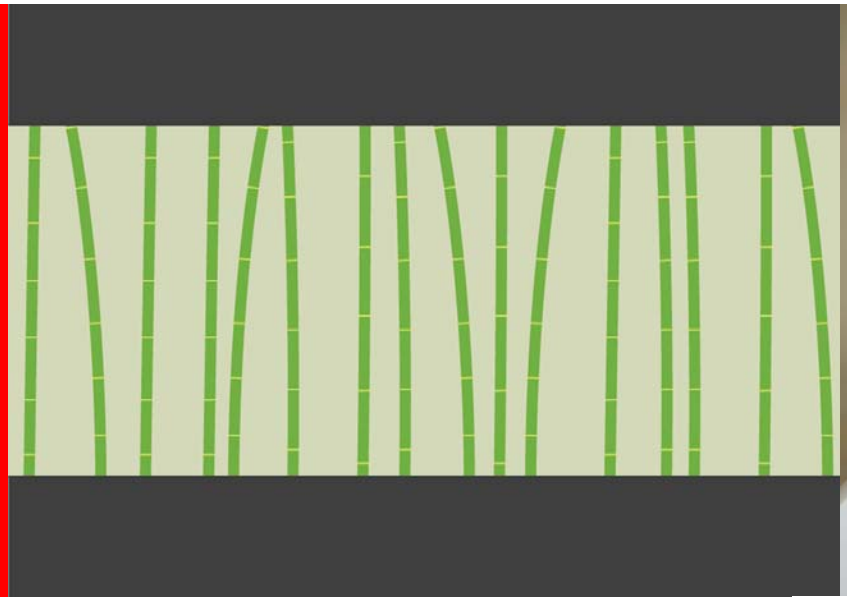

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Combining EHR (Care Record) and BRIDG models in a genomics clinical research setting

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- Principle Investigator
  - John Quackenbush, PhD
    - professor of biostatistics and computational biology
- Research Institution
  - Dana Farber Cancer Institute, Boston
- Partner Vendor
  - InforSence
    - Clinical research analytics dashboards

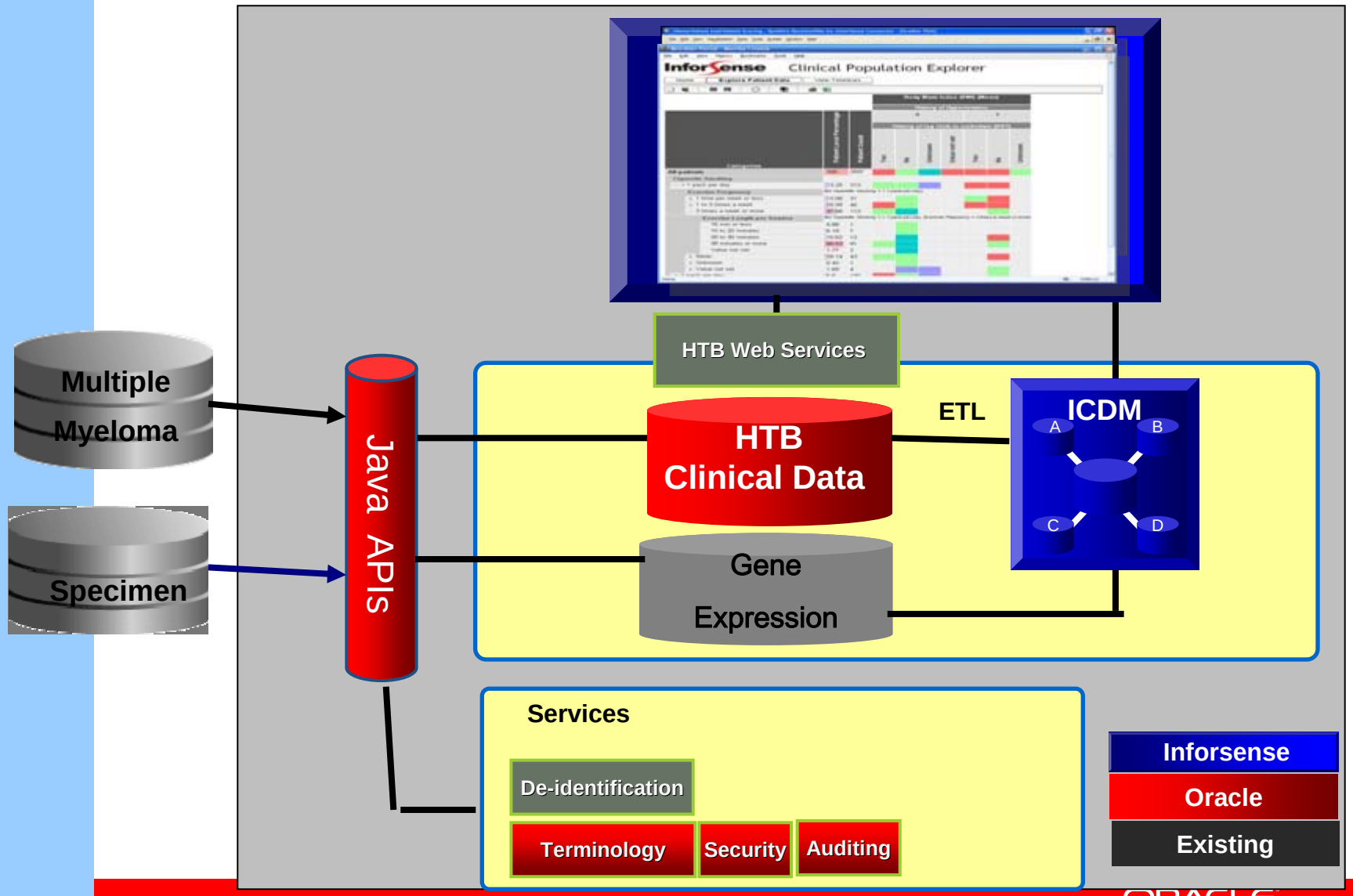
Dana Farber Cancer Institute-- researcher problem statement

- Do we have enough specimen on patients with this <phenotypic profile> to consider this <research topic> investigation?
  - Specimen information on location and amounts and some results held in patient care specimen tracking system (tracked and stored by patient identifier and specimen identifier)
  - Phenotypic information held in multiple myeloma patient visit research database that supported pre and post treatment data and related specimen collections (tracked by study protocol and study subject identifiers)
  - Genotypic (micro array) results data in third database
  - Two databases protected by two separate organizations for privacy and security
    - >>>*many forms to fill out and months waiting time to research answer to question*

- Desired Researcher Functions to be Supported
  - Ability to query for availability of tissues matching study requirements
    - Correct tissue-donor phenotypic (high-level) characteristics
    - Correct tissue types and tissue volumes
    - Drill-back to additional phenotypic data for additional detailed information
    - Associated tissue locations for tissue retrieval
  - Access security policies applied for both access from within Dana Farber (for multiple roles) and access over the Internet for selected roles and individuals

Dana Farber *Bedside* Phenotypes *to* Genetic *Bench*

– Phase 1 - Multiple Myeloma



Dana Farber Clinical Systems

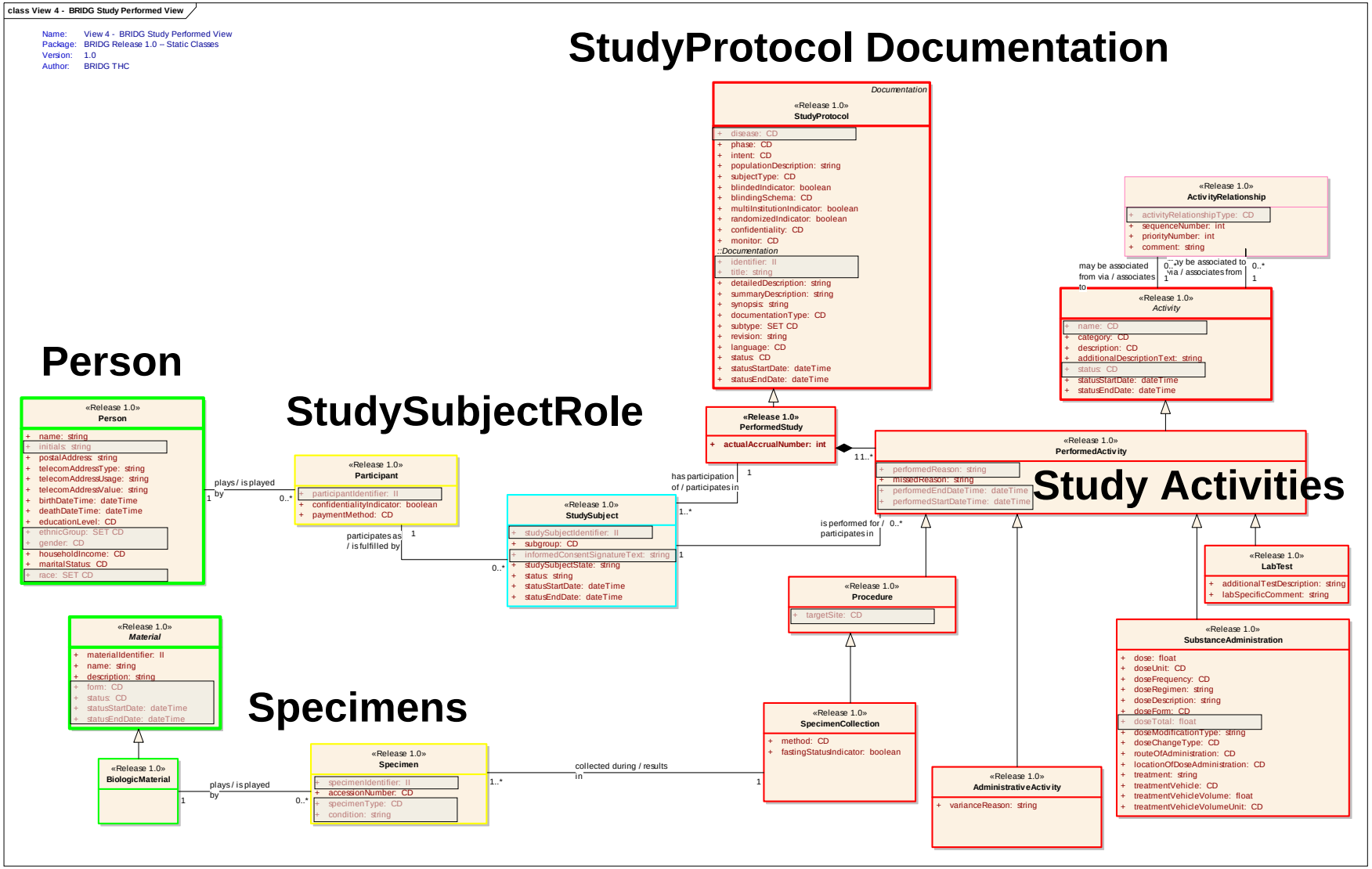
EHR and Research Data Concepts

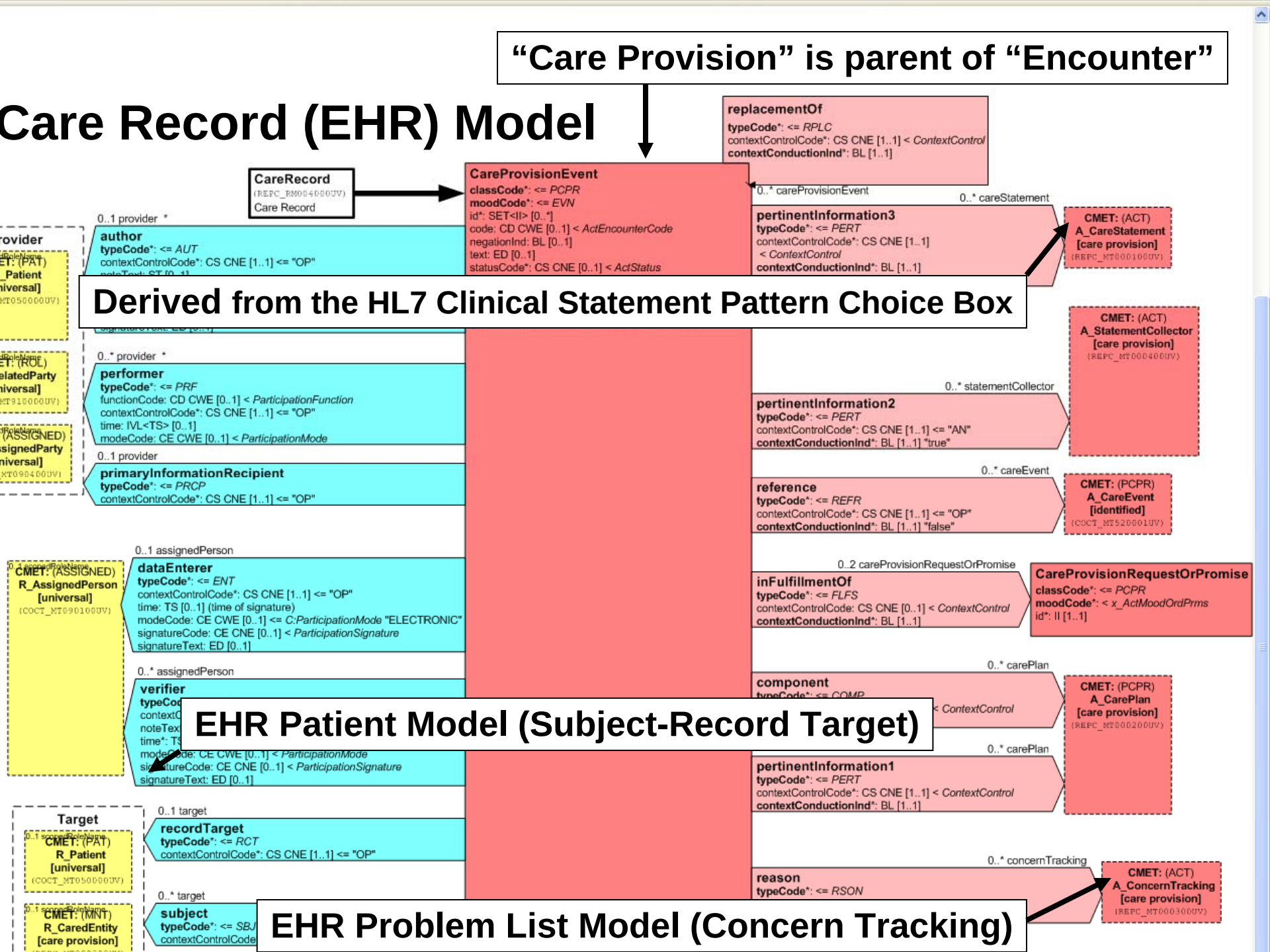
Key relationships discovered in the Dana Farber research data

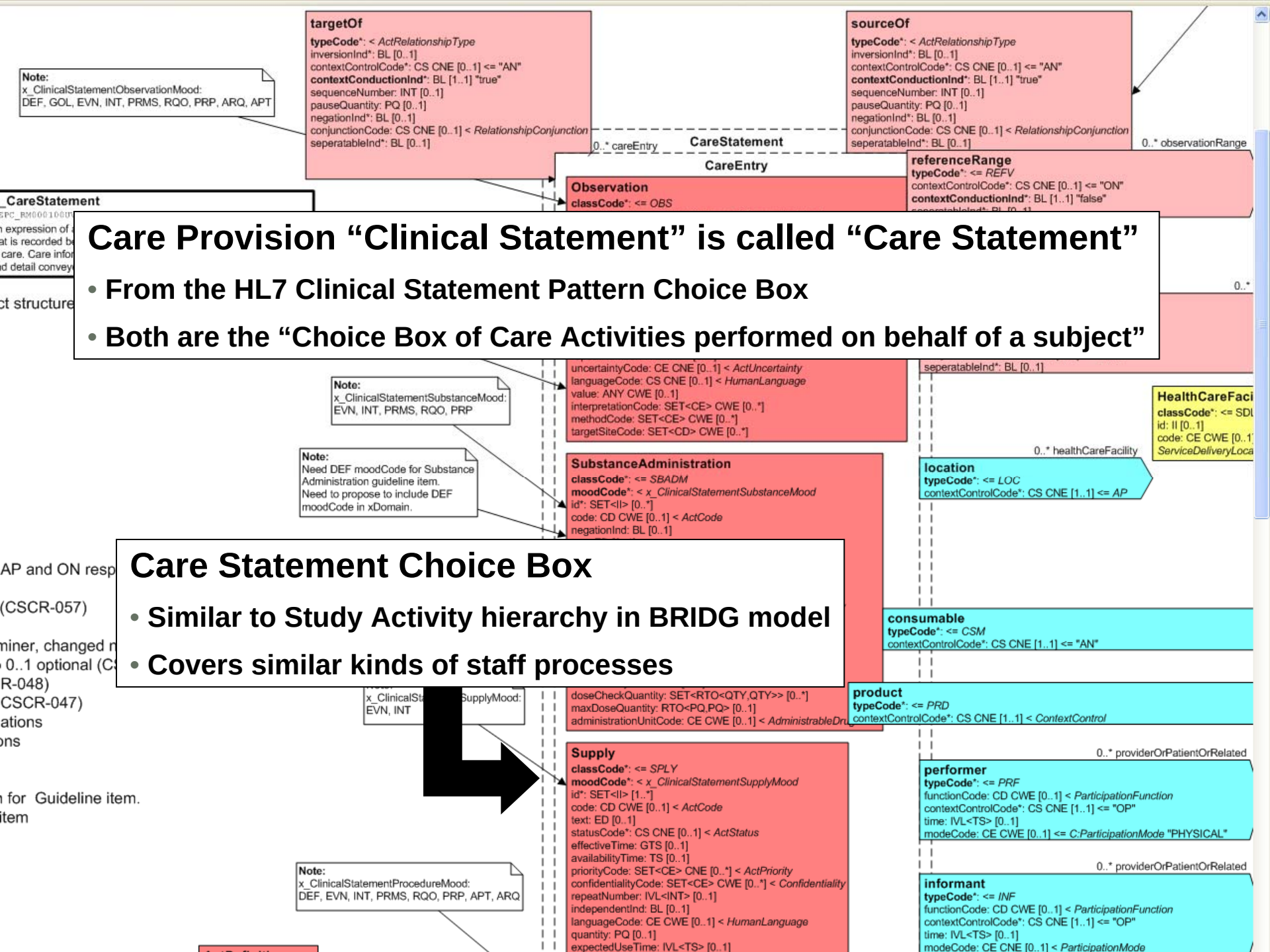
- A “patient identifier” in the Dana Farber Cancer Institute could relate to zero-to-many “study subject identifiers” for the various study protocols
- Much of the phenotypic data in the “multiple myeloma” research database was typical of information found in a patient care (EHR) database, e.g. many of the lab tests, medication lists, and other kinds of traditional EHR data were found in the “research” database.
- Additional phenotypic data was stored in a patient care specimen tracking database along with specimen information

- These findings caused Oracle to merge two HL7 models in the storage configuration of HTB in order to support the Dana Farber project
  - The joint *HL7-CDISC “BRIDG”* model, which focuses on study subjects and study protocols and which is one model consistent with the HL7 Reference Information Model (RIM)
  - The *HL7 “Care Record”* model, which focuses on patients and EHR data and is a model directly derived from the RIM

BRIDG—Performed View

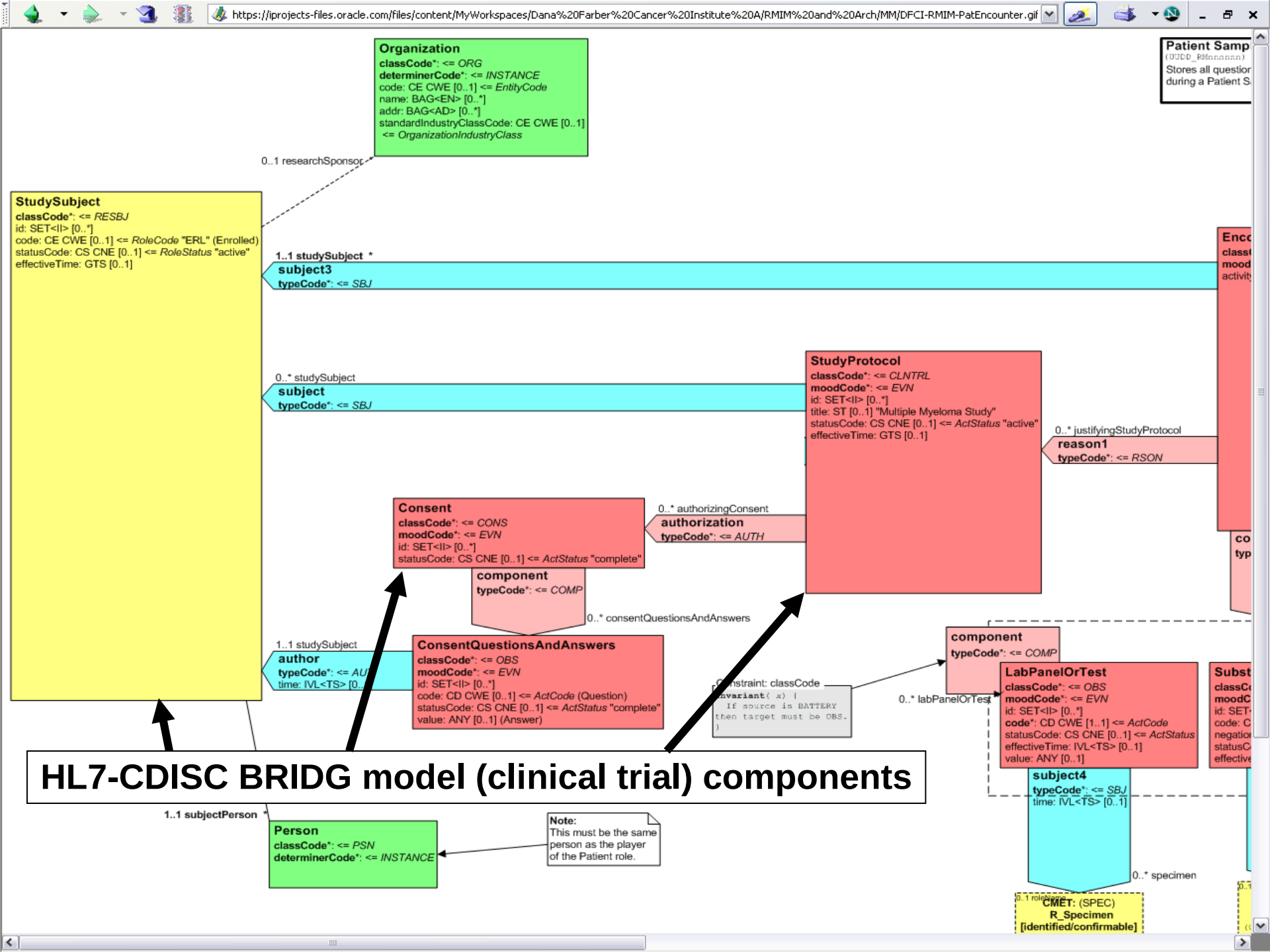


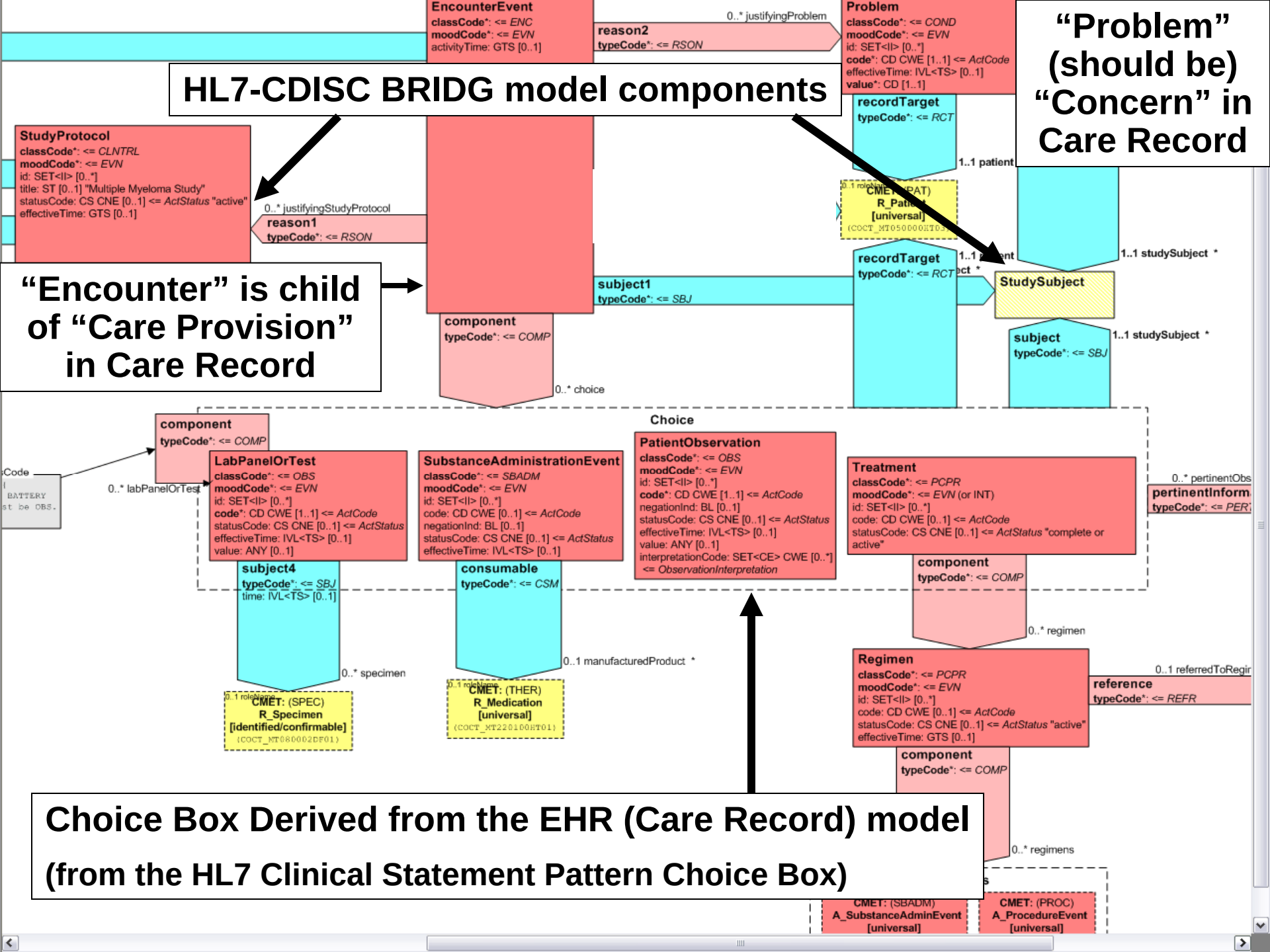

"Care Provision" is parent of "Encounter"
Care Record (EHR) Model
CareRecord
(REPC_RM004000UV)
Care Record
CareProvisionEvent
classCode*: <= PCPR
moodCode*: <= EVN
id*: SET<II> [0..*]
code: CD CWE [0..1] < ActEncounterCode
negationInd: BL [0..1]
text: ED [0..1]
statusCode*: CS CNE [0..1] < ActStatus
replacementOf
typeCode*: <= RPLC
contextControlCode*: CS CNE [1..1] < ContextControl
contextConductionInd*: BL [1..1]
0..* careProvisionEvent
0..* careStatement
pertinentInformation3
typeCode*: <= PERT
contextControlCode*: CS CNE [1..1]
< ContextControl
contextConductionInd*: BL [1..1]
CMET: (ACT)
A_CareStatement
[care provision]
(REPC_MT000100UV)
Derived from the HL7 Clinical Statement Pattern Choice Box
0..1 provider *
author
typeCode*: <= AUT
contextControlCode*: CS CNE [1..1] <= "OP"
CMET: (ACT)
A_StatementCollector
[care provision]
(REPC_MT000400UV)
0..* provider *
performer
typeCode*: <= PRF
functionCode: CD CWE [0..1] < ParticipationFunction
contextControlCode*: CS CNE [1..1] <= "OP"
time: IVL<TS> [0..1]
modeCode: CE CWE [0..1] < ParticipationMode
0..* statementCollector
pertinentInformation2
typeCode*: <= PERT
contextControlCode*: CS CNE [1..1] <= "AN"
contextConductionInd*: BL [1..1] "true"
0..1 provider
primaryInformationRecipient
typeCode*: <= PRCP
contextControlCode*: CS CNE [1..1] <= "OP"
0..* careEvent
reference
typeCode*: <= REFR
contextControlCode*: CS CNE [1..1] <= "OP"
contextConductionInd*: BL [1..1] "false"
CMET: (PCPR)
A_CareEvent
[identified]
(COCT_MT520001UV)
0..1 assignedPerson
dataEnterer
typeCode*: <= ENT
contextControlCode*: CS CNE [1..1] <= "OP"
time: TS [0..1] (time of signature)
modeCode: CE CWE [0..1] <= C:ParticipationMode "ELECTRONIC"
signatureCode: CE CNE [0..1] < ParticipationSignature
signatureText: ED [0..1]
0..2 careProvisionRequestOrPromise
inFulfillmentOf
typeCode*: <= FLFS
contextControlCode: CS CNE [0..1] < ContextControl
contextConductionInd*: BL [1..1]
CareProvisionRequestOrPromise
classCode*: <= PCPR
moodCode*: < x_ActMoodOrdPrms
id*: II [1..1]
CMET: (ASSIGNED)
R_AssignedPerson
[universal]
(COCT_MT090100UV)
0..* assignedPerson
verifier
typeCode*: <= VRF
contextControlCode*: CS CNE [1..1] <= "OP"
noteText: ED [0..1]
time*: TS [1..1] (time of signature)
modeCode: CE CWE [0..1] < ParticipationMode
signatureCode: CE CNE [0..1] < ParticipationSignature
signatureText: ED [0..1]
0..* carePlan
component
typeCode*: <= COMP
< ContextControl
CMET: (PCPR)
A_CarePlan
[care provision]
(REPC_MT000200UV)
EHR Patient Model (Subject-Record Target)
0..* carePlan
pertinentInformation1
typeCode*: <= PERT
contextControlCode*: CS CNE [1..1] < ContextControl
contextConductionInd*: BL [1..1]
Target
0..1 target
recordTarget
typeCode*: <= RCT
contextControlCode*: CS CNE [1..1] <= "OP"
CMET: (PAT)
R_Patient
[universal]
(COCT_MT050000UV)
0..* concernTracking
reason
typeCode*: <= RSON
CMET: (ACT)
A_ConcernTracking
[care provision]
(REPC_MT000300UV)
CMET: (MNT)
R_CaredEntity
[care provision]
0..* target
subject
typeCode*: <= SBJ
contextControlCode
EHR Problem List Model (Concern Tracking)


targetOf
typeCode*: < ActRelationshipType
inversionInd*: BL [0..1]
contextControlCode*: CS CNE [0..1] <= "AN"
contextConductionInd*: BL [1..1] "true"
sequenceNumber: INT [0..1]
pauseQuantity: PQ [0..1]
negationInd*: BL [0..1]
conjunctionCode: CS CNE [0..1] < RelationshipConjunction
seperatableInd*: BL [0..1]
sourceOf
typeCode*: < ActRelationshipType
inversionInd*: BL [0..1]
contextControlCode*: CS CNE [0..1] <= "AN"
contextConductionInd*: BL [1..1] "true"
sequenceNumber: INT [0..1]
pauseQuantity: PQ [0..1]
negationInd*: BL [0..1]
conjunctionCode: CS CNE [0..1] < RelationshipConjunction
seperatableInd*: BL [0..1]
Note:
x_ClinicalStatementObservationMood:
DEF, GOL, EVN, INT, PRMS, RQO, PRP, ARQ, APT
0..* careEntry
CareStatement
CareEntry
Observation
classCode*: <= OBS
0..* observationRange
referenceRange
typeCode*: <= REFV
contextControlCode*: CS CNE [0..1] <= "ON"
contextConductionInd*: BL [1..1] "false"
Care Provision “Clinical Statement” is called “Care Statement”
• From the HL7 Clinical Statement Pattern Choice Box
• Both are the “Choice Box of Care Activities performed on behalf of a subject”
uncertaintyCode: CE CNE [0..1] < ActUncertainty
languageCode: CS CNE [0..1] < HumanLanguage
value: ANY CWE [0..1]
interpretationCode: SET<CE> CWE [0..*]
methodCode: SET<CE> CWE [0..*]
targetSiteCode: SET<CD> CWE [0..*]
seperatableInd*: BL [0..1]
Note:
x_ClinicalStatementSubstanceMood:
EVN, INT, PRMS, RQO, PRP
HealthCareFaci
classCode*: <= SDL
id: II [0..1]
code: CE CWE [0..1
ServiceDeliveryLoca
Note:
Need DEF moodCode for Substance
Administration guideline item.
Need to propose to include DEF
moodCode in xDomain.
0..* healthCareFacility
location
typeCode*: <= LOC
contextControlCode*: CS CNE [1..1] <= AP
SubstanceAdministration
classCode*: <= SBADM
moodCode*: < x_ClinicalStatementSubstanceMood
id*: SET<II> [0..*]
code: CD CWE [0..1] < ActCode
negationInd: BL [0..1]
Care Statement Choice Box
• Similar to Study Activity hierarchy in BRIDG model
• Covers similar kinds of staff processes
consumable
typeCode*: <= CSM
contextControlCode*: CS CNE [1..1] <= "AN"
doseCheckQuantity: SET<RTO<QTY,QTY>> [0..*]
maxDoseQuantity: RTO<PQ,PQ> [0..1]
administrationUnitCode: CE CWE [0..1] < AdministrableDru
product
typeCode*: <= PRD
contextControlCode*: CS CNE [1..1] < ContextControl
EVN, INT
Supply
classCode*: <= SPLY
moodCode*: < x_ClinicalStatementSupplyMood
id*: SET<II> [1..*]
code: CD CWE [0..1] < ActCode
text: ED [0..1]
statusCode*: CS CNE [0..1] < ActStatus
effectiveTime: GTS [0..1]
availabilityTime: TS [0..1]
priorityCode: SET<CE> CNE [0..*] < ActPriority
confidentialityCode: SET<CE> CWE [0..*] < Confidentiality
repeatNumber: IVL<INT> [0..1]
independentInd: BL [0..1]
languageCode: CE CWE [0..1] < HumanLanguage
quantity: PQ [0..1]
expectedUseTime: IVL<TS> [0..1]
0..* providerOrPatientOrRelated
performer
typeCode*: <= PRF
functionCode: CD CWE [0..1] < ParticipationFunction
contextControlCode*: CS CNE [1..1] <= "OP"
time: IVL<TS> [0..1]
modeCode: CE CWE [0..1] <= C:ParticipationMode "PHYSICAL"
0..* providerOrPatientOrRelated
informant
typeCode*: <= INF
functionCode: CD CWE [0..1] < ParticipationFunction
contextControlCode*: CS CNE [1..1] <= "OP"
time: IVL<TS> [0..1]
modeCode: CE CNE [0..1] < ParticipationMode
Note:
x_ClinicalStatementProcedureMood:
DEF, EVN, INT, PRMS, RQO, PRP, APT, ARQ

DFCI Reference Implementation Model

derived from BRIDG and Care Record models

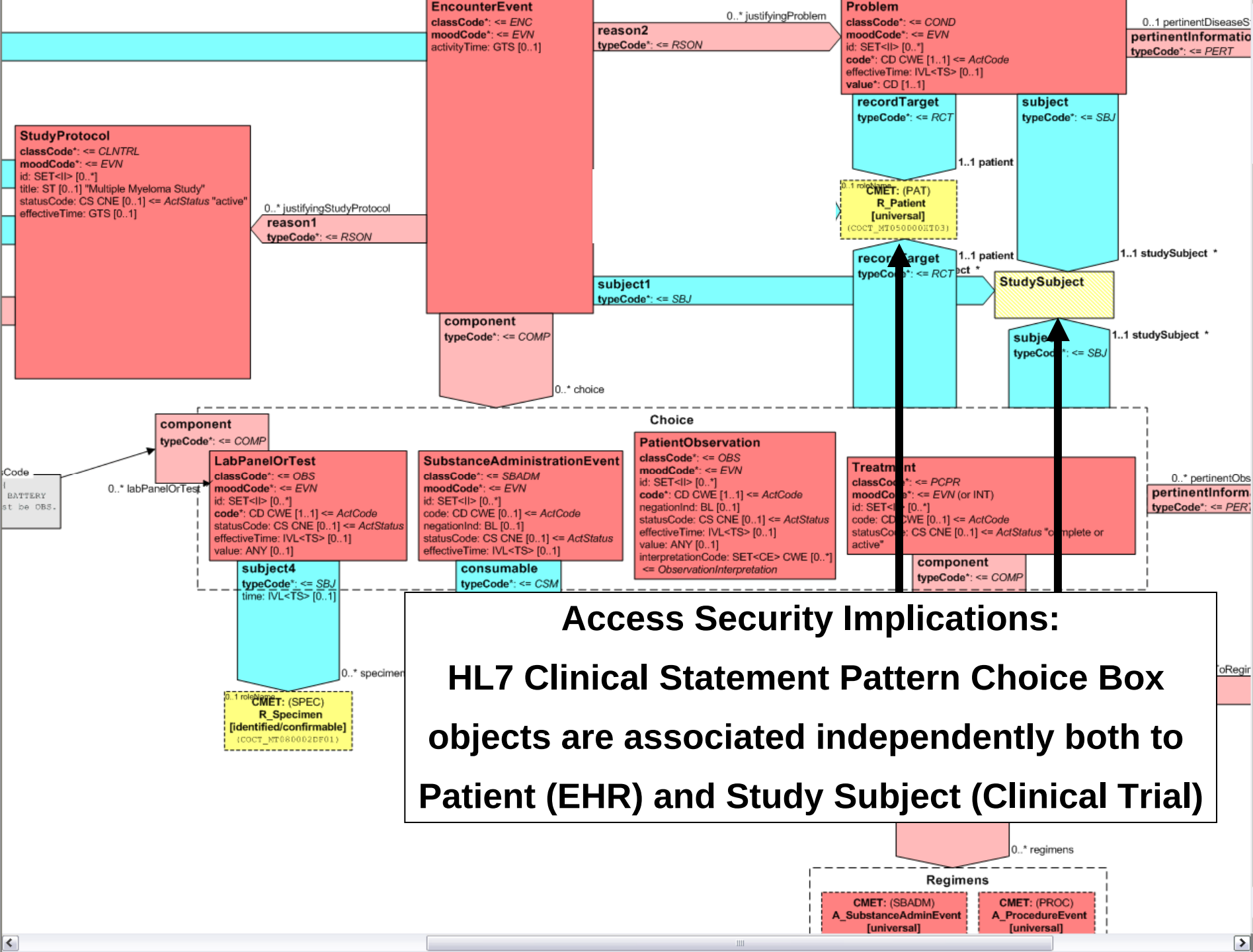

Organization
classCode*: <= ORG
determinerCode*: <= INSTANCE
code: CE CWE [0..1] <= EntityCode
name: BAG<EN> [0..*]
addr: BAG<AD> [0..*]
standardIndustryClassCode: CE CWE [0..1]
<= OrganizationIndustryClass
0..1 researchSponsor
StudySubject
classCode*: <= RESBJ
id: SET<II> [0..*]
code: CE CWE [0..1] <= RoleCode "ERL" (Enrolled)
statusCode: CS CNE [0..1] <= RoleStatus "active"
effectiveTime: GTS [0..1]
1..1 studySubject *
subject3
typeCode*: <= SBJ
0..* studySubject
subject
typeCode*: <= SBJ
StudyProtocol
classCode*: <= CLNTRL
moodCode*: <= EVN
id: SET<II> [0..*]
title: ST [0..1] "Multiple Myeloma Study"
statusCode: CS CNE [0..1] <= ActStatus "active"
effectiveTime: GTS [0..1]
0..* justifyingStudyProtocol
reason1
typeCode*: <= RSON
Consent
classCode*: <= CONS
moodCode*: <= EVN
id: SET<II> [0..*]
statusCode: CS CNE [0..1] <= ActStatus "complete"
0..* authorizingConsent
authorization
typeCode*: <= AUTH
component
typeCode*: <= COMP
0..* consentQuestionsAndAnswers
1..1 studySubject
author
typeCode*: <= AUT
time: IVL<TS> [0..
ConsentQuestionsAndAnswers
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code: CD CWE [0..1] <= ActCode (Question)
statusCode: CS CNE [0..1] <= ActStatus "complete"
value: ANY [0..1] (Answer)
Constraint: classCode
invariant(x) |
If source is BATTERY
then target must be OBS.
)
component
typeCode*: <= COMP
0..* labPanelOrTest
LabPanelOrTest
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
value: ANY [0..1]
subject4
typeCode*: <= SBJ
time: IVL<TS> [0..1]
0..* specimen
CMET: (SPEC)
R_Specimen
[identified/confirmable]
1..1 subjectPerson *
Person
classCode*: <= PSN
determinerCode*: <= INSTANCE
Note:
This must be the same person as the player of the Patient role.
Patient Samp
Stores all questior
during a Patient S
HL7-CDISC BRIDG model (clinical trial) components


HL7-CDISC BRIDG model components
"Problem" (should be) "Concern" in Care Record
"Encounter" is child of "Care Provision" in Care Record
Choice Box Derived from the EHR (Care Record) model
(from the HL7 Clinical Statement Pattern Choice Box)
EncounterEvent
classCode*: <= ENC
moodCode*: <= EVN
activityTime: GTS [0..1]
0..* justifyingProblem
reason2
typeCode*: <= RSON
Problem
classCode*: <= COND
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
effectiveTime: IVL<TS> [0..1]
value*: CD [1..1]
StudyProtocol
classCode*: <= CLNTRL
moodCode*: <= EVN
id: SET<II> [0..*]
title: ST [0..1] "Multiple Myeloma Study"
statusCode: CS CNE [0..1] <= ActStatus "active"
effectiveTime: GTS [0..1]
0..* justifyingStudyProtocol
reason1
typeCode*: <= RSON
recordTarget
typeCode*: <= RCT
1..1 patient
CMET: (PAT)
R_Patient
[universal]
(COCT_MT050000HT03)
1..1 studySubject *
StudySubject
subject1
typeCode*: <= SBJ
component
typeCode*: <= COMP
0..* choice
subject
typeCode*: <= SBJ
Choice
component
typeCode*: <= COMP
0..* labPanelOrTest
LabPanelOrTest
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
value: ANY [0..1]
SubstanceAdministrationEvent
classCode*: <= SBADM
moodCode*: <= EVN
id: SET<II> [0..*]
code: CD CWE [0..1] <= ActCode
negationInd: BL [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
PatientObservation
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
negationInd: BL [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
value: ANY [0..1]
interpretationCode: SET<CE> CWE [0..*]
<= ObservationInterpretation
Treatment
classCode*: <= PCPR
moodCode*: <= EVN (or INT)
id: SET<II> [0..*]
code: CD CWE [0..1] <= ActCode
statusCode: CS CNE [0..1] <= ActStatus "complete or active"
0..* pertinentObs
pertinentInform
typeCode*: <= PERT
subject4
typeCode*: <= SBJ
time: IVL<TS> [0..1]
consumable
typeCode*: <= CSM
component
typeCode*: <= COMP
0..* regimen
0..* specimen
0..1 manufacturedProduct *
CMET: (SPEC)
R_Specimen
[identified/confirmable]
(COCT_MT080002DF01)
CMET: (THER)
R_Medication
[universal]
(COCT_MT220100HT01)
Regimen
classCode*: <= PCPR
moodCode*: <= EVN
id: SET<II> [0..*]
code: CD CWE [0..1] <= ActCode
statusCode: CS CNE [0..1] <= ActStatus "active"
effectiveTime: GTS [0..1]
0..1 referredToRegir
reference
typeCode*: <= REFR
component
typeCode*: <= COMP
0..* regimens
CMET: (SBADM)
A_SubstanceAdminEvent
[universal]
CMET: (PROC)
A_ProcedureEvent
[universal]

Access Security and the Merged Model

- Although in this original research data sample, there was a very large overlap between data on the study subject and “EHR” data about the patient, this original sample did not allow segregation for good access security policies.
- Accordingly, for the new implementation, “Study subject data” was classified separately from “patient data” by using the “subject” participation relationship for data to the “study subject “and “record target” participation relationship for data to the “patient.”

- This classification of the data allowed the application of security rules applied to different types of clinical researchers, e.g.
  - Researchers who have access to “patient” may be configured to have access to all patient data
  - Researchers who have access to “study subject only” may be limited to “study subject data only”
  - Researchers viewing from the internet (outside DFCI) do not view any individual PHI or identifiers, i.e. limited to aggregate information


EncounterEvent
classCode*: <= ENC
moodCode*: <= EVN
activityTime: GTS [0..1]
0..* justifyingProblem
reason2
typeCode*: <= RSON
Problem
classCode*: <= COND
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
effectiveTime: IVL<TS> [0..1]
value*: CD [1..1]
0..1 pertinentDiseaseS
pertinentInformatio
typeCode*: <= PERT
recordTarget
typeCode*: <= RCT
1..1 patient
subject
typeCode*: <= SBJ
1..1 studySubject *
StudyProtocol
classCode*: <= CLNTRL
moodCode*: <= EVN
id: SET<II> [0..*]
title: ST [0..1] "Multiple Myeloma Study"
statusCode: CS CNE [0..1] <= ActStatus "active"
effectiveTime: GTS [0..1]
0..* justifyingStudyProtocol
reason1
typeCode*: <= RSON
CMET: (PAT)
R_Patient
[universal]
(COCT_MT050000HT03)
subject1
typeCode*: <= SBJ
StudySubject
component
typeCode*: <= COMP
0..* choice
Choice
component
typeCode*: <= COMP
0..* labPanelOrTest
LabPanelOrTest
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
value: ANY [0..1]
SubstanceAdministrationEvent
classCode*: <= SBADM
moodCode*: <= EVN
id: SET<II> [0..*]
code: CD CWE [0..1] <= ActCode
negationInd: BL [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
PatientObservation
classCode*: <= OBS
moodCode*: <= EVN
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ActCode
negationInd: BL [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
value: ANY [0..1]
interpretationCode: SET<CE> CWE [0..*]
<= ObservationInterpretation
component
typeCode*: <= COMP
0..* pertinentObs
pertinentInform
typeCode*: <= PERT
subject4
typeCode*: <= SBJ
time: IVL<TS> [0..1]
consumable
typeCode*: <= CSM
0..* specimen
CMET: (SPEC)
R_Specimen
[identified/confirmable]
(COCT_MT080002DF01)
Access Security Implications:
HL7 Clinical Statement Pattern Choice Box objects are associated independently both to Patient (EHR) and Study Subject (Clinical Trial)
0..* regimens
Regimens
CMET: (SBADM)
A_SubstanceAdminEvent
[universal]
CMET: (PROC)
A_ProcedureEvent
[universal]

Informatics Research Findings

- A set of functional requirements requested by researchers in a genomics clinical research setting with existing sets of research and patient care data were successfully met by integrating an HL7 clinical research model (BRIDG) and an HL7 EHR model (Care Record) into a single reference implementation model
- The single reference implementation model also supported the integration of two different vendors that, together, supported the functional requirements of the researchers
- The design of the single reference implementation model was very important to fulfilling the role-based access security requirements from DFCI
- Qualification: The modeling solution was designed to support an initial proof-of-concept informatics research project that could be utilized for immediate clinical research needs at DFCI and does not represent a definitive reference implementation model that is recommended for direct adoption by others