

Mapping SDTM to the BRIDG What does that really mean?

Diane Wold, Ph.D.

Director, Data Standards

GlaxoSmithKline

Overview

- The BRIDG Model
 - Purpose
 - How it's supposed to work
 - What it looks like
- Mapping SDTM to the BRIDG
 - Process
 - What the mapping looks like
 - Demography and Laboratory examples
- What good is the mapping?

Purpose of the BRIDG Model

- Originally proposed as a way to create a mapping between ODM and the HL7 RIM
- Also seen as a way to “harmonize” existing CDISC standards developed in parallel (LAB, ODM, SDS, ADaM)
- Extended to harmonization of CDISC standards with HL7 messages
 - Adopted as RCRIM domain model
- Extended to support interoperability of systems built by NCI’s CaBIG
- Open development model – anyone can contribute

BRIDG

How it's supposed to work

- Domain experts identify the concepts important to **protocol-driven (clinical) research**
 - Develop good definitions, including examples
 - Identify & define attributes
- Domain experts also identify relationships between these concepts
- These constitute an information model, written down using UML (Unified Modeling Language)
- Standards, messages, and systems that use this domain model share the same **semantics**, which is a necessary (though not sufficient) condition for **interoperability**.

Mapping SDTM to the BRIDG Mapping Process

- Ideally, CDISC would have developed a domain model *first*, then created SDTM.
- A UML model based on SDTM was started but not completed. It influenced BRIDG but was not a formal input to BRIDG.
- The current mapping of SDTM to BRIDG was done by looking at each SDTM variable in turn, and finding the relevant concept in BRIDG

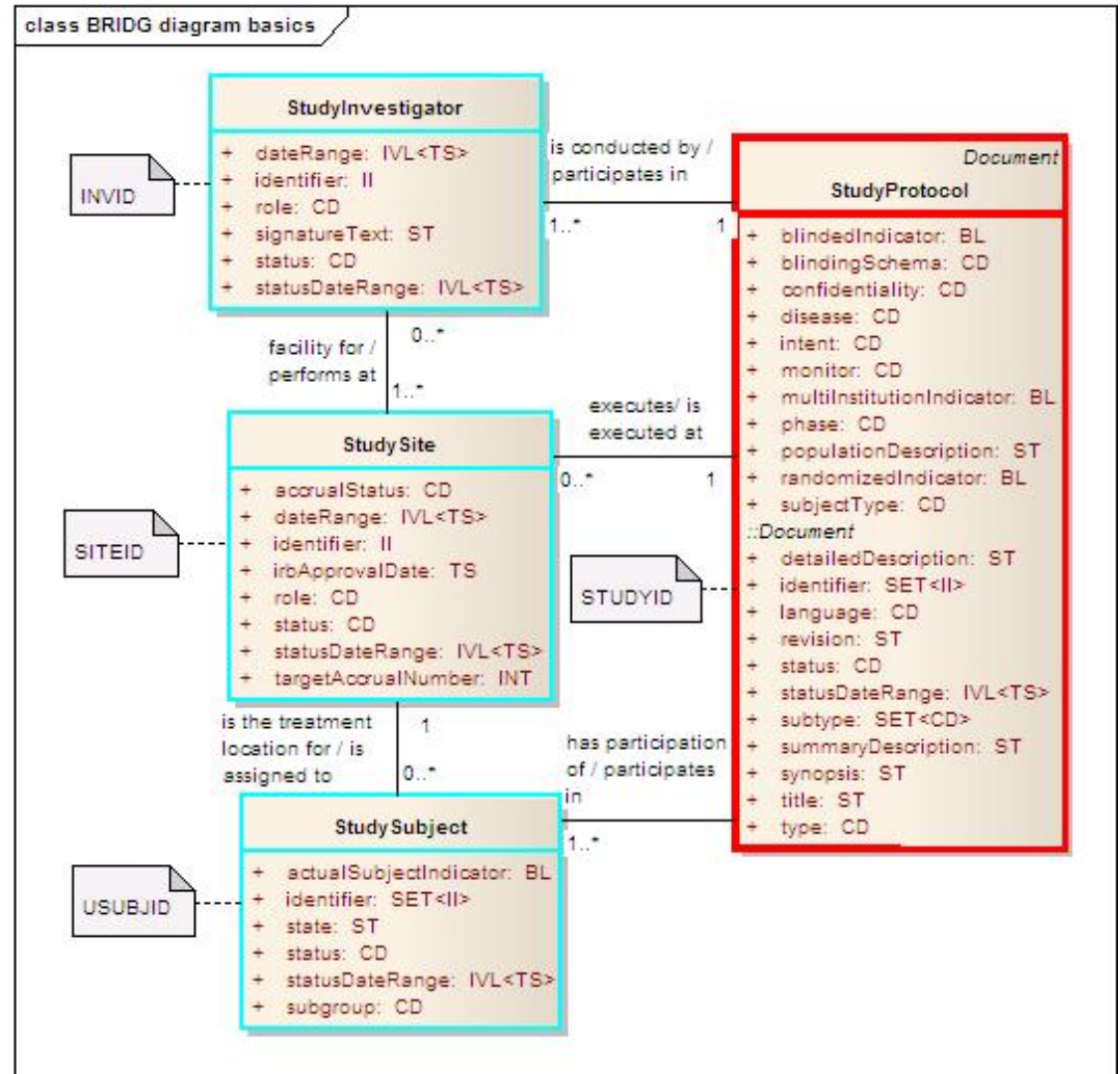
Mapping SDTM to the BRIDG Review Process

- Several SDS team members reviewed the mapping spreadsheet, domain by domain
- For each domain, a UML diagram which includes only the relevant classes was created, with notes indicating the attributes to which SDTM variables were mapped
- Annotated UML diagrams proved more user friendly than the spreadsheet

BRIDG Diagrams

UML Basics

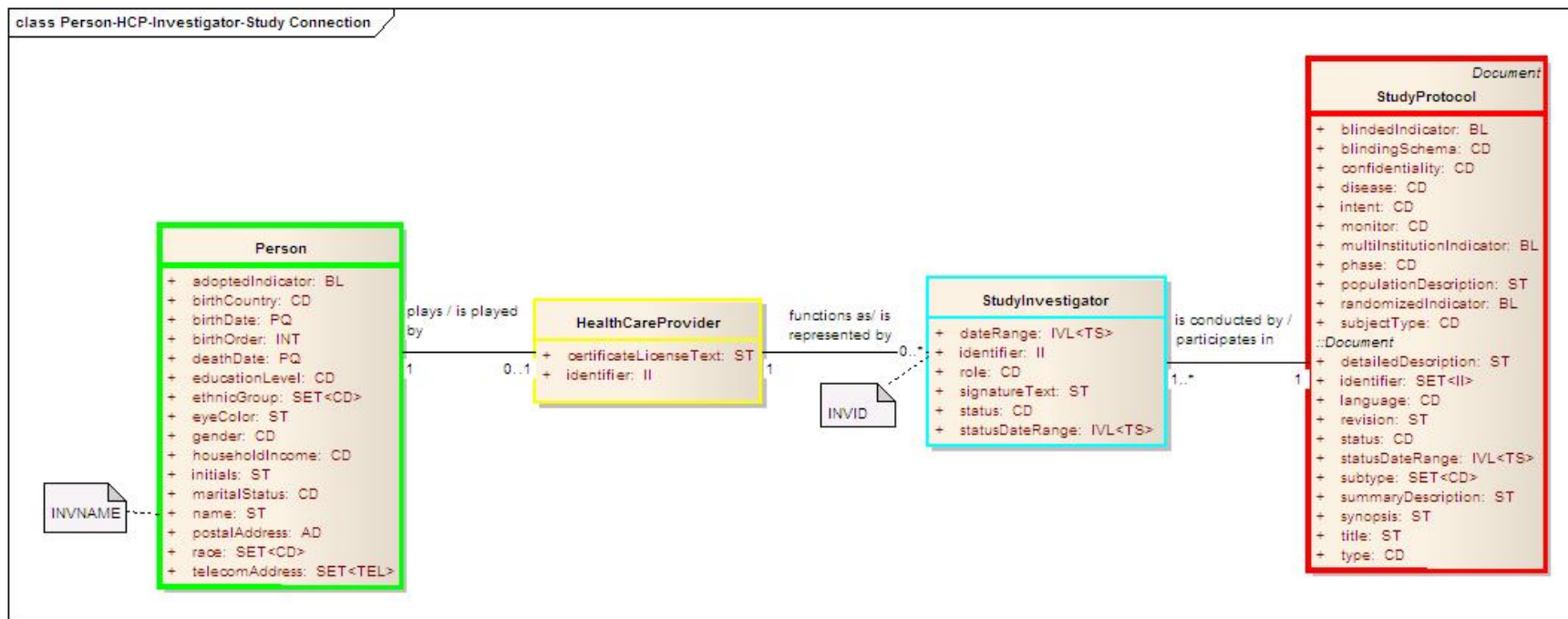
- Rectangles are Classes
- Classes have Attributes
- Lines connecting Classes are Relationships
- Small white objects are Notes (used for mapping – not part of the model)



BRIDG Diagrams

HL7 Conventions

- Green = Entity
- Yellow = Role played by an Entity (permanent)
- Red = Act (BRIDG Activity)
- Blue = Participation of a Role in an Activity (time-bounded)

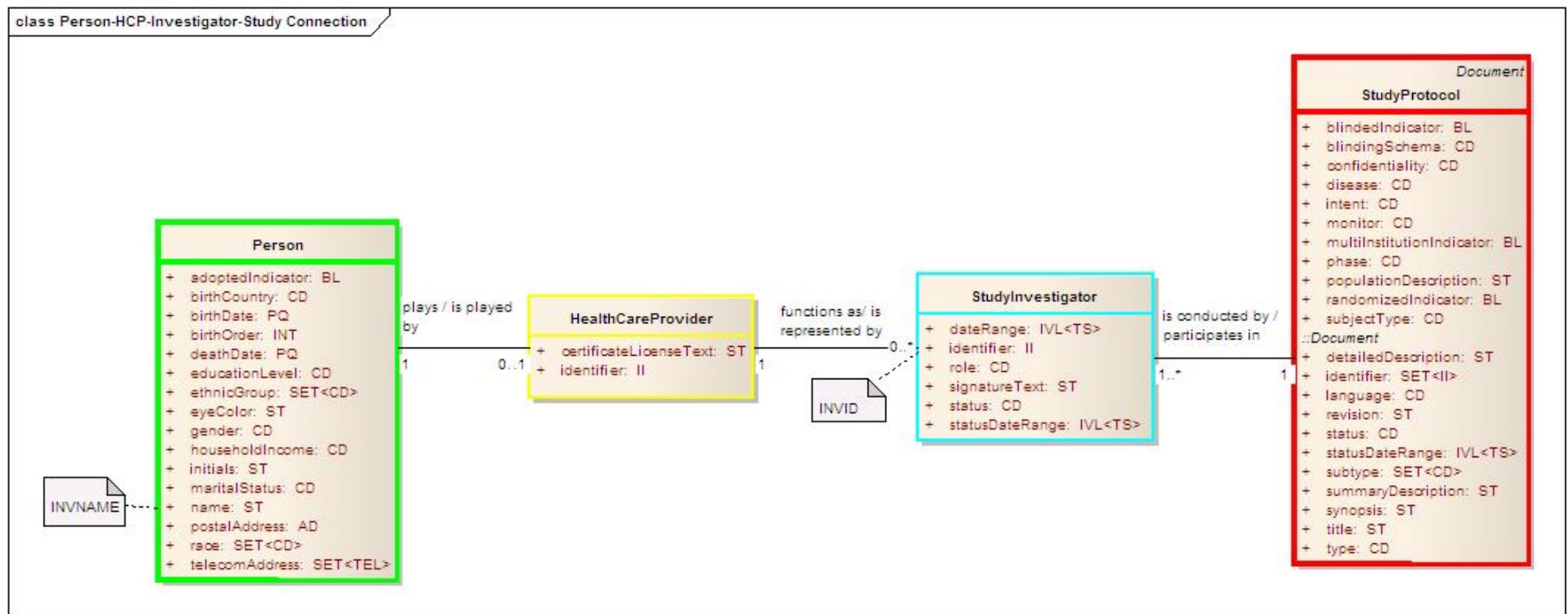


Mapping SDTM DM to BRIDG Demography Observation

- Investigator name
- Country
- Demography data
- Identifiers
- Arm
- Demography dates
- SDTM Demography variables not mapped

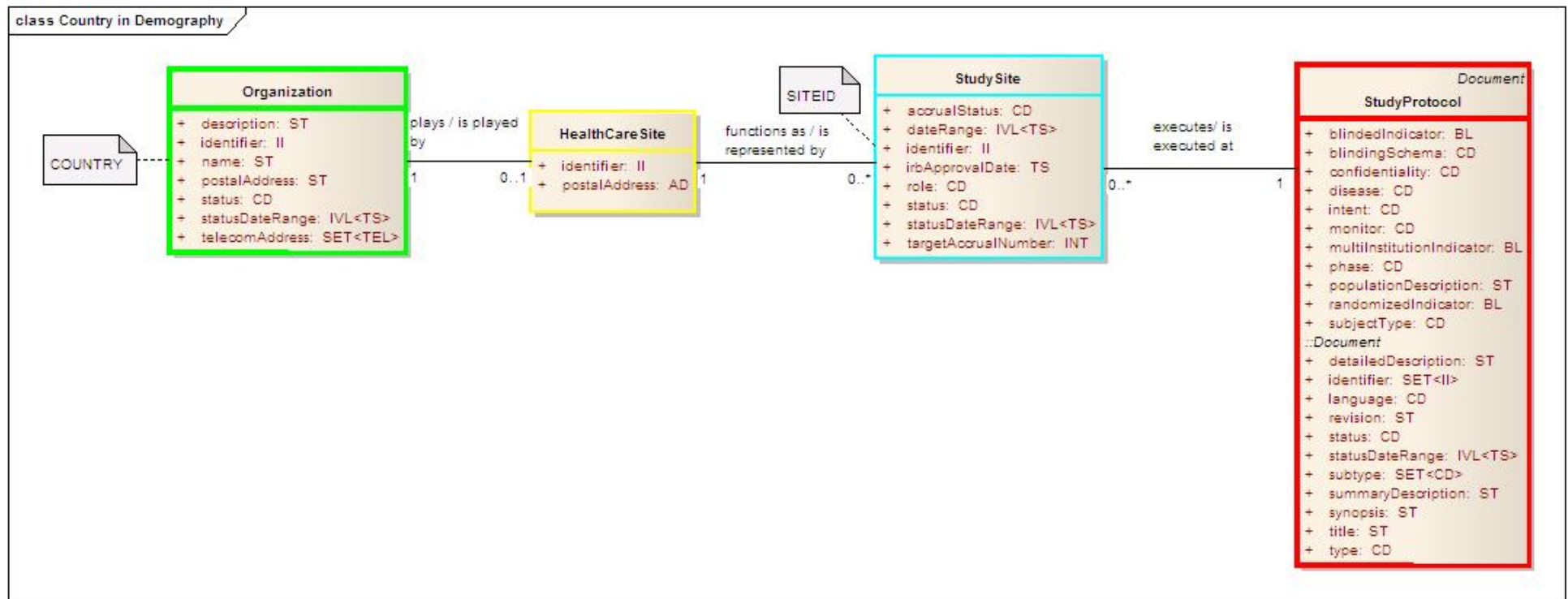
Mapping SDTM DM to BRIDG Investigator Name

- Name is a property of the Person playing the role of Health Care Provider participating as Study Investigator in the study



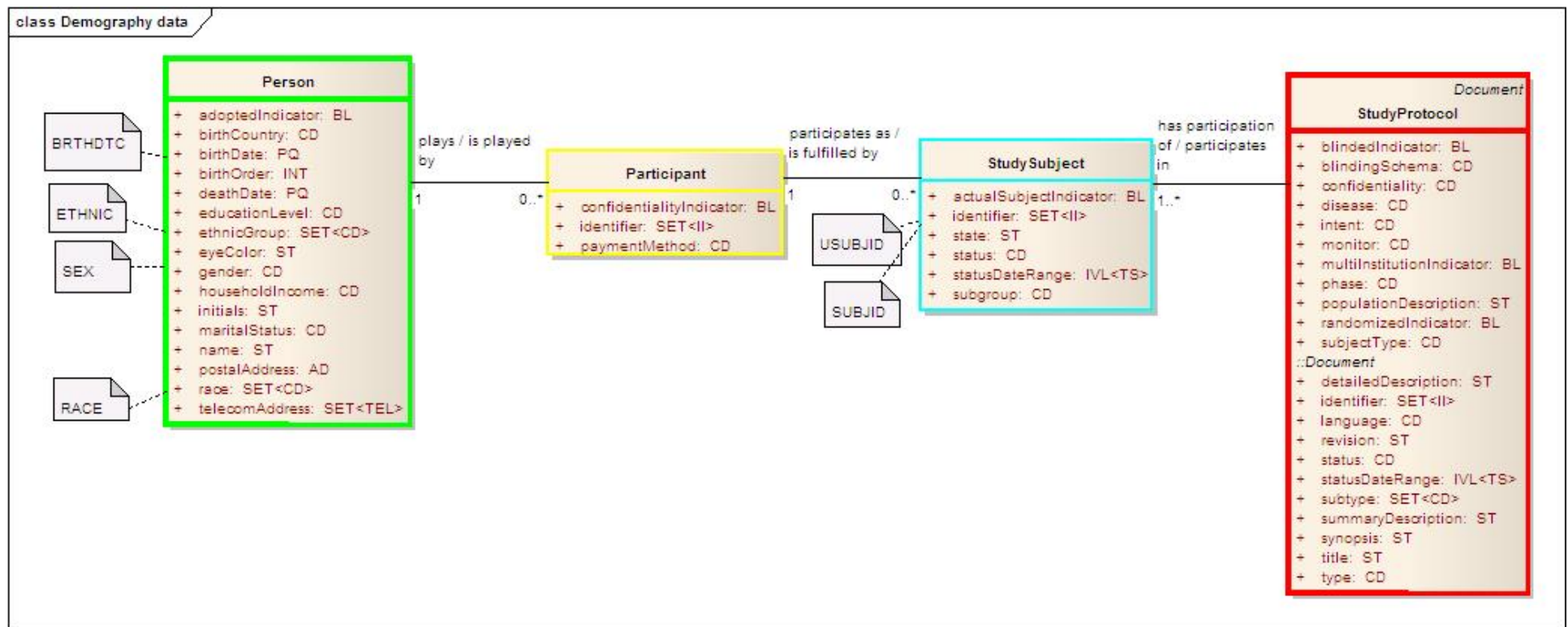
Mapping SDTM DM to BRIDG Country

- Country is a property of the Organization playing the role of Health Care Site participating as Study Site



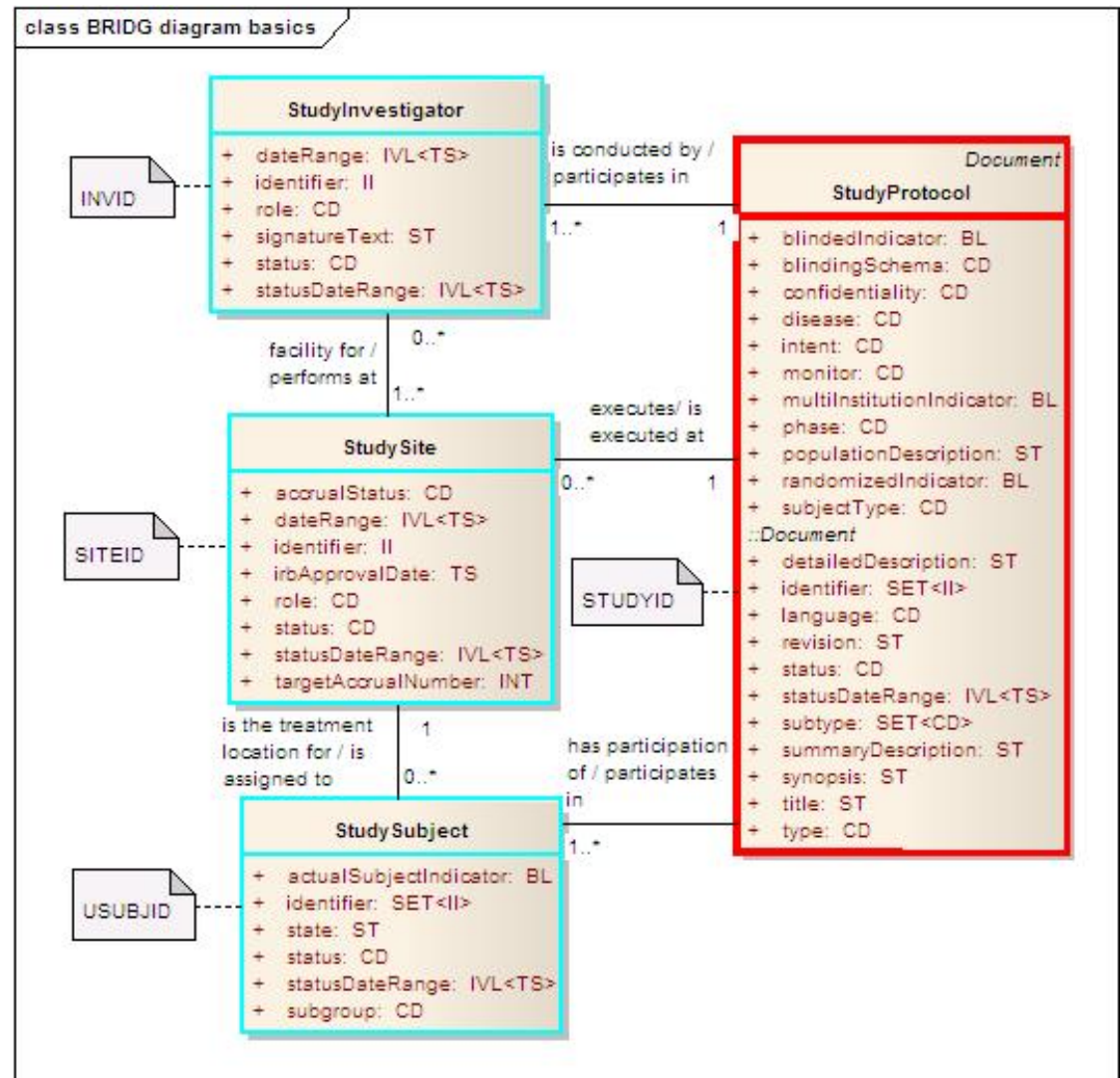
Mapping SDTM DM to BRIDG Demography data

- Birth date, sex, race, and ethnicity are person attributes
- SUBJID and USUBJID go with participation in the study



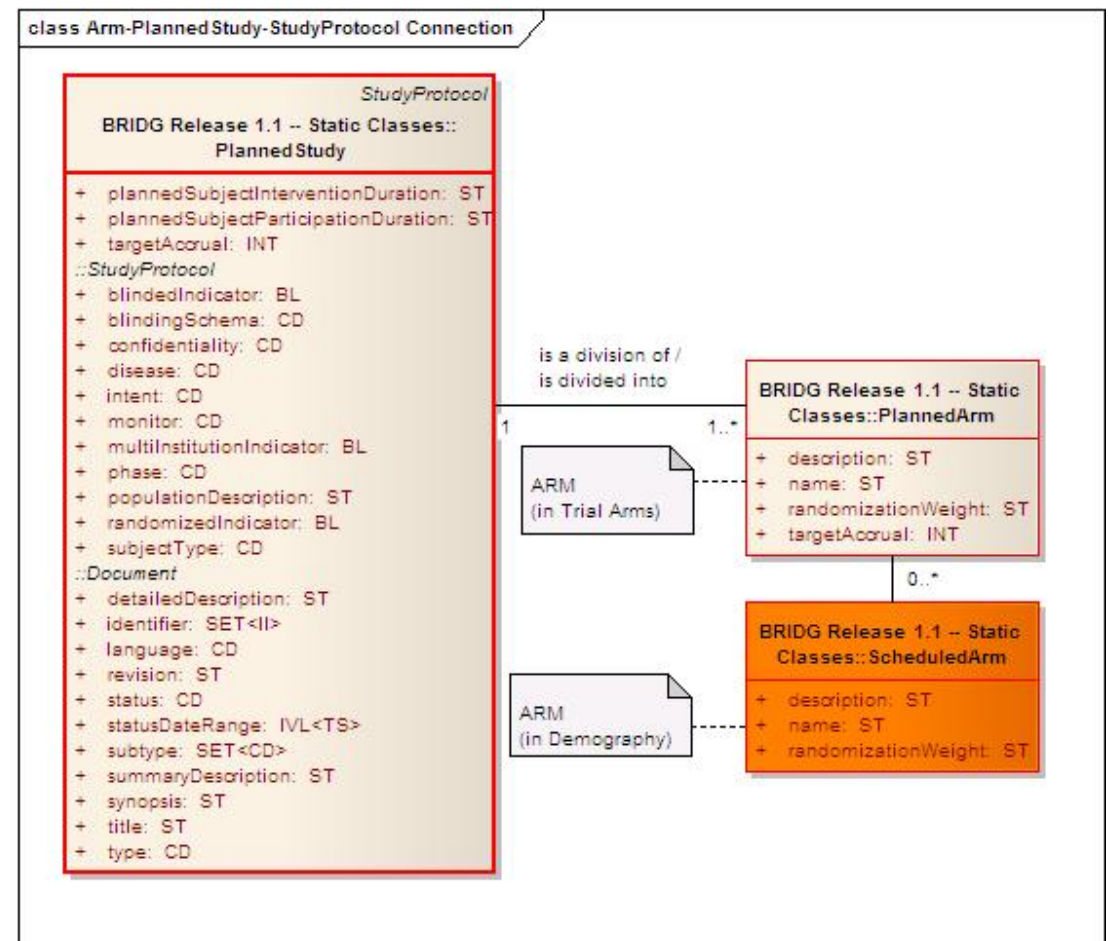
Mapping SDTM DM to BRIDG Identifiers

- Study has an ID
- Site, Investigator, Subject all have IDs
- Note these are attributes of the time-bounded participations, not the underlying persons or organizations



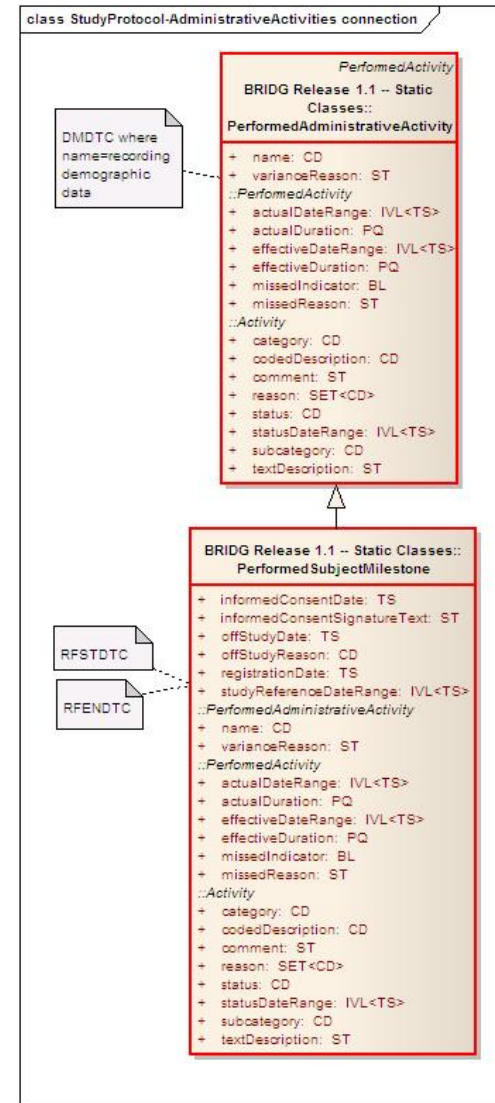
Mapping SDTM DM to BRIDG Arm

- Planned Study is divided into Planned Arms
- The ARM in the SDTM Trial Arms domain is Planned Arm
- The ARM in the SDTM Demography domain is the one to which a particular subject is assigned, Scheduled Arm
- Classes shown in orange were draft in BRIDG 1.1



Mapping SDTM DM to BRIDG Dates in Demography

- Recording demography data in a CRF is a study Administrative Activity, i.e., an activity undertaken as part of the study, not as part of regular health care
- DMDTC maps to actual date of the Performed Administrative Activity of recording demography data
- Protocol Milestones are Performed Administrative Activities; the start and end of the study reference periods are Protocol Milestones, so RFSTDTC and RFENDTC map to dates here.



Mapping SDTM DM to BRIDG

Demography Variables not mapped

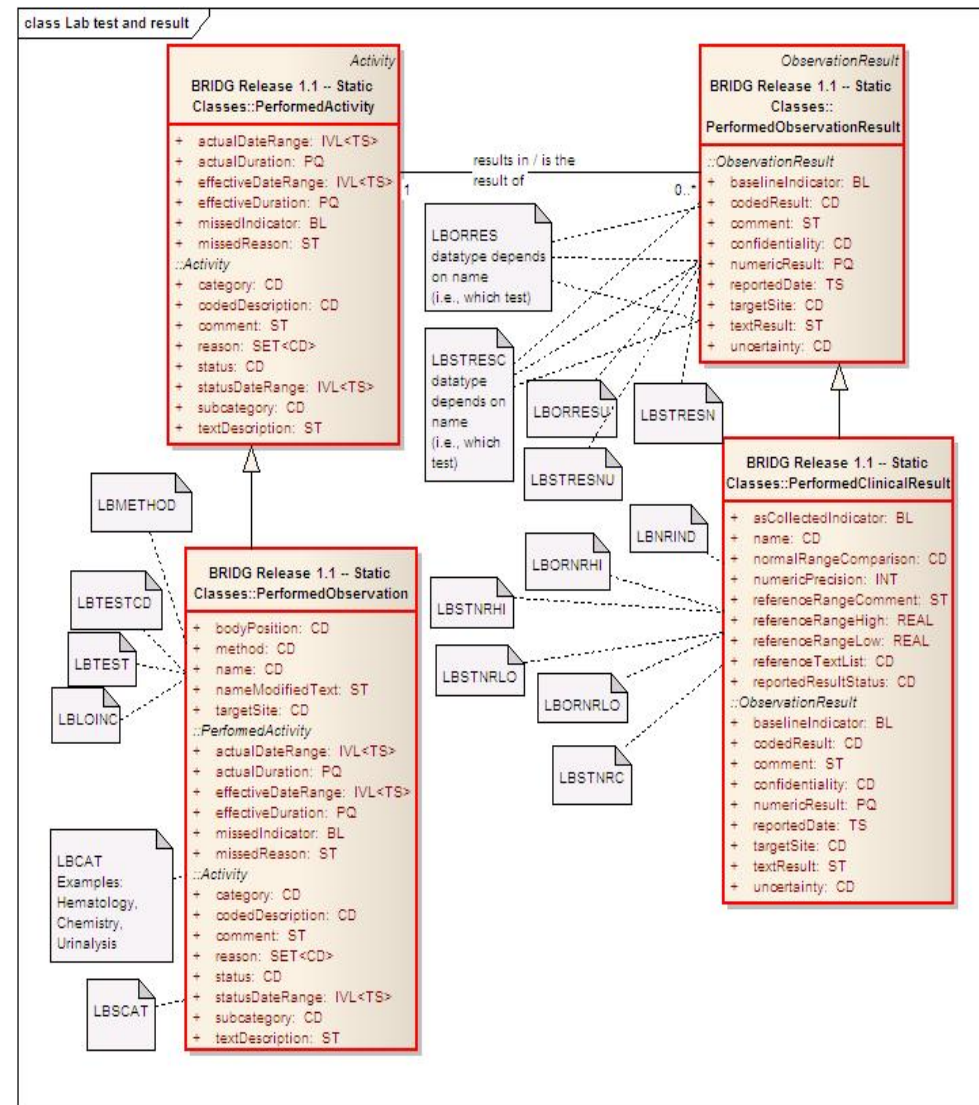
- DOMAIN is not mapped, since the SDTM division of data into datasets is **implementation specific**, not inherent in clinical research
- DMDY is not mapped, since it is **derived**
- AGE and AGEU are not mapped, since they are **derived**.
 - Birth date is the unchanging person attribute
 - “Derived” in this context doesn’t depend on whether the sponsor collects age on a CRF or derives it in house

Lab Mapping

- Identifiers (Study & Subject) as for Demography
- Findings basics: test and result
- Specimen collection
- Laboratory
- Timing (Visit, Timepoint)
- Observations not done

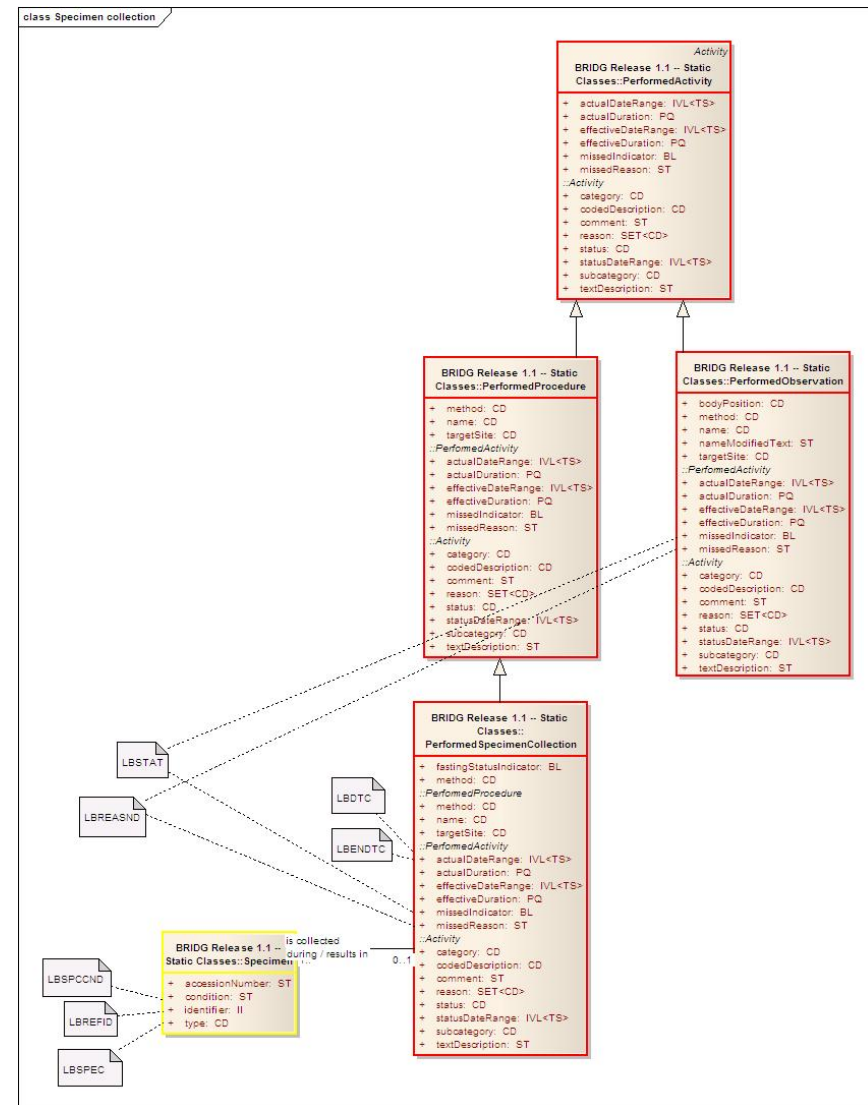
Mapping SDTM LB to BRIDG Test and Result

- Test variables map to attributes of Performed Observation
- Performed Observations results in Performed Observation Results
- Several data types (e.g., text, coded, numeric) for results, in both BRIDG and SDTM
- Normal Range variables map to attributes of Performed Clinical Results



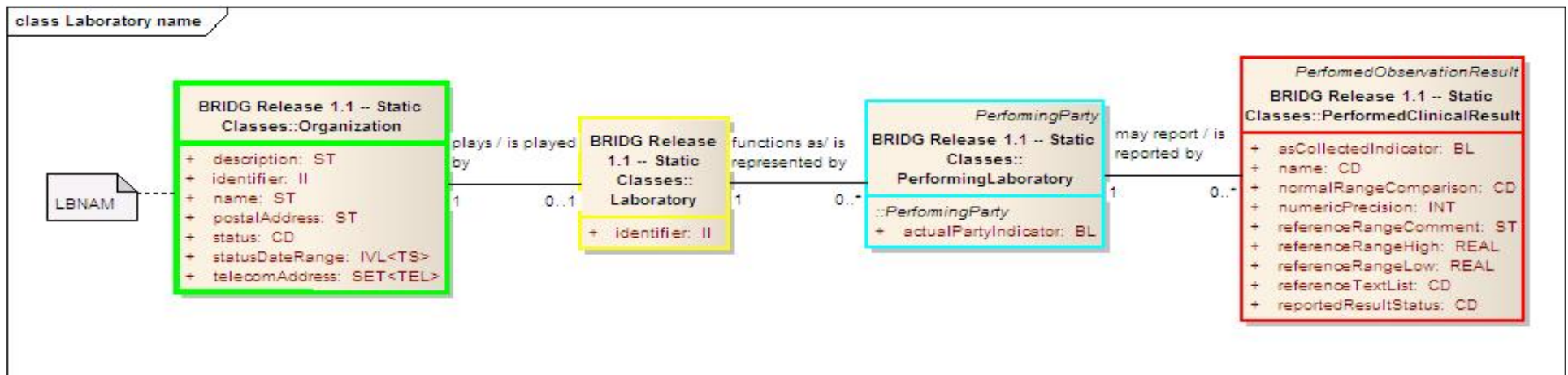
Mapping SDTM LB to BRIDG Specimen Collection

- Specimen collection is a kind of Procedure, rather than a kind of Observation
- LBDTC is the actual date of specimen collection (rather than, e.g., assay date)
- Specimen is a Role class; specimen type, condition and identifier are attributes of Specimen



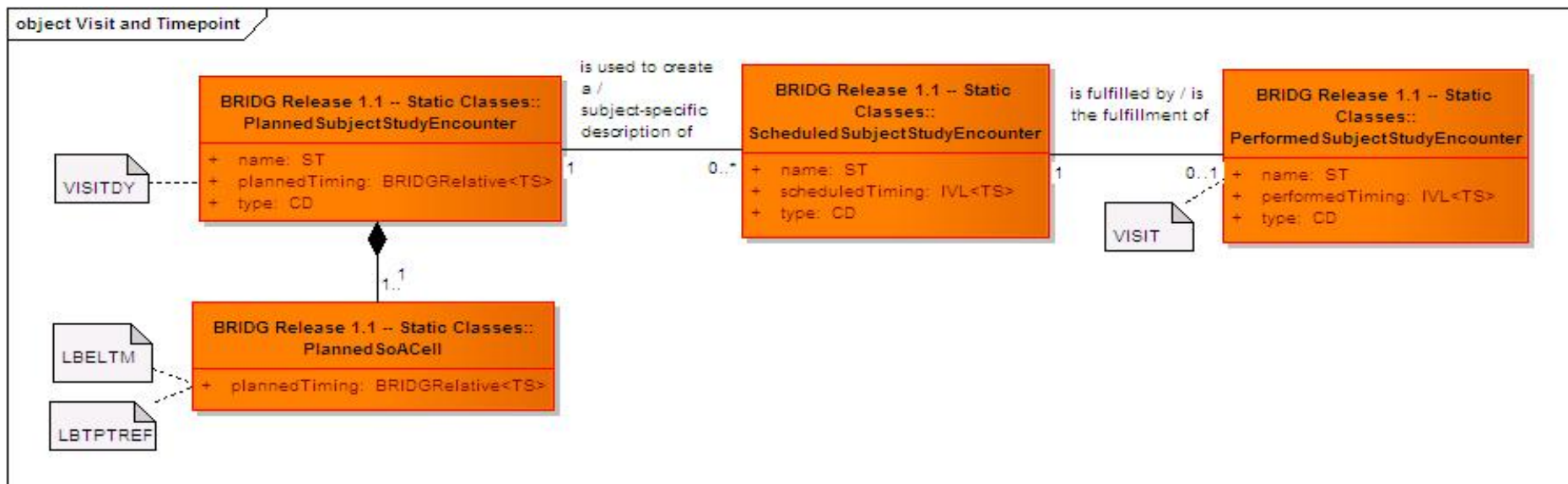
Mapping SDTM LB to BRIDG Laboratory

- Laboratory name is the name of the Organization reporting the Performed Clinical Result



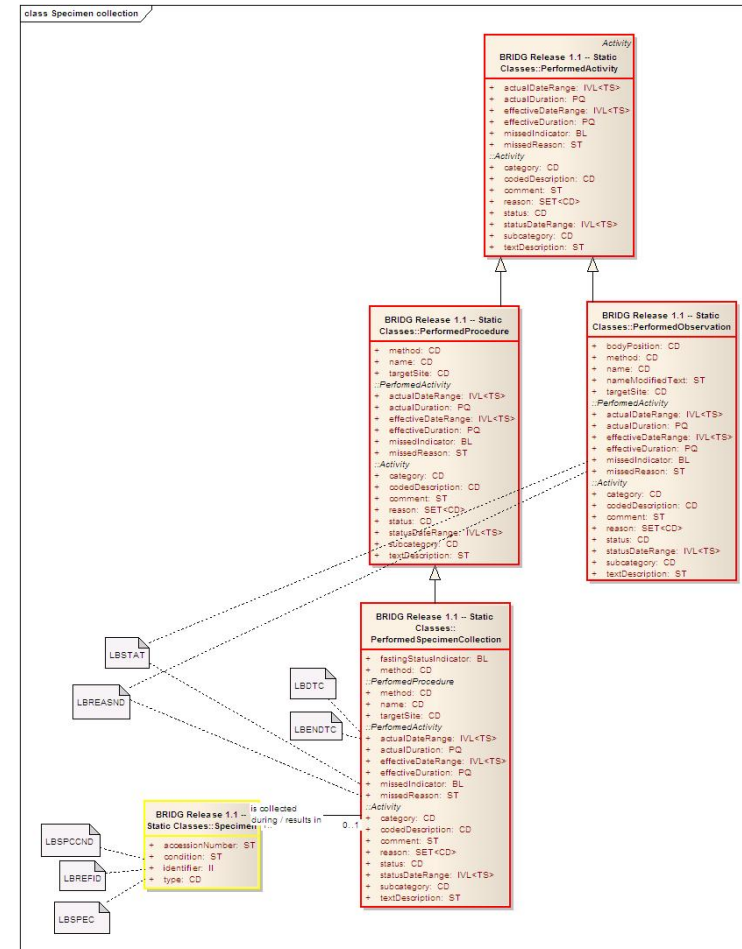
Mapping SDTM LB to BRIDG Visit, Timepoint

- BRIDG Subject Study Encounter generalizes the SDTM concept of Visit
- Since VISITDY is the planned day of a visit, it maps to the planned timing in Planned Subject Study Encounter
- VISIT may be populated even for visits that weren't planned, so has been mapped to Performed Subject Study Encounter
- BRIDG Schedule of Activity Cell (SoACell) is used to indicate that a particular activity is to be performed at a particular Subject Study Encounter (visit).
- The planned timing with a Schedule of Activity Cell is used for a planned timepoint. Planned Elapsed Time and Reference Timepoint are part of that planned timing.



Mapping SDTM LB to BRIDG Observations not Done

- LBSTAT and LBREASND map to Performed Specimen Collection or to Performed Observation, depending on how a result came to be missing
- If no sample was taken, the mapping is to Performed Specimen Collection
- If a sample was taken, but no result was obtained, the mapping is to Performed Observation



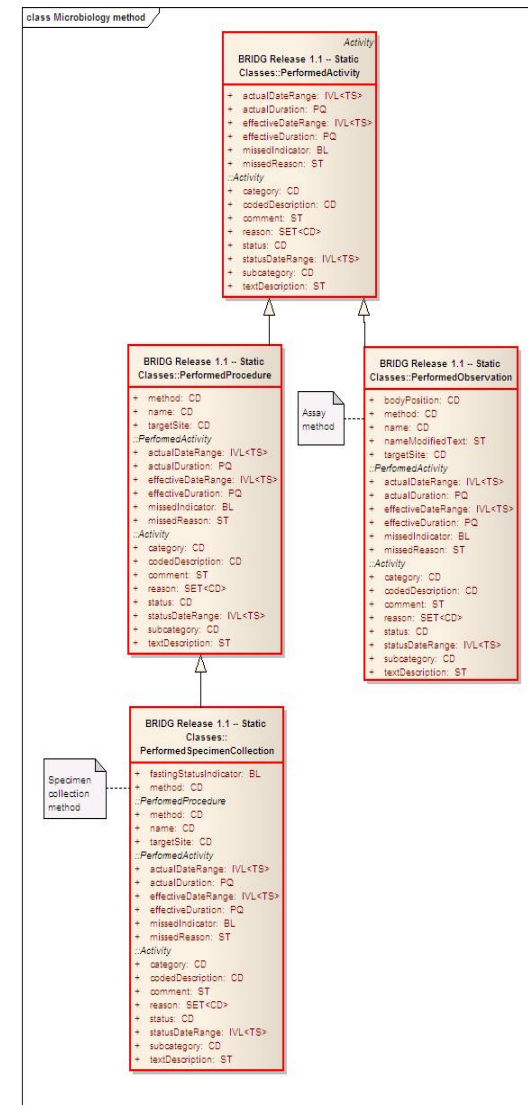
What good is the mapping?

- SDTM is based on a fairly simple implicit data model. Those trying to map data into SDTM often approach this as a matter of deciding which “box” to put data into.
- BRIDG provides a richer, better-described model, so “which box” decisions are easier.
- BRIDG modeling can also help to show when SDTM doesn’t have an appropriate “box” and needs to be extended.

Microbiology Method

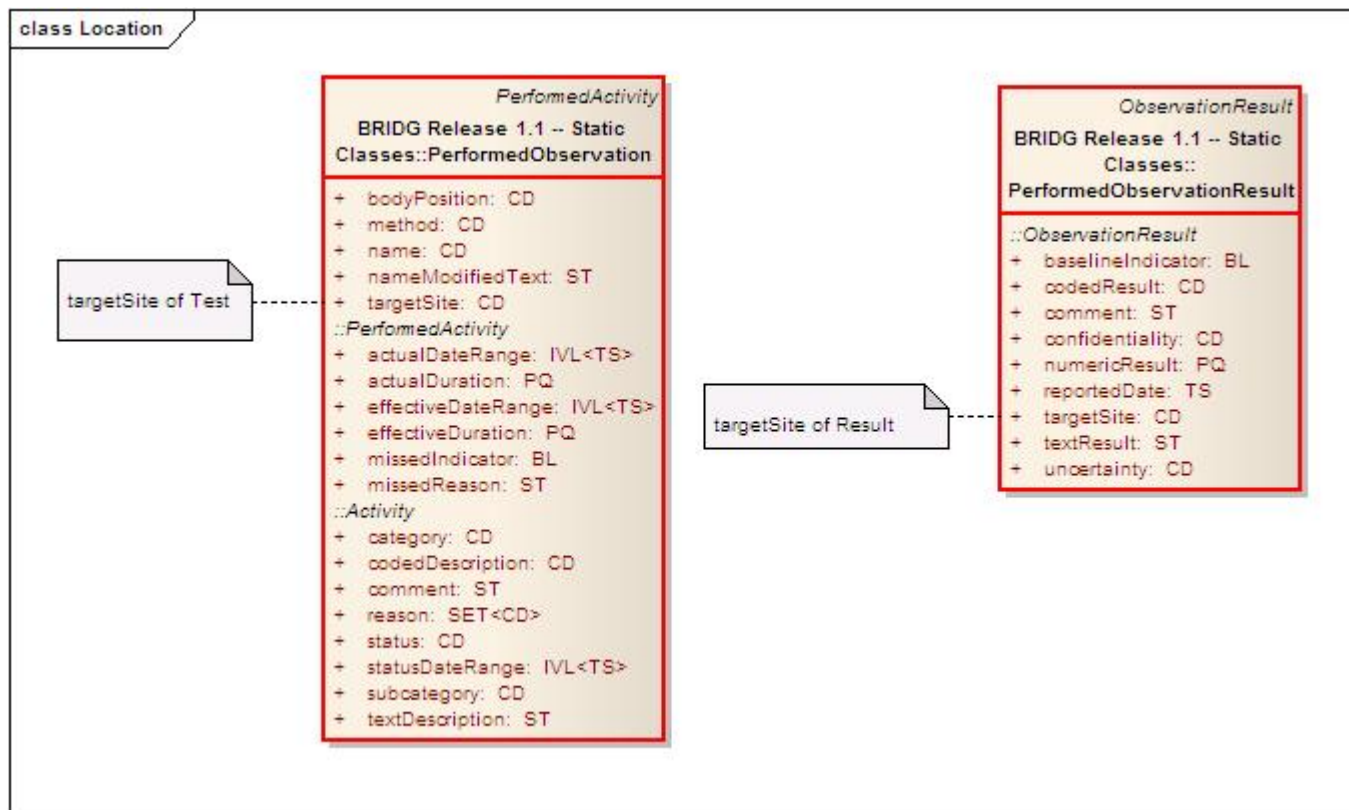
Identifying an Issue

- “Method” could refer to either method of the test (assay) or method of specimen collection
- After the issue was identified, the SDS team decided it should be the method of the assay
- This issue was identified without reference to BRIDG, but the model diagrams make the issue very clear.



Location, Test or Result?

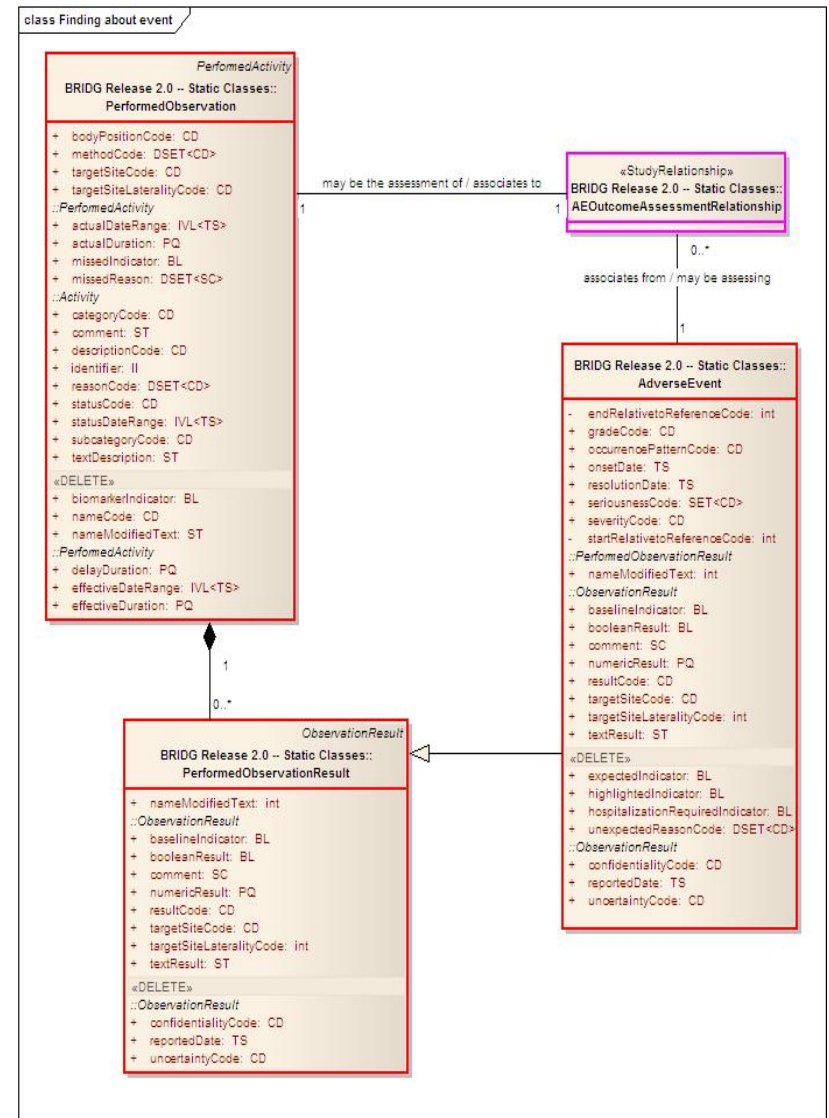
- Both Observation and Observation Result have attributes of “targetSite”
- At first the review thought this might be redundancy, but then we decided there were real differences.
- The targetSite present in both Planned and Performed Observation is part of the test – the location where the test is to be or was performed.
- The targetSite in Observation Result describes where the result was seen
- VSLOC maps to Observation (for example, location where temperature was taken)
- AELOC maps to Observation Result (for example, site where rash was seen)



Findings about Events

Example from AE Harmonization

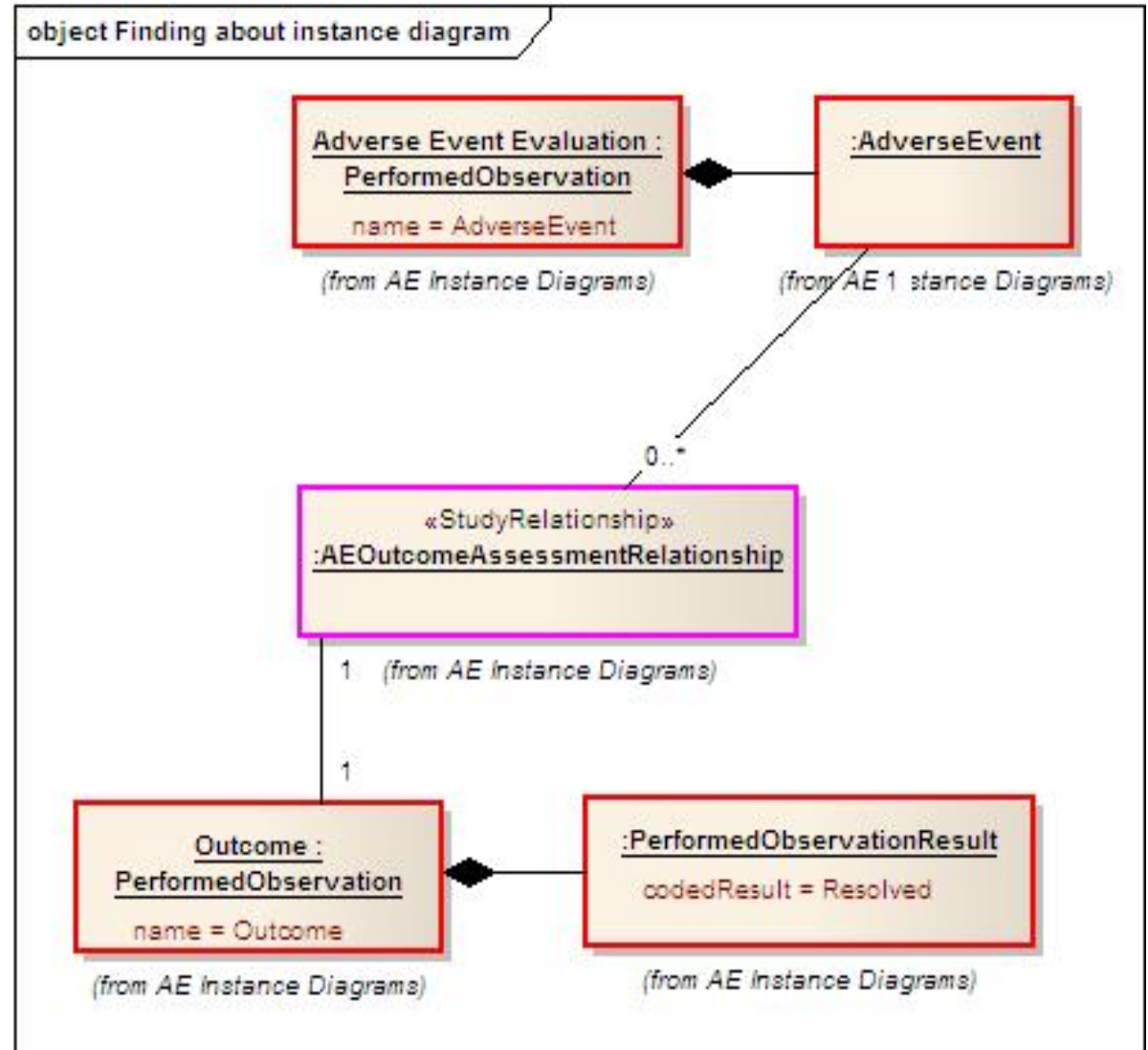
- AE Harmonization with BRIDG was done for Release 2.0, after the SDTM mapping review
- AEOU (Outcome Assessment) illustrates how findings about events appear in the model
- An AE is an Observation Result
- The assessment of an AE's outcome is another Observation, which has an Observation Result
- The pink-bordered class is the relationship between the outcome assessment result and the AE.
- A “finding about an event” consists of an event (AE in this case), a finding (observation and observation result), and the relationship between the event and the finding.



Findings about Events

Instance Diagram

- The parts of a “finding about an event” are clearer in an “Instance Diagram”
- In the class diagram in the last slide, the class PerformedObservation was used for both the AE and the Outcome of the AE
- An instance diagram has a rectangle for each instance of a class, so this diagram has two instances of Performed Observation and two instances of Performed Observation Result



Conclusion

- My intention in this talk was to help de-mystify BRIDG.
 - Some basic instruction in UML
 - For those familiar with SDTM, concrete examples of mappings from SDTM to BRIDG
 - Examples to show how modeling can clarify understanding of issues
- Creating models such as BRIDG is hard work
- Reading UML diagrams is similar to reading flowcharts, and not much more difficult to learn