Setting Clinical Research on FHIR

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Wayne R. Kubick, CTO,
Health Level Seven International
Agenda

• The current state of the pharmaceutical industry
• Biopharma use of EHR clinical data
• What FHIR can mean for Biopharma
  – Clinical trial planning and management
  – Clinical trial data management
  – Regulatory and safety
• Setting clinical research on FHIR
>10 years; ~$2.6B

~10% Chance

Source: PhRMA
Pharmaceutical Costs Under Fire

$86M spent by pharma to defeat Prop 61 in California

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

1. Approved Protocol
2. Investigator selection
3. Approval Process
4. Statistical Analysis
5. Data Entered and reviewed
6. Patient recruitment and participation
7. Data filed and registration obtained
8. Presentation and publication of report

Source: d-Wise
Typically 6 or more transformations of data (red arrows), increasing cost and risk of error
• Very difficult to trace back to source
• Risk of nuance lost when transcribing to CRFs and SAS v5 Transport file format
Healthcare and Pharma Clinical Research: Separate Worlds

HL7 Vision: A world in which everyone can securely access and use the right health data when and where they need it.
What’s Changed

The American Recovery and Reinvestment Act of 2009

$17.2 Billion in Medicare and Medicaid incentives designed to facilitate widespread implementation of certified EHR systems in physician practices and hospitals.

MACRA

2017: TWO PATHWAYS FOR PAYMENTS

ALTERNATIVE PAYMENT MODELS

MERIT-BASED INCENTIVE PAYMENT SYSTEM

What you do in 2017 will impact your pay in 2019

Use of Electronic Health Record Data in Clinical Investigations

Guidance for Industry

US Food and Drug Administration - Califf: Leveraging Real World Evidence is 'Top Programmatic Priority' for FDA
The Common Clinical Data Set includes key health data that should be exchanged using specified vocabulary standards and code sets as applicable.

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Lab values/results</th>
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<tbody>
<tr>
<td>Sex</td>
<td>Vital signs</td>
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<tr>
<td>Date of birth</td>
<td>Procedures</td>
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<tr>
<td>Race</td>
<td>Care team members</td>
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<tr>
<td>Ethnicity</td>
<td>Immunizations</td>
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<tr>
<td>Preferred language</td>
<td>Unique device identifiers for implantable devices</td>
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<tr>
<td>Problems</td>
<td>Assessment and plan of treatment</td>
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<tr>
<td>Medications</td>
<td>Goals</td>
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<tr>
<td>Medication allergies</td>
<td>Health concerns</td>
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<tr>
<td>Lab tests</td>
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ONC Interoperability Roadmap Goal

2015-2017
Send, receive, find and use a common clinical data set to improve health and health care quality.
FHIR Resources

Smallest logically discrete unit of transaction “of interest” to healthcare
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
Clinical Study Planning & Management

- Use FHIR API to evaluate feasibility of protocol eligibility criteria
- Identify potential subjects for clinical trials
- A better way to manage e-Consent
- Potentially provide a window into protocol execution to prevent critical protocol violations that could compromise quality/usability of study data
The Costs of Protocol Complexity

Tufts Center for the Study of Drug Development

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.
Clinical Trial Data Use Cases

- Use FHIR API to pull EHR source data to pre-populate EDC CRFs
- Use FHIR API to apply study database changes to update EHR (sync with EDC)
- Collect patient-originated data (eCOA, ePRO, symptoms) for EHR or EDC with SMART-on-FHIR
- Capture and use genetic information to support precision medicine with SMART-on-FHIR
- Make study data more available to patients and EHRs
Potential Future Study Data Flow Using FHIR

Orders, Results, Notes

Coordinator

eForms

Aggregate Study DB

SDTM Views

Analysis Views & Models (Sentinel, OMOP...)

FDA Review

EHR

HL7 C-CDA CCD Document & Form Archive

External Data Feeds

Discrepancy Mgmt
SMART on FHIR® – Open Platform Architecture

SOA Orchestration

mHealth

OAuth

FHIR REST API

FHIR Profiles from CIMI Models
(using standard terminology)

Heterogeneous Systems

Commercial EHR

Home Grown System

System Integrator

Others...

http://smartplatforms.org/smart-on-fhir/

Source: Josh Mandel
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.
Information Exchange and Data Transformation (INFORMED)

A holistic approach to oncology regulatory science and big data analytics

Source: Sean Khozin, FDA
Forums for Clinical Research on FHIR

• Biopharma track at HL7 Partners in Interoperability
• Clinical Research track at FHIR Connectathons
• Collaboration with TransCelerate Biopharma eSource Team on proof of concept projects
• Biopharma stream on chat.fhir.org
• More to come
Questions

Setting Clinical Research on FHIR

Wayne R. Kubick, CTO
Health Level Seven International
wkubick@hl7.org
@WayneKubick
https://www.linkedin.com/in/waynekubick
www.hl7.org