

## model

*Package in package 'DDF'*

model  
Version 1.0 Phase 1.0 Proposed  
cupke created on 1/17/2023. Last modified 1/17/2023

## model diagram

*Class diagram in package 'model'*

model  
Version 1.0  
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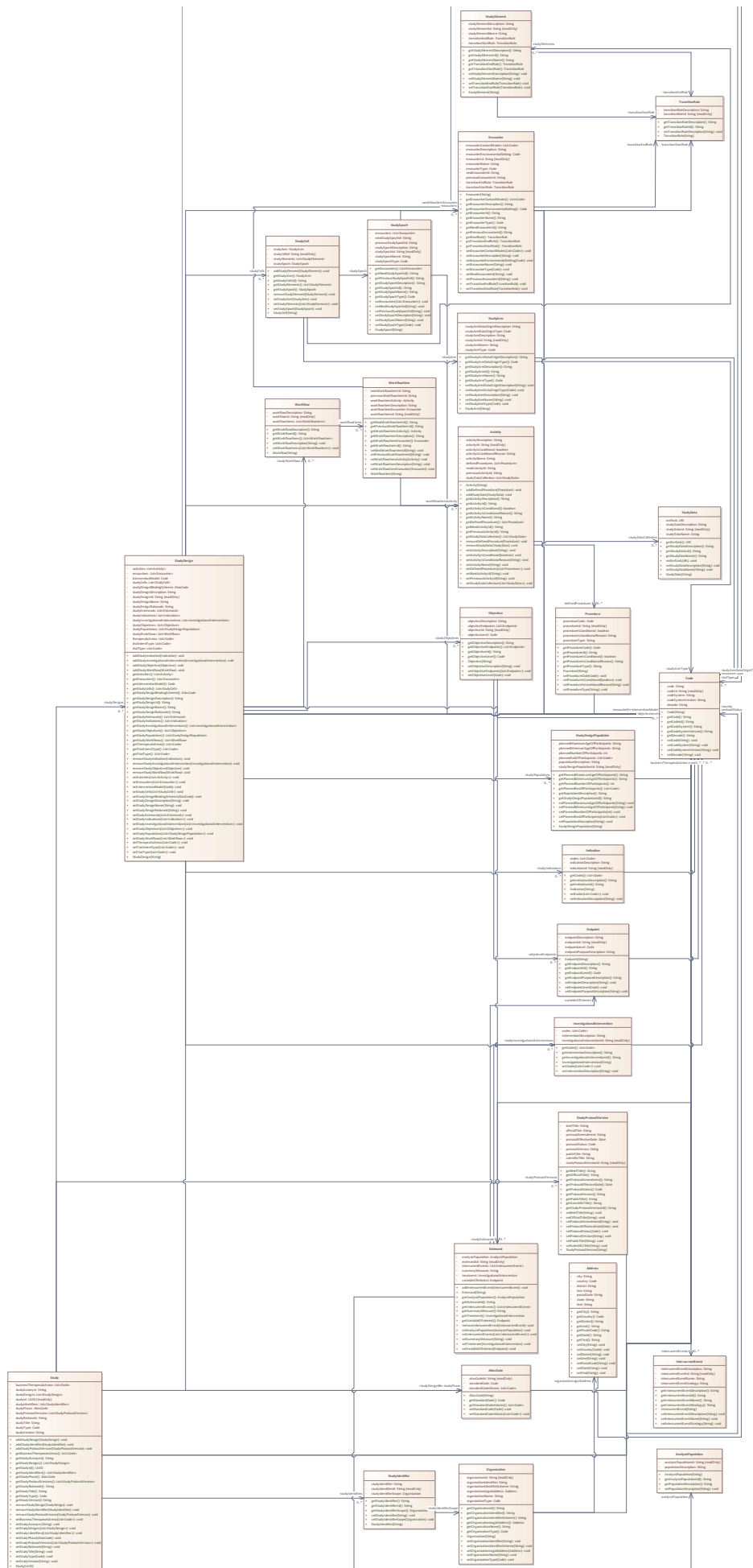


Figure 1: model

## 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. ]
 activityIsConditional : boolean Private	[ Is static True. Containment is Not Specified. ]
 activityIsConditionalReason : String Private	[ Is static True. Containment is Not Specified. ]
 activityName : String Private  The literal identifier (i.e., distinctive designation) of the clinical study activity.	[ Is static True. Containment is Not Specified. ]
 definedProcedures : List<Procedure> Private	[ Is static True. Containment is Not Specified. ]
 nextActivityId : String Private  A system identifier assigned to a study activity that occurs immediately after the current study activity.	[ Is static True. Containment is Not Specified. ]
 previousActivityId : String Private  A system identifier assigned to a study activity that occurs immediately prior to the current study activity.	

**ATTRIBUTES**

[ Is static True. Containment is Not Specified. ]

 studyDataCollection : List<StudyData> Private

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**
 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private studyDataCollection (Class)  
StudyData

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private definedProcedures (Class)  
Procedure

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) 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
 <b>getActivityId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getActivityIsConditional () : boolean Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getActivityIsConditionalReason () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getActivityName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getDefinedProcedures () : List&lt;Procedure&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getNextActivityId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getPreviousActivityId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDataCollection () : List&lt;StudyData&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeDefinedProcedure (procedure : Procedure ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyData (studyData : StudyData ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivityDescription (description : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivityIsConditional (activityIsConditional : boolean ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivityIsConditionalReason (activityIsConditionalReason : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

OPERATIONS	
 <b>setActivityName (activityName : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setDefinedProcedures (definedProcedures : List&lt;Procedure&gt; ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setNextActivityId (nextActivityId : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPreviousActivityId (previousActivityId : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyDataCollection (studyDataCollection : List&lt;StudyData&gt; ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]


## Address

*Class in package 'model'*

Address  
Version 1.0 Phase 1.0 Proposed  
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ATTRIBUTES	
 <b>city : String Private</b>	[ Is static True. Containment is Not Specified. ]
 <b>country : Code Private</b>	[ Is static True. Containment is Not Specified. ]
 <b>district : String Private</b>	[ Is static True. Containment is Not Specified. ]
 <b>line : String Private</b>	[ Is static True. Containment is Not Specified. ]
 <b>postalCode : String Private</b>	[ Is static True. Containment is Not Specified. ]
 <b>state : String Private</b>	[ 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) Address


Target: Private country (Class) Code

 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 () : Code 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. ]

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

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ATTRIBUTES
 <b>aliasCodeId : String Private Const</b> [ Is static True. Containment is Not Specified. ]
 <b>standardCode : Code Private</b> [ Is static True. Containment is Not Specified. ]
 <b>standardCodeAliases : List&lt;Code&gt; Private</b> [ Is static True. Containment is Not Specified. ]

ASSOCIATIONS
 Association (direction: Source -> Destination)



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

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

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

OPERATIONS	
 AnalysisPopulation (analysisPopulationId : String ) : Public	[ 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.


ATTRIBUTES

## ATTRIBUTES


 code : String Private

The literal value of a code.

[ Is static True. Containment is Not Specified. ]


 codeId : String Private Const

[ Is static True. Containment is Not Specified. ]

 codeSystem : String Private


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

[ Is static True. Containment is Not Specified. ]

 codeSystemVersion : String Private

The version of the code system.

[ Is static True. Containment is Not Specified. ]

 decode : String Private

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

[ 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) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Procedure

Target: Private procedureCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code











 Association (direction: Source -> Destination)

Source: Public (Class) Address

Target: Private country (Class) Code

ASSOCIATIONS		
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private trialType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) Encounter		Target: Private encounterEnvironmentalSetting (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Study		Target: Private businessTherapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) AliasCode		Target: Private standardCode (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private interventionModel (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyArm		Target: Private studyArmDataOriginType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private therapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) AliasCode		Target: Private standardCodeAliases (Class) Code Cardinality: [0..*]

ASSOCIATIONS		
 Association (direction: Source -> Destination)		
Source: Public (Class) Encounter		Target: Private encounterContactModes (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) StudyEpoch		Target: Private studyEpochType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Encounter		Target: Private encounterType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyProtocolVersion		Target: Private protocolStatus (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) InvestigationalIntervention		Target: Private codes (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) Study		Target: Private studyType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Organization		Target: Private organizationType (Class) Code











OPERATIONS	
 <b>Code (codeId : String ) : Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCode () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeId () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeSystem () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeSystemVersion () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getDecode () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCode (code : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCodeSystem (codeSystem : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCodeSystemVersion (codeSystemVersion : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setDecode (decode : String ) : void Public</b>	[ 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	<p>The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device).</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 encounterDescription : String Private	<p>The textual representation of the protocol-defined clinical encounter.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 encounterEnvironmentalSetting : Code Private	<p>The environment/setting where the event, intervention, or finding occurred.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 encounterId : String Private Const	<p>[ Is static True. Containment is Not Specified. ]</p>
 encounterName : String Private	<p>The literal identifier (i.e., distinctive designation) for a protocol-defined clinical encounter.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 encounterType : Code Private	<p>A characterization or classification of contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 nextEncounterId : String Private	<p>A system identifier assigned to a clinical encounter that occurs immediately after the current clinical encounter.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 previousEncounterId : String Private	<p>A system identifier assigned to a clinical encounter that occurs immediately prior to the current clinical encounter.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 transitionEndRule : TransitionRule Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 transitionStartRule : TransitionRule Private	

**ATTRIBUTES**

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS** Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

Source: Public (Class) Encounter

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

Source: Public (Class) Encounter

Target: Private encounterContactModes (Class)  
Code  
Cardinality: [0..\*] Association (direction: Source -> Destination)

Source: Public (Class) Encounter

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

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

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














Source: Public (Class) StudyDesign

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

Source: Public (Class) WorkflowItem

Target: Private workflowItemEncounter (Class)  
Encounter



OPERATIONS
 <b>Encounter (encounterId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterContactModes () : List&lt;Code&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterEnvironmentalSetting () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounterType () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getNextEncounterId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getPreviousEncounterId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStartRule () : TransitionRule Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getTransitionEndRule () : TransitionRule Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getTransitionStartRule () : TransitionRule Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setEncounterContactModes (encounterContactModes : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

OPERATIONS	
 <b>setEncounterDescription (encounterDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setEncounterEnvironmentalSetting (encounterEnvironmentalSetting : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setEncounterName (encounterName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setEncounterType (encounterType : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setNextEncounterId (nextEncounterId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setPreviousEncounterId (previousEncounterId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setTransitionEndRule (transitionEndRule : TransitionRule ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setTransitionStartRule (transitionStartRule : TransitionRule ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	

## Endpoint


*Class in package 'model'*

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


Endpoint  
Version 1.0 Phase 1.0 Proposed  
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ATTRIBUTES	
 <b>endpointDescription : String Private</b>	
The textual representation of the study endpoint.	[ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

 endpointId : String Private Const

[ Is static True. Containment is Not Specified. ]

 endpointLevel : Code Private

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

[ Is static True. Containment is Not Specified. ]

 endpointPurposeDescription : String Private

The textual representation of the study endpoint purpose.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand


Target: Private variableOfInterest (Class) Endpoint

 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

OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getEndpointPurposeDescription () : String Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setEndpointDescription (endpointDescription : String ) : void Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setEndpointLevel (endpointLevel : Code ) : void Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setEndpointPurposeDescription (endpointPurposeDescription : String ) : void Public</code>	[ 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


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

## ATTRIBUTES

[ Is static True. Containment is Not Specified. ]

 variableOfInterest : Endpoint Private

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

 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 treatment (Class)  
InvestigationalIntervention
 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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


## OPERATIONS

 addIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public












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

 Estimand (estimandId : String ) : Public

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

 getAnalysisPopulation () : AnalysisPopulation Public

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


OPERATIONS
 <b>getEstimandId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getIntercurrentEvents () : List&lt;IntercurrentEvent&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getSummaryMeasure () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getTreatment () : InvestigationalIntervention Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getVariableOfInterest () : Endpoint Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setAnalysisPopulation (analysisPopulation : AnalysisPopulation ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setIntercurrentEvents (intercurrentEvents : List&lt;IntercurrentEvent&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setSummaryMeasure (summaryMeasure : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTreatment (treatment : InvestigationalIntervention ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setVariableOfInterest (variableOfInterest : Endpoint ) : void Public</b> [ 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

**ATTRIBUTES** codes : List<Code> Private


A short sequence of characters that represents the disease indication.

[ Is static True. Containment is Not Specified. ]

 indicationDescription : String Private

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

[ Is static True. Containment is Not Specified. ]

 indicationId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS** Association (direction: Source -> Destination)

Source: Public (Class) Indication

Target: Private codes (Class) Code


Cardinality: [0..\*]

 Association (direction: Source -> Destination)


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

**OPERATIONS**

[ 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 1/17/2023. Last modified 1/17/2023


**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
 <b>getIntercurrentEventDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getIntercurrentEventId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getIntercurrentEventName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getIntercurrentEventStrategy () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>IntercurrentEvent (intercurrentEventId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setIntercurrentEventDescription (intercurrentEventDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setIntercurrentEventName (intercurrentEventName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setIntercurrentEventStrategy (intercurrentEventStrategy : String ) : void Public</b> [ 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](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 1/17/2023. Last modified 1/17/2023


ATTRIBUTES
 <b>codes : List&lt;Code&gt; Private</b>  A short sequence of characters that represents the investigational intervention. [ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

 interventionDescription : String Private

The textual representation of the study intervention.

[ Is static True. Containment is Not Specified. ]

 investigationalInterventionId : String Private Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyInvestigationalInterventions  
(Class) InvestigationalIntervention  
Cardinality: [0..\*]

 Association (direction: Source -> Destination)


Source: Public (Class) Estimand

Target: Private treatment (Class)  
InvestigationalIntervention


## OPERATIONS

 getCodes () : List<Code> Public


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

 getInterventionDescription () : String Public

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

 getInvestigationalInterventionId () : String Public

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


 InvestigationalIntervention (investigationalInterventionId : String ) : Public

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

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

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

## OPERATIONS

 `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


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## 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..\*]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

## OPERATIONS


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


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

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

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

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

 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 1/17/2023. Last modified 1/17/2023

ATTRIBUTES	
 organizationId : String Private Const	[ Is static True. Containment is Not Specified. ]
 organizationIdentifier : String Private  A unique symbol that establishes identity of the organization. (BRIDG)	[ Is static True. Containment is Not Specified. ]
 organizationIdentifierScheme : String Private  The name of the organization that provides the identifier for the entity.	[ Is static True. Containment is Not Specified. ]
 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	
 <b>getOrganizationId () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationIdentifier () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationIdentifierScheme () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationLegalAddress () : Address Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationName () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationType () : Code Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>Organization (organizationId : String ) : Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationIdentifier (organizationIdentifier : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationIdentifierScheme (organizationIdentifierScheme : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationLegalAddress (organizationLegalAddress : Address ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationName (organizationName : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationType (organizationType : Code ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Procedure









*Class in package 'model'*










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

Procedure

Version 1.0 Phase 1.0 Proposed

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ATTRIBUTES	
 procedureCode : Code Private  A symbol or combination of symbols which is assigned to medical procedure.	[ Is static True. Containment is Not Specified. ]
 procedureId : String Private Const	[ Is static True. Containment is Not Specified. ]
 procedureIsConditional : boolean Private	[ Is static True. Containment is Not Specified. ]
 procedureIsConditionalReason : 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. ]	

OPERATIONS
 <b>getProcedureId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getProcedureIsConditional () : boolean Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getProcedureIsConditionalReason () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getProcedureType () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>Procedure (procedureId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setProcedureCode (procedureCode : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setProcedureIsConditional (procedureIsConditional : boolean ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setProcedureIsConditionalReason (procedureIsConditionalReason : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setProcedureType (procedureType : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Study










*Class in package 'model'*

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

Study  
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ATTRIBUTES
 <b>businessTherapeuticAreas : List&lt;Code&gt; Private</b>



ATTRIBUTES	
	<p>A therapeutic area classification based on the structure and operations of the business unit.</p> <p>[ Is static True. Containment is Not Specified. ]</p>
 studyAcronym : String Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyDesigns : List<StudyDesign> Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyId : UUID Private Const	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyIdentifiers : List<StudyIdentifier> Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyPhase : AliasCode Private  <p>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]</p>	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyProtocolVersions : List<StudyProtocolVersion> Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyRationale : String Private	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyTitle : String Private  <p>The sponsor-defined name of the clinical study.</p>	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyType : Code Private  <p>The nature of the investigation for which study information is being collected. (AfterÂ clinicaltrials.gov)</p>	<p>[ Is static True. Containment is Not Specified. ]</p>
 studyVersion : String Private  <p>A plan at a particular point in time for a study.</p>	

**ATTRIBUTES**

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS** Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion  
Cardinality: [0..\*] Association (direction: Source -> Destination)

Source: Public (Class) Study

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

Source: Public (Class) Study

Target: Private studyIdentifiers (Class)  
StudyIdentifier  
Cardinality: [0..\*] 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 studyType (Class) Code


 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. ]

OPERATIONS	
 <b>addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBusinessTherapeuticAreas () : List&lt;Code&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyAcronym () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesigns () : List&lt;StudyDesign&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyId () : UUID Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyIdentifiers () : List&lt;StudyIdentifier&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyPhase () : AliasCode Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyProtocolVersions () : List&lt;StudyProtocolVersion&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyRationale () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyTitle () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyType () : Code Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyVersion () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyDesign (studyDesign : StudyDesign) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public</b>	

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

## StudyArm







*Class in package 'model'*



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

StudyArm

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 1/17/2023. Last modified 1/17/2023

ATTRIBUTES	
 studyArmDataOriginDescription : String Private  The textual representation of the study arm data origin.	[ Is static True. Containment is Not Specified. ]
 studyArmDataOriginType : Code Private  A characterization or classification of the study arm with respect to where the study arm data originates.	[ Is static True. Containment is Not Specified. ]
 studyArmDescription : String Private  The textual representation of the study arm.	[ Is static True. Containment is Not Specified. ]
 studyArmId : String Private Const  	[ Is static True. Containment is Not Specified. ]
 studyArmName : String Private  The literal identifier (i.e., distinctive designation) of the study arm.	[ Is static True. Containment is Not Specified. ]
 studyArmType : Code Private  The literal identifier (i.e., distinctive designation) of the study arm type.	[ Is static True. Containment is Not Specified. ]

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

## ASSOCIATIONS

Source: Public (Class) StudyArm

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

Source: Public (Class) StudyCell

Target: Private studyArm (Class) StudyArm


## OPERATIONS

 **getStudyArmDataOriginDescription () : String Public**

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

 **getStudyArmDataOriginType () : Code Public**


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

 **getStudyArmDescription () : String Public**

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

 **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**

**OPERATIONS**

[ 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 1/17/2023. Last modified 1/17/2023

**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 studyEpoch (Class) StudyEpoch

 Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyElements (Class)  
StudyElement

**ASSOCIATIONS**


Cardinality: [0..\*]

 Association (direction: Source -> Destination)


Source: Public (Class) StudyDesign

Target: Private studyCells (Class) StudyCell


Cardinality: [0..\*]

**OPERATIONS** addStudyElement (studyElement : StudyElement ) : void Public


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

 getStudyArm () : StudyArm Public


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

 getStudyCellId () : String Public


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

 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 1/17/2023. Last modified 1/17/2023

### 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. ]





OPERATIONS
 <code>getStudyDataName () : String Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setEcrfLink (ecrfLink : URI ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <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 1/17/2023. Last modified 1/17/2023


ATTRIBUTES
 <code>activities : List&lt;Activity&gt; Private</code> [ Is static True. Containment is Not Specified. ]
 <code>encounters : List&lt;Encounter&gt; 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&lt;StudyCell&gt; Private</code> [ Is static True. Containment is Not Specified. ]

ATTRIBUTES	
 studyDesignBlindingScheme : AliasCode Private	[ Is static True. Containment is Not Specified. ]
 studyDesignDescription : String Private  The textual representation of the study design.	[ Is static True. Containment is Not Specified. ]
 studyDesignId : String Private Const	[ Is static True. Containment is Not Specified. ]
 studyDesignName : String Private  The literal identifier (i.e., distinctive designation) of the study design.	[ Is static True. Containment is Not Specified. ]
 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	

## ATTRIBUTES

prevention.

[ Is static True. Containment is Not Specified. ]

 trialIntentType : List<Code> Private

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

[ Is static True. Containment is Not Specified. ]

 trialType : List<Code> Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyIndications (Class) Indication

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyWorkflows (Class) Workflow

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyDesignBlindingScheme  
(Class) AliasCode
 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 studyEstimands (Class) Estimand

Cardinality: [0..\*]

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 interventionModel (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private therapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyObjectives (Class) Objective Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyInvestigationalInterventions (Class) InvestigationalIntervention Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private activities (Class) Activity Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyPopulations (Class) StudyDesignPopulation Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) Study	Target: Private studyDesigns (Class) StudyDesign

**ASSOCIATIONS**

Cardinality: [0..\*]

**OPERATIONS**

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

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

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

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

◆ **getActivities () : List<Activity> Public**  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

◆ **getEncounters () : List<Encounter> Public**  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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















◆ **getStudyCells () : List<StudyCell> Public**  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]














◆ **getStudyDesignBlindingScheme () : AliasCode 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. ]

OPERATIONS	
 <code>getStudyDesignRationale () : String Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyEstimands () : List&lt;Estimand&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyIndications () : List&lt;Indication&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyInvestigationalInterventions () : List&lt;InvestigationalIntervention&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyObjectives () : List&lt;Objective&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyPopulations () : List&lt;StudyDesignPopulation&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyWorkflows () : List&lt;Workflow&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getTherapeuticAreas () : List&lt;Code&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getTrialIntentType () : List&lt;Code&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getTrialType () : List&lt;Code&gt; Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>removeStudyIndication (indication : Indication ) : void Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>removeStudyObjective (objective : Objective ) : void Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>removeStudyWorkflow (workflow : Workflow ) : void Public</code>	

OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivities (activities : List&lt;Activity&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setEncounters (encounters : List&lt;Encounter&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setInterventionModel (interventionModel : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyCells (studyCells : List&lt;StudyCell&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyDesignBlindingScheme (studyDesignBlindingScheme : AliasCode ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyDesignDescription (studyDesignDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyDesignName (studyDesignName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyDesignRationale (studyDesignRationale : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyEstimands (studyEstimands : List&lt;Estimand&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyIndications (studyIndications : List&lt;Indication&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyInvestigationalInterventions (studyInvestigationalInterventions : List&lt;InvestigationalIntervention&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyObjectives (studyObjectives : List&lt;Objective&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyPopulations (studyStudyDesignPopulations : List&lt;StudyDesignPopulation&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	



OPERATIONS
 <b>setStudyWorkflows (studyWorkflows : List&lt;Workflow&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTherapeuticAreas (therapeuticAreas : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTrialIntentType (trialIntentType : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTrialType (trialType : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyDesign (studyDesignId : String ) : Public</b> [ 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 1/17/2023. Last modified 1/17/2023

ATTRIBUTES
 <b>plannedMaximumAgeOfParticipants : String Private</b> [ Is static True. Containment is Not Specified. ]
 <b>plannedMinimumAgeOfParticipants : String Private</b> [ Is static True. Containment is Not Specified. ]
 <b>plannedNumberOfParticipants : int Private</b> [ Is static True. Containment is Not Specified. ]
 <b>plannedSexOfParticipants : List&lt;Code&gt; Private</b> [ Is static True. Containment is Not Specified. ]
 <b>populationDescription : String Private</b>

**ATTRIBUTES**

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


[ 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. ]

OPERATIONS
 <b>setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPlannedNumberOfParticipants (plannedNumberOfParticipants : int ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPlannedSexOfParticipants (plannedSexOfParticipants : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPopulationDescription (populationDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyDesignPopulation (uuid : String ) : Public</b> [ 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 1/17/2023. Last modified 1/17/2023

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






## ATTRIBUTES





-  transitionEndRule : TransitionRule Private  
[ Is static True. Containment is Not Specified. ]
-  transitionStartRule : TransitionRule Private  
all elements point to transition rules  
[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

-  Association (direction: Source -> Destination)  
Source: Public (Class) StudyElement  
Target: Private transitionStartRule (Class) TransitionRule
-  Association (direction: Source -> Destination)  
Source: Public (Class) StudyElement  
Target: Private transitionEndRule (Class) TransitionRule
-  Association (direction: Source -> Destination)  
Source: Public (Class) StudyCell  
Target: Private studyElements (Class) StudyElement  
Cardinality: [0..\*]

## OPERATIONS

-  getStudyElementDescription () : String Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
-  getStudyElementId () : String Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
-  getStudyElementName () : String Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
-  getTransitionEndRule () : TransitionRule Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
-  getTransitionStartRule () : TransitionRule Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]





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

## StudyEpoch

*Class in package 'model'*

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


StudyEpoch  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 1/17/2023. Last modified 1/17/2023

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


**ATTRIBUTES**

The textual representation of the study epoch.

[ Is static True. Containment is Not Specified. ]

 studyEpochId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyEpochName : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyEpochType : Code Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch


Target: Private studyEpochType (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) StudyCell

Target: Private studyEpoch (Class) StudyEpoch

**OPERATIONS**












 getEncounters () : List<Encounter> Public

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

 getNextStudyEpochId () : String Public

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

 getPreviousStudyEpochId () : String Public

OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyEpochDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getStudyEpochId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getStudyEpochName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getStudyEpochType () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setEncounters (encounters : List&lt;Encounter&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setNextStudyEpochId (nextStudyEpochId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setPreviousStudyEpochId (previousStudyEpochId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyEpochDescription (studyEpochDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyEpochName (studyEpochName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyEpochType (studyEpochType : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>StudyEpoch (studyEpochId : String ) : Public</b> [ 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 1/17/2023. Last modified 1/17/2023

**ATTRIBUTES**


 studyIdentifier : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyIdentifierId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyIdentifierScope : Organization Private

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier


Target: Private studyIdentifierScope (Class)  
Organization

 Association (direction: Source -> Destination)


Source: Public (Class) Study

Target: Private studyIdentifiers (Class)  
StudyIdentifier  
Cardinality: [0..\*]

**OPERATIONS**

 getStudyIdentifier () : String Public

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

 getStudyIdentifierId () : String Public

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

 getStudyIdentifierScope () : Organization Public



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

 setStudyIdentifier (studyIdentifier : String ) : void Public

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



**OPERATIONS**

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






## StudyProtocolVersion

*Class in package 'model'*


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

StudyProtocolVersion  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 1/17/2023. Last modified 1/17/2023

**ATTRIBUTES**


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

**ATTRIBUTES**

 protocolVersion : String Private


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

[ Is static True. Containment is Not Specified. ]

 publicTitle : String Private


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

[ Is static True. Containment is Not Specified. ]

 scientificTitle : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyProtocolVersionId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code


 Association (direction: Source -> Destination)

Source: Public (Class) Study


Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion

Cardinality: [0..\*]

**OPERATIONS**

 getBriefTitle () : String Public















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

 getOfficialTitle () : String Public

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

 getProtocolAmendment () : String Public

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

OPERATIONS	
 <b>getProtocolEffectiveDate () : Date Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getProtocolStatus () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getProtocolVersion () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getPublicTitle () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getScientificTitle () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getStudyProtocolVersionId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setBriefTitle (briefTitle : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setOfficialTitle (officialTitle : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setProtocolAmendment (protocolAmendment : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setProtocolEffectiveDate (protocolEffectiveDate : Date ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setProtocolStatus (protocolStatus : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setProtocolVersion (protocolVersion : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setPublicTitle (publicTitle : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setScientificTitle (scientificTitle : String ) : void Public</b>	

**OPERATIONS**

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

 StudyProtocolVersion (studyProtocolVersionId : String ) : Public


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

## TransitionRule

*Class in package 'model'*


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

TransitionRule  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 1/17/2023. Last modified 1/17/2023

**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) StudyElement

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

Source: Public (Class) Encounter

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

**ASSOCIATIONS**

Source: Public (Class) Encounter

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

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 1/17/2023. Last modified 1/17/2023

**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&lt;WorkflowItem&gt; Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)  
WorkflowItem

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyWorkflows (Class) Workflow

Cardinality: [0..\*]


## OPERATIONS

 getWorkflowDescription () : String Public


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

 getWorkflowId () : String Public


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

 getWorkflowItems () : List<WorkflowItem> Public

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

 setWorkflowDescription (workflowDescription : String ) : void Public

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

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

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

 Workflow (workFlowUUID : String ) : Public

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

## WorkflowItem


*Class in package 'model'*

WorkflowItem

Version 1.0 Phase 1.0 Proposed

Chris Upkes created on 1/17/2023. Last modified 1/17/2023


## ATTRIBUTES

 nextWorkflowItemId : String Private

**ATTRIBUTES**


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

[ Is static True. Containment is Not Specified. ]


 previousWorkflowItemId : String Private

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

[ Is static True. Containment is Not Specified. ]

 workflowItemActivity : Activity Private

[ Is static True. Containment is Not Specified. ]


 workflowItemDescription : String Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

 workflowItemEncounter : Encounter Private

[ Is static True. Containment is Not Specified. ]

 workflowItemId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private 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

OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getPreviousWorkflowItemId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getWorkflowItemActivity () : Activity Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getWorkflowItemDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getWorkflowItemEncounter () : Encounter Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getWorkflowItemId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setNextWorkflowItemId (nextWorkflowItemId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setPreviousWorkflowItemId (previousWorkflowItemId : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setWorkflowItemActivity (workflowItemActivity : Activity ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setWorkflowItemDescription (workflowItemDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setWorkflowItemEncounter (workflowItemEncounter : Encounter ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>WorkflowItem (workflowItemId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	