



The role of FHIR Resources in ensuring semantic equivalence in EHR2EDC direct data capture

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Quick Introduction to FHIR



- **F**ast **H**ealthcare **I**nteroperability **R**esources
- Standard to quickly and efficiently exchange health data created by the standards development organization Health Level 7 (HL7®).
- The core of HL7 FHIR is a set of modular components i.e., "Resources".
- Resources define the component data elements, constraints, and relationships needed to create an exchangeable patient record.



Quick Introduction to FHIR



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Resources

This page is part of the FHIR Specification (v4.0.1: R4 - Mixed Normative and STU). This is the current published version. For a full list of available versions, see the [Directory of published versions](#).

1.2 Resource Index

FHIR Infrastructure

Work Group

Maturity Level: N/A

Standards Status: Informative

This page is provided to help find resources quickly. There is also a more detailed classification, ontology, and description. For background to the layout on the layers in this page, see the [Architect's Overview](#). See also the abstract [Base Resources](#) [Resource](#) and [DomainResource](#).

Categorized

Alphabetical

R2 Layout

By Maturity

Security Category

By Standards Status

By Committee

Foundation Conformance - CapabilityStatement N - StructureDefinition N - ImplementationGuide 1 - SearchParameter 3 - MessageDefinition 1 - OperationDefinition N - CompartmentDefinition 1 - StructureMap 2 - GraphDefinition 1 - ExampleScenario 0	Terminology - CodeSystem N - ValueSet N - ConceptMap 3 - NamingSystem 1 - TerminologyCapabilities 0	Security - Provenance 3 - AuditEvent 3 - Consent 2	Documents - Composition 2 - DocumentManifest 2 - DocumentReference 3 - CatalogEntry 0	Other - Basic 1 - Binary N - Bundle N - Linkage 0 - MessageHeader 4 - OperationOutcome N - Parameters N - Subscription 3
Base Individuals - Patient N - Practitioner 3 - PractitionerRole 2 - RelatedPerson 2 - Person 2 - Group 1	Entities #1 - Organization 3 - OrganizationAffiliation 0 - HealthcareService 2 - Endpoint 2 - Location 3	Entities #2 - Substance 2 - BiologicallyDerivedProduct 0 - Device 2 - DeviceMetric 1	Workflow - Task 2 - Appointment 3 - AppointmentResponse 3 - Schedule 3 - Slot 3 - VerificationResult 0	Management - Encounter 2 - EpisodeOfCare 2 - Flag 1 - List 1 - Library 2

<http://hl7.org/fhir/resourcelist.html>

observation

medication

research subject

activity definition

plan definition

Clinical Summary - AllergyIntolerance 3 - AdverseEvent 0 - Condition (Problem) 3 - Procedure 3 - FamilyMemberHistory 2 - ClinicalImpression 0 - DetectedIssue 1	Diagnostic - Observation N - Media 1 - DiagnosticsReport 3 - Specimen 2 - BodyStructure 1 - ImagingStudy 3 - QuestionnaireResponse 3 - MolecularSequence 1	Medications - MedicationRequest 3 - MedicationAdministration 2 - MedicationDispense 2 - MedicationStatement 3 - Medication 3 - MedicationKnowledge 0 - Immunization 3 - ImmunizationEvaluation 0 - ImmunizationRecommendation 1	Care Provision - CareTeam 2 - Goal 2 - ServiceRequest 2 - NutritionOrder 2 - VisionPrescription 2 - RiskAssessment 1 - RequestGroup 2	Request & Response - Communication 2 - CommunicationRequest 2 - DeviceRequest 1 - DeviceUseStatement 0 - GuidanceResponse 2 - SupplyRequest 1 - SupplyDelivery 1
Financial Support - Coverage 2 - CoverageEligibilityRequest 2 - CoverageEligibilityResponse 2 - EnrollmentRequest 0 - EnrollmentResponse 0	Billing - Claim 2 - ClaimResponse 2 - Invoice 0	Payment - PaymentNotice 2 - PaymentReconciliation 2	General - Account 2 - ChargeItem 0 - ChargeItemDefinition 0 - Contract 1 - InsurancePlan 0	
Specialized Public Health & Research - ResearchStudy 1 - ResearchSubject 1	Definitional Artifacts - ActivityDefinition 2 - DeviceDefinition 0 - EventDefinition 0 - ObservationDefinition 0 - PlanDefinition 2 - Questionnaire 3 - SpecimenDefinition 0	Evidence-Based Medicine - ResearchDefinition 0 - ResearchElementDefinition 0 - Evidence 0 - EvidenceVariable 0 - EffectEvidenceSynthesis 0 - RiskEvidenceSynthesis 0	Quality Reporting & Testing - Measure 2 - MeasureReport 2 - TestScript 2 - TestReport 0	Medication Definition - MedicinalProduct 0 - MedicinalProductAuthorization 0 - MedicinalProductContraindication 0 - MedicinalProductIndication 0 - MedicinalProductIngredient 0 - MedicinalProductInteraction 0 - MedicinalProductManufactured 0 - MedicinalProductPackaged 0 - MedicinalProductPharmaceutical 0 - MedicinalProductUndesirableEffect 0 - SubstanceNucleicAcid 0 - SubstancePolymer 0 - SubstanceProtein 0 - SubstanceReferenceInformation 0 - SubstanceSpecification 0 - SubstanceSourceMaterial 0

 fhir4pharma

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[4]

Clinical Data Standards

Quick Introduction to FHIR

Patient Resource

8.1.2 Resource Content

Structure	UML	XML	JSON	Turtle	R3 Diff	All
Structure						
Name	Flags	Card.	Type	Description & Constraints		
 Patient	N		DomainResource	Information about an individual or animal receiving health care services Elements defined in Ancestors: id , meta , implicitRules , language , text , contained , extension , modifierExtension		
 identifier	Σ	0..*	Identifier	An identifier for this patient		
 active	?! Σ	0..1	boolean	Whether this patient's record is in active use		
 name	Σ	0..*	HumanName	A name associated with the patient		
 telecom	Σ	0..*	ContactPoint	A contact detail for the individual		
 gender	Σ	0..1	code	male female other unknown AdministrativeGender (Required)		
 birthDate	Σ	0..1	date	The date of birth for the individual		
 deceased[x]	?! Σ	0..1		Indicates if the individual is deceased or not		
 deceasedBoolean			boolean			
 deceasedDateTime			dateTime			
 address	Σ	0..*	Address	An address for the individual		
 maritalStatus		0..1	CodeableConcept	Marital (civil) status of a patient MaritalStatus (Extensible)		
 multipleBirth[x]		0..1		Whether patient is part of a multiple birth		
 multipleBirthBoolean			boolean			
 multipleBirthInteger			integer			



Quick Introduction to FHIR

Patient Jim:

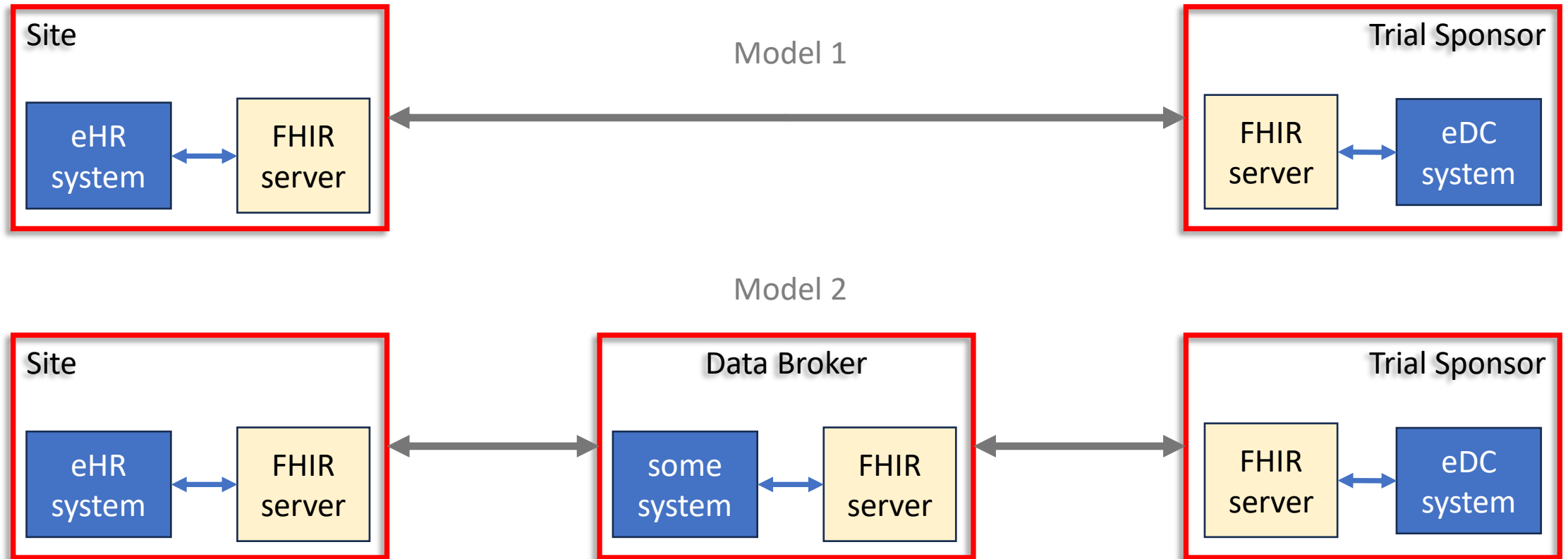
- Male
- DoB: 1974-12-25
- Medical record no: 12345
- Official name: Peter James Chalmers
- Maiden name: Peter James Windsor

Patient Example

```
Instance: example
InstanceOf: Patient
Usage: #example
* identifier.use = #usual
* identifier.system = "urn:oid:1.2.36.146.595.217.0.1"
* identifier.value = "12345"
* identifier.period.start = "2001-05-06"
* identifier.assigner.display = "Acme Healthcare"
* active = true
* name[0].use = #official
* name[=].family = "Chalmers"
* name[=].given[0] = "Peter"
* name[=].given[+] = "James"
* name[+].use = #usual
* name[=].given = "Jim"
* name[+].use = #maiden
* name[=].family = "Windsor"
* name[=].given[0] = "Peter"
* name[=].given[+] = "James"
* name[=].period.end = "2002"
...
```

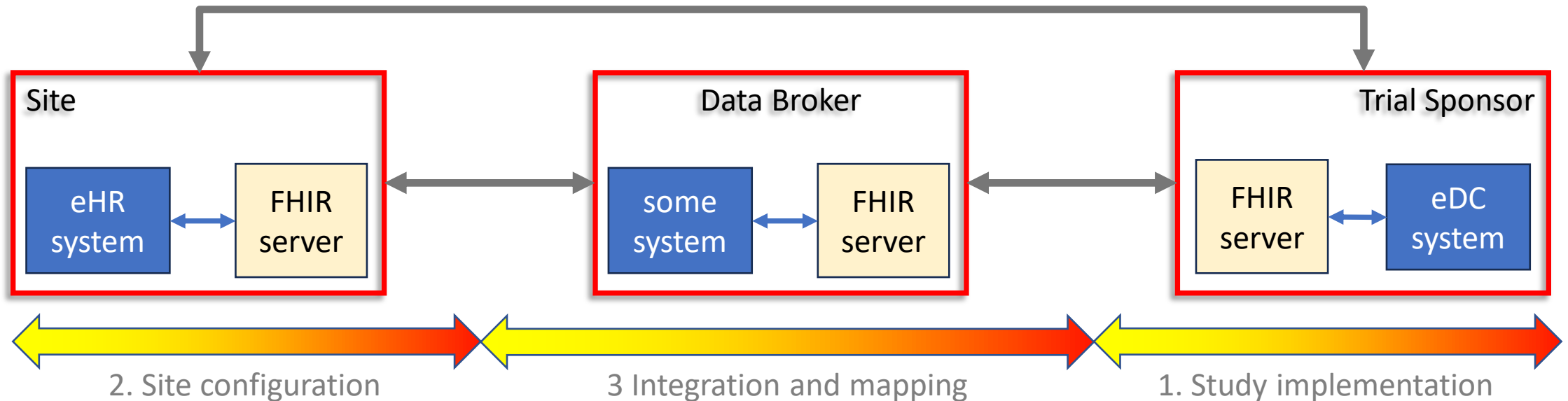
Using FHIR in clinical trials

Models



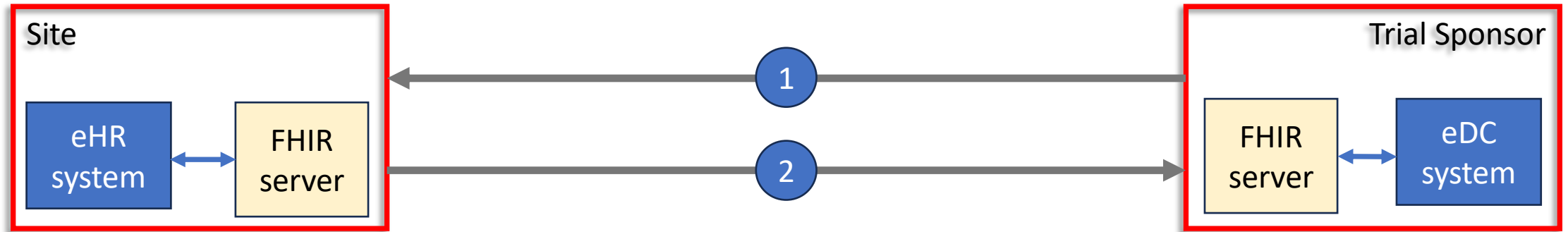
Using FHIR in clinical trials

Processes



1. Study implementation: representing the study as FHIR resources (e.g. Schedule of Activities, windowing, ...)
2. Site configuration: representing the patient, encounters, observations, etc. as FHIR resources
3. Integration and mapping: creating the data pipeline between site and sponsor

The challenge



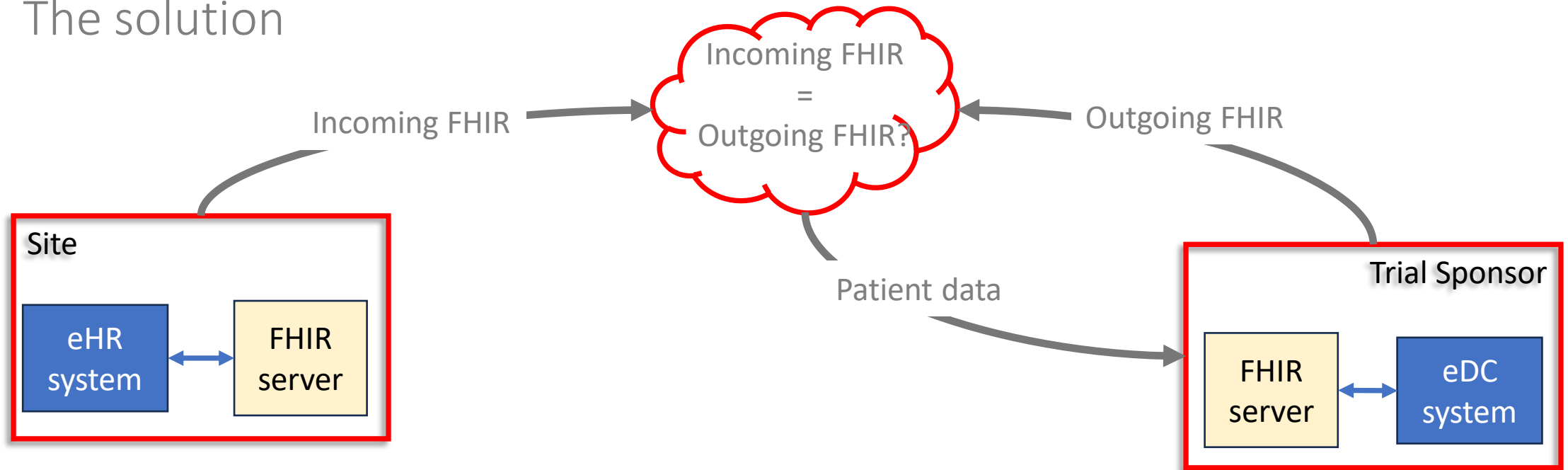
In the current eDC set-up, fit for purpose data is achieved through a manual process:

- 1 The eCRF dictates what data is needed when, in support of the protocol.
- 2 Site staff interprets the data in the eHR system and transcribes it into the eDC.

The challenge

- 1 How to define the data requirements unambiguously supporting the trial protocol using FHIR resources?
- 2 How to use the eHR data in order to meet the protocol requirements using FHIR resources?

The solution



Outgoing FHIR specifies: what data is required by the study?

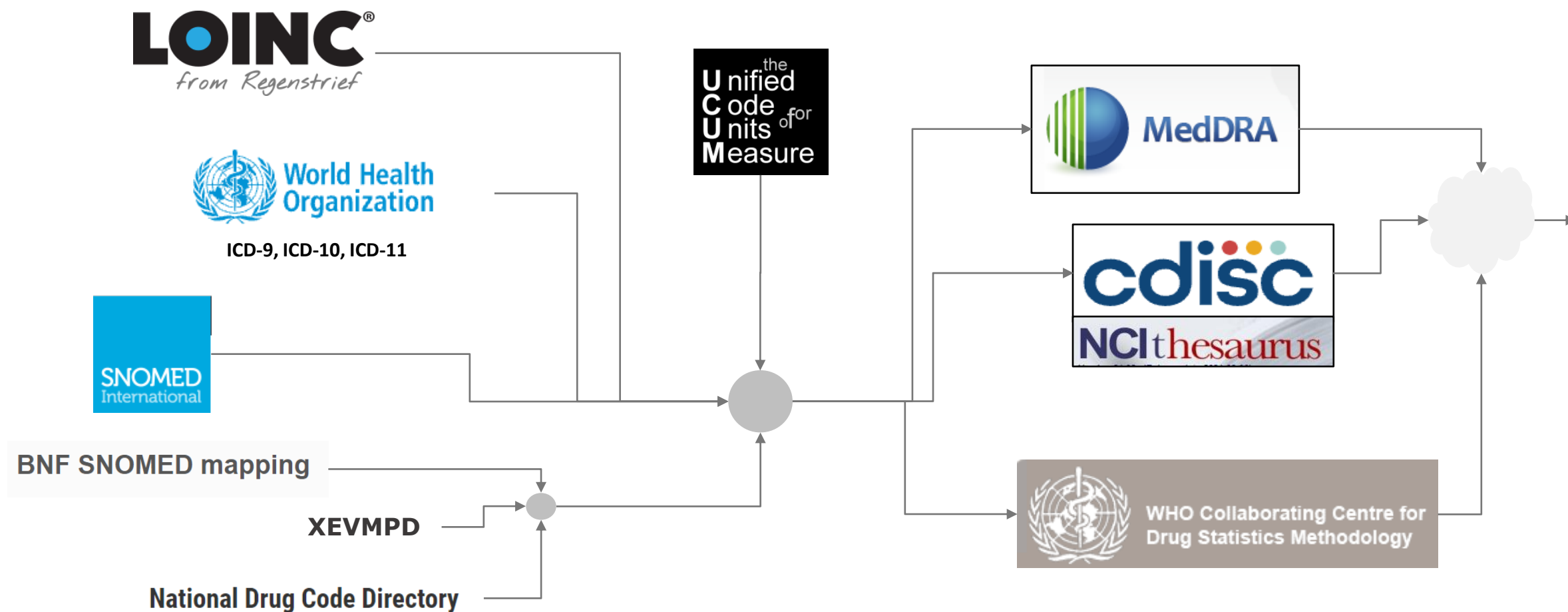
Incoming FHIR specifies: what data is available in the eHR system?

Incoming FHIR = Outgoing FHIR specifies: Are they semantically equivalent?

If yes, then the patient data can be mapped, coded, ... and transferred to the trial sponsor's system.

If no, then raise an exception and handle the semantic inequivalence.

Clinical coding systems





Semantic Equivalence

- Issue: DDC removes the person from determining if the EHR data is equivalent to that required by the protocol.
- Two important concepts to consider:
 - 1. That DDC is in essence an ETL operation
 - Extract, Transform, Load
 - Extract, Transform, Load, Analyze
 - Extract, Clean, Transform, Load, Analyze
 - 2. That DDC must enable the exchange AND retain consistency in the meaning i.e., be Interoperable



Interoperability

- Foundational interoperability
 - Is the ability of one IT system to send data to another IT system
- Structural interoperability
 - Is the ability of the recipient system to interpret information at the data field level
- Semantic interoperability
 - is the ability of systems to exchange and interpret information
- Organizational interoperability
 - Is the ability to align processes to achieve a common goal



Semantic Equivalence

- Is a declaration that two data elements from different **vocabularies** contain **data** that has **similar meaning**
 - Concept Equivalence [Class]
 - Confirmation that 2 high level concepts have similar or equivalent meaning
 - Attribute Equivalence [Property]
 - Confirmation that 2 properties have similar or equivalent meaning
 - Instance Equivalence [Instantiation]
 - Confirmation that 2 examples/instances of the data are equivalent

<https://en-academic.com>



Semantic Broker:

- Is a computer service that automatically provides semantic mapper services. That is, extracts data from a system and applies semantic equivalence statements to transform into any system

Semantic Mapper:

- is tool or service that aids in the transformation of data elements from one namespace into another namespace

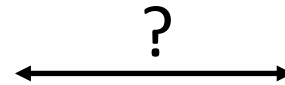
<https://en-academic.com>

Example: Concept Equivalence

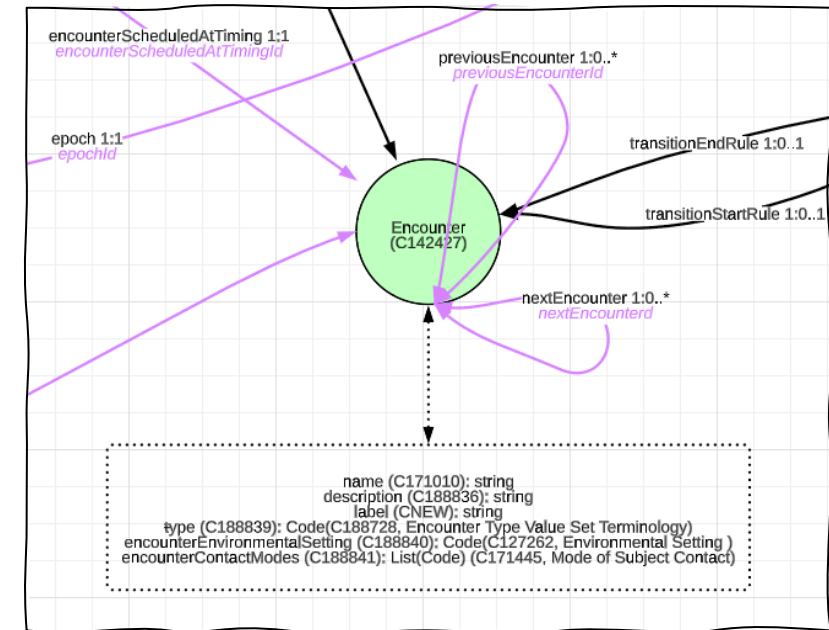
FHIR Resource - Encounter

Name	Flags	Card.	Type
Encounter	TU		DomainResource
identifier	Σ	0..*	Identifier
status	?! Σ	1..1	code
class	Σ	0..*	CodeableConcept
priority		0..1	CodeableConcept
type	Σ	0..*	CodeableConcept
serviceType	Σ	0..*	CodeableReference(HealthcareService)
subject	Σ	0..1	Reference(Patient Group)
subjectStatus		0..1	CodeableConcept
episodeOfCare	Σ	0..*	Reference(EpisodeOfCare)

Is... an interaction between a patient and healthcare provider



USDM Class - Encounter



Is... the specification (definition) of a (planned) study interaction (visit)



Example: Attribute Equivalence

Label	FHIR map (or gap)		CDISC		Comment
	Element	FHIRPath	CDASH	SDTM	
Visit Date	Encounter.period 0..1 Period	Observation.encounter.resolve().period.start	VISDAT Core: R/C Type: Char		Linked via Observation.encounter
Vital Signs Performed	Observation.status 1..1 code Binding: ObservationStatus required	Observation.status=('final' or 'cancelled')	VSPERF Core: O Type: Char	VSSTAT Core: Perm Type: Char	
Vital Signs Date	Observation.effectiveDateTime 0..1 dateTime	Observation.effectiveDateTime	VSDAT Core: R/C Type: Char	VSDTC Core: Exp Type: Char values: IS O 8601	
Vital Signs Time	Observation.effectiveDateTime 0..1 dateTime	Observation.effectiveDateTime	VSTIM Core: R/C Type: Char	VSDTC Core: Exp Type: Char values: IS O 8601	

<https://hl7.org/fhir/uv/cdisc-mapping/STU1/vs.html>



Example: Coding Equivalence

Code	Component	System
2096-6	Cholesterol/Triglyceride	Ser/Plas
34695-7	Cholesterol.in VLDL/Triglyceride	Ser/Plas
35363-1	Triglyceride.in chylomicrons	Ser/Plas
35362-3	Triglyceride.in chylomicrons	Ser/Plas
53527-8	Triglyceride.in HDL 2	Ser/Plas
53528-6	Triglyceride.in HDL 3	Ser/Plas
35360-7	Triglyceride.in lipoprotein (little a)	Ser/Plas
35361-5	Triglyceride.in lipoprotein (little a)	Ser/Plas
53526-0	Triglyceride.in VLDL	Ser/Plas
3044-5	Triglyceride+ester.in HDL	Ser/Plas
3045-2	Triglyceride+ester.in IDL	Ser/Plas
3046-0	Triglyceride+ester.in LDL	Ser/Plas
3047-8	Triglyceride+ester.in VLDL	Ser/Plas
2571-8	Triglyceride	Ser/Plas
12951-0	Triglyceride	Ser/Plas
35217-9	Triglyceride	Ser/Plas
30570-6	Triglyceride	Ser/Plas
28554-4	Triglyceride	Ser/Plas
14927-8	Triglyceride	Ser/Plas
44733-4	Triglyceride/Cholesterol.in HDL	Ser/Plas
55607-6	Triglyceride/Cholesterol.in HDL	Ser/Plas
47210-0	Triglyceride^post CFst	Ser/Plas
44718-5	Lipoprotein.pre-beta/Triglyceride	Ser/Plas
94859-6	Glycerol & Glycerol-corrected triglyceride panel	Ser/Plas
1644-4	Triglyceride^post 12H CFst	Ser/Plas
30524-3	Triglyceride^post 12H CFst	Ser/Plas
3048-6	Triglyceride^post CFst	Ser/Plas

LOINC 'Triglyceride' in 'Ser/Plas'
27 codes

Code	CDISC Synonym(s)	CDISC Definition
C174302	Chylomicron Triglyceride	A measurement of the chylomicron triglyceride in a biological specimen.
C189507	IDL Triglyceride	A measurement of the intermediate density lipoprotein triglyceride in a biological specimen.
C189506	LDL Triglyceride	A measurement of the low density lipoprotein triglyceride in a biological specimen.
C64812	Triglycerides	A measurement of the triglycerides in a biological specimen.
C121165	Triglycerides/HDL Cholesterol	A relative measurement (ratio or percentage) of the triglycerides to high density lipoprotein cholesterol in a biological specimen.
C174303	VLDL Triglyceride	A measurement of the very low density lipoprotein triglyceride in a biological specimen.
C174301	VLDL Trig + Chylomicron Trig; VLDL Triglyceride + Chylomicron Triglyceride	A measurement of the very low density lipoprotein triglyceride and chylomicron triglyceride in a biological specimen.

CDISC SCDM CT 'Triglyceride'
7 codes

Component	Property
Triglyceride	MCnc
Triglyceride	MCnc
Triglyceride	MSCnc
Triglyceride	Prctl
Triglyceride	PrThr
Triglyceride	SCnc



Example 1: Glucose - semantically equivalent

```
Alias: $loinc = http://loinc.org
Alias: $api = https://library.cdisc.org/api
```

```
Instance: LOINC-2339-0-ObservationDefinition
InstanceOf: ObservationDefinition
Usage: #example
* name = "Glucose (Bld) [Mass/Vol]"
* title = "Glucose [Mass/volume] in Blood"
* status = "active"
* code
  * coding[0] = $loinc#2339-0
    * version = "2.74"
  * coding[+] = $api#C105585 "Glucose"
* identifier
  * use = #secondary
  * value = "CDISC Mapping"
  * assigner = Reference(fhir4pharma)
* permittedDataType = #Quantity
* permittedUnit
  * system = "https://ucum.org"
  * code = "mg/dL"
  * display = "mg/dL"
* specimen.identifier
  * use = "official"
  * type.coding
    * system = "http://loinc.org"
    * code = "LP7057-5"
    * display = "Bld"
```

Outgoing FHIR

```
Alias: $observation-category = http://terminology.hl7.org/CodeSystem/observation-category
Alias: $loinc = http://loinc.org
```

```
Instance: f54b9d4b-dc0e-45f0-a6f2-89d054cb2339
InstanceOf: Observation
Usage: #example
* status = #final
* category = $observation-category#laboratory "laboratory"
* code = $loinc#2339-0 "Glucose"
  * text = "Glucose"
* subject = Reference(urn:uuid:abbd3c1b-3048-49f2-95c9-9303b3b73d34)
* encounter = Reference(urn:uuid:57e06431-50f2-47ff-821f-7f2aacba51ae)
* effectiveDateTime = "1984-10-22T10:04:10-04:00"
* issued = "1984-10-22T10:04:10.192-04:00"
* valueQuantity = 116.26405768012262 'mg/dL' "mg/dL"
```

Incoming FHIR

Example 2: Glucose - semantically inequivalent

Alias: \$loinc = <http://loinc.org>
 Alias: \$api = <https://library.cdisc.org/api>

Instance: LOINC-2339-0-ObservationDefinition
 InstanceOf: ObservationDefinition
 Usage: #example
 * name = "Glucose (Bld) [Mass/Vol]"
 * title = "Glucose [Mass/volume] in Blood"
 * status = "active"
 * code
 | * coding[0] = \$loinc#2339-0
 | * version = "2.74"
 | * coding[+] = \$api#C105585 "Glucose"
 * identifier
 * use = #secondary
 * value = "CDISC Mapping"
 * assigner = Reference(fhir4pharma)
 * permittedDataType = #Quantity
 * permittedUnit
 | * system = "<https://ucum.org>"
 | * code = "mg/dL"
 | * display = "mg/dL"
 * specimen.identifier
 * use = "official"
 * type.coding
 | * system = "<http://loinc.org>"
 | * code = "LP7057-5"
 | * display = "Bld"

Outgoing FHIR

Alias: \$observation-category = <http://terminology.hl7.org/CodeSystem/observation-category>
 Alias: \$loinc = <http://loinc.org>

Instance: 18461bd8-bc61-4efc-a652-5c69366d4321
 InstanceOf: Observation
 Usage: #example
 * status = #final
 * category = \$observation-category#laboratory "laboratory"
 * code = \$loinc#2345-7 "Glucose"
 | * text = "Glucose"
 * subject = Reference(urn:uuid:cfd05495-435d-4fb8-b06b-84ac17b664bf)
 * encounter = Reference(urn:uuid:1ba33750-8a55-4443-94fd-796009d0035f)
 * effectiveDateTime = "1985-07-21T10:04:10-04:00"
 * issued = "1985-07-21T10:04:10.192-04:00"
 * valueQuantity = 71.60256378214879 'mg/dL' "mg/dL"

Incoming FHIR

parameter[+]
 * name = "property"
 * part[0]
 | * name = "code"
 | * valueCode = #DisplayName
 * part[+]
 | * name = "value"
 | * valueString = "Glucose [Mass/Vol]"

* parameter[+]
 * name = "property"
 * part[0]
 | * name = "code"
 | * valueCode = #system-core
 * part[+]
 | * name = "value"
 | * valueCoding = \$loinc#LP7576-4 "Ser/Plas"

LOINC

Example 3: Blood Pressure (diastolic) - semantically equivalent

```
Alias: $loinc = http://loinc.org
Alias: $api = https://library.cdisc.org/api
```

```
Instance: LOINC-8462-4-ObservationDefinition
InstanceOf: ObservationDefinition
Usage: #example
* title = "Diastolic blood pressure"
* status = "active"
* code.coding[0].version = "2.74"
* code.coding[+] = $loinc#8462-4
* code.coding[+] = $api#C25299 "Diastolic Blood Pressure"
* identifier.use = #secondary
* identifier.value = "CDISC Mapping"
* identifier.assigner = Reference(fhir4pharma)
* permittedDataType = #Quantity
* permittedUnit.system = "https://ucum.org"
* permittedUnit.code = "mm[Hg]"
* permittedUnit.display = "mm[Hg]"
* specimen.identifier.use = "official"
* specimen.identifier.type.coding.system = "http://loinc.org"
* specimen.identifier.type.coding.code = "LP7034-4"
* specimen.identifier.type.coding.display = "Arterial system"
```

Outgoing FHIR

```
Alias: $observation-category = http://terminology.hl7.org/CodeSystem/observation-category
Alias: $loinc = http://loinc.org
```

```
Instance: 140909eb-8693-4210-a286-aea2e2399d34
InstanceOf: Observation
Usage: #example
* status = #final
* category = $observation-category#vital-signs "vital-signs"
* code = $loinc#55284-4 "Blood Pressure"
* text = "Blood Pressure"
* subject = Reference(urn:uuid:751a3384-dfb5-4b17-987d-e828d7b02acc)
* encounter = Reference(urn:uuid:866efbcc-5a9d-4dbe-a30a-6bf5a72c9a94)
* effectiveDateTime = "2011-09-23T11:53:18-04:00"
* issued = "2011-09-23T11:53:18.131-04:00"
* component[0]
  * code = $loinc#8462-4 "Diastolic Blood Pressure"
  * text = "Diastolic Blood Pressure"
  * valueQuantity = 73.5566946815124 'mm[Hg]' "mm[Hg]"
* component[+]
  * code = $loinc#8480-6 "Systolic Blood Pressure"
  * text = "Systolic Blood Pressure"
  * valueQuantity = 136.2868873297329 'mm[Hg]' "mm[Hg]"
```

Incoming FHIR



Example 3: Blood Pressure (systolic) - semantically equivalent

```
Alias: $loinc = http://loinc.org
Alias: $api = https://library.cdisc.org/api
```

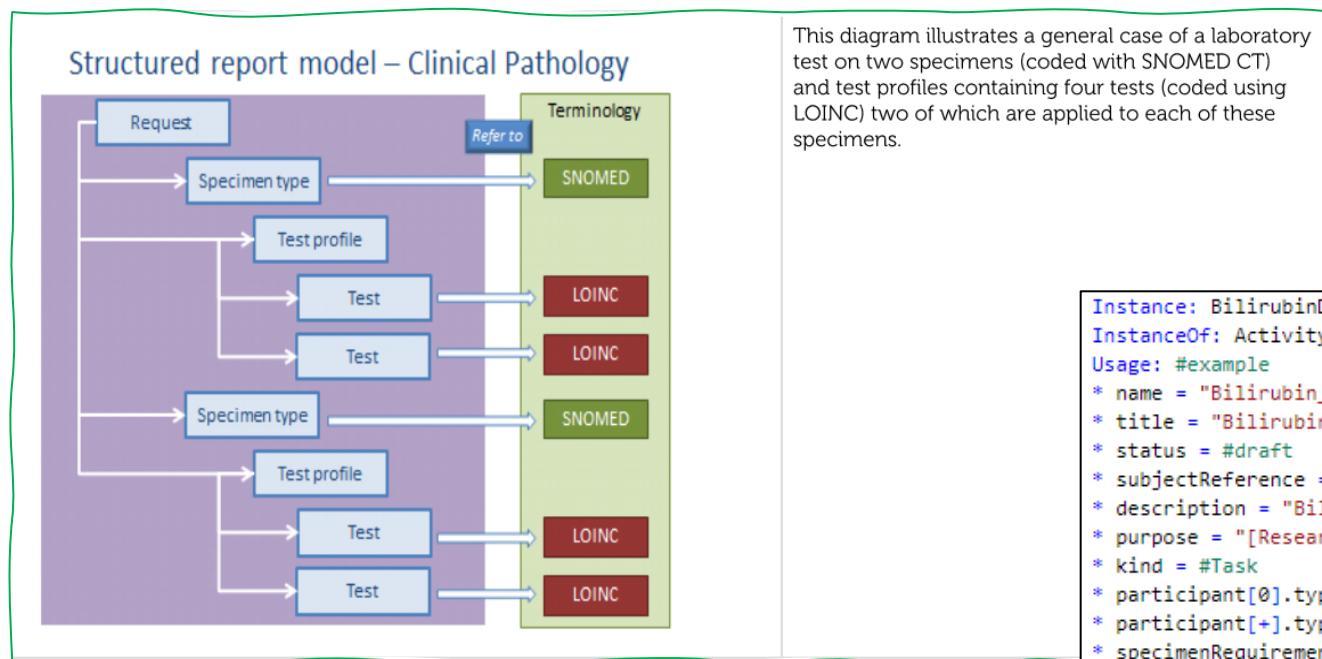
```
Instance: LOINC-8480-6-ObservationDefinition
InstanceOf: ObservationDefinition
Usage: #example
* title = "Systolic blood pressure"
* status = "active"
* code.coding[0].version = "2.74"
* code.coding[0] = $loinc#8480-6
* code.coding[+] = $api#C25298 "Systolic Blood Pressure"
* identifier.use = #secondary
* identifier.value = "CDISC Mapping"
* identifier.assigner = Reference(fhir4pharma)
* permittedDataType = #Quantity
* permittedUnit.system = "https://ucum.org"
* permittedUnit.code = "mm[Hg]"
* permittedUnit.display = "mm[Hg]"
* specimen.identifier.use = "official"
* specimen.identifier.type.coding.system = "http://loinc.org"
* specimen.identifier.type.coding.code = "LP7034-4"
* specimen.identifier.type.coding.display = "Arterial system"
```

Outgoing FHIR

```
Alias: $observation-category = http://terminology.hl7.org/CodeSystem/observation-category
Alias: $loinc = http://loinc.org
```

```
Instance: 140909eb-8693-4210-a286-aea2e2399d34
InstanceOf: Observation
Usage: #example
* status = #final
* category = $observation-category#vital-signs "vital-signs"
* code = $loinc#55284-4 "Blood Pressure"
* text = "Blood Pressure"
* subject = Reference(urn:uuid:751a3384-dfb5-4b17-987d-e828d7b02acc)
* encounter = Reference(urn:uuid:866efbcc-5a9d-4dbe-a30a-6bf5a72c9a94)
* effectiveDateTime = "2011-09-23T11:53:18-04:00"
* issued = "2011-09-23T11:53:18.131-04:00"
* component[0]
  * code = $loinc#8462-4 "Diastolic Blood Pressure"
  * text = "Diastolic Blood Pressure"
  * valueQuantity = 73.5566946815124 'mm[Hg]' "mm[Hg]"
* component[+]
  * code = $loinc#8480-6 "Systolic Blood Pressure"
  * text = "Systolic Blood Pressure"
  * valueQuantity = 136.2868873297329 'mm[Hg]' "mm[Hg]"
```

Incoming FHIR

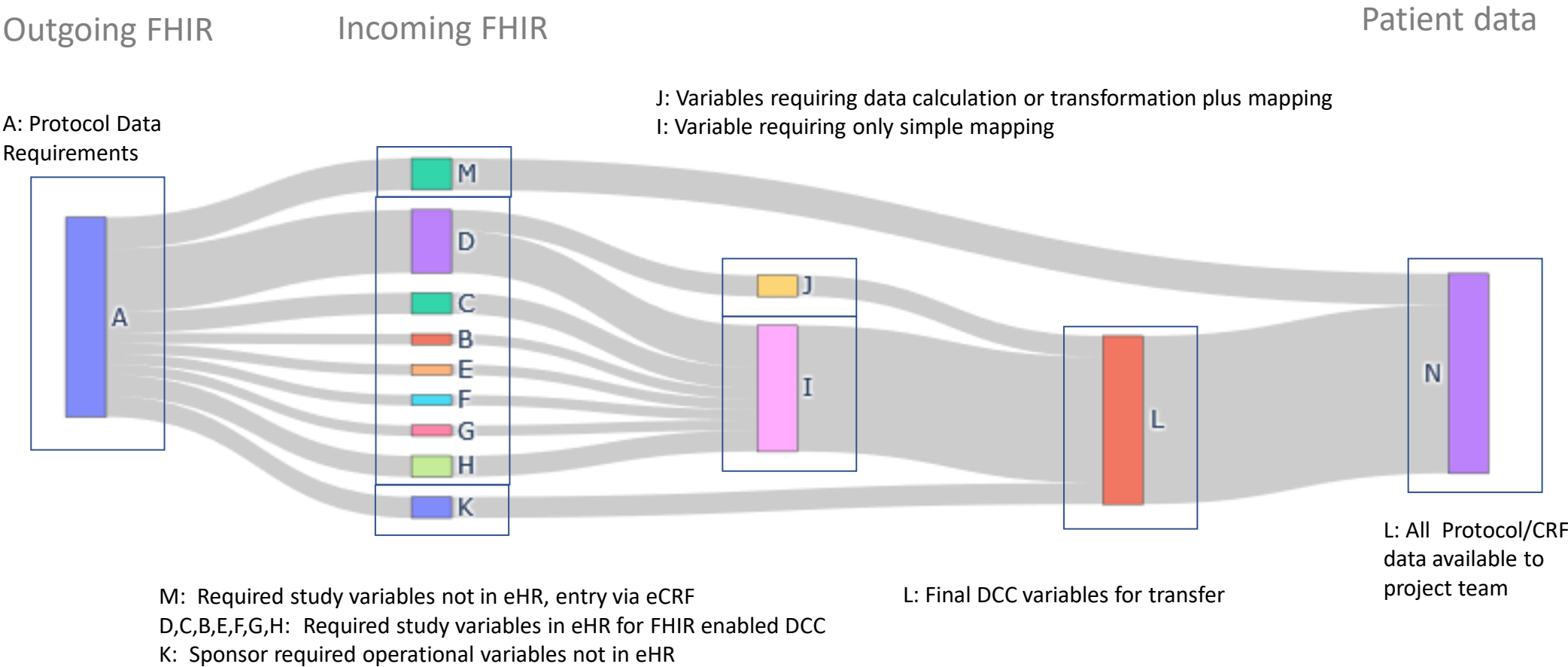


Outgoing FHIR

```
Instance: BilirubinDirect
InstanceOf: ActivityDefinition
Usage: #example
* name = "Bilirubin_Direct_Tot_Pnl_SerPl_mCnc-34543-9"
* title = "Bilirubin_Direct_Tot_Pnl_SerPl_mCnc-34543-9"
* status = #draft
* subjectReference = Reference(Group/ResearchStudySubject)
* description = "Bilirubin_Direct_Tot_Pnl_SerPl_mCnc-34543-9"
* purpose = "[ResearchStudy] Activity Bilirubin_Direct_Tot_Pnl_SerPl_mCnc-34543-9 Specification"
* kind = #Task
* participant[0].type = #patient
* participant[+].type = #practitioner
* specimenRequirement = Reference(SpecimenDefinition/SNOMED-119297000-SpecimenDefinition)
* observationRequirement[0] = Reference(ObservationDefinition/LOINC-1968-7-ObservationDefinition)
* observationRequirement[+] = Reference(ObservationDefinition/LOINC-1975-2-ObservationDefinition)
```

Extract From Table 5.2.7-1 ‘Using LOINC with SNOMED’

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In Summary

The replacement of a qualified person from determining if the EHR data is equivalent to that required by the protocol requires careful consideration of healthcare record coding

FHIR Resources will expose EHR codes but cannot confirm compliance with protocol requirements or subsequent re-coding

To ensure automated semantic equivalence between EHR records and protocol requirements validated semantic mapping tools or services must be put in place

For any one study semantic equivalence must be established between the protocol and each site and between sites in the study database

Standardised coding methods based on publicly available clinical coding systems aids in reducing the burden of confirming semantic equivalence



Bridging clinical care and clinical research
using FHIR standards

Patrick Genyn & Andy Richardson