model

Package in package 'DDF'

model diagram

Class diagram in package 'model'

model

Package in package 'DDF'

Activity
- activityDesc: String
- activityName: String
- definedProcedures: List<Procedure>
- nextActivityId: UUID
- previousActivityId: UUID
- studyDataCollection: List<StudyData>
- uuid: UUID (readOnly)

+ Activity(UUID)
+ addDefinedProcedure(Procedure): void
+ addStudyData(StudyData): void
+ getActivityDesc(): String
+ getActivityName(): String
+ getDefinedProcedures(): List<Procedure>
+ getNextActivityId(): UUID
+ getPreviousActivityId(): UUID
+ getStudyDataCollection(): List<StudyData>
+ getUuid(): UUID
+ removeDefinedProcedure(Procedure): void
+ removeStudyData(StudyData): void
+ setActivityDesc(String): void
+ setActivityName(String): void
+ setDefinedProcedures(List<Procedure>): void
+ setNextActivityId(UUID): void
+ setPreviousActivityId(UUID): void
+ setStudyDataCollection(List<StudyData>): void

Workflowitem
- nextWorkflowItemId: UUID
- previousWorkflowItemId: UUID
- uuid: UUID (readOnly)
- workflowItemActivity: Activity
- workflowItemDesc: String
- workflowItemEncounter: Encounter

+ getNextWorkflowItemId(): UUID
+ getPreviousWorkflowItemId(): UUID
+ getUuid(): UUID
+ getWorkflowItemActivity(): Activity
+ getWorkflowItemDesc(): String
+ getWorkflowItemEncounter(): Encounter
+ setNextWorkflowItemId(UUID): void
+ setPreviousWorkflowItemId(UUID): void
+ setWorkflowItemActivity(Activity): void
+ setWorkflowItemDesc(String): void
+ setWorkflowItemEncounter(Encounter): void
+ WorkflowItem(UUID)

Workflow
- uuid: UUID (readOnly)
- workflowDesc: String
- workflowItems: List<WorkflowItem>

+ getWorkflowDesc(): String
+ getWorkflowId(): UUID
+ getWorkflowItems(): List<WorkflowItem>
+ setWorkflowDesc(String): void
+ setWorkflowItems(List<WorkflowItem>): void
+ Workflow(UUID)

StudyElement
- studyElementDesc: String
- studyElementName: String
- transitionEndRule: TransitionRule
- transitionStartRule: TransitionRule
- uuid: UUID (readOnly)

+ getStudyElementDesc(): String
+ getStudyElementName(): String
+ getTransitionEndRule(): TransitionRule
+ getTransitionStartRule(): TransitionRule
+ getUuid(): UUID
+ setStudyElementDesc(String): void
+ setStudyElementName(String): void
+ setTransitionEndRule(TransitionRule): void
+ setTransitionStartRule(TransitionRule): void
+ StudyElement(UUID)

Encounter
- encounterContactMode: Code
- encounterDesc: String
- encounterEnvironmentalSetting: Code
- encounterName: String
- encounterType: Code
- nextEncounterId: UUID
- previousEncounterId: UUID
- transitionEndRule: TransitionRule
- transitionStartRule: TransitionRule
- uuid: UUID (readOnly)

+ Encounter(UUID)
+ getEncounterContactMode(): Code
+ getEncounterDesc(): String
+ getEncounterEnvironmentalSetting(): Code
+ getEncounterName(): String
+ getEncounterType(): Code
+ getEndRule(): TransitionRule
+ getNextEncounterId(): UUID
+ getPreviousEncounterId(): UUID
+ getStartRule(): TransitionRule
+ getUuid(): UUID
+ setEncounterContactMode(Code): void
+ setEncounterDesc(String): void
+ setEncounterEnvironmentalSetting(Code): void
+ setEncounterName(String): void
+ setEncounterType(Code): void
+ setEndRule(TransitionRule): void
+ setNextEncounterId(UUID): void
+ setPreviousEncounterId(UUID): void
+ setStartRule(TransitionRule): void

StudyEpoch
- encounters: List<Encounter>
- nextStudyEpochId: UUID
- previousStudyEpochId: UUID
- studyEpochDesc: String
- studyEpochName: String
- studyEpochType: Code
- uuid: UUID (readOnly)

+ getEncounters(): List<Encounter>
+ getNextStudyEpochId(): UUID
+ getPreviousStudyEpochId(): UUID
+ getStudyEpochDesc(): String
+ getStudyEpochName(): String
+ getStudyEpochType(): Code
+ getUuid(): UUID
+ setEncounters(List<Encounter>): void
+ setNextStudyEpochId(UUID): void
+ setPreviousStudyEpochId(UUID): void
+ setStudyEpochDesc(String): void
+ setStudyEpochName(String): void
+ setStudyEpochType(Code): void
+ StudyEpoch(UUID)

StudyCell
- studyArm: StudyArm
- studyElements: List<StudyElement>
- studyEpoch: StudyEpoch
- uuid: UUID (readOnly)

+ addStudyElement(StudyElement): void
+ getStudyArm(): StudyArm
+ getStudyElements(): List<StudyElement>
+ getStudyEpoch(): StudyEpoch
+ getUuid(): UUID
+ removeStudyElement(StudyElement): void
+ setStudyArm(StudyArm): void
+ setStudyElements(List<StudyElement>): void
+ setStudyEpoch(StudyEpoch): void
+ StudyCell(UUID)

StudyArm
- studyArmDataOriginDesc: String
- studyArmDataOriginType: Code
- studyArmDesc: String
- studyArmName: String
- studyArmType: Code
- uuid: UUID (readOnly)

+ getStudyArmDataOriginDesc(): String
+ getStudyArmDataOriginType(): Code
+ getStudyArmDesc(): String
+ getStudyArmName(): String
+ getStudyArmType(): Code
+ getUuid(): UUID
+ setStudyArmDataOriginDesc(String): void
+ setStudyArmDataOriginType(Code): void
+ setStudyArmDesc(String): void
+ setStudyArmName(String): void
+ setStudyArmType(Code): void
+ StudyArm(UUID)

Objective
- objectiveDesc: String
- objectiveEndpoints: List<Endpoint>
- objectiveLevel: Code
- uuid: UUID (readOnly)

+ getObjectiveDesc(): String
+ getObjectiveEndpoints(): List<Endpoint>
+ getObjectiveLevel(): Code
+ getUuid(): UUID
+ Objective(UUID)
+ setObjectiveDesc(String): void
+ setObjectiveEndpoints(List<Endpoint>): void
+ setObjectiveLevel(Code): void

StudyDesign
- interventionalModel: Code
- studyCells: List<StudyCell>
- studyEstimands: List<Estimand>
- studyIndications: List<Indication>
- studyInvestigationalInterventions: List<InvestigationalIntervention>
- studyObjectives: List<Objective>
- studyStudyDesignPopulations: List<StudyDesignPopulation>
- studyWorkflows: List<Workflow>
- therapeuticAreas: List<Code>
- trialIntentTypes: List<Code>
- trialType: Code
- uuid: UUID (readOnly)

+ addStudyIndication(Indication): void
+ addStudyInvestigationalIntervention(InvestigationalIntervention): void
+ addStudyObjective(Objective): void
+ addStudyWorkflow(Workflow): void
+ getInterventionalModel(): Code
+ getStudyCells(): List<StudyCell>
+ getStudyEstimands(): List<Estimand>
+ getStudyIndications(): List<Indication>
+ getStudyInvestigationalInterventions(): List<InvestigationalIntervention>
+ getStudyObjectives(): List<Objective>
+ getStudyPopulations(): List<StudyDesignPopulation>
+ getStudyWorkflows(): List<Workflow>
+ getTherapeuticAreas(): List<Code>
+ getTrialIntentTypes(): List<Code>
+ getTrialType(): Code
+ getUuid(): UUID
+ removeStudyIndication(Indication): void
+ removeStudyInvestigationalIntervention(InvestigationalIntervention): void
+ removeStudyObjective(Objective): void
+ removeStudyWorkflow(Workflow): void
+ setInterventionalModel(Code): void
+ setStudyCells(List<StudyCell>): void
+ setStudyEstimands(List<Estimand>): void
+ setStudyIndications(List<Indication>): void
+ setStudyInvestigationalInterventions(List<InvestigationalIntervention>): void
+ setStudyObjectives(List<Objective>): void
+ setStudyPopulations(List<StudyDesignPopulation>): void
+ setStudyWorkflows(List<Workflow>): void
+ setTherapeuticAreas(List<Code>): void
+ setTrialIntentTypes(List<Code>): void
+ setTrialType(Code): void
+ StudyDesign(UUID)

Estimand
- analysisPopulation: AnalysisPopulation
- intercurrentEvents: List<IntercurrentEvent>
- summaryMeasure: String
- treatment: InvestigationalIntervention
- uuid: UUID (readOnly)
- variableOfInterest: Endpoint

+ addIntercurrentEvent(IntercurrentEvent): void
+ Estimand(UUID)
+ getAnalysisPopulation(): AnalysisPopulation
+ getIntercurrentEvents(): List<IntercurrentEvent>
+ getSummaryMeasure(): String
+ getTreatment(): InvestigationalIntervention
+ getUuid(): UUID
+ getVariableOfInterest(): Endpoint
+ removeIntercurrentEvent(IntercurrentEvent): void
+ setAnalysisPopulation(AnalysisPopulation): void
+ setIntercurrentEvents(List<IntercurrentEvent>): void

Figure 1: model

Activity

Class in package 'model'

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

Chris Upkes created on 11.

ATTRIBUTES
◆ activityDesc : String Private
◆ activityName : String Private
◆ definedProcedures : List<Procedure> Private
◆ nextActivityId : UUID Private
◆ previousActivityId : UUID Private
◆ studyDataCollection : List<StudyData> Private
◆ uuid : UUID Private Const

[Is static True

[Is static True

[Is static True

[Is static True

[Is static True

[Is static True

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private wo
Activity

OPERATIONS

🔹 Activity (activityId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 addDefinedProcedure (procedure : Procedure) : void Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 addStudyData (studyData : StudyData) : void Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 getActivityDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 getActivityName () : String Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 getDefinedProcedures () : List<Procedure> Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 getNextActivityId () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 getPreviousActivityId () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

◆ setActivityName (activityName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

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

[Is static False. Is abstract False. Is return array False. Is que

◆ setNextActivityId (nextActivityId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setPreviousActivityId (previousActivityId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyDataCollection (studyDataCollection : List<StudyData>) : void Public

[Is static False. Is abstract False. Is return array False. Is que

AnalysisPopulation

Class in package 'model'

cupke created on 11/

ATTRIBUTES

◆ populationDesc : String Private

[Is static Tru

◆ uuid : UUID Private Const

[Is static Tru

OPERATIONS

🔹 getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

🔹 setPopulationDesc (populationDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

Code

Class in package 'model'

Chris Upkes created on 11/

ATTRIBUTES

🔹 code : String Private

[Is static Tru

🔹 codeSystem : String Private

[Is static Tru

🔹 codeSystemVersion : String Private

[Is static Tru

🔹 decode : String Private

[Is static Tru

🔹 uuid : UUID Private Const

[Is static Tru

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private stu

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private int

Association (direction: Source -> Destination)

Source: Public (Class) Organization   Target: Private org

Association (direction: Source -> Destination)

Source: Public (Class) Procedure   Target: Private pro

Association (direction: Source -> Destination)

Source: Public (Class) InvestigationalIntervention   Target: Private co
                                                                       Cardinality: [0

Association (direction: Source -> Destination)

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

Association (direction: Source -> Destination)

Source: Public (Class) Encounter   Target: Private en

Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion   Target: Private pr

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private the
Cardinality: [0

✏ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private enc
(Class) Code

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private stu

✏ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private bus
Code
Cardinality: [0

✏ Association (direction: Source -> Destination)

Source: Public (Class) Endpoint

Target: Private enc

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private tria
Cardinality: [0

OPERATIONS

🔺 Code (codeId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is que

♦ setCode (code : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

♦ setCodeSystem (codeSystem : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

♦ setCodeSystemVersion (codeSystemVersion : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

♦ setDecode (decode : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

Encounter

Class in package 'model'

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

Chris Upkes created on 11/

ATTRIBUTES

♦ encounterContactMode : Code Private

[Is static True

♦ encounterDesc : String Private

[Is static True

ATTRIBUTES

[Is static True

🔹 transitionEndRule : TransitionRule Private

[Is static True

🔹 transitionStartRule : TransitionRule Private

[Is static True

🔹 uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private enc
Code

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private tran
TransitionRule

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private enc

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Encounter

Target: Private tran
TransitionRule

✏️ Association (direction: Source -> Destination)

OPERATIONS

◈ Encounter (encounterId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEncounterContactMode () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEncounterDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEncounterEnvironmentalSetting () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEncounterName () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEncounterType () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getEndRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getNextEncounterId () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getPreviousEncounterId () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getStartRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is que

◈ getUuid () : UUID Public

OPERATIONS

◆ setEncounterType (encounterType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setEndRule (endTransitionRule : TransitionRule) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setNextEncounterId (nextEncounterId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setPreviousEncounterId (previousEncounterId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStartRule (startTransitionRule : TransitionRule) : void Public

[Is static False. Is abstract False. Is return array False. Is que

Endpoint

Class in package 'model'

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

Chris Upkes created on 11/

ATTRIBUTES

◆ endpointDesc : String Private

[Is static True

ASSOCIATIONS

Source: Public (Class) Endpoint   Target: Private end

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Estimand   Target: Private var

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Objective   Target: Private obj
                                                                         Endpoint
                                                                            Cardinality: [0

OPERATIONS

🔷 Endpoint (endpointId : UUID) : Public
                        [Is static False. Is abstract False. Is return array False. Is que

🔷 getEndpointDesc () : String Public
                        [Is static False. Is abstract False. Is return array False. Is que

🔷 getEndpointLevel () : Code Public
                        [Is static False. Is abstract False. Is return array False. Is que

🔷 getEndpointPurpose () : String Public
                        [Is static False. Is abstract False. Is return array False. Is que

🔷 getUuid () : UUID Public
                        [Is static False. Is abstract False. Is return array False. Is que

🔷 setEndpointDesc (endpointDesc : String) : void Public
                        [Is static False. Is abstract False. Is return array False. Is que

ATTRIBUTES

◆ analysisPopulation : AnalysisPopulation Private

[Is static True

◆ intercurrentEvents : List<IntercurrentEvent> Private

[Is static True

◆ summaryMeasure : String Private

[Is static True

◆ treatment : InvestigationalIntervention Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

◆ variableOfInterest : Endpoint Private

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private ana
AnalysisPopulation

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private trea
InvestigationalInte

✎ Association (direction: Source -> Destination)

OPERATIONS

⬧ addIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ Estimand (estimandId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getAnalysisPopulation () : AnalysisPopulation Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getIntercurrentEvents () : List<IntercurrentEvent> Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getSummaryMeasure () : String Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getTreatment () : InvestigationalIntervention Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ getVariableOfInterest () : Endpoint Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ removeIntercurrentEvent (intercurrentEvent : IntercurrentEvent) : void Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ setAnalysisPopulation (analysisPopulation : AnalysisPopulation) : void Public

[Is static False. Is abstract False. Is return array False. Is que

⬧ setIntercurrentEvents (intercurrentEvents : List<IntercurrentEvent>) : void Public

Indication

Class in package 'model'

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

Chris Upkes created on 11/

ATTRIBUTES

🔹 codes : List<Code> Private

[Is static Tru

🔹 indicationDesc : String Private

[Is static Tru

🔹 uuid : UUID Private Const

[Is static Tru

ASSOCIATIONS

✏️ Association (direction: Source -> Destination)

Source: Public (Class) Indication

Target: Private co

Cardinality: [0

✏️ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stu

Cardinality: [0

OPERATIONS

🔹 getCodes () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

◆ setIndicationDesc (indicationDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

IntercurrentEvent

Class in package 'model'

Chris Upkes created on 11/

ATTRIBUTES

◆ intercurrentEventDesc : String Private

[Is static True

◆ intercurrentEventName : String Private

[Is static True

◆ intercurrentEventStrategy : String Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private inte
IntercurrentEvent
Cardinality: [0

OPERATIONS

◆ IntercurrentEvent (intercurrentEventId : UUID) : Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setIntercurrentEventDesc (intercurrentEventDesc : String) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setIntercurrentEventName (intercurrentEventName : String) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setIntercurrentEventStrategy (strategy : String) : void Public
[Is static False. Is abstract False. Is return array False. Is que

InvestigationalIntervention

Class in package 'model'

The drug, device, therapy, or process under investigation in a clinical study that is belie
of interest in a study. [After https://grants.nih.gov/grants/policy/faq_clinical_trial_defin
(CDISC-Glossary)

Chris Upkes created on 11/

ATTRIBUTES

◆ codes : List<Code> Private
[Is static Tru

◆ interventionDesc : String Private
[Is static Tru

◆ uuid : UUID Private Const

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) Estimand

Target: Private trea
InvestigationalInte

OPERATIONS

◆ getCodes () : List<Code> Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getInterventionDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◆ InvestigationalIntervention (investigationalInterventionId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

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

[Is static False. Is abstract False. Is return array False. Is que

◆ setInterventionDesc (interventionDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

Objective

Class in package 'model'

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

ATTRIBUTES

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private obj
Endpoint
Cardinality: [0

✎ Association (direction: Source -> Destination)

Source: Public (Class) Objective

Target: Private obj

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stud
Cardinality: [0

OPERATIONS

◆ getObjectiveDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getObjectiveEndpoints () : List<Endpoint> Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getObjectiveLevel () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

Organization

Class in package 'model'

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

Chris Upkes created on 11/

ATTRIBUTES	
◆ organizationIdentifier : String Private	[Is static True
◆ organizationIdentifierScheme : String Private	[Is static True
◆ organizationName : String Private	[Is static True
◆ organizationType : Code Private	[Is static True
◆ uuid : UUID Private Const	[Is static True

ASSOCIATIONS	
✏ Association (direction: Source -> Destination)	
Source: Public (Class) Organization	Target: Private org

OPERATIONS	
	[Is static False. Is abstract False. Is return array False. Is que
getOrganizationType () : Code Public	
	[Is static False. Is abstract False. Is return array False. Is que
getUuid () : UUID Public	
	[Is static False. Is abstract False. Is return array False. Is que
Organization (organizationId : UUID) : Public	
	[Is static False. Is abstract False. Is return array False. Is que
setOrganizationIdentifier (organizationIdentifier : String) : void Public	
	[Is static False. Is abstract False. Is return array False. Is que
setOrganizationIdentifierScheme (organizationIdentifierScheme : String) : void Public	
	[Is static False. Is abstract False. Is return array False. Is que
setOrganizationName (organizationName : String) : void Public	
	[Is static False. Is abstract False. Is return array False. Is que
setOrganizationType (organizationType : Code) : void Public	
	[Is static False. Is abstract False. Is return array False. Is que

Procedure

Class in package 'model'

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

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Procedure   Target: Private pr

Association (direction: Source -> Destination)

Source: Public (Class) Activity   Target: Private def
                                                                    Procedure
                                                                    Cardinality: [0

OPERATIONS

getProcedureCode () : Code Public
[Is static False. Is abstract False. Is return array False. Is que

getProcedureType () : String Public
[Is static False. Is abstract False. Is return array False. Is que

getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is que

Procedure (procedureId : UUID) : Public
[Is static False. Is abstract False. Is return array False. Is que

setProcedureCode (procedureCode : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is que

setProcedureType (procedureType : String) : void Public
[Is static False. Is abstract False. Is return array False. Is que

ATTRIBUTES

studyDesigns : List<StudyDesign> Private

[Is static True

studyIdentifiers : List<StudyIdentifier> Private

[Is static True

studyPhase : Code Private

[Is static True

studyProtocolVersions : List<StudyProtocolVersion> Private

[Is static True

studyTitle : String Private

[Is static True

studyType : Code Private

[Is static True

studyVersion : String Private

[Is static True

uuid : UUID Private Const

[Is static True

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Study   Target: Private stu

Association (direction: Source -> Destination)

ASSOCIATIONS

Source: Public (Class) Study

Target: Private stud
StudyIdentifier
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private bus
Code
Cardinality: [0

OPERATIONS

addStudyDesign (studyDesign : StudyDesign) : void Public
[Is static False. Is abstract False. Is return array False. Is que

addStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public
[Is static False. Is abstract False. Is return array False. Is que

addStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Public
[Is static False. Is abstract False. Is return array False. Is que

getBusinessTherapeuticAreas () : List<Code> Public
[Is static False. Is abstract False. Is return array False. Is que

getStudyDesigns () : List<StudyDesign> Public
[Is static False. Is abstract False. Is return array False. Is que

getStudyIdentifiers () : List<StudyIdentifier> Public
[Is static False. Is abstract False. Is return array False. Is que

getStudyPhase () : Code Public
[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

◆ getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is que

◆ removeStudyDesign (studyDesign : StudyDesign) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ removeStudyIdentifier (studyIdentifier : StudyIdentifier) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ removeStudyProtocolVersion (studyProtocolVersion : StudyProtocolVersion) : void Publ
[Is static False. Is abstract False. Is return array False. Is que

◆ setBusinessTherapeuticAreas (businessTherapeuticAreas : List<Code>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyDesigns (studyDesigns : List<StudyDesign>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyIdentifiers (studyIdentifiers : List<StudyIdentifier>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyPhase (studyPhase : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyProtocolVersions (studyProtocolVersions : List<StudyProtocolVersion>) : void
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyTitle (studyTitle : String) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyType (studyType : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is que

one or more treatments, exposures, and/or controls included in the path.

ATTRIBUTES

◆ studyArmDataOriginDesc : String Private

[Is static True

◆ studyArmDataOriginType : Code Private

[Is static True

◆ studyArmDesc : String Private

[Is static True

◆ studyArmName : String Private

[Is static True

◆ studyArmType : Code Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private stu
Code

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyArm

Target: Private stu

OPERATIONS

◆ getStudyArmDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyArmName () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyArmType () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyArmDataOriginDesc (studyArmDataOriginDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyArmDataOriginType (studyArmDataOriginType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyArmDesc (studyArmDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyArmName (studyArmName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyArmType (studyArmType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ StudyArm (studyArmId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

ATTRIBUTES

◆ studyElements : List<StudyElement> Private

[Is static True

◆ studyEpoch : StudyEpoch Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private stud

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private stud
                                                     StudyElement
                                                        Cardinality: [0

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell   Target: Private stud

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign   Target: Private stud
                                                        Cardinality: [0

OPERATIONS

◆ addStudyElement (studyElement : StudyElement) : void Public

OPERATIONS

● removeStudyElement (studyElement : StudyElement) : void Public

[Is static False. Is abstract False. Is return array False. Is que

● setStudyArm (studyArm : StudyArm) : void Public

[Is static False. Is abstract False. Is return array False. Is que

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

[Is static False. Is abstract False. Is return array False. Is que

● setStudyEpoch (studyEpoch : StudyEpoch) : void Public

[Is static False. Is abstract False. Is return array False. Is que

● StudyCell (studyCellId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

StudyData

Class in package 'model'

Chris Upkes created on 11/

ATTRIBUTES

● crfLink : URI Private

[Is static True

● studyDataDesc : String Private

[Is static True

OPERATIONS

getCrfLink () : URI Public

[Is static False. Is abstract False. Is return array False. Is que

getStudyDataDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

getStudyDataName () : String Public

[Is static False. Is abstract False. Is return array False. Is que

getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

setCrfLink (crfLink : URI) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setStudyDataDesc (studyDataDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setStudyDataName (studyDataName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

StudyData (studyDataId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

StudyDesign

Class in package 'model'

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

ATTRIBUTES

◆ studyIndications : List<Indication> Private

[Is static True

◆ studyInvestigationalInterventions : List<InvestigationalIntervention> Private

[Is static True

◆ studyObjectives : List<Objective> Private

[Is static True

◆ studyStudyDesignPopulations : List<StudyDesignPopulation> Private

[Is static True

◆ studyWorkflows : List<Workflow> Private

[Is static True

◆ therapeuticAreas : List<Code> Private

[Is static True

◆ trialIntentTypes : List<Code> Private

[Is static True

◆ trialType : Code Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

ASSOCIATIONS

Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stuc
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stuc
(Class) StudyDesig
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stuc
(Class) Investigatio
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stuc
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private the
Cardinality: [0

Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private tria
Cardinality: [0

Association (direction: Source -> Destination)

OPERATIONS

◆ addStudyInvestigationalIntervention (investigationalIntervention : InvestigationalInterven
[Is static False. Is abstract False. Is return array False. Is que

◆ addStudyObjective (objective : Objective) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ addStudyWorkflow (workflow : Workflow) : void Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getInterventionalModel () : Code Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyCells () : List<StudyCell> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyEstimands () : List<Estimand> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyIndications () : List<Indication> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyInvestigationalInterventions () : List<InvestigationalIntervention> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyObjectives () : List<Objective> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyPopulations () : List<StudyDesignPopulation> Public
[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyWorkflows () : List<Workflow> Public
[Is static False. Is abstract False. Is return array False. Is

OPERATIONS

🔹 removeStudyIndication (indication : Indication) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 removeStudyInvestigationalIntervention (investigationalIntervention : InvestigationalInter
[Is static False. Is abstract False. Is return array False. Is que

🔹 removeStudyObjective (objective : Objective) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 removeStudyWorkflow (workflow : Workflow) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setInterventionalModel (interventionalModel : Code) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyCells (studyCells : List<StudyCell>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyEstimands (studyEstimands : List<Estimand>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyIndications (studyIndications : List<Indication>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyInvestigationalInterventions (studyInvestigationalInterventions : List<Investigatio
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyObjectives (studyObjectives : List<Objective>) : void Public
[Is static False. Is abstract False. Is return array False. Is que

🔹 setStudyPopulations (studyStudyDesignPopulations : List<StudyDesignPopulation>) :

OPERATIONS

◆ StudyDesign (studyDesignId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

StudyDesignPopulation

Class in package 'model'

cupke created on 11/

ATTRIBUTES

◆ populationDesc : String Private

[Is static Tru

◆ uuid : UUID Private Const

[Is static Tru

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyDesign

Target: Private stu
(Class) StudyDesi
Cardinality: [0

OPERATIONS

◆ getPopulationDesc () : String Public

[Is static False. Is abstract False. Is return array False. Is que

A basic building block for time within a clinical study comprising the following charact
happens to the subject during the element; a definition of the start of the element; a rule

ATTRIBUTES

◆ studyElementDesc : String Private

[Is static True

◆ studyElementName : String Private

[Is static True

◆ transitionEndRule : TransitionRule Private

[Is static True

◆ transitionStartRule : TransitionRule Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private tran
TransitionRule

✏ Association (direction: Source -> Destination)

Source: Public (Class) StudyElement

Target: Private tran
TransitionRule

OPERATIONS

◆ getTransitionEndRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getTransitionStartRule () : TransitionRule Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyElementDesc (studyElementDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyElementName (studyElementName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setTransitionEndRule (transitionEndRule : TransitionRule) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setTransitionStartRule (transitionStartRule : TransitionRule) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ StudyElement (studyElementId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

StudyEpoch

Class in package 'model'

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

ATTRIBUTES

◆ studyEpochDesc : String Private

[Is static Tru

◆ studyEpochName : String Private

[Is static Tru

◆ studyEpochType : Code Private

[Is static Tru

◆ uuid : UUID Private Const

[Is static Tru

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private en
Cardinality: [0

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyEpoch

Target: Private stu

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyCell

Target: Private stu

OPERATIONS

◆ getEncounters () : List<Encounter> Public

[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is que

getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

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

[Is static False. Is abstract False. Is return array False. Is que

setNextStudyEpochId (nextStudyEpochId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setPreviousStudyEpochId (previousStudyEpochId : UUID) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setStudyEpochDesc (studyEpochDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setStudyEpochName (studyEpochName : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setStudyEpochType (studyEpochType : Code) : void Public

[Is static False. Is abstract False. Is return array False. Is que

StudyEpoch (studyEpochId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

StudyIdentifier

Class in package 'model'

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyIdentifier

Target: Private stu
Organization

✎ Association (direction: Source -> Destination)

Source: Public (Class) Study

Target: Private stu
StudyIdentifier
Cardinality: [0

OPERATIONS

◆ getStudyIdentifier () : String Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getStudyIdentifierScope () : Organization Public

[Is static False. Is abstract False. Is return array False. Is que

◆ getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyIdentifier (studyIdentifier : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ setStudyIdentifierScope (studyIdentifierScope : Organization) : void Public

[Is static False. Is abstract False. Is return array False. Is que

◆ StudyIdentifier (studyIdentifierId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

ATTRIBUTES

◆ officialTitle : String Private

[Is static True

◆ protocolAmendment : String Private

[Is static True

◆ protocolEffectiveDate : Date Private

[Is static True

◆ protocolStatus : Code Private

[Is static True

◆ protocolVersion : String Private

[Is static True

◆ publicTitle : String Private

[Is static True

◆ scientificTitle : String Private

[Is static True

◆ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

✎ Association (direction: Source -> Destination)

Source: Public (Class) StudyProtocolVersion   Target: Private pro

✎ Association (direction: Source -> Destination)

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is que

getProtocolEffectiveDate () : Date Public

[Is static False. Is abstract False. Is return array False. Is que

getProtocolStatus () : Code Public

[Is static False. Is abstract False. Is return array False. Is que

getProtocolVersion () : String Public

[Is static False. Is abstract False. Is return array False. Is que

getPublicTitle () : String Public

[Is static False. Is abstract False. Is return array False. Is que

getScientificTitle () : String Public

[Is static False. Is abstract False. Is return array False. Is que

getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

setBriefTitle (briefTitle : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setOfficialTitle (officialTitle : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setProtocolAmendment (protocolAmendment : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

setProtocolEffectiveDate (protocolEffectiveDate : Date) : void Public

[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS
🔷 StudyProtocolVersion (studyProtocolVersionId : UUID) : Public
[Is static False. Is abstract False. Is return array False. Is que

TransitionRule

Class in package 'model'

A guide that governs the allocation of subjects to operational options at a discrete decisi
assignment to a particular arm, discontinuation) within a clinical trial plan.

Chris Upkes created on 11/

ATTRIBUTES
🔷 transitionRuleDesc : String Private
[Is static True
🔷 uuid : UUID Private Const
[Is static True

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

OPERATIONS

getUuid () : UUID Public

[Is static False. Is abstract False. Is return array False. Is que

setTransitionRuleDesc (transitionRuleDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

TransitionRule (ruleId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

Workflow

Class in package 'model'

Chris Upkes created on 11/

ATTRIBUTES

uuid : UUID Private Const

[Is static True

workflowDesc : String Private

[Is static True

workflowItems : List<WorkflowItem> Private

[Is static True

ASSOCIATIONS

Association (direction: Source -> Destination)

Source: Public (Class) Workflow   Target: Private wo

OPERATIONS

[Is static False. Is abstract False. Is return array False. Is que

⬥ getWorkflowItems () : List<WorkflowItem> Public

[Is static False. Is abstract False. Is return array False. Is que

⬥ setWorkflowDesc (workflowDesc : String) : void Public

[Is static False. Is abstract False. Is return array False. Is que

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

[Is static False. Is abstract False. Is return array False. Is que

⬥ Workflow (workFlowUUID : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is que

WorkflowItem

Class in package 'model'

Chris Upkes created on 11/

ATTRIBUTES

⬥ nextWorkflowItemId : UUID Private

[Is static True

⬥ previousWorkflowItemId : UUID Private

[Is static True

⬥ uuid : UUID Private Const

[Is static True

ASSOCIATIONS

Source: Public (Class) WorkflowItem

Target: Private wo
Encounter

Association (direction: Source -> Destination)

Source: Public (Class) WorkflowItem

Target: Private wo
Activity

Association (direction: Source -> Destination)

Source: Public (Class) Workflow

Target: Private wo
WorkflowItem
Cardinality: [0

OPERATIONS

getNextWorkflowItemId () : UUID Public
[Is static False. Is abstract False. Is return array False. Is que

getPreviousWorkflowItemId () : UUID Public
[Is static False. Is abstract False. Is return array False. Is que

getUuid () : UUID Public
[Is static False. Is abstract False. Is return array False. Is que

getWorkflowItemActivity () : Activity Public
[Is static False. Is abstract False. Is return array False. Is que

getWorkflowItemDesc () : String Public
[Is static False. Is abstract False. Is return array False. Is que

getWorkflowItemEncounter () : Encounter Public
[Is static False. Is abstract False. Is return array False. Is que

OPERATIONS

setWorkflowItemEncounter (workflowItemEncounter : Encounter) : void Public

[Is static False. Is abstract False. Is return array False. Is qu

WorkflowItem (workflowItemId : UUID) : Public

[Is static False. Is abstract False. Is return array False. Is qu