

Direct Data Exchange (DDE) with EHR

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Direct Data Exchange (DDE) with EHR

FHIR® (very) Quick Introduction

The Triple DDE Challenge

The Implementation Challenge

What's going on in the industry?

What is FHIR®

FHIR®: Fast Healthcare Interoperability Resources.

- Three important relevant definitions
 - The basic building block in FHIR is a Resource ~ standard definition as metadata.
 - The Capability Statement documents the actual FHIR server functionality ~ what data is exposed with what version
 - Profiles and Implementation Guides contain the sets of rules about how FHIR Resources are used or should be used for specific use cases (<https://www.fhir.org/guides/registry/>)
- FHIR® Resources
 - Organized on 5 Levels (<http://hl7.org/fhir/index.html>)
 - Framework, Implementation, Real World Concepts, Records/Data Exchange, Clinical Reasoning
 - Organized into 5 Categories: (<http://hl7.org/fhir/resourcelist.html>)
 - Foundation, Base, Clinical, Financial, Specialized

FHIR® Resources

HL7

FHIR®

Release 4

HL7

International

[Home](#)
[Getting Started](#)
[Documentation](#)
[Resources](#)
[Profiles](#)
[Extensions](#)
[Operations](#)
[Terminologies](#)

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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](#) and [Domain Resource](#).

Categorized

Alphabetical

R2 Layout

By Maturity

By Security Status

By Status

By Committee

code system

value set

patient

practitioner

organization

related person

	Conformance	Terminology	Security	Documents	Other
Foundation	<ul style="list-style-type: none"> CapabilityStatement [N] StructureDefinition [N] ImplementationGuide 1 SearchParameter 3 MessageDefinition 1 OperationDefinition [N] CompartmentDefinition 1 StructureMap 2 GraphDefinition 1 ExampleScenario 0 	<ul style="list-style-type: none"> CodeSystem [N] ValueSet [N] ConceptMap 3 NamingSystem 1 TerminologyCapabilities 0 	<ul style="list-style-type: none"> Provenance 3 AuditEvent 3 Consent 2 	<ul style="list-style-type: none"> Composition 2 DocumentManifest 2 DocumentReference 3 CatalogEntry 0 	<ul style="list-style-type: none"> Basic [N] Binary [N] Bundle [N] Linkage 0 MessageHeader 4 OperationOutcome [N] Parameters [N] Subscription 3
	Base	<div>Individuals</div> <ul style="list-style-type: none"> Individual [N] Patient [N] Practitioner 3 PractitionerRole 2 RelatedPerson 2 Person 2 Group 1 	<div>Organization</div> <ul style="list-style-type: none"> Organization 3 OrganizationAffiliation 0 HealthcareService 2 Endpoint 2 Location 3 	<div>Substance</div> <ul style="list-style-type: none"> Substance 2 BiologicallyDerivedProduct 0 Device 2 DeviceMetric 1 	<div>Workflow</div> <ul style="list-style-type: none"> Task 2 Appointment 3 AppointmentResponse 3 Schedule 3 Slot 3 VerificationResult 0

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

Clinical	Summary <ul style="list-style-type: none"> AllergyIntolerance 3 AdverseEvent 0 Condition (Problem) 3 Procedure 3 FamilyMemberHistory 2 ClinicalImpression 0 DetectedIssue 1 	Diagnosis <ul style="list-style-type: none"> Observation [N] Media 1 DiagnosticReport 3 Specimen 2 BodyStructure 1 ImagingStudy 3 QuestionnaireResponse 3 MolecularSequence 1 	Medication <ul style="list-style-type: none"> MedicationRequest 3 MedicationAdministration 2 MedicationDispense 2 MedicationStatement 3 Medication 3 MedicationKnowledge 0 Immunization 3 ImmunizationEvaluation 0 ImmunizationRecommendation 1 	Care Provision <ul style="list-style-type: none"> CareTeam 2 Goal 2 ServiceRequest 2 NutritionOrder 2 VisionPrescription 2 RiskAssessment 1 RequestGroup 2 	Request & Response <ul style="list-style-type: none"> CommunicationRequest 2 DeviceRequest 1 DeviceUseStatement 0 GuidanceResponse 2 SupplyRequest 1 SupplyDelivery 1
	Support <ul style="list-style-type: none"> Coverage 2 CoverageEligibilityRequest 2 CoverageEligibilityResponse 2 EnrollmentRequest 0 EnrollmentResponse 0 	Billing <ul style="list-style-type: none"> Claim 2 ClaimResponse 2 Invoice 0 	Payment <ul style="list-style-type: none"> PaymentNotice 2 PaymentReconciliation 2 	General <ul style="list-style-type: none"> Account 2 ChargeItem 0 ChargeItemDefinition 0 Contract 1 InsurancePlan 0 InsurancePolicy 0 	
Specialized	Public Health & Research <ul style="list-style-type: none"> ResearchStudy 1 ResearchSubject 1 	Definitional Artifacts <ul style="list-style-type: none"> ActivityDefinition 2 DeviceDefinition 0 EventDefinition 0 ObservationDefinition 0 PlanDefinition 2 Questionnaire 3 SpecimenDefinition 0 	Evidence-Based Medicine <ul style="list-style-type: none"> ResearchDefinition 0 ResearchElementDefinition 0 Evidence 0 EvidenceVariable 0 EffectEvidenceSynthesis 0 RiskEvidenceSynthesis 0 	Quality Reporting & Improvement <ul style="list-style-type: none"> Measure 2 MeasureReport 2 TestScript 2 TestReport 0 	Medication Definition <ul style="list-style-type: none"> 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

FHIR® Resources example

Patient

8.1.2 Resource Content

Structure					
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		

Element Name

Cardinality

Type

Description and Constraints

Flags (e.g. Σ: part of a summary set, ?!: This element is a modifying element)

Resource Formats

Direct Data Exchange (DDE) with EHR

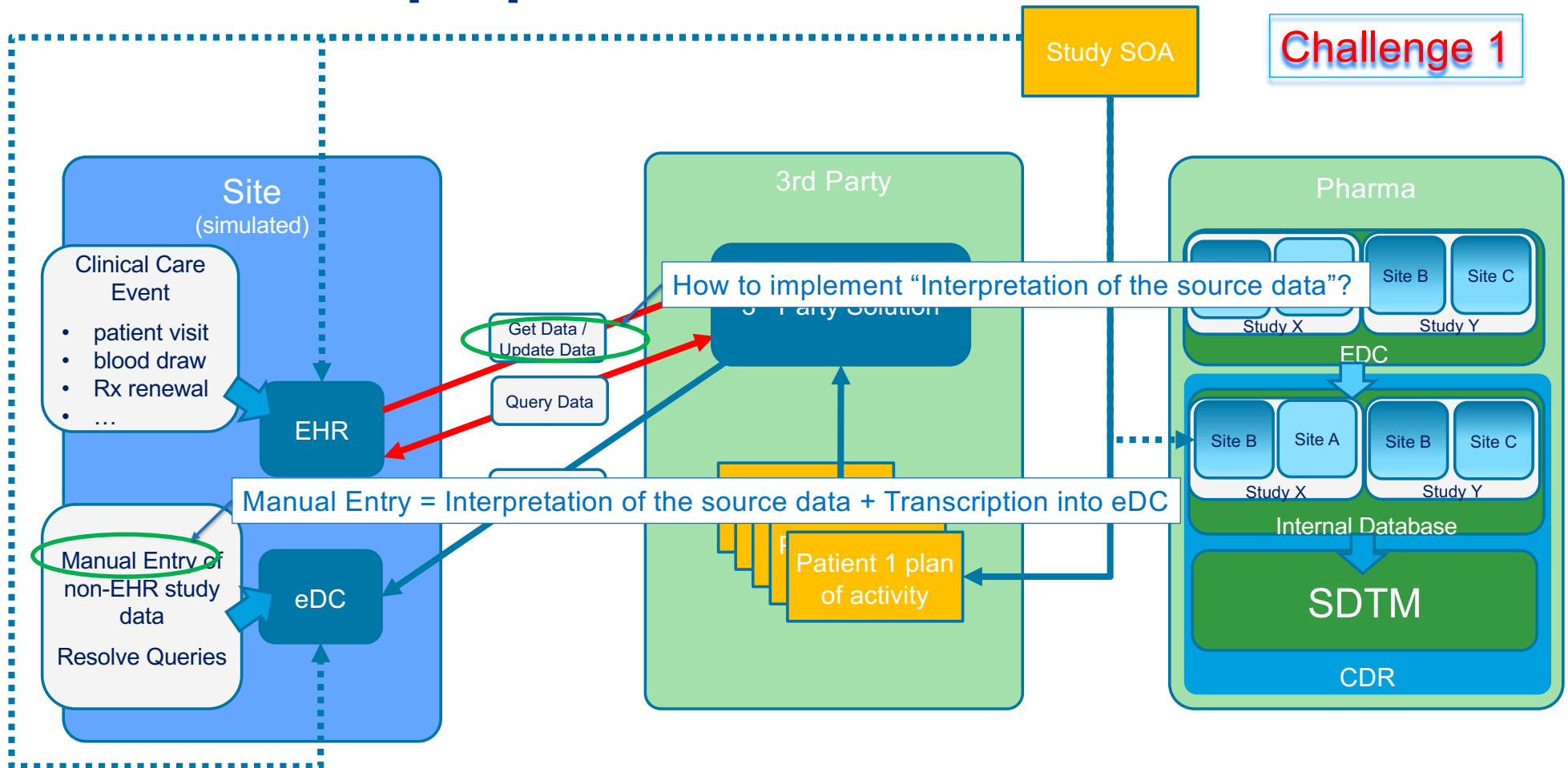
FHIR® (very) Quick Introduction

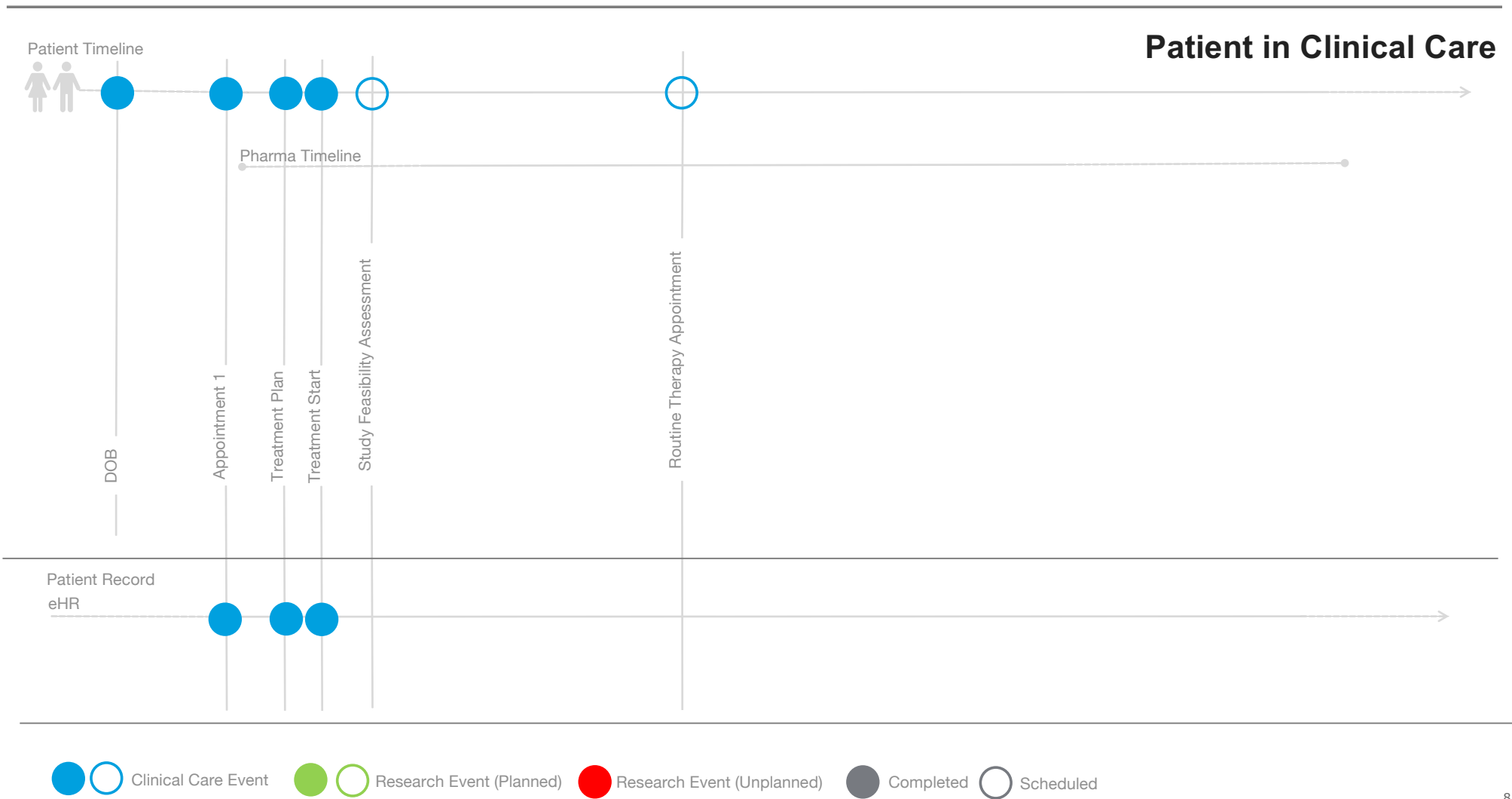
The Triple DDE Challenge

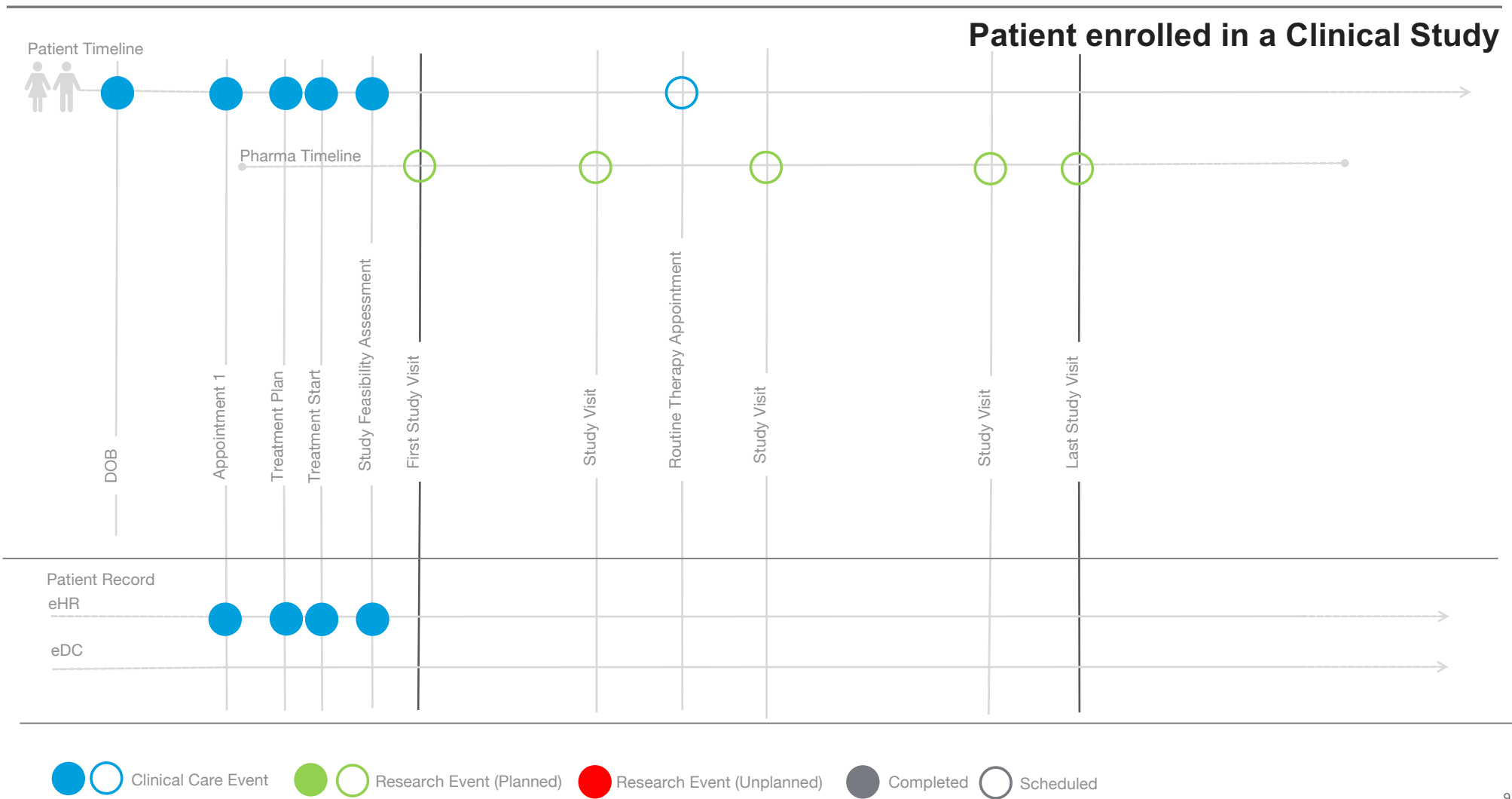
The Implementation Challenge

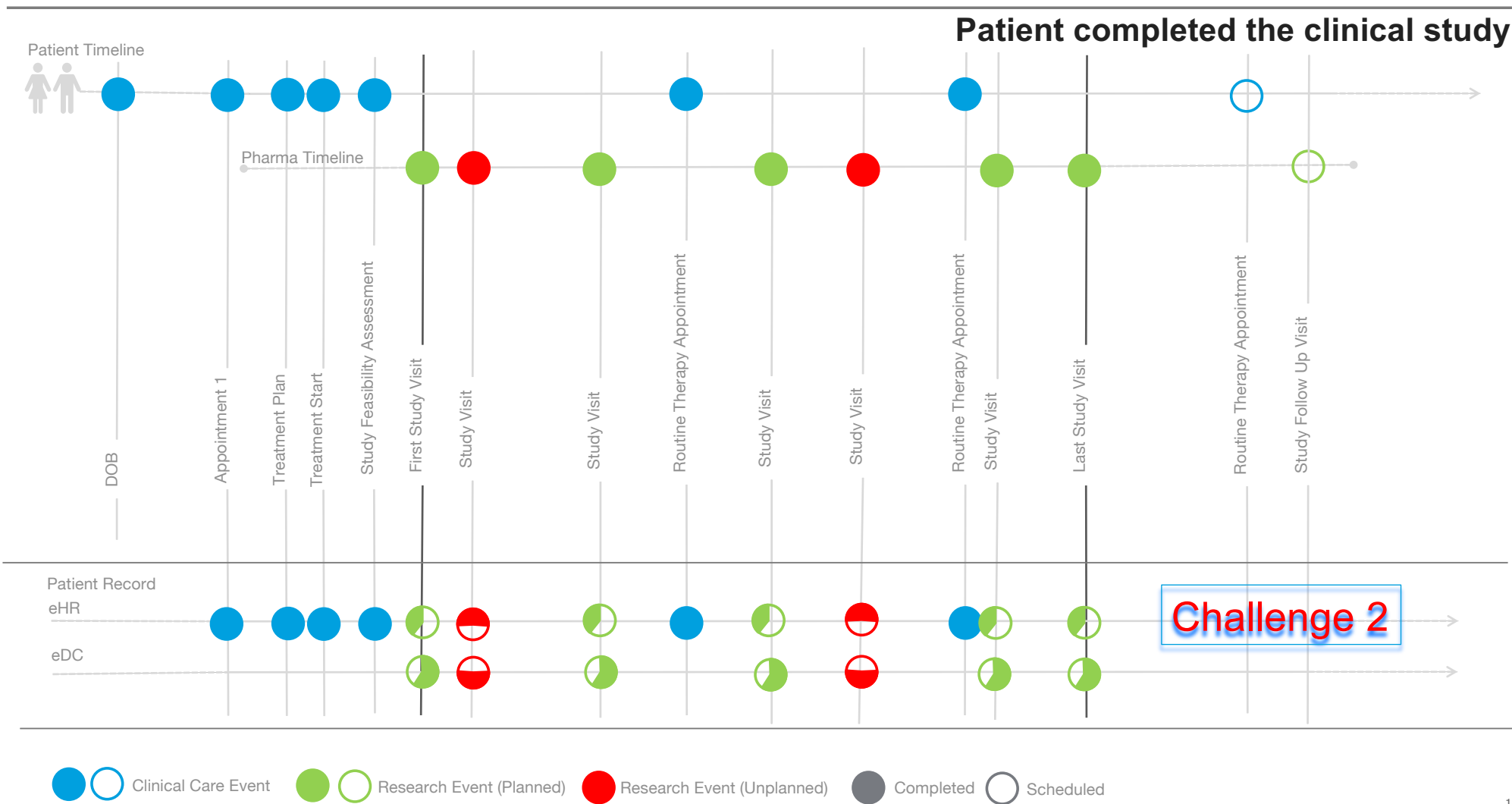
What's going on in the industry?

Data fit-for-purpose.



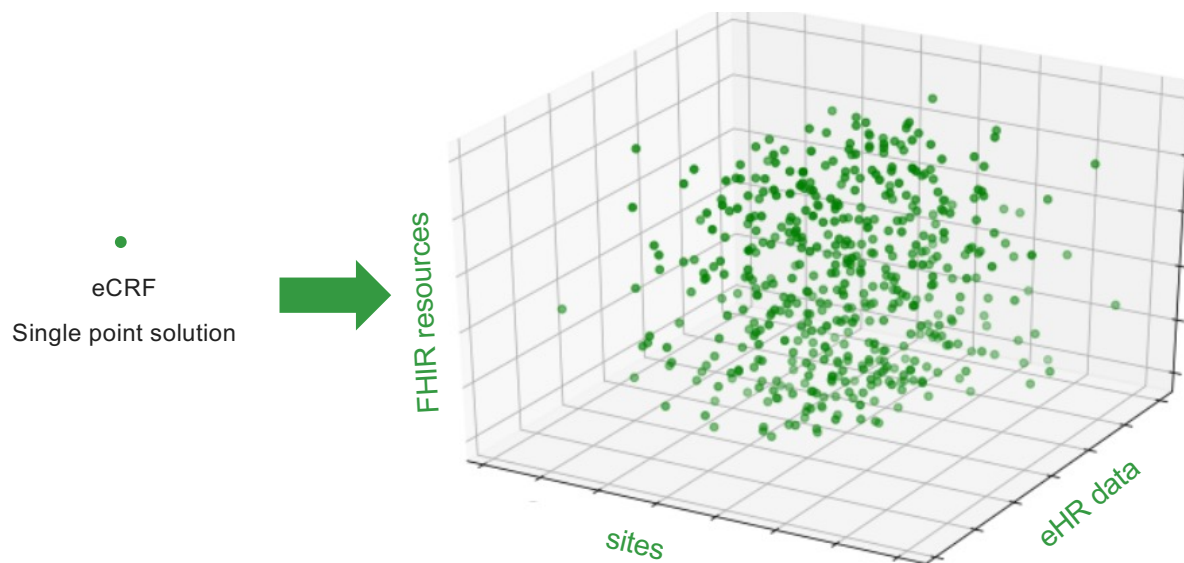






Scalability

Challenge 3



Across sites

- Different eHR systems
- Variable use of the same eHR system

eHR data

- Multiple datasets meeting protocol requirements
- Variable fit-for-purpose

FHIR resources

- Multiple FHIR Capability Statements
- Multiple FHIR Implementation Guidelines

Can we get an idea of how much data we can collect now and how this will evolve over the future?

Direct Data Exchange (DDE) with EHR

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The Triple DDE Challenge

The Implementation Challenge

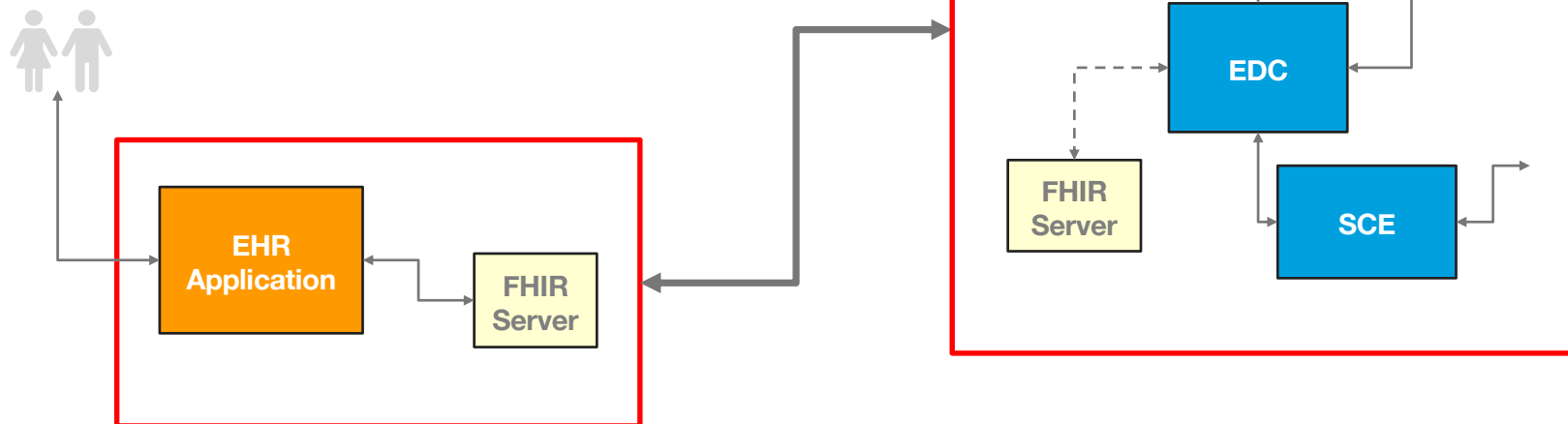
What's going on in the industry?

DDE Objective

...is to establish confirmed study dataflows – data pipelines – from investigator sites to sponsor

- Technically – with attention to security, authorization, privacy, contractually
- Accurately – to ensure research objectives are met, data is as study expects, provenance can be determined etc.
- and System / Solution validated

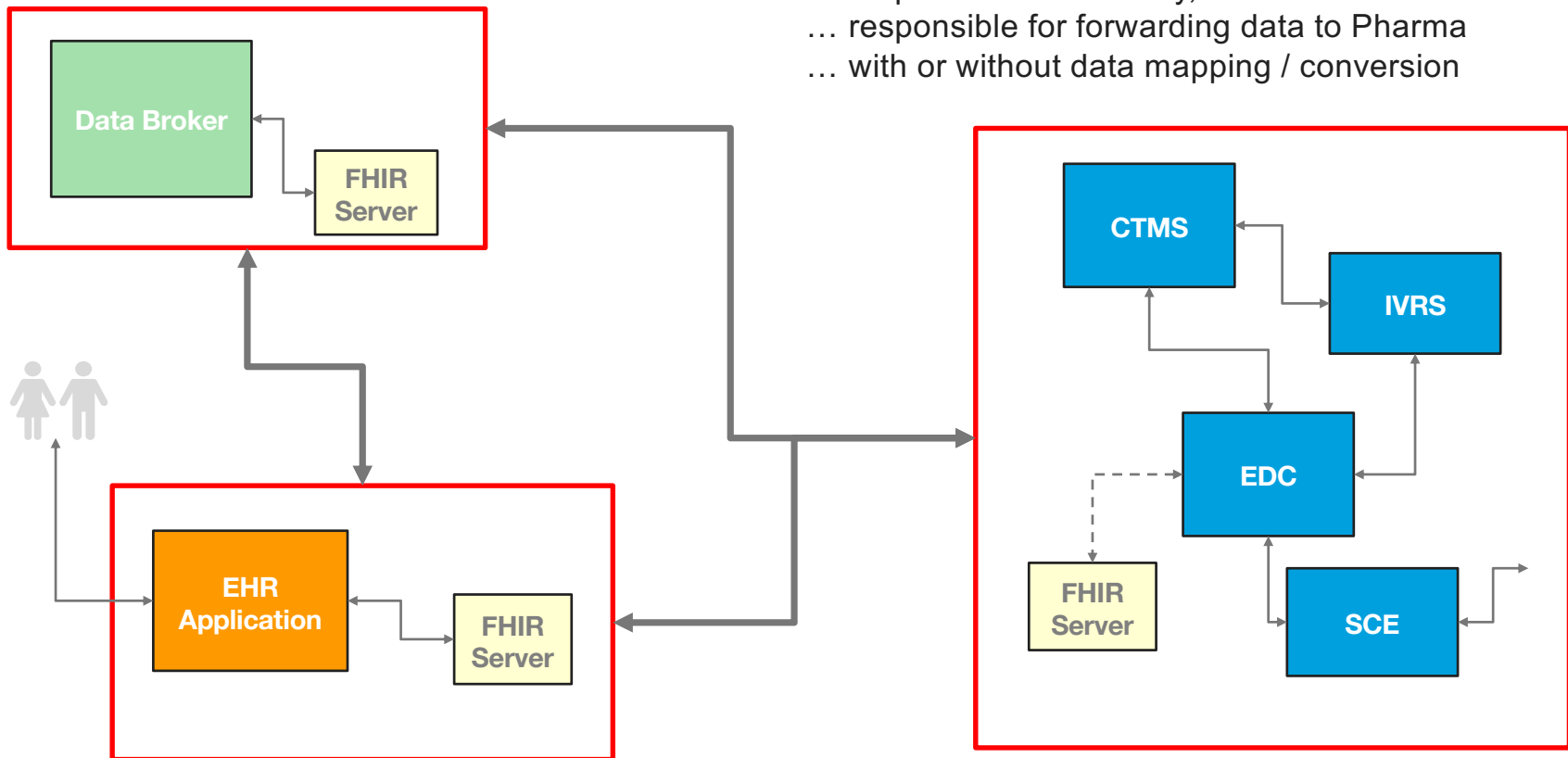
...using FHIR as the interoperability standard



DDE Approach

Technical – via 3rd Party Data Brokers

- ... responsible for establishing data pipeline with sites
- ... responsible for security, authorizations etc.
- ... responsible for forwarding data to Pharma
- ... with or without data mapping / conversion

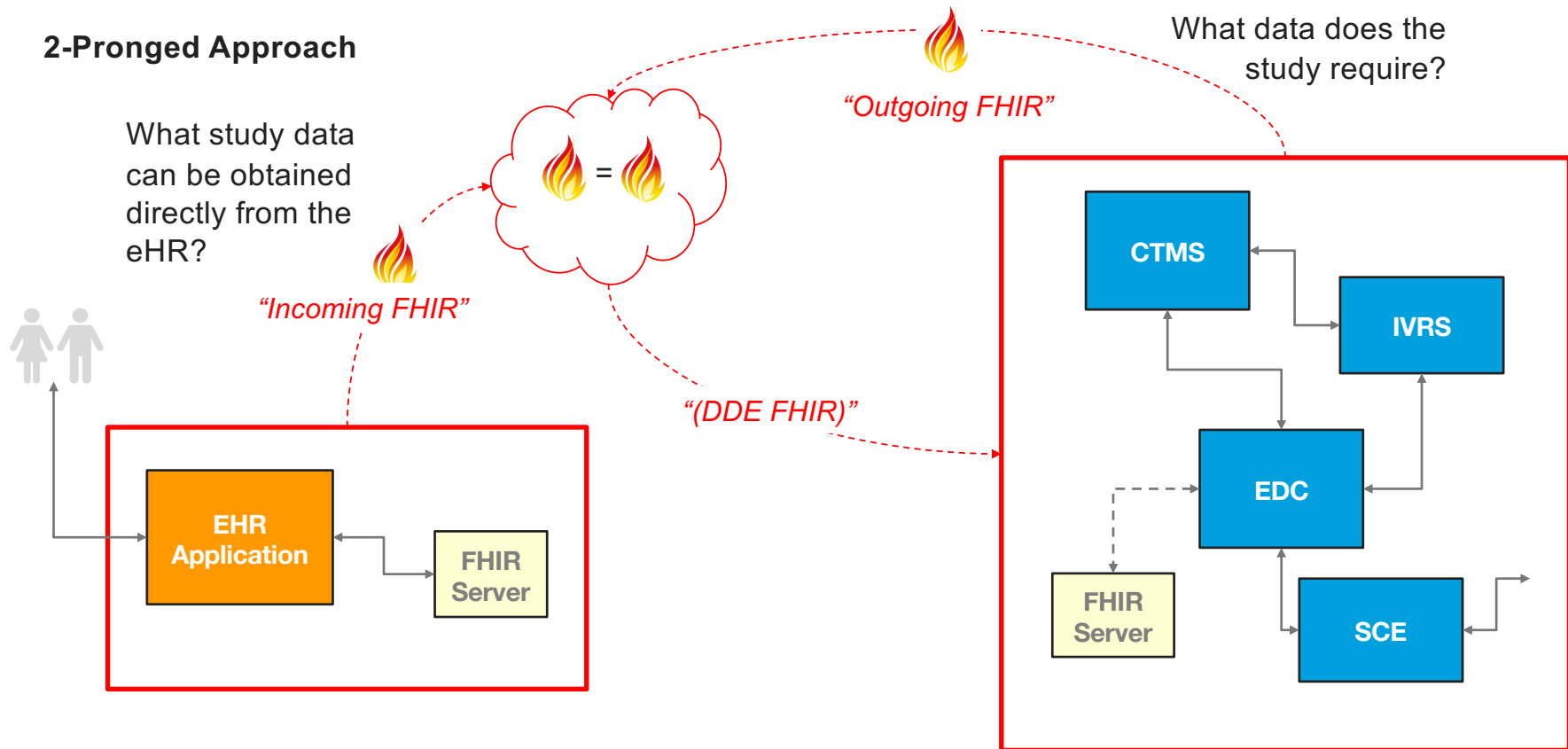


DDE Approach

Direct (Study) Data Capture

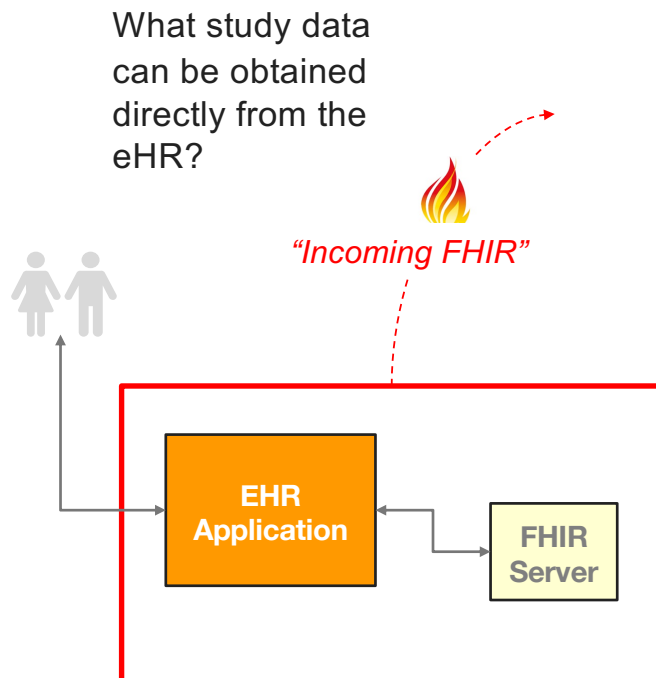
2-Pronged Approach

What study data can be obtained directly from the eHR?



DDE Approach

'Incoming FHIR' – What is available and how from the eHR?



- What Resources are exposed by the eHR API?
- What study data is not available by DDE?
- Does the eHR support research projects?
- Are the eHR / site coding systems and practice compatible with study expectations?
- Work with data brokers and sites to compare and contrast and develop necessary mappings and/or conversions

DDE Approach

‘Outgoing FHIR’ – Describing Studies using FHIR Resources

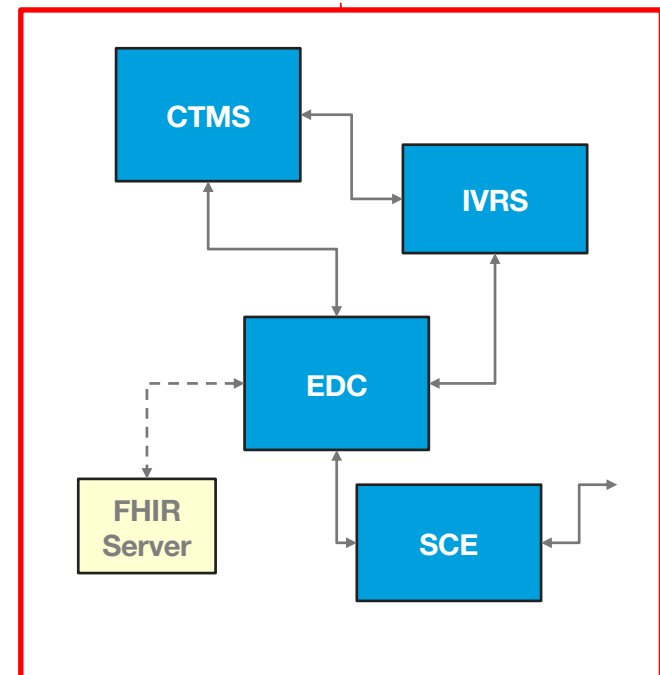
2 tracks...

External / Industry Initiatives

- HL7 Vulcan Projects – RWD, SoA, Adverse Event...
 - Contributing to the development of common approaches and methods using FHIR Resources

Internal / Study Focused

- Global FHIR-specified eCRF Library
 - Evolution – as part of current practice and system
 - Revolution – as a key component of future practice
- Creation of synthetic study subject data as FHIR Resources



FHIR® Specified eCRF

Form VS - Vital Signs HorizontalGeneric			
1.1	Were vital signs performed?	<input type="radio"/> No <input type="radio"/> Yes	VSPERF
1.2	Date (DD-MMM-YYYY)	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>	VSDAT
2 Vital Signs Details			
2.1	Systolic Blood Pressure	<div> <div></div> <div></div> <div></div> </div>	SYSBP_VSORRES
2.2	Systolic Blood Pressure Unit	<div> <div></div> <div></div> </div> mmHg	SYSBP_VSORRESU
2.3	Diastolic Blood Pressure	<div> <div></div> <div></div> <div></div> </div>	DIABP_VSORRES
2.4	Diastolic Blood Pressure Unit	<div> <div></div> <div></div> </div> mmHg	DIABP_VSORRESU
2.5	Blood Pressure Position	<input type="radio"/> (PRONE) Prone <input type="radio"/> (SEMI-RECUMBENT) Semi-Recumbent <input type="radio"/> (SITTING) Sitting <input type="radio"/> (STANDING) Standing <input type="radio"/> (SUPINE) Supine	BP_VSPOS
2.6	Blood Pressure Location	<input type="radio"/> (BRACHIAL ARTERY) Brachial Artery <input type="radio"/> (FINGER) Finger <input type="radio"/> (PERIPHERAL ARTERY) Peripheral Artery <input type="radio"/> (RADIAL ARTERY) Radial Artery	BP_VSLOC
2.7	Height		HEIGHT_VSORRES
2.8	Height Unit	<input type="radio"/> (CM) Centimeter <input type="radio"/> (IN) Inch	HEIGHT_VSORRESU
2.9	Weight		WEIGHT_VSORRES
2.10	Weight Unit	<input type="radio"/> (KG) Kilogram <input type="radio"/> (LB) Pound	WEIGHT_VSORRESU

VS aCRF

Towards a Global eCRF FHIR Library

Name	Flags	Card.	Type	Description & Constraints
Observation	1 [N]		DomainResource	Measurements and simple assertions + Rule: dataAbsentReason SHALL only be present if Observation.value[x] is not present + Rule: If Observation.code is the same as an Observation.component.code then the value element associated with the code SHALL NOT be present read the full specification
Identifier	1	0..*	Identifier	Business Identifier for observation
basedOn	1	0..*	Reference(CarePlan DeviceRequest ImmunizationRecommendation MedicationRequest NutritionOrder ServiceRequest)	Fulfills plan, proposal or order
partOf	1	0..*	Reference(MedicationAdministration MedicationDispense Procedure Immunization ImagingStudy)	Part of referenced event
status	1	1..1	code	registered preliminary final amended + ObservationStatus (terminology)
category	1	0..*	CodeableConcept	Classification of type of observation Observation Category Codes (Preferred) Observation Codes (Examples)
code	1	1..1	CodeableConcept	Type of observation (code / type)
subject	1	0..1	Reference(Patient Group Device Location)	Who and/or what the observation is about
focus	1 [TU]	0..*	Reference(Any)	What the observation is about, when it is not about the subject of record
encounter	1	0..1	Reference(Encounter)	Healthcare event during which this observation is made
effective[x]	1	0..1		Clinically relevant time/time-period for observation
effectiveDateTime			dateTime	
effectivePeriod			Period	
effectiveTiming			Timing	
effectiveInstant			instant	
issued	1	0..1	instant	Date/Time this version was made available
performer	1	0..*	Reference(Practitioner PractitionerRole Organization CareTeam Patient RelatedPerson)	Who is responsible for the observation
value[x]	1	0..1		Actual result
valueQuantity			Quantity	
valueCodeableConcept			CodeableConcept	
valueString			string	
valueBoolean			boolean	
valueInteger			integer	
valueRange			Range	

LOINC codes
Height: 8308-9
Weight: 29463-7

10.1 Resource Observation

Minimum Observation requirement

- status
- code

FHIR® Specified eCRF

FSH - FHIR Shorthand – for fs-eCRF Development

```
// FormOID [VS] FieldOID [HEIGHT] to fs-eCRF [vs-gl-height-v00] //

Instance: vs-gl-900-height-v00
InstanceOf: Observation
Usage: #example

* status = #registered

// Coding //
* code.text = "HEIGHT"
* code.coding[+].code = #8308-9
* code.coding[=].system = "http://loinc.org"
* code.coding[=].display = "Height"

// FormOID [VS] FieldOID [WEIGHT] to fs-eCRF [vs-gl-weight-v00] //

Instance: vs-gl-900-weight-v00
InstanceOf: Observation
Usage: #example

* status = #registered

// Coding //
* code.text = "WEIGHT"
* code.coding[+].code = #29463-7
* code.coding[=].system = "http://loinc.org"
* code.coding[=].display = "Weight"
```

Form-VS.fsh

Definition and Review using FSH

sushi

```
{
  "resourceType": "Observation",
  "id": "vs-gl-height-v00",
  "status": "registered",
  "code": {
    "text": "HEIGHT",
    "coding": [
      {
        "code": "8308-9",
        "system": "http://loinc.org",
        "display": "Height"
      }
    ]
  }
}
```

Observation-vs-height.json

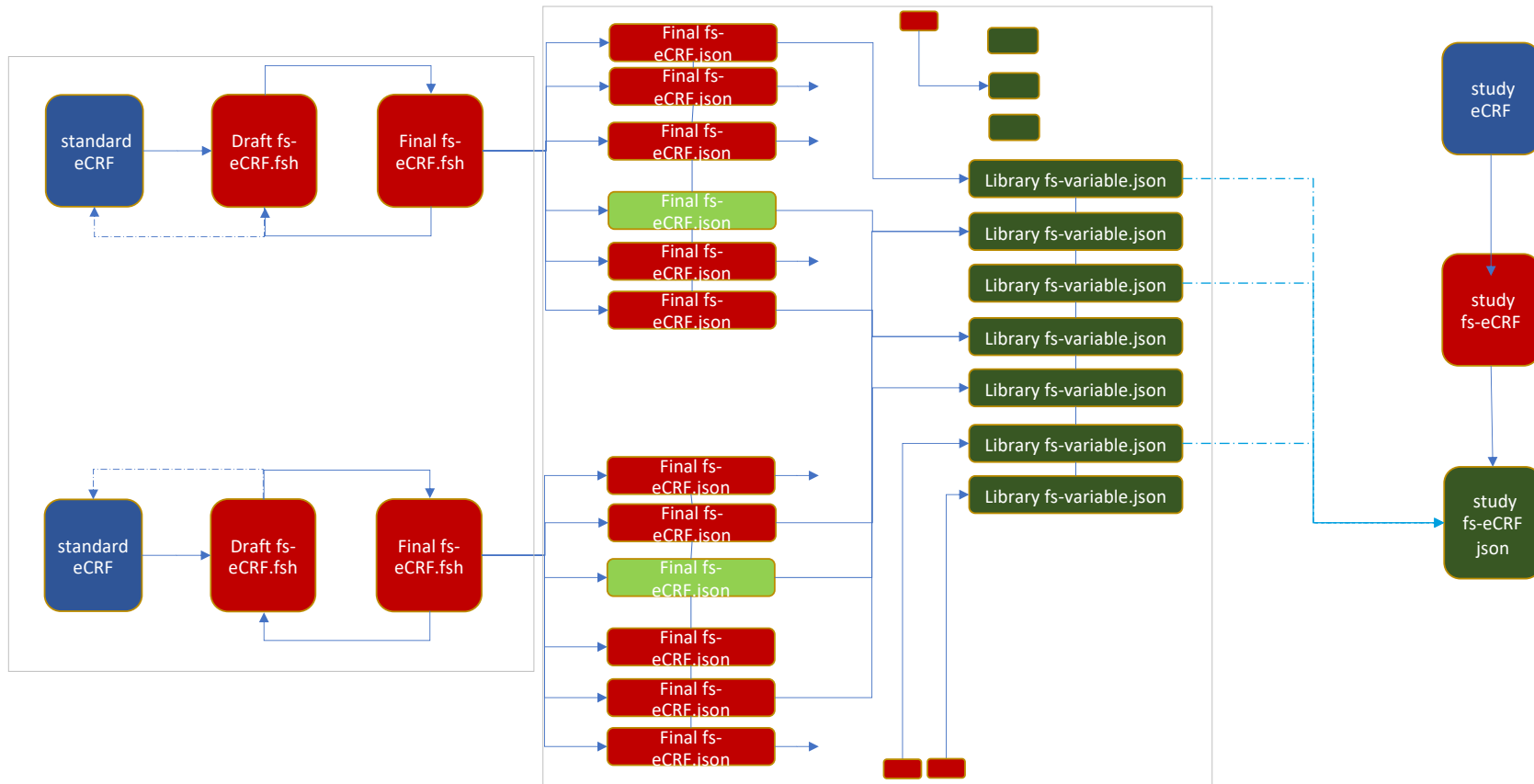
goFsh

```
{
  "resourceType": "Observation",
  "id": "vs-weight-v00",
  "status": "registered",
  "code": {
    "text": "WEIGHT",
    "coding": [
      {
        "code": "29463-7",
        "system": "http://loinc.org",
        "display": "Weight"
      }
    ]
  }
}
```

Observation-vs-weight.json

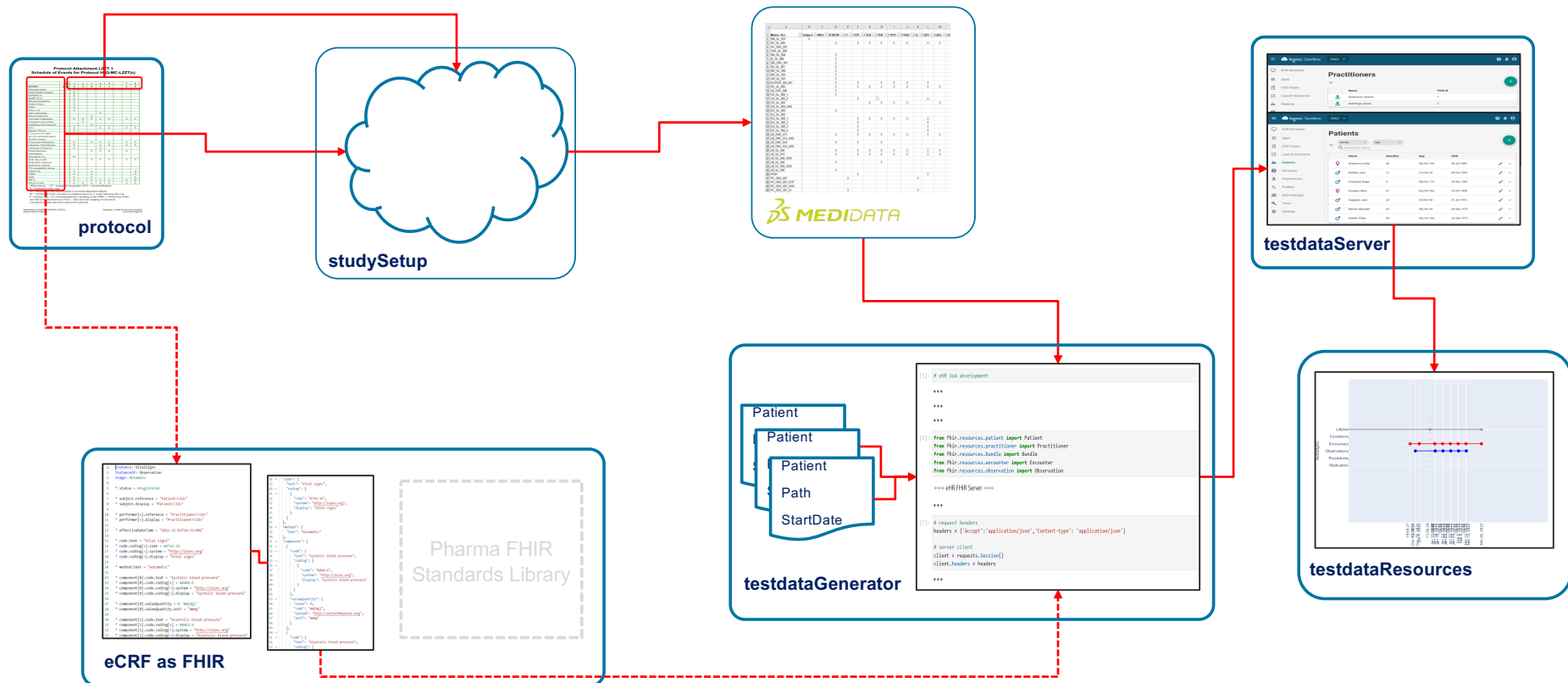
FHIR Resources as JSON

Building a library of FHIR® Specified eCRF



FHIR® Specified eCRF Test Data

Current Operational Approach



FHIR® Specified eCRF Test Data

Study Test Data with Sponsor's Informational Mapping and Coding Details

```
// FormOID [VS_GL_900] FieldOID [HEIGHT] to fs-eCRF [vs-gl-900-height-v00] //
Instance: vs-height-v00
InstanceOf: Observation
Usage: #example

* status = #registered

// Patient ID - Research Subject ID //
* subject = Reference(Patient/*****)
* identifier[+].type = #researchSubject
* identifier[+].value = "*****"

// Observation DateTime //
* effectiveDateTime = 2022-04-12

// RAVE Mapping //
* identifier[+].type = #raveStudy
* identifier[+].value = "*****"
* identifier[+].type = #raveFolder
* identifier[+].value = "*****"
* identifier[+].type = #raveFormOID
* identifier[+].value = "VS_001"
* identifier[+].type = #raveFieldOID
* identifier[+].value = "HEIGHT"

// Pharma Preferred Coding Options //
* component[+].code.coding.code = #8302-2
* component[+].code.coding.system = "http://pharma.com"
* component[+].code.text = "{ 'FieldOID': 'HEIGHT', 'CODE': '8302-2', 'DICTID': 'VS', 'DICTCODE': '50059', 'ORRESU': 'cm' }"
* component[+].valueQuantity.unit = "cm"
* component[+].code.coding.code = #8302-2
* component[+].code.coding.system = "http://pharma.com"
* component[+].code.text = "{ 'FieldOID': 'HEIGHT', 'CODE': '8302-2', 'DICTID': 'VS', 'DICTCODE': '50059', 'ORRESU': 'in' }"
* component[+].valueQuantity.unit = "in"
* component[+].code.coding.code = #8308-9
* component[+].code.coding.system = "http://pharma.com"
* component[+].code.text = "{ 'FieldOID': 'HEIGHT', 'CODE': '8308-9', 'DICTID': 'VS', 'DICTCODE': '50060', 'ORRESU': 'cm' }"
* component[+].valueQuantity.unit = "cm"
* component[+].code.coding.code = #8308-9
* component[+].code.coding.system = "http://pharm.com"
* component[+].code.text = "{ 'FieldOID': 'HEIGHT', 'CODE': '8308-9', 'DICTID': 'VS', 'DICTCODE': '50060', 'ORRESU': 'in' }"
* component[+].valueQuantity.unit = "in"

// Test Data Coding //
* code.text = "HEIGHT"
* code.coding[+].code = #8308-9
* code.coding[+].system = "http://loinc.org"
* code.coding[+].display = "Height"

// Test Data Value //
* valueQuantity.value = 175.0
* valueQuantity.unit = "cm"
```

Observation Instance [height]

Patient/Research Subject details

'Visit' date

Target eDC mappings

Pharma dictionary preferred coding (.... To SDTM, etc.)

Test Data Coding

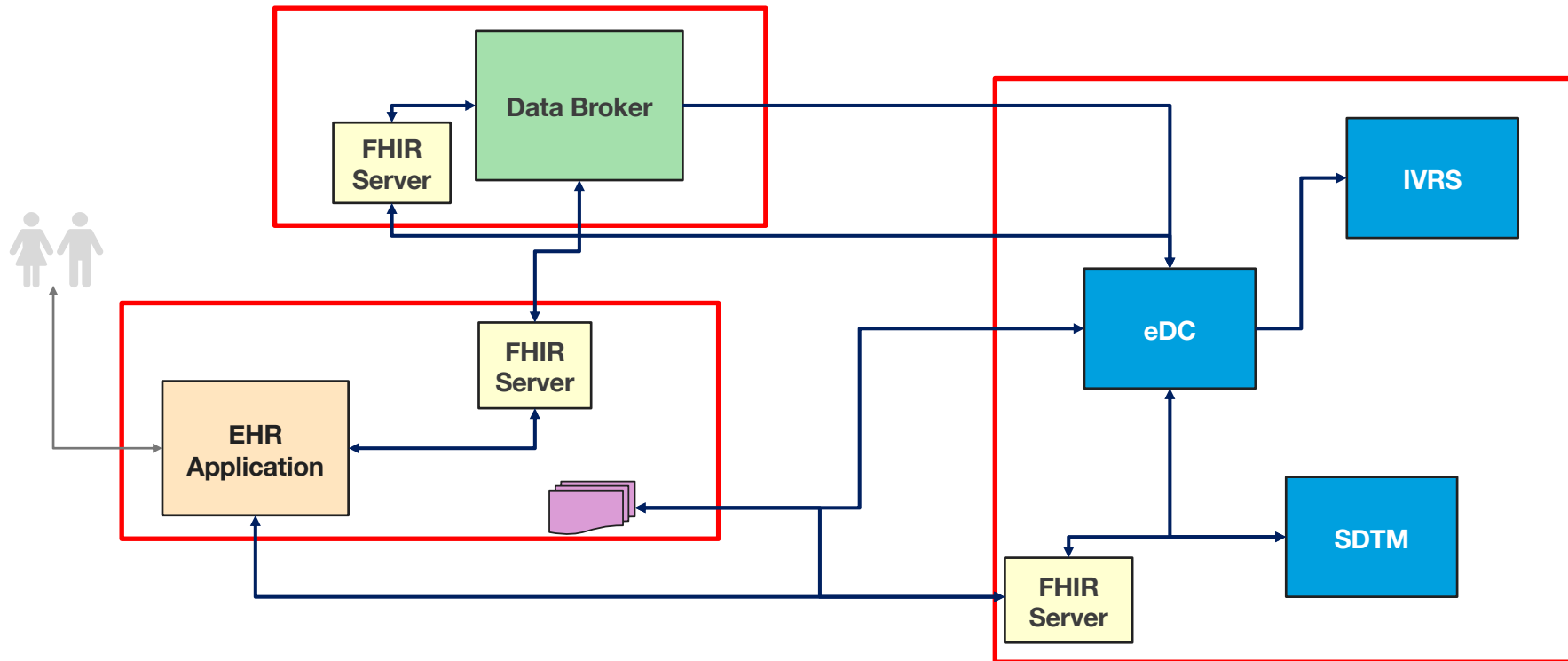
Test Data

```
// Test Data Value //
* valueQuantity.value = 175.0
* valueQuantity.unit = "cm"
```



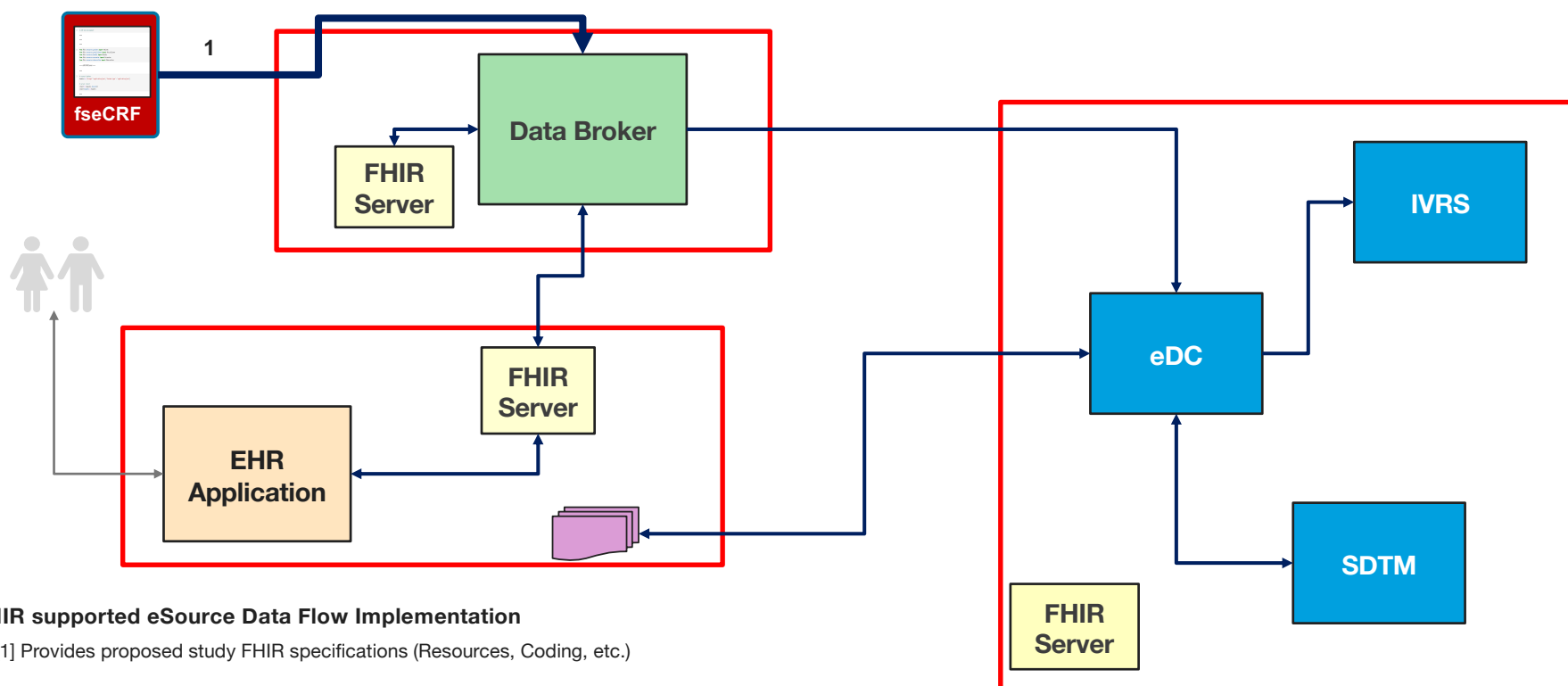
FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data



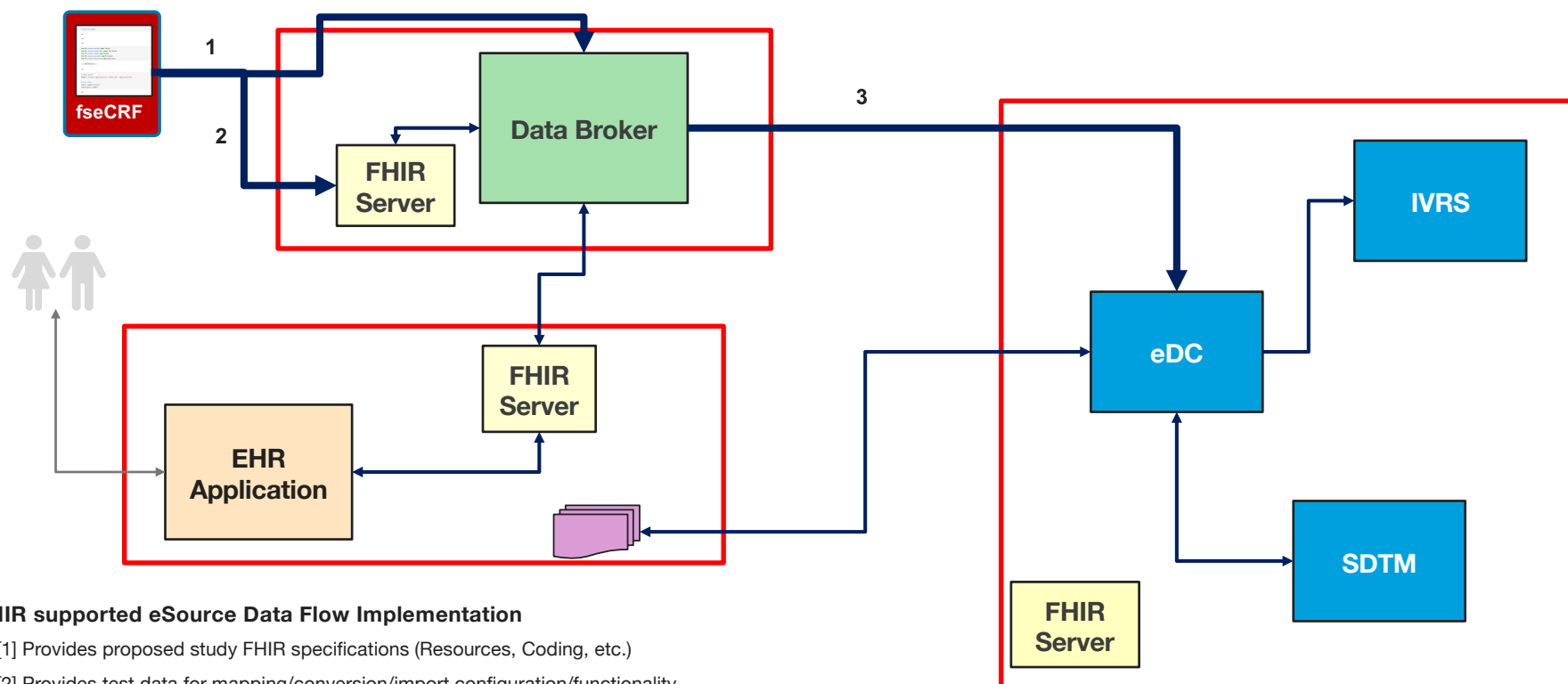
FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data



FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data

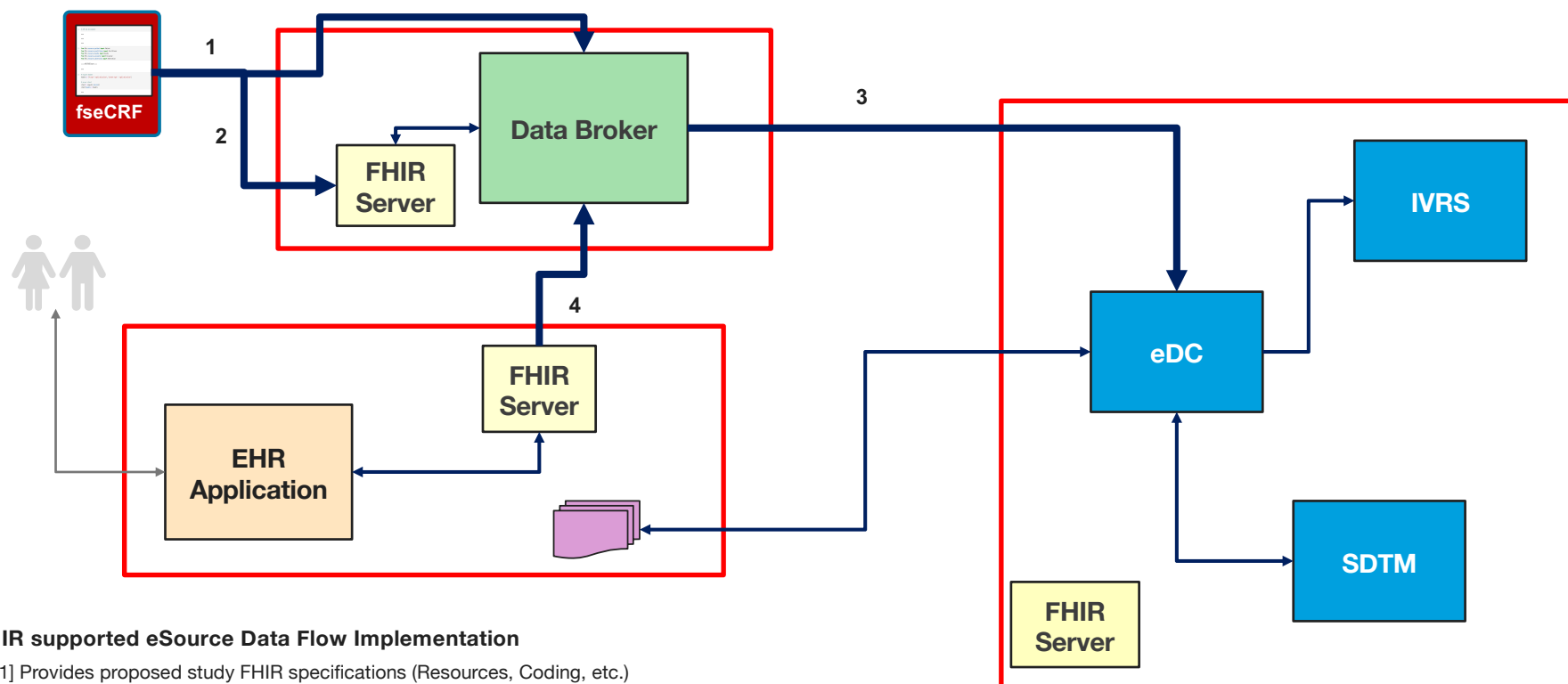


FHIR supported eSource Data Flow Implementation

- [1] Provides proposed study FHIR specifications (Resources, Coding, etc.)
- [2] Provides test data for mapping/conversion/import configuration/functionality
- [3] Provides study compliant test data for data broker to eDC data exchange

FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data

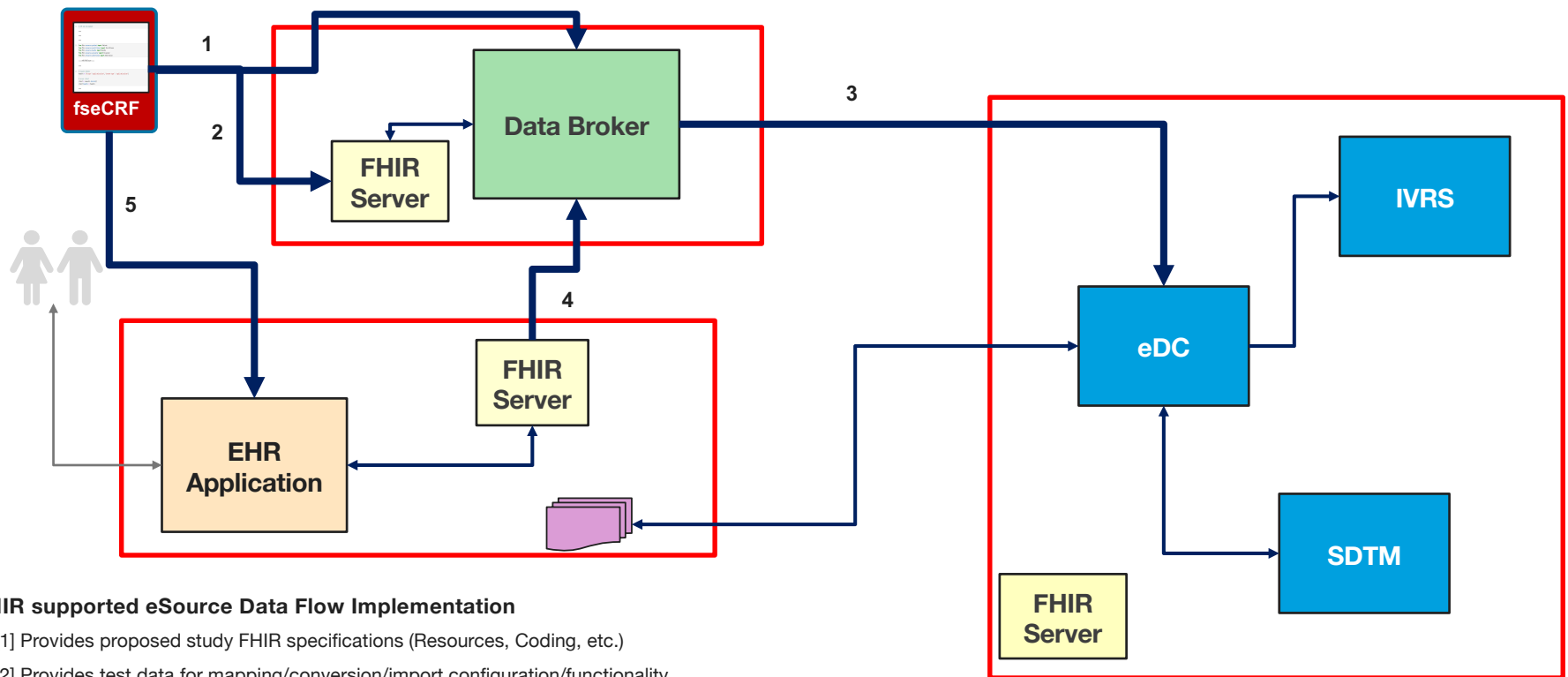


FHIR supported eSource Data Flow Implementation

- [1] Provides proposed study FHIR specifications (Resources, Coding, etc.)
- [2] Provides test data for mapping/conversion/import configuration/functionality
- [3] Provides study compliant test data for data broker to eDC data exchange
- [4] Provides initial FHIR data exchange specification for required study data

FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data

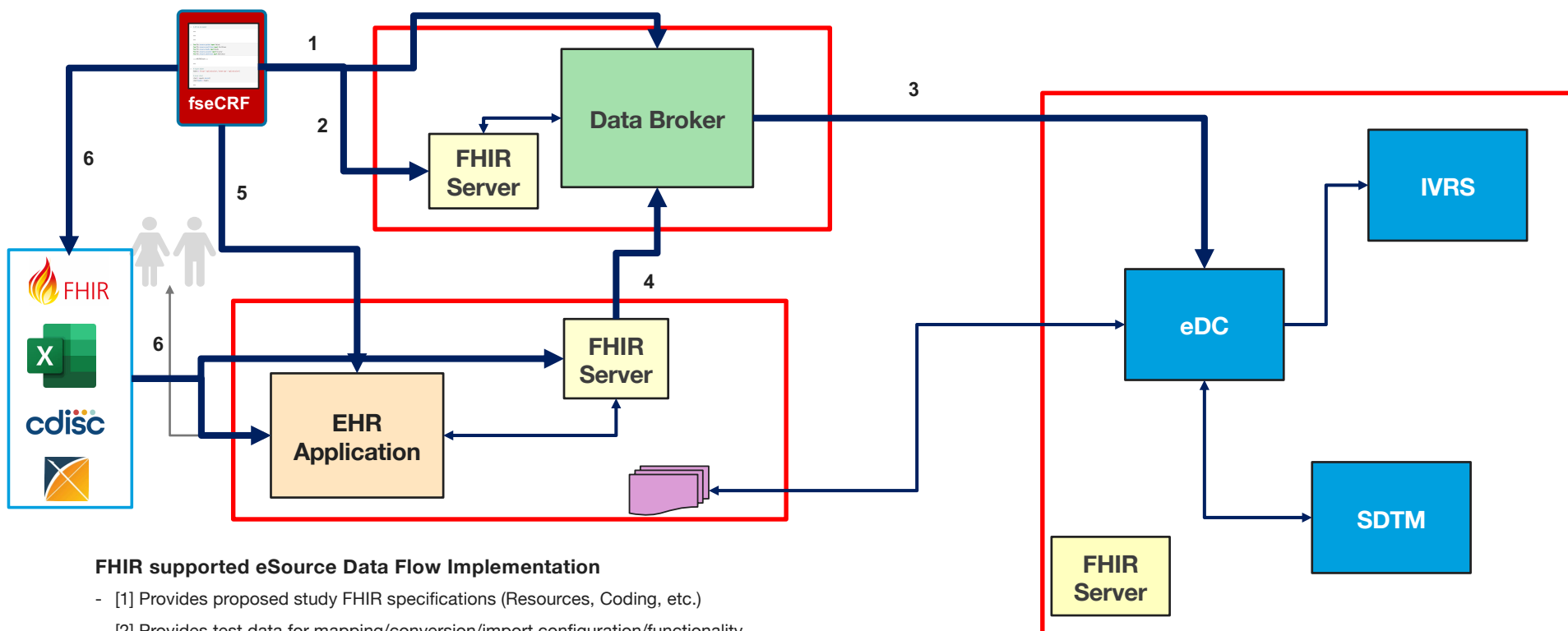


FHIR supported eSource Data Flow Implementation

- [1] Provides proposed study FHIR specifications (Resources, Coding, etc.)
- [2] Provides test data for mapping/conversion/import configuration/functionality
- [3] Provides study compliant test data for data broker to eDC data exchange
- [4] Provides initial FHIR data exchange specification for required study data
- [5] Provides proposed study FHIR specifications (Resources, Coding, etc.)

FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data



FHIR supported eSource Data Flow Implementation

- [1] Provides proposed study FHIR specifications (Resources, Coding, etc.)
- [2] Provides test data for mapping/conversion/import configuration/functionality
- [3] Provides study compliant test data for data broker to eDC data exchange
- [4] Provides initial FHIR data exchange specification for required study data
- [5] Provides proposed study FHIR specifications (Resources, Coding, etc.)
- [6] Provides proposed study specifications/test data for EHR exposure as FHIR Resources

Direct Data Exchange (DDE) with EHR

FHIR® (very) Quick Introduction

The Triple DDE Challenge

The Implementation Challenge

What's going on in the industry?

Vulcan: HL7 FHIR Accelerator Program



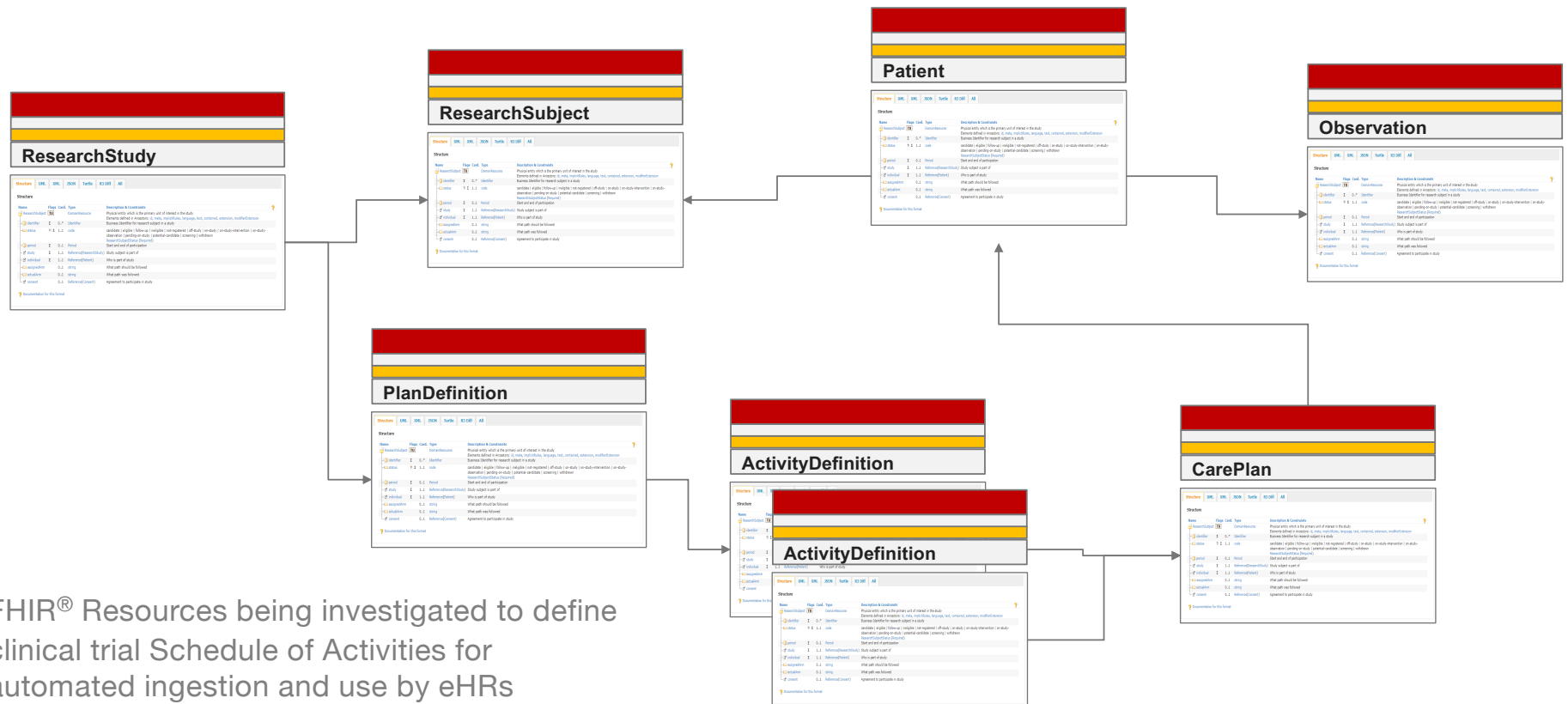
- The vision for an Accelerator dedicated to connecting clinical research and healthcare
- Vulcan brings together stakeholders across the translational and clinical research community in order to bridge existing gaps between clinical care and clinical research, strategically connect industry collaboratives, maximize collective resources, and deliver integrated tools and resources.

Vulcan Active Projects

Project	Description
Real World Data	Utilizing EHR source data to directly populate clinical research data capture systems wherever feasible would save cost and time. The July 2018 FDA guidance Use of Electronic Health Record Data in Clinical Investigations encourages this and there is a clear need to develop HL7 FHIR capabilities to fulfill this requirement.
Schedule of Activities	Adoption of a FHIR based representation of the Schedule of Activities in a study will introduce consistency, avoid repeated data entry and enable automation.
Phenopackets	Phenopackets is a standard for exchanging phenotype data to support de-identified case level patient information that can be shared broadly and used in a wide variety of settings, such as EHRs, Journals, Clinical Labs, Patient Registries, and Knowledge bases.
Electronic Product Information	The current objective of this project is to create a new digital platform that gives patients a more accessible way of acquiring trusted medicinal product Information. This will be done by combining information from the International Patient Summary (IPS) document, a selected list of medication list with ePIs for each medication and the associated medicationproductdefinition resources.
Adverse Events	This use case investigates the feasibility of utilizing the EHR as a mechanism for recording and reporting Adverse Events that occur during a clinical trial. Use of the EHR would provide a common, consistent source for sponsors and regulators.
FHIR to OMOP	This project support the development of FHIR to OMOP data transfer for better analysis of clinical data for research.

FHIR® – Vulcan SoA Project

Example: SoA Implementation Guide



FHIR® Resources being investigated to define clinical trial Schedule of Activities for automated ingestion and use by eHRs