



Use of HL7 FHIR as eSource to Pre-populate CDASH CRFs using a CDISC ODM API

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This Project Extends the Initial Research on FHIR (RoF) Project



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Use of Fast Healthcare Interoperability Resources (FHIR) in the Generation of Real World Evidence (RWE)

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Consider reading the papers in order if you are new to eSource and HL7 FHIR

What we did

- Test use of HL7 FHIR standard for data exchange
- Extracted data for diabetic type 2 patients from the MITRE SyntheticMass Synthea Health Information Exchange (HIE) in FHIR format
- Mapped certain data points from FHIR to CDASH & SDTM
- Generated CDASH-compliant CRFs
- Generated SDTM-compliant datasets
- Realized further exploration & more work is needed

FHIR

Highlights

Intuitive, easy to learn

EHR standard accepted **globally**

Uses **RESTful APIs** to exchange data

Can **query** for specific data points

80 / 20 rule followed

Data organized as **Resources**

Resources can be **combined**

Integrates **diverse** data

Machine & **human** readable

Easier to **find & access** data

Hierarchical metadata structure – **better organized**

BUT! Do not forget about **CCD** ... it is still most commonly used



Clinical Resources

General

AllergyIntolerance 3
Condition (Problem) 3
Procedure 3
ClinicalImpression 0
FamilyMemberHistory 2
RiskAssessment 1
DetectedIssue 1

Care Provision

CarePlan 2
Goal 2
ReferralRequest 1
ProcedureRequest 3
NutritionalOrder 3
VisionPrescription 1

Medication & Immunization

Medication 3
MedicationRequest 3
MedicationDispense 2
MedicationStatement 3
Immunization 3
ImmunizationRecommendation 1

Diagnostics

Observation 5
DiagnosticRequest 3
ProcedureRequest 3
Specimen 2
BodySite 2
ImagingStudy 3
ImagingManifest 1

<https://www.hl7.org/fhir/resource-list.html>

Project Purpose

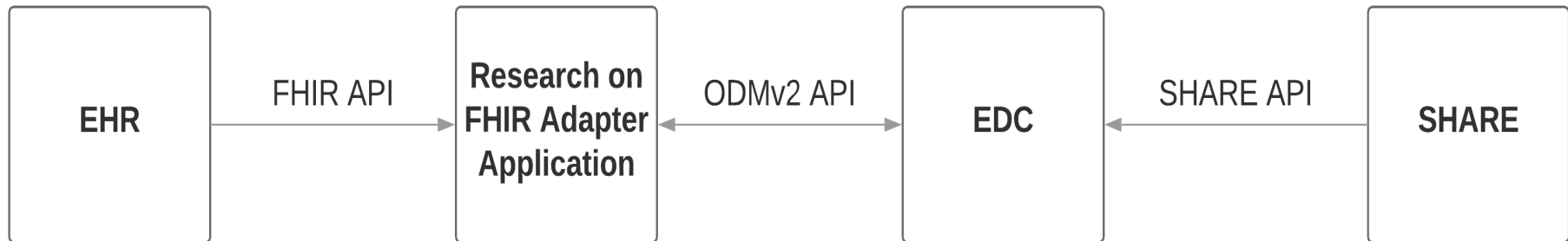


- Automate populating EDC from eSource/EHR
- Adds FHIR API use to the initial Research on FHIR (RoF) paper
- Demonstrates how data standards, workflows, and APIs reduce eSource implementation barriers
- Develops and demonstrates the use of new extensions to the CDISC ODM and CDASH standards metadata
- Provides access to the E2C FHIR mapping for CDASH variables in ODM using the SHARE API
- Tests the new ResearchStudy and ResearchSubject FHIR resources

RoF Adapter Prototype



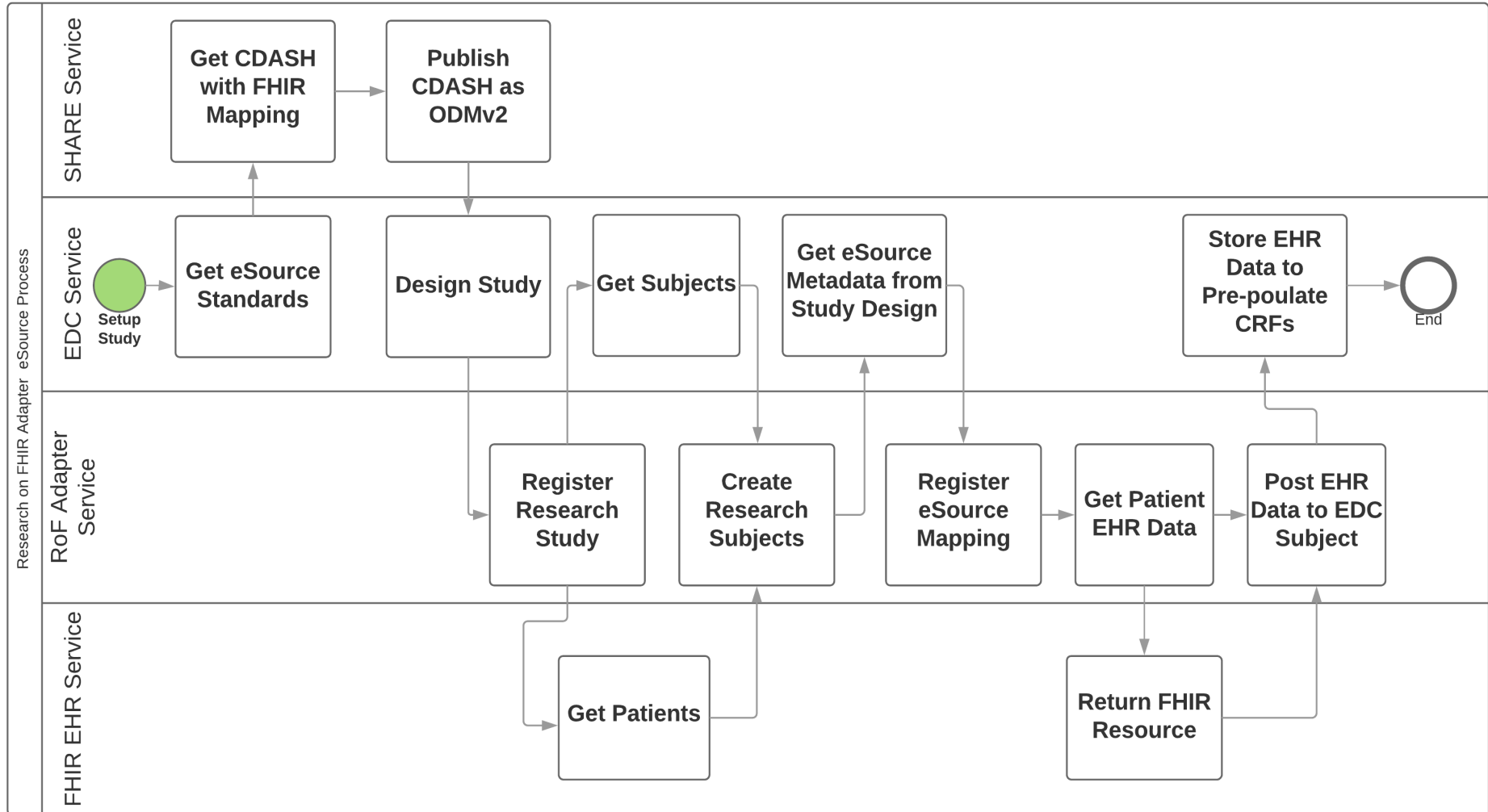
RESEARCH ON FHIR ADAPTER FOR PRE-POPULATING CRFS



RoF Adapter eSource Process



RESEARCH ON FHIR ADAPTER ESOURCE PROCESS



RoF Prototype

- Retrieves FHIR resource mapping to CDASH on specified research variables using draft ODMv2 API
- Generates FHIR API requests to retrieve patient data from EHR
- Post mapped EHR data to EDC system using ODMv2 API
- Populates ODM and CDASH based CRFs



**Computational Science
Working Groups**

Increasing Open, Standard APIs



- RoF Adapter demonstrated the use of current and future open, standard APIs
 - HL7 FHIR API
 - ODMv2 API
 - SHARE API v2.x (working on becoming more open)
- Provide on-demand access to the source of truth
- Drives automation and the standardization of data

RoF Adapter eSource Process



Use the ODM metadata to build a FHIR request to retrieve EHR content to populate the associated EDC variable

```
<ItemDef OID="ODM.IT.VS.TEMP.VSORRES" Name="Temperature" DataType="float">
  <Description>
    <TranslatedText xml:lang="en">Result of the vital signs measurement as originally received or collected.</TranslatedText>
  </Description>
  <Question>
    <TranslatedText xml:lang="en">Temperature</TranslatedText>
  </Question>
  <Alias Context="CDASH" Name="TEMP.VSORRES"/>
  <Alias Context="CDASH/SDTM" Name="VSORRES+VSORRESU"/>
  <odmv2:Origin Type="Collected" Source="Investigator">
    <odmv2:FHIR Resource="Observation" Attribute="valueQuantity.value"/>
  </odmv2:Origin>
  <odmv2:Code Code="8310-5" CodeSystem="urn:oid:2.16.840.1.113883.6.1" CodeSystemName="LOINC" CodeSystemVersion="2.61"/>
</ItemDef>
```

LOINC Code

FHIR Resource

FHIR Attribute

EHR Server: HSPC + Synthea Data



Secure | <https://syntheticmass.mitre.org/about.html>

SyntheticMass

Home

SyntheticMass Dashboard

About This Project

Feedback



About Synthea

Synthea – Synthetic Patient Population Simulator

[Synthea](#) is a Synthetic Patient Population Simulator that is used to generate the synthetic patients within SyntheticMass. Synthea outputs synthetic, realistic (but not real) patient data and associated health records in a variety of formats. Read our [wiki](#) for more information.

HSPC | Sandbox Sandboxes ▾

Research on FHIR

Apps

EHR Simulator

Launch Scenarios

Patients

Practitioners

Personas

Data Manager

User Management

EHR Integration

Documentation

Settings

Query Browser

External FHIR Data

Import

Export

FHIR Query

Condition?code:text=diabetes

x Q

Total 12 Current Set 12

Summary

Condition Text	Diabetes mellitus type 2
Onset Date	2007-08-31T00:00:00-06:00
Condition Text	Diabetes mellitus type 2
Onset Date	2006-03-15T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2004-12-10T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2009-01-07T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2007-05-13T00:00:00-06:00
Condition Text	Diabetes mellitus type 2
Onset Date	2005-01-18T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2006-11-13T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2005-03-12T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2007-01-07T00:00:00-07:00
Condition Text	Diabetes mellitus type 2
Onset Date	2006-07-17T00:00:00-06:00
Condition Text	Diabetes mellitus type 2
Onset Date	2007-11-14T00:00:00-07:00
Condition Text	Diabetes Mellitus, Type 2
Onset Date	2011-05-10T00:00:00-06:00

Result JSON Bundle

```
{
  "resourceType": "Bundle",
  "id": "8ef11361-d501-43ce-8874-9130c56deaf0",
  "meta": {
    "lastUpdated": "2018-04-03T19:32:09.928+00:00"
  },
  "type": "searchset",
  "total": 12,
  "link": [
    {
      "relation": "self",
      "url": "https://api-stu3.hspconsortium.org/phusefhir/data/Condition?_count=50&code%3Atext=diabetes"
    }
  ],
  "entry": [
    {
      "fullUrl": "https://api-stu3.hspconsortium.org/phusefhir/data/Condition/SMART-Condition-94",
      "resource": {
        "resourceType": "Condition",
        "id": "SMART-Condition-94",
        "meta": {
          "versionId": "1",
          "lastUpdated": "2017-03-29T11:15:19.000+00:00"
        },
        "text": {
          "status": "generated",
          "div": "<div xmlns='http://www.w3.org/1999/xhtml'>Diabetes mellitus type 2</div>"
        },
        "clinicalStatus": "active",
        "verificationStatus": "confirmed",
        "code": {
          "coding": [
            {
              "system": "http://snomed.info/sct",
              "code": "440541000"
            }
          ]
        }
      }
    }
  ]
}
```

New FHIR Resources



- Developed to support clinical research
- ResearchStudy
 - Contains study info such as title, protocol info, study design, arms, schedule of events, visits/dates
 - Study drug/device.....
- ResearchSubject
 - Contains study and subject identifiers (non-PII)
 - Links subjects to studies
 - Arm assigned to
 - Consent info
- Provides a NON-PII subject identifier

- EDC design tool can retrieve standard metadata using the CDISC SHARE API
- Will include metadata that maps CDASH to FHIR
- SHARE API v2.x will retrieve CDASH FHIR mappings in ODM
- Used to generate FHIR API calls to retrieve EHR content
- E2C group is currently mapping CDASH to FHIR
 - **Volunteers???**

New CDISC ODM Standard



- Prototype utilized new draft ODMv2 standard
- ODMv2 can reference eSource content (FHIR mappings)
- ODMv2
 - provides the specification for a standardized REST API
 - retrieves FHIR resource mappings for selected CDASH variables
 - generates FHIR API requests to retrieve data from HER
- ODMv2 API
 - provides a standard spec to exchange ODM content(metadata, data, reference data..)
 - promotes dynamic, software-driven data exchange between clinical research application
 - will support XML, JSON, and RDF media-types

EDC Server: ODMv2 API Test Server



StudyEvent ▾

POST `/studies/{studyOID}/mdv/{mdvOID}/studyevents` Creates a new StudyEvent

GET `/studies/{studyOID}/mdv/{mdvOID}/studyevents` Returns the list of StudyEventDefs

GET `/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}` Returns the StudyEventDef and a list Form references

PUT `/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}` Update a StudyEvent

DELETE `/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}` Removes the StudyEventDef

Form ▾

POST `/studies/{studyOID}/mdv/{mdvOID}/forms` Creates a new Form

GET `/studies/{studyOID}/mdv/{mdvOID}/forms` Returns the list of FormDefs

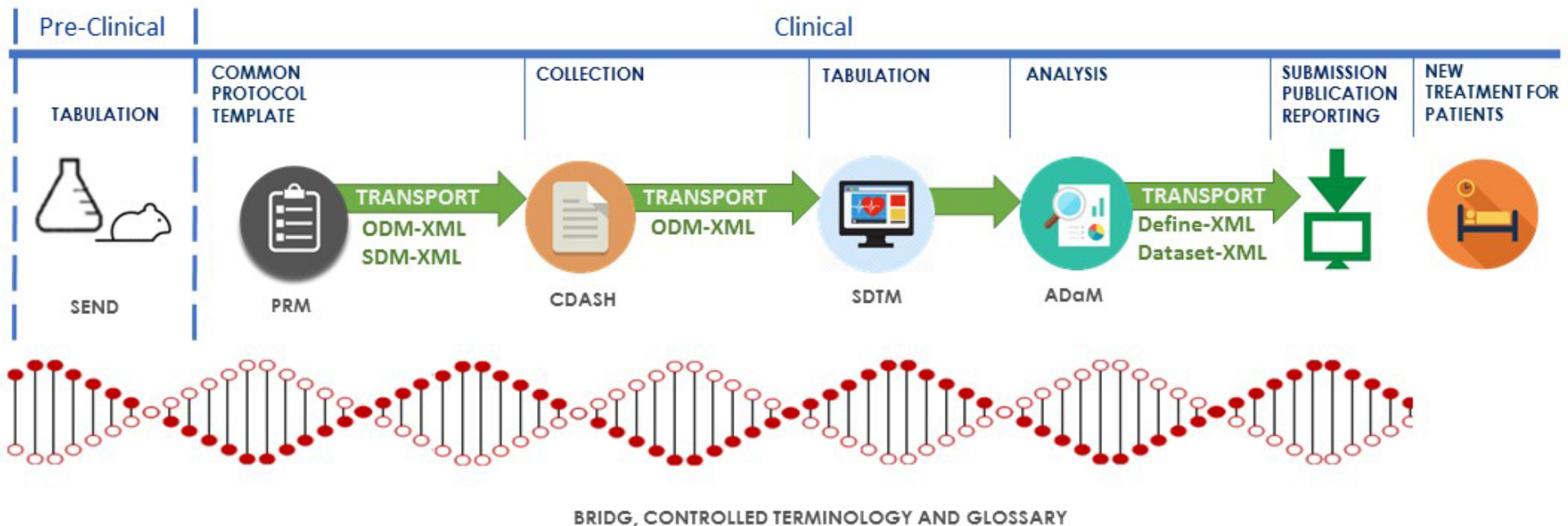
GET `/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}` Returns the FormDef and the associated list of ItemGroupRefs

PUT `/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}` Update a Form

DELETE `/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}` Removes the FormDef

Extend CDISC End-to-End Standards to include eSource

CDISC Standards in the Clinical Research Process



Pilot RoF Adapter Limitations



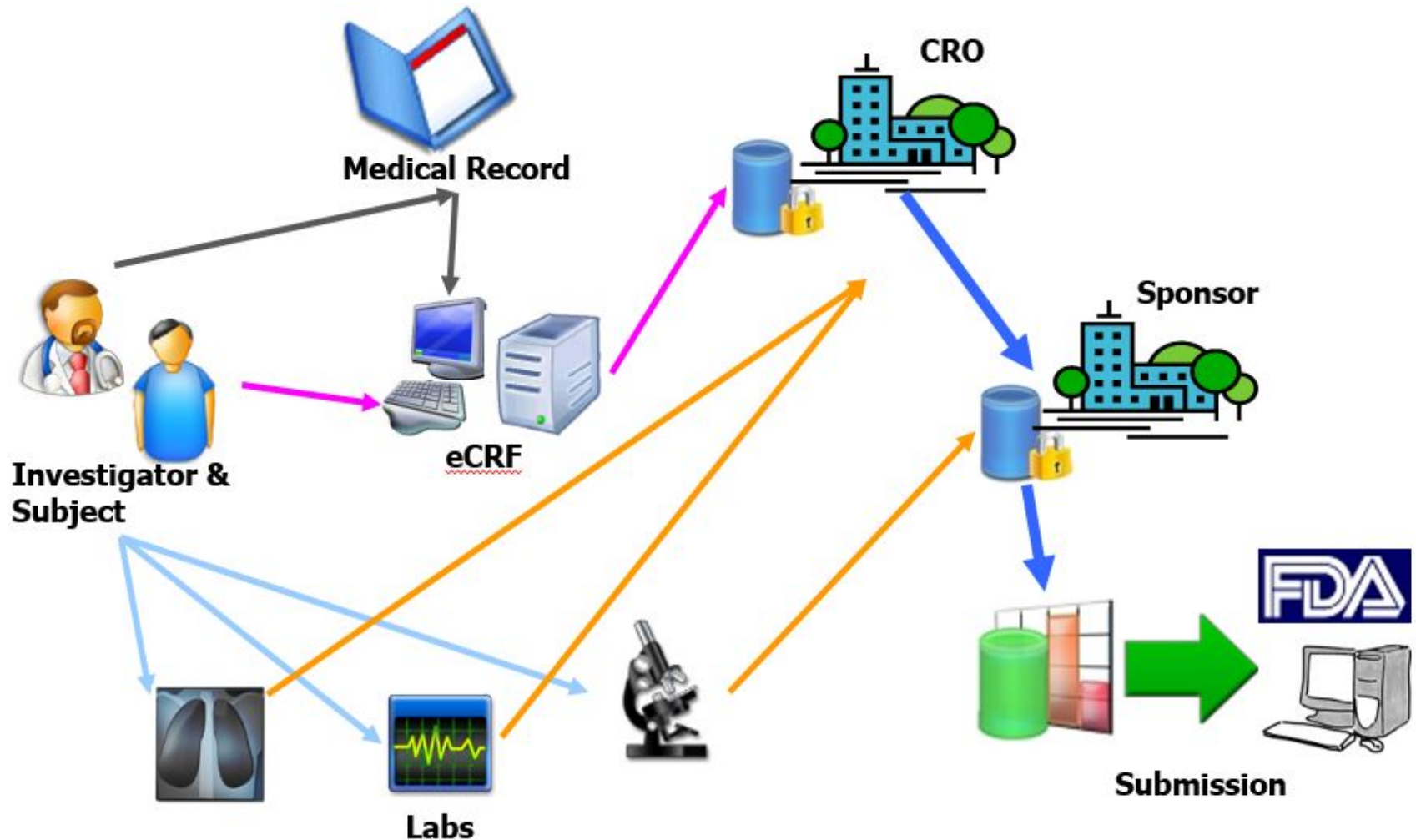
- Used basic mechanisms for slotting EHR data into the EDC visit structure
 - Visit type
 - EHR and visit dates
- Resource substitution for resources missing in the EHR
- No automated terminology mapping
- Uses draft versions of new standards

RoF Discussion Topics Warranting Additional Attention in Future Projects



- Site-driven approach
- Healthcare / research terminology differences
- Visit vs. visitless (longitudinal) studies
- Test environment to limit mapping / data issues
- Determining which fields use eSource content
- Consent and privacy rules

Open, Standard APIs Improve Scalability of Data Exchange Solutions



Want to get involved?

Contact

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**The premier community for people
working in the biometric area**



 **phuse.eu**

 **@PhUSETwitta**

 **/PhUSE**

 **phusewiki.org**

Thank You!

EXTRA Slides



**Computational Science
Working Groups**

EDC eSource Mapping Metadata



Research On FHIR eSource: Retrieve Study Metadata

Study ID: 16676

FHIR Endpoint: <https://api-stu3.hspconsortium.org/phusefhir/open/>

Register Study and Retrieve Study Metadata

URL to Retrieve EDC Metadata

Study OID

Username

Password

Metadata

ODM.IT.LB.LBDBC FHIR: Observation.effectiveDateTime
ODM.IT.LB.WBC.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.WBC.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.LB.ALB.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.ALB.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.LB.GLUC.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.GLUC.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.LB.HBA1CHGB.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.HBA1CHGB.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.LB.ALB.CREAT.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.ALB.CREAT.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.CM.CMTRT FHIR: Medication.display
ODM.IT.CM.CMDOSE FHIR: MedicationStatement.dose.doseQuantity.value
ODM.IT.CM.CMDOSE.FREQ FHIR: MedicationStatement.dose.timing
ODM.IT.CM.CMROUTE FHIR: MedicationStatement.dose.route

Select Study

Register Study

Transfer Data



CW



Initiate EHR Patient Data Transfer



Research On FHIR eSource: Retrieve EHR Data and Post to EDC

Study ID: 16676

FHIR Endpoint: <https://api-stu3.hspconsortium.org/phusefhir/open/>

Retrieve EHR eSource Data and Post to EDC System

StudyEvents

Baseline Visit (BASELINE) Scheduled ▼

EHRDate

VisitDate

2018-02-12

Patients

Subject SK-0002 - Patient Frank Taylor (SMART-1627321) ▲▼

Metadata

Collection Date and Time (ODM.IT.LB.LBDC)
WBC (ODM.IT.LB.WBC.VSORRES)
WBC Units (ODM.IT.LB.WBC.LBORRESU)
ALB (ODM.IT.LB.ALB.VSORRES)
ALB Units (ODM.IT.LB.ALB.LBORRESU)
Glucose (ODM.IT.LB.GLUC.VSORRES)
Glucose Units (ODM.IT.LB.GLUC.LBORRESU)
Hemoglobin (ODM.IT.LB.HBA1CHGB.VSORRES)
Hemoglobin Units (ODM.IT.LB.HBA1CHGB.LBORRESU)
Albumin/Creatinine (ODM.IT.LB.ALBCREAT.VSORRES)
Albumin/Creatinine Units (ODM.IT.LB.ALBCREAT.LBORRESU)
Medication or Therapy (ODM.IT.CM.CMTRT)
Dose (ODM.IT.CM.CMDOSE)
Frequency (ODM.IT.CM.CMDOSFRQ)
Route (ODM.IT.CM.CMROUTE) ▲▼

Transfer EHR Data

Select Study

Register Study

Transfer Data



EHR Patient Data Transferred to EDC Server



Research On FHIR eSource: Data Transferred from EHR to the EDC System

Study ID: 16676

FHIR Endpoint: <https://api-stu3.hspconsortium.org/phusefhir/open/>

Data Transferred from EHR to the EDC System

Data transfer successfully completed.

Data transferred from 1 patients.

29 EDC data fields pre-populated with EHR data for each subject.

Data transferred to EDC visit date 2018-02-12

Select Study

Register Study

Transfer Data



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