

Meeting Minutes

CDISC-HL7 Stage II

April 16, 2008

11:00 am – 12:00 pm (EST)

Attendees / Affiliation

Jason Rock/Global Submit (Chair)
Patty Garvey/FDA
Scott Getzin/Eli Lilly
Wayne Kubick/Lincoln Technologies
Armando Oliva/FDA
Bill Rosen/Pfizer
Marti Velezis/Booz Allen Hamilton

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 for Regulated Clinical Research Information Management (RCRIM) members to discuss develop consensus necessary for a path forward on CDISC-HL7 Stage II activities.

Discussion

- The March 19, 2008 meeting minutes were approved without Joyce Niland's ASPIRE Data Dictionary summary. An addendum to the minutes will be provided if the summary is provided at a later date.
- The April 2, 2008 meeting minutes were approved.
- Jason presented the Study Participation Message and focused on how the messages map to the Reference Information Model (RIM). He noted that the Biomedical Research Information Domain Group (BRIDG) definitions have been slightly modified for presentation purposes because BRIDG definitions are very long. During the presentation, the following major points were discussed:

- Currently, the study site BRIDG model is Study to Site to Investigator, however the team felt that it should be Study to Investigator to Site. The team will inform BRIDG of this inconsistency and continue to model as Study to Investigator to Site.
- Institutional Review Board (IRB)
 - Scott inquired whether IRB approval is for the site or for the investigator. Scott and Armando will both look further into this.
 - Armando asked whether the model can handle a withdrawal of an approval. Jason indicated that it possibly can by the negation identifier.
 - It was noted that the change 'effective time' will be changed to 'end time'.
- It was recommended that Diane Wold's presentation on the extension of BRIDG analysis be deferred to the next Stage IB open public meeting.
- For the next meeting, Jason indicated that he will continue his Study Participation presentation and define the messages more.

Action Items

1. Jason will inform BRIDG of the inconsistency regarding the study site BRIDG model as discussed above.
2. Scott and Armando will research whether IRB approval is for the site or investigator.
3. Inform Stage IB that Diane Wold's presentation on the extension of BRIDG analysis should be presented at the next Stage IB open public meeting.
4. The next meeting scheduled will be Wednesday, April 30, 2008.

Attachment: Study Participation messages

Drafted: PGarvey/4-17-2008

Approved: 4-30-2008

Study Participation

Jason Rock

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215-253-7474

Table of Contents

- Goals of the Study Participation Message
- Scope of work
- Overview of Study Participation
- How the proposed message design meets the requirements

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 their roles
 - Where is their 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)

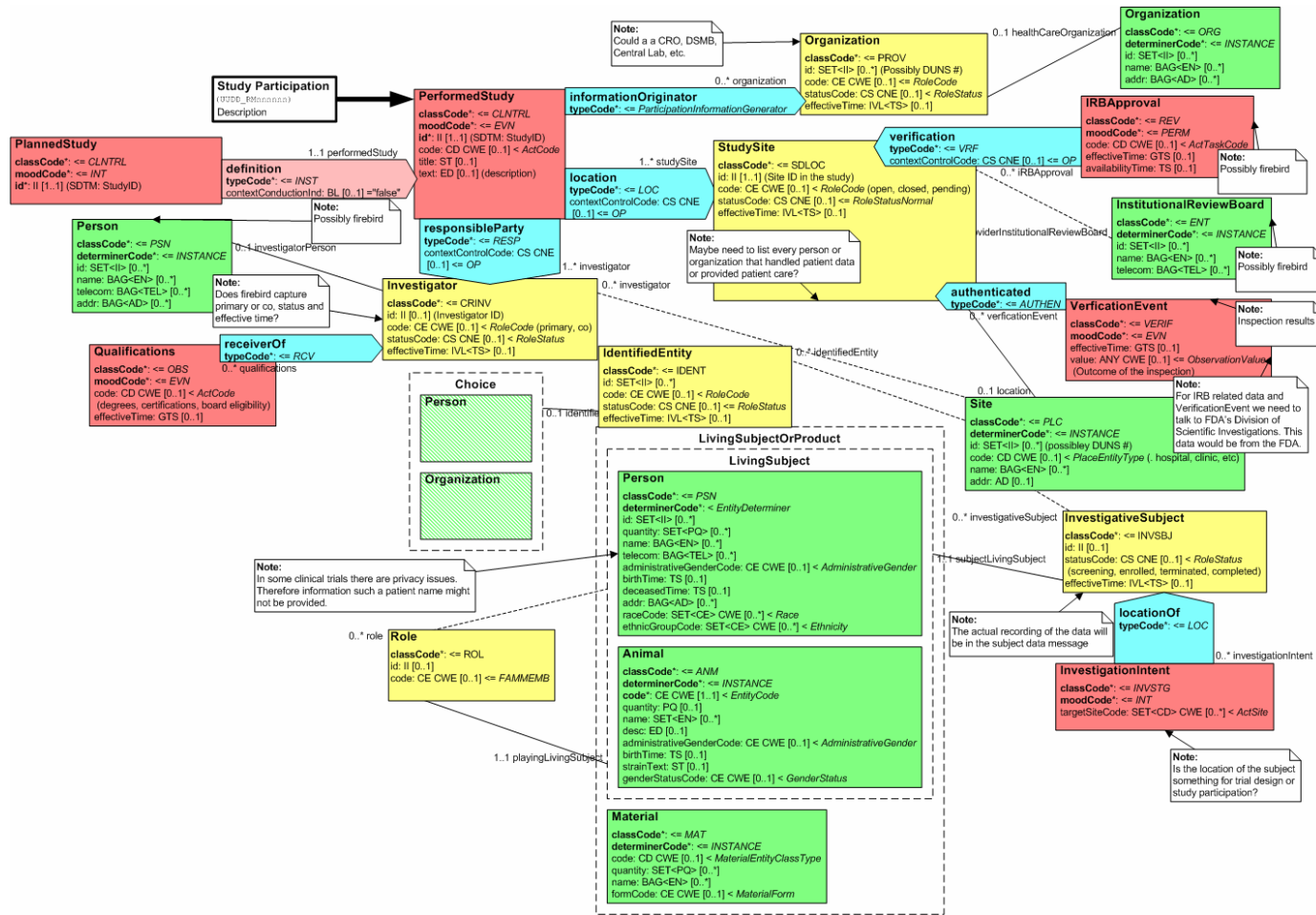
What is a Study?

- 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)

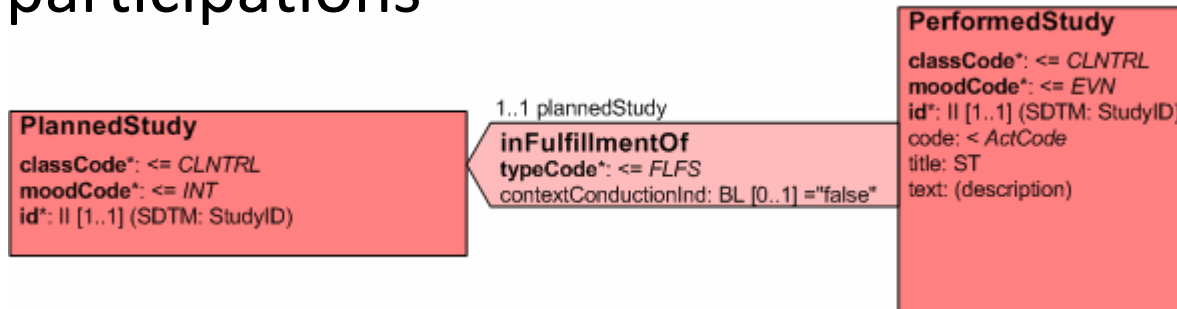


Planned and Performed Study

- 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?

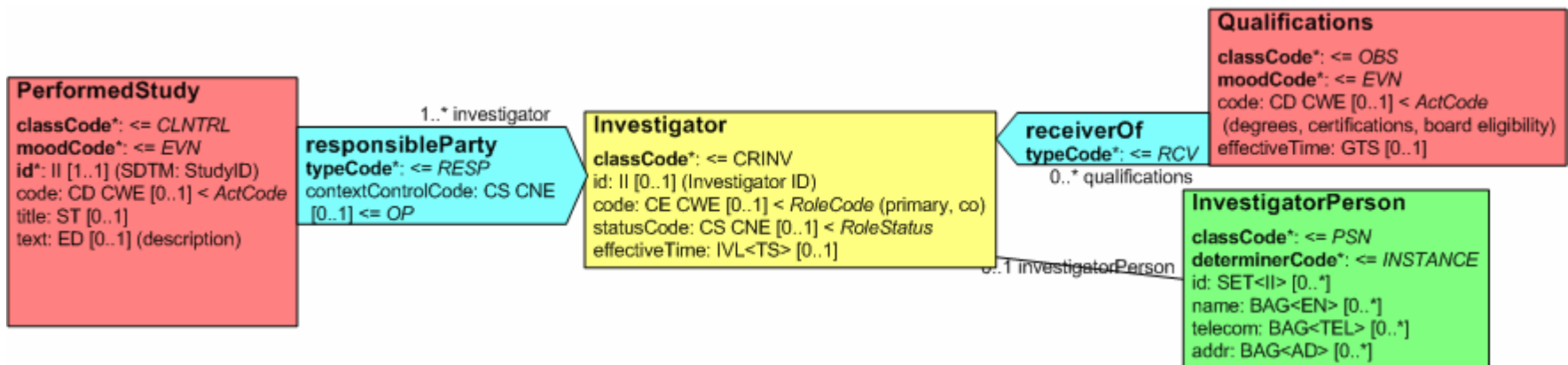
- Information about who was involved in the study and what activities occurred during the study
 - Investigators
 - Sites
 - Other Organizations
 - Sponsors, CRO's
- Site participation will be discussed in later slides

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

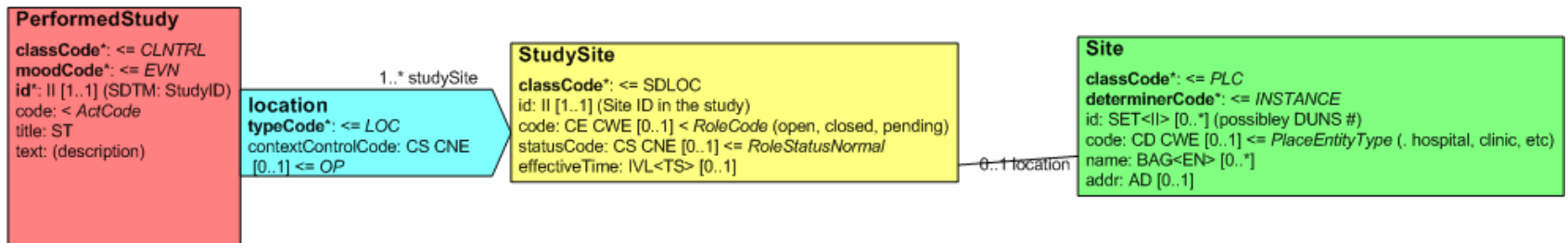


Study Site

- 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

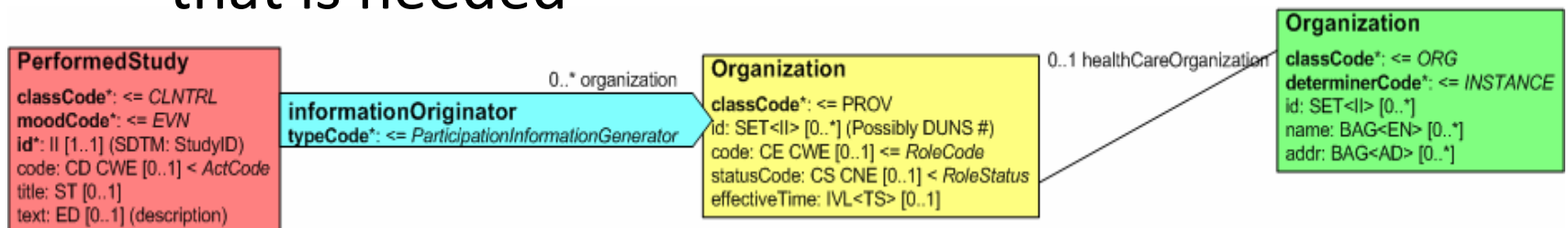
Study Site described in RIM

- 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?

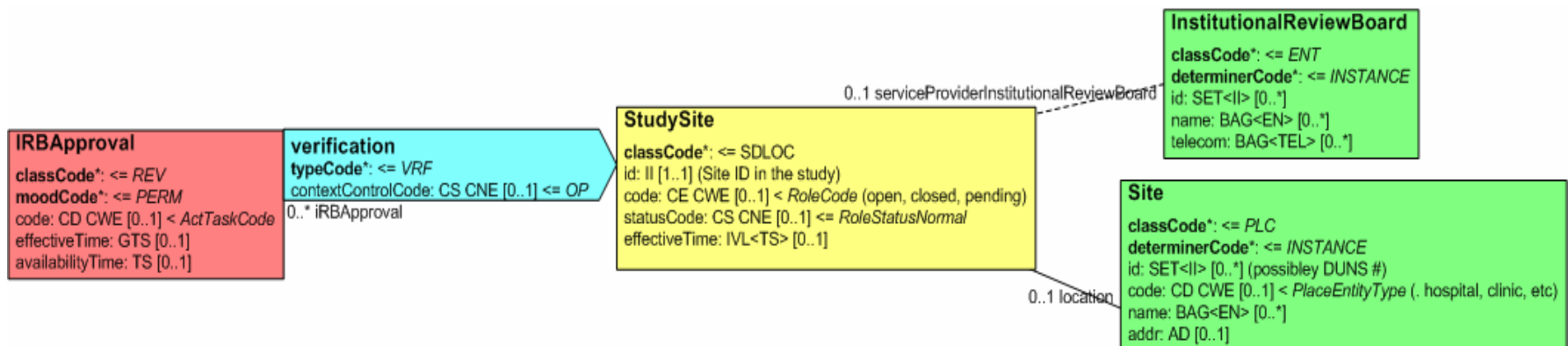
- Intuition Review Board approvals (possibly firebird)
- Site investigators (possibly firebird)
- Subject that are involved in a study for a particular site
- Results of inspections (generated by regulators)
- Other organizations involved in the site
 - e.g. monitors

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)

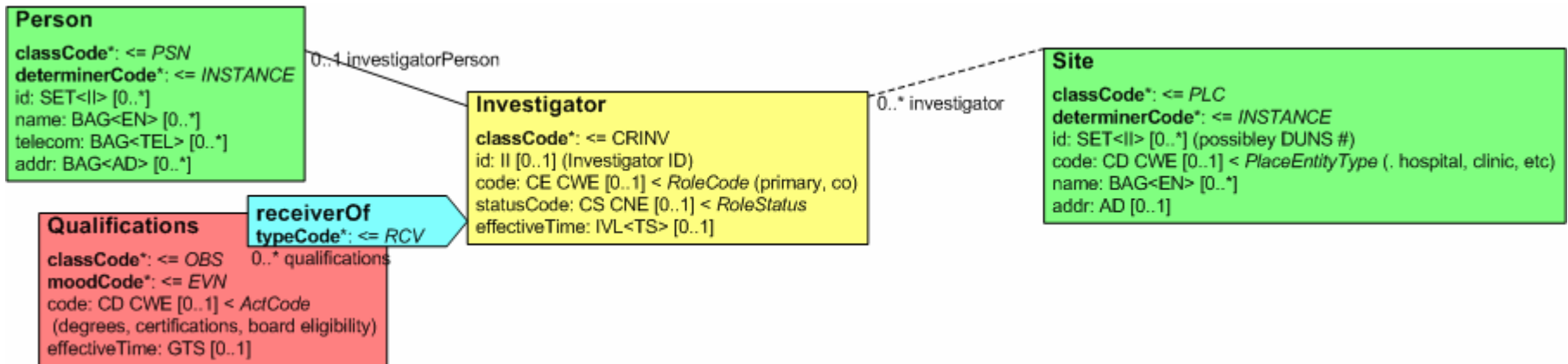


Site Investigator

- 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

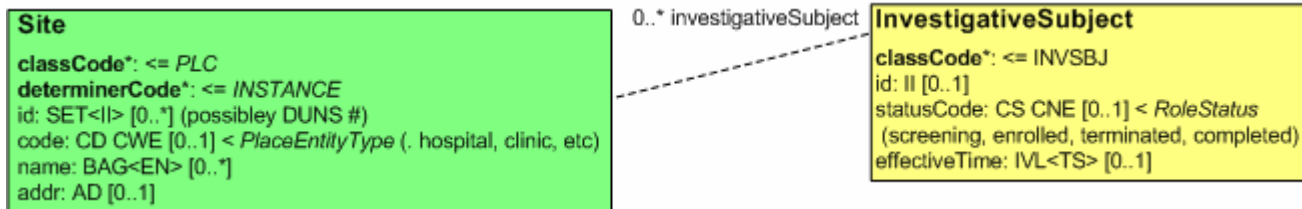


Investigative Subject

- 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

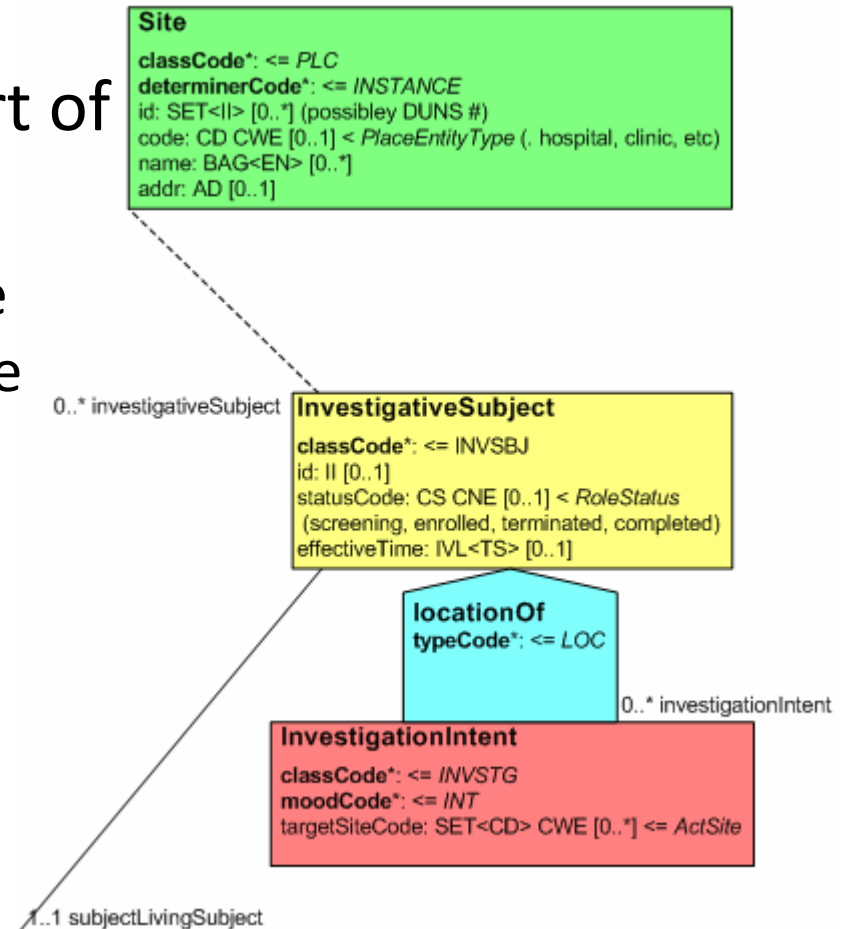
Subject described in RIM

- 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.



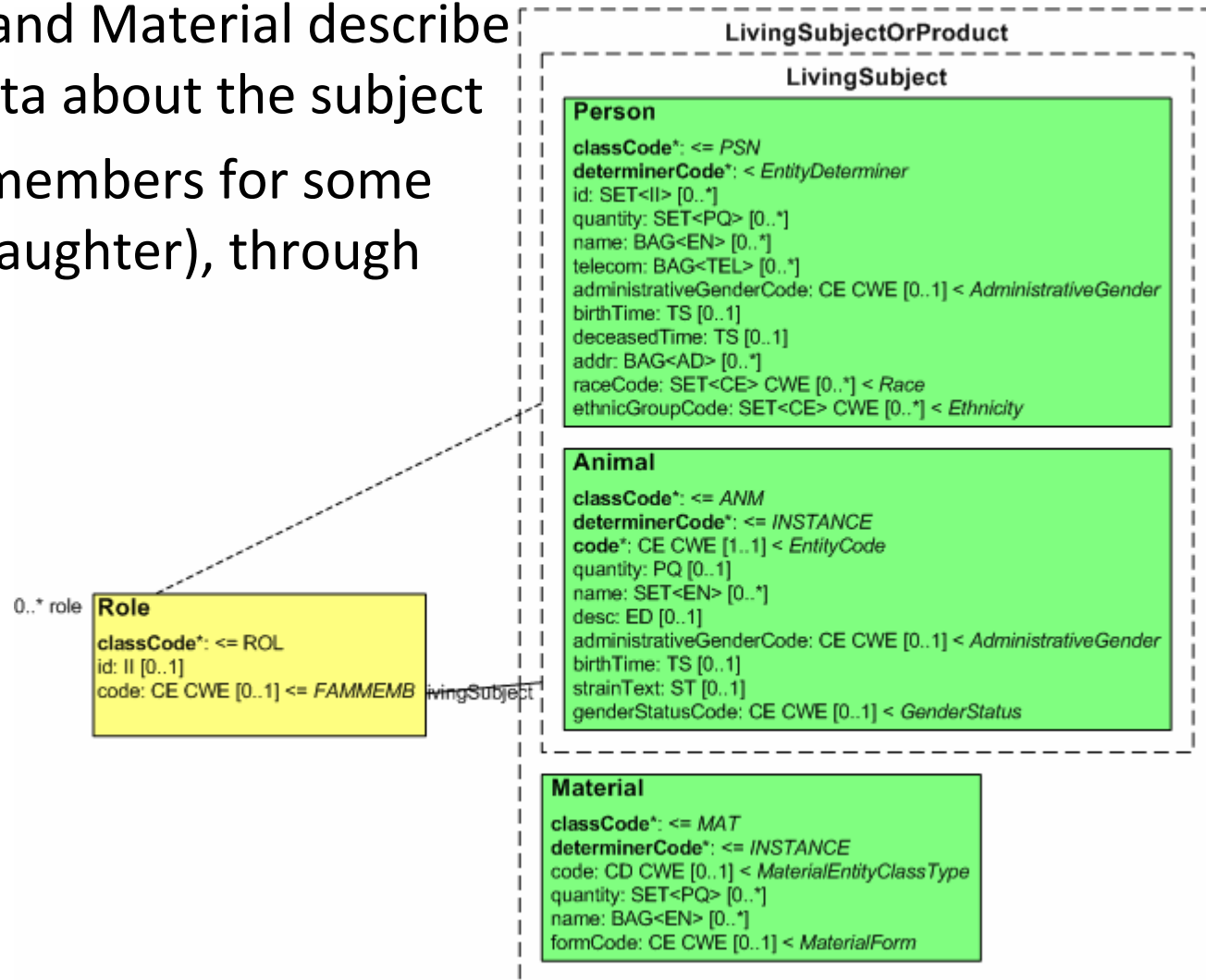
Investigative Subject Cntd.

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



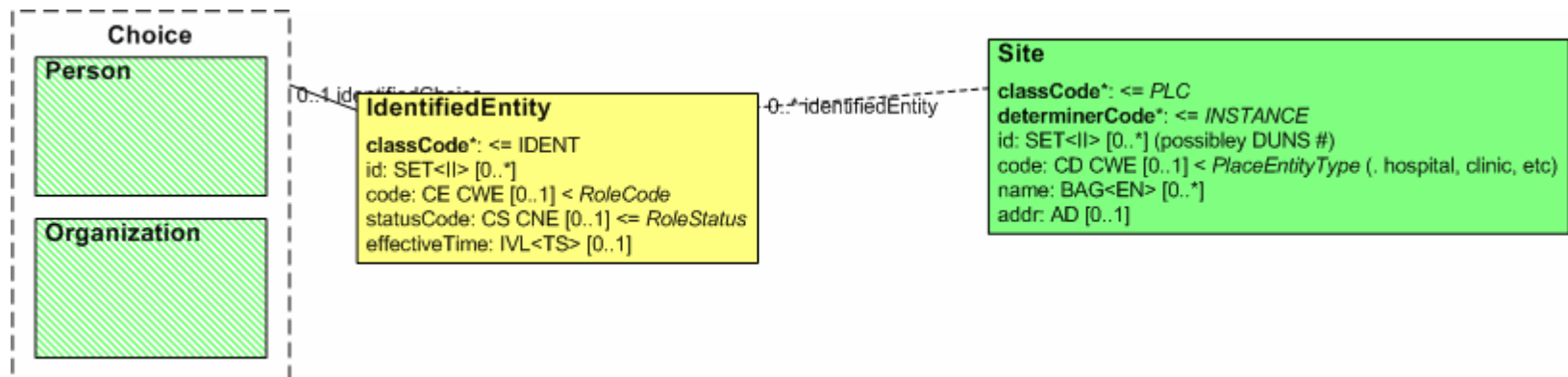
Investigative Subject Cntd.

- 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

