Partners in Interoperability: What FHIR Means to Biopharma

October 18-19, 2016
Johns Hopkins University
Mt. Washington Conference Center
Baltimore, MD
Public Perceptions of Pharma

- Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients
- Bad Medicine: Pharmaceuticals’ Prescription for PROFITS over PEOPLE.
Pharma Under Fire

Growth in Healthcare Spending

- Drug Spending
- Other Medical Spending


Spending Percentage: 0.0%, 2.0%, 4.0%, 6.0%, 8.0%, 10.0%, 12.0%, 14.0%
>10 years; ~$2.6B

Source: PhRMA

~10% Chance
Changing Perceptions

- Historically, Pharma has viewed healthcare as a market and customer.

- Recently Pharma is being viewed as a key part of the healthcare ecosystem – increasing focus on patient centricity.

- Past silo mentality has resisted using healthcare data or sharing research data:
  - Data quality insufficient for research
  - Key data buried in unstructured notes.
What FHIR Means for BioPharma

- Make healthcare data more consistent and more available for research, safety, epidemiology, HEOR…

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

- Open new pathways to improve interactions with clinicians, payers and patients
  - SMART-on-FHIR as an example
FHIR Uses in Clinical Research

- Evaluate feasibility of protocol eligibility; find subjects
- Pull EHR data to pre-populate EDC CRFs
- Apply DCF changes to update EHR (sync with EDC)
- Collect patient-originated data (eCOA, ePRO, symptoms) for EHR or EDC
- Capture genetic information to support precision medicine
- Capture real world evidence from multiple EHR systems for signal detection, pragmatic trials …
- Improved method of eConsent
- FDA Reviewer drilldown to view EHR source records
- Improve Risk Evaluation and Mitigation Strategies
- Potentially provide a window into protocol execution
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