreas : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setTrialIntentType (trialIntentType : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setTrialType (trialType : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 StudyDesign (studyDesignId : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	


StudyDesignPopulation

Class in package 'model'












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

StudyDesignPopulation
Version 1.0 Phase 1.0 Proposed
cupke created on 12/14/2022. Last modified 12/14/2022

ATTRIBUTES	
 plannedMaximumAgeOfParticipants : String Private	[Is static True. Containment is Not Specified.]
 plannedMinimumAgeOfParticipants : String Private	[Is static True. Containment is Not Specified.]
 plannedNumberOfParticipants : int Private	[Is static True. Containment is Not Specified.]
 plannedSexOfParticipants : List<Code> Private	[Is static True. Containment is Not Specified.]
 populationDescription : String Private The textual representation of the study population.	[Is static True. Containment is Not Specified.]
 studyDesignPopulationId : String Private Const	[Is static True. Containment is Not Specified.]

ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesignPopulation	Target: Private plannedSexOfParticipants (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyPopulations (Class) StudyDesignPopulation Cardinality: [0..*]

OPERATIONS	
 getPlannedMaximumAgeOfParticipants () : String Public	

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 getPlannedMinimumAgeOfParticipants () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getPlannedNumberOfParticipants () : int Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getPlannedSexOfParticipants () : List<Code> Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getPopulationDescription () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 getStudyDesignPopulationId () : String Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPlannedNumberOfParticipants (plannedNumberOfParticipants : int) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPlannedSexOfParticipants (plannedSexOfParticipants : List<Code>) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 setPopulationDescription (populationDescription : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	
 StudyDesignPopulation (uuid : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]	

StudyElement

Class in package 'model'




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

StudyElement

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 12/14/2022. Last modified 12/14/2022











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

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

ASSOCIATIONS

Cardinality: [0..*]

OPERATIONS


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

StudyEpoch

Class in package 'model'

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

ATTRIBUTES

 encounters : List<Encounter> Private

[Is static True. Containment is Not Specified.]

 nextStudyEpochId : String Private


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

[Is static True. Containment is Not Specified.]

 previousStudyEpochId : String Private


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

[Is static True. Containment is Not Specified.]


 studyEpochDescription : String Private

The textual representation of the study epoch.

[Is static True. Containment is Not Specified.]


 studyEpochId : String Private Const

[Is static True. Containment is Not Specified.]

 studyEpochName : String Private

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

[Is static True. Containment is Not Specified.]

 studyEpochType : Code Private

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

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

 Association (direction: Source -> Destination)

ASSOCIATIONS



Source: Public (Class) StudyEpoch





Target: Private encounters (Class) Encounter
Cardinality: [0..*] Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyEpoch (Class) StudyEpoch

OPERATIONS

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




OPERATIONS	
 setStudyEpochDescription (studyEpochDescription : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyEpochName (studyEpochName : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setStudyEpochType (studyEpochType : Code) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 StudyEpoch (studyEpochId : String) : Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]



StudyIdentifier

Class in package 'model'

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

StudyIdentifier
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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)	

ASSOCIATIONS


Source: Public (Class) Study

 Target: Private studyIdentifiers (Class)
 StudyIdentifier
 Cardinality: [0..*]
OPERATIONS
 **getStudyIdentifier () : String Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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

 **getStudyIdentifierScope () : Organization Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

 **setStudyIdentifier (studyIdentifier : String) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

 **setStudyIdentifierScope (studyIdentifierScope : Organization) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

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


StudyProtocolVersion

Class in package 'model'

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

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ATTRIBUTES
 **briefTitle : String Private**
 The short descriptive name for the protocol.
 [Is static True. Containment is Not Specified.]

 **officialTitle : String Private**

ATTRIBUTES

The formal descriptive name for the protocol.

[Is static True. Containment is Not Specified.]

 protocolAmendment : String Private


A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)

[Is static True. Containment is Not Specified.]

 protocolEffectiveDate : Date Private

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

[Is static True. Containment is Not Specified.]

 protocolStatus : Code Private


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

[Is static True. Containment is Not Specified.]

 protocolVersion : String Private


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

[Is static True. Containment is Not Specified.]

 publicTitle : String Private

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

[Is static True. Containment is Not Specified.]

 scientificTitle : String Private

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

[Is static True. Containment is Not Specified.]

 studyProtocolVersionId : String Private Const

[Is static True. Containment is Not Specified.]

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code


ASSOCIATIONS

 Association (direction: Source -> Destination)


Source: Public (Class) Study

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


OPERATIONS

 getBriefTitle () : String Public


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

 getOfficialTitle () : String Public


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

 getProtocolAmendment () : String Public


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

 getProtocolEffectiveDate () : Date Public


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

 getProtocolStatus () : Code Public

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

 getProtocolVersion () : String Public


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

 getPublicTitle () : String Public

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

 getScientificTitle () : String Public

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

 getStudyProtocolVersionId () : String Public

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

 setBriefTitle (briefTitle : String) : void Public

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

 setOfficialTitle (officialTitle : String) : void Public

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



OPERATIONS
 setProtocolAmendment (protocolAmendment : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setProtocolEffectiveDate (protocolEffectiveDate : Date) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setProtocolStatus (protocolStatus : Code) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setProtocolVersion (protocolVersion : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setPublicTitle (publicTitle : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setScientificTitle (scientificTitle : String) : void Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 StudyProtocolVersion (studyProtocolVersionId : String) : Public [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

TransitionRule

Class in package 'model'

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

TransitionRule
Version 1.0 Phase 1.0 Proposed
Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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

ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionEndRule (Class)
TransitionRule


OPERATIONS

 getTransitionRuleDescription () : String Public

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

 getTransitionRuleId () : String Public

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

 setTransitionRuleDescription (transitionRuleDescription : String) : void Public

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

 TransitionRule (ruleId : String) : Public


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

Workflow

Class in package 'model'

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

Workflow


ATTRIBUTES workflowDescription : String Private

The textual representation of the workflow.

[Is static True. Containment is Not Specified.]

 workflowId : String Private Const

[Is static True. Containment is Not Specified.]

 workflowItems : List<WorkflowItem> Private

The textual representation of the workflow item.

[Is static True. Containment is Not Specified.]

ASSOCIATIONS Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)
WorkflowItem


Cardinality: [0..*]

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

Target: Private studyWorkflows (Class) Workflow


Cardinality: [0..*]

OPERATIONS getWorkflowDescription () : String Public


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

 getWorkflowId () : String Public

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



 getWorkflowItems () : List<WorkflowItem> Public

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

 setWorkflowDescription (workflowDescription : String) : void Public

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

OPERATIONS







-  **setWorkflowItems (workflowItems : List<WorkflowItem>) : void Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
-  **Workflow (workFlowUUID : String) : Public**
 [Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]

WorkflowItem

Class in package 'model'

WorkflowItem
 Version 1.0 Phase 1.0 Proposed
 Chris Upkes created on 12/14/2022. Last modified 12/14/2022

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)**

ASSOCIATIONS

Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class)
Activity Association (direction: Source -> Destination)




Source: Public (Class) WorkflowItem




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

Source: Public (Class) Workflow

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

OPERATIONS

 getNextWorkflowItemId () : 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

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setWorkflowItemDescription (workflowItemDescription : String) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 setWorkflowItemEncounter (workflowItemEncounter : Encounter) : void Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]
 WorkflowItem (workflowItemId : String) : Public	[Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False.]