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

Data organized as Resources

80 / 20 rule followed

Can query for specific data points

Resources can be combined

Easier to find & access data

Hierarchical metadata structure – better organized

Uses RESTful APIs to exchange data

Integrates diverse data

Machine & human readable

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/resourcelist.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

EHR \(\rightarrow\) FHIR API \(\rightarrow\) Research on FHIR Adapter Application \(\rightarrow\) ODMv2 API \(\rightarrow\) EDC \(\rightarrow\) SHARE API \(\rightarrow\) SHARE
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
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 prepopulate the associated EDC variable

```xml
<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>
</ItemDef>
```

LOINC Code  FHIR Resource  FHIR Attribute
EHR Server: HSPC + Synthea Data

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.
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

<table>
<thead>
<tr>
<th>Method</th>
<th>Path</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POST</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/studyevents</td>
<td>Creates a new StudyEvent</td>
</tr>
<tr>
<td><strong>GET</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/studyevents</td>
<td>Returns the list of StudyEventDefs</td>
</tr>
<tr>
<td><strong>GET</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}</td>
<td>Returns the StudyEventDef and a list Form references</td>
</tr>
<tr>
<td><strong>PUT</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}</td>
<td>Update a StudyEvent</td>
</tr>
<tr>
<td><strong>DELETE</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/studyevents/{studyEventOID}</td>
<td>Removes the StudyEventDef</td>
</tr>
</tbody>
</table>

### Form

<table>
<thead>
<tr>
<th>Method</th>
<th>Path</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POST</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/forms</td>
<td>Creates a new Form</td>
</tr>
<tr>
<td><strong>GET</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/forms</td>
<td>Returns the list of FormDefs</td>
</tr>
<tr>
<td><strong>GET</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}</td>
<td>Returns the FormDef and the associated list of ItemGroupRefs</td>
</tr>
<tr>
<td><strong>PUT</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}</td>
<td>Update a Form</td>
</tr>
<tr>
<td><strong>DELETE</strong></td>
<td>/studies/{studyOID}/mdv/{mdvOID}/forms/{formOID}</td>
<td>Removes the FormDef</td>
</tr>
</tbody>
</table>
Extend CDISC End-to-End Standards to include eSource
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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Lauren White laurenwhite@phuse.eu

The premier community for people working in the biometric area

Thank You!

phuse.eu
@PhUSETwitta
/PhUSE
phusewiki.org
EXTRA Slides
Research On FHIR eSource: Retrieve Study Metadata

Study ID: 16676
FHIR Endpoint: https://api-stu3.hsconsortium.org/phusefhir/open/

Register Study and Retrieve Study Metadata

URL to Retrieve EDC Metadata
http://127.0.0.1:8080/odm1-3-2-api/

Study OID
16676

Username
Tom Swift

Password
******

Load Study Metadata

Metadata
ODM.IT.LB.LBDTC 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.ALCBREAT.VSORRES FHIR: Observation.valueQuantity.value
ODM.IT.LB.ALCBREAT.LBORRESU FHIR: Observation.valueQuantity.unit
ODM.IT.CM.CMTRT FHIR: Medication.display
ODM.IT.CM.CMDOSE FHIR: MedicationStatement.dosage.doseQuantity.value
ODM.IT.CM.CMDOSFRO FHIR: MedicationStatement.dosage.timing
ODM.IT.CM.CMROUTE FHIR: MedicationStatement.dosage.route

Select Study  Register Study  Transfer Data
Initiate EHR Patient Data Transfer

Research On FHIR eSource: Retrieve EHR Data and Post to EDC
Study ID: 16676
FHIR Endpoint: https://api-stu3.hspsconsortium.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.LBDTC)
WBC (ODM.IT.LB.WBC.VSORES)
WBC Units (ODM.IT.LB.WBC.LBORRESU)
ALB (ODM.IT.LB ALB.VSORES)
ALB Units (ODM.IT.LB ALB.LBORRESU)
Gloose (ODM.IT.LB.GLUC.VSORES)
Glocuse Units (ODM.IT.LB.GLUC.LBORRESU)
Hemoglobin (ODM.IT.LB HBA1CHGB VSORES)
Hemoglobin Units (ODM.IT.LB HBA1CHGB.LBORRESU)
Albumin/Creatinine (ODM.IT.LB ALBCREAT VSORES)
Albumin/Creatinine Units (ODM.IT.LB ALBCREAT.LBORRESU)
Medication or Therapy (ODM.IT.CM.CMTRT)
Dose (ODM.IT.CM.CMDOSE)
Frequency (ODM.IT.CM.CMDOSEFRQ)
Route (ODM.IT.CM.CMROUTE)

Transfer EHR Data

Select Study  Register Study  Transfer Data
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