Meeting Minutes

CDISC-HL7 Stage II
April 30, 2008
11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Jason Rock/Global Submit (Chair)
Kevin Ace/Mayo Clinic Foundation
Julie Evans/CDISC
Patty Garvey/FDA (Facilitator)
Scott Getzin/Eli Lilly
Pierre-Yves Lastic/Sanofi Aventis
Jay Levin/FDA
Saurin Mehta/Novartis
Armando Oliva/FDA
Bill Rosen/Pfizer

Background

FDA wishes to receive, in regulatory submissions, standard clinical study information content developed by the Clinical Data Interchange Standards Consortium (CDISC) in an Health Level 7 (HL7) message exchange format. This is key to the FDA strategic initiatives to improve public health and patient safety.

This project is currently broken into two stages: requirements analysis and message development. Stage IB team was developed and tasked with the requirements analysis responsibilities. Stage II team was developed and tasked with the message development responsibilities.

The purpose of the meeting is to discuss the mapping of the Study Participation Message to the Reference Information Model.

Discussion

- The April 16, 2008 meeting minutes were approved.

- At the April 16th meeting, Scott and Armando were tasked with finding out what is approved under Institutional Review Board approval. They shared that the IRB can approve investigators, staff, site and/or protocol. Therefore, during the discussion it was determined that the IRB messages should capture specific site, date and organization. The specific site can be referred by ID number if already assigned. The organization is the official approval body and is independent from the approval process.

- Jason continued his presentation on the Study Participation Model starting at the 'Investigative Subject' slide.

- New Business
  - Jason proposed sharing the draft message models on the HL7 website. The purpose would only to allow individuals to review the models. The documents will be in a ballot format, be use to track progress, and updated every 4 months. Individuals will be able to provide their comments through the list serve procedures, which would be an advantage of sharing the draft on the HL7 website. Also, a summary of changes would be available in a communication format prior to sending to RCRIM.

    At this time, it was felt that more details are needed about the benefits of sharing the documents on the HL7 website as well as the ability to update the documents on a more frequent basis. It was suggested that Jason look into using the HL7 wiki instead of the website.

  - Patty proposed that the Stage II meeting time be extended by an hour. Therefore, the bi-weekly meeting time would be 11:00 am to 1:00 pm (EST). It is anticipated that the Study Participation, Study Design and Subject Data messages be submitted for DSTU Ballot in September 2008. The meeting extension was recommended to allow for adequate review and discussion time to prepare for the DSTU Ballot.

Attachment: Study Participation Presentation

Drafted: PGarvey/5-12-2008
Approved: 5-14-08

Study Participation

Jason Rock
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215-253-7474

Table of Contents

Source Information

- Started with the BRIDG
  - Need to harmonize CRO, animal, part of organism, IRB (possibly firebird), site investigators (possibly firebird), Inspection Results (site audits)
- Validated against CDISC SDTM DM and DS domains
  - Study Participation message does not include when information about the subject is recorded.
    - Will be captured in the Study Subject message

Study Participation

- Who is involved in the conduct of the study?
  - What are there roles
  - Where is there involvement
  - When are they involved

- It is probable that not all use cases will be implemented by any one party

Scope

- Studies that are performed to determine the quality, safety and efficacy of regulated products.
- Including but not limited to:
  - human clinical studies (drugs, devices, biologics, combination products)
  - animal pharmacology and toxicology studies (drugs, devices, biologics, combination products, food additives, cosmetics)
  - target animal veterinary studies
  - device performance studies
  - in vitro studies (drugs, biologics)

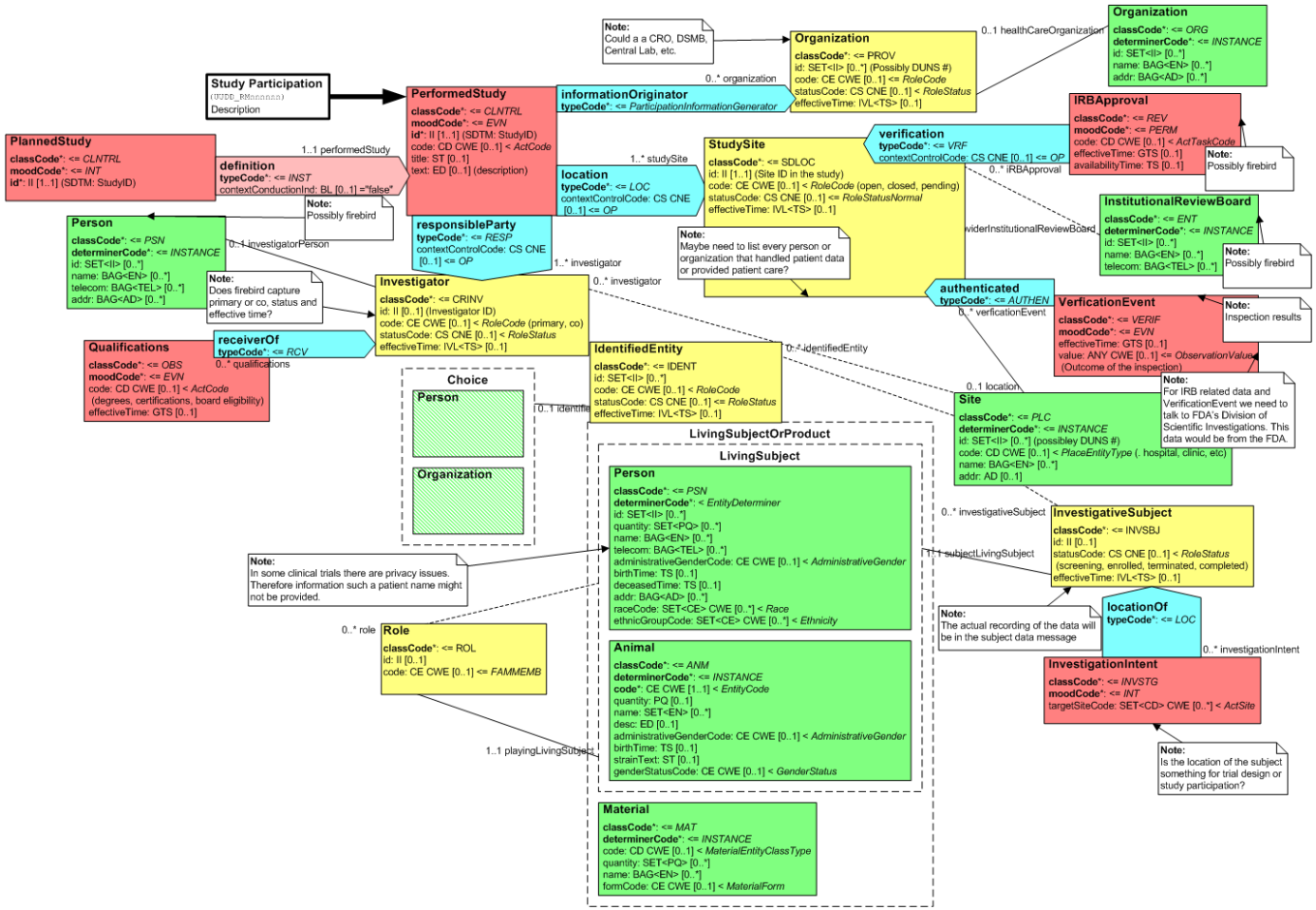
What is a Study?

- A set of observations performed in the context of testing a particular hypothesis(-es) (e.g. solving a particular problem or question)
  - Subject could be living or inanimate (device, pill, etc.)
- A study of the effects of a medical intervention, such as a comparison test of medical treatment, versus a placebo (inactive look-a-like), other medications or devices, or the standard medical treatment for a patient's condition

Model (1)

- The next slide will show a proposed model of Study Participation
- We will break down each class one by one and explain how it meets the defined requirements

Model (2)

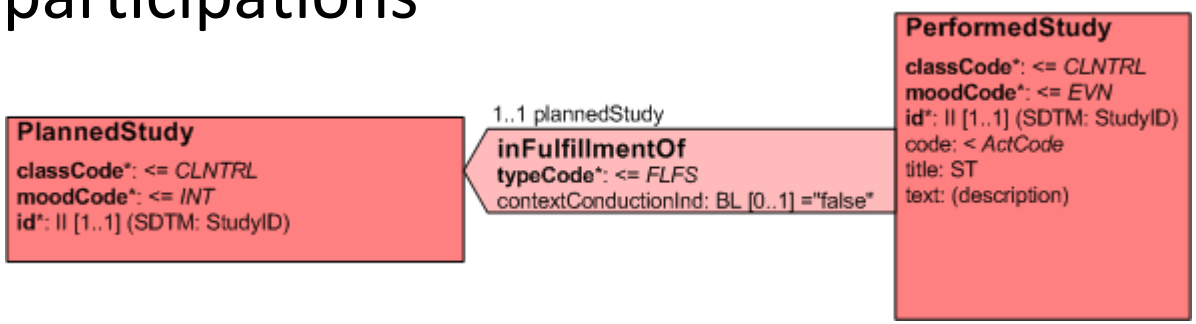

Study Participation
(UUID, RMoooooo)
Description
PerformedStudy
classCode*: <= CLNTRL
moodCode*: <= EVN
id*: II [1..1] (SDTM: StudyID)
code: CD CWE [0..1] < ActCode
title: ST [0..1]
text: ED [0..1] (description)
PlannedStudy
classCode*: <= CLNTRL
moodCode*: <= INT
id*: II [1..1] (SDTM: StudyID)
definition
typeCode*: <= INST
contextConductionInd: BL [0..1] ="false"
1..1 performedStudy
Note:
Possibly firebird
Note:
Could a a CRO, DSMB, Central Lab, etc.
informationOriginator
typeCode*: <= ParticipationInformationGenerator
0..* organization
Organization
classCode*: <= PROV
id: SET<II> [0..*] (Possibly DUNS #)
code: CE CWE [0..1] <= RoleCode
statusCode: CS CNE [0..1] < RoleStatus
effectiveTime: IVL<TS> [0..1]
0..1 healthCareOrganization
Organization
classCode*: <= ORG
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
addr: BAG<AD> [0..*]
IRBApproval
classCode*: <= REV
moodCode*: <= PERM
code: CD CWE [0..1] < ActTaskCode
effectiveTime: GTS [0..1]
availabilityTime: TS [0..1]
Note:
Possibly firebird
verification
typeCode*: <= VRF
contextControlCode: CS CNE [0..1] <= OP
0..* IRBApproval
StudySite
classCode*: <= SDLOC
id: II [1..1] (Site ID in the study)
code: CE CWE [0..1] < RoleCode (open, closed, pending)
statusCode: CS CNE [0..1] <= RoleStatusNormal
effectiveTime: IVL<TS> [0..1]
1..* studySite
location
typeCode*: <= LOC
contextControlCode: CS CNE [0..1] <= OP
Note:
Maybe need to list every person or organization that handled patient data or provided patient care?
InstitutionalReviewBoard
classCode*: <= ENT
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
Note:
Possibly firebird
widerInstitutionalReviewBoard
Person
classCode*: <= PSN
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
addr: BAG<AD> [0..*]
0..1 investigatorPerson
Note:
Does firebird capture primary or co, status and effective time?
responsibleParty
typeCode*: <= RESP
contextControlCode: CS CNE [0..1] <= OP
1..* investigator
Investigator
classCode*: <= CRINV
id: II [0..1] (Investigator ID)
code: CE CWE [0..1] < RoleCode (primary, co)
statusCode: CS CNE [0..1] < RoleStatus
effectiveTime: IVL<TS> [0..1]
0..* investigator
authenticated
typeCode*: <= AUTHEN
0..* verficationEvent
VerficationEvent
classCode*: <= VERIF
moodCode*: <= EVN
effectiveTime: GTS [0..1]
value: ANY CWE [0..1] <= ObservationValue
(Outcome of the inspection)
Note:
Inspection results
Note:
For IRB related data and VerificationEvent we need to talk to FDA's Division of Scientific Investigations. This data would be from the FDA.
receiverOf
typeCode*: <= RCV
0..* qualifications
Qualifications
classCode*: <= OBS
moodCode*: <= EVN
code: CD CWE [0..1] < ActCode
(degrees, certifications, board eligibility)
effectiveTime: GTS [0..1]
Choice
Person
Organization
0..1 identifiedEntity
IdentifiedEntity
classCode*: <= IDENT
id: SET<II> [0..*]
code: CE CWE [0..1] < RoleCode
statusCode: CS CNE [0..1] <= RoleStatus
effectiveTime: IVL<TS> [0..1]
0..* identifiedEntity
0..1 location
Site
classCode*: <= PLC
determinerCode*: <= INSTANCE
id: SET<II> [0..*] (possibley DUNS #)
code: CD CWE [0..1] < PlaceEntityType (. hospital, clinic, etc)
name: BAG<EN> [0..*]
addr: AD [0..1]
LivingSubjectOrProduct
LivingSubject
Person
classCode*: <= PSN
determinerCode*: < EntityDeterminer
id: SET<II> [0..*]
quantity: SET<PQ> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
administrativeGenderCode: CE CWE [0..1] < AdministrativeGender
birthTime: TS [0..1]
deceasedTime: TS [0..1]
addr: BAG<AD> [0..*]
raceCode: SET<CE> CWE [0..*] < Race
ethnicGroupCode: SET<CE> CWE [0..*] < Ethnicity
Animal
classCode*: <= ANM
determinerCode*: <= INSTANCE
code*: CE CWE [1..1] < EntityCode
quantity: PQ [0..1]
name: SET<EN> [0..*]
desc: ED [0..1]
administrativeGenderCode: CE CWE [0..1] < AdministrativeGender
birthTime: TS [0..1]
strainText: ST [0..1]
genderStatusCode: CE CWE [0..1] < GenderStatus
Material
classCode*: <= MAT
determinerCode*: <= INSTANCE
code: CD CWE [0..1] < MaterialEntityClassType
quantity: SET<PQ> [0..*]
name: BAG<EN> [0..*]
formCode: CE CWE [0..1] < MaterialForm
Note:
In some clinical trials there are privacy issues. Therefore information such a patient name might not be provided.
0..* role
Role
classCode*: <= ROL
id: II [0..1]
code: CE CWE [0..1] <= FAMMEMB
1..1 playingLivingSubject
0..* investigativeSubject
InvestigativeSubject
classCode*: <= INVSBJ
id: II [0..1]
statusCode: CS CNE [0..1] < RoleStatus
(screening, enrolled, terminated, completed)
effectiveTime: IVL<TS> [0..1]
1..1 subjectLivingSubject
Note:
The actual recording of the data will be in the subject data message
locationOf
typeCode*: <= LOC
0..* investigationIntent
InvestigationIntent
classCode*: <= INVSTG
moodCode*: <= INT
targetSiteCode: SET<CD> CWE [0..*] < ActSite
Note:
Is the location of the subject something for trial design or study participation?

Planned and Performed Study

- Planned Study: A collector of planned activities, including a description of the planned number of subjects and the duration of their participation.
- Planned study will be further defined in the Study Design message
- Performed Studies “perform” the activates in a plan study
  - Characteristics, such as, objectives, phase, population description are in a planned study

Study Described in the RIM

- Refer to a planned study by the Id provided in a Study Design message
- Need Id to provide updates to an existing performed study
- Title is the study title (could possible get from Study Design)
- Text is a textual description about the study and their participations



Who Participated in Study?

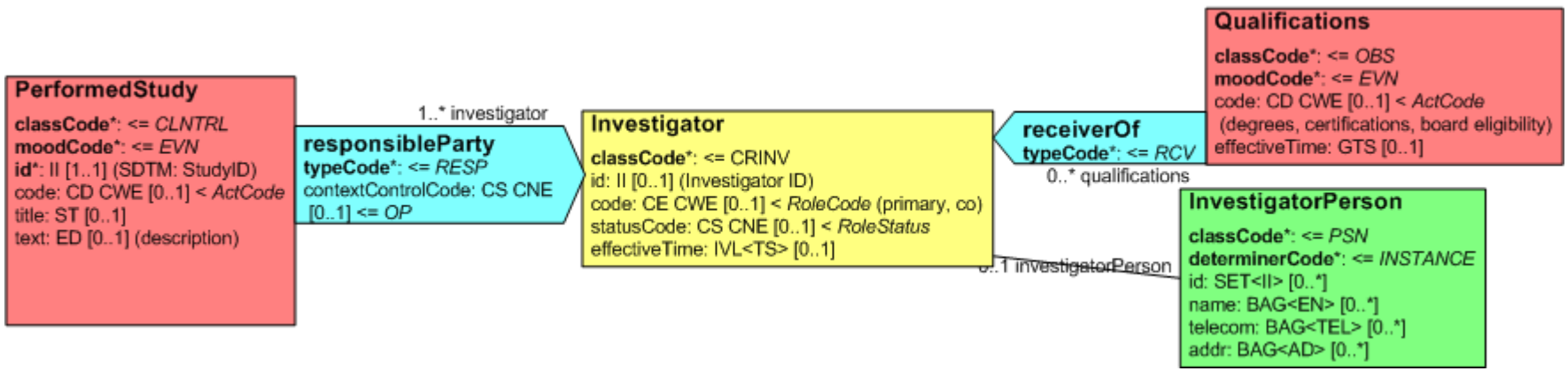
- Information about who was involved in the study and what activities occurred during the study
  - Investigators
  - Sites
  - Other Organizations
    - Sponsors, CRO's
- Site participation will be discussed in later slides

Study Investigator

- Oversees all aspects of the trial
  - such as protocol writing, IRB approval, recruitment, informed consent, analysis, etc.
- Must have one principal investigator per study
  - Can have many sub-investigators
- Investigator has qualification
  - Degrees certifications, board eligibility etc
- Investigators can be added and removed
  - Dates of the change of an investigator must be captured

Investigators described in RIM

- Investigator code describes the role of either the primary or sub investigator
  - Effective time describes when the investigator was either the primary or sub investigator
- Investigator is a person that we need to track their name, address and phone number
- We need to know are the qualified
  - code is the qualification, effective time is when the received the qualification and the time period of the qualification

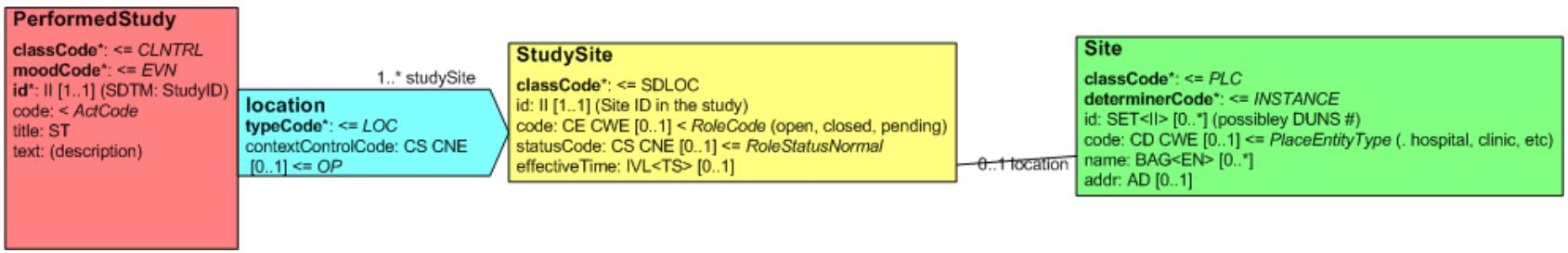


Study Site

- Where trial activities are conducted.
  - For example, the site where the subject encounter occurs or the site of the Investigator.
- There can be many sites for one study
- A site can be added or removed at any time

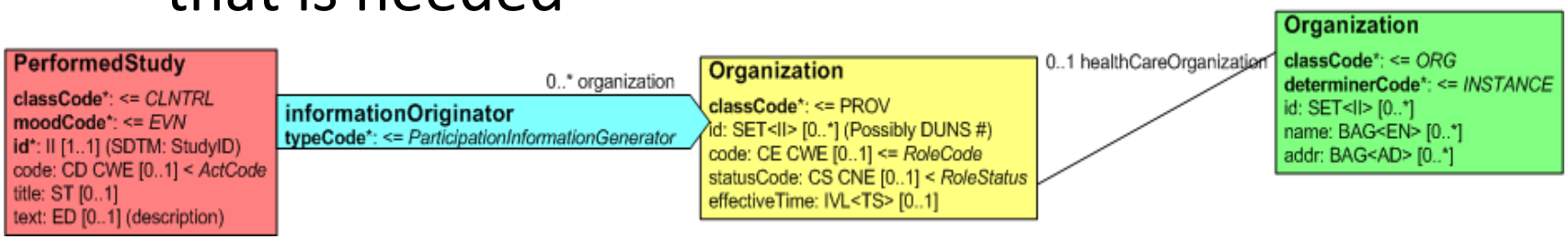
Study Site described in RIM

- Need site identifier for the study and universal identifier for the site (possibly DUNS #)
  - Need for any updates to the site
- StudySite code capture status of site in study (opened for accrual, closed for accrual, pending accrual)
  - Effective time describes when the site is in a certain status
- Site code captures type of site (hospital, clinic, etc)



Organization Described in RIM

- Any other organization that was involved in the Study
  - Code will be a pick list of organization types (e.g. CRO) – will be limited in Implementation Guide
  - Effective time when a certain organization was involved in the study
  - At this point name and Id of organization is all that is needed



What we need to know about the site?

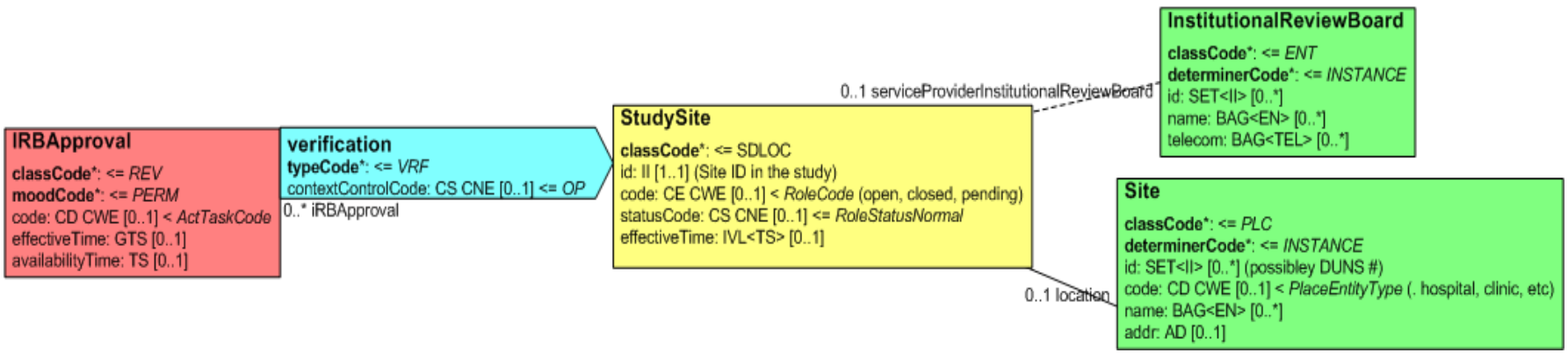
- Intuitional Review Board approvals (possibly firebird)
- Site investigators (possibly firebird)
- Subject that are involved in a study for a particular site
- Results of inspections (generated by regulators)
- Other organizations involved in the site
  - e.g. monitors

Institutional Review Board

- A board that approves, monitors and reviews biomedical research to protect the rights, safety and welfare of the subjects
- IRB approval site(s) for a specific study
- Captures when approval was recorded and effective time

IRB described in RIM

- Each site has one IRB
- IRB approval was recorded at a certain time (availability time)
- IRB approved a protocol for a specified time period (effective time)

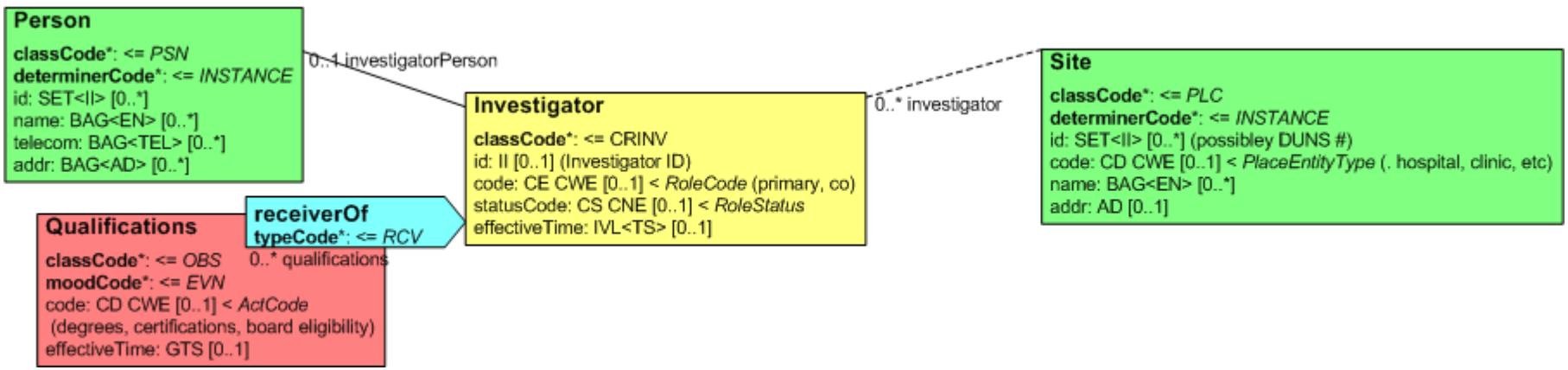


Site Investigator

- Oversees all aspects of a study at a certain site
- Must have one principal investigator per site
  - Can have many sub-investigators
- Site investigators can be added and removed
  - Dates of the change of an investigator must be captured

Site Investigator described in RIM

- Site has a relationships to investigators like study.
  - Investigators in RIM are described above

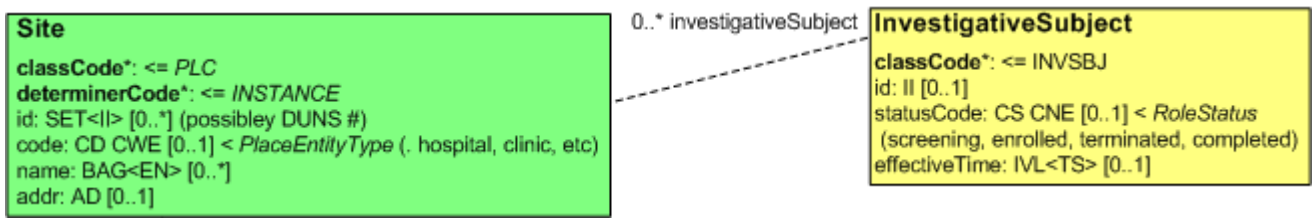


Investigative Subject

- Participates in a trials
  - a single organism (human, animal)
  - many living organisms (herds, flocks, etc.)
  - a part of an organism (artery, patch of skin, etc.) related to the organism
  - an inanimate object (pill, device, etc.)
- There could be many subjects in one trial

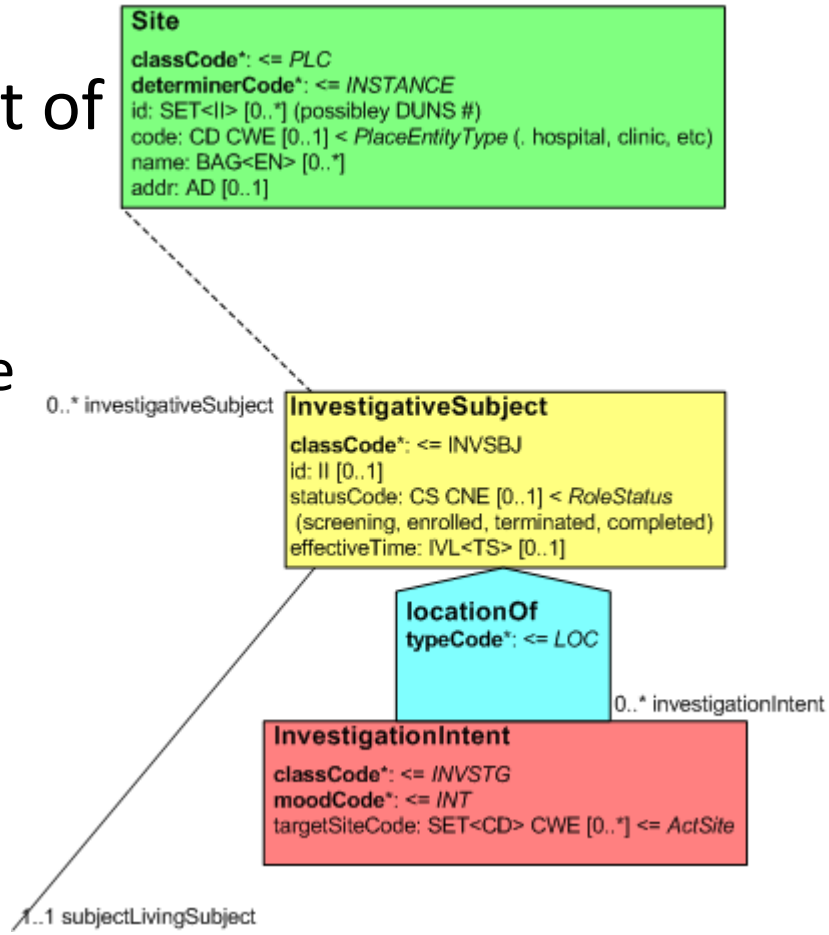
Subject described in RIM

- Id is the Id of the subject in a study
- Status code describes the state the subject is in the study
  - E.g. screening, enrolled, completed, etc.
- Effective time is the time the subject was in a certain state.



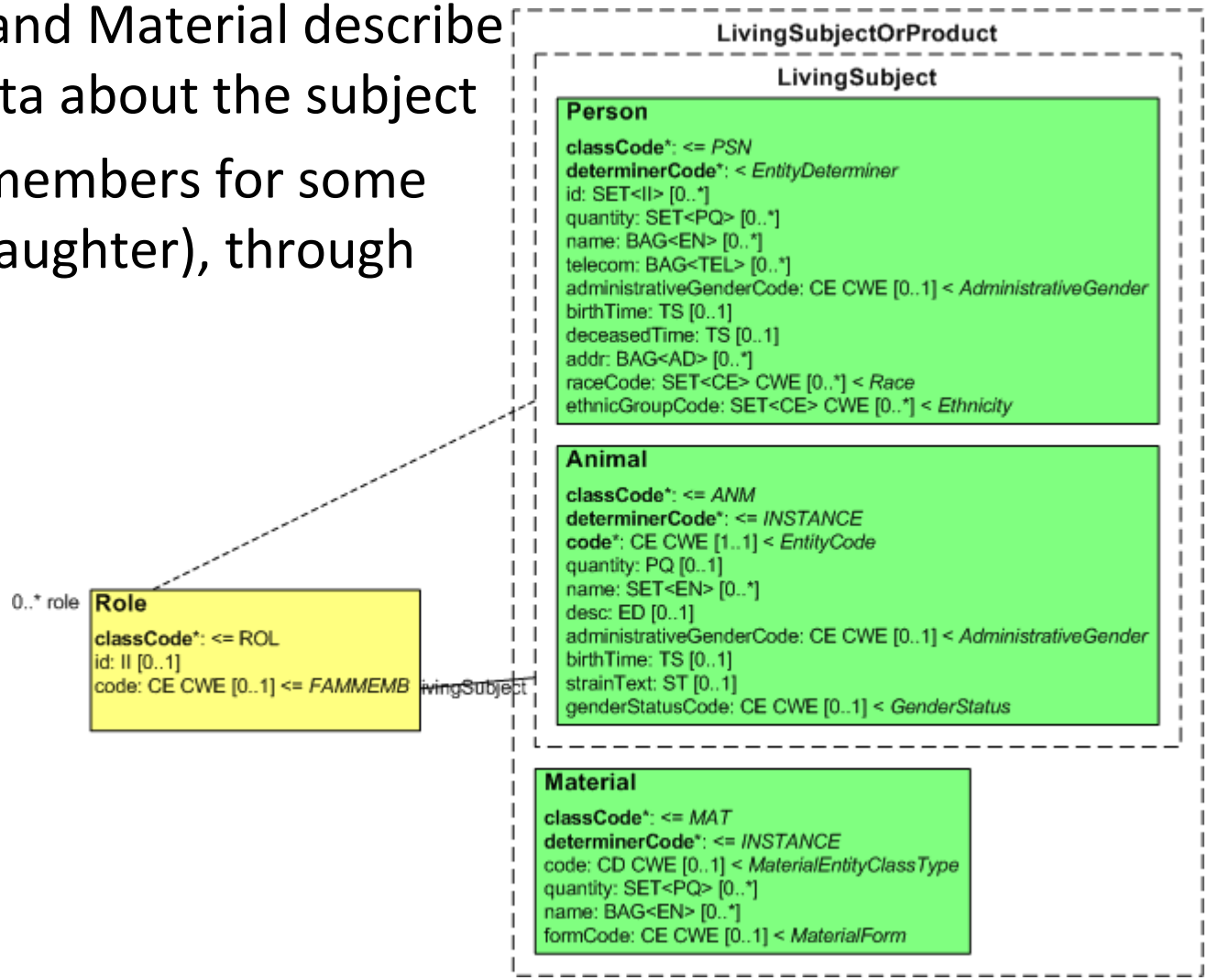
Investigative Subject Cntd.

- Could be interested in a part of the subject (Target Site)
  - Controlled vocabulary can be used to discuss the target site



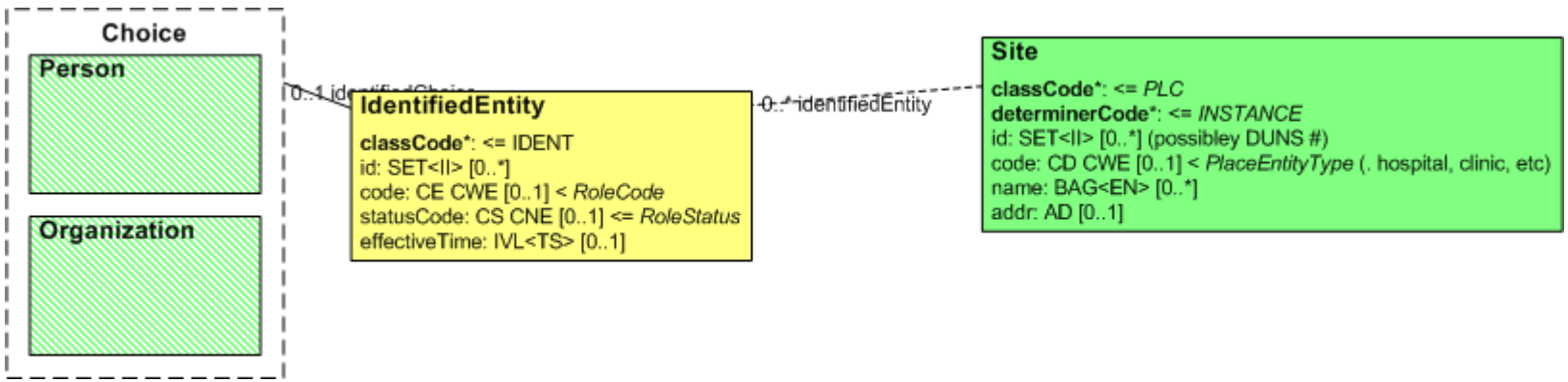
Investigative Subject Cntd.

- People, Animal and Material describe demographic data about the subject
- Capture family members for some trials (mother/daughter), through code

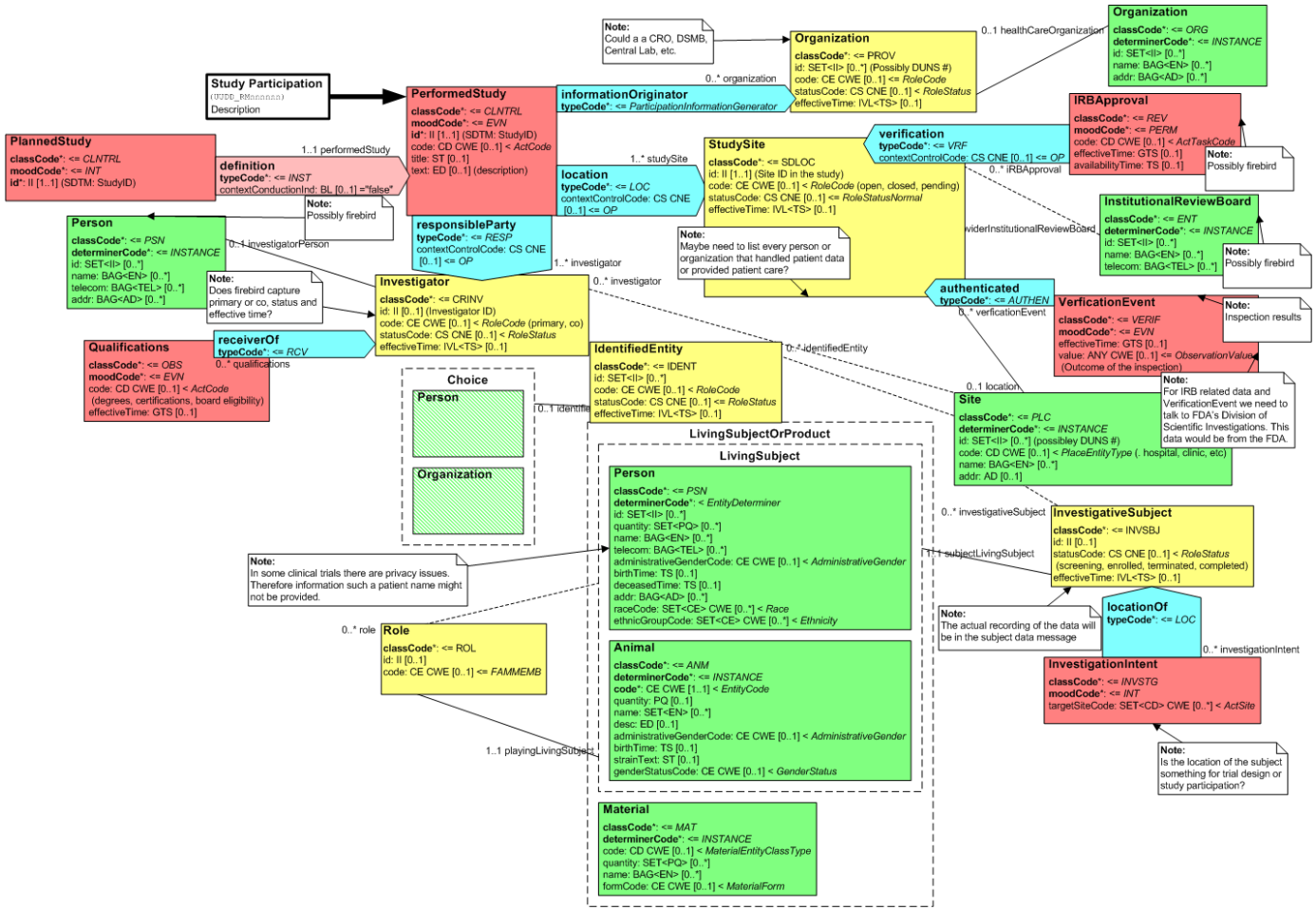


Other People or Organizations

- There could be other people or organizations involved in a site
  - Code will be a pick list of types (e.g. site monitors) – will be limited in Implementation Guide
  - Effective time when a certain organization was involved in the study
  - At this point name and Id of organization is all that is needed



Model


Study Participation
(UUID_RMsnnnn)
Description
PerformedStudy
classCode*: <= CLNTRL
moodCode*: <= EVN
id*: II [1..1] (SDTM: StudyID)
code: CD CWE [0..1] < ActCode
title: ST [0..1]
text: ED [0..1] (description)
PlannedStudy
classCode*: <= CLNTRL
moodCode*: <= INT
id*: II [1..1] (SDTM: StudyID)
definition
typeCode*: <= INST
contextConductionInd: BL [0..1] ="false"
1..1 performedStudy
Note:
Possibly firebird
Note:
Could a a CRO, DSMB, Central Lab, etc.
Organization
classCode*: <= PROV
id: SET<II> [0..*] (Possibly DUNS #)
code: CE CWE [0..1] <= RoleCode
statusCode: CS CNE [0..1] < RoleStatus
effectiveTime: IVL<TS> [0..1]
0..* organization
informationOriginator
typeCode*: <= ParticipationInformationGenerator
0..1 healthCareOrganization
Organization
classCode*: <= ORG
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
addr: BAG<AD> [0..*]
IRBApproval
classCode*: <= REV
moodCode*: <= PERM
code: CD CWE [0..1] < ActTaskCode
effectiveTime: GTS [0..1]
availabilityTime: TS [0..1]
Note:
Possibly firebird
StudySite
classCode*: <= SDLOC
id: II [1..1] (Site ID in the study)
code: CE CWE [0..1] < RoleCode (open, closed, pending)
statusCode: CS CNE [0..1] <= RoleStatusNormal
effectiveTime: IVL<TS> [0..1]
1..* studySite
location
typeCode*: <= LOC
contextControlCode: CS CNE [0..1] <= OP
verification
typeCode*: <= VRF
contextControlCode: CS CNE [0..1] <= OP
0..* IRBApproval
Note:
Maybe need to list every person or organization that handled patient data or provided patient care?
InstitutionalReviewBoard
classCode*: <= ENT
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
Note:
Possibly firebird
responsibleParty
typeCode*: <= RESP
contextControlCode: CS CNE [0..1] <= OP
Person
classCode*: <= PSN
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
addr: BAG<AD> [0..*]
0..1 investigatorPerson
Note:
Does firebird capture primary or co, status and effective time?
Investigator
classCode*: <= CRINV
id: II [0..1] (Investigator ID)
code: CE CWE [0..1] < RoleCode (primary, co)
statusCode: CS CNE [0..1] < RoleStatus
effectiveTime: IVL<TS> [0..1]
1..* investigator
0..* investigator
authenticated
typeCode*: <= AUTHEN
0..* verficationEvent
VerficationEvent
classCode*: <= VERIF
moodCode*: <= EVN
effectiveTime: GTS [0..1]
value: ANY CWE [0..1] <= ObservationValue
(Outcome of the inspection)
Note:
Inspection results
Note:
For IRB related data and VerificationEvent we need to talk to FDA's Division of Scientific Investigations. This data would be from the FDA.
receiverOf
typeCode*: <= RCV
0..* qualifications
Qualifications
classCode*: <= OBS
moodCode*: <= EVN
code: CD CWE [0..1] < ActCode
(degrees, certifications, board eligibility)
effectiveTime: GTS [0..1]
IdentifiedEntity
classCode*: <= IDENT
id: SET<II> [0..*]
code: CE CWE [0..1] < RoleCode
statusCode: CS CNE [0..1] <= RoleStatus
effectiveTime: IVL<TS> [0..1]
0..* identifiedEntity
0..1 location
Site
classCode*: <= PLC
determinerCode*: <= INSTANCE
id: SET<II> [0..*] (possibley DUNS #)
code: CD CWE [0..1] < PlaceEntityType (. hospital, clinic, etc)
name: BAG<EN> [0..*]
addr: AD [0..1]
Choice
Person
Organization
0..1 identifie
LivingSubjectOrProduct
LivingSubject
Person
classCode*: <= PSN
determinerCode*: < EntityDeterminer
id: SET<II> [0..*]
quantity: SET<PQ> [0..*]
name: BAG<EN> [0..*]
telecom: BAG<TEL> [0..*]
administrativeGenderCode: CE CWE [0..1] < AdministrativeGender
birthTime: TS [0..1]
deceasedTime: TS [0..1]
addr: BAG<AD> [0..*]
raceCode: SET<CE> CWE [0..*] < Race
ethnicGroupCode: SET<CE> CWE [0..*] < Ethnicity
Animal
classCode*: <= ANM
determinerCode*: <= INSTANCE
code*: CE CWE [1..1] < EntityCode
quantity: PQ [0..1]
name: SET<EN> [0..*]
desc: ED [0..1]
administrativeGenderCode: CE CWE [0..1] < AdministrativeGender
birthTime: TS [0..1]
strainText: ST [0..1]
genderStatusCode: CE CWE [0..1] < GenderStatus
Material
classCode*: <= MAT
determinerCode*: <= INSTANCE
code: CD CWE [0..1] < MaterialEntityClassType
quantity: SET<PQ> [0..*]
name: BAG<EN> [0..*]
formCode: CE CWE [0..1] < MaterialForm
Note:
In some clinical trials there are privacy issues. Therefore information such a patient name might not be provided.
0..* role
Role
classCode*: <= ROL
id: II [0..1]
code: CE CWE [0..1] <= FAMMEMB
1..1 playingLivingSubject
0..* investigativeSubject
InvestigativeSubject
classCode*: <= INVSBJ
id: II [0..1]
statusCode: CS CNE [0..1] < RoleStatus
(screening, enrolled, terminated, completed)
effectiveTime: IVL<TS> [0..1]
1..1 subjectLivingSubject
Note:
The actual recording of the data will be in the subject data message
locationOf
typeCode*: <= LOC
0..* investigationIntent
InvestigationIntent
classCode*: <= INVSTG
moodCode*: <= INT
targetSiteCode: SET<CD> CWE [0..*] < ActSite
Note:
Is the location of the subject something for trial design or study participation?