HL7® FHIR® Applications Roundtable

eConnect

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EHR data and Clinical Research – a match made – over and over again!

• Secondary use of healthcare data in clinical research has a broad range of use cases, including:
  - Protocol Feasibility
  - Subject Recruitment
  - ‘Virtual’ Clinical Studies
  - Lower patient load, lower site load

• “Insanity: doing the same thing over and over again and expecting different results.”
What are the common ‘barriers’ to adoption?

- no continuum of regulatory requirements between clinical research and health care;
- different data standards between clinical research and health care;
- unreliable, nonstandard, non-validated, or outdated EHR systems;
- concerns with interoperability;
- uneven adoption of EHRs across geographical regions;
- concerns with data quality.

Optimizing the Use of Electronic Data Sources in Clinical Trials: The Landscape, Part 1 – Kellar et al, Therapeutic Innovation & Regulatory Science 2016, Vol. 50(6) 682-696
Paradigms for change – Regulatory Clarification

Source Data Capture From Electronic Health Records: Using Standardized Clinical Research Data

A Notice by the Food and Drug Administration on 06/26/2015

Agency:
Food and Drug Administration, HHS.

Action:
Notice.

Summary:
The Center for Drug Evaluation and Research (CDER) is interested in supporting...
Paradigms for Change – Data Standards, Quality and Interoperability

• CDISC Healthcare Link (with HL7/IHE)
  o RFD
  o RPE

• CDISC eSource Stakeholders forum
  o CDISC EHR to CDASH (E2C) Project

• Support
  o Well documented APIs
  o Well supported system integrators
How can we use FHIR to improve this?

- **Current standard is IHE RFD**
  - Large XML documents cutting across multiple contexts

- **Local context of a FHIR resource is much closer to that of a Case Report Form (CRF)**
  - Extract specified data from a FHIR endpoint
Bootstrap

- FHIR Connectathon Baltimore, 2016
  - Retrieved Patient Resources from FHIR Server
  - Matched FHIR Resources and Attributes to CDASH Data Elements
    - Used Patient for Demography (DM)
  - Constructed a Operational Data Model (ODM) instance with matched data
  - POST to Medidata Rave CDMS
So, we can integrate data; how do we build the business case?

- Need to demystify the “quality” metric

- Coverage

- Usability
How do we help the sites?

- **Sites**
  - are not systems integrators
  - want it to ‘just work’

- **Reuse existing technology capabilities**
  - Assume provision of FHIR capabilities to improve with programs like 21st Century
  - Leverage these on an ongoing basis
  - Give sites the support to get up and running

- **Consolidate into a support program - eConnect**
What’s next?

• With increasing focus on patient centricity we are looking at OAuth using SMART-on-FHIR
• With wider adoption (READ: more darn pilots…. ) we are looking to improve how we manage the workflow
• Evaluate CDS-Hooks and/or Resource Subscription to set up a Pub/Sub level of trial engagement
• Bring more and more sites online in a collaborative manner, we should be doing research more SMARTly