# model

*Package in package 'DDF'*

model
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

# model diagram

*Class diagram in package 'model'*

model
Version 1.0
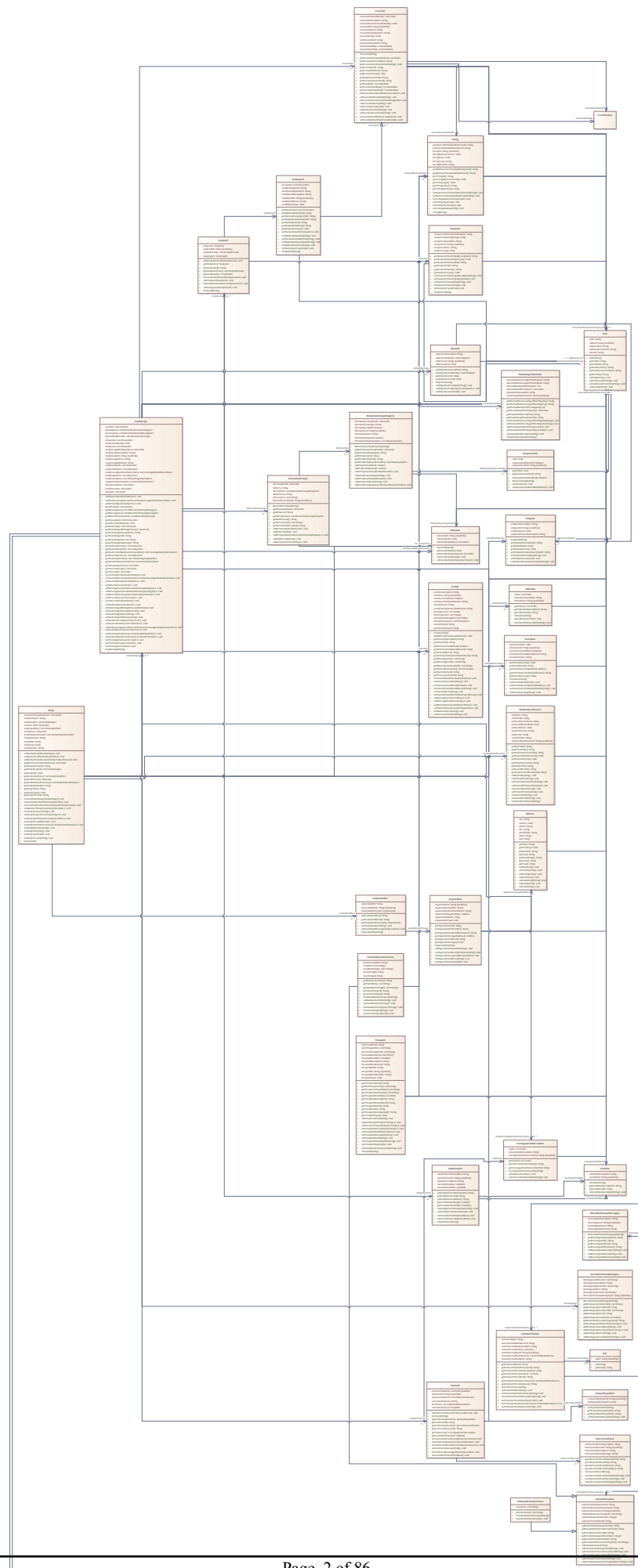cupke created on 3/1/2023.  Last modified 3/1/2023

model

*Package in package 'DDF'*

Figure 1: model

# Activity

*Class in package 'model'*

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

Activity
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|
| activityDescription : String  Private<br><br>The textual representation of the study activity.<br><br>[ Is static True. Containment is Not Specified. ] |
| activityId : String  Private  Const<br><br>[ Is static True. Containment is Not Specified. ] |
| activityIsConditional : boolean  Private<br><br>[ Is static True. Containment is Not Specified. ] |
| activityIsConditionalReason : String  Private<br><br>[ Is static True. Containment is Not Specified. ] |
| activityName : String  Private<br><br>The literal identifier (i.e., distinctive designation) of the clinical study activity.<br><br>[ Is static True. Containment is Not Specified. ] |
| activityScheduleTimelineEntryId : String  Private<br><br>OK, I'm super-struggling with this one here.  If we have instances of activities in a ScheduleTimeline that reference activities, then this means that we should have timelines with one Activity, and one ScheduledActvitiyInstance with the same definition that both point to ScheduleTimelines.  We also may have an Activity that points to a ScheduleTimeline and a ScheduledActivityInstance that points to same Activity, but to a different ScheduleTimeline.  This will likely happen...correct? At the surface it seems so. I'm thinking this won't work and that only ScheduledActivityInstances should ever point to a ScheduleTimeline.  Also it's possible for an Activity to be the start of more than one ScheduleTimeline, correct?  If so, then this can't be a scalar variable. Hence the association defined (1 to 0..*) between Activity objects and ScheduledActivityInstance objects.<br><br>[ Is static True. Containment is Not Specified. ] |
| bcCategoryIds : List<String>  Private |

| ATTRIBUTES |
| --- |

[ 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

[ 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) 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. ]

**OPERATIONS**

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. ]

getActivityIsConditional () : boolean Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

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

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

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

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

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

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

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

removeDefinedProcedure (procedure : Procedure ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

setActivityDescription (description : String ) : void Public

| OPERATIONS |
|---|

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

🔷 setActivityIsConditional (activityIsConditional : boolean ) : void Public

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

🔷 setActivityIsConditionalReason (activityIsConditionalReason : String ) : void Public

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

🔷 setActivityName (activityName : String ) : void Public

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

🔷 setActivityScheduleTimelineEntryId (activityScheduleTimelineEntryId : String ) : void Public

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

🔷 setBcCategoryIds (bcCategoryIds : List<String> ) : void Public

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

🔷 setBcSurrogateIds (bcSurrogateIds : List<String> ) : void Public

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

🔷 setBiomedicalConceptIds (biomedicalConceptIds : List<String> ) : void Public

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

🔷 setDefinedProcedures (definedProcedures : List<Procedure> ) : void Public

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

🔷 setNextActivityId (nextActivityId : String ) : void Public

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

🔷 setPreviousActivityId (previousActivityId : String ) : void Public

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

# Address

*Class in package 'model'*

Address
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|

## ATTRIBUTES

🔹 city : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 country : Code  Private

[ Is static True. Containment is Not Specified. ]

🔹 district : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 line : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 postalCode : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 state : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 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. ]

| OPERATIONS |
| --- |
| getDistrict () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| getLine () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| getPostalCode () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| getState () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| getText () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setCity (city : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setCountry (country : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setDistrict (district : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setLine (line : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setPostalCode (postalCode : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setState (state : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| setText (text : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# AliasCode

*Class in package 'model'*

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

AliasCode
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

## ATTRIBUTES

🔹 aliasCodeId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔹 standardCode : Code  Private

[ Is static True. Containment is Not Specified. ]

🔹 standardCodeAliases : List<Code>  Private

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ 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) Study                         Target: Private studyPhase (Class) AliasCode

✏️ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty     Target: Private bcPropertyConceptCode (Class)
                                                     AliasCode

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign                   Target: Private studyDesignBlindingScheme
                                                     (Class) AliasCode

| OPERATIONS |
|---|
| 🔶 AliasCode (aliasCodeId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 getStandardCode () : Code Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 getStandardCodeAliases () : List<Code> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setStandardCode (standardCode : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setStandardCodeAliases (standardCodeAliases : List<Code> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# AnalysisPopulation

*Class in package 'model'*

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

AnalysisPopulation
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

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

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

| ASSOCIATIONS |
| --- |
| |

| OPERATIONS |
| --- |

🔶 AnalysisPopulation (analysisPopulationId : String ) :  Public

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

🔶 getAnalysisPopulationId () : String Public

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

🔶 getPopulationDescription () : String Public

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

🔶 setPopulationDescription (populationDescription : String ) : void Public

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

# BiomedicalConcept

*Class in package 'model'*

BiomedicalConcept
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

| 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

| ATTRIBUTES | |
|---|---|
| | [ Is static True. Containment is Not Specified. ] |

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept          Target: Private bcConceptCode (Class) AliasCode

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConcept          Target: Private bcProperties (Class) BiomedicalConceptProperty
                                                   Cardinality:  [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign                Target: Private biomedicalConcepts (Class) BiomedicalConcept
                                                   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. ]

| OPERATIONS |
| --- |
| |
| 🔷 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. ] |
| 🔷 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
cupke created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |
| 🔷 bcCategoryChildrenIds : List<String>  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. ] |
| 🔷 bcCategoryParentIds : List<String>  Private |
| [ Is static True. Containment is Not Specified. ] |
| |

## ATTRIBUTES

◆ biomedicalConceptCategoryId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private bcCategories (Class)
BiomedicalConceptCategory
Cardinality:  [0..*]

## OPERATIONS

◆ BiomedicalConceptCategory (bcCategoryId : String ) :  Public

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

◆ getBcCategoryChildrenIds () : List<String> 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. ]

◆ getBcCategoryMemberIds () : List<String> Public

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

◆ getBcCategoryName () : String Public

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

◆ getBcCategoryParentIds () : List<String> Public

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

◆ getBiomedicalConceptCategoryId () : String Public

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

◆ setBcCategoryChildrenIds (bcCategoryChildrenIds : List<String> ) : void Public

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

◆ setBcCategoryDescription (bcCategoryDescription : String ) : void Public

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

◆ setBcCategoryMemberIds (bcCategoryMemberIds : List<String> ) : void Public

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

| 🔷 setBcCategoryName (bcCategoryName : String ) : void Public |
|---|
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

| 🔷 setBcCategoryParentIds (bcCategoryParentIds : List<String> ) : void Public |
|---|
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |


# BiomedicalConceptProperty

*Class in package 'model'*

<div align="right">

BiomedicalConceptProperty
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

</div>

| ATTRIBUTES |
|---|
| 🔷 bcPropertyConceptCode : AliasCode  Private |
| [ Is static True. Containment is Not Specified. ] |

| 🔷 bcPropertyDatatype : String  Private |
|---|
| [ 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 |
|---|

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty

Target: Private bcPropertyResponseCodes (Class) ResponseCode
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) BiomedicalConceptProperty

Target: Private bcPropertyConceptCode (Class) AliasCode

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

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

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

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

◆ getBcPropertyResponseCodes () : List<ResponseCode> Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

| OPERATIONS |
|---|

◆ setBcPropertyConceptCode (bcPropertyConceptCode : AliasCode ) : void Public

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

◆ setBcPropertyDatatype (bcPropertyDatatype : String ) : void Public

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

◆ setBcPropertyEnabled (bcPropertyEnabled : boolean ) : void Public

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

◆ setBcPropertyName (bcPropertyName : String ) : void Public

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

◆ setBcPropertyResponseCodes (bcPropertyResponseCodes : List<ResponseCode> ) : void Public

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

# BiomedicalConceptSurrogate

*Class in package 'model'*

BiomedicalConceptSurrogate
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

| 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. ]

| ASSOCIATIONS |
|---|

✎ Association (direction: Source -> Destination)

| ASSOCIATIONS |
|---|

| Source: Public (Class) StudyDesign | Target: Private bcSurrogates (Class) BiomedicalConceptSurrogate |
|---|---|
| | Cardinality:  [0..*] |

| 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
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|

◆ code : String  Private

**ATTRIBUTES**

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) ResponseCode                    Target: Private code (Class) Code

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter                       Target: Private encounterEnvironmentalSetting

| ASSOCIATIONS | |
|---|---|
| | (Class) Code |

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter | Target: Private encounterType (Class) Code

---

✏ Association (direction: Source -> Destination)

Source: Public (Class) Timepoint | Target: Private timepointType (Class) Code

---

✏ Association (direction: Source -> Destination)

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

---

✏ Association (direction: Source -> Destination)

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

---

✏ Association (direction: Source -> Destination)

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

---

✏ Association (direction: Source -> Destination)

Source: Public (Class) Address | Target: Private country (Class) Code

---

✏ Association (direction: Source -> Destination)

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

---

✏ Association (direction: Source -> Destination)

Source: Public (Class) Timing | Target: Private timingRelativeToFrom (Class) Code

---

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesignPopulation | Target: Private plannedSexOfParticipants (Class) Code
Cardinality: [0..*]

---

✏ Association (direction: Source -> Destination)

## ASSOCIATIONS

| | |
|---|---|
| Source: Public (Class) Endpoint | Target: Private endpointLevel (Class) Code |

🖊 Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) InvestigationalIntervention | Target: Private codes (Class) Code<br>Cardinality:  [0..*] |

🖊 Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) StudyDesign | Target: Private trialIntentType (Class) Code<br>Cardinality:  [0..*] |

🖊 Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) Timing | Target: Private timingType (Class) Code |

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) StudyDesign | Target: Private trialType (Class) Code<br>Cardinality:  [0..*] |

🖊 Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) Study | Target: Private businessTherapeuticAreas (Class) Code<br>Cardinality:  [0..*] |

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

## 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. ]

| OPERATIONS |
| --- |
| 🔶 setCodeSystemVersion (codeSystemVersion : String ) : void Public<br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setDecode (decode : String ) : void Public<br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Condition

*Class in package 'model'*

This class wrapts a single string description that poses a yes or no question that can be used in a decision or branching mechanism when working with timepoints in a timeline or can be used to define when a particular timeline should be executed.

Condition
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |
| 🔷 conditionDescription : String  Private<br><br>The textual representation of the condition rule.  'Nuff said.<br>[ Is static True. Containment is Not Specified. ] |
| 🔷 conditionId : String  Private  Const<br>[ Is static True. Containment is Not Specified. ] |

| ASSOCIATIONS | |
| --- | --- |
| 🖊 Association (direction: Source -> Destination) | |
| Source: Public (Class) Timepoint | Target: Private timepointCondition (Class) Condition |
| 🖊 Association (direction: Source -> Destination) | |
| Source: Public (Class) StudyElement | Target: Private transitionStartRule (Class) Condition |
| 🖊 Association (direction: Source -> Destination) | |
| Source: Public (Class) StudyElement | Target: Private transitionEndRule (Class) Condition |

| OPERATIONS |
| --- |
| ◆ Condition (conditionId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getConditionDescription () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getConditionId () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setConditionDescription (conditionDescription : 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.

<div align="right">

Encounter
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

</div>

| ATTRIBUTES |
| --- |
| ◆ encounterContactModes : List<Code>  Private |
| The means by which an interaction occurs between the subject/participant and person or entity (e.g., a device). |
| [ Is static True. Containment is Not Specified. ] |
| ◆ encounterDescription : String  Private |
| The textual representation of the protocol-defined clinical encounter. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ encounterEnvironmentalSetting : Code  Private |
| The environment/setting where the event, intervention, or finding occurred. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ encounterId : String  Private  Const |
| [ Is static True. Containment is Not Specified. ] |

| ATTRIBUTES |
|---|

🔷 encounterName : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 encounterScheduledAt : Timing  Private

Ok, so now that we have a better understanding of the ScheduleTimeline, we need to think about what encounters should point to.  In this case I believe the only relevent information in a Timing object re: Encounters is the window data which is just a string (could be meaningless). When managing patient protocols, encounters begin with some type of event, not a constraint such as a Timing.  Encounters are an umbrella concept for a series of events (px, rx, labs, etc..) that a patient encounters during a provider visit.  In patient protocols they often involve diagnoses and claims of "conditions"...not to be confused with conditions associated with ScheduledDecisionInstances. Which makes me think that we might not want to overload the term "condition". Anyway, I won't change this to a collection until we've figured out why the pointer exists.

[ Is static True. Containment is Not Specified. ]

🔷 encounterType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 nextEncounterId : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 previousEncounterId : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 transitionEndRule : TransitionRule  Private

[ Is static True. Containment is Not Specified. ]

🔷 transitionStartRule : TransitionRule  Private

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter                          Target: Private encounterScheduledAt (Class) Timing

✏️ Association (direction: Source -> Destination)

| ASSOCIATIONS | |
| --- | --- |
| Source: Public (Class) Encounter | Target: Private encounterEnvironmentalSetting (Class) Code |

✎ Association (direction: Source -> Destination)

| | |
| --- | --- |
| Source: Public (Class) Encounter | Target: Private encounterType (Class) Code |

✎ Association (direction: Source -> Destination)

| | |
| --- | --- |
| Source: Public (Class) Encounter | Target: Private transitionEndRule (Class) TransitionRule |

✎ Association (direction: Source -> Destination)

| | |
| --- | --- |
| Source: Public (Class) Encounter | Target: Private encounterContactModes (Class) Code<br>     Cardinality: [0..*] |

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

| | |
| --- | --- |
| Source: Public (Class) StudyDesign | Target: Private encounters (Class) Encounter<br>     Cardinality: [0..*] |

✎ Association (direction: Source -> Destination)

| | |
| --- | --- |
| Source: Public (Class) StudyEpoch | Target: Private encounters (Class) Encounter<br>     Cardinality: [0..*] |

| OPERATIONS |
| --- |

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

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

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

**OPERATIONS**

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

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

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

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

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

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

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

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

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

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

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

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

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

| OPERATIONS |
| --- |

🔶 setEncounterType (encounterType : Code ) : void Public

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

🔶 setNextEncounterId (nextEncounterId : String ) : void Public

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

🔶 setPreviousEncounterId (previousEncounterId : String ) : void Public

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

🔶 setTransitionEndRule (transitionEndRule : TransitionRule ) : void Public

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

🔶 setTransitionStartRule (transitionStartRule : TransitionRule ) : void Public

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

# Endpoint

*Class in package 'model'*

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

Endpoint
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| 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. ]

## ATTRIBUTES

🔷 endpointPurposeDescription : String  Private

The textual representation of the study endpoint purpose.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint                                    Target: Private endpointLevel (Class) Code

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

## OPERATIONS

🔷 Endpoint (endpointId : String ) :  Public

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

🔷 getEndpointDescription () : String Public

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

🔷 getEndpointId () : String Public

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

🔷 getEndpointLevel () : Code Public

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

🔷 getEndpointPurposeDescription () : String Public

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

🔷 setEndpointDescription (endpointDescription : String ) : void Public

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

| OPERATIONS |
|---|
| ◆ setEndpointLevel (endpointLevel : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setEndpointPurposeDescription (endpointPurposeDescription : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Estimand

*Class in package 'model'*

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

<div align="right">

Estimand
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

</div>

| 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 <br><br> 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) |

| ASSOCIATIONS | |
|---|---|
| Source: Public (Class) Estimand | Target: Private treatment (Class) InvestigationalIntervention |

| | |
|---|---|
| ✏ Association (direction: Source -> Destination) | |
| Source: Public (Class) Estimand | Target: Private intercurrentEvents (Class) IntercurrentEvent<br>    Cardinality:  [0..*] |

| | |
|---|---|
| ✏ Association (direction: Source -> Destination) | |
| Source: Public (Class) Estimand | Target: Private variableOfInterest (Class) Endpoint |

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

| | |
|---|---|
| ✏ Association (direction: Source -> Destination) | |
| Source: Public (Class) StudyDesign | Target: Private studyEstimands (Class) Estimand<br>    Cardinality:  [0..*] |

| OPERATIONS |
|---|
| ◆ addIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ Estimand (estimandId : String ) :  Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getAnalysisPopulation () : AnalysisPopulation Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getEstimandId () : String Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getIntercurrentEvents () : List<IntercurrentEvent> Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getSummaryMeasure () : String Public<br>                    [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

**OPERATIONS**

🔸 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. ]

🔸 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. ]

# Exit

*Class in package 'model'*

Is just Exit intuitive enough in the model as a concept.  Does it exist outside of a ScheduleTimeline? If not, then it's maybe a ScheduleTimelineExit or a TimelineExit?

Exit
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

**ATTRIBUTES**

🔹 exitId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

| ASSOCIATIONS |
| --- |

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline          Target: Private scheduleTimelineExits (Class) Exit
                                                                                    Cardinality:  [0..*]

| OPERATIONS |
| --- |

🔶 Exit (exitId : String ) :  Public

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

🔶 getExitId () : String 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 3/1/2023.  Last modified 3/1/2023

| 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..*]

| ASSOCIATIONS |
| --- |

✏ Association (direction: Source -> Destination)

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

| OPERATIONS |
| --- |

◆ getCodes () : List<Code> Public

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

◆ getIndicationDescription () : String Public

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

◆ getIndicationId () : String Public

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

◆ Indication (indicationId : String ) :  Public

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

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

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

◆ setIndicationDescription (indicationDescription : String ) : void Public

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

# IntercurrentEvent

*Class in package 'model'*

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

IntercurrentEvent
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |

◆ intercurrentEventDescription : String  Private

The textual representation of the intercurrent event.

[ Is static True. Containment is Not Specified. ]

| ATTRIBUTES |
|---|

🔷 intercurrentEventId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 intercurrentEventName : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 intercurrentEventStrategy : String  Private

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

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private intercurrentEvents (Class) IntercurrentEvent

Cardinality:  [0..*]

| OPERATIONS |
|---|

🔶 getIntercurrentEventDescription () : String Public

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

🔶 getIntercurrentEventId () : String Public

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

🔶 getIntercurrentEventName () : String Public

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

🔶 getIntercurrentEventStrategy () : String Public

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

🔶 IntercurrentEvent (intercurrentEventId : String ) :  Public

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

🔶 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

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

🔶 setIntercurrentEventStrategy (intercurrentEventStrategy : String ) : void Public

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

# InvestigationalIntervention

*Class in package 'model'*

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

InvestigationalIntervention
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| 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..*]

| ASSOCIATIONS |
|---|

✎  Association (direction: Source -> Destination)

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

| OPERATIONS |
|---|

🔶  getCodes () : List<Code> Public

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

🔶  getInterventionDescription () : String Public

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

🔶  getInvestigationalInterventionId () : String Public

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

🔶  InvestigationalIntervention (investigationalInterventionId : String ) :  Public

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

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

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

🔶  setInterventionDescription (interventionDescription : String ) : void Public

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

# Objective

*Class in package 'model'*

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

<div align="right">

Objective
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</div>

| ATTRIBUTES |
|---|

🔷  objectiveDescription : String  Private

The textual representation of the study objective. (BRIDG)

[ Is static True. Containment is Not Specified. ]

🔷  objectiveEndpoints : List<Endpoint>  Private

**ATTRIBUTES**

[ Is static True. Containment is Not Specified. ]

◆ objectiveId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

◆ objectiveLevel : Code  Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

**OPERATIONS**

◆ getObjectiveDescription () : String Public

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

◆ getObjectiveEndpoints () : List<Endpoint> Public

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

◆ getObjectiveId () : String Public

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

◆ getObjectiveLevel () : Code Public

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

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

# Organization

*Class in package 'model'*

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

Organization
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| 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) |

## ATTRIBUTES

[ 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

| OPERATIONS |
|---|
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ Organization (organizationId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setOrganizationIdentifier (organizationIdentifier : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setOrganizationIdentifierScheme (organizationIdentifierScheme : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setOrganizationLegalAddress (organizationLegalAddress : Address ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setOrganizationName (organizationName : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setOrganizationType (organizationType : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Procedure

*Class in package 'model'*

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

Procedure
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

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

### ATTRIBUTES

🔹 procedureIsConditionalReason : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 procedureType : String  Private

A characterization or classification of the study procedure.

[ Is static True. Containment is Not Specified. ]

### ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

### OPERATIONS

🔶 getProcedureCode () : Code Public

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

🔶 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. ]

| OPERATIONS |
| --- |
| ◆ setProcedureCode (procedureCode : Code ) : void Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setProcedureIsConditional (procedureIsConditional : boolean ) : void Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setProcedureIsConditionalReason (procedureIsConditionalReason : String ) : void Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setProcedureType (procedureType : String ) : void Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# ResponseCode

*Class in package 'model'*

ResponseCode
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |
| ◆ code : Code  Private<br><br>[ Is static True. Containment is Not Specified. ] |
| ◆ responseCodeEnabled : boolean  Private<br><br>[ Is static True. Containment is Not Specified. ] |
| ◆ responseCodeId : String  Private  Const<br><br>[ Is static True. Containment is Not Specified. ] |

| ASSOCIATIONS |
| --- |
| ✎ Association (direction: Source -> Destination)<br><br>Source: Public (Class) ResponseCode                         Target: Private code (Class) Code |
| ✎ Association (direction: Source -> Destination)<br><br>Source: Public (Class) BiomedicalConceptProperty          Target: Private bcPropertyResponseCodes (Class) ResponseCode<br>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. ]

🔷 ResponseCode (responseCodeId : String ) :  Public

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

🔷 setCode (code : Code ) : void Public

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

🔷 setResponseCodeEnabled (responseCodeEnabled : boolean ) : void Public

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


# ScheduledActivityInstance

*Class in package 'model'*

The ScheduledActivityInstance class is used to extend the ScheduledInstance class with activity-specific information and behaviors needed for the ScheduleTimeline.

        ScheduledActivityInstance
        Version 1.0  Phase 1.0  Proposed
        Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| OUTGOING STRUCTURAL RELATIONSHIPS |
|---|

⬅ Generalization from  ScheduledActivityInstance to  ScheduledInstance

        [ Direction is 'Source -> Destination'. ]

| ATTRIBUTES |
|---|

🔷 activityIds : List<String>  Private

This is the list of ID references to Activity definitions. There can be 1 or many.  This allows for a simpler mechanism for associating non-sequential tasks that have similar constraints to other sequential tasks to be added to the timeline.

        [ Is static True. Containment is Not Specified. ]

| OPERATIONS |
| --- |

🔸 getActivityIds () : List<String> Public

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

🔸 ScheduledActivityInstance (scheduledInstanceId : String ) :  Public

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

🔸 setActivityIds (activityIds : List<String> ) : void Public

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

# ScheduledDecisionInstance

*Class in package 'model'*

The ScheduledDecisionInstance class is used to extend the ScheduledInstance class with decision-specific information and behaviors needed for the ScheduleTimeline.  Different from other ScheduledInstance extensions, this class will be used for flow-control logic such as branching and looping (cycling).

> ScheduledDecisionInstance
> Version 1.0  Phase 1.0  Proposed
> Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| OUTGOING STRUCTURAL RELATIONSHIPS |
| --- |

⬅ Generalization from  ScheduledDecisionInstance to  ScheduledInstance

> [ Direction is 'Source -> Destination'. ]

| ATTRIBUTES |
| --- |

🔹 booleanCondition : String  Private

I was only required to provide a simple boolean condition.  The Condition class seems superfluous as it isn't referenced outside of this class. So, there might be a need to specify the boolean condition, but do we need to track the result?  I don't think so... I think the booleanCondition is read by some other process and chooses a particular timing to traverse based on that condition. ScheduledDecisionInstances should not know anything about Timing even though timing is used to traverse from instance to instance and (I assume) timeline to timeline. This class is a way for the study builder to persist the "switch" logic that is needed to understand why two different timing objects were pointing to the same decision instance.  However, at this point, there is nowhere to store which timing is associated with the TRUE vs the FALSE value.  Why, because ScheduledInstances don't point to timing objects (it is vice versa). It could be that ScheduledInstanceDecision objects (vs. ShcheduledActivityInstance) point back to Timing objects?  Then we would have trueTimingId, falseTimingId.

> [ Is static True. Containment is Not Specified. ]

🔹 conditions : List<String>  Private

Here we have an option for a multiple-choice switch where we have many conditions and we point to many timing constraints associated with each condition being true or false.

> [ Is static True. Containment is Not Specified. ]

| ATTRIBUTES |
|---|

🔷 conditionTimings : List<Timing>  Private

In exact order with the list of conditions are a list of timing constraints to be associated with the result of any condition being true.

[ Is static True. Containment is Not Specified. ]

🔷 falseTimingId : String  Private

And this is the Timing object you point to if the boolean condition is false. If there is a multiple choice, then we would have to have a map or dictionary data representation because we can't define the number of options at design time.

[ Is static True. Containment is Not Specified. ]

🔷 trueTimingId : String  Private

I like what I just thought.  Decisions point to Timing because they are selective. Activies do not, even though I went ahead and pointed to Timing objects at the ScheduledInstance.  All Timings associated with decisions are regarded.  Agree? If we have to maybe we should differentiate between inbound and outbound timing? So, this is the Timing that you point to if the condition is TRUE;

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

✏️ Association (direction: Source -> Destination)

Source: Public (Class) ScheduledDecisionInstance          Target: Private conditionTimings (Class) Timing

Cardinality:  [0..*]

| OPERATIONS |
|---|

🔷 getBooleanCondition () : String Public

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

🔷 getConditions () : List<String> Public

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

🔷 getConditionTimings () : List<Timing> Public

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

🔷 getFalseTimingId () : String Public

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

🔷 getTrueTiminingId () : String Public

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

| OPERATIONS |
| --- |
| 🔶 ScheduledDecisionInstance (scheduledInstanceId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setBooleanCondition (booleanCondition : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setConditions (conditions : List<String> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setConditionTimings (conditionTimings : List<Timing> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setFalseTimingId (falseTimingId : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 setTrueTiminingId (trueTiminingId : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# ScheduledInstance

*Class in package 'model'*

The ScheduledInstance abstract class is used by ScheduleTimelines to build a sequence of activities and decisions that will define a schedule.

<div align="right">

ScheduledInstance
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</div>

| INCOMING STRUCTURAL RELATIONSHIPS |
| --- |
| ➡ Generalization  from  ScheduledDecisionInstance to  ScheduledInstance |
| [ Direction is 'Source -> Destination'. ] |
| ➡ Generalization  from  ScheduledActivityInstance to  ScheduledInstance |
| [ Direction is 'Source -> Destination'. ] |

| ATTRIBUTES |
| --- |
| 🔷 entryScheduleSequenceId : String  Private |

I am going to keep these next two fields in the design, however, after much thought I'm concerned about the process of determining what timelines are branched to what others if we have to examine collections of ScheduledInstances.  That's a

## ATTRIBUTES

drag. ScheduleTimeline objects might be more useful if they provided information regarding the first and last ScheduledInstance objects that they reference for the sake of traversal and sequencing, and then I suppose we could use those pointers to hop ScheduleTimelines via ScheduledInstances. Alternatively, we could simply point ScheduleInstances to each other in a doubly-linked list with previousScheduleTimeline(s) and nextScheduledTimeline(s). Thoughts?

[ Is static True. Containment is Not Specified. ]

◆ scheduledInstanceEncounterId : String  Private

I get this now.  You do want to know if the instance is part of an encounter. This field points to the encounter that the activity is taking part of.

[ Is static True. Containment is Not Specified. ]

◆ scheduledInstanceId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

◆ scheduledInstanceTimingIds : List<String>  Private

Ok, I'll add this, but it isn't very useful.  You're better off starting at a ScheduleTimeline.  In this case, you could have an instance pointing to a large number of Timing objects because it has a large number of scheduling constraints.  I like the idea of activites not having any Timing references; just decisions because they are selective. If we must, we may want to consider changing this to be directionaly at least...incoming and outgoing?

[ Is static True. Containment is Not Specified. ]

◆ scheduleSequenceNumber : Integer  Private

There has been an ask for sequencing of ScheduledInstance in a ScheduleTimeline. In order to do this, the entire ScheduleTimeline must be constructed with all of the necessary ScheduledInstance, Timing and Exit objects. Once this is complete, a some sequencing process can then annotate the ScheduleTimeline's collection of ScheduleInstance objects and update this field.  This is a hard field to name, btw. Is scheduleTimelineScheduledInstanceSequenceNumber manageable?

[ Is static True. Containment is Not Specified. ]

◆ scheduleTimelineExitId : String  Private

In the last version of the model, there was a pointer to an Exit object in the previous version of this class.  I'm struggling with this, as the exit is the property of a ScheduleTimeline already. I can understand why we need an entry pointer but not an exit. Is this just a wqy of identifying a final ScheduledInstance in some ScheduleTimeline? Isn't that still the perspective of the timeline? Just trying to name it really shows that I'm trying to point to something that's really something my parent cares about.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline

Target: Private scheduleTimelineIinstances (Class) ScheduledInstance

Cardinality:  [0..*]

## OPERATIONS

getEntryScheduleSequenceId () : String Public

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

getScheduledInstanceEncounterId () : String Public

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

getScheduledInstanceid () : String Public

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

getScheduleSequenceNumber () : Integer Public

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

getScheduleTimelineExitId () : String Public

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

getSecheduledInstanceTimingIds () : List<String> Public

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

ScheduledInstance (scheduledInstanceId : String ) :  Public

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

setEntryScheduleSequenceId (entryScheduleSequenceId : String ) : void Public

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

setScheduledInstanceEncounterId (scheduledInstanceEncounterId : String ) : void Public

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

setScheduleSequenceNumber (scheduleSequenceNumber : Integer ) : void Public

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

setScheduleTimelineExitId (scheduleTimelineExitId : String ) : void Public

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

setSecheduledInstanceTimingIds (secheduledInstanceTimingIds : List<String> ) : void Public

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

# ScheduleTimeline

*Class in package 'model'*

regarding TimeLine Entry as a new class name.  I feel that TimelineEtry is confusing.  If there is a timeline entry, then there must be a timeline.  Yet, in the diagram, the two concepts are conflated into the TimelineEntry.  I suggest keeping ScheduleTimeline and adding entry attribution as a simple condition field.

<div align="right">

ScheduleTimeline

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| ATTRIBUTES |
|---|
| ◆ entryCondition : String  Private |
| Here we again place information at two levels:  The ScheduledDecisionInstance and The ScheduleTimeline.  If the timeline owns all of the instances then it already has a way to get to a condition on a decision. We should ponder this further. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ entryScheduledInstanceId : String  Private |
| If the timeline was due to a condition that was met for traversal from a previous timpoint, then we should have a handle to that timepoint. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ scheduleTimelineDescription : String  Private |
| A textual description of the timeline.  There will likely be numerous timelines in a study and this field provides the context for the particular timeline. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ scheduleTimelineExits : List<Exit>  Private |
| This field represents the Exit object associated with the ScheduleTimeline. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ scheduleTimelineId : String  Private  Const |
| [ Is static True. Containment is Not Specified. ] |
| ◆ scheduleTimelineIinstances : List<ScheduledInstance>  Private |
| At this point, this is an unordered list of instances.  We might consider more encapsulation by creating a timepointSequence wrapper. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ scheduleTimelineName : String  Private |
| This is field provides a name for the timeline |
| [ Is static True. Containment is Not Specified. ] |

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline | Target: Private scheduleTimelineIinstances (Class) ScheduledInstance
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduleTimeline | Target: Private scheduleTimelineExits (Class) Exit
Cardinality: [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private studyScheduleTimelines (Class) ScheduleTimeline
Cardinality: [0..*]

## OPERATIONS

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

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

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

◆ getScheduleTimelineExits () : List<Exit> Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

◆ getScheduleTimelineIinstances () : List<ScheduledInstance> Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

| OPERATIONS |
| --- |
| |
| ◆ setEntryCondition (entryCondition : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setEntryScheduledInstanceId (entryScheduledInstanceId : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setScheduleTimelineDescription (scheduleTimelineDescription : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setScheduleTimelineExits (scheduleTimelineExits : List<Exit> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setScheduleTimelineIinstances (scheduleTimelineIinstances : List<ScheduledInstance> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setScheduleTimelineName (scheduleTimelineName : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Study

*Class in package 'model'*

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

Study
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| ATTRIBUTES |
| --- |
| ◆ businessTherapeuticAreas : List<Code>  Private |
| A therapeutic area classification based on the structure and operations of the business unit. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyAcronym : String  Private |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyDesigns : List<StudyDesign>  Private |
| [ Is static True. Containment is Not Specified. ] |

| ATTRIBUTES |
| --- |
| |

🔷 studyId : UUID  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 studyIdentifiers : List<StudyIdentifier>  Private

[ Is static True. Containment is Not Specified. ]

🔷 studyPhase : AliasCode  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 studyProtocolVersions : List<StudyProtocolVersion>  Private

[ Is static True. Containment is Not Specified. ]

🔷 studyRationale : String  Private

[ Is static True. Containment is Not Specified. ]

🔷 studyTitle : String  Private

The sponsor-defined name of the clinical study.

[ Is static True. Containment is Not Specified. ]

🔷 studyType : Code  Private

The nature of the investigation for which study information is being collected. (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..*]

| ASSOCIATIONS |
| --- |
| |

🖊 Association (direction: Source -> Destination)

Source: Public (Class) Study                    Target: Private studyPhase (Class) AliasCode

🖊 Association (direction: Source -> Destination)

Source: Public (Class) Study                    Target: Private studyDesigns (Class) StudyDesign
                                                  Cardinality:  [0..*]

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

| OPERATIONS |
| --- |

🔶 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. ]

**OPERATIONS**

◆ getStudyDesigns () : List<StudyDesign> Public

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

◆ getStudyId () : UUID Public

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

◆ getStudyIdentifiers () : List<StudyIdentifier> Public

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

◆ getStudyPhase () : AliasCode Public

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

◆ getStudyProtocolVersions () : List<StudyProtocolVersion> Public

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

◆ getStudyRationale () : String Public

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

◆ getStudyTitle () : String Public

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

◆ getStudyType () : Code Public

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

◆ getStudyVersion () : String Public

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

◆ removeStudyDesign (studyDesign : StudyDesign ) : void Public

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

◆ removeStudyIdentifier (studyIdentifier : StudyIdentifier ) : void Public

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

◆ removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion ) : void Public

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

◆ setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code> ) : void Public

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

| OPERATIONS |
|---|

🔶 setStudyAcronym (studyAcronym : String ) : void Public

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

🔶 setStudyDesigns (studyDesigns : List<StudyDesign> ) : void Public

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

🔶 setStudyIdentifiers (studyIdentifiers : List<StudyIdentifier> ) : void Public

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

🔶 setStudyPhase (studyPhase : AliasCode ) : void Public

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

🔶 setStudyProtocolVersions (studyProtocolVersions : List<StudyProtocolVersion> ) : void Public

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

🔶 setStudyRationale (studyRationale : String ) : void Public

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

🔶 setStudyTitle (studyTitle : String ) : void Public

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

🔶 setStudyType (studyType : Code ) : void Public

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

🔶 setStudyVersion (studyVersion : String ) : void Public

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

🔶 Study (studyId : UUID ) :  Public

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

# StudyArm

*Class in package 'model'*

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

<div align="right">

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| ATTRIBUTES |
|---|

**ATTRIBUTES**

◆ studyArmDataOriginDescription : String  Private

The textual representation of the study arm data origin.

[ Is static True. Containment is Not Specified. ]

◆ studyArmDataOriginType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

◆ studyArmDescription : String  Private

The textual representation of the study arm.

[ Is static True. Containment is Not Specified. ]

◆ studyArmId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

◆ studyArmName : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ studyArmType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

## OPERATIONS

◈ getStudyArmDataOriginDescription () : String Public

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

◈ getStudyArmDataOriginType () : Code Public

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

◈ getStudyArmDescription () : String Public

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

◈ getStudyArmId () : String Public

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

◈ getStudyArmName () : String Public

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

◈ getStudyArmType () : Code Public

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

◈ setStudyArmDataOriginDescription (studyArmDataOriginDescription : String ) : void Public

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

◈ setStudyArmDataOriginType (studyArmDataOriginType : Code ) : void Public

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

◈ setStudyArmDescription (studyArmDescription : String ) : void Public

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

◈ setStudyArmName (studyArmName : String ) : void Public

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

◈ setStudyArmType (studyArmType : Code ) : void Public

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

◈ StudyArm (studyArmId : String ) :  Public

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

# StudyCell

*Class in package 'model'*

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

<div align="right">

StudyCell
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</div>

### ATTRIBUTES

⬦ studyArm : StudyArm  Private

[ Is static True. Containment is Not Specified. ]

⬦ studyCellId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

⬦ studyElements : List<StudyElement>  Private

[ Is static True. Containment is Not Specified. ]

⬦ studyEpoch : StudyEpoch  Private

[ Is static True. Containment is Not Specified. ]

### ASSOCIATIONS

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

### OPERATIONS

⬦ addStudyElement (studyElement : StudyElement ) : void Public

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

🔷 getStudyArm () : StudyArm Public

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

🔷 getStudyCellId () : String Public

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

🔷 getStudyElements () : List<StudyElement> Public

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

🔷 getStudyEpoch () : StudyEpoch Public

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

🔷 removeStudyElement (studyElement : StudyElement ) : void Public

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

🔷 setStudyArm (studyArm : StudyArm ) : void Public

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

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

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

🔷 setStudyEpoch (studyEpoch : StudyEpoch ) : void Public

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

🔷 StudyCell (studyCellId : String ) :  Public

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


# 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 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|
| |

**ATTRIBUTES**

◆ activities : List<Activity>  Private

[ Is static True. Containment is Not Specified. ]

◆ bcCategories : List<BiomedicalConceptCategory>  Private

[ Is static True. Containment is Not Specified. ]

◆ bcSurrogates : List<BiomedicalConceptSurrogate>  Private

[ Is static True. Containment is Not Specified. ]

◆ biomedicalConcepts : List<BiomedicalConcept>  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

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. ]

| ATTRIBUTES |
|---|

◆ 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. ]

◆ studyScheduleTimelines : List<ScheduleTimeline>  Private

This field provides a collection of all of the ScheduleTimeline objects associated with the StudyDesign.

[ Is static True. Containment is Not Specified. ]

◆ therapeuticAreas : List<Code>  Private

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

[ Is static True. Containment is Not Specified. ]

◆ trialIntentType : List<Code>  Private

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

[ Is static True. Containment is Not Specified. ]

◆ trialType : List<Code>  Private

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

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign                                    Target: Private studyScheduleTimelines (Class) ScheduleTimeline

## ASSOCIATIONS

|  | Cardinality:  [0..*] |

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private 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) StudyDesign

Target: Private bcCategories (Class)
BiomedicalConceptCategory
Cardinality:  [0..*]

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private bcSurrogates (Class)
BiomedicalConceptSurrogate
Cardinality:  [0..*]

---

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private biomedicalConcepts (Class) BiomedicalConcept
Cardinality: [0..*]

---

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign | Target: Private studyDesignBlindingScheme (Class) AliasCode

---

✎ Association (direction: Source -> Destination)

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

---

✎ Association (direction: Source -> Destination)

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

---

✎ Association (direction: Source -> Destination)

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

---

✎ Association (direction: Source -> Destination)

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

---

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study | Target: Private studyDesigns (Class) StudyDesign

**ASSOCIATIONS**

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

**OPERATIONS**

⬦ addStudyIndication (indication : Indication ) : void Public

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

⬦ addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public

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

⬦ addStudyObjective (objective : Objective ) : void Public

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

⬦ getActivities () : List<Activity> Public

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

⬦ getBcCategories () : List<BiomedicalConceptCategory> Public

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

⬦ getBcSurrogates () : List<BiomedicalConceptSurrogate> Public

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

⬦ getBiomedicalConcepts () : List<BiomedicalConcept> Public

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

⬦ getEncounters () : List<Encounter> Public

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

⬦ getInterventionModel () : Code Public

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

⬦ getStudyCells () : List<StudyCell> Public

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

⬦ getStudyDesignBlindingScheme () : AliasCode Public

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

⬦ getStudyDesignDescription () : String Public

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

| OPERATIONS |
| --- |
| ◆ getStudyDesignId () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyDesignName () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyDesignRationale () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyEstimands () : List<Estimand> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyIndications () : List<Indication> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyObjectives () : List<Objective> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyPopulations () : List<StudyDesignPopulation> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getStudyScheduleTimelines () : List<ScheduleTimeline> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getTherapeuticAreas () : List<Code> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getTrialIntentType () : List<Code> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getTrialType () : List<Code> Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ removeStudyIndication (indication : Indication ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public |

**OPERATIONS**

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

🔷 removeStudyObjective (objective : Objective ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setActivities (activities : List<Activity> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setBcCategories (bcCategories : List<BiomedicalConceptCategory> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setBcSurrogates (bcSurrogates : List<BiomedicalConceptSurrogate> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setBiomedicalConcepts (biomedicalConcepts : List<BiomedicalConcept> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setEncounters (encounters : List<Encounter> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

🔷 setStudyCells (studyCells : List<StudyCell> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 setStudyDesignBlindingScheme (studyDesignBlindingScheme : AliasCode ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

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

🔷 setStudyEstimands (studyEstimands : List<Estimand> ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

| OPERATIONS |
|---|
| |
| ◆ setStudyIndications (studyIndications : List<Indication> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setStudyInvestigationalInterventions (studyInvestigationalInterventions : List<InvestigationalIntervention> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setStudyObjectives (studyObjectives : List<Objective> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setStudyScheduleTimelines (studyScheduleTimelines : List<ScheduleTimeline> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setTherapeuticAreas (therapeuticAreas : List<Code> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setTrialIntentType (trialIntentType : List<Code> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setTrialType (trialType : List<Code> ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ StudyDesign (studyDesignId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# StudyDesignPopulation

*Class in package 'model'*

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

StudyDesignPopulation
Version 1.0  Phase 1.0  Proposed
cupke created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|
| ◆ plannedMaximumAgeOfParticipants : String  Private |
| [ Is static True. Containment is Not Specified. ] |

## ATTRIBUTES

🔷 plannedMinimumAgeOfParticipants : String  Private

[ Is static True. Containment is Not Specified. ]

🔷 plannedNumberOfParticipants : int  Private

[ Is static True. Containment is Not Specified. ]

🔷 plannedSexOfParticipants : List<Code>  Private

[ Is static True. Containment is Not Specified. ]

🔷 populationDescription : String  Private

The textual representation of the study population.

[ Is static True. Containment is Not Specified. ]

🔷 studyDesignPopulationId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesignPopulation                Target: Private plannedSexOfParticipants (Class)
                                                            Code
                                                                Cardinality:  [0..*]

✏️ Association (direction: Source -> Destination)

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

## OPERATIONS

🔷 getPlannedMaximumAgeOfParticipants () : String Public
                    [ 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. ]

| OPERATIONS |
| --- |

◆ getPlannedSexOfParticipants () : List<Code> Public

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

◆ getPopulationDescription () : String Public

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

◆ getStudyDesignPopulationId () : String Public

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

◆ setPlannedMaximumAgeOfParticipants (plannedMaximumAgeOfParticipants : String ) : void Public

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

◆ setPlannedMinimumAgeOfParticipants (plannedMinimumAgeOfParticipants : String ) : void Public

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

◆ setPlannedNumberOfParticipants (plannedNumberOfParticipants : int ) : void Public

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

◆ setPlannedSexOfParticipants (plannedSexOfParticipants : List<Code> ) : void Public

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

◆ setPopulationDescription (populationDescription : String ) : void Public

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

◆ StudyDesignPopulation (uuid : String ) :  Public

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

# StudyElement

*Class in package 'model'*

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

StudyElement
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |

◆ studyElementDescription : String  Private

| ATTRIBUTES |
|---|

The textual representation of the study design element.

[ Is static True. Containment is Not Specified. ]

🔷 studyElementId : String  Private  Const

element only attributes - these purely describe an element

[ Is static True. Containment is Not Specified. ]

🔷 studyElementName : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 transitionEndRule : Condition  Private

[ Is static True. Containment is Not Specified. ]

🔷 transitionStartRule : Condition  Private

all elements point to transition rules Are transitionRules the same as conditions?  Should eventing, etc..be different based on the existence of a condition vs a transitionRule? are Conditions unscripted and transition rules scripted?

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

🖊 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement                    Target: Private transitionStartRule (Class) Condition

🖊 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement                    Target: Private transitionEndRule (Class) Condition

🖊 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. ]

| OPERATIONS |
| --- |

◆ getStudyElementId () : String Public

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

◆ getStudyElementName () : String Public

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

◆ getTransitionEndRule () : Condition Public

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

◆ getTransitionStartRule () : Condition Public

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

◆ setStudyElementDescription (studyElementDescription : String ) : void Public

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

◆ setStudyElementName (studyElementName : String ) : void Public

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

◆ setTransitionEndRule (transitionEndRule : Condition ) : void Public

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

◆ setTransitionStartRule (transitionStartRule : Condition ) : void Public

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

◆ StudyElement (studyElementId : String ) :  Public

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

# StudyEpoch

*Class in package 'model'*

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

StudyEpoch
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |

◆ encounters : List<Encounter>  Private

[ Is static True. Containment is Not Specified. ]

| ATTRIBUTES |
| --- |

◈ nextStudyEpochId : String  Private

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

[ Is static True. Containment is Not Specified. ]

◈ previousStudyEpochId : String  Private

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

[ Is static True. Containment is Not Specified. ]

◈ studyEpochDescription : String  Private

The textual representation of the study epoch.

[ Is static True. Containment is Not Specified. ]

◈ studyEpochId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

◈ studyEpochName : String  Private

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

[ Is static True. Containment is Not Specified. ]

◈ studyEpochType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
| --- |

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

**ASSOCIATIONS**

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

**OPERATIONS**

🔶 getEncounters () : List<Encounter> Public

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

🔶 getNextStudyEpochId () : String Public

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

🔶 getPreviousStudyEpochId () : String Public

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

🔶 getStudyEpochDescription () : String Public

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

🔶 getStudyEpochId () : String Public

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

🔶 getStudyEpochName () : String Public

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

🔶 getStudyEpochType () : Code Public

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

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

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

🔶 setNextStudyEpochId (nextStudyEpochId : String ) : void Public

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

🔶 setPreviousStudyEpochId (previousStudyEpochId : String ) : void Public

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

🔶 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. ]

| OPERATIONS |
| --- |
| 🔶 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 3/1/2023.  Last modified 3/1/2023

| 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 |

| ASSOCIATIONS (cont.) |
| --- |
| ✏️ Association (direction: Source -> Destination) |

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

| OPERATIONS |
| --- |
| |

| OPERATIONS |
| --- |

◆ getStudyIdentifier () : String Public

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

◆ getStudyIdentifierId () : String Public

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

◆ getStudyIdentifierScope () : Organization Public

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

◆ setStudyIdentifier (studyIdentifier : String ) : void Public

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

◆ setStudyIdentifierScope (studyIdentifierScope : Organization ) : void Public

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

◆ StudyIdentifier (studyIdentifierId : String ) :  Public

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

# StudyProtocolVersion

*Class in package 'model'*

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

StudyProtocolVersion
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |

◆ briefTitle : String  Private

The short descriptive name for the protocol.

[ Is static True. Containment is Not Specified. ]

◆ officialTitle : String  Private

The formal descriptive name for the protocol.

[ Is static True. Containment is Not Specified. ]

◆ protocolAmendment : String  Private

| ATTRIBUTES |
| --- |

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

[ Is static True. Containment is Not Specified. ]

◆ protocolEffectiveDate : Date  Private

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

[ Is static True. Containment is Not Specified. ]

◆ protocolStatus : Code  Private

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

[ Is static True. Containment is Not Specified. ]

◆ protocolVersion : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ publicTitle : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ scientificTitle : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ studyProtocolVersionId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
| --- |

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

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

Cardinality:  [0..*]

**ASSOCIATIONS**

**OPERATIONS**

◆ getBriefTitle () : String Public

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

◆ getOfficialTitle () : String Public

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

◆ getProtocolAmendment () : String Public

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

◆ getProtocolEffectiveDate () : Date Public

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

◆ getProtocolStatus () : Code Public

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

◆ getProtocolVersion () : String Public

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

◆ getPublicTitle () : String Public

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

◆ getScientificTitle () : String Public

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

◆ getStudyProtocolVersionId () : String Public

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

◆ setBriefTitle (briefTitle : String ) : void Public

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

◆ setOfficialTitle (officialTitle : String ) : void Public

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

◆ setProtocolAmendment (protocolAmendment : String ) : void Public

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

◆ setProtocolEffectiveDate (protocolEffectiveDate : Date ) : void Public

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

🔶 setProtocolStatus (protocolStatus : Code ) : void Public

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

🔶 setProtocolVersion (protocolVersion : String ) : void Public

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

🔶 setPublicTitle (publicTitle : String ) : void Public

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

🔶 setScientificTitle (scientificTitle : String ) : void Public

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

🔶 StudyProtocolVersion (studyProtocolVersionId : String ) :  Public

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

# Timepoint

*Class in package 'model'*

The Timepoint class is used to link activities and encounters to a schedule timeline.

Timepoint
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
|---|

🔷 entryTimelineId : String  Private

In the diagram, this is timelineEntryId but I'm worried that will me misinterpreted since it's just a string. I propose entryTimelineId because it points to the entry to a new timeline. if this is the case, then we don't have to have this timepoint branch to another timepoint, but to another timeline.  Thoughts?

[ Is static True. Containment is Not Specified. ]

🔷 nextTimepointIds : List<String>  Private

[ Is static True. Containment is Not Specified. ]

🔷 previousTimepointIds : List<String>  Private

when referencing objects from the timeline, it's important to use id references because the API JSON payload would result in duplicate expressions of objects pointing to the timeline.  This assumption should be asserted. All of these fields below should be defined as relationships in the CT. In particular for pointers between timepoints, it seems to me that there should be some

| ATTRIBUTES |
| --- |

clear understanding that only a Branch type timepoint is capable of pointing to more than one previous or next timepoint.  Am I misunderstanding the the use of the type attribute?

[ Is static True. Containment is Not Specified. ]

🔹 timepointActivityIds : List<String>  Private

This is the only way to associate activities with timepoints, as we've decided that the cardinality from timepoint to activities is one to many, correct?

[ Is static True. Containment is Not Specified. ]

🔹 timepointCondition : Condition  Private

The condition that may be associated with the timepoint, if the timepoint is of type branch (according to the presentation material). Even though a condition could or should be re-used across multiple timepoints and/or entries this reference should be an object reference as there would be no other object reference available to ensure inclusion in the JSON payload (to my understanding)

[ Is static True. Containment is Not Specified. ]

🔹 timepointDescription : String  Private

The textual representation of the timepoint.

[ Is static True. Containment is Not Specified. ]

🔹 timepointEncounterId : String  Private

I'm somewhat confused as to why an encounter has multiple touchpoints in the timeline, but I haven't heard of a broad set of use cases for traversal of the timeline. You can get to a timepoint from an encounter via a timing.  You then have a circular reference from the timing via the timepoint.  There is potential for these to be out of sync as well, correct?

[ Is static True. Containment is Not Specified. ]

🔹 timepointExitId : String  Private

Unsure of the nescessity of this id reference to an actual Exit class. It seems to make sense to associate an exit condition and maybe an exit flag to a timepoint. What attributes are required to be associated with an Exit that should be solely contained in an Exit class?  Maybe just saying a timepoint is a final timepoint is just as intuitive?

[ Is static True. Containment is Not Specified. ]

🔹 timepointId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔹 timepointScheduledAt : Timing  Private

Must assume this is an object reference as no other references exist in the model except for Encounter and that would not necessarily be the same timepoint being referenced, so no duplication will likely exist. This could be considered an attribute of the timepoint because I'm not sure that the timing has any value outside of its inclusion in the timepoint data (except for maybe...reuse?)

[ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

◆ timepointType : Code  Private

Denotes the type timepoint object added to the timeline.  The value can be either a node, a decision or a branch. a branch being used to link alternate or sub-timelines to an existing timeline.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timepoint                    Target: Private timepointCondition (Class) Condition

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timepoint                    Target: Private timepointType (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timepoint                    Target: Private timepointScheduledAt (Class) Timing

## OPERATIONS

◆ getEntryTimelineId () : String Public

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

◆ getNextTimepointIds () : List<String> Public

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

◆ getPreviousTimepointIds () : List<String> Public

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

◆ getTimepointActivityIds () : List<String> Public

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

◆ getTimepointCondition () : Condition Public

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

◆ getTimepointDescription () : String Public

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

**OPERATIONS**

◆ getTimepointEncounterId () : String Public

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

◆ getTimepointExitId () : String Public

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

◆ getTimepointId () : String Public

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

◆ getTimepointScheduledAt () : Timing Public

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

◆ getTimepointType () : Code Public

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

◆ setEntryTimelineId (entryTimelineId : String ) : void Public

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

◆ setNextTimepointIds (nextTimepointIds : List<String> ) : void Public

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

◆ setPreviousTimepointIds (previousTimepointIds : List<String> ) : void Public

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

◆ setTimepointActivityIds (timepointActivityIds : List<String> ) : void Public

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

◆ setTimepointCondition (timepointCondition : Condition ) : void Public

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

◆ setTimepointDescription (timepointDescription : String ) : void Public

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

◆ setTimepointExitId (timepointExitId : String ) : void Public

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

◆ setTimepointScheduledAt (timepointScheduledAt : Timing ) : void Public

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

| OPERATIONS |
| --- |

  🔶 setTimepointType (timepointType : Code ) : void Public

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

  🔶 setWorkflowItemEncounter (workflowItemEncounterId : String ) : void Public

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

  🔶 Timepoint (timepointId : String ) :  Public

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

# Timing

*Class in package 'model'*

The Timing class is used to relate ScheduledInstance objects. In graph, this information would likely sit on relationship that exists between ScheduledInstances.  ScheduledInstances have no information regarding their relationships with other ScheduledInstances in a ScheduleTimeline. This is where that information is captured.  In a typical GANTT chart, these are the arrows you see between the task boxes that tell us how the work should be sequenced.

Timing
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 3/1/2023.  Last modified 3/1/2023

| ATTRIBUTES |
| --- |

  🔷 relativeFromScheduledInstanceId : String  Private

This field defines the ScheduledInstance object that the timing defines as the anchor. When we define a timing relationship between two ScheduledInstances, one instance is the from and the other is the to in what is essentially a "timing between" constraint.

        [ Is static True. Containment is Not Specified. ]

  🔷 relativeToScheduledInstanceId : String  Private

This field defines the ScheduledInstance object that has the timing constraint associated with the anchor instance.  This is the instance that has the "timingRelativeToFrom" constraint associated with the fromScheduledInstance object.

        [ Is static True. Containment is Not Specified. ]

  🔷 timingId : String  Private  Const

        [ Is static True. Containment is Not Specified. ]

  🔷 timingRelativeToFrom : Code  Private

Code values that describe the timing relative to the associated timepoint, I believe.  Somewhat unsure here. Values are typical of gant task relationship dependencies.  They are:  StartToStart, StartToEnd, EndToEnd and EndToStart.

        [ Is static True. Containment is Not Specified. ]

| ATTRIBUTES |
|---|

◆ timingType : Code  Private

Code values that describe the type of timing.  Valid values include Before, After and Absolute.

[ Is static True. Containment is Not Specified. ]

◆ timingValue : String  Private

According to the presentation, the value will be provide further context based on the type of the timing. For example, if the timing type is absolute then maybe something like "first dose, day 0" and if the type is Before it could be "1 day before x".

[ Is static True. Containment is Not Specified. ]

◆ timingWindow : String  Private

Defines window of time associated with the timing. We could either define slack or lead time as two variables to ensure consistency however, this can be inferred along with the timingRelativeToFrom value.

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timing                    Target: Private timingRelativeToFrom (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timing                    Target: Private timingType (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) Encounter                 Target: Private encounterScheduledAt (Class) Timing

✎ Association (direction: Source -> Destination)

Source: Public (Class) ScheduledDecisionInstance    Target: Private conditionTimings (Class) Timing
                                                   Cardinality:  [0..*]

✎ Association (direction: Source -> Destination)

Source: Public (Class) Timepoint                 Target: Private timepointScheduledAt (Class) Timing

| OPERATIONS |
|---|

◆ getRelativeFromScheduledInstanceId () : String Public

**OPERATIONS**

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

🔹 getRelativeToScheduledInstanceId () : String Public

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

🔹 getTimingId () : String Public

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

🔹 getTimingRelativeToFrom () : Code Public

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

🔹 getTimingType () : Code Public

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

🔹 getTimingValue () : String Public

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

🔹 getTimingWindow () : String Public

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

🔹 setRelativeFromScheduledInstanceId (relativeFromScheduledInstanceId : String ) : void Public

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

🔹 setRelativeToScheduledInstanceId (relativeToScheduledInstanceId : String ) : void Public

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

🔹 setTimingRelativeToFrom (timingRelativeToFrom : Code ) : void Public

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

🔹 setTimingType (timingType : Code ) : void Public

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

🔹 setTimingValue (timingValue : String ) : void Public

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

🔹 setTimingWindow (timingWindow : String ) : void Public

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

🔹 Timing (timingId : String ) :  Public

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

| OPERATIONS |
|---|
|  |

# TransitionRule

*Class in package 'model'*

<div align="right">

TransitionRule

Version 1.0  Phase 1.0  Proposed

cupke created on 3/1/2023.  Last modified 3/1/2023

</div>

| ASSOCIATIONS |
|---|

    🖉 Association (direction: Source -> Destination)

| Source: Public (Class) Encounter | Target: Private transitionEndRule (Class) TransitionRule |
|---|---|

    🖉 Association (direction: Source -> Destination)

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