# model

*Package in package 'DDF'*

model
Version 1.0  Phase 1.0  Proposed
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# model diagram

*Class diagram in package 'model'*

model
Version 1.0
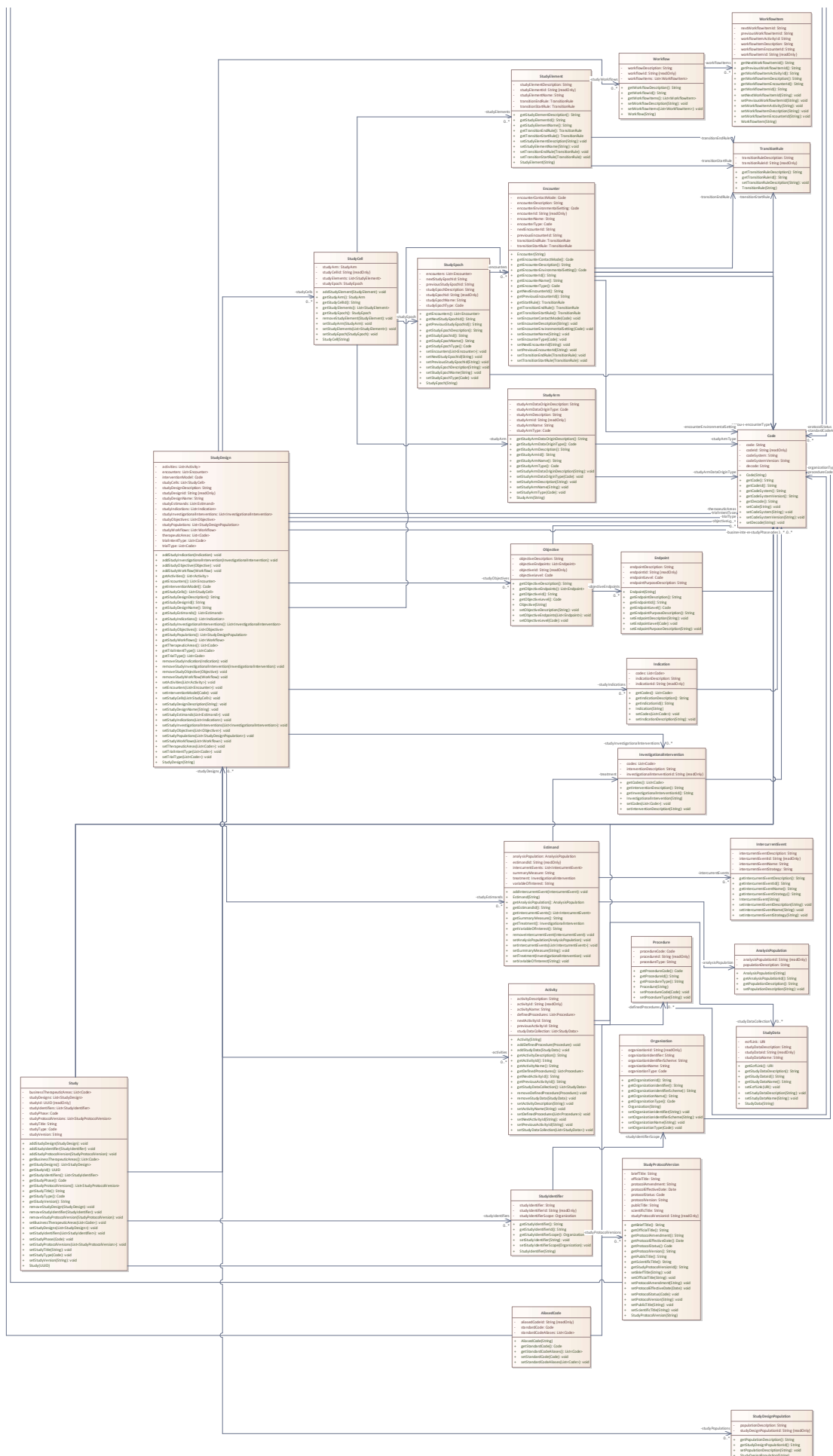cupke created on 11/21/2022.  Last modified 11/21/2022

*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
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| ATTRIBUTES |
| --- |

**activityDescription : String  Private**

The textual representation of the study activity.

[ Is static True. Containment is Not Specified. ]

**activityId : String  Private  Const**

[ Is static True. Containment is Not Specified. ]

**activityName : String  Private**

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

[ Is static True. Containment is Not Specified. ]

**definedProcedures : List<Procedure>  Private**

[ Is static True. Containment is Not Specified. ]

**nextActivityId : String  Private**

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

[ Is static True. Containment is Not Specified. ]

**previousActivityId : String  Private**

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

[ Is static True. Containment is Not Specified. ]

**studyDataCollection : List<StudyData>  Private**

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
| --- |

## ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private studyDataCollection (Class) StudyData
  Cardinality: [0..*]

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private activities (Class) Activity
  Cardinality: [0..*]

## OPERATIONS

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

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

◆ addStudyData (studyData : StudyData ) : void Public
  [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

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

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

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

| OPERATIONS |
|---|
| |

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

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

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

**removeStudyData (studyData : StudyData ) : void Public**
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

**setDefinedProcedures (definedProcedures : List<Procedure> ) : void Public**
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

**setStudyDataCollection (studyDataCollection : List<StudyData> ) : void Public**
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

# AliasedCode

*Class in package 'model'*

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

AliasedCode
Version 1.0  Phase 1.0  Proposed
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## ATTRIBUTES

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) AliasedCode                    Target: Private standardCode (Class) Code

## OPERATIONS

◆ AliasedCode (aliasedCodeId : 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 11/21/2022.  Last modified 11/21/2022

**ATTRIBUTES**

🔹 analysisPopulationId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔹 populationDescription : String  Private

The textual representation of the study population for analysis.

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand                          Target: Private analysisPopulation (Class)
                                                         AnalysisPopulation

**OPERATIONS**

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

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

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

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

# Code

*Class in package 'model'*

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

Code
Version 1.0  Phase 1.0  Proposed
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## ATTRIBUTES

🔷 code : String  Private

The literal value of a code.

[ Is static True. Containment is Not Specified. ]

🔷 codeId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 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) StudyProtocolVersion                    Target: Private protocolStatus (Class) Code

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) AliasedCode

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study

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

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyPhase (Class) Code

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Procedure

Target: Private procedureCode (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Indication

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterContactMode (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) AliasedCode

Target: Private standardCode (Class) Code

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmDataOriginType (Class) Code

## OPERATIONS

| OPERATIONS |
| --- |

◆ Code (codeId : String ) :  Public

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

◆ getCode () : String Public

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

◆ getCodeId () : String Public

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

◆ getCodeSystem () : String Public

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

◆ getCodeSystemVersion () : String Public

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

◆ getDecode () : String Public

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

◆ setCode (code : String ) : void Public

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

◆ setCodeSystem (codeSystem : String ) : void Public

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

◆ setCodeSystemVersion (codeSystemVersion : String ) : void Public

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

◆ setDecode (decode : String ) : void Public

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

# Encounter

*Class in package 'model'*

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

Encounter
Version 1.0  Phase 1.0  Proposed
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| ATTRIBUTES |
| --- |

| ATTRIBUTES |
| --- |

◆ encounterContactMode : 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. ]

◆ encounterName : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ encounterType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

◆ nextEncounterId : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ previousEncounterId : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ transitionEndRule : TransitionRule  Private

[ Is static True. Containment is Not Specified. ]

◆ transitionStartRule : TransitionRule  Private

## ATTRIBUTES

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

Source: Public (Class) Encounter                          Target: Private encounterEnvironmentalSetting (Class) Code

Association (direction: Source -> Destination)

Source: Public (Class) Encounter                          Target: Private encounterContactMode (Class) Code

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

## OPERATIONS

Encounter (encounterId : String ) :  Public

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

**OPERATIONS**

getEncounterContactMode () : Code Public

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

getEncounterDescription () : String Public

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

getEncounterEnvironmentalSetting () : Code Public

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

getEncounterId () : String Public

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

getEncounterName () : String Public

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

getEncounterType () : Code Public

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

getNextEncounterId () : String Public

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

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. ]

setEncounterContactMode (encounterContactMode : 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

| OPERATIONS |
| --- |
| [ 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. ]

🔹 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
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| ATTRIBUTES |
| --- |

🔹 endpointDescription : String  Private

The textual representation of the study endpoint.

[ Is static True. Containment is Not Specified. ]

🔹 endpointId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

**endpointLevel : Code  Private**

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

[ Is static True. Containment is Not Specified. ]

**endpointPurposeDescription : String  Private**

The textual representation of the study endpoint purpose.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

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

## OPERATIONS

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

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

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

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

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

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

| OPERATIONS |
|---|

🔷 setEndpointLevel (endpointLevel : Code ) : void Public

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

🔷 setEndpointPurposeDescription (endpointPurposeDescription : String ) : void Public

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

# Estimand

*Class in package 'model'*

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

Estimand
Version 1.0  Phase 1.0  Proposed
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| ATTRIBUTES |
|---|

🔷 analysisPopulation : AnalysisPopulation  Private

[ Is static True. Containment is Not Specified. ]

🔷 estimandId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 intercurrentEvents : List<IntercurrentEvent>  Private

[ Is static True. Containment is Not Specified. ]

🔷 summaryMeasure : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 treatment : InvestigationalIntervention  Private

[ Is static True. Containment is Not Specified. ]

🔷 variableOfInterest : String  Private

Points to an Endpoint (cross-reference)

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
|---|

**ASSOCIATIONS**

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

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

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private treatment (Class)
InvestigationalIntervention

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private analysisPopulation (Class)
AnalysisPopulation

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

**OPERATIONS**

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

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

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

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

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

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

🔷 getTreatment () : InvestigationalIntervention Public

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

getVariableOfInterest () : String 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 : String ) : void Public

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

# Indication

*Class in package 'model'*

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

Indication
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| 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.

| ATTRIBUTES | |
|---|---|
| | [ Is static True. Containment is Not Specified. ] |
| 🔷 indicationId : String  Private  Const | |
| | [ Is static True. Containment is Not Specified. ] |

## ASSOCIATIONS

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

## OPERATIONS

🔷 getCodes () : List<Code> Public

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

🔷 getIndicationDescription () : String Public

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

🔷 getIndicationId () : String Public

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

🔷 Indication (indicationId : String ) :  Public

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

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

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

🔷 setIndicationDescription (indicationDescription : String ) : void Public

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

# IntercurrentEvent

*Class in package 'model'*

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

IntercurrentEvent
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

## ATTRIBUTES

◆ intercurrentEventDescription : String  Private

The textual representation of the intercurrent event.

[ Is static True. Containment is Not Specified. ]

◆ intercurrentEventId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

◆ intercurrentEventName : String  Private

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

[ Is static True. Containment is Not Specified. ]

◆ intercurrentEventStrategy : String  Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

## OPERATIONS

◆ getIntercurrentEventDescription () : String Public

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

◆ getIntercurrentEventId () : String Public

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

◆ getIntercurrentEventName () : String Public

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

| OPERATIONS |
|---|
| 🔷 getIntercurrentEventStrategy () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 IntercurrentEvent (intercurrentEventId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 setIntercurrentEventDescription (intercurrentEventDescription : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 setIntercurrentEventName (intercurrentEventName : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 setIntercurrentEventStrategy (intercurrentEventStrategy : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# InvestigationalIntervention

*Class in package 'model'*

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

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InvestigationalIntervention
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

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| 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 |
|---|

| ASSOCIATIONS |
| --- |

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

| OPERATIONS |
| --- |

◆ getCodes () : List<Code> Public

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

◆ getInterventionDescription () : String Public

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

◆ getInvestigationalInterventionId () : String Public

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

◆ InvestigationalIntervention (investigationalInterventionId : String ) :  Public

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

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

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

◆ setInterventionDescription (interventionDescription : String ) : void Public

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

# Objective

*Class in package 'model'*

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

Objective
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

## ATTRIBUTES

🔷 objectiveDescription : String  Private

The textual representation of the study objective. (BRIDG)

[ Is static True. Containment is Not Specified. ]

🔷 objectiveEndpoints : List<Endpoint>  Private

[ Is static True. Containment is Not Specified. ]

🔷 objectiveId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 objectiveLevel : Code  Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

## OPERATIONS

🔶 getObjectiveDescription () : String Public

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

🔶 getObjectiveEndpoints () : List<Endpoint> Public

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

🔶 getObjectiveId () : String Public

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

🔶 getObjectiveLevel () : Code Public

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

🔶 Objective (objectiveId : String ) :  Public

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

🔶 setObjectiveDescription (objectiveDescription : String ) : void Public

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

🔶 setObjectiveEndpoints (objectiveEndpoints : List<Endpoint> ) : void Public

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

🔶 setObjectiveLevel (objectiveLevel : Code ) : void Public

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

# Organization

*Class in package 'model'*

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

Organization
Version 1.0  Phase 1.0  Proposed
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| 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

| ATTRIBUTES |
| --- |
| The name of the organization that provides the identifier for the entity.<br><br>[ Is static True. Containment is Not Specified. ] |

| |
| --- |
| ◆ organizationName : String  Private<br><br>A non-unique textual identifier for the organization. (BRIDG)<br><br>[ Is static True. Containment is Not Specified. ] |
| ◆ organizationType : Code  Private<br><br>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.<br><br>[ Is static True. Containment is Not Specified. ] |

| ASSOCIATIONS |
| --- |
| ✎ Association (direction: Source -> Destination)<br><br>Source: Public (Class) Organization                Target: Private organizationType (Class) Code |
| ✎ Association (direction: Source -> Destination)<br><br>Source: Public (Class) StudyIdentifier             Target: Private studyIdentifierScope (Class) Organization |

| OPERATIONS |
| --- |
| ◆ getOrganizationId () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getOrganizationIdentifier () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getOrganizationIdentifierScheme () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getOrganizationName () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ getOrganizationType () : Code Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

| OPERATIONS |
| --- |
| ◈ 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. ] |
| ◈ 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 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |
| ◈ procedureCode : Code  Private |
| A symbol or combination of symbols which is assigned to medical procedure. |
| [ Is static True. Containment is Not Specified. ] |
| ◈ procedureId : String  Private  Const |
| [ Is static True. Containment is Not Specified. ] |
| ◈ procedureType : String  Private |
| A characterization or classification of the study procedure. |
| [ Is static True. Containment is Not Specified. ] |

| ASSOCIATIONS |
| --- |
| ✎ Association (direction: Source -> Destination) |

| ASSOCIATIONS | |
|---|---|
| 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. ] |
| ◆ getProcedureType () : String Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ Procedure (procedureId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setProcedureCode (procedureCode : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| ◆ setProcedureType (procedureType : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Study

*Class in package 'model'*

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

Study
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
|---|
| ◆ businessTherapeuticAreas : List<Code>  Private |

| ATTRIBUTES |
| --- |

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

[ Is static True. Containment is Not Specified. ]

🔹 studyDesigns : List<StudyDesign>  Private

[ Is static True. Containment is Not Specified. ]

🔹 studyId : UUID  Private  Const

[ Is static True. Containment is Not Specified. ]

🔹 studyIdentifiers : List<StudyIdentifier>  Private

[ Is static True. Containment is Not Specified. ]

🔹 studyPhase : Code  Private

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

[ Is static True. Containment is Not Specified. ]

🔹 studyProtocolVersions : List<StudyProtocolVersion>  Private

[ Is static True. Containment is Not Specified. ]

🔹 studyTitle : String  Private

The sponsor-defined name of the clinical study.

[ Is static True. Containment is Not Specified. ]

🔹 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)

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

✏ Association (direction: Source -> Destination)

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

✏ Association (direction: Source -> Destination)

| | |
|---|---|
| Source: Public (Class) Study | Target: Private studyIdentifiers (Class) StudyIdentifier<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) Study | Target: Private studyPhase (Class) Code |

✏ Association (direction: Source -> Destination)

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

## OPERATIONS

🔷 addStudyDesign (studyDesign : StudyDesign ) : void Public
> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 addStudyIdentifier (studyIdentifier : StudyIdentifier ) : void Public
> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

🔷 addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion ) : void Public
> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

**OPERATIONS**

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

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

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

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

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

removeStudyDesign (studyDesign : StudyDesign ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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. ]

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

| OPERATIONS |
|---|
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔹 setStudyPhase (studyPhase : Code ) : 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. ] |
| 🔹 setStudyTitle (studyTitle : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔹 setStudyType (studyType : Code ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔹 setStudyVersion (studyVersion : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔹 Study (studyId : UUID ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# StudyArm

*Class in package 'model'*

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

StudyArm
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| 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. ] |
| |

## ATTRIBUTES

🔹 studyArmDescription : String  Private

The textual representation of the study arm.

[ Is static True. Containment is Not Specified. ]

🔹 studyArmId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔹 studyArmName : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔹 studyArmType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

## OPERATIONS

🔹 getStudyArmDataOriginDescription () : String Public

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

🔹 getStudyArmDataOriginType () : Code Public

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

🔹 getStudyArmDescription () : String Public

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

| OPERATIONS |
| --- |

◆ getStudyArmId () : String Public

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

◆ getStudyArmName () : String Public

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

◆ getStudyArmType () : Code Public

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

◆ setStudyArmDataOriginDescription (studyArmDataOriginDescription : String ) : void Public

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

◆ setStudyArmDataOriginType (studyArmDataOriginType : Code ) : void Public

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

◆ setStudyArmDescription (studyArmDescription : String ) : void Public

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

◆ setStudyArmName (studyArmName : String ) : void Public

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

◆ setStudyArmType (studyArmType : Code ) : void Public

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

◆ StudyArm (studyArmId : String ) :  Public

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

# StudyCell

*Class in package 'model'*

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

StudyCell
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |

◆ studyArm : StudyArm  Private

## ATTRIBUTES

| | |
|---|---|
| | [ Is static True. Containment is Not Specified. ] |
| ◈ studyCellId : String  Private  Const | |
| | [ Is static True. Containment is Not Specified. ] |
| ◈ studyElements : List<StudyElement>  Private | |
| | [ Is static True. Containment is Not Specified. ] |
| ◈ studyEpoch : StudyEpoch  Private | |
| | [ Is static True. Containment is Not Specified. ] |

## ASSOCIATIONS

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

## OPERATIONS

◈ addStudyElement (studyElement : StudyElement ) : void Public
  [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

◈ getStudyArm () : StudyArm Public
  [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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

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

# StudyData

*Class in package 'model'*

Data collected in the course of a clinical study.

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StudyData
Version 1.0  Phase 1.0  Proposed
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| ATTRIBUTES |
|---|
| ◆ ecrfLink : URI  Private<br><br>The uniform resource locator used to access the digital case report form.<br><br>[ Is static True. Containment is Not Specified. ] |
| ◆ studyDataDescription : String  Private<br><br>The textual representation of the study data.<br><br>[ Is static True. Containment is Not Specified. ] |

## ATTRIBUTES

⬥ studyDataId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

⬥ studyDataName : String  Private

The literal identifier (i.e., distinctive designation) for the study data.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private studyDataCollection (Class)
StudyData
Cardinality:  [0..*]

## OPERATIONS

⬥ getEcrfLink () : URI Public

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

⬥ getStudyDataDescription () : String Public

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

⬥ getStudyDataId () : String Public

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

⬥ getStudyDataName () : String Public

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

⬥ setEcrfLink (ecrfLink : URI ) : void Public

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

⬥ setStudyDataDescription (studyDataDescription : String ) : void Public

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

⬥ setStudyDataName (studyDataName : String ) : void Public

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

⬥ StudyData (studyDataId : String ) :  Public

| OPERATIONS |
|---|
| [ 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 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
|---|
| ◆ activities : List<Activity>  Private |
| [ Is static True. Containment is Not Specified. ] |
| ◆ encounters : List<Encounter>  Private |
| [ Is static True. Containment is Not Specified. ] |
| ◆ interventionModel : Code  Private |
| The general design of the strategy for assigning interventions to participants in a clinical study. (clinicaltrials.gov) |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyCells : List<StudyCell>  Private |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyDesignDescription : String  Private |
| The textual representation of the study design. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyDesignId : String  Private  Const |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyDesignName : String  Private |
| The literal identifier (i.e., distinctive designation) of the study design. |
| [ Is static True. Containment is Not Specified. ] |
| ◆ studyEstimands : List<Estimand>  Private |
| [ Is static True. Containment is Not Specified. ] |

| ATTRIBUTES |
|---|

◆ studyIndications : List&lt;Indication&gt;  Private

[ Is static True. Containment is Not Specified. ]

◆ studyInvestigationalInterventions : List&lt;InvestigationalIntervention&gt;  Private

[ Is static True. Containment is Not Specified. ]

◆ studyObjectives : List&lt;Objective&gt;  Private

[ Is static True. Containment is Not Specified. ]

◆ studyPopulations : List&lt;StudyDesignPopulation&gt;  Private

[ Is static True. Containment is Not Specified. ]

◆ studyWorkflows : List&lt;Workflow&gt;  Private

[ Is static True. Containment is Not Specified. ]

◆ therapeuticAreas : List&lt;Code&gt;  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&lt;Code&gt;  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&lt;Code&gt;  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 interventionModel (Class) Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign                          Target: Private activities (Class) Activity

Cardinality:  [0..*]

| ASSOCIATIONS |
| --- |

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

## ASSOCIATIONS

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

✎ Association (direction: Source -> Destination)

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

## OPERATIONS

⬡ addStudyIndication (indication : Indication ) : void Public

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

⬡ addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public

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

⬡ addStudyObjective (objective : Objective ) : void Public

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

⬡ addStudyWorkflow (workflow : Workflow ) : void Public

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

⬡ getActivities () : List<Activity> Public

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

⬡ 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. ]

**OPERATIONS**

🔶 getStudyCells () : List<StudyCell> Public

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

🔶 getStudyDesignDescription () : String Public

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

🔶 getStudyDesignId () : String Public

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

🔶 getStudyDesignName () : String Public

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

🔶 getStudyEstimands () : List<Estimand> Public

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

🔶 getStudyIndications () : List<Indication> Public

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

🔶 getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public

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

🔶 getStudyObjectives () : List<Objective> Public

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

🔶 getStudyPopulations () : List<StudyDesignPopulation> Public

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

🔶 getStudyWorkflows () : List<Workflow> Public

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

🔶 getTherapeuticAreas () : List<Code> Public

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

🔶 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. ]

**OPERATIONS**

removeStudyIndication (indication : Indication ) : void Public

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

removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public

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

removeStudyObjective (objective : Objective ) : void Public

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

removeStudyWorkflow (workflow : Workflow ) : void Public

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

setActivities (activities : List<Activity> ) : void Public

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

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

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

setInterventionModel (interventionModel : Code ) : void Public

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

setStudyCells (studyCells : List<StudyCell> ) : void Public

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

setStudyDesignDescription (studyDesignDescription : String ) : void Public

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

setStudyDesignName (studyDesignName : String ) : void Public

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

setStudyEstimands (studyEstimands : List<Estimand> ) : void Public

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

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

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

🔶 setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation> ) : void Public

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

🔶 setStudyWorkflows (studyWorkflows : List<Workflow> ) : void Public

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

🔶 setTherapeuticAreas (therapeuticAreas : List<Code> ) : void Public

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

🔶 setTrialIntentType (trialIntentType : List<Code> ) : void Public

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

🔶 setTrialType (trialType : List<Code> ) : void Public

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

🔶 StudyDesign (studyDesignId : String ) :  Public

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

# StudyDesignPopulation

*Class in package 'model'*

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

StudyDesignPopulation
Version 1.0  Phase 1.0  Proposed
cupke created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |

🔷 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)

| ASSOCIATIONS |
| --- |

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

| OPERATIONS |
| --- |

🔷 getPopulationDescription () : String Public

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

🔷 getStudyDesignPopulationId () : String Public

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

🔷 setPopulationDescription (populationDescription : String ) : void Public

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

🔷 StudyDesignPopulation (uuid : String ) :  Public

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

# StudyElement

*Class in package 'model'*

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

StudyElement
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |

🔷 studyElementDescription : String  Private

The textual representation of the study design element.

[ Is static True. Containment is Not Specified. ]

🔷 studyElementId : String  Private  Const

element only attributes - these purely describe an element

[ Is static True. Containment is Not Specified. ]

🔷 studyElementName : String  Private

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

## ATTRIBUTES

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

🔹 transitionEndRule : TransitionRule  Private

[ Is static True. Containment is Not Specified. ]

🔹 transitionStartRule : TransitionRule  Private

all elements point to transition rules

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

✏️ Association (direction: Source -> Destination)

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

## OPERATIONS

🔹 getStudyElementDescription () : String Public

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

🔹 getStudyElementId () : String Public

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

🔹 getStudyElementName () : String Public

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

🔹 getTransitionEndRule () : TransitionRule Public

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

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

# StudyEpoch

*Class in package 'model'*

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

StudyEpoch
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

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

| ATTRIBUTES |
| --- |

🔷 studyEpochDescription : String  Private

The textual representation of the study epoch.

[ Is static True. Containment is Not Specified. ]

🔷 studyEpochId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

🔷 studyEpochName : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 studyEpochType : Code  Private

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

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
| --- |

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

🖊 Association (direction: Source -> Destination)

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

| OPERATIONS |
| --- |

🔷 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. ]

**OPERATIONS**

getPreviousStudyEpochId () : String Public

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

getStudyEpochDescription () : String Public

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

getStudyEpochId () : String Public

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

getStudyEpochName () : String Public

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

getStudyEpochType () : Code Public

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

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

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

setNextStudyEpochId (nextStudyEpochId : String ) : void Public

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

setPreviousStudyEpochId (previousStudyEpochId : String ) : void Public

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

setStudyEpochDescription (studyEpochDescription : String ) : void Public

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

setStudyEpochName (studyEpochName : String ) : void Public

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

setStudyEpochType (studyEpochType : Code ) : void Public

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

StudyEpoch (studyEpochId : String ) :  Public

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

# StudyIdentifier

*Class in package 'model'*

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

StudyIdentifier

Version 1.0  Phase 1.0  Proposed

Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

---

### ATTRIBUTES

🔷 studyIdentifier : String  Private

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

[ Is static True. Containment is Not Specified. ]

---

🔷 studyIdentifierId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

---

🔷 studyIdentifierScope : Organization  Private

[ Is static True. Containment is Not Specified. ]

---

### ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier

Target: Private studyIdentifierScope (Class) Organization

---

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyIdentifiers (Class) StudyIdentifier

Cardinality:  [0..*]

---

### OPERATIONS

🔷 getStudyIdentifier () : String Public

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

---

🔷 getStudyIdentifierId () : String Public

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

---

🔷 getStudyIdentifierScope () : Organization Public

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

---

🔷 setStudyIdentifier (studyIdentifier : String ) : void Public

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

| OPERATIONS |
| --- |

🔶 setStudyIdentifierScope (studyIdentifierScope : Organization ) : void Public

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

🔶 StudyIdentifier (studyIdentifierId : String ) :  Public

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

# StudyProtocolVersion

*Class in package 'model'*

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

StudyProtocolVersion
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |

🔷 briefTitle : String  Private

The short descriptive name for the protocol.

[ Is static True. Containment is Not Specified. ]

🔷 officialTitle : String  Private

The formal descriptive name for the protocol.

[ Is static True. Containment is Not Specified. ]

🔷 protocolAmendment : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 protocolEffectiveDate : Date  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 protocolStatus : Code  Private

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

[ Is static True. Containment is Not Specified. ]

**ATTRIBUTES**

🔷 protocolVersion : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 publicTitle : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 scientificTitle : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔷 studyProtocolVersionId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Study

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

**OPERATIONS**

🔷 getBriefTitle () : String Public

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

🔷 getOfficialTitle () : String Public

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

🔷 getProtocolAmendment () : String Public

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

**OPERATIONS**

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

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

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

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

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

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

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

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

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

◆ setProtocolEffectiveDate (protocolEffectiveDate : Date ) : void Public
[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

◆ setProtocolStatus (protocolStatus : Code ) : void Public
[ 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. ]

| OPERATIONS |
| --- |
| 🔶 setScientificTitle (scientificTitle : String ) : void Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔶 StudyProtocolVersion (studyProtocolVersionId : String ) :  Public |
| [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# TransitionRule

*Class in package 'model'*

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

TransitionRule
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

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

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

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

| OPERATIONS |
| --- |
| 🔷 getTransitionRuleDescription () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 getTransitionRuleId () : String Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 setTransitionRuleDescription (transitionRuleDescription : String ) : void Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |
| 🔷 TransitionRule (ruleId : String ) :  Public<br><br>[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ] |

# Workflow

*Class in package 'model'*

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

Workflow
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

| ATTRIBUTES |
| --- |
| 🔷 workflowDescription : String  Private<br><br>The textual representation of the workflow.<br><br>[ Is static True. Containment is Not Specified. ] |
| 🔷 workflowId : String  Private  Const<br><br>[ Is static True. Containment is Not Specified. ] |
| 🔷 workflowItems : List<WorkflowItem>  Private<br><br>The textual representation of the workflow item.<br><br>[ Is static True. Containment is Not Specified. ] |

**ASSOCIATIONS**

✏ Association (direction: Source -> Destination)

Source: Public (Class) Workflow

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

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

**OPERATIONS**

🔶 getWorkflowDescription () : String Public

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

🔶 getWorkflowId () : String Public

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

🔶 getWorkflowItems () : List<WorkflowItem> Public

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

🔶 setWorkflowDescription (workflowDescription : String ) : void Public

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

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

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

🔶 Workflow (workFlowUUID : String ) :  Public

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

# WorkflowItem

*Class in package 'model'*

WorkflowItem
Version 1.0  Phase 1.0  Proposed
Chris Upkes created on 11/21/2022.  Last modified 11/21/2022

**ATTRIBUTES**

🔷 nextWorkflowItemId : String  Private

| ATTRIBUTES |
| --- |

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

[ Is static True. Containment is Not Specified. ]

🔹 previousWorkflowItemId : String  Private

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

[ Is static True. Containment is Not Specified. ]

🔹 workflowItemActivityId : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 workflowItemDescription : String  Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

🔹 workflowItemEncounterId : String  Private

[ Is static True. Containment is Not Specified. ]

🔹 workflowItemId : String  Private  Const

[ Is static True. Containment is Not Specified. ]

| ASSOCIATIONS |
| --- |

✏️ Association (direction: Source -> Destination)

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

| OPERATIONS |
| --- |

🔹 getNextWorkflowItemId () : String Public

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

🔹 getPreviousWorkflowItemId () : String Public

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

🔹 getWorkflowItemActivityId () : String Public

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

**OPERATIONS**

◆ getWorkflowItemDescription () : String Public

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

◆ getWorkflowItemEncounterId () : String Public

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

◆ getWorkflowItemId () : String Public

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

◆ setNextWorkflowItemId (nextWorkflowItemId : String ) : void Public

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

◆ setPreviousWorkflowItemId (previousWorkflowItemId : String ) : void Public

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

◆ setWorkflowItemActivity (workflowItemActivity : String ) : void Public

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

◆ setWorkflowItemDescription (workflowItemDescription : String ) : void Public

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

◆ setWorkflowItemEncounterId (workflowItemEncounterId : String ) : void Public

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

◆ WorkflowItem (workflowItemId : String ) :  Public

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