WITH STANDARDS – UNLOCK THE POWER OF DATA

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2022
JAPAN
INTERCHANGE
13-14 JUNE | VIRTUAL EVENT

FHIR to CDISC: Mapping Real World Data Connections

Rebecca Baker, Standards Development, CDISC

Meet the Speaker

Rebecca Baker

Title: Standards Developer and Real World Data

Organization: CDISC

Rebecca Baker, a Standards Developer and Real World Data Expert at CDISC, has over 20 years of experience in the healthcare industry in nursing, clinical research and informatics. Rebecca joined CDISC in 2019. Rebecca served as a project manager for the Real World Data Initiative mapping HL7 FHIR to CDISC standards (CDASH and SDTM) and other standards development projects. She holds a Master of Science in Health Informatics, Master of Healthcare Administration, and a Bachelor's of Science in Nursing.

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- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. FHIR to CDISC Mapping
2. LOINC
3. UCUM

Background

FHIR to CDISC Mapping

The problem we are trying to solve

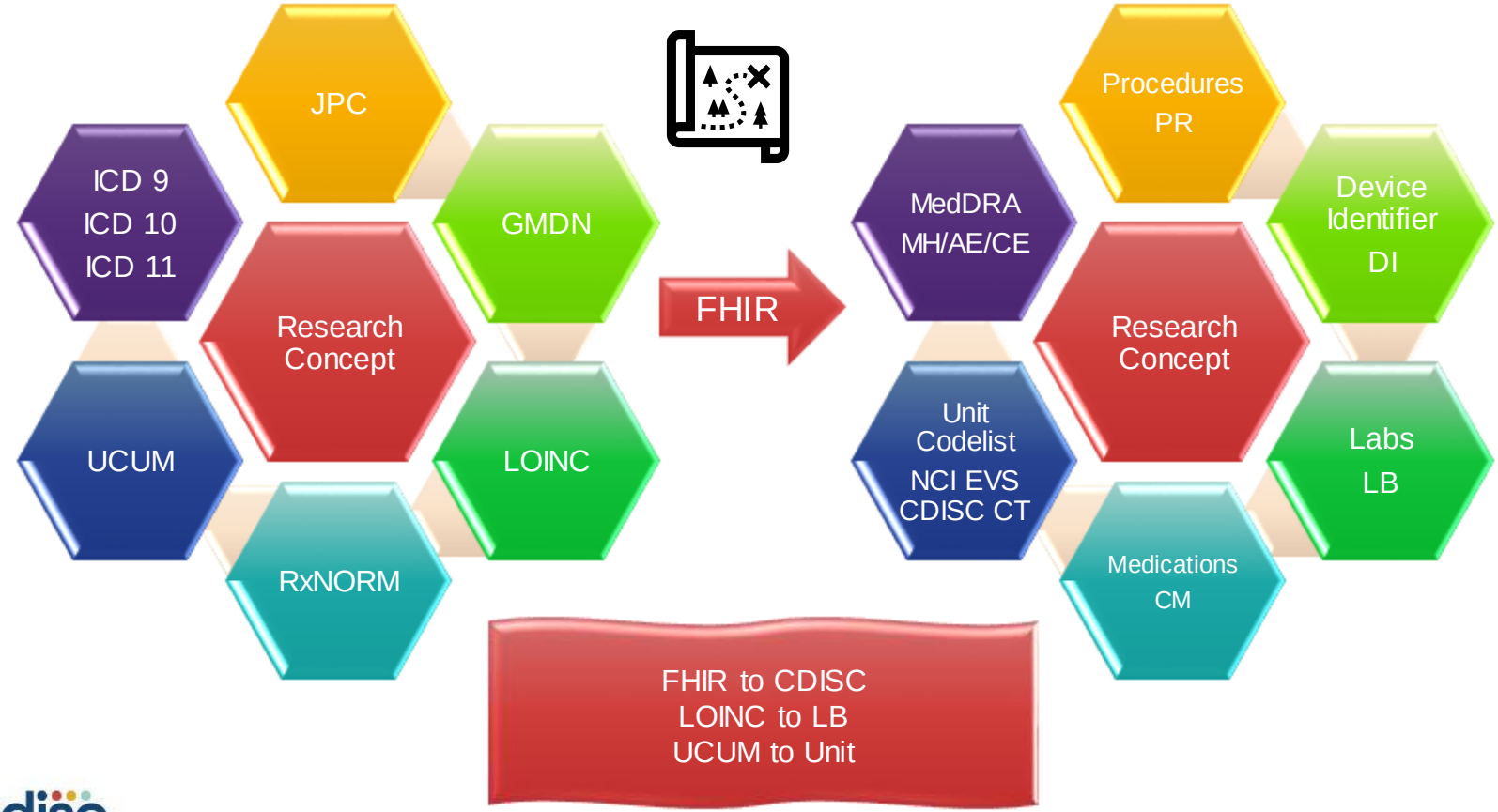
Swivel chair interoperability….

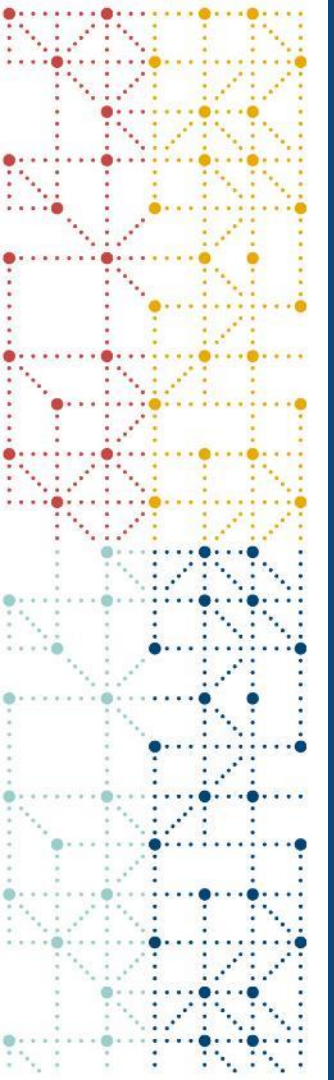
https://www.modernhealthcare.com/article/20150801/MAGAZINE/308019979/swivel-chair-interoperability-fda-seeks-solutions-to-mesh-ehrs-and-drug-research-record-systems

The interoperability puzzle…

Using all standards and available tools at the right place and the right time.

Real world data to CDISC standards





What is FHIR?

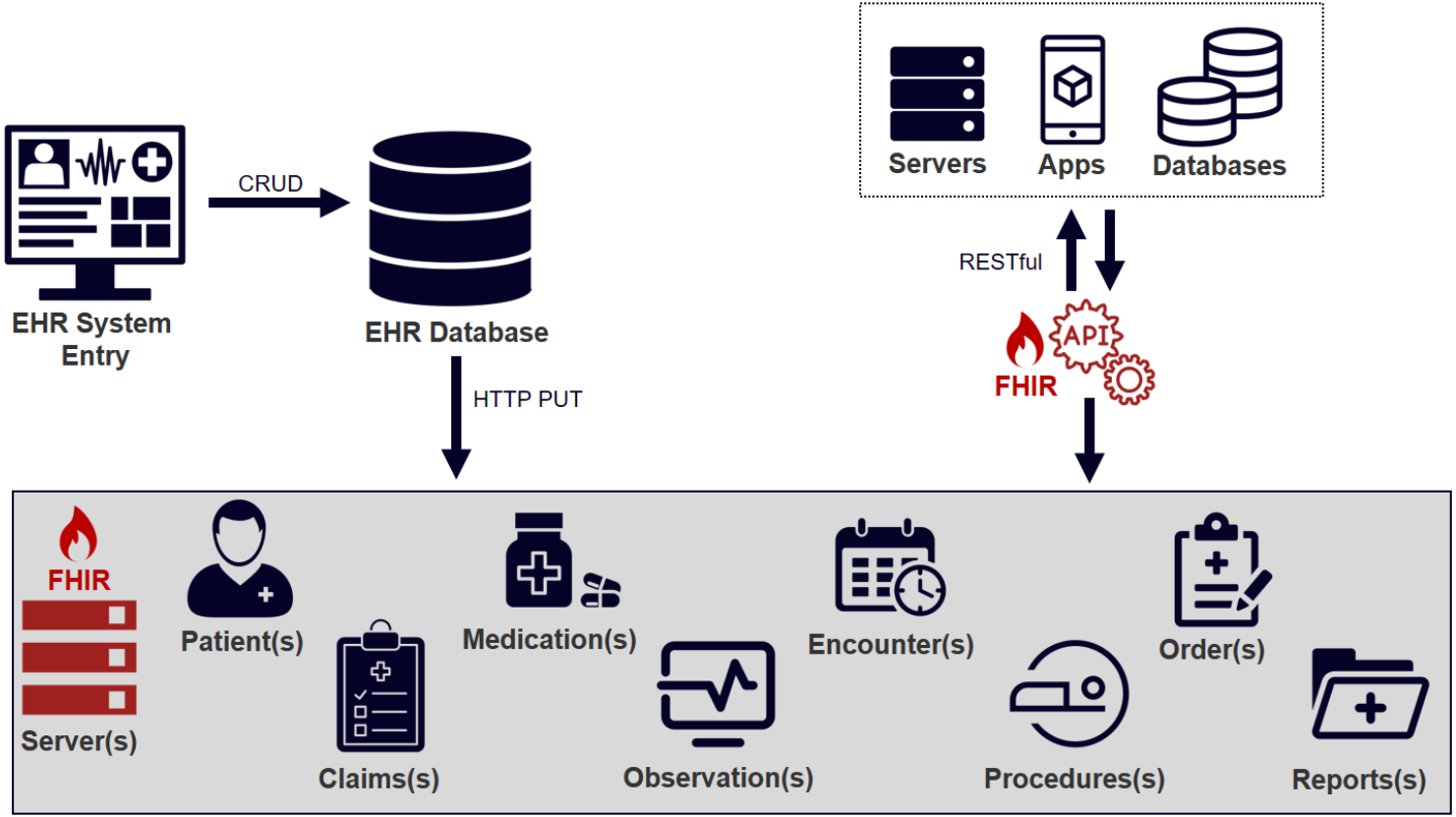
HL7 standard -

Fast Healthcare Interoperability Resources (FHIR)

FHIR-to-CDISC: Goal

Credit: Mike Hamidi

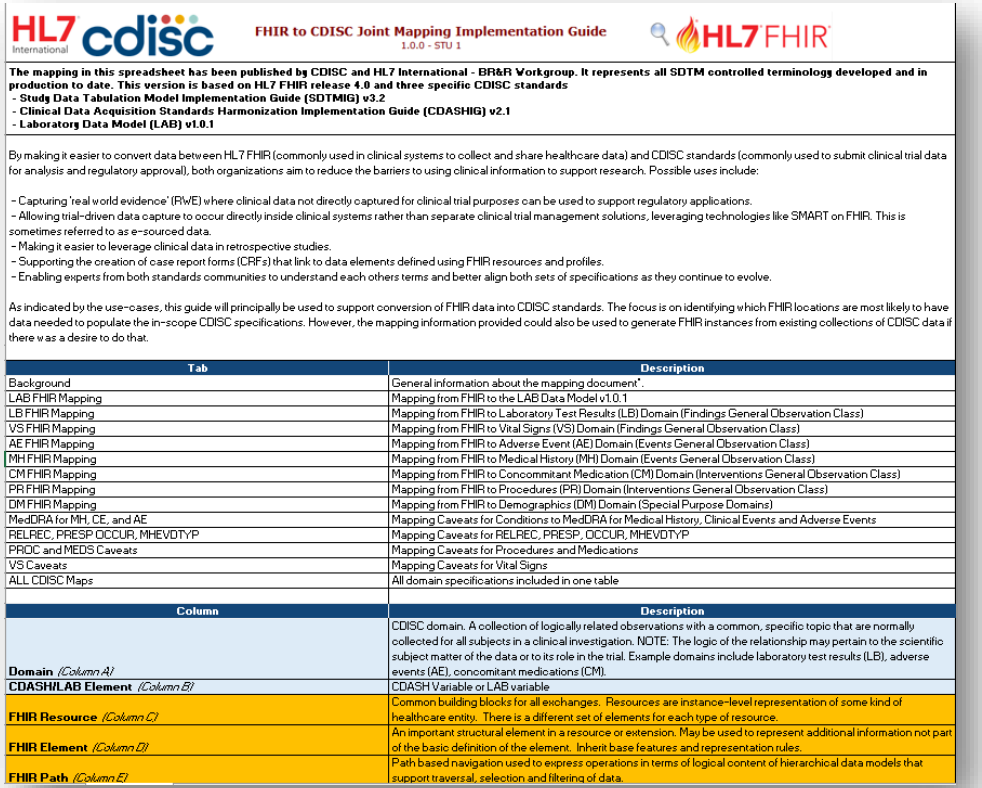
Leverage EHRs built on FHIR R4/R5 and extrapolate, either directly or in an intermediary mechanism, into a sponsors clinical trial system (e.g., EDC, MDR, etc.). Helping to more efficiently access and integrate EHR-based sources of data for clinical research.



The start of a solution…..

CDISC website
Mapping document
XLSX
XML
CDISC Library
JSON

HL7 website
Mapping IG
XLSX
XML



HL7 International cdisc — FHIR to CDISC Joint Mapping Implementation Guide 1.0.0 - STU 1 — HL7 FHIR

The mapping in this spreadsheet has been published by CDISC and HL7 International - BR&R Workgroup. It represents all SDTM controlled terminology developed and in production to date. This version is based on HL7 FHIR release 4.0 and three specific CDISC standards
- Study Data Tabulation Model Implementation Guide (SDTMIG) v3.2
- Clinical Data Acquisition Standards Harmonization Implementation Guide (CDASHIG) v2.1
- Laboratory Data Model (LAB) v1.0.1

By making it easier to convert data between HL7 FHIR (commonly used in clinical systems to collect and share healthcare data) and CDISC standards (commonly used to submit clinical trial data for analysis and regulatory approval), both organizations aim to reduce the barriers to using clinical information to support research. Possible uses include:

- Capturing 'real world evidence' (RWE) where clinical data not directly captured for clinical trial purposes can be used to support regulatory applications.
- Allowing trial-driven data capture to occur directly inside clinical systems rather than separate clinical trial management solutions, leveraging technologies like SMART on FHIR. This is sometimes referred to as e-sourced data.
- Making it easier to leverage clinical data in retrospective studies.
- Supporting the creation of case report forms (CRFs) that link to data elements defined using FHIR resources and profiles.
- Enabling experts from both standards communities to understand each others terms and better align both sets of specifications as they continue to evolve.

As indicated by the use-cases, this guide will principally be used to support conversion of FHIR data into CDISC standards. The focus is on identifying which FHIR locations are most likely to have data needed to populate the in-scope CDISC specifications. However, the mapping information provided could also be used to generate FHIR instances from existing collections of CDISC data if there was a desire to do that.

Tab	Description
Background	General information about the mapping document*.
LAB FHIR Mapping	Mapping from FHIR to the LAB Data Model v1.0.1
LB FHIR Mapping	Mapping from FHIR to Laboratory Test Results (LB) Domain (Findings General Observation Class)
VS FHIR Mapping	Mapping from FHIR to Vital Signs (VS) Domain (Findings General Observation Class)
AE FHIR Mapping	Mapping from FHIR to Adverse Event (AE) Domain (Events General Observation Class)
MH FHIR Mapping	Mapping from FHIR to Medical History (MH) Domain (Events General Observation Class)
CM FHIR Mapping	Mapping from FHIR to Concommitant Medication (CM) Domain (Interventions General Observation Class)
PR FHIR Mapping	Mapping from FHIR to Procedures (PR) Domain (Interventions General Observation Class)
DM FHIR Mapping	Mapping from FHIR to Demographics (DM) Domain (Special Purpose Domains)
MedDRA for MH, CE, and AE	Mapping Caveats for Conditions to MedDRA for Medical History, Clinical Events and Adverse Events
RELREC, PRESP OCCUR, MHEVDTYP	Mapping Caveats for RELREC, PRESP, OCCUR, MHEVDTYP
PROC and MEDS Caveats	Mapping Caveats for Procedures and Medications
VS Caveats	Mapping Caveats for Vital Signs
ALL CDISC Maps	All domain specifications included in one table

Column	Description
Domain *(Column A)*	CDISC domain. A collection of logically related observations with a common, specific topic that are normally collected for all subjects in a clinical investigation. NOTE: The logic of the relationship may pertain to the scientific subject matter of the data or to its role in the trial. Example domains include laboratory test results (LB), adverse events (AE), concomitant medications (CM).
CDASH/LAB Element *(Column B)*	CDASH Variable or LAB variable
FHIR Resource *(Column C)*	Common building blocks for all exchanges. Resources are instance-level representation of some kind of healthcare entity. There is a different set of elements for each type of resource.
FHIR Element *(Column D)*	An important structural element in a resource or extension. May be used to represent additional information not part of the basic definition of the element. Inherit base features and representation rules.
FHIR Path *(Column E)*	Path based navigation used to express operations in terms of logical content of hierarchical data models that support traversal, selection and filtering of data.

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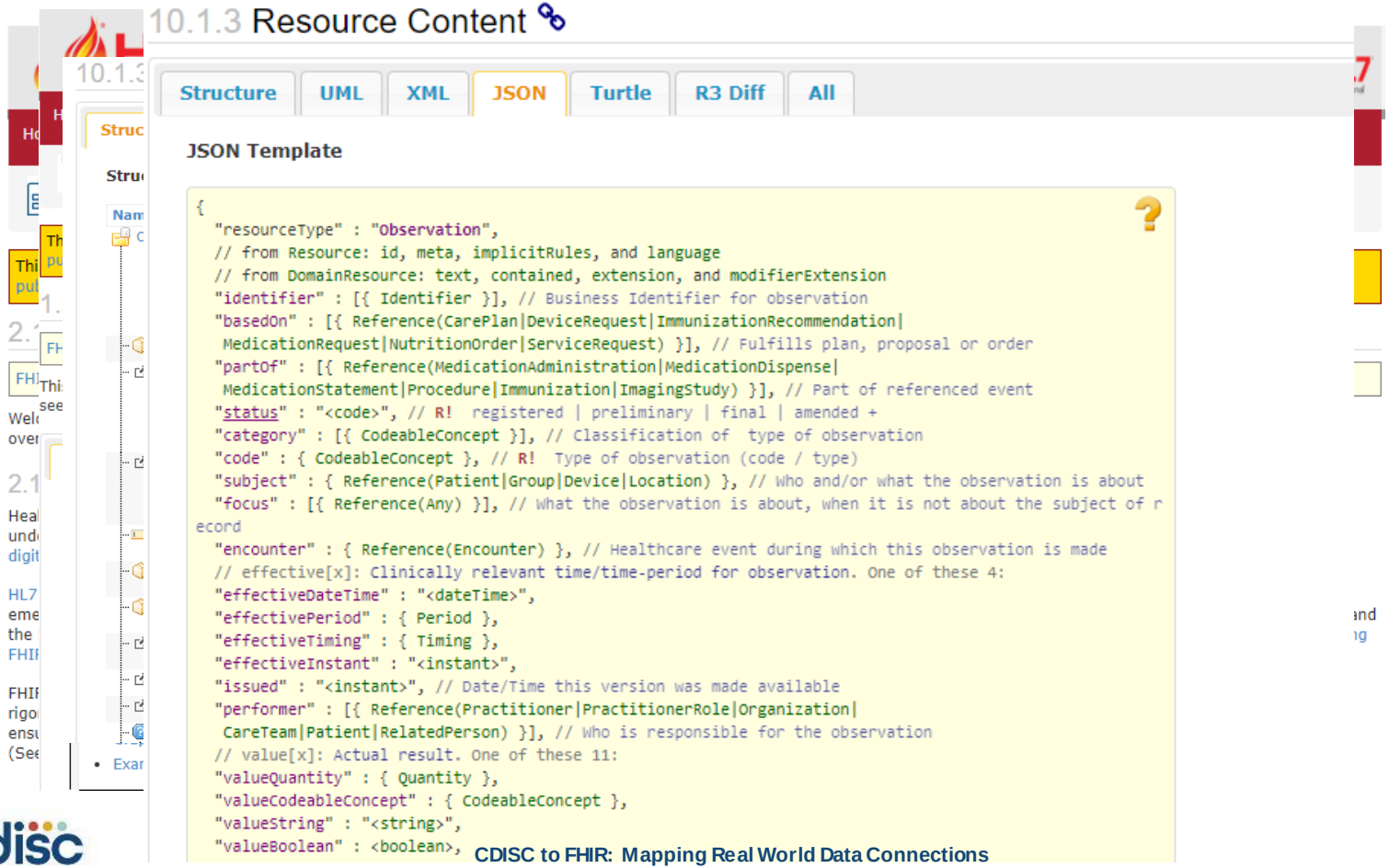
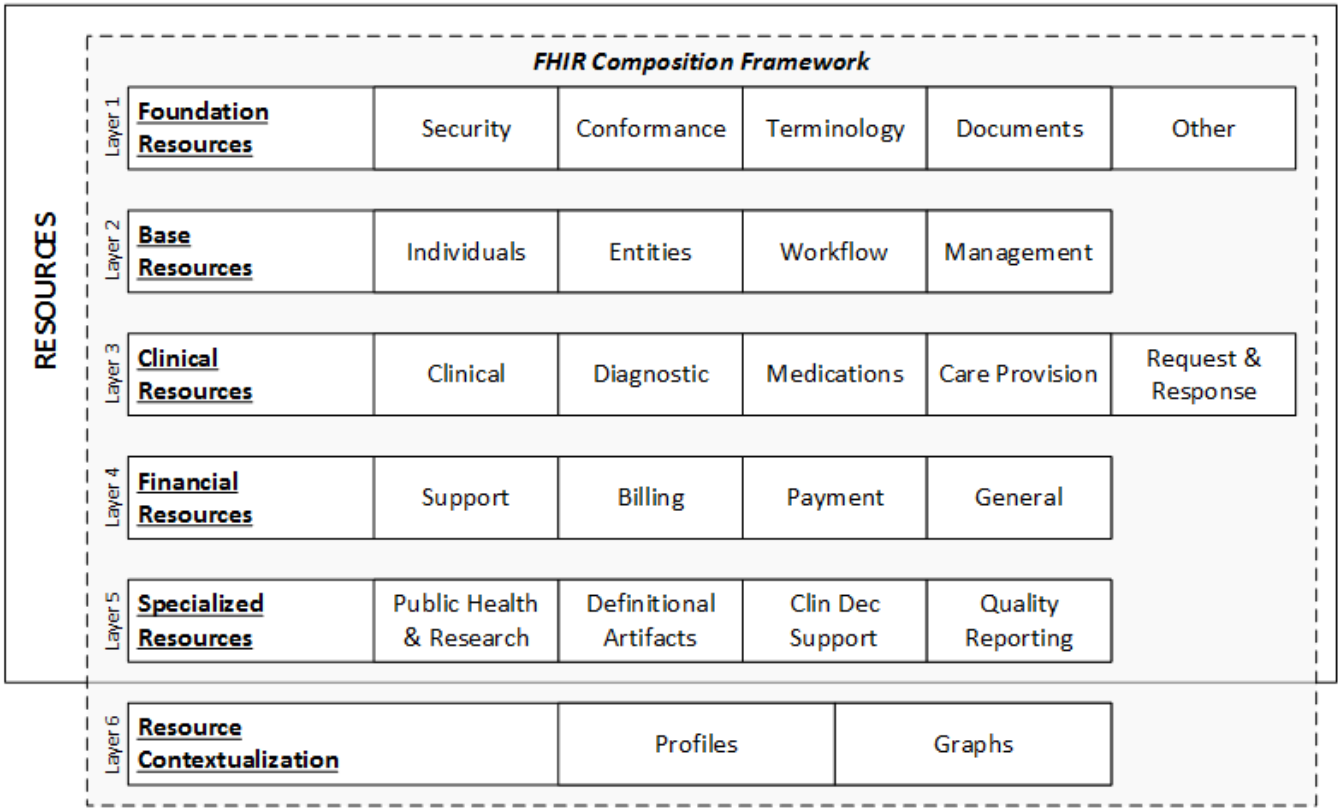
HL7 Community and FHIR

- Identified a need to share healthcare information electronically
- Pressure increases for broadened sharing of data
- Took a “Fresh look” to see what would healthcare exchange look like if they started from scratch?
- Drafted a healthcare exchange API based on RESTful APIs
  - Implementer Focused
  - Target the 80% common
  - Use web technology
  - Support human readability
  - Paradigm & architecture agnostic
  - Open source

What is FHIR?


10.1.3 Resource Content
Structure
UML
XML
JSON
Turtle
R3 Diff
All
JSON Template
{
"resourceType" : "Observation",
// from Resource: id, meta, implicitRules, and language
// from DomainResource: text, contained, extension, and modifierExtension
"identifier" : [{ Identifier }], // Business Identifier for observation
"basedOn" : [{ Reference(CarePlan|DeviceRequest|ImmunizationRecommendation|
MedicationRequest|NutritionOrder|ServiceRequest) }], // Fulfills plan, proposal or order
"partOf" : [{ Reference(MedicationAdministration|MedicationDispense|
MedicationStatement|Procedure|Immunization|ImagingStudy) }], // Part of referenced event
"status" : "<code>", // R! registered | preliminary | final | amended +
"category" : [{ CodeableConcept }], // Classification of type of observation
"code" : { CodeableConcept }, // R! Type of observation (code / type)
"subject" : { Reference(Patient|Group|Device|Location) }, // Who and/or what the observation is about
"focus" : [{ Reference(Any) }], // What the observation is about, when it is not about the subject of r
ecord
"encounter" : { Reference(Encounter) }, // Healthcare event during which this observation is made
// effective[x]: Clinically relevant time/time-period for observation. One of these 4:
"effectiveDateTime" : "<dateTime>",
"effectivePeriod" : { Period },
"effectiveTiming" : { Timing },
"effectiveInstant" : "<instant>",
"issued" : "<instant>", // Date/Time this version was made available
"performer" : [{ Reference(Practitioner|PractitionerRole|Organization|
CareTeam|Patient|RelatedPerson) }], // Who is responsible for the observation
// value[x]: Actual result. One of these 11:
"valueQuantity" : { Quantity },
"valueCodeableConcept" : { CodeableConcept },
"valueString" : "<string>",
"valueBoolean" : <boolean>,

The FHIR Architecture



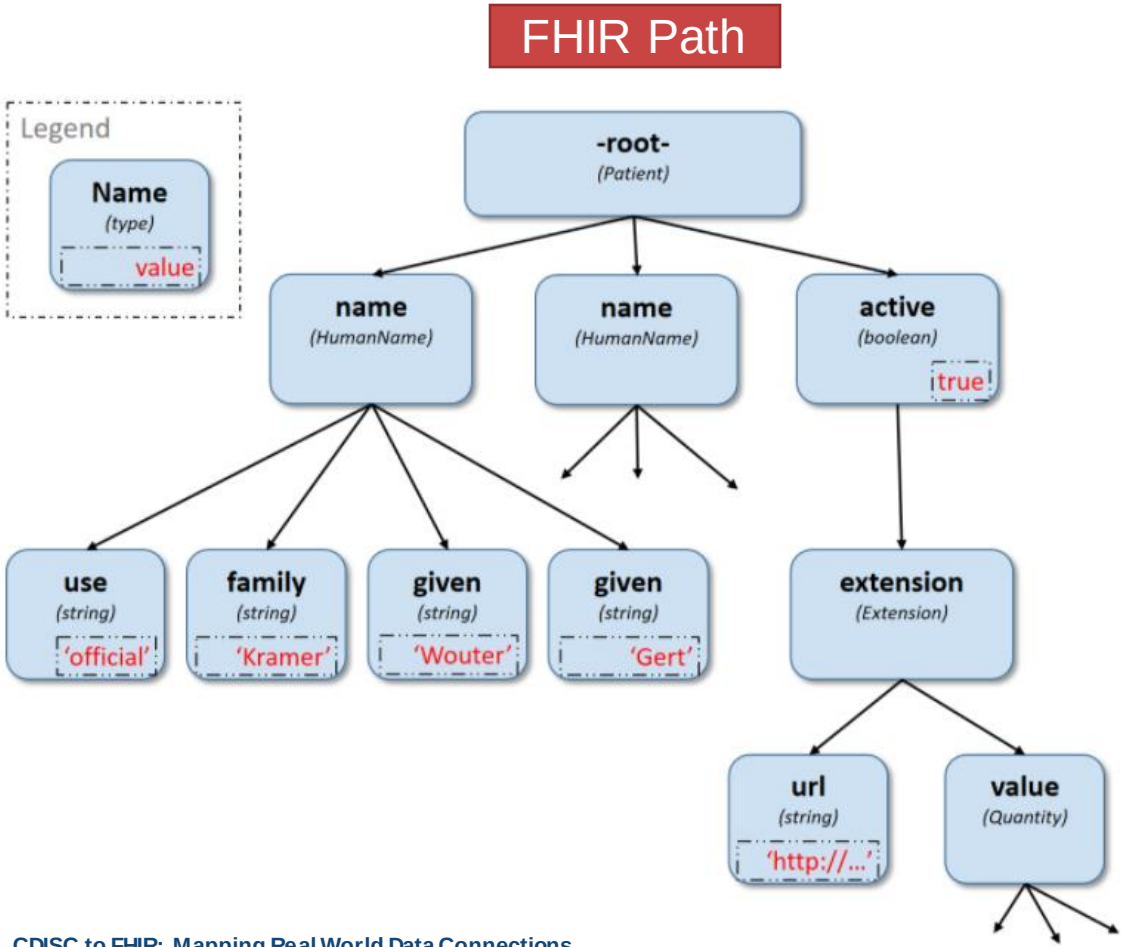
FHIR Path

Example #1:

Patient.name.given

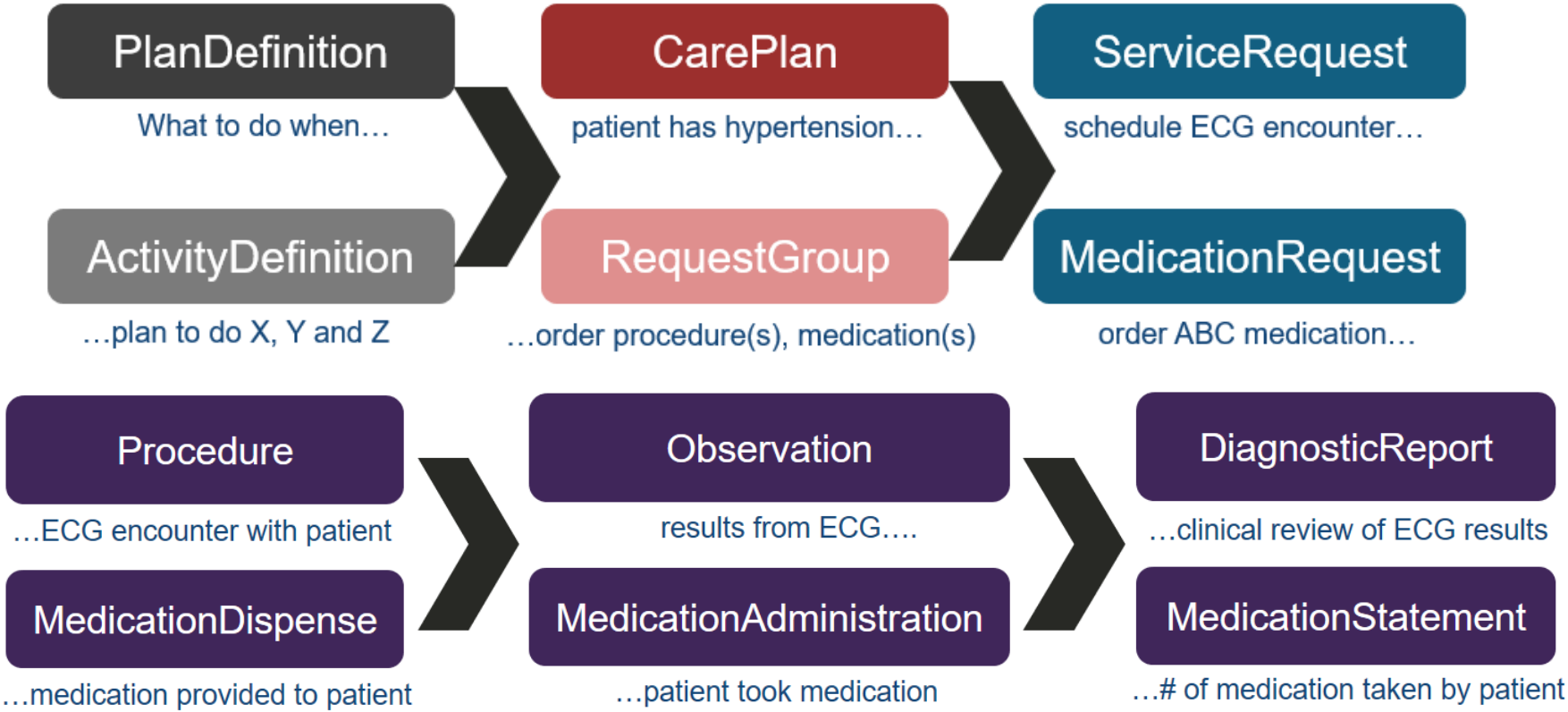
Example #2:

ResearchSubject.where(individual =Patient).identifier.identifier



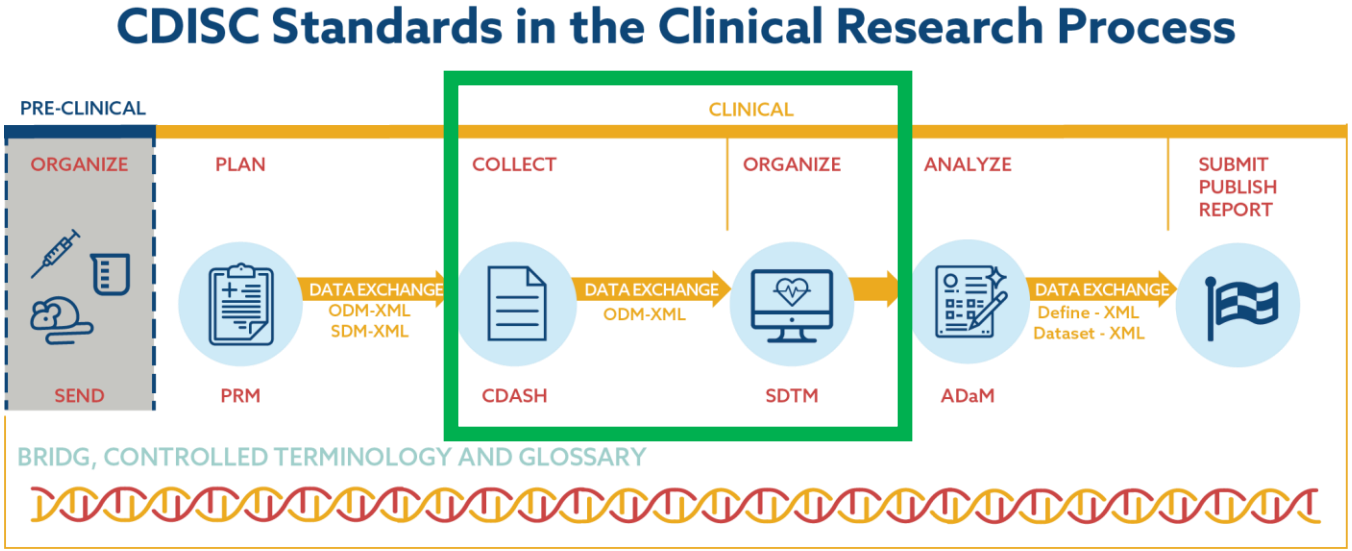
The FHIR Infrastructure of the Resources

Credit: Mike Hamidi



Note: There are additional FHIR resources not shown.

Foundational Standards



End to End

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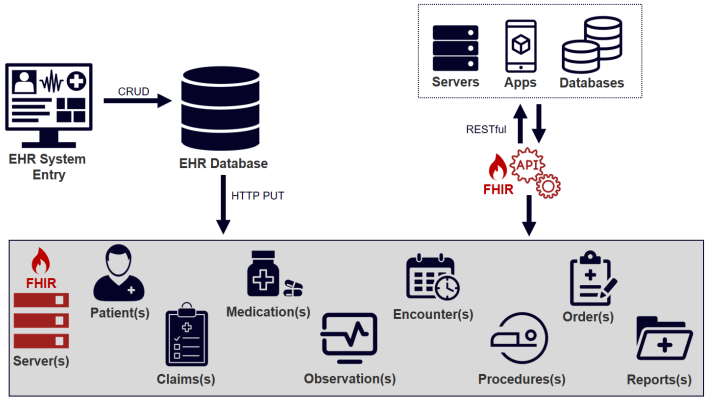
Example FHIR Message

Credit: Mike Hamidi



Example EHR FHIR Resource Message

```
<Patient xmlns="http://hl7.org/fhir">
  <id value="glossy"/>
  <meta>
    <lastUpdated value="2014-11-13T11:41:00+11:00"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456. Male, 24-Sept 1932</p>
    </div>
  </text>
  <extension url="http://example.org/StructureDefinition/trials">
    <valueCode value="renal"/>
  </extension>
  <identifier>
    <use value="usual"/>
    <type>
      <coding>
        <system value="http://hl7.org/fhir/v2/0203"/>
        <code value="MR"/>
      </coding>
    </type>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <active value="true"/>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender value="male"/>
  <birthDate value="1932-09-24"/>
  <careProvider>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </careProvider>
</Patient>
```

Resource Identity & Metadata

Human Readable Summary

Extension with URL to definition

Standard Data:
- MRN
- Name
- Gender
- Birth Date
- Provider

How it would work

Credit: Mike Hamidi

Example EHR FHIR Resource Message

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<Patient xmlns="http://hl7.org/fhir">
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  </extension>
  <identifier>
    <use value="usual"/>
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      <coding>
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        <code value="MR"/>
      </coding>
    </type>
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    <value value="123456"/>
  </identifier>
  <active value="true"/>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender value="male"/>
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  </careProvider>
</Patient>
```

Resource Identity & Metadata

Human Readable Summary

Extension with URL to definition

Standard Data:
- MRN
- Name
- Gender
- Birth Date
- Provider

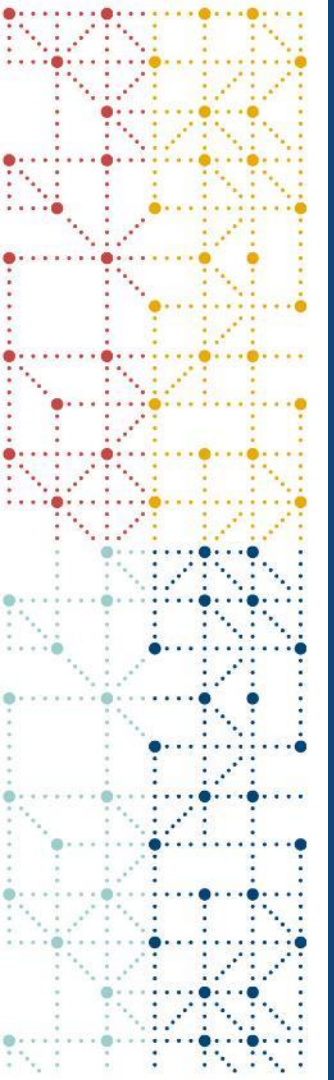
Dependent on requirements, message exchange can flow into CDASH then SDTM or SDTM directly

CDISC Library CDASHIG DM (JSON)


```
"ordinal": "7",
"name": "DM",
"label": "Demographics",
"_links": {
    "self": {
        "href": "/mdr/cdashig/2-1/domains/DM",
        "title": "Demographics",
        "type": "CDASH Domain"
    },
    "parentProduct": {
        "href": "/mdr/cdashig/2-1",
        "title": "Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials
        "type": "Implementation Guide"
    },
    "parentClass": {
        "href": "/mdr/cdashig/2-1/classes/SpecialPurpose",
        "title": "Special-Purpose",
        "type": "Class"
    },
    "priorVersion": {
        "href": "/mdr/cdashig/2-0/domains/DM",
        "title": "Demographics",
        "type": "CDASH Domain"
```

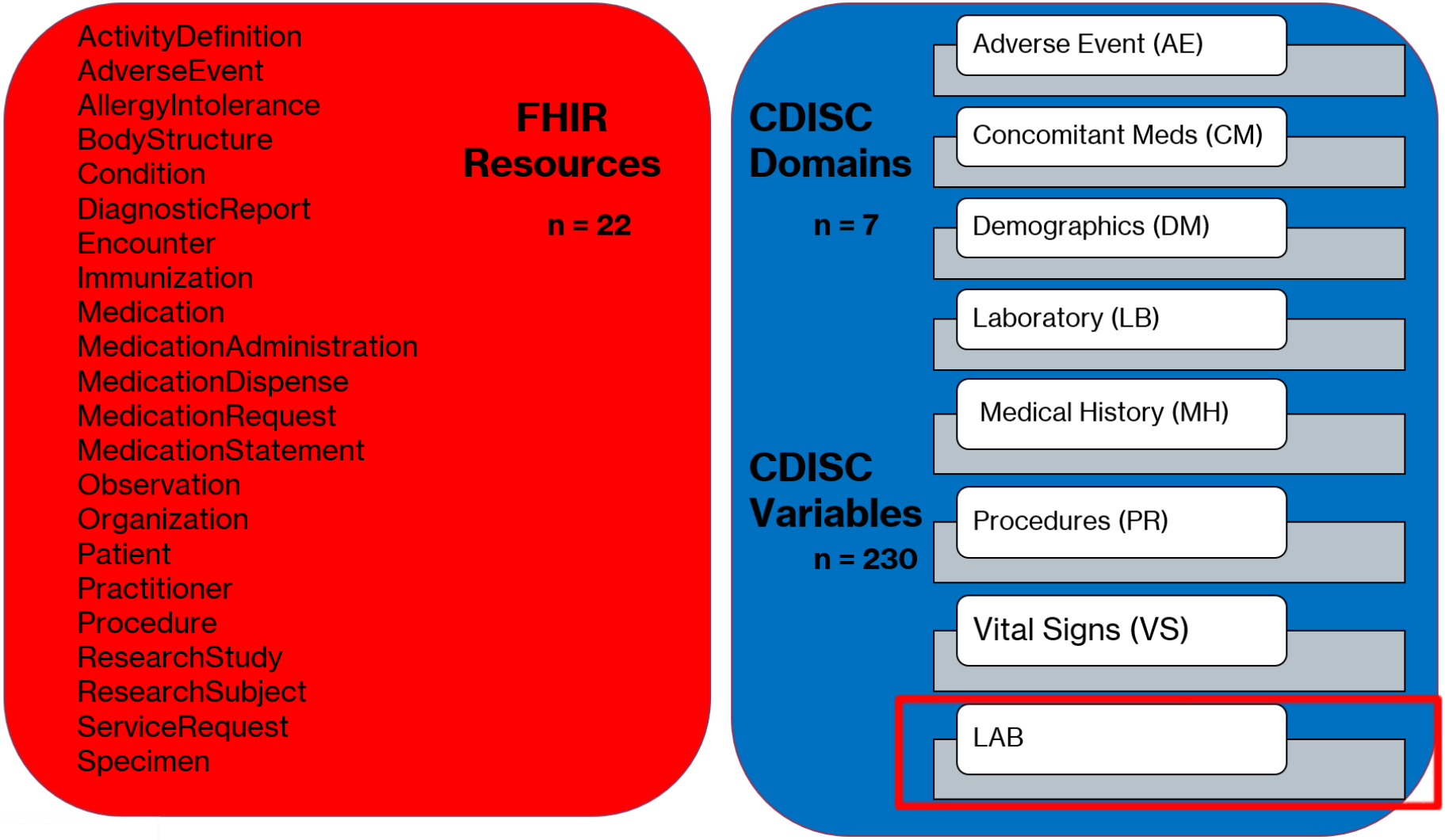

CDISC Library SDTMIG DM (JSON)

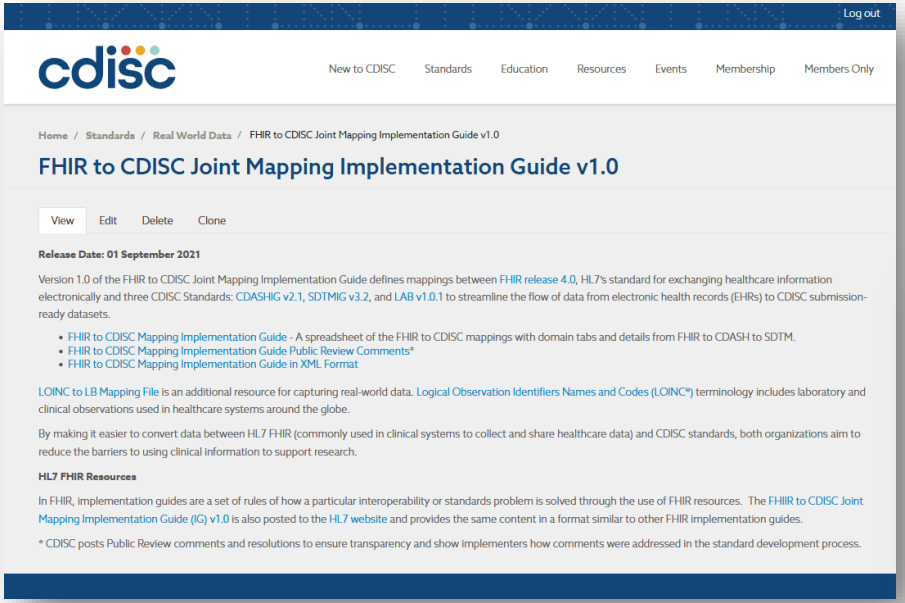

```
"ordinal": "2",
"name": "DM",
"label": "Demographics",
"description": "A special-purpose domain that includes a set of essential standard variables that describe each
    It is the parent domain for all other observations for human clinical subjects. (Source: CDISC Controlled Te
    2018-06-29)",
"datasetStructure": "One record per subject",
"_links": {
    "self": {
        "href": "/mdr/sdtmig/3-2/datasets/DM",
        "title": "Demographics",
        "type": "SDTM Dataset"
    },
    "modelDataset": {
        "href": "/mdr/sdtm/1-4/datasets/DM",
        "title": "Demographics",
        "type": "SDTM Dataset"
    },
    "parentProduct": {
        "href": "/mdr/sdtmig/3-2",
        "title": "Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.2 (Final)",
        "type": "Implementation Guide"
    },
```



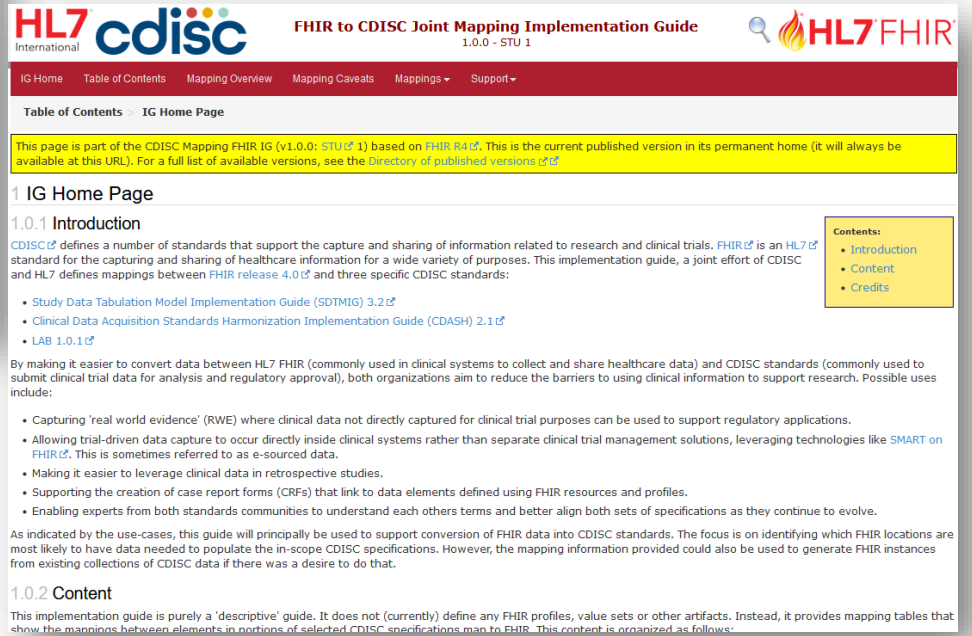
What domains were mapped?

CDISC domains likely be found in real world data


ActivityDefinition
AdverseEvent
AllergyIntolerance
BodyStructure
Condition
DiagnosticReport
Encounter
Immunization
Medication
MedicationAdministration
MedicationDispense
MedicationRequest
MedicationStatement
Observation
Organization
Patient
Practitioner
Procedure
ResearchStudy
ResearchSubject
ServiceRequest
Specimen
FHIR Resources
n = 22
CDISC Domains
n = 7
CDISC Variables
n = 230
Adverse Event (AE)
Concomitant Meds (CM)
Demographics (DM)
Laboratory (LB)
Medical History (MH)
Procedures (PR)
Vital Signs (VS)
LAB



Published by HL7 and CDISC simultaneously



https://www.cdisc.org/standards/real-world-data/fhir-cdisc-joint-mapping-implementation-guide-v1-0

Disclaimers

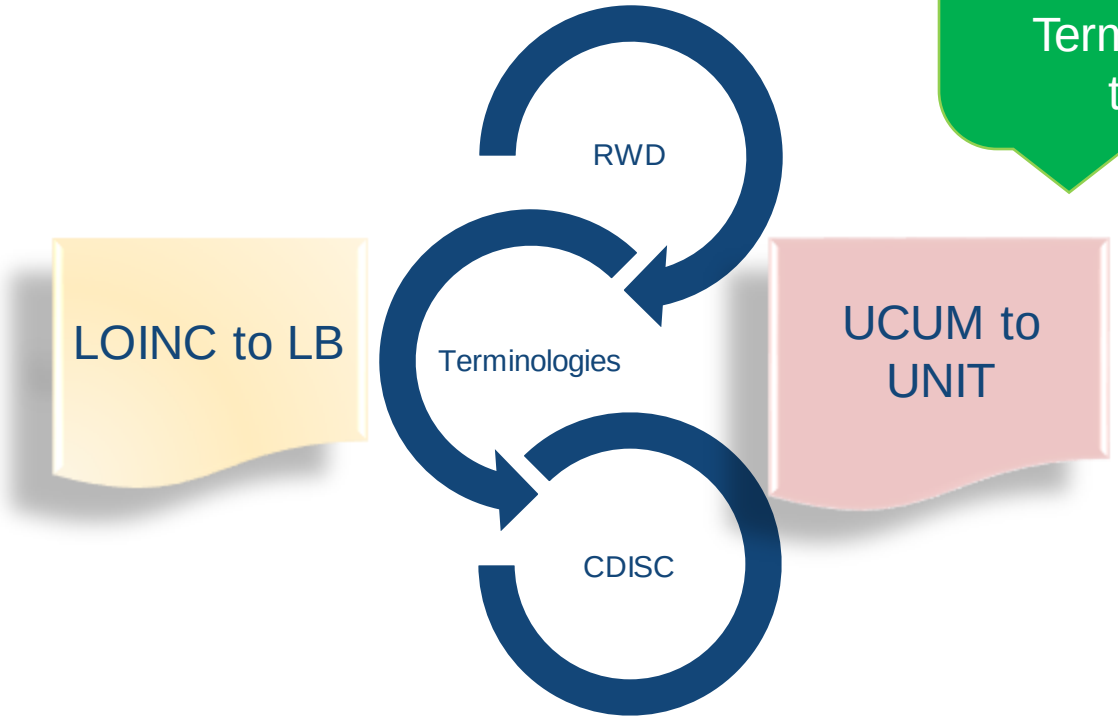
Identified several points to place disclaimers regarding mapping between CDISC and HL7.

Differences in:

- Concepts
- Definitions
- Terminologies

Leveraging other connectors

Thank you to the NIH NCI EVS Controlled Terminology team



Take home message

- FHIR to CDISC Joint Mapping Guide is available as a resource for mapping data from FHIR resources to CDASH and SDTM variables.

Additional tools

- LOINC to LB mapping file
- UCUM to Unit code list mapping file

Action

Try it

Is it helpful?

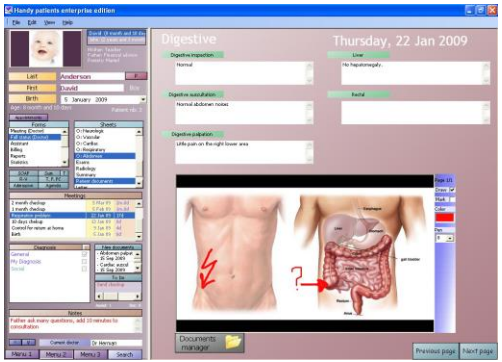
How can it be improved?

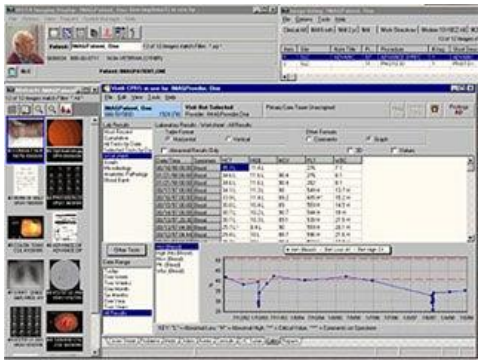
Give feedback

Email: rbaker@cdisc.org

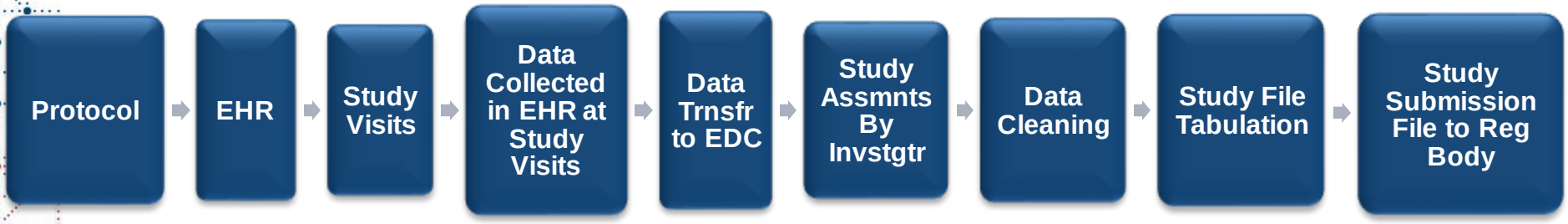
Real World Data Collection Considerations

- Each clinical trail has different data requirements
- Each health system/hospital/clinic has different data elements available in their EHR/EMR systems
- IT queue in the health system – Example request for Medical Research flag





The vision of what could be…



Walk through the documents

HL7 FHIR to CDISC Mapping v1.0 as a start towards leveraging Real World Data (RWD) for clinical research

Thank You!