CLINICAL RESEARCH ON FHIR

Wayne Kubick
Chief Technology Officer, HL7
Wkubick@hl7.org
THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

- BASIC RESEARCH
- DRUG DISCOVERY
- PRE-CLINICAL
- CLINICAL TRIALS
- FDA REVIEW
- POST-APPROVAL RESEARCH & MONITORING

PHASE I
PHASE II
PHASE III
PHASE IV

POTENTIAL NEW MEDICINES


TENS
HUNDREDS
THOUSANDS

IND SUBMITTED
NDA/BLA SUBMITTED
FDA APPROVAL
Pharmaceutical Costs Under Fire

Growth in Nominal Aggregate Health Care Spending

Source: Census Bureau, Quarterly Services Survey (hospital services & ambulatory services); Bureau of Economic Analysis National Income and Product Accounts (prescription drugs, population, GDP price index).
Clinical Trials in a Nut Shell

- Approved Protocol
- Investigator selection
- Approval Process
- Statistical Analysis
- Data Entered and reviewed
- Patient recruitment and participation
- Presentation and publication of report
- Data filed and registration obtained
INTEROPERABILITY AND CDISC

 Achieving Interoperability

 HL7 RIM

 BRIDG

 CLINICAL & NON-CLINICAL RESEARCH

 Protocol

 Data Collection

 Tabulation & Analyses

 Submission/ Publication Reporting

 Controlled Terminology

 THERAPEUTIC AREA STANDARDS & QUESTIONNAIRES

 CDISC SHARE

 Healthcare Link

 Patients

 Healthcare Link

 HEALTHCARE

 Foundational Standards

 Data Exchange

 Semantics
ABOUT HEALTH LEVEN 7 INTERNATIONAL

• ANSI-accredited healthcare standards development organization with >2500 members in more than 55 countries
  • >300 standards products
  • Major product families: v2, v3, CDA, FHIR
  • Regulated Research products: SPL, ICSR, IDMP
• HL7 Vision: A world in which everyone can securely access and use the right health data when and where they need it
• HL7 Mission: To provide standards that empower global health data interoperability

z z z iko truj
Fast Healthcare Interoperability Resources
THE FUNDAMENTALS OF FHIR

• A next generation standards framework & platform, built on 30 years of HL7 experience, designed for implementation

• Based on REST, a pattern for using web technologies to manage information (the platform used by Facebook, Twitter…) and APIs

• Content based on Resources: essential, portable modular information components easily assembled into working systems

• - Like web pages directed toward computers; fast and scalable

• Flexible outputs: web, messages, documents, services
RESTFUL SERVICES
A CHANGE IN THINKING – FROM FILES TO APIS
## Draft USCDI Version 1 Data Classes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Patient name</td>
</tr>
<tr>
<td>2.</td>
<td>Sex (birth sex)</td>
</tr>
<tr>
<td>3.</td>
<td>Date of Birth</td>
</tr>
<tr>
<td>4.</td>
<td>Preferred Language</td>
</tr>
<tr>
<td>5.</td>
<td>Race</td>
</tr>
<tr>
<td>6.</td>
<td>Ethnicity</td>
</tr>
<tr>
<td>7.</td>
<td>Smoking Status</td>
</tr>
<tr>
<td>8.</td>
<td>Laboratory tests</td>
</tr>
<tr>
<td>9.</td>
<td>Laboratory values/results</td>
</tr>
<tr>
<td>10.</td>
<td>Vital signs</td>
</tr>
<tr>
<td>11.</td>
<td>Problems</td>
</tr>
<tr>
<td>12.</td>
<td>Medications</td>
</tr>
<tr>
<td>13.</td>
<td>Medication Allergies</td>
</tr>
<tr>
<td>14.</td>
<td>Health concerns</td>
</tr>
<tr>
<td>15.</td>
<td>Care Team members</td>
</tr>
<tr>
<td>16.</td>
<td>Assessment and plan of treatment</td>
</tr>
<tr>
<td>17.</td>
<td>Immunizations</td>
</tr>
<tr>
<td>18.</td>
<td>Procedures</td>
</tr>
<tr>
<td>19.</td>
<td>Unique device identifier(s) for a patient’s implantable device(s)</td>
</tr>
<tr>
<td>20.</td>
<td>Goals</td>
</tr>
<tr>
<td>21.</td>
<td>Provenance</td>
</tr>
<tr>
<td>22.</td>
<td>Clinical Notes</td>
</tr>
</tbody>
</table>
SMART on FHIR®© – Open Platform Architecture
NIH and ONC Launch the Sync for Science (S4S) Pilot: Enabling Individual Health Data Access and Donation

March 21, 2016, 11:46 am / Jon White, M.D. / Deputy National Coordinator, Office of the National Coordinator for Health IT, Josephine Briggs, M.D. / Interim Director, Precision Medicine Initiative Cohort Program, and Josh Mandel, M.D. / Research Scientist, Harvard Medical School Department of Biomedical Informatics

S4S pilots are coming!

On February 25, 2016, the National Institutes of Health (NIH), in collaboration with the Office of the National Coordinator for Health IT (ONC), announced the launch of Sync for Science (S4S), a pilot to allow individuals to access their health data and send it to researchers in support of the goals of the Precision Medicine Initiative (PMI). Individual data donation will be a key component of the PMI Cohort Program, which aims to enroll more than one million U.S. participants who will volunteer to donate health data about themselves for precision medicine research. ONC, NIH, and the Harvard Medical School Department of Biomedical Informatics will coordinate the implementation of the S4S pilot in collaboration with EHR developers who have committed to participate: Allscripts, athenahealth, Cerner, drchrono, Epic, and McKesson.

S4S pilot developers will implement a consistent, standards-based workflow, building on open specifications including Health Level 7’s Fast Healthcare Interoperability Resources (FHIR®) and OAuth. Once developed and implemented, this functionality will allow individuals to connect a research app to their electronic health data, facilitating individual data donation for research and leveraging patients’ access...
FHIREXPER FOR BULK DATA EXPORT

- Using FHIREXPER to provide or consume FHIREXPER resources for use cases such as analyzing drug Safety, assessing the value of care, conducting population analyses, identifying at-risk populations, and tracking progress on quality improvement
- Full Bulk Data Export (Open Endpoint)
- Targeted Bulk Data Export (Open Endpoint)
- Secured Bulk Data Export (SMART Backend Services Protected Endpoint)

Functions of the asynchronous API:
- Client App ("Data Consumer") kicks off a data export job through an API call
- FHIREXPER Server ("Data Provider") generates newline-delimited JSON files for each resource type
- Client App polls for status updates and learns when the files are ready
- Client App fetches files and gets to work
Observation = Systolic BP
name: “Systolic”
coding: LOINC 8480-6
value.units: “mmHg”
WHAT FHIR CAN MEAN FOR BIOPHARMA

- Make healthcare data more consistent and more available for clinical research, safety, epidemiology, health economics, outcomes research ...

- Opportunities to improve efficiency of clinical trials, shorten timelines, reduce costs

- Open new pathways to improve interactions with clinicians, payers and patients
How HL7 FHIR Can Support Biomedical Research

- Feasibility, Investigator & Subject Searches
- Monitor Protocol Execution
- Pre-populate EDC CRFs
- Collect Patient-Generated Data; eConsent
- Apply Data Corrections simultaneously to EHR & EDC
- Drive pragmatic trials and precision medicine
- Drilldown analysis of source data by regulatory reviewers
- Bulk transfer of clinical data for analytics
What is a Connectathon?

A Connectathon is an event where innovative, boundary-breaking expertise from business, academia, and technology come together to solve critical challenges and test solutions in a safe environment.

The HL7 FHIR Connectathon aims to progress the Clinical Trial research community towards utilizing complete and interoperable electronic health data sources in clinical trials.

What is HL7 and why does FHIR matter?

As healthcare records have been increasingly digitized, sources of electronic health data need to be structured and standardized. HL7 (Health Level Seven International) is a not-for-profit, ANSI-accredited standards developing organization that has developed the FHIR (Fast Health Interoperability Resources) Specification, which serves as a standard for the electronic exchange of healthcare information.

What is a FHIR Connectathon?

A FHIR Connectathon gives participants the chance to work with the FHIR specification outside a production environment. This feedback improves FHIR and ultimately advances the industry.

When are HL7 FHIR Connectathons?

Connectathons take place 3 times annually.
Overview of the Scenarios:

**Scenario 1:** Examining EHR patient data for protocol feasibility and clinical trial recruitment for a specific clinical trial
- Identify qualified patients for trials

**Scenario 2:** Extract relevant EHR data for ResearchSubject and import into Study Database
- Automatically populate eHR information in EDC

**Scenario 3:** Receive and apply Real World Evidence updates to the study database as new or changed data is recorded in the EHR or received
- Apply Real World Evidence updates to study databases

**Scenario 4:** Extract lab data from Site EHR to Study database
- Available data is made accessible for a Study
Amendments reduce number of patients, but at high cost, longer study times

Nearly half of all substantial amendments are deemed avoidable

- The most frequent changes stemming from amendments are associated with modifications and revisions to study volunteer demographics and eligibility criteria.
- The total median direct cost to implement a substantial amendment for Phase II and Phase III protocols is $141,000 and $535,000, respectively.
REGULATORY & SAFETY USE CASES

• Access to multiple EHR data sources through FHIR API for product safety signal detection and exploration

• Closely monitor responses to new product rollouts — and give early indication of serious adverse events — real-time Risk Evaluation and Mitigation Strategies

• Allow reviewers of new drug applications to drill down into the details of the patient EHR record when exploring serious adverse events
HEALTH IT 2018 VISION

LEVERAGE HEALTH IT TO FACILITATE REGULATORY DECISIONS

CURRENT PRIORITIES

Sentinel

Adverse Event Reporting from Various Sources -
(GHIS, chemical & biologic &
genome data, social media...)

Integrating Clinical Research & Healthcare Using eSource at UCSF

REMS Shared System

Transforming Research through eSource & Standards
CLINICAL RESEARCH ON FHIR

Wayne Kubick
Chief Technology Officer, HL7
Wkubick@hl7.org