

## model

*Package in package 'DDF'*

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

## model diagram

*Class diagram in package 'model'*

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

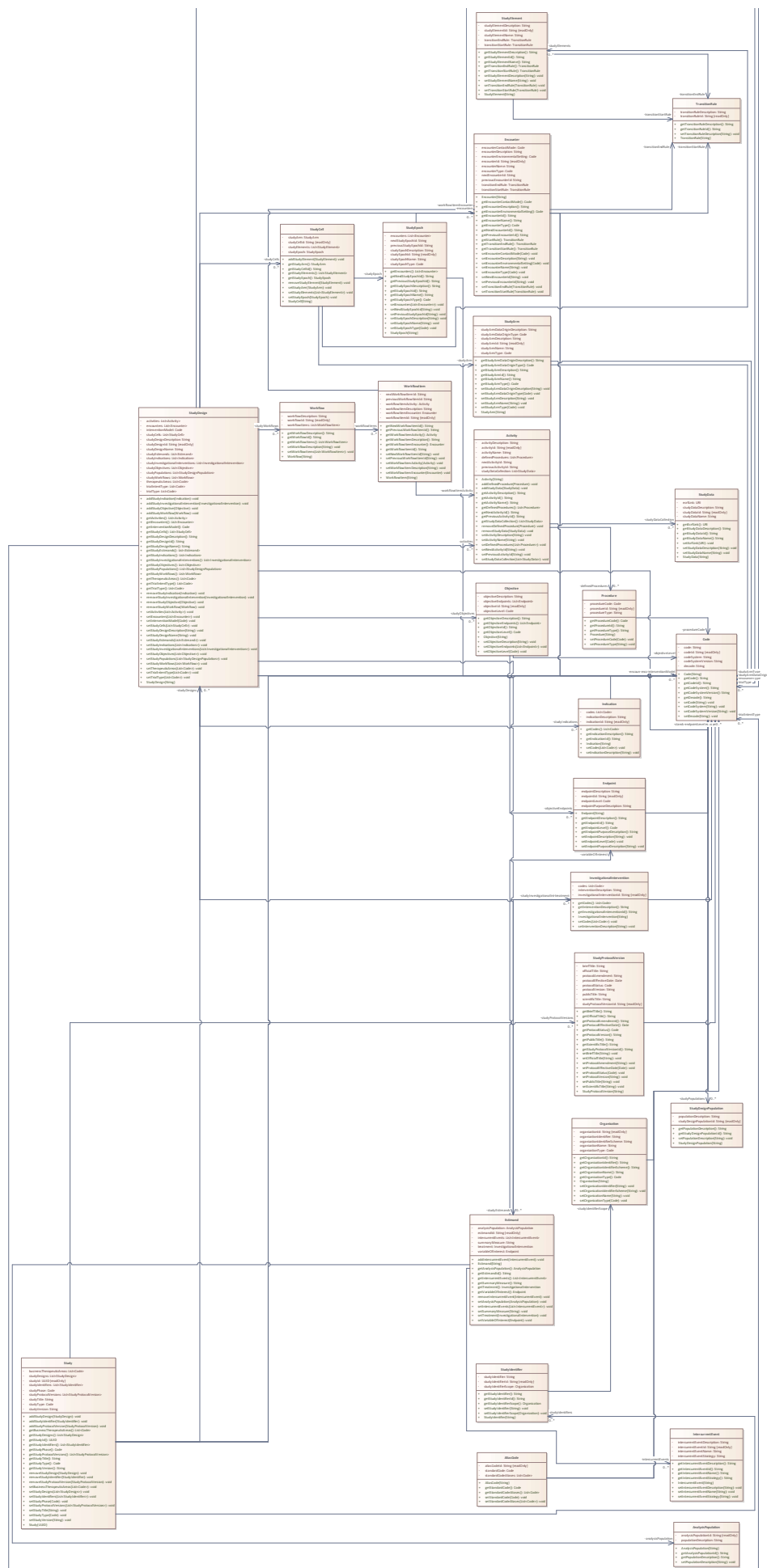


Figure 1: model

## Activity








*Class in package 'model'*

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

Activity

Version 1.0 Phase 1.0 Proposed

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

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 studyDataCollection (Class)  
StudyData

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Activity

Target: Private definedProcedures (Class)  
Procedure

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private workflowItemActivity (Class)  
Activity


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private activities (Class) Activity

Cardinality: [0..\*]

## OPERATIONS

 Activity (activityId : String ) : Public


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

 addDefinedProcedure (procedure : Procedure ) : void Public


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

 addStudyData (studyData : StudyData ) : void Public

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

 getActivityDescription () : String Public













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

 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. ]

OPERATIONS	
 <b>getDefinedProcedures () : List&lt;Procedure&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getNextActivityId () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getPreviousActivityId () : String Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDataCollection () : List&lt;StudyData&gt; Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeDefinedProcedure (procedure : Procedure ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyData (studyData : StudyData ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivityDescription (description : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivityName (activityName : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setDefinedProcedures (definedProcedures : List&lt;Procedure&gt; ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setNextActivityId (nextActivityId : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPreviousActivityId (previousActivityId : String ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyDataCollection (studyDataCollection : List&lt;StudyData&gt; ) : void Public</b>	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## AliasCode


*Class in package 'model'*

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


AliasCode

Version 1.0 Phase 1.0 Proposed


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

**ATTRIBUTES**
 aliasCodeId : String Private Const

[ Is static True. Containment is Not Specified. ]

 standardCode : Code Private

[ Is static True. Containment is Not Specified. ]

 standardCodeAliases : List<Code> Private

[ Is static True. Containment is Not Specified. ]

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

Source: Public (Class) AliasCode

Target: Private standardCode (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) AliasCode

Target: Private standardCodeAliases (Class) Code


Cardinality: [0..\*]

**OPERATIONS**
 AliasCode (aliasCodeId : String ) : Public

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

 getStandardCode () : Code Public

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

 getStandardCodeAliases () : List<Code> Public

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

 setStandardCode (standardCode : Code ) : void Public

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

 setStandardCodeAliases (standardCodeAliases : List<Code> ) : void Public

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


## AnalysisPopulation

*Class in package 'model'*


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

AnalysisPopulation  
Version 1.0 Phase 1.0 Proposed  
cupke created on 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






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

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

ASSOCIATIONS	
 Association (direction: Source -> Destination)  Source: Public (Class) AliasCode	Target: Private standardCode (Class) Code
 Association (direction: Source -> Destination)  Source: Public (Class) Encounter	Target: Private encounterContactMode (Class) Code
 Association (direction: Source -> Destination)	













ASSOCIATIONS	
Source: Public (Class) Study	Target: Private studyPhase (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Organization	Target: Private organizationType (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Study	Target: Private studyType (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Study	Target: Private businessTherapeuticAreas (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Objective	Target: Private objectiveLevel (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) AliasCode	Target: Private standardCodeAliases (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Encounter	Target: Private encounterType (Class) Code
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Indication	Target: Private codes (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) InvestigationalIntervention	Target: Private codes (Class) Code Cardinality: [0..*]
✎ Association (direction: Source -> Destination)	
Source: Public (Class) Endpoint	Target: Private endpointLevel (Class) Code

ASSOCIATIONS		
 Association (direction: Source -> Destination)		
Source: Public (Class) Procedure		Target: Private procedureCode (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) Encounter		Target: Private encounterEnvironmentalSetting (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyEpoch		Target: Private studyEpochType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyArm		Target: Private studyArmType (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private therapeuticAreas (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyProtocolVersion		Target: Private protocolStatus (Class) Code
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyDesign		Target: Private interventionModel (Class) Code
 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 trialIntentType (Class) Code Cardinality: [0..*]
 Association (direction: Source -> Destination)		
Source: Public (Class) StudyArm		Target: Private studyArmDataOriginType (Class) Code

## ASSOCIATIONS

## OPERATIONS


 <b>Code (codeId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCode () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeSystem () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getCodeSystemVersion () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getDecode () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCode (code : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCodeSystem (codeSystem : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setCodeSystemVersion (codeSystemVersion : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setDecode (decode : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Encounter


*Class in package 'model'*

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

Encounter

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. ]	

## ATTRIBUTES

 transitionStartRule : TransitionRule Private

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterContactMode (Class)  
Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionEndRule (Class)  
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private transitionStartRule (Class)  
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private encounterEnvironmentalSetting  
(Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)














Source: Public (Class) WorkflowItem









Target: Private workflowItemEncounter (Class)  
Encounter

 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. ]
 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. ]

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

## Endpoint


*Class in package 'model'*

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


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

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

## ATTRIBUTES

 endpointId : String Private Const

[ Is static True. Containment is Not Specified. ]

 endpointLevel : Code Private

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

[ Is static True. Containment is Not Specified. ]

 endpointPurposeDescription : String Private

The textual representation of the study endpoint purpose.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private endpointLevel (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint


 Association (direction: Source -> Destination)

Source: Public (Class) Objective


 Target: Private objectiveEndpoints (Class)  
Endpoint

Cardinality: [0..\*]


## OPERATIONS

 Endpoint (endpointId : String) : Public

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






 getEndpointDescription () : String Public

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

 getEndpointId () : String Public

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







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


## Estimand

*Class in package 'model'*


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

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

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

**ATTRIBUTES**
 **treatment : InvestigationalIntervention Private**

[ Is static True. Containment is Not Specified. ]

 **variableOfInterest : Endpoint Private**

[ Is static True. Containment is Not Specified. ]

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

Source: Public (Class) Estimand

Target: Private variableOfInterest (Class) Endpoint

 Association (direction: Source -> Destination)

Source: Public (Class) Estimand

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

Source: Public (Class) Estimand

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

Source: Public (Class) Estimand

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


Source: Public (Class) StudyDesign

Target: Private studyEstimands (Class) Estimand  
Cardinality: [0..\*]**OPERATIONS**
 **addIntercurrentEvent (intercurrentEvent : IntercurrentEvent ) : void Public**












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

 **Estimand (estimandId : String ) : Public**

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

 **getAnalysisPopulation () : AnalysisPopulation Public**

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


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

## Indication

*Class in package 'model'*


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

**ATTRIBUTES**

 codes : List<Code> Private


A short sequence of characters that represents the disease indication.

[ Is static True. Containment is Not Specified. ]

 indicationDescription : String Private

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

[ Is static True. Containment is Not Specified. ]

 indicationId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) Indication

Target: Private codes (Class) Code

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyIndications (Class) Indication

Cardinality: [0..\*]


**OPERATIONS**

 getCodes () : List<Code> Public


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

 getIndicationDescription () : String Public

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



 getIndicationId () : String Public

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

 Indication (indicationId : String ) : Public

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

**OPERATIONS**

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

## InvestigationalIntervention


*Class in package 'model'*

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

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


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

## ATTRIBUTES

 interventionDescription : String Private

The textual representation of the study intervention.

[ Is static True. Containment is Not Specified. ]

 investigationalInterventionId : String Private Const

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention

Target: Private codes (Class) Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) 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. ]

## OPERATIONS

 `setInterventionDescription (interventionDescription : String ) : void Public`  
 [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

## Objective

*Class in package 'model'*


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

Objective

Version 1.0 Phase 1.0 Proposed


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 objectiveEndpoints (Class)  
Endpoint

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private objectiveLevel (Class) Code



## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

## OPERATIONS


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


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

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

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

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

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

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

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


## Organization

*Class in package 'model'*


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

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

**ATTRIBUTES**

 organizationId : String Private Const

[ Is static True. Containment is Not Specified. ]

 organizationIdentifier : String Private


A unique symbol that establishes identity of the organization. (BRIDG)

[ Is static True. Containment is Not Specified. ]

 organizationIdentifierScheme : String Private


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

[ Is static True. Containment is Not Specified. ]

 organizationName : String Private

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

[ Is static True. Containment is Not Specified. ]

 organizationType : Code Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) Organization

Target: Private organizationType (Class) Code

 Association (direction: Source -> Destination)


Source: Public (Class) StudyIdentifier

Target: Private studyIdentifierScope (Class)  
Organization









**OPERATIONS**

 getOrganizationId () : String Public

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

 getOrganizationIdentifier () : String Public

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


OPERATIONS
 <b>getOrganizationIdentifierScheme () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getOrganizationType () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>Organization (organizationId : String ) : Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationIdentifier (organizationIdentifier : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationIdentifierScheme (organizationIdentifierScheme : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationName (organizationName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setOrganizationType (organizationType : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]


## Procedure

*Class in package 'model'*


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

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

ATTRIBUTES
 <b>procedureCode : Code Private</b>  A symbol or combination of symbols which is assigned to medical procedure. <div style="text-align: right;">[ Is static True. Containment is Not Specified. ]</div>

**ATTRIBUTES**
 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)

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  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. (AfterÂ clinicaltrials.gov)	[ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

 studyVersion : String Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyPhase (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private businessTherapeuticAreas (Class)  
Code

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyIdentifiers (Class)  
StudyIdentifier

Cardinality: [0..\*]

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) Study














Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion











Cardinality: [0..\*]

## OPERATIONS

 addStudyDesign (studyDesign : StudyDesign ) : void Public

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

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

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




## ATTRIBUTES

 studyArmDataOriginDescription : String Private


The textual representation of the study arm data origin.

[ Is static True. Containment is Not Specified. ]

 studyArmDataOriginType : Code Private


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

[ Is static True. Containment is Not Specified. ]


 studyArmDescription : String Private

The textual representation of the study arm.

[ Is static True. Containment is Not Specified. ]

 studyArmId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyArmName : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyArmType : Code Private

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

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private studyArmType (Class) Code

 Association (direction: Source -> Destination)













Source: Public (Class) StudyArm

Target: Private studyArmDataOriginType (Class) Code

 Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private studyArm (Class) StudyArm

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

## StudyCell

Class in package 'model'

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


StudyCell










Version 1.0 Phase 1.0 Proposed

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

ATTRIBUTES	
 studyArm : StudyArm Private	[ Is static True. Containment is Not Specified. ]
 studyCellId : String Private Const	[ Is static True. Containment is Not Specified. ]
 studyElements : List<StudyElement> Private	[ Is static True. Containment is Not Specified. ]
 studyEpoch : StudyEpoch Private	[ Is static True. Containment is Not Specified. ]

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

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

## StudyData

*Class in package 'model'*

Data collected in the course of a clinical study.


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

ATTRIBUTES	
 <b>ecrfLink : URI Private</b>	

**ATTRIBUTES**


The uniform resource locator used to access the digital case report form.

[ Is static True. Containment is Not Specified. ]

 studyDataDescription : String Private

The textual representation of the study data.

[ Is static True. Containment is Not Specified. ]

 studyDataId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyDataName : String Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**


 Association (direction: Source -> Destination)

Source: Public (Class) Activity


Target: Private studyDataCollection (Class)  
StudyData

Cardinality: [0..\*]

**OPERATIONS**

 getEcrlLink () : 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. ]

 setEcrlLink (ecrlLink : URI ) : void Public

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







OPERATIONS
 <b>setStudyDataDescription</b> (studyDataDescription : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyDataName</b> (studyDataName : String ) : void Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyData</b> (studyDataId : String ) : Public [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]











## StudyDesign

*Class in package 'model'*

A plan detailing how a study will be performed in order to represent the phenomenon under examination, to answer the research questions that have been asked, and informing the statistical approach.

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

ATTRIBUTES
 <b>activities</b> : List<Activity> Private [ Is static True. Containment is Not Specified. ]
 <b>encounters</b> : List<Encounter> Private [ Is static True. Containment is Not Specified. ]
 <b>interventionModel</b> : 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. ]
 <b>studyCells</b> : List<StudyCell> Private [ Is static True. Containment is Not Specified. ]
 <b>studyDesignDescription</b> : String Private The textual representation of the study design. [ Is static True. Containment is Not Specified. ]
 <b>studyDesignId</b> : String Private Const [ Is static True. Containment is Not Specified. ]

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

ASSOCIATIONS

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



## ASSOCIATIONS

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

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

 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


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

 Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private studyDesigns (Class) StudyDesign  
Cardinality: [0..\*]


## OPERATIONS

 addStudyIndication (indication : Indication ) : void Public

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

 addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public


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

 addStudyObjective (objective : Objective ) : void Public














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














 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. ]

OPERATIONS
 <b>getEncounters () : List&lt;Encounter&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getInterventionModel () : Code Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyCells () : List&lt;StudyCell&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignDescription () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignId () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyDesignName () : String Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyEstimands () : List&lt;Estimand&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyIndications () : List&lt;Indication&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyInvestigationalInterventions () : List&lt;InvestigationalIntervention&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyObjectives () : List&lt;Objective&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyPopulations () : List&lt;StudyDesignPopulation&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getStudyWorkflows () : List&lt;Workflow&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getTherapeuticAreas () : List&lt;Code&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

OPERATIONS
 <b>getTrialIntentType () : List&lt;Code&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>getTrialType () : List&lt;Code&gt; Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyIndication (indication : Indication ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalIntervention ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyObjective (objective : Objective ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>removeStudyWorkflow (workflow : Workflow ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setActivities (activities : List&lt;Activity&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setEncounters (encounters : List&lt;Encounter&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setInterventionModel (interventionModel : Code ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyCells (studyCells : List&lt;StudyCell&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyDesignDescription (studyDesignDescription : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyDesignName (studyDesignName : String ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setStudyEstimands (studyEstimands : List&lt;Estimand&gt; ) : void Public</b> [ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]

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







## StudyDesignPopulation

*Class in package 'model'*

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

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

ATTRIBUTES	
 <b>populationDescription</b> : String Private	
The textual representation of the study population.	[ Is static True. Containment is Not Specified. ]


ATTRIBUTES	
 studyDesignPopulationId : String Private Const	
[ Is static True. Containment is Not Specified. ]	
ASSOCIATIONS	
 Association (direction: Source -> Destination)	
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. ]

**ATTRIBUTES**

 studyElementId : String Private Const


element only attributes - these purely describe an element

[ Is static True. Containment is Not Specified. ]


 studyElementName : String Private

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

[ Is static True. Containment is Not Specified. ]

 transitionEndRule : TransitionRule Private

[ Is static True. Containment is Not Specified. ]

 transitionStartRule : TransitionRule Private

all elements point to transition rules

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionEndRule (Class)  
TransitionRule

 Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private transitionStartRule (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. ]

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

## StudyEpoch

*Class in package 'model'*

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

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

ATTRIBUTES
 <b>encounters : List&lt;Encounter&gt; Private</b> [ Is static True. Containment is Not Specified. ]
 <b>nextStudyEpochId : String Private</b>

**ATTRIBUTES**


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

[ Is static True. Containment is Not Specified. ]

 previousStudyEpochId : String Private


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

[ Is static True. Containment is Not Specified. ]


 studyEpochDescription : String Private

The textual representation of the study epoch.

[ Is static True. Containment is Not Specified. ]

 studyEpochId : String Private Const

[ Is static True. Containment is Not Specified. ]

 studyEpochName : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyEpochType : Code Private

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

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private studyEpochType (Class) Code

 Association (direction: Source -> Destination)

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**



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

**OPERATIONS**

 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. ]




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

## StudyProtocolVersion

*Class in package 'model'*

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

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


ATTRIBUTES	
 <b>briefTitle : String Private</b>  The short descriptive name for the protocol.  [ Is static True. Containment is Not Specified. ]	
 <b>officialTitle : String Private</b>  The formal descriptive name for the protocol.  [ Is static True. Containment is Not Specified. ]	
 <b>protocolAmendment : String Private</b>  A written description of a change(s) to, or formal clarification of, a protocol. (ICH E6)  [ Is static True. Containment is Not Specified. ]	

**ATTRIBUTES**

 protocolEffectiveDate : Date Private


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

[ Is static True. Containment is Not Specified. ]

 protocolStatus : Code Private


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

[ Is static True. Containment is Not Specified. ]

 protocolVersion : String Private


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

[ Is static True. Containment is Not Specified. ]

 publicTitle : String Private


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

[ Is static True. Containment is Not Specified. ]

 scientificTitle : String Private

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

[ Is static True. Containment is Not Specified. ]

 studyProtocolVersionId : String Private Const

[ Is static True. Containment is Not Specified. ]

**ASSOCIATIONS**

 Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion

Target: Private protocolStatus (Class) Code















 Association (direction: Source -> Destination)



Source: Public (Class) Study

Target: Private studyProtocolVersions (Class)  
StudyProtocolVersion

Cardinality: [0..\*]

**OPERATIONS**

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



OPERATIONS	
	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setProtocolVersion</b> (protocolVersion : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setPublicTitle</b> (publicTitle : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>setScientificTitle</b> (scientificTitle : String ) : void Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]
 <b>StudyProtocolVersion</b> (studyProtocolVersionId : String ) : Public	[ Is static False. Is abstract False. Is return array False. Is query False. Is synchronized False. ]



## TransitionRule



*Class in package 'model'*





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

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

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

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

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

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

## Workflow


*Class in package 'model'*

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


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

ATTRIBUTES	
 workflowDescription : String Private  The textual representation of the workflow.	[ Is static True. Containment is Not Specified. ]

## ATTRIBUTES

 workflowId : String Private Const

[ Is static True. Containment is Not Specified. ]

 workflowItems : List<WorkflowItem> Private

The textual representation of the workflow item.

[ Is static True. Containment is Not Specified. ]

## ASSOCIATIONS

 Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private workflowItems (Class)  
WorkflowItem

Cardinality: [0..\*]


 Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign


Target: Private studyWorkflows (Class) Workflow

Cardinality: [0..\*]


## OPERATIONS

 getWorkflowDescription () : String Public


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

 getWorkflowId () : String Public


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

 getWorkflowItems () : List<WorkflowItem> Public

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

 setWorkflowDescription (workflowDescription : String) : void Public

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

 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  A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item. [ Is static True. Containment is Not Specified. ]	
 previousWorkflowItemId : String Private  A system identifier assigned to a workflow item that occurs immediately prior to the current workflow item. [ Is static True. Containment is Not Specified. ]	
 workflowItemActivity : Activity Private  [ Is static True. Containment is Not Specified. ]	
 workflowItemDescription : String Private  The textual representation of the workflow item. [ Is static True. Containment is Not Specified. ]	
 workflowItemEncounter : Encounter Private  [ Is static True. Containment is Not Specified. ]	
 workflowItemId : String Private Const  [ Is static True. Containment is Not Specified. ]	

ASSOCIATIONS	
 Association (direction: Source -> Destination)  Source: Public (Class) WorkflowItem Target: Private workflowItemActivity (Class) Activity	
 Association (direction: Source -> Destination)  Source: Public (Class) WorkflowItem Target: Private workflowItemEncounter (Class) Encounter	

## 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. ]


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


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


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


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

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

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

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

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

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

**OPERATIONS**

**WorkflowItem (workflowItemId : String ) : Public**

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