Direct Data Exchange (DDE) with EHR

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June 2022

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 <u>Resource</u> ~ standard definition as metadata.
  - The <u>Capability Statement</u> documents the actual FHIR server functionality ~ what data is exposed with what version
  - <u>Profiles</u> and <u>Implementation Guides</u> 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

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

FHIR® Resources example

Patient

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		

Resource Formats

Element Name

Cardinality

Type

Description and Constraints

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

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What's going on in the industry?

Data fit-for-purpose.

Patient Timeline

Patient in Clinical Care

DOB

Appointment 1

Treatment Plan

Treatment Start

Study Feasibility Assessment

Routine Therapy Appointment

Pharma Timeline

Patient Record
eHR

Clinical Care Event   Research Event (Planned)   Research Event (Unplanned)   Completed   Scheduled

Patient enrolled in a Clinical Study

Patient Timeline

Pharma Timeline

DOB
Appointment 1
Treatment Plan
Treatment Start
Study Feasibility Assessment
First Study Visit
Study Visit
Routine Therapy Appointment
Study Visit
Study Visit
Last Study Visit

Patient Record
eHR

eDC

Clinical Care Event   Research Event (Planned)   Research Event (Unplanned)   Completed   Scheduled

9

Patient completed the clinical study

Patient Timeline

Pharma Timeline

DOB

Appointment 1

Treatment Plan

Treatment Start

Study Feasibility Assessment

First Study Visit

Study Visit

Study Visit

Routine Therapy Appointment

Study Visit

Study Visit

Routine Therapy Appointment

Study Visit

Last Study Visit

Routine Therapy Appointment

Study Follow Up Visit

Patient Record

eHR

eDC

Challenge 2

Clinical Care Event   Research Event (Planned)   Research Event (Unplanned)   Completed   Scheduled

10

Scalability

Challenge 3

eCRF

Single point solution
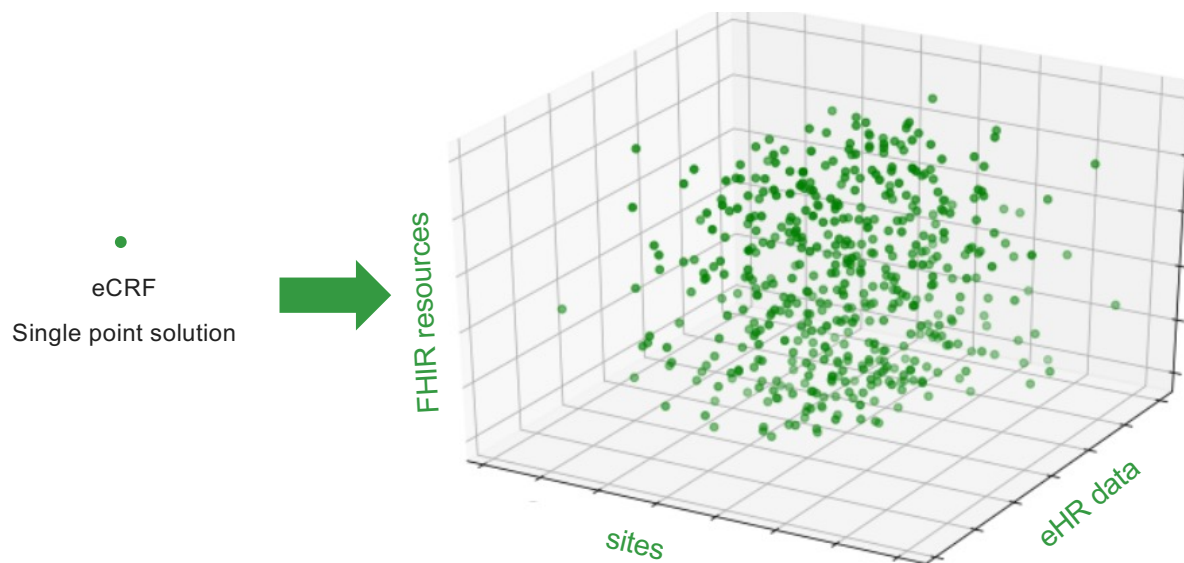
Across sites

- 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?
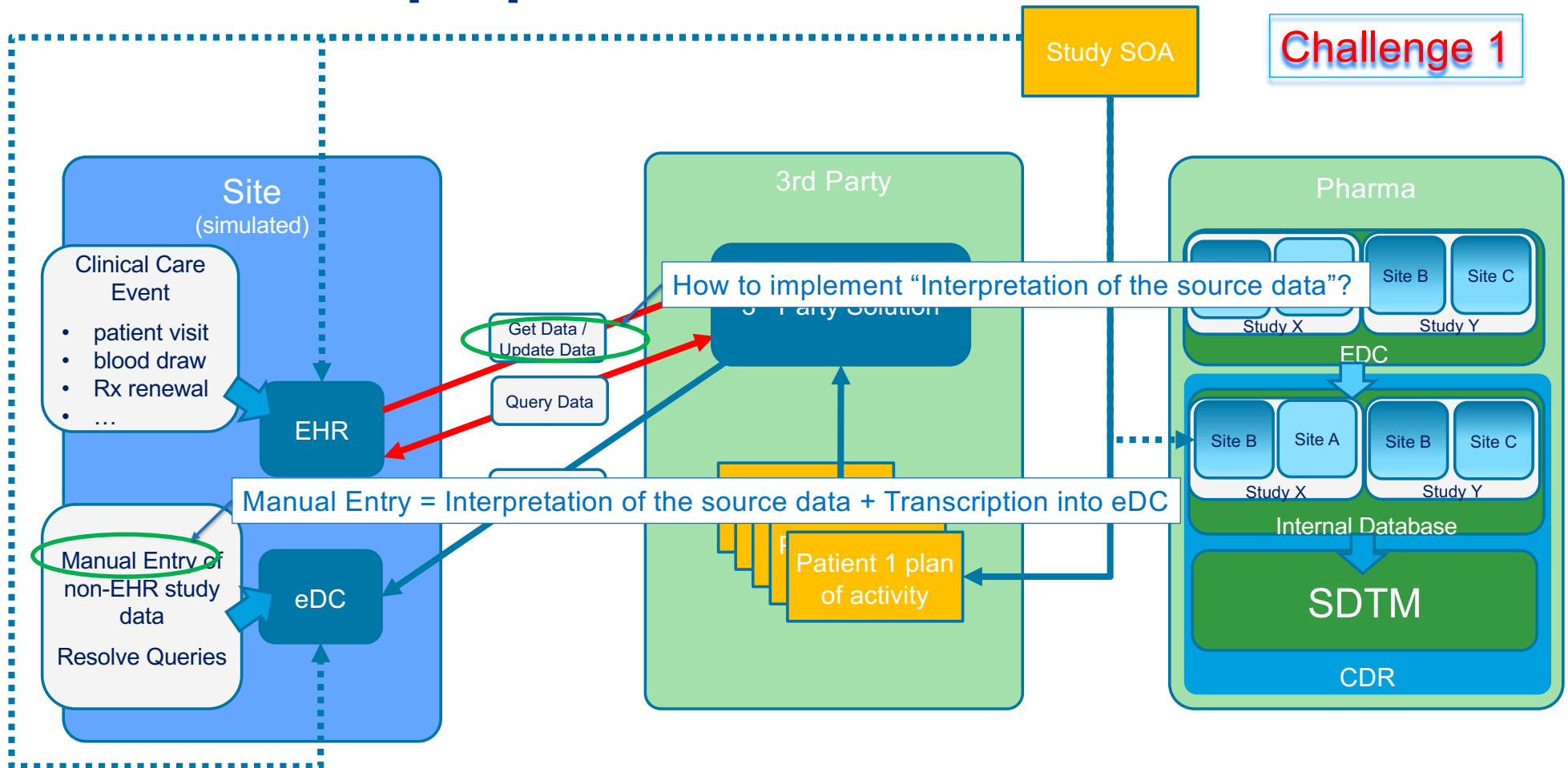
Direct Data Exchange (DDE) with EHR

FHIR® (very) Quick Introduction

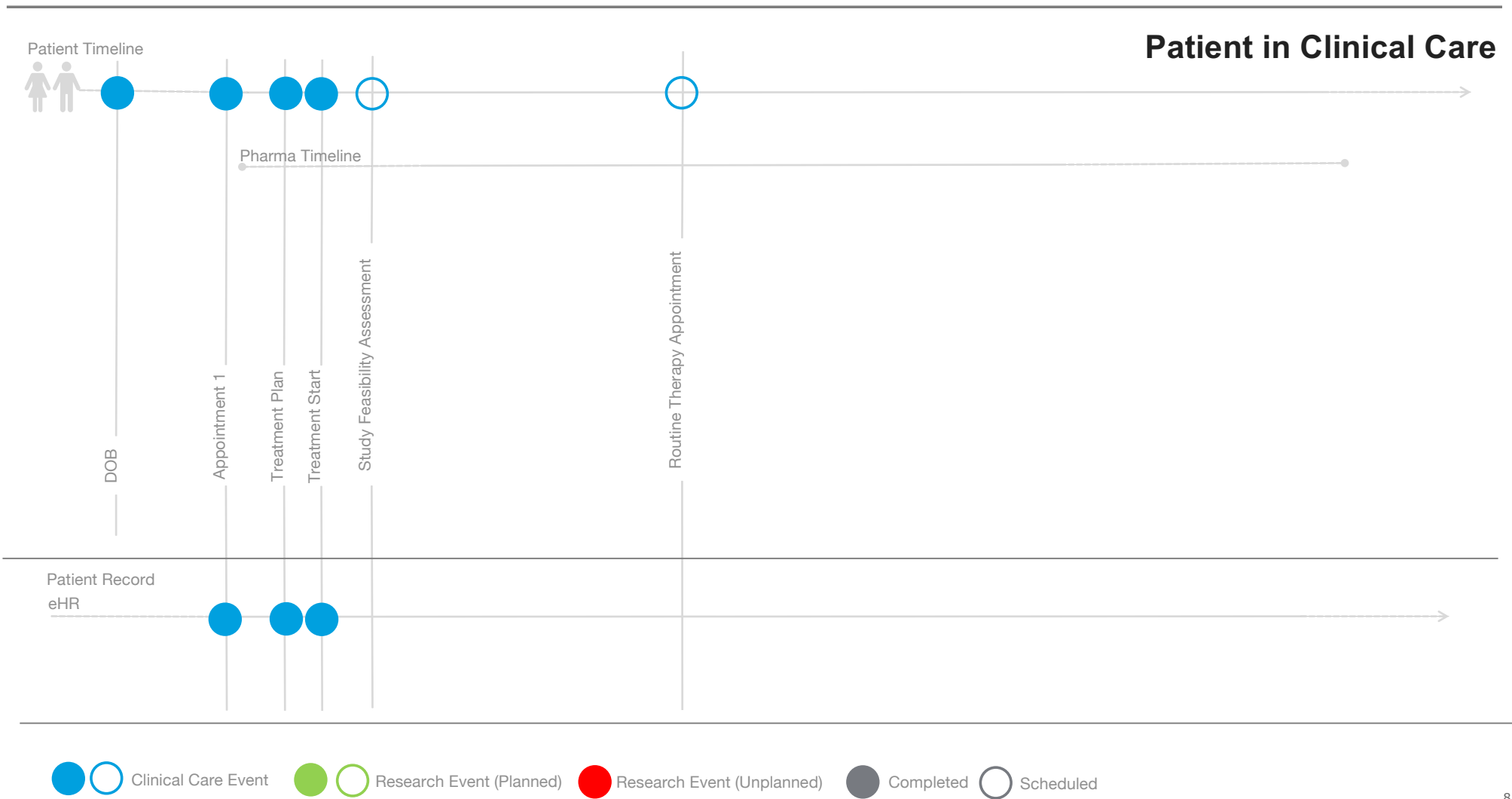
The Triple DDE Challenge

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
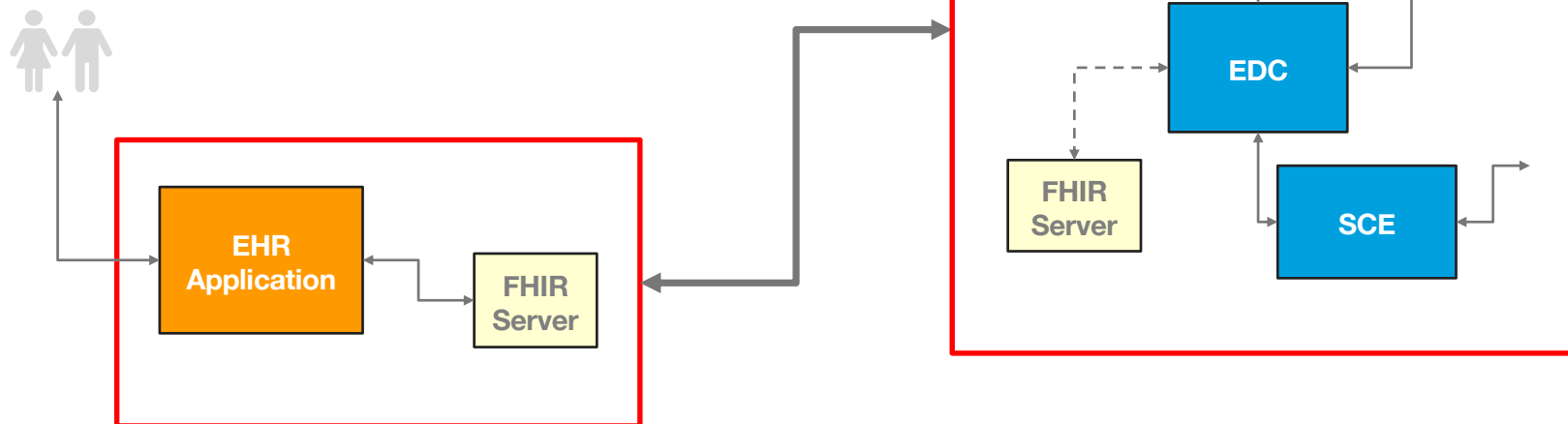
DDE Approach

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
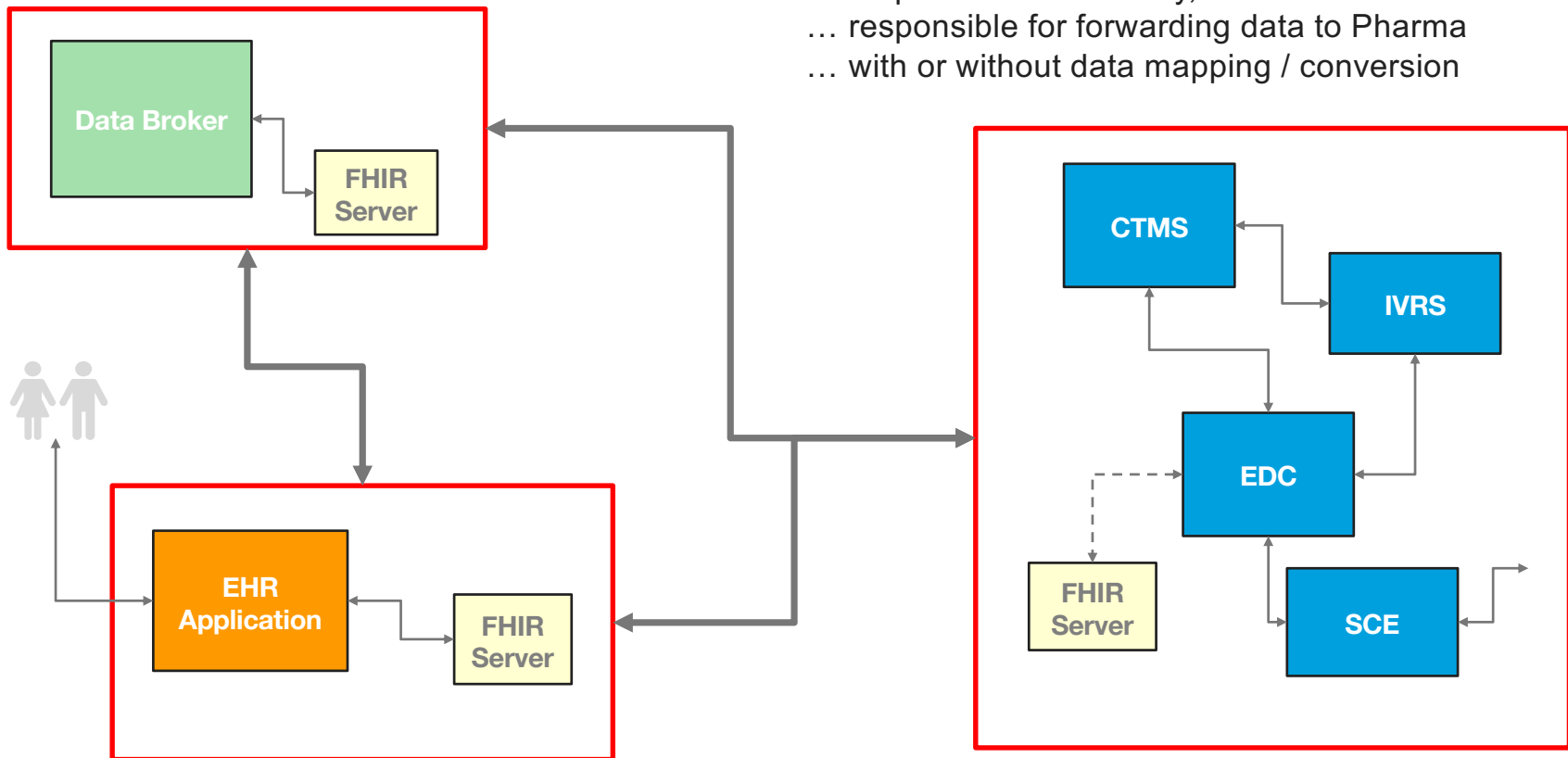
DDE Approach

Direct (Study) Data Capture

2-Pronged Approach

What data does the study require?

What study data can be obtained directly from the eHR?

"Outgoing FHIR"

"Incoming FHIR"

"(DDE FHIR)"
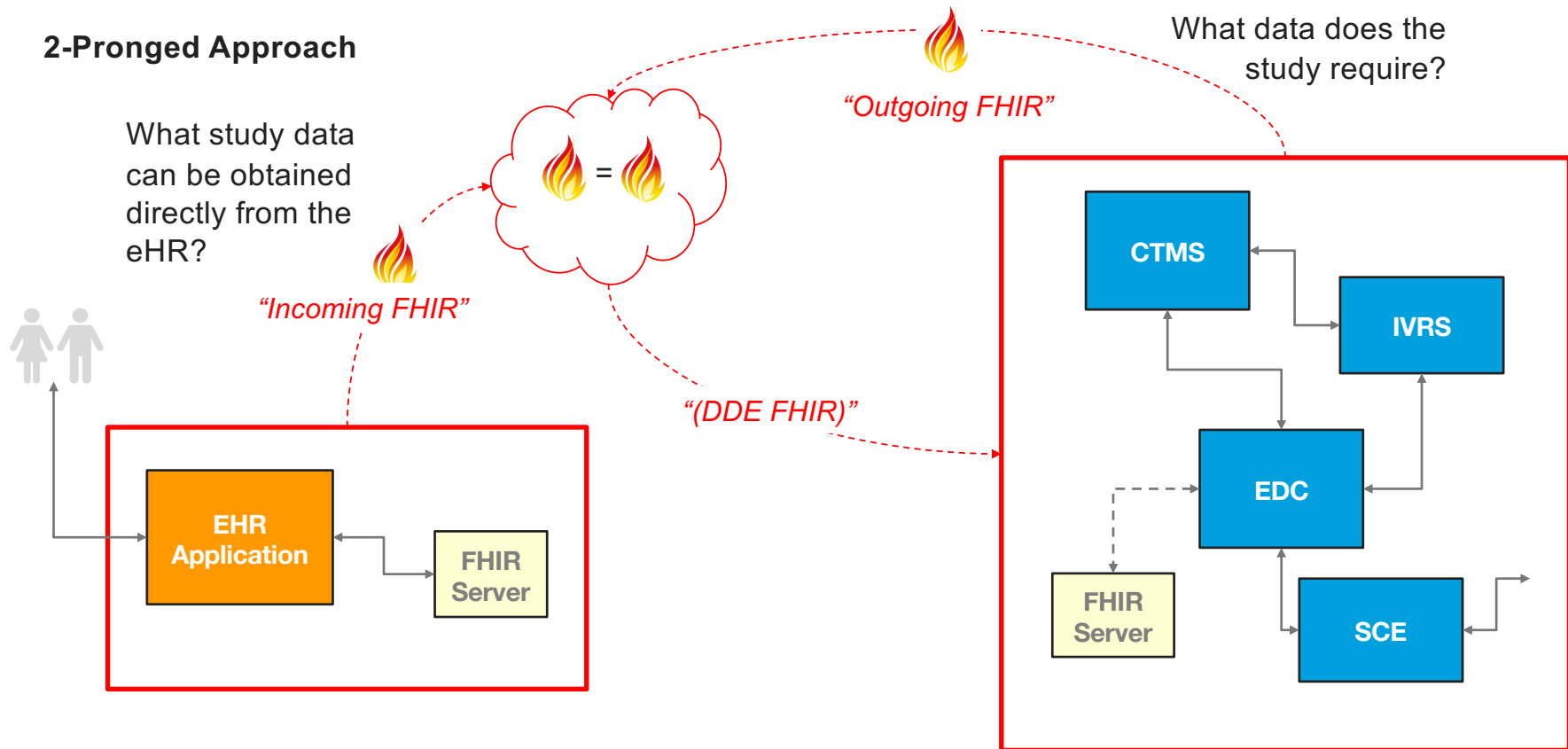
DDE Approach

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

What study data can be obtained directly from the eHR?

"Incoming FHIR"

EHR Application

FHIR Server
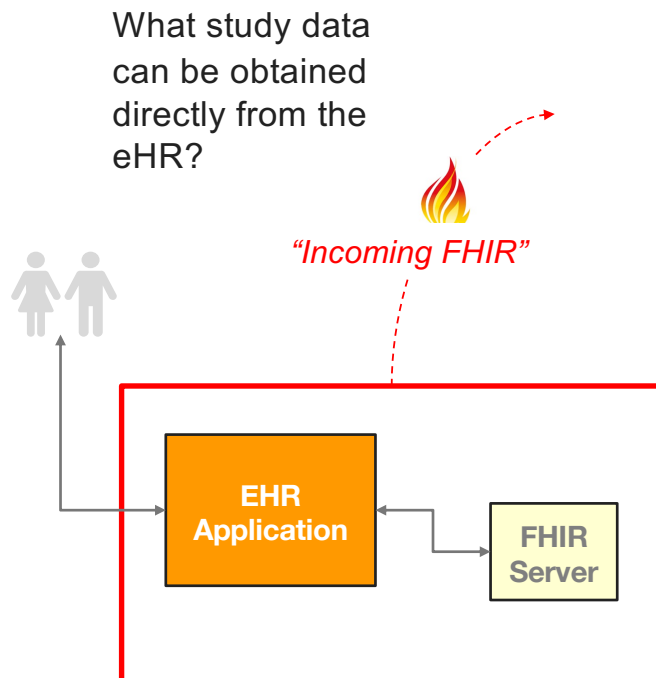
- What Resources are exposed by the eHR API?

- 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

"Outgoing FHIR"

What data does the study require?

CTMS

IVRS

EDC

FHIR Server

SCE

FHIR® Specified eCRF

Towards a Global eCRF FHIR Library
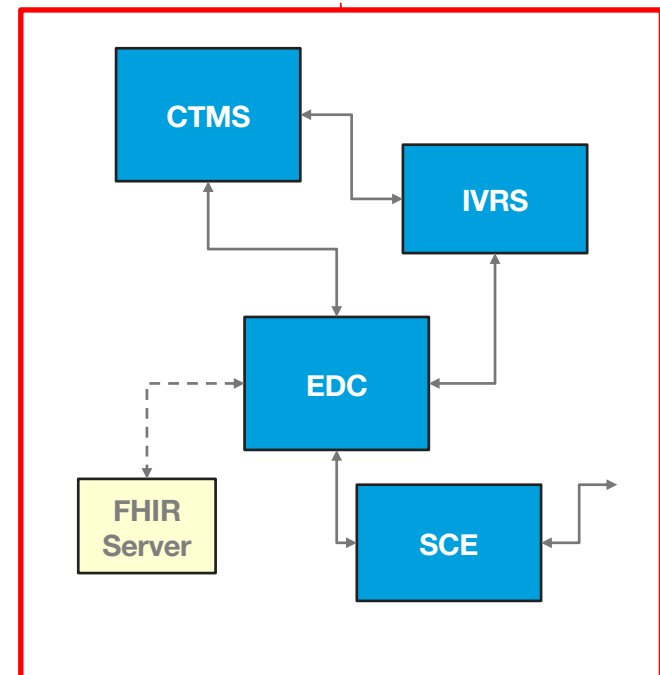
Form VS - Vital Signs HorizontalGeneric			
1.1	Were vital signs performed?	☐ [N] No ☐ [Y] Yes	VSPERF
1.2	Date (DD-MMM-YYYY)		VSDAT
2	**Vital Signs Details**		
2.1	Systolic Blood Pressure		SYSBP_VSORRES
2.2	Systolic Blood Pressure Unit	mmHg	SYSBP_VSORRESU
2.3	Diastolic Blood Pressure		DIABP_VSORRES
2.4	Diastolic Blood Pressure Unit	mmHg	DIABP_VSORRESU
2.5	Blood Pressure Position	☐ [PRONE] Prone ☐ [SEMI-RECUMBENT] Semi-Recumbent ☐ [SITTING] Sitting ☐ [STANDING] Standing ☐ [SUPINE] Supine	BP_VSPOS
2.6	Blood Pressure Location	☐ [BRACHIAL ARTERY] Brachial Artery ☐ [FINGER] Finger ☐ [PERIPHERAL ARTERY] Peripheral Artery ☐ [RADIAL ARTERY] Radial Artery	BP_VSLOC
2.7	Height		HEIGHT_VSORRES
2.8	Height Unit	☐ [cm] Centimeter ☐ [in] Inch	HEIGHT_VSORRESU
2.9	Weight		WEIGHT_VSORRES
2.10	Weight Unit	☐ [kg] Kilogram ☐ [LB] Pound	WEIGHT_VSORRESU

VS aCRF

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

goFsh

```
{
  "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

```
{
  "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
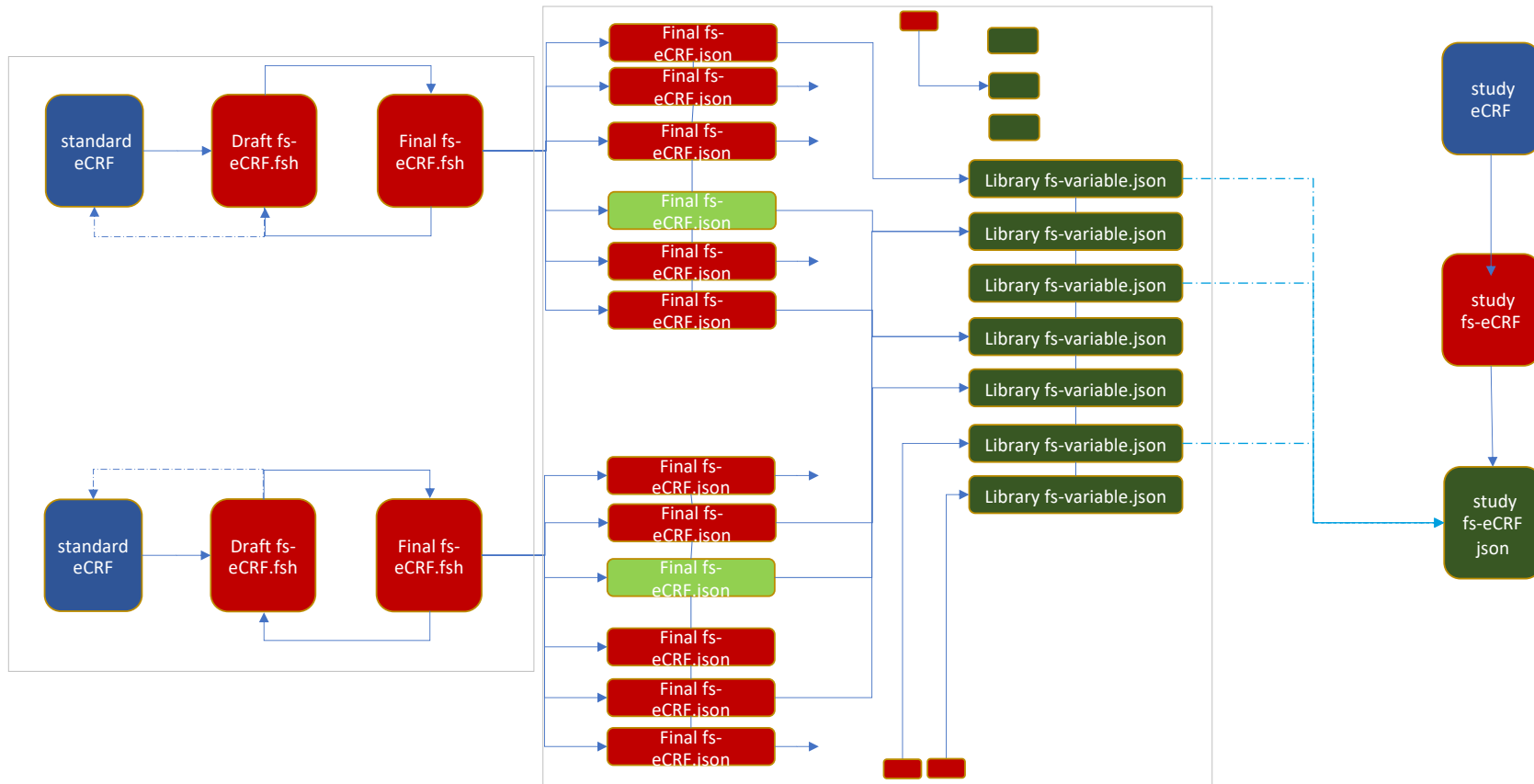
FHIR® Specified eCRF Test Data

Current Operational Approach

protocol

studySetup

testdataServer

eCRF as FHIR

Pharma FHIR Standards Library

testdataGenerator

testdataResources

Patient
Patient
Patient
Path
StartDate

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"
```
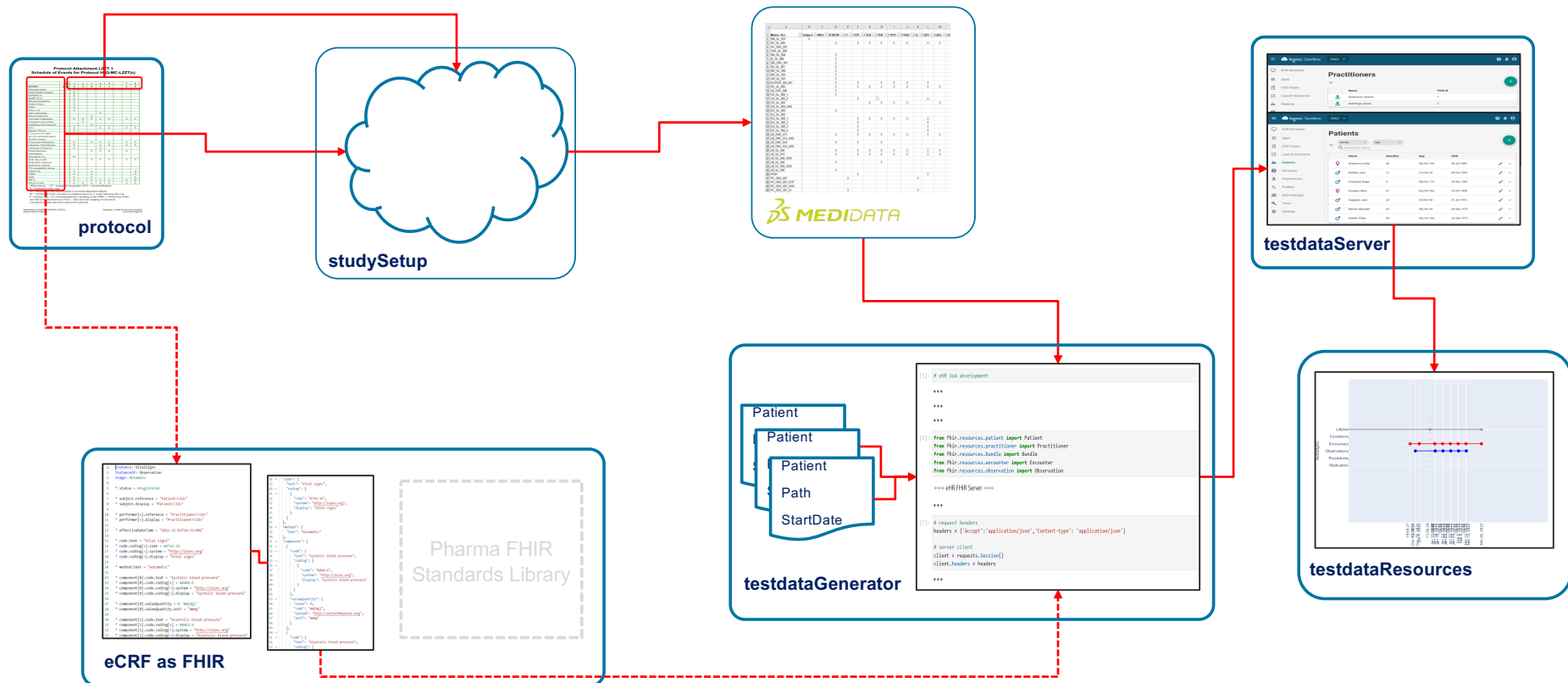
Observation Instance [height]

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
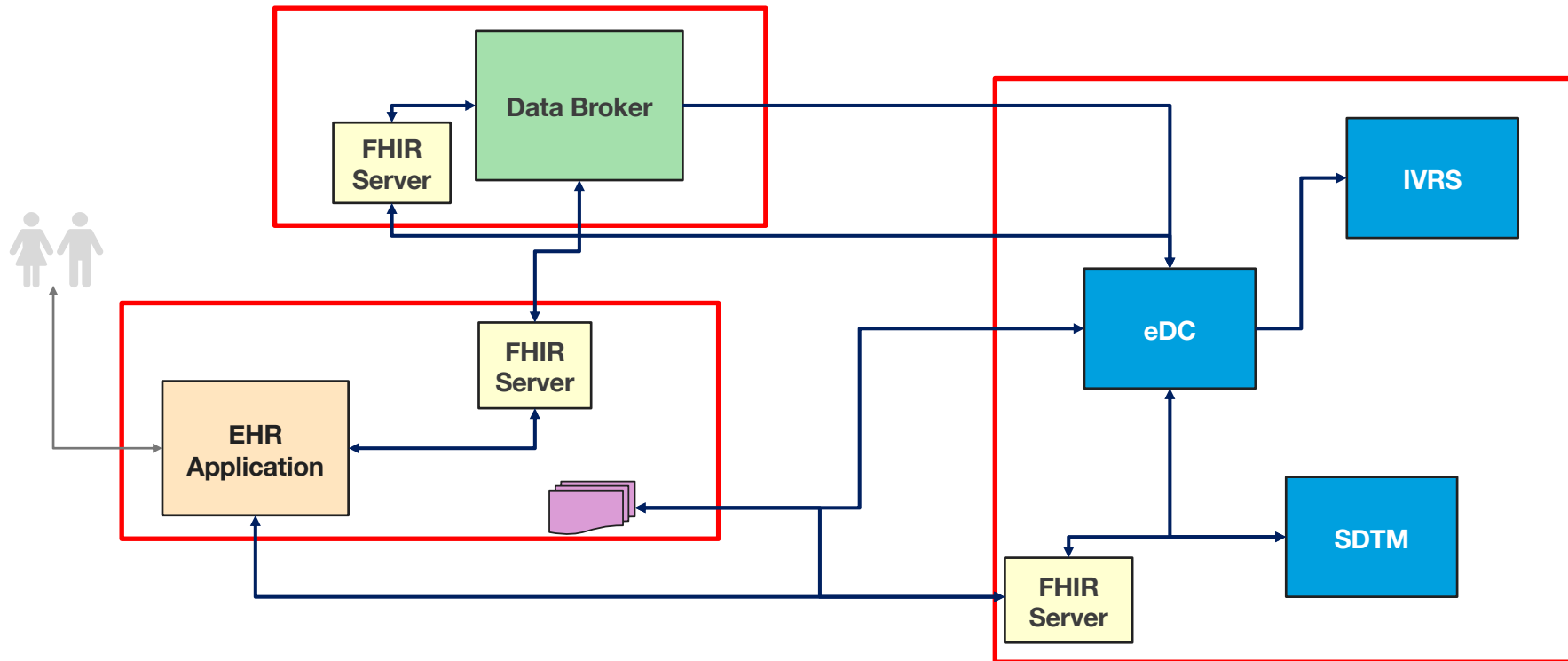
FHIR® Implementation

System / Solution Validation – Role of FHIR Test Data

fseCRF

1

Data Broker

FHIR Server

FHIR Server

EHR Application

eDC

IVRS

SDTM

FHIR Server

FHIR supported eSource Data Flow Implementation
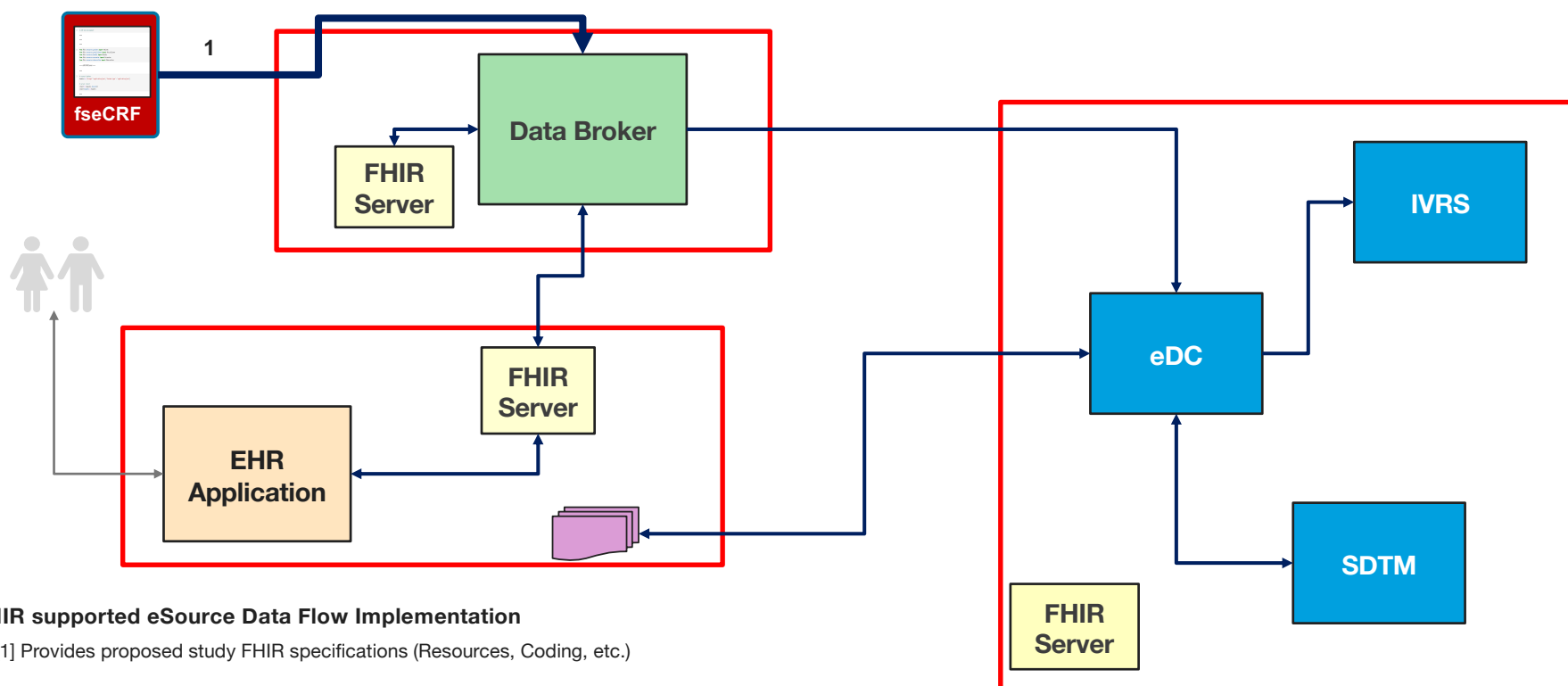
- [1] Provides proposed study FHIR specifications (Resources, Coding, etc.)

FHIR® Implementation
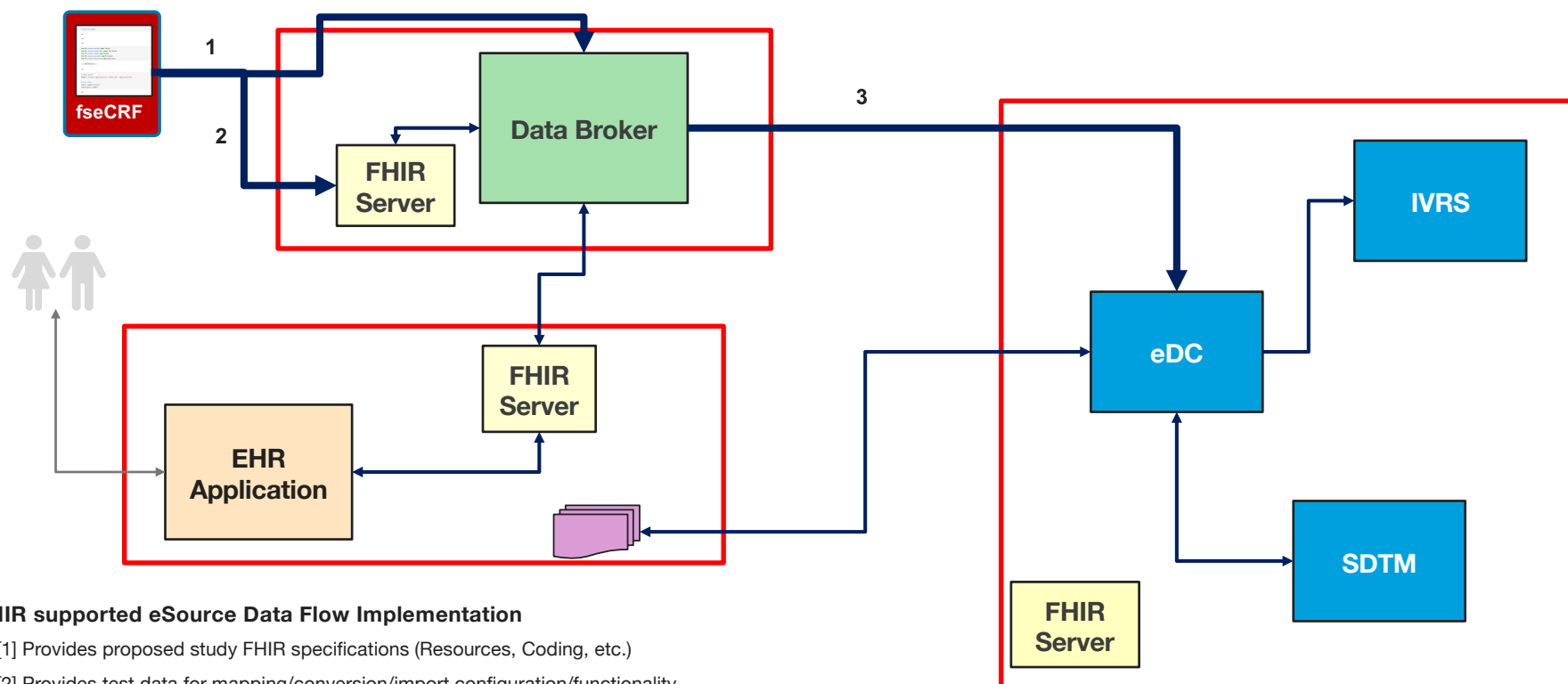
FHIR supported eSource Data Flow Implementation

- [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

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

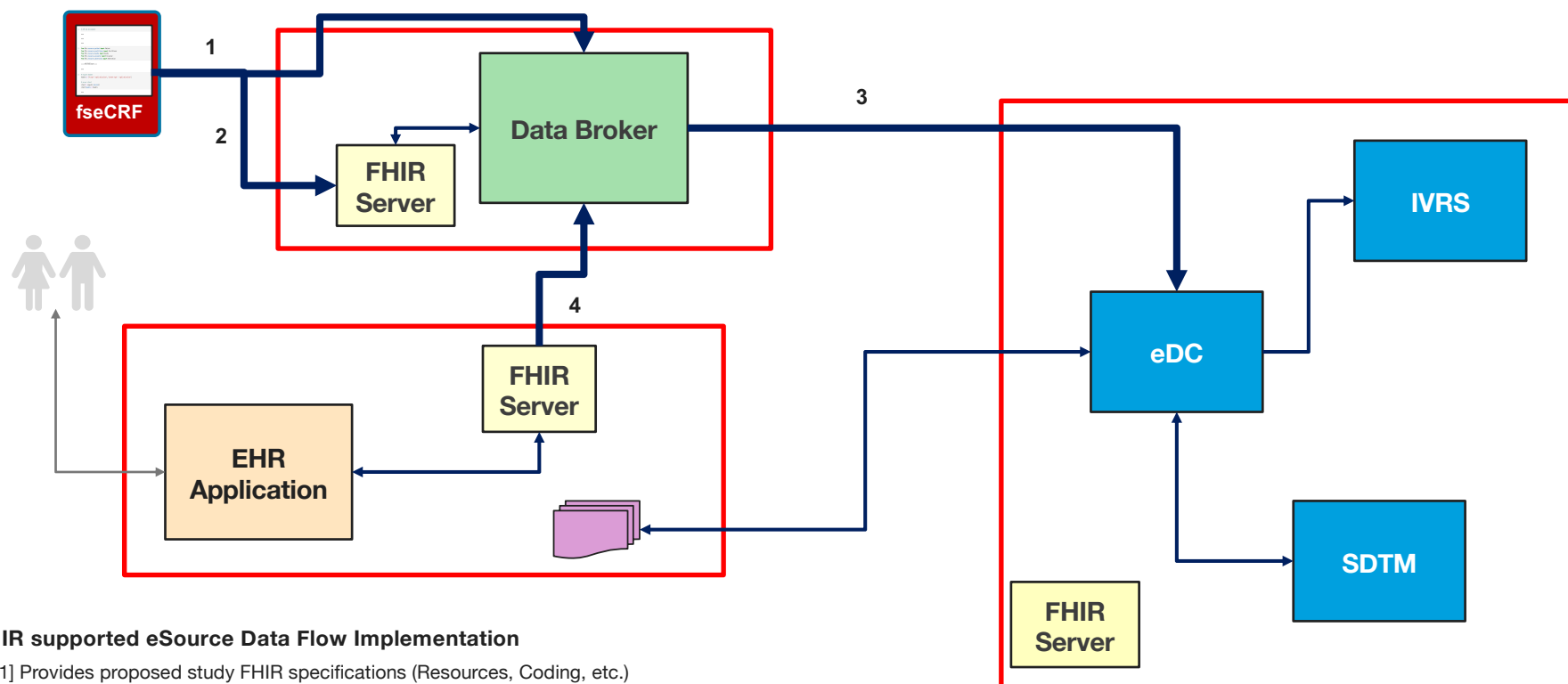**System / Solution Validation – Role of FHIR Test Data**

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

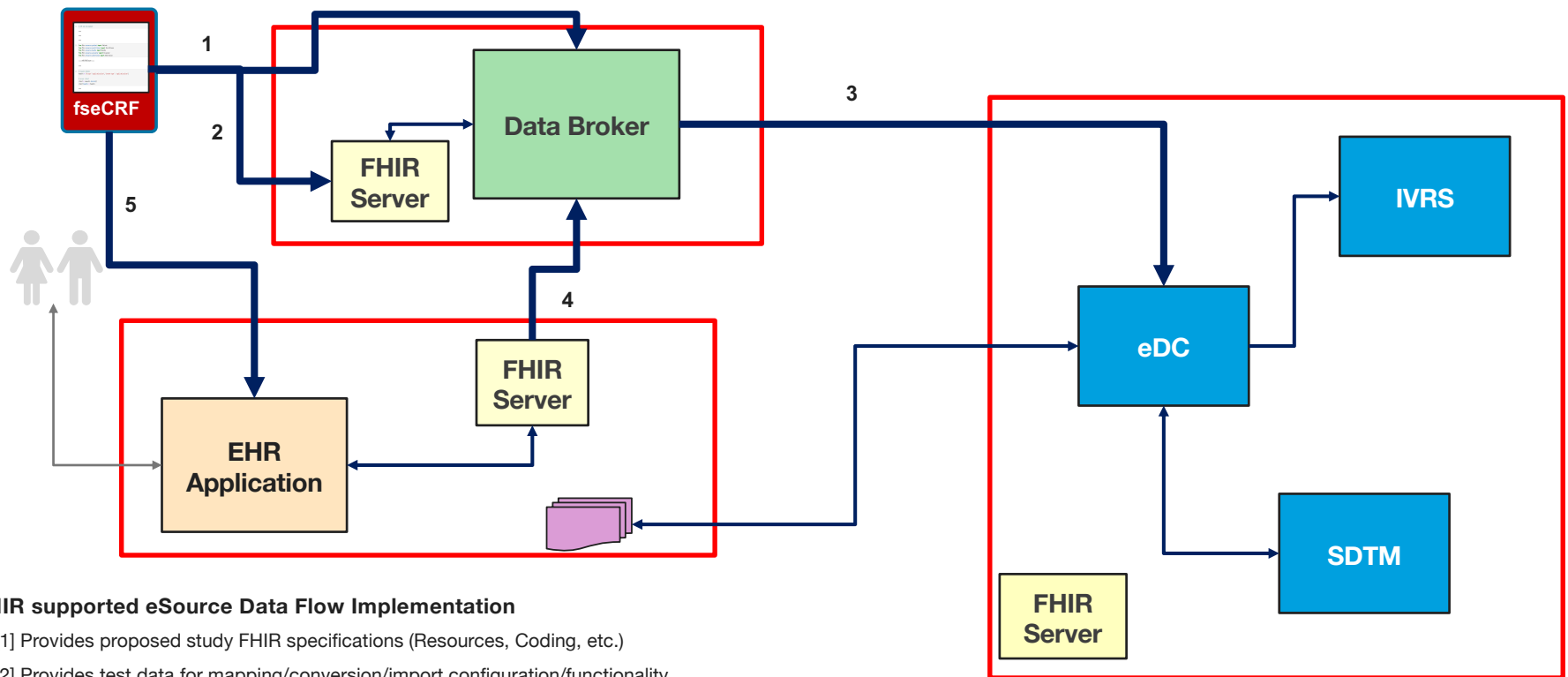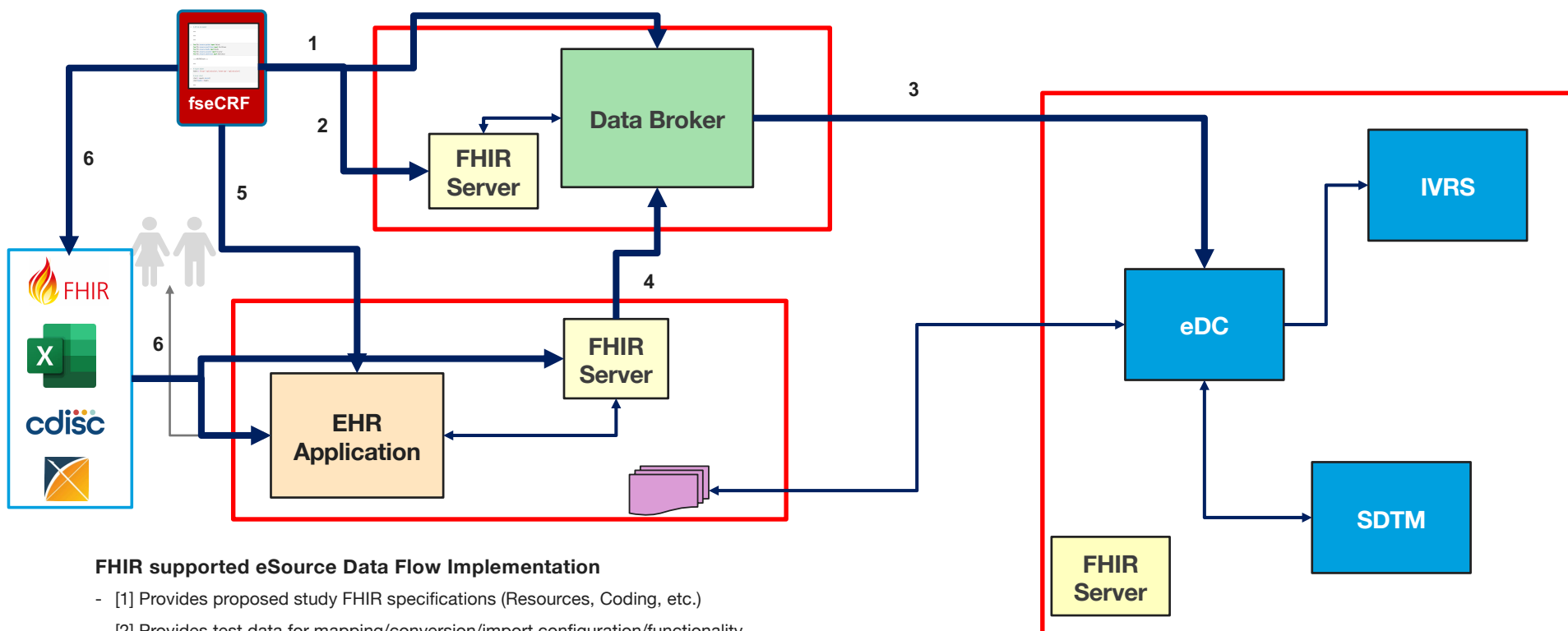**System / Solution Validation – Role of FHIR Test Data**

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

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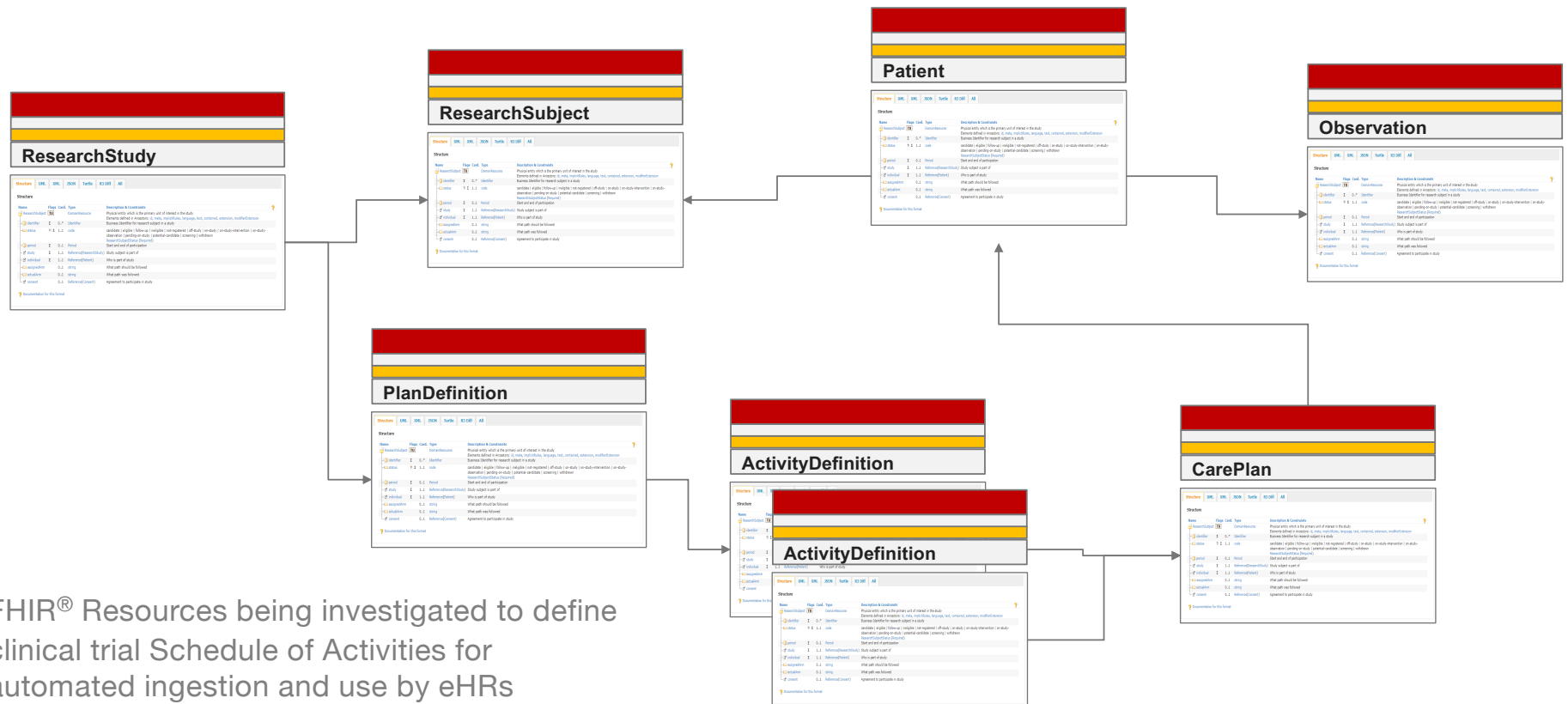
FHIR® Resources being investigated to define clinical trial Schedule of Activities for automated ingestion and use by eHRs