

## model

*Package in package 'DDF'*

model  
Version 1.0 Phase 1.0 Proposed  
cupkes created on 2/2/2023. Last modified 2/2/2023

## model diagram

*Class diagram in package 'model'*

model  
Version 1.0  
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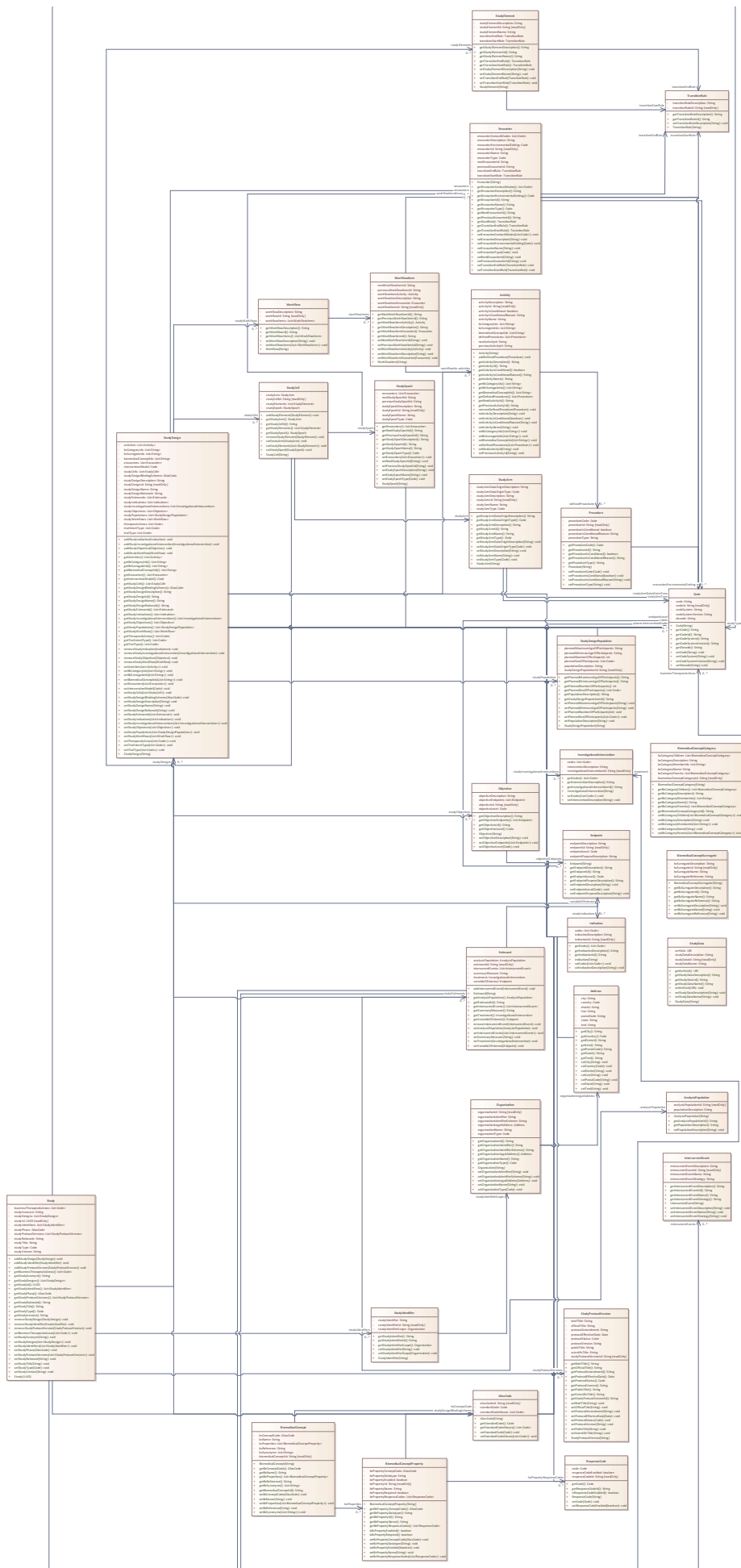











Figure 1: model

## 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. ]
 bcCategoryIds : List<String> Private	[ Is static True. Containment is Not Specified. ]
 bcSurrogateIds : List<String> Private	[ Is static True. Containment is Not Specified. ]
 biomedicalConceptIds : List<String> Private	[ Is static True. Containment is Not Specified. ]
 definedProcedures : List<Procedure> Private	


## ATTRIBUTES

[ Is static True. Containment is Not Specified. ]

 nextActivityId : String Private

A system identifier assigned to a study activity that occurs immediately after the current study activity.

[ Is static True. Containment is Not Specified. ]

 previousActivityId : String Private

A system identifier assigned to a study activity that occurs immediately prior to the current study activity.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 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. ]






 getActivityDescription () : String Public

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

 getActivityId () : String Public

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

OPERATIONS
 <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>getBcCategoryIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcSurrogateIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBiomedicalConceptIds () : List&lt;String&gt; 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>removeDefinedProcedure (procedure : Procedure ) : 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>setBcCategoryIds (bcCategoryIds : List&lt;String&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcSurrogateIds (bcSurrogateIds : List&lt;String&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBiomedicalConceptIds (biomedicalConceptIds : List&lt;String&gt; ) : 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. ]

## 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>

ATTRIBUTES	
	[ Is static True. Containment is Not Specified. ]
 postalCode : String Private	[ Is static True. Containment is Not Specified. ]
 state : String Private	[ Is static True. Containment is Not Specified. ]
 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. ]

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

## AliasCode

*Class in package 'model'*


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

AliasCode  
Version 1.0 Phase 1.0 Proposed  
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ATTRIBUTES	
 <code>aliasCodeId : String Private Const</code> [ Is static True. Containment is Not Specified. ]	
 <code>standardCode : Code Private</code> [ Is static True. Containment is Not Specified. ]	



## ATTRIBUTES

 standardCodeAliases : List<Code> Private

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

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

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept

Target: Private bcConceptCode (Class) AliasCode

 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

 Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty

Target: Private bcPropertyConceptCode (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



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


## AnalysisPopulation



*Class in package 'model'*

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



AnalysisPopulation  
Version 1.0 Phase 1.0 Proposed  
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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)  <div> <div>Source: Public (Class) Estimand</div> <div>Target: Private analysisPopulation (Class) AnalysisPopulation</div> </div>

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. ]

## OPERATIONS

-  **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. ]

## BiomedicalConcept

*Class in package 'model'*

BiomedicalConcept  
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## ATTRIBUTES

-  **bcConceptCode : AliasCode Private**  
[ Is static True. Containment is Not Specified. ]
-  **bcName : String Private**  
[ Is static True. Containment is Not Specified. ]
-  **bcProperties : List<BiomedicalConceptProperty> Private**  
[ Is static True. Containment is Not Specified. ]
-  **bcReference : String Private**  
[ Is static True. Containment is Not Specified. ]
-  **bcSynonyms : List<String> Private**  
[ Is static True. Containment is Not Specified. ]
-  **biomedicalConceptId : String Private Const**  
[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

-  **Association (direction: Source -> Destination)**
- Source: Public (Class) BiomedicalConcept      Target: Private bcConceptCode (Class) AliasCode

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept

Target: Private bcProperties (Class)  
BiomedicalConceptProperty  
Cardinality: [0..\*]

## OPERATIONS

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

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

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

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

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

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

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

 setBcConceptCode (bcConceptCode : AliasCode ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

 setBcProperties (bcProperties : List<BiomedicalConceptProperty> ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

**OPERATIONS**


 **setBcSynonyms (bcSynonyms : List<String> ) : void Public**  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## BiomedicalConceptCategory

*Class in package 'model'*

BiomedicalConceptCategory  
 Version 1.0 Phase 1.0 Proposed  
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**ATTRIBUTES**

 **bcCategoryChildren : List<BiomedicalConceptCategory> Private**  
 [ Is static True. Containment is Not Specified. ]

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

 **bcCategoryMemberIds : List<String> Private**  
 [ Is static True. Containment is Not Specified. ]


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

 **bcCategoryParents : List<BiomedicalConceptCategory> Private**  
 [ Is static True. Containment is Not Specified. ]










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

**OPERATIONS**

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

 **getBcCategoryChildren () : List<BiomedicalConceptCategory> Public**  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]



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

OPERATIONS
 <b>getBcCategoryMemberIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcCategoryName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcCategoryParents () : List&lt;BiomedicalConceptCategory&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBiomedicalConceptCategoryId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryChildren (bcCategoryChildren : List&lt;BiomedicalConceptCategory&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryDescription (bcCategoryDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryMemberIds (bcCategoryMemberIds : List&lt;String&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryName (bcCategoryName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryParents (bcCategoryParents : List&lt;BiomedicalConceptCategory&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]




## BiomedicalConceptProperty



*Class in package 'model'*












BiomedicalConceptProperty  
 Version 1.0 Phase 1.0 Proposed  
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ATTRIBUTES
 <b>bcPropertyConceptCode : AliasCode Private</b> [ Is static True. Containment is Not Specified. ]
 <b>bcPropertyDatatype : String Private</b>

ATTRIBUTES	
	[ Is static True. Containment is Not Specified. ]
 bcPropertyEnabled : boolean Private	[ Is static True. Containment is Not Specified. ]
 bcPropertyId : String Private Const	[ Is static True. Containment is Not Specified. ]
 bcPropertyName : String Private	[ Is static True. Containment is Not Specified. ]
 bcPropertyRequired : boolean Private	[ Is static True. Containment is Not Specified. ]
 bcPropertyResponseCodes : List<ResponseCode> Private	[ Is static True. Containment is Not Specified. ]

ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConceptProperty	Target: Private bcPropertyConceptCode (Class) AliasCode
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConceptProperty	Target: Private bcPropertyResponseCodes (Class) ResponseCode Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) BiomedicalConcept	Target: Private bcProperties (Class) BiomedicalConceptProperty Cardinality: [0..*]

OPERATIONS	
 BiomedicalConceptProperty (bcPropertyId : String ) : Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 getBcPropertyConceptCode () : AliasCode Public	













OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcPropertyDatatype () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcPropertyId () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcPropertyName () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcPropertyResponseCodes () : List&lt;ResponseCode&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>isBcPropertyEnabled () : boolean Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>isBcPropertyRequired () : boolean Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcPropertyConceptCode (bcPropertyConceptCode : AliasCode ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcPropertyDatatype (bcPropertyDatatype : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcPropertyEnabled (bcPropertyEnabled : boolean ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcPropertyName (bcPropertyName : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcPropertyResponseCodes (bcPropertyResponseCodes : List&lt;ResponseCode&gt; ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## BiomedicalConceptSurrogate

*Class in package 'model'*

BiomedicalConceptSurrogate



ATTRIBUTES	
 bcSurrogateDescription : String Private	[ Is static True. Containment is Not Specified. ]
 bcSurrogateId : String Private Const	[ Is static True. Containment is Not Specified. ]
 bcSurrogateName : String Private	[ Is static True. Containment is Not Specified. ]
 bcSurrogateReference : String Private	[ Is static True. Containment is Not Specified. ]
OPERATIONS	
 BiomedicalConceptSurrogate (bcSurrogateId : String ) : Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getBcSurrogateDescription () : String Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getBcSurrogateId () : String Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getBcSurrogateName () : String Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getBcSurrogateReference () : String Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setBcSurrogateDescription (bcSurrogateDescription : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setBcSurrogateName (bcSurrogateName : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setBcSurrogateReference (bcSurrogateReference : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Code

*Class in package 'model'*

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

Code

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ATTRIBUTES	
 code : String Private  The literal value of a code.	[ Is static True. Containment is Not Specified. ]
 codeId : String Private Const	[ Is static True. Containment is Not Specified. ]
 codeSystem : String Private  The literal identifier (i.e., distinctive designation) of the system used to assign and/or manage codes.	[ Is static True. Containment is Not Specified. ]
 codeSystemVersion : String Private  The version of the code system.	[ Is static True. Containment is Not Specified. ]
 decode : String Private  Standardized or dictionary-derived human readable text associated with a code.	[ Is static True. Containment is Not Specified. ]

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

ASSOCIATIONS	
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Objective	Target: Private objectiveLevel (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) StudyProtocolVersion	Target: Private protocolStatus (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) StudyEpoch	Target: Private studyEpochType (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) StudyArm	Target: Private studyArmType (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) InvestigationalIntervention	Target: Private codes (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) 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) StudyDesignPopulation	Target: Private plannedSexOfParticipants (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) ResponseCode	Target: Private code (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Procedure	Target: Private procedureCode (Class) Code

ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyArm	Target: Private studyArmDataOriginType (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) Organization	Target: Private organizationType (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) Study	Target: Private studyType (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) Endpoint	Target: Private endpointLevel (Class) Code
 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 encounterType (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) Address	Target: Private country (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) Indication	Target: Private codes (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	

## ASSOCIATIONS

Source: Public (Class) Study

Target: Private businessTherapeuticAreas (Class)  
Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter


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

Source: Public (Class) Encounter


Target: Private encounterContactModes (Class)  
Code

Cardinality: [0..\*]


## OPERATIONS

 Code (codeId : String ) : Public


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

 getCode () : String Public


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

 getCodeId () : String Public


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

 getCodeSystem () : String Public


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

 getCodeSystemVersion () : String Public


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

 getDecode () : String Public

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


 setCode (code : String ) : void Public

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

 setCodeSystem (codeSystem : String ) : void Public

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

 setCodeSystemVersion (codeSystemVersion : String ) : void Public







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





## Encounter






*Class in package 'model'*

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

Encounter  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

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>

ATTRIBUTES	
	[ Is static True. Containment is Not Specified. ]
 nextEncounterId : String Private  A system identifier assigned to a clinical encounter that occurs immediately after the current clinical encounter.	[ Is static True. Containment is Not Specified. ]
 previousEncounterId : String Private  A system identifier assigned to a clinical encounter that occurs immediately prior to the current clinical encounter.	[ Is static True. Containment is Not Specified. ]
 transitionEndRule : TransitionRule Private	[ Is static True. Containment is Not Specified. ]
 transitionStartRule : TransitionRule Private	[ Is static True. Containment is Not Specified. ]

ASSOCIATIONS	
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private transitionStartRule (Class) TransitionRule
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private transitionEndRule (Class) TransitionRule
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private encounterType (Class) Code
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private encounterEnvironmentalSetting (Class) Code
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private encounterContactModes (Class) Code Cardinality: [0..*]

## ASSOCIATIONS

 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

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

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

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

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














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

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

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

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







OPERATIONS
 <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. ]
 <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  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

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

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

ASSOCIATIONS
<div>Endpoint</div> <div>Cardinality: [0..*]</div>

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

## Estimand

*Class in package 'model'*

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


Estimand

Version 1.0 Phase 1.0 Proposed


Chris Upkes created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES


## ATTRIBUTES

 analysisPopulation : AnalysisPopulation Private


[ Is static True. Containment is Not Specified. ]

 estimandId : String Private Const

[ Is static True. Containment is Not Specified. ]


 intercurrentEvents : List<IntercurrentEvent> Private

[ Is static True. Containment is Not Specified. ]

 summaryMeasure : String Private

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

[ Is static True. Containment is Not Specified. ]

 treatment : InvestigationalIntervention Private

[ Is static True. Containment is Not Specified. ]

 variableOfInterest : Endpoint Private

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

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

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

 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)

## ASSOCIATIONS

Source: Public (Class) StudyDesign

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

## OPERATIONS

addIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

getAnalysisPopulation () : AnalysisPopulation Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

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

getTreatment () : InvestigationalIntervention Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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



removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

setAnalysisPopulation (analysisPopulation : AnalysisPopulation ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

setIntercurrentEvents (intercurrentEvents : List<IntercurrentEvent> ) : void Public  
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

## OPERATIONS

-  `setTreatment (treatment : InvestigationalIntervention ) : void Public`  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
-  `setVariableOfInterest (variableOfInterest : Endpoint ) : void Public`  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Indication

*Class in package 'model'*




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

Indication



Version 1.0 Phase 1.0 Proposed





Chris Upkes created on 2/2/2023. Last modified 2/2/2023

## 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	
 <b>getCodes () : List&lt;Code&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getIndicationDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>getIndicationId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>Indication (indicationId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setCodes (codes : List&lt;Code&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setIndicationDescription (indicationDescription : String ) : void Public</b> [ 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 2/2/2023. Last modified 2/2/2023

ATTRIBUTES	
 <b>intercurrentEventDescription : String Private</b>  The textual representation of the intercurrent event.  [ Is static True. Containment is Not Specified. ]	
 <b>intercurrentEventId : String Private Const</b>  [ Is static True. Containment is Not Specified. ]	
 <b>intercurrentEventName : String Private</b>  The literal identifier (i.e., distinctive designation) of the intercurrent event.  [ Is static True. Containment is Not Specified. ]	

## ATTRIBUTES

 intercurrentEventStrategy : String Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand


Target: Private intercurrentEvents (Class)  
IntercurrentEvent

Cardinality: [0..\*]

## OPERATIONS

 getIntercurrentEventDescription () : String Public

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

 getIntercurrentEventId () : String Public


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

 getIntercurrentEventName () : String Public


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

 getIntercurrentEventStrategy () : String Public


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

 IntercurrentEvent (intercurrentEventId : String ) : Public


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

 setIntercurrentEventDescription (intercurrentEventDescription : String ) : void Public

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

 setIntercurrentEventName (intercurrentEventName : String ) : void Public

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

 setIntercurrentEventStrategy (intercurrentEventStrategy : String ) : void Public

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



## InvestigationalIntervention

Class in package 'model'

The drug, device, therapy, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study. [After [https://grants.nih.gov/grants/policy/faq\\_clinical\\_trial\\_definition.htm#5224](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 2/2/2023. Last modified 2/2/2023

### ATTRIBUTES

 codes : List<Code> Private


A short sequence of characters that represents the investigational intervention.

[ Is static True. Containment is Not Specified. ]

 interventionDescription : String Private

The textual representation of the study intervention.

[ Is static True. Containment is Not Specified. ]

 investigationalInterventionId : String Private Const

[ Is static True. Containment is Not Specified. ]

### ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

Target: Private codes (Class) Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) 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. ]

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

## Objective

*Class in package 'model'*

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

Objective  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <code>objectiveDescription : String Private</code>  The textual representation of the study objective. (BRIDG) [ Is static True. Containment is Not Specified. ]
 <code>objectiveEndpoints : List&lt;Endpoint&gt; Private</code> [ Is static True. Containment is Not Specified. ]
 <code>objectiveId : String Private Const</code> [ Is static True. Containment is Not Specified. ]
 <code>objectiveLevel : Code Private</code>  A characterization or classification of the study endpoint that determines its category of importance relative to other study

**ATTRIBUTES**

objectives.

[ Is static True. Containment is Not Specified. ]

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

Source: Public (Class) Objective


Target: Private objectiveLevel (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) Objective

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


Source: Public (Class) StudyDesign

Target: Private studyObjectives (Class) Objective  
Cardinality: [0..\*]**OPERATIONS** getObjectiveDescription () : String Public


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

 getObjectiveEndpoints () : List<Endpoint> Public


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

 getObjectiveId () : String Public


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

 getObjectiveLevel () : Code Public

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

 Objective (objectiveId : String ) : Public

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

 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. ]

## OPERATIONS



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 2/2/2023. Last modified 2/2/2023

## 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 organizationType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationLegalAddress (Class)  
Address

 Association (direction: Source -> Destination)


Source: Public (Class) StudyIdentifier

Target: Private studyIdentifierScope (Class)  
Organization


## OPERATIONS

 getOrganizationId () : String Public

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

 getOrganizationIdentifier () : String Public

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

 getOrganizationIdentifierScheme () : String Public

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

 getOrganizationLegalAddress () : Address Public


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

 getOrganizationName () : String Public


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

 getOrganizationType () : Code Public


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




 Organization (organizationId : String ) : Public

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

 setOrganizationIdentifier (organizationIdentifier : String ) : void Public

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

 setOrganizationIdentifierScheme (organizationIdentifierScheme : String ) : void Public






OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationLegalAddress</b> (organizationLegalAddress : Address ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setOrganizationName</b> (organizationName : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setOrganizationType</b> (organizationType : Code ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	

## Procedure

*Class in package 'model'*

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

Procedure  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES	
 <b>procedureCode</b> : Code Private  A symbol or combination of symbols which is assigned to medical procedure. [ Is static True. Containment is Not Specified. ]	
 <b>procedureId</b> : String Private Const  [ Is static True. Containment is Not Specified. ]	
 <b>procedureIsConditional</b> : boolean Private  [ Is static True. Containment is Not Specified. ]	
 <b>procedureIsConditionalReason</b> : String Private  [ Is static True. Containment is Not Specified. ]	
 <b>procedureType</b> : String Private  A characterization or classification of the study procedure. [ Is static True. Containment is Not Specified. ]	

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Procedure

Target: Private procedureCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Activity


Target: Private definedProcedures (Class)  
Procedure

Cardinality: [0..\*]


## OPERATIONS

 getProcedureCode () : Code Public


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

 getProcedureId () : String Public

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

 getProcedureIsConditional () : boolean Public


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

 getProcedureIsConditionalReason () : String Public


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

 getProcedureType () : String Public


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

 Procedure (procedureId : String ) : Public


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

 setProcedureCode (procedureCode : Code ) : void Public


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

 setProcedureIsConditional (procedureIsConditional : boolean ) : void Public

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

 setProcedureIsConditionalReason (procedureIsConditionalReason : String ) : void Public

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

 setProcedureType (procedureType : String ) : void Public

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

## OPERATIONS

## ResponseCode

Class in package 'model'

ResponseCode  
Version 1.0 Phase 1.0 Proposed  
cupke created on 2/2/2023. Last modified 2/2/2023

## ATTRIBUTES

code : Code Private

[ Is static True. Containment is Not Specified. ]

responseCodeEnabled : boolean Private

[ Is static True. Containment is Not Specified. ]

responseCodeId : String Private Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

Association (direction: Source -&gt; Destination)

Source: Public (Class) ResponseCode

Target: Private code (Class) Code

Association (direction: Source -&gt; Destination)

Source: Public (Class) BiomedicalConceptProperty

Target: Private bcPropertyResponseCodes (Class)  
ResponseCode

Cardinality: [0..\*]

## OPERATIONS

getCode () : Code Public

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




getResponseCodeId () : String Public

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

isResponseCodeEnabled () : boolean Public

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









OPERATIONS
 <b>ResponseCode (responseCodeId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCode (code : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setResponseCodeEnabled (responseCodeEnabled : boolean ) : 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  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <b>businessTherapeuticAreas : List&lt;Code&gt; Private</b>  A therapeutic area classification based on the structure and operations of the business unit. [ Is static True. Containment is Not Specified. ]
 <b>studyAcronym : String Private</b>  [ Is static True. Containment is Not Specified. ]
 <b>studyDesigns : List&lt;StudyDesign&gt; Private</b>  [ Is static True. Containment is Not Specified. ]
 <b>studyId : UUID Private Const</b>  [ Is static True. Containment is Not Specified. ]
 <b>studyIdentifiers : List&lt;StudyIdentifier&gt; Private</b>  [ Is static True. Containment is Not Specified. ]
 <b>studyPhase : AliasCode Private</b>  A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical


**ATTRIBUTES**

trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]


[ Is static True. Containment is Not Specified. ]

 studyProtocolVersions : List<StudyProtocolVersion> Private

[ Is static True. Containment is Not Specified. ]


 studyRationale : String Private

[ Is static True. Containment is Not Specified. ]

 studyTitle : String Private


The sponsor-defined name of the clinical study.

[ Is static True. Containment is Not Specified. ]

 studyType : Code Private

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

[ Is static True. Containment is Not Specified. ]

 studyVersion : String Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion  
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

 Association (direction: Source -> Destination)

## ASSOCIATIONS

Source: Public (Class) Study

Target: Private studyIdentifiers (Class)  
StudyIdentifier

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) Study


Target: Private businessTherapeuticAreas (Class)  
Code

Cardinality: [0..\*]

## OPERATIONS

 addStudyDesign (studyDesign : StudyDesign ) : void Public

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

 addStudyIdentifier (studyIdentifier : StudyIdentifier ) : void Public


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

 addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion ) : void Public


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

 getBusinessTherapeuticAreas () : List<Code> Public


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

 getStudyAcronym () : String Public


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

 getStudyDesigns () : List<StudyDesign> Public















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







 getStudyId () : UUID Public

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

 getStudyIdentifiers () : List<StudyIdentifier> Public

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

OPERATIONS	
 <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>	[ 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>	



OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyProtocolVersions</b> (studyProtocolVersions : List<StudyProtocolVersion> ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyRationale</b> (studyRationale : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyTitle</b> (studyTitle : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyType</b> (studyType : Code ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyVersion</b> (studyVersion : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>Study</b> (studyId : UUID ) : Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]


## StudyArm

*Class in package 'model'*

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


StudyArm  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES	
 <b>studyArmDataOriginDescription</b> : String Private	
The textual representation of the study arm data origin.	[ Is static True. Containment is Not Specified. ]
 <b>studyArmDataOriginType</b> : 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. ]


**ATTRIBUTES**
 studyArmDescription : String Private

The textual representation of the study arm.

[ Is static True. Containment is Not Specified. ]


 studyArmId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyArmName : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyArmType : Code Private

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

[ Is static True. Containment is Not Specified. ]

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

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

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

Source: Public (Class) StudyCell


Target: Private studyArm (Class) StudyArm

**OPERATIONS**
 getStudyArmDataOriginDescription () : String Public










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

 getStudyArmDataOriginType () : Code Public

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

 getStudyArmDescription () : String Public

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

OPERATIONS
 <b>getStudyArmId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyArmName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyArmType () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArmDataOriginDescription (studyArmDataOriginDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArmDataOriginType (studyArmDataOriginType : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArmDescription (studyArmDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArmName (studyArmName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArmType (studyArmType : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyArm (studyArmId : String ) : Public</b> [ 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 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <b>studyArm : StudyArm Private</b>

ATTRIBUTES	
	[ 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 Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyCells (Class) StudyCell Cardinality: [0..*]

OPERATIONS	
 addStudyElement (studyElement : StudyElement ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 getStudyArm () : StudyArm Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 getStudyCellId () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	





OPERATIONS
 <b>getStudyElements () : List&lt;StudyElement&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyEpoch () : StudyEpoch Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyElement (studyElement : StudyElement ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyArm (studyArm : StudyArm ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyElements (studyElements : List&lt;StudyElement&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyEpoch (studyEpoch : StudyEpoch ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyCell (studyCellId : String ) : Public</b> [ 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 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <b>ecrfLink : URI Private</b>  The uniform resource locator used to access the digital case report form. [ Is static True. Containment is Not Specified. ]
 <b>studyDataDescription : String Private</b>  The textual representation of the study data. [ Is static True. Containment is Not Specified. ]

ATTRIBUTES	
 <code>studyDataId : String Private Const</code>	[ Is static True. Containment is Not Specified. ]
 <code>studyDataName : String Private</code>  The literal identifier (i.e., distinctive designation) for the study data.	[ Is static True. Containment is Not Specified. ]

OPERATIONS	
 <code>getEcrfLink () : URI Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyDataDescription () : String Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>getStudyDataId () : String Public</code>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <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 2/2/2023. Last modified 2/2/2023

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

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

## ASSOCIATIONS

ASSOCIATIONS	
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyPopulations (Class) StudyDesignPopulation Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private therapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyCells (Class) StudyCell Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private interventionModel (Class) Code
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyDesignBlindingScheme (Class) AliasCode
 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 studyWorkflows (Class) Workflow Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private studyInvestigationalInterventions (Class) InvestigationalIntervention Cardinality: [0..*]
 Association (direction: Source -> Destination)	
Source: Public (Class) StudyDesign	Target: Private trialType (Class) Code

## ASSOCIATIONS

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyIndications (Class) Indication

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private trialIntentType (Class) Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private encounters (Class) Encounter

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyEstimands (Class) Estimand

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign

Cardinality: [0..\*]


## OPERATIONS

 addStudyIndication (indication : Indication ) : void Public














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















 addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public

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














 addStudyObjective (objective : Objective ) : void Public




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

OPERATIONS
 <b>addStudyWorkflow (workflow : Workflow ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getActivities () : List&lt;Activity&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcCategoryIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBcSurrogateIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getBiomedicalConceptIds () : List&lt;String&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getEncounters () : List&lt;Encounter&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getInterventionModel () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyCells () : List&lt;StudyCell&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignBlindingScheme () : AliasCode Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignRationale () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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



OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setBcCategoryIds (bcCategoryIds : List&lt;String&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setBcSurrogateIds (bcSurrogateIds : List&lt;String&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setBiomedicalConceptIds (biomedicalConceptIds : List&lt;String&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. ]	

OPERATIONS
 <b>setStudyObjectives</b> (studyObjectives : List<Objective> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyPopulations</b> (studyStudyDesignPopulations : List<StudyDesignPopulation> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyWorkflows</b> (studyWorkflows : List<Workflow> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTherapeuticAreas</b> (therapeuticAreas : List<Code> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTrialIntentType</b> (trialIntentType : List<Code> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setTrialType</b> (trialType : List<Code> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyDesign</b> (studyDesignId : String ) : Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## StudyDesignPopulation


*Class in package 'model'*

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


StudyDesignPopulation  
Version 1.0 Phase 1.0 Proposed  
cupke created on 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <b>plannedMaximumAgeOfParticipants</b> : String Private [ Is static True. Containment is Not Specified. ]
 <b>plannedMinimumAgeOfParticipants</b> : String Private [ Is static True. Containment is Not Specified. ]
 <b>plannedNumberOfParticipants</b> : int Private [ Is static True. Containment is Not Specified. ]

## ATTRIBUTES


 plannedSexOfParticipants : List<Code> Private

[ Is static True. Containment is Not Specified. ]

 populationDescription : String Private

The textual representation of the study population.

[ Is static True. Containment is Not Specified. ]

 studyDesignPopulationId : String Private Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesignPopulation

Target: Private plannedSexOfParticipants (Class)  
Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private studyPopulations (Class)  
StudyDesignPopulation

Cardinality: [0..\*]

## OPERATIONS

 getPlannedMaximumAgeOfParticipants () : String Public


[ 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. ]



OPERATIONS
 <code>getStudyDesignPopulationId () : String Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setPlannedNumberOfParticipants (plannedNumberOfParticipants : int ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setPlannedSexOfParticipants (plannedSexOfParticipants : List&lt;Code&gt; ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>setPopulationDescription (populationDescription : String ) : void Public</code> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <code>StudyDesignPopulation (uuid : String ) : Public</code> [ 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 2/2/2023. Last modified 2/2/2023

ATTRIBUTES
 <code>studyElementDescription : String Private</code>  The textual representation of the study design element. [ Is static True. Containment is Not Specified. ]
 <code>studyElementId : String Private Const</code>  element only attributes - these purely describe an element


**ATTRIBUTES**

[ Is static True. Containment is Not Specified. ]


 studyElementName : String Private

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

[ Is static True. Containment is Not Specified. ]

 transitionEndRule : TransitionRule Private

[ Is static True. Containment is Not Specified. ]

 transitionStartRule : TransitionRule Private

all elements point to transition rules

[ Is static True. Containment is Not Specified. ]

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

Source: Public (Class) StudyElement

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

Source: Public (Class) StudyElement

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

Source: Public (Class) StudyCell

Target: Private studyElements (Class)  
StudyElement  
Cardinality: [0..\*]**OPERATIONS**
 getStudyElementDescription () : String Public

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

 getStudyElementId () : String Public

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

 getStudyElementName () : String Public

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



OPERATIONS
 <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>setStudyElementDescription (studyElementDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyElementName (studyElementName : 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. ]
 <b>StudyElement (studyElementId : String ) : Public</b> [ 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 2/2/2023. Last modified 2/2/2023


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

## ATTRIBUTES

 previousStudyEpochId : String Private


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

[ Is static True. Containment is Not Specified. ]


 studyEpochDescription : String Private

The textual representation of the study epoch.

[ Is static True. Containment is Not Specified. ]


 studyEpochId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyEpochName : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyEpochType : Code Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private 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. ]

OPERATIONS
 getNextStudyEpochId () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getPreviousStudyEpochId () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getStudyEpochDescription () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getStudyEpochId () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getStudyEpochName () : String Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 getStudyEpochType () : Code Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setEncounters (encounters : List<Encounter> ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setNextStudyEpochId (nextStudyEpochId : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setPreviousStudyEpochId (previousStudyEpochId : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setStudyEpochDescription (studyEpochDescription : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setStudyEpochName (studyEpochName : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 setStudyEpochType (studyEpochType : Code ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 StudyEpoch (studyEpochId : String ) : Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]




## StudyIdentifier

Class in package 'model'

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


StudyIdentifier  
Version 1.0 Phase 1.0 Proposed  
Chris Upkes created on 2/2/2023. Last modified 2/2/2023

### 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





OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyIdentifier (studyIdentifier : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>setStudyIdentifierScope (studyIdentifierScope : Organization ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <b>StudyIdentifier (studyIdentifierId : String ) : Public</b> [ 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 2/2/2023. Last modified 2/2/2023


ATTRIBUTES	
 <b>briefTitle : String Private</b>  The short descriptive name for the protocol.  [ Is static True. Containment is Not Specified. ]	
 <b>officialTitle : String Private</b>  The formal descriptive name for the protocol.  [ Is static True. Containment is Not Specified. ]	
 <b>protocolAmendment : String Private</b>  A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)  [ Is static True. Containment is Not Specified. ]	
 <b>protocolEffectiveDate : Date Private</b>  The date and time specifying when the protocol amendment takes effect or becomes operative.  [ Is static True. Containment is Not Specified. ]	

## ATTRIBUTES

 protocolStatus : Code Private


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

[ Is static True. Containment is Not Specified. ]

 protocolVersion : String Private


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

[ Is static True. Containment is Not Specified. ]

 publicTitle : String Private


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

[ Is static True. Containment is Not Specified. ]

 scientificTitle : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyProtocolVersionId : String Private Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code


 Association (direction: Source -> Destination)

Source: Public (Class) Study


Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion














Cardinality: [0..\*]




## OPERATIONS

 getBriefTitle () : String Public

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

 getOfficialTitle () : String Public

OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getProtocolAmendment () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]	
 <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. ]	



OPERATIONS
 <b>setPublicTitle</b> (publicTitle : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setScientificTitle</b> (scientificTitle : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyProtocolVersion</b> (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 2/2/2023. Last modified 2/2/2023

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

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

ASSOCIATIONS	
Source: Public (Class) StudyElement	Target: Private transitionEndRule (Class) TransitionRule
 Association (direction: Source -> Destination)	
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 2/2/2023. Last modified 2/2/2023

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. ]

**ATTRIBUTES**

 workflowItems : List<WorkflowItem> Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)  
WorkflowItem

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyWorkflows (Class) Workflow

Cardinality: [0..\*]


**OPERATIONS**

 getWorkflowDescription () : String Public


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

 getWorkflowId () : String Public


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

 getWorkflowItems () : List<WorkflowItem> Public

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

 setWorkflowDescription (workflowDescription : String ) : void Public

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

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

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


 Workflow (workFlowUUID : String ) : Public

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

## WorkflowItem


Class in package 'model'

**ATTRIBUTES**

 nextWorkflowItemId : String Private


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

[ Is static True. Containment is Not Specified. ]


 previousWorkflowItemId : String Private

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

[ Is static True. Containment is Not Specified. ]


 workflowItemActivity : Activity Private

[ Is static True. Containment is Not Specified. ]


 workflowItemDescription : String Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

 workflowItemEncounter : Encounter Private

[ Is static True. Containment is Not Specified. ]

 workflowItemId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private 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



## ASSOCIATIONS

Cardinality: [0..\*]

## OPERATIONS

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

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

✦ getWorkflowItemActivity () : Activity Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

✦ getWorkflowItemEncounter () : Encounter Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

✦ setNextWorkflowItemId (nextWorkflowItemId : String ) : void Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

✦ setPreviousWorkflowItemId (previousWorkflowItemId : String ) : void Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

✦ setWorkflowItemActivity (workflowItemActivity : Activity ) : void Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

✦ setWorkflowItemDescription (workflowItemDescription : String ) : void Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

✦ setWorkflowItemEncounter (workflowItemEncounter : Encounter ) : void Public  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

