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Interoperability with HL7 FHIR®

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What is FHIR®?

FHIR® – Fast Healthcare Interoperability Resources (http://hl7.org/fhir)

- A next generation standards framework created by HL7
- Takes the best features of HL7 V3 and Clinical Document Architecture (CDA)
  - Interoperability out of the box
    - Base resources can be used for most things but also extended
  - Human-readable serialization
  - Solid ontology based analysis with a rigorous formal mapping
- Make use of the latest web standards and technologies
  - XML, JSON, HTTP, OAuth, etc…
  - Support for RESTful architectures
- Has a strong focus on implementation
  - Many implementation libraries available
  - Many examples and reference implementations available

FHIR® Resources

All data is exchanged as Resources

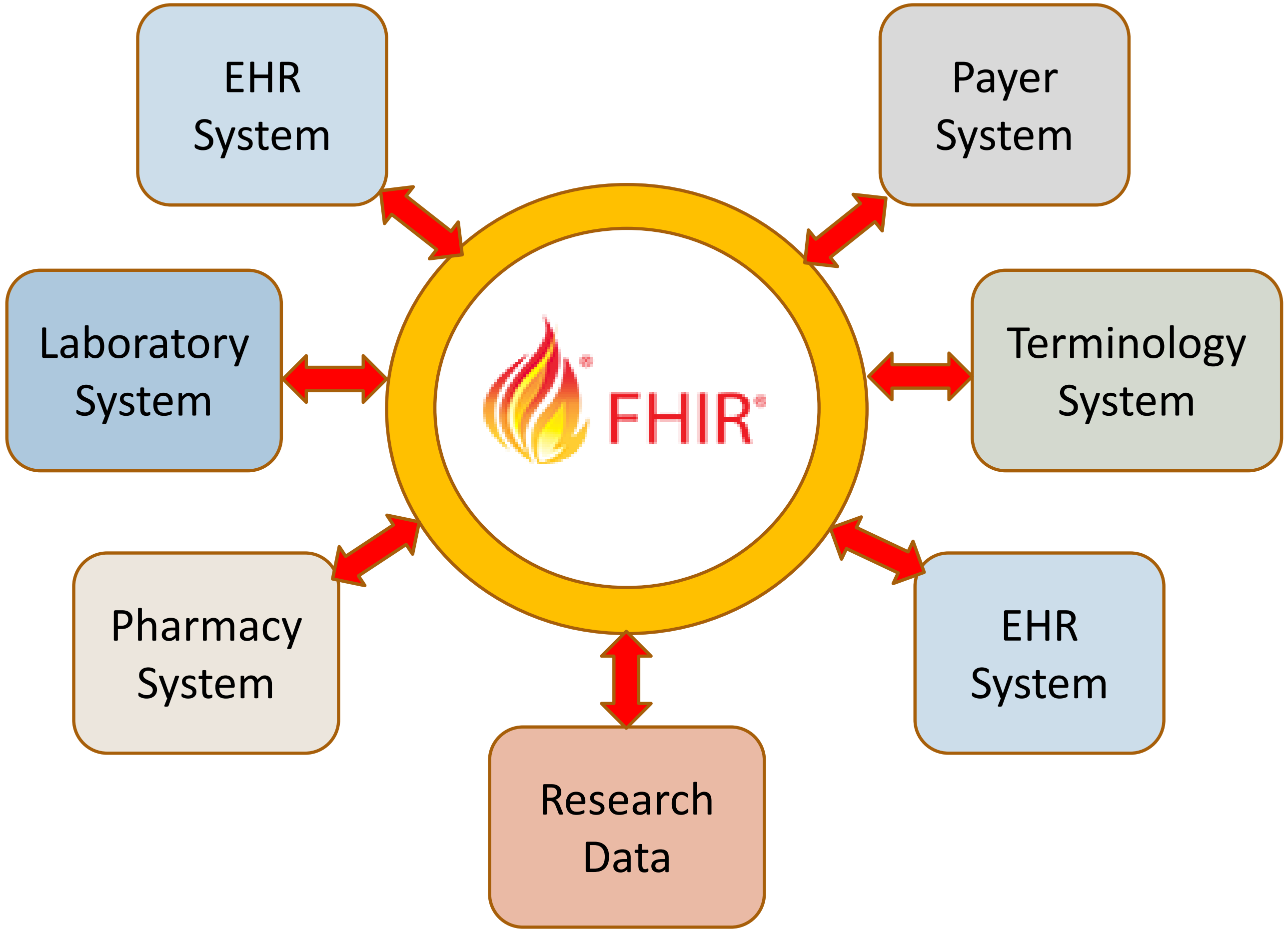
- Resources contain common metadata
  - All Resources SHOULD contain narrative text
  - Provides a human readable version of the content of the Resource using HTML
  - Can be used as a fallback for manual processing
- Resources contain attributes and can contain references to other Resources
- Supports terminology to ensure semantic interoperability
  - Code Systems, Value Sets, Identifier Systems
- Resources can be serialized in JSON or XML
- https://www.hl7.org/fhir/resourcelist.html

Extensibility

FHIR supports extensions for all resources

- Extensibility was designed in from the beginning
- Resources can be extended to include additional attributes not included in the base Resource
- Extensions can also enforce the cardinality of attributes both existing and new
  - Much of the base resource attributes are optional
- Systems should not reject a resource because they do not support the extension
  - They may not process the additional elements

FHIR® Interoperability



EHR System

Payer System

Laboratory System

FHIR®

Terminology System

Pharmacy System

EHR System

Research Data

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FHIR® Interoperability Use Cases

Electronic Clinical Quality Measure (eCQM) Reporting

Measure Development

- Previously measures were developed using Quality Data Model (QDM) for both the model and the logic
- Clinical Quality Language (CQL) was developed as a new measure definition standard to separate the logic from the model
  - This was an important step to allowing measure reporting in FHIR
  - Measures can be developed using FHIR as the model
  - Measures developed for 2019 eCQM reporting will be defined in CQL with QDM still as the model

Measure Reporting

- eCQMs are currently reported using Quality Reporting Document Architecture (QRDA)
  - QRDA I for patient level
  - QRDA III for population level
- QRDA is based on Clinical Document Architecture (CDA) which is an HL7 V3 standard

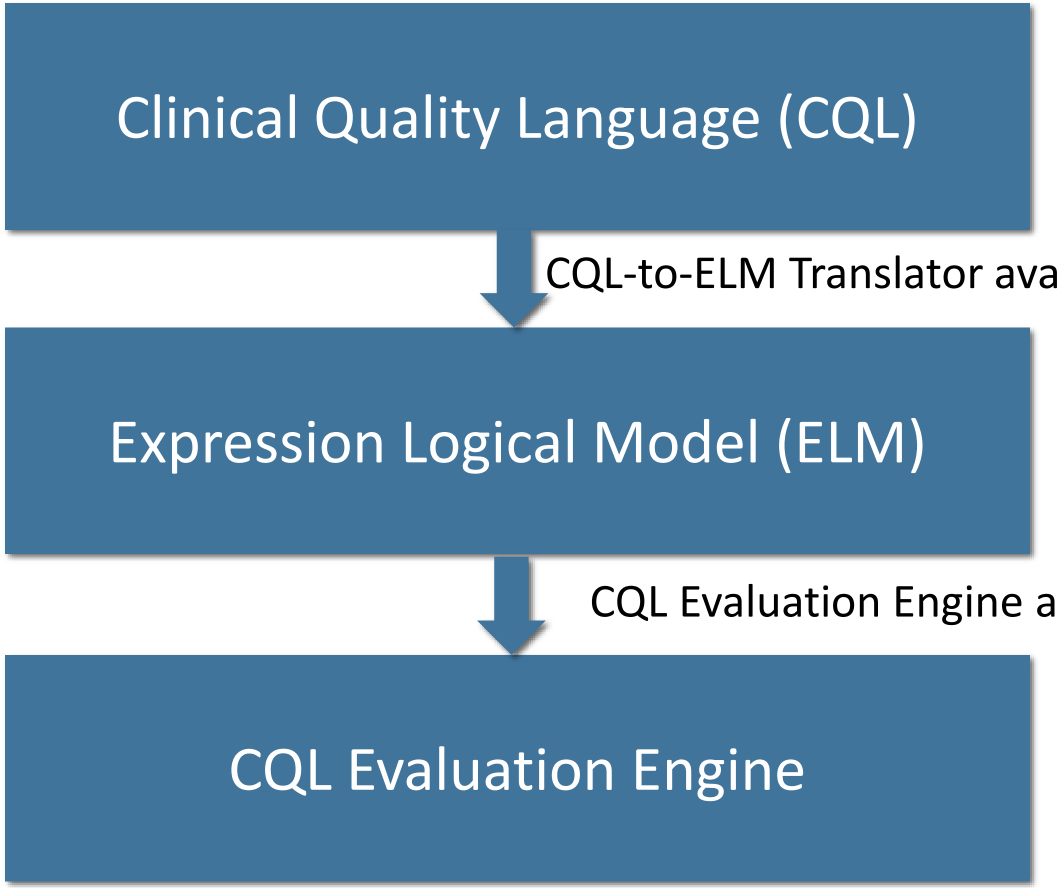
Quality Reporting Using FHIR®

FHIR Clinical Reasoning Module

- Provides resources and operations to enable the representation, distribution, and evaluation of clinical knowledge artifacts
  - Decision Support Rules
  - Quality Measures
- Allows for sharing of artifacts across systems
- Allows for evaluation of artifacts for a patient or population
- Defines the Measure and MeasureReport Resources

```
▼<MeasureReport xmlns="http://hl7.org/fhir">
  ▼<contained>
    ▼<Bundle xmlns="http://hl7.org/fhir">
       <id value="b37603d0-3f49-49a5-a772-a18071c49eeb"/>
       <type value="collection"/>
      ▼<entry>
         <fullUrl value="Observation/Observation-18/_history/1"/>
        ▼<resource>
          ▼<Observation xmlns="http://hl7.org/fhir">
             <id value="Observation-18"/>
            ▼<meta>
               <versionId value="1"/>
               <lastUpdated value="2017-03-30T13:01:08.917-04:00"/>
             </meta>
            ▼<extension url="http://mihin.org/fhir/templateId">
               <valueString value="2.16.840.1.113883.10.20.22.4.69"/>
             </extension>
            ▼<extension url="http://mihin.org/fhir/templateId">
               <valueString value="2.16.840.1.113883.10.20.24.3.69"/>
             </extension>
            ▼<identifier>
               <system value="http://hl7.org/fhir/identifier"/>
               <value value="1.3.6.1.4.1.115:579f4eb5aeac500a550c5c7d"/>
             </identifier>
             <status value="final"/>
            ▼<code>
              ▼<coding>
                 <system value="http://snomed.info/sct"/>
                 <code value="73761001"/>
               </coding>
               <text value="Colonoscopy procedure result"/>
             </code>
            ▼<subject>
               <reference value="Patient/Patient-12214"/>
               <display value="Joe Jones Jr"/>
             </subject>
             <effectiveDateTime value="2010-04-18"/>
             <issued value="2010-06-22T11:00:00-04:00"/>
            ▼<performer>
               <reference value="Practitioner/Practitioner-12208"/>
               <display value="Jay McCann Sawyer MD"/>
             </performer>
           </Observation>
         </resource>
       </entry>
```

Quality Reporting Using FHIR®



Clinical Quality Language (CQL)

The Measure is defined in CQL using precise logic

CQL-to-ELM Translator available as open source

Expression Logical Model (ELM)

The CQL is translated to ELM which contains sufficient semantics for implementation

CQL Evaluation Engine available as open source

CQL Evaluation Engine

The CQL Evaluation Engine takes the ELM, a FHIR URL, and a terminology server and evaluates the measure

Quality Reporting Using FHIR®

Implementation Burden Lowered

- If you already expose your data using the FHIR API your implementation for quality reporting is simply implementing the $evaluate-measure operation on the Measure Resource
  - Using the open source CQL Evaluation Engine this is only about 10 lines of code
  - Will work for any measure defined using CQL and translated to ELM
  - CQL to ELM Translator and the CQL Evaluation engine are maintained as a part of the CQL standard tooling
- No need to understand CDA and QRDA standards and XML formats

SMART on FHIR Application can encapsulate the evaluation operation

- We developed the $evaluate-measure operation as a SMART on FHIR app to verify that if you are using SMART on FHIR to access your data it will evaluate the measure with no development required

Population - http://{FHIR_URL}/Measure/NQF0034/$evaluate-measure?startPeriod=2017-01&endPeriod=2017-12

Patient- http://{FHIR_URL}/Measure/NQF0034/$evaluate-measure?startPeriod=2017-01&endPeriod=2017-12&patient={patient_ID}

Adverse Event Reporting

Adverse events are reported using the HL7 Individual Case Safety Report (ICSR) standard

- Supports adverse event reporting for
  - Use of Drugs
  - Therapeutic Biologics
  - Vaccines
  - Devices
- Mostly information about the adverse event and then observations about the individual
- Another HL7 V3 Standard

```xml
<?xml version="1.0" encoding="UTF-8"?>
<!-- Masked age information.  No error. -->
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3  ../4_ICH_ICSR_Schema_Files
    <id extension="30jan2021-3aea-4069-a2dd-08002b30309d" root="2.16.840.1.113883.3.989.2.1.3.22"/>
    <!-- N.1.2 Batch Number -->
    <creationTime value="20101214151617-0500"/>
    <!-- N.1.5 Date of Batch Transmission -->
    <responseModeCode code="D"/>
    <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
    <name code="1" displayName="ichicsr" codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
    <!--N.1.1: Type of Messages in Batch -->
    <!-- Message #1 -->
    <PORR_IN049016UV>
        <id extension="21ec1492-3aea-4069-a2ab-08002b30309d" root="2.16.840.1.113883.3.989.2.1.3.1"/>
        <!-- N.2.r.1: Message Identifier -->
        <creationTime value="20140714151617-0500"/>
        <!-- N.2.r.4:Date of Message Creation -->
        <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
        <processingCode code="P"/>
        <processingModeCode code="I"/>
        <acceptAckCode code="AL"/>
        <receiver typeCode="RCV">
            <device classCode="DEV" determinerCode="INSTANCE">
                <id extension="CBER_VAERS" root="2.16.840.1.113883.3.989.2.1.3.12"/>
                <!-- N.2.r.3:Message Receiver Identifier -->
            </device>
        </receiver>
        <sender typeCode="SND">
            <device classCode="DEV" determinerCode="INSTANCE">
                <id extension="4567AB89012" root="2.16.840.1.113883.3.989.2.1.3.11"/>
                <!-- N.2.r.2: Message Sender Identifier -->
            </device>
        </sender>
```

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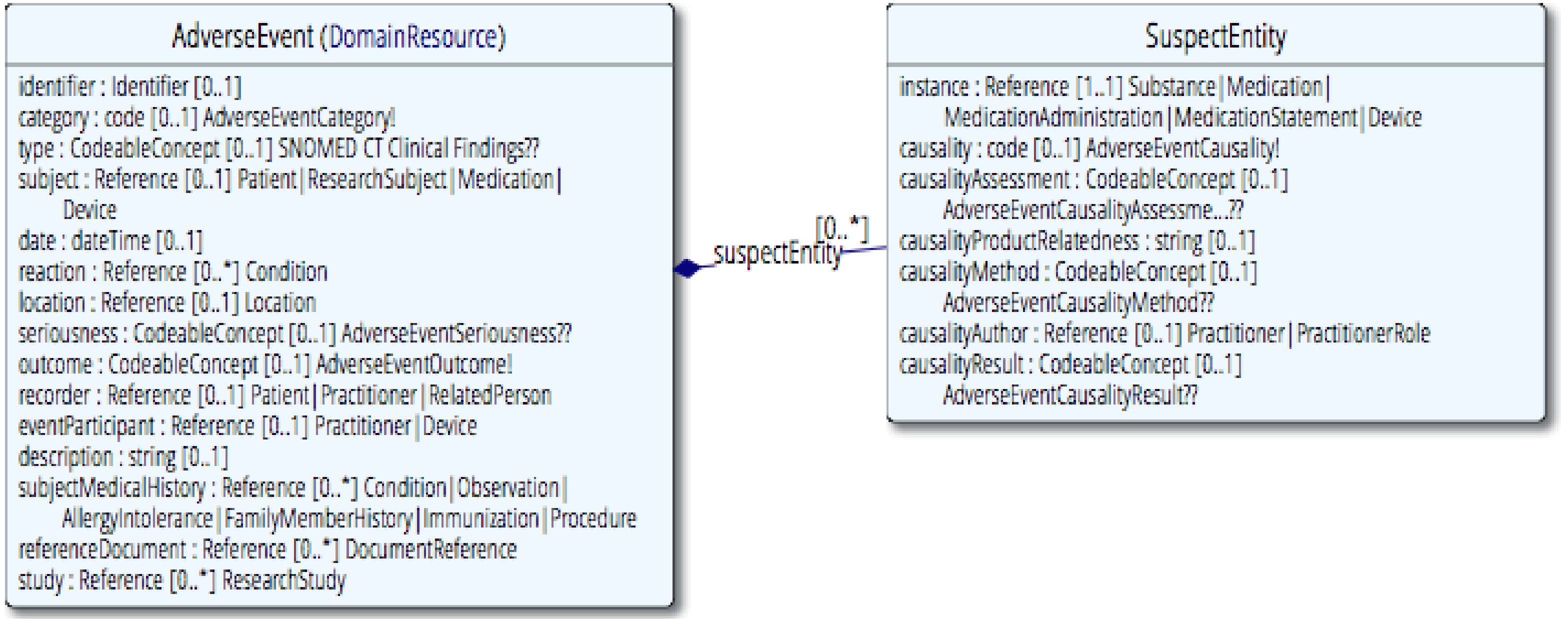
Adverse Event Reporting Using FHIR®

HL7 FHIR® defines an AdverseEvent Resource

- Has the necessary information for adverse event reporting
- Can also use the Observation Resource to include additional information relevant to the report



AdverseEvent (DomainResource)

identifier : Identifier [0..1]
category : code [0..1] AdverseEventCategory!
type : CodeableConcept [0..1] SNOMED CT Clinical Findings??
subject : Reference [0..1] Patient | ResearchSubject | Medication | Device
date : dateTime [0..1]
reaction : Reference [0..*] Condition
location : Reference [0..1] Location
seriousness : CodeableConcept [0..1] AdverseEventSeriousness??
outcome : CodeableConcept [0..1] AdverseEventOutcome!
recorder : Reference [0..1] Patient | Practitioner | RelatedPerson
eventParticipant : Reference [0..1] Practitioner | Device
description : string [0..1]
subjectMedicalHistory : Reference [0..*] Condition | Observation | AllergyIntolerance | FamilyMemberHistory | Immunization | Procedure
referenceDocument : Reference [0..*] DocumentReference
study : Reference [0..*] ResearchStudy

SuspectEntity

instance : Reference [1..1] Substance | Medication | MedicationAdministration | MedicationStatement | Device
causality : code [0..1] AdverseEventCausality!
causalityAssessment : CodeableConcept [0..1] AdverseEventCausalityAssessme...??
causalityProductRelatedness : string [0..1]
causalityMethod : CodeableConcept [0..1] AdverseEventCausalityMethod??
causalityAuthor : Reference [0..1] Practitioner | PractitionerRole
causalityResult : CodeableConcept [0..1] AdverseEventCausalityResult??

Genomic Data Exchange Using FHIR®

There is a Genomics module defined in FHIR for exchanging clinical and genetics data

- http://hl7.org/implement/standards/fhir/genomics.html
- Defines a new resource called Sequence
- Defines a genetics profile for the following resources
    - Observation-genetics on Observation
    - DiagnosticReport-genetics on DiagnosticReport
    - ProcedureRequest-genetics on ProcedureRequest
- Focuses on the exchange of clinically related genetics data rather than research data
    - Global Alliance for Genomics and Health (GA4GH) defines APIs for researchers
        - Focused more on pushing the full sequence genomic data

Genomic Data Exchange Using FHIR®

Sequence Resource

- Designed for next-generation sequencing data
- Can represent patients' observed sequences and detected variances compared to a reference sequence
- Has references to patient, specimen, device, and performer

Observation-genetics profile

- observation-geneticsSequence extension refers to the Sequence resource for sequence information related to this variant
- observation-geneticsInterpretation extension refers to an Observation instance which can contain clinical interpretations for the variant described
- code, effective[x], issued, performer, method, specimen elements are used to describe how the genetic observation (variant and sequence data) was obtained

Genomic Data Exchange Using FHIR®

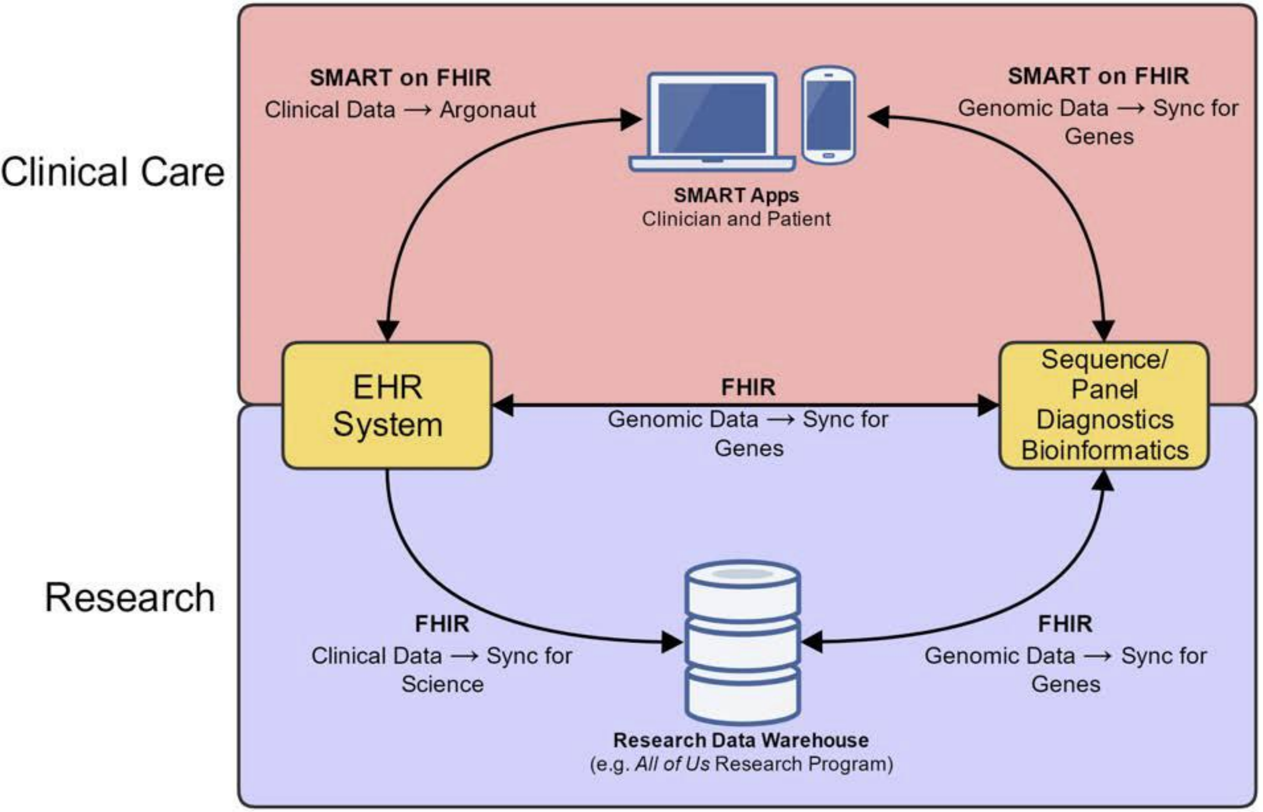
DiagnosticReport-genetics profile

- Describes the genetic test report
- Result element refers to a bundle of genetic observations
- code, effective[x], issued, performer, request, specimen are used to describe the details of the genetic test

ProcedureRequest-genetics profile

- Describes an order requested for sequence variant detection

Sync for Genes Project


Clinical Care

Research

SMART on FHIR
Clinical Data → Argonaut

SMART on FHIR
Genomic Data → Sync for Genes

SMART Apps
Clinician and Patient

EHR System

FHIR
Genomic Data → Sync for Genes

Sequence/ Panel Diagnostics Bioinformatics

FHIR
Clinical Data → Sync for Science

FHIR
Genomic Data → Sync for Genes

Research Data Warehouse
(e.g. *All of Us* Research Program)

Utilize FHIR Genomics to exchange genomic information

- Profiles that build upon base FHIR Resources
- Allow for a range of use case complexity as well as high-level summary data or low-level sequence data

Helps deliver on goals of *All of Us* along with Sync for Science

Goal of Phase 2 is to drive towards the next level of FHIR maturity

Sync for Genes Phase I Pilots

5 Pilot sites' use cases

- Counsyl/Intermountain Healthcare – Shared genomic and family history data
- FDA – Added FHIR Genomics-based API to precisionFDA, a platform for NGS assay evaluation and regulatory science exploration
- Foundation Medicine/Vanderbilt – Transformed custom XML post-processed laboratory reports into FHIR specification for broader access
- Illumina – Integrated FHIR Genomics into their NGS data platform called BaseSpace Suite; converted Variant Call Format (VCF)-derived data to FHIR Sequence Resource
- National Marrow Donor Program – Developed HLA typing reports for FHIR Genomics Resources

Mapped use cases to the Clinical Genomics Workgroup's HL7 Domain Analysis Model, which FHIR Genomics is designed to implement

- http://www.hl7.org/implement/standards/product_brief.cfm?product_id=446