



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

Initial Research on FHIR (ROF) Project



- Extracted data for diabetic type 2 patients from the MITRE SyntheticMass Synthea Health Information Exchange (HIE)
- Mapped certain data points to CDASH & SDTM
- Generated CDASH-compliant CRFs
- Generated SDTM-compliant datasets
- Ran across a few needed tweaks to FHIR, CDASH & SDTM
- Realized further exploration & more work is needed

Current RoF Project Purpose



- Automates the EHR data retrieval approach used in the initial Research on FHIR (RoF) paper
- Provides a model for retrieving EHR data, converting it to CDISC standards, and loading it in a CRF
- Demonstrates how data standards, workflows, and APIs reduce eSource implementation barriers
- Demonstrates the use of HL7 FHIR as an eSource technology that can be used with the CDISC standards
- Extends the CDISC standards to better support eSource

FHIR Highlights



- EHR standard accepted **globally**
- Truly **interoperable** – can be used on any system
- Machine & **human** readable
- Can **query** for specific data points
- Uses **RESTful APIs** to exchange data
- Extensible
- **Hierarchical** metadata structure – **better organized**
- Data organized as **Resources**
- Resources can be **combined**

<https://www.hl7.org/fhir/>

FHIR Resources

Clinical Resources

General

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

Medication & Immunization

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

Care Provision

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

Diagnostics

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

Smallest
logically
discrete units
of “transaction
of interest” to
healthcare



RoF Adapter Prototype



RESEARCH ON FHIR ADAPTER FOR PRE-POPULATING CRFS



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"
            }
          ]
        }
      }
    }
  ]
}
```

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

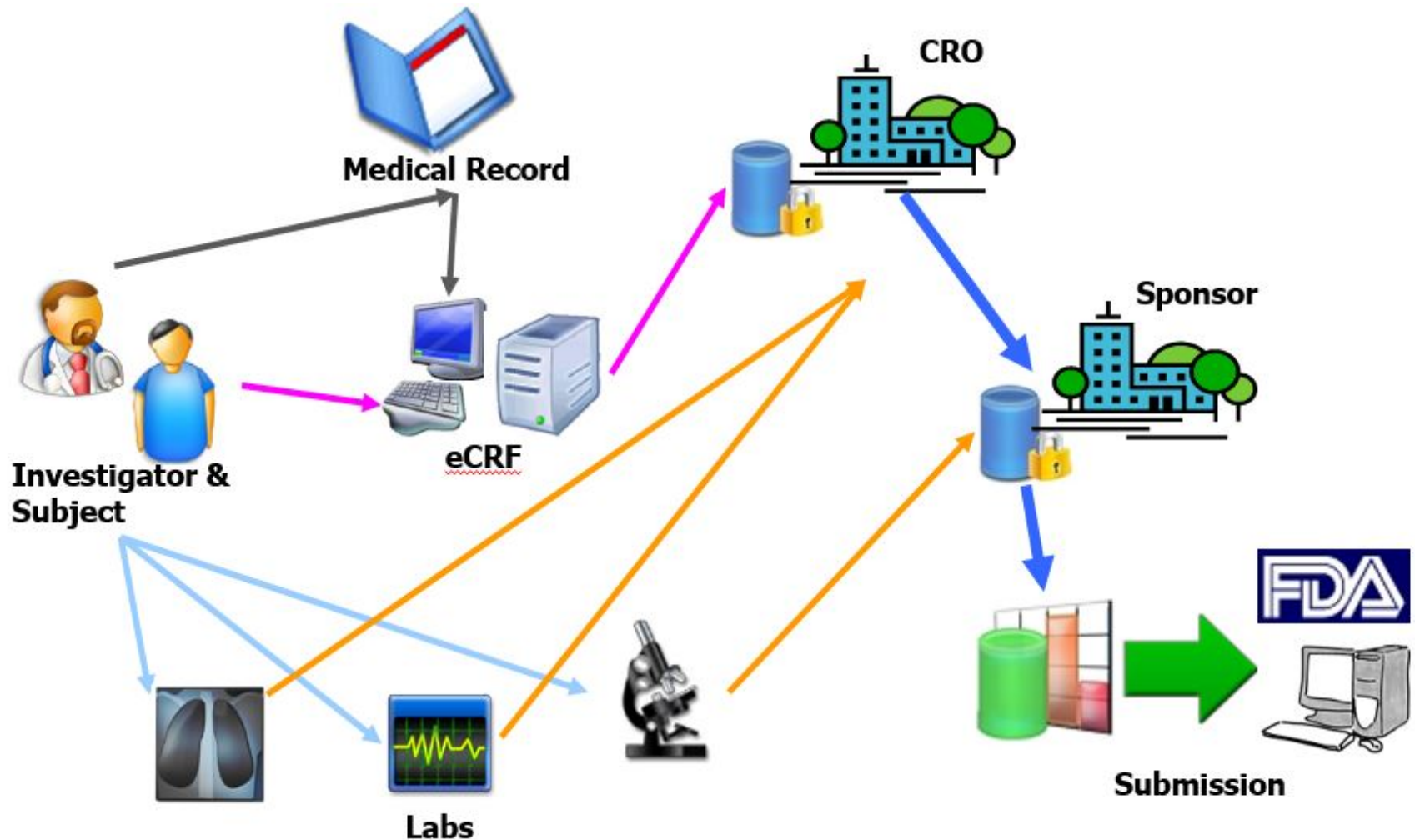
GET `/studies/{studyOID}/mdv/{mdvOID}/forms` Returns the list of FormDefs

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

Open, Standard APIs Improve Scalability of Data Exchange Solutions



Increasing Open, Standard APIs

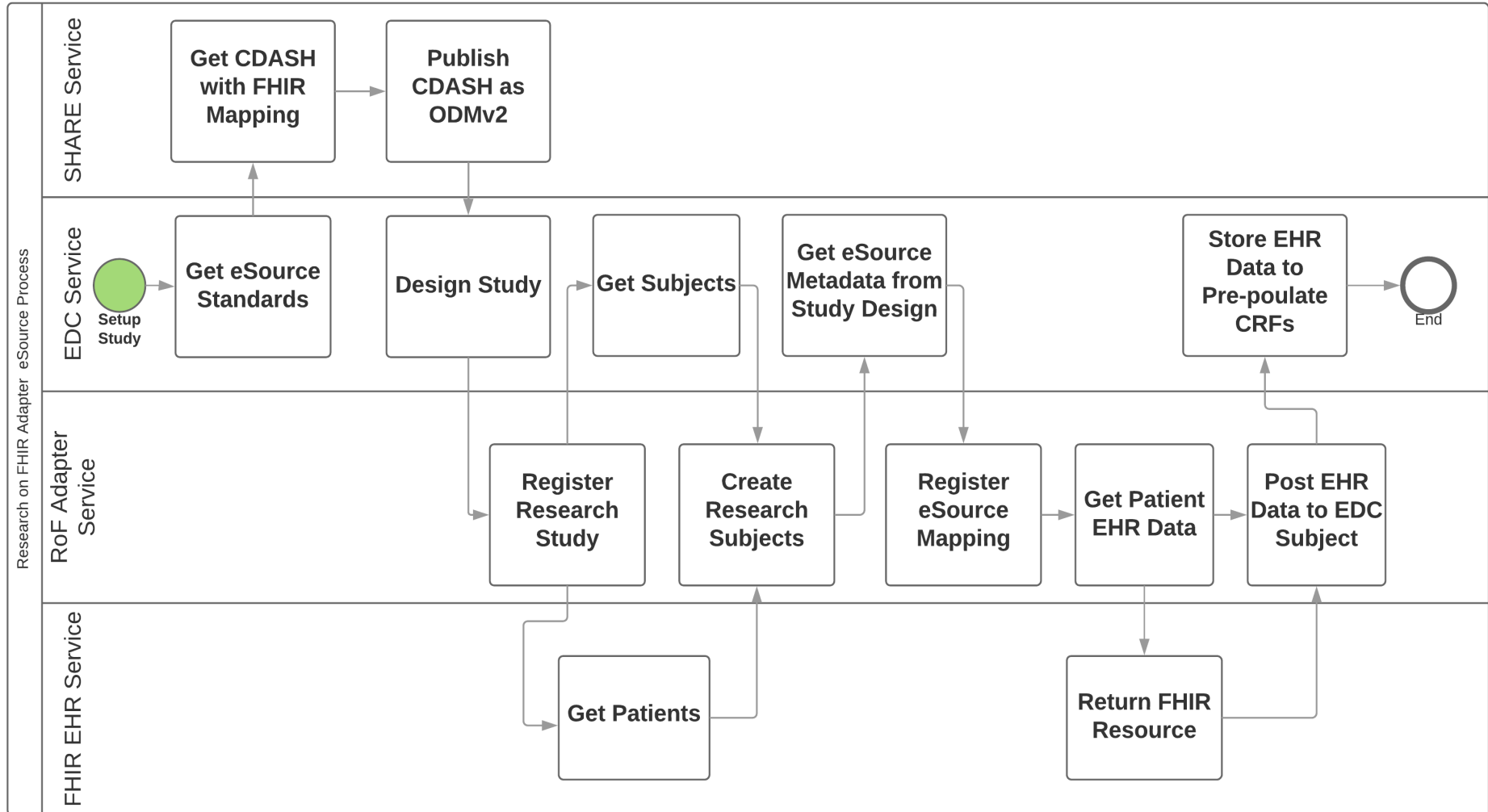


- RoF Adapter demonstrated the use of current and future open, standard APIs
 - HL7 FHIR API
 - ODMv2 API
 - SHARE API v2.x (working on becoming more open)
- Provide on-demand access to the source of truth
- Drives automation and the standardization of data

RoF Adapter eSource Process



RESEARCH ON FHIR ADAPTER ESOURCE PROCESS



RoF Adapter eSource Process



Use the ODM metadata to build a FHIR request to retrieve EHR content to prepopulate 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

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

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.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.doseage.doseQuantity.value
ODM.IT.CM.CMDOSFRQ FHIR:MedicationStatement.doseage.timing
ODM.IT.CM.CMROUTE FHIR:MedicationStatement.doseage.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.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

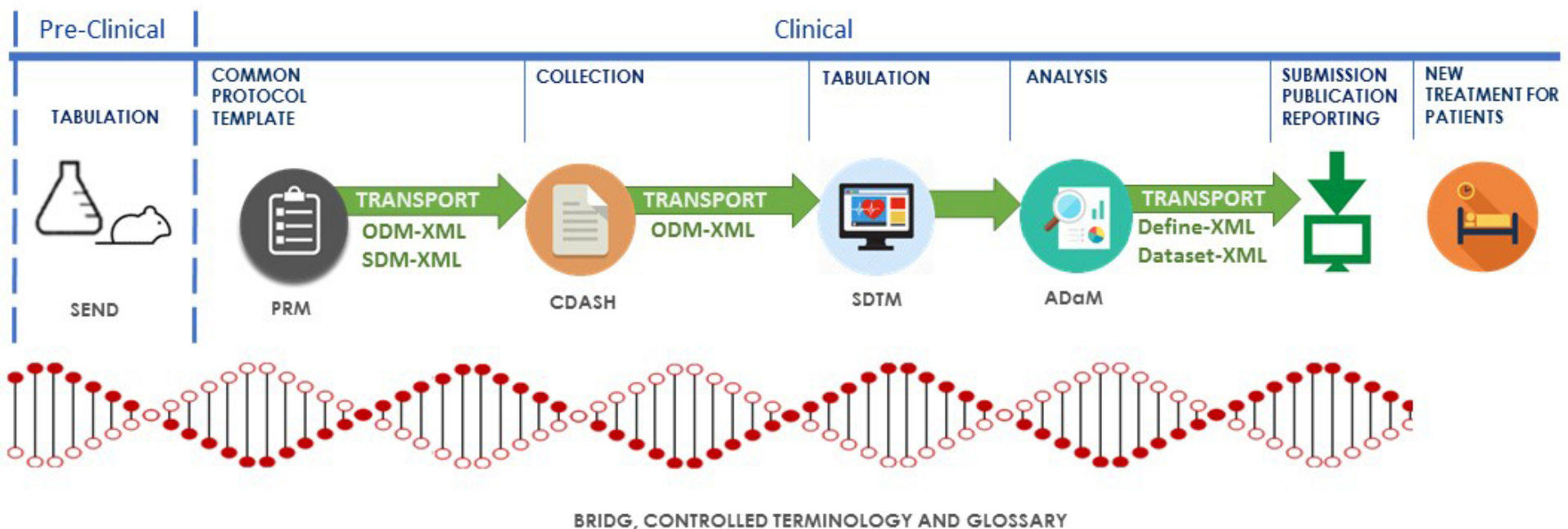
Future CDISC Developments Piloted in this Project



- ODMv2
 - API
 - ODM in JSON
 - FHIR mapping metadata
 - Formalized semantics (e.g. LOINC and SNOMED-CT)
- CDASH
 - Extended to include E2C FHIR mapping metadata for select variables
- SHARE API v2.x
 - Retrieve CDASH FHIR mappings in ODM using the SHARE API

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



- 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

Want to get involved?

Contact

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Thank You!