Session title: S4S – FHIR Application to connect Precision Medicine Initiative (PMI) to EHRs

HL7 FHIR Applications Roundtable

March 7–8, 2017
Duke University School of Medicine

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**All of Us** Research Program

**WHAT IS IT?**

**Precision medicine** is a groundbreaking approach to disease prevention and treatment based on people’s individual differences in environment, genes and lifestyle.

The *All of Us* Research Program will lay the foundation for using this approach in **clinical practice**.
WHAT ARE THE GOALS?

Engage a group of 1 million or more U.S. research participants who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for many diseases and conditions.

Pioneer a new model of research that emphasizes engaged research participants, responsible data sharing and privacy protection.
Who is Vibrent Health?

- Vibrent partners with health eco-system to accelerate the translation of evidence-based research to real world applications, through applied technologies.

- We **combine the power of data** across a wide variety of sources such as omics, environment, family history, electronic health records, bio-bank and life-style management to derive insights and actionable guidance to empower consumers in their health journey.

- Committed to collaboration and shared findings, Vibrent Health enables the eco-system to bring products to market and empowers advocacy groups, care providers, payers, researchers, businesses, and consumers to connect and innovate.

- Strong Cybersecurity Program. HIPAA and privacy data protection regulations compliant Cloud hosted solutions.
How is Vibrent involved in the All of Us Program (aka Precision Medicine Initiative)?

- Vibrent has been tasked with developing all participant facing technology platform and user experiences which includes a large range of user facing data assessment needs.

- The platform takes into consideration genomics data, EHR data, environment data, ancestry data, biological samples and life-style data to create unique “personalized engagement”.

- Vibrent is also responsible for ensuring that all participant EHR data is collected from participants using Sync4Science (S4S) initiative driven by the ONC. (S4S uses FHIR at its core.)
Why FHIR for Vibrent?

• We don’t have to start from scratch when representing health data.

• It provides an extraordinarily flexible way to represent data in our full range of offerings that can be understood and directly used by participant electronic health records.

• It is the most reliable and consistent way we’ve found to POST and GET information to and from the electronic health records of our study participants.
How does the Vibrent support FHIR in PMI?

• We are the primary integration partner for Sync4Science (S4S) in the Precision Medicine Initiative

• We use several Clinical Resource schemas to represent various data types:
  - Questionnaire
  - Questionnaire Response
  - Allergies and intolerances
  - Immunizations
  - Lab results
  - Medication administrations dispensations orders statements
  - Patient documents
  - Patient demographics
  - Problems
  - Procedures
  - Smoking status
  - Vital signs
What is Sync 4 Science (S4S)?

- Sync 4 Science (S4S) program will allow individuals to access their health data and send it to researchers. The pilot program will build off existing community standards and specification efforts (e.g., FHIR, SMART Health IT, Argonaut, CMS EHR Incentive Program) to support use cases for: **giving patients an easy way to share their health data with researchers.**

- EHR makers including Allscripts, Athenahealth, Cerner, drchrono, Epic and McKesson said they will embrace open specs including S4S APIs and FHIR to connect research apps to electronic health records software. Vendors will implement a "consistent, standards-based workflow," building on open specifications such as OAuth and HL7’s FHIR protocol.
Goals of Sync 4 Science (S4S)

- Develop structured methods to facilitate participant-controlled clinical data sharing for health research
- Allow patients to access data through tools and applications of their choice
- Diversify patients access view, aggregate, and understand their health data
- Collect information on individual participant preferences to alternative approaches for data donation
- Accelerate and guide the national ecosystem by providing patient-mediated health data access through APIs
Who Supports Sync 4 Science (S4S)?

**Government**
- The Office of the National Coordinator for Health Information Technology
- NIH

**Researchers**
- Harvard Medical School

**Electronic health record vendors**
- Epic
- eClinicalWorks
- Allscripts
- drchrono
- athenahealth
- Cerner
- McKesson
Sync 4 Science empowers

- **Participants and patients** by providing a controlled way to share their health with researchers (like All of Us)

- **EMR vendors** by giving them a standardized, FHIR based path to exchanging data with researchers and participants (this also enables their customers to add value to patients)

- **Researchers** by opening up closed health data ecosystems

- **Technology developers** by simplifying the process to accessing EMR data
Sync 4 Science works by giving consumers the control

1. Participants and patients indicate that they wish to share their health data with a specific research study.
2. Participants then register with S4S.
3. Participants indicate the member institution at which they health data is stored.
4. Participants authorize their institution to share their health data with a specific research study.
5. The research study receives access to FHIR representations of supported health data.
All of Us Program – S4S/FHIR Data Sharing

S4S data sharing authorization

Patient Portal Screens

Research App sends control to Patient Portal

Portal Login

Select Patient

Confirm 1

Confirm 2

Confirm 3

Confirm 4

Confirm 5

Approve

Patient Portal returns control to Research App

Select Provider

Delegation

Special Cases

Aggregating Portal
Participant Authorizes Access in EMR

- Participant uses an EHR vendor user interface to authorize access to Sync 4 Science

Participant Authorizes Access in Vibrent Platform to Sync 4 Science

- Participant is able to select the data they want to provide from the EHR they have authorized to provide data

Vibrent Platform Collects and Securely Stores (and Forwards, if Authorized) Data

- After the participant has been made aware of all consumers of their data, the Vibrent platform collects health data and transmits on to approved parties
The FHIR schema for self-report (PROs) data is considerably more flexible than other formats because it allows for better representation of:

- Many levels of nested questionnaire forms
- A clear connection between questions and established health ontologies
- Multiple languages to be represented in a single form
- Other systems to render questionnaires authored in our platform

Why the Questionnaire and QuestionnaireResponse
Thank You

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