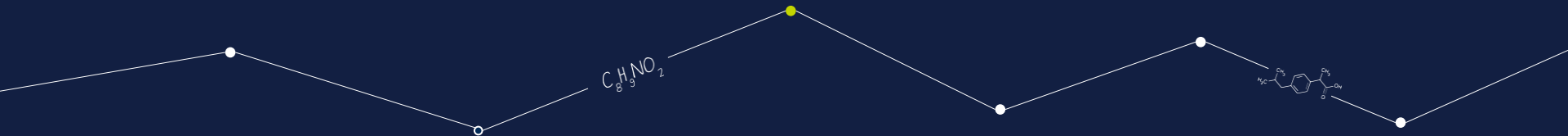


HL7® FHIR® Applications Roundtable

eConnect

Click to edit master sub-header style



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- unreliable, nonstandard, non-validated, or outdated EHR systems;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

PUBLISHED DOCUMENT

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice.

SUMMARY:
The Center for Drug Evaluation and Research (CDER) is interested in supporting

DOCUMENT DETAILS

Printed version
[PDF](#)

Publication Date
06/26/2015

Agencies:
Food and Drug Administration

Dates:
Submit either requests for demonstration or requests for information on or before October 10, 2015.

2016

Use of Electronic Health Record Data in Clinical Investigations

Guidance for Industry

DRAFT GUIDANCE

2015

Paradigms for Change – Data Standards, Quality and Interoperability

- CDISC Healthcare Link (with HL7/IHE)
 - RFD
 - RPE
- CDISC eSource Stakeholders forum
 - CDISC EHR to CDASH (E2C) Project
- Support
 - Well documented APIs
 - 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

The screenshot shows a web-based form for patient demographics. The subject ID is 200200. The form includes fields for Date of Birth (01 Jan 1942), Age (years), Sex (Female), Ethnicity, and Country. Each field has a set of icons for actions like edit, delete, and print. At the bottom, there are links for 'Printable Version', 'View PDF', and 'Icon Key', along with 'Save' and 'Cancel' buttons.

Subject: 200200
Page: Demographics - Screening

Date of Birth: 01 Jan 1942

Age: years

Sex: Female

Ethnicity: ...

Country: ...

[Printable Version](#) [View PDF](#) [Icon Key](#)

Save Cancel

So, we can integrate data; how do we build the business case?

- Need to demystify the “quality” metric

Subject: **Subject**
Page: **Demographics**

Date of Birth (DD MON YYYY) [?]

Sex [?]

Race [?]

Age (YEARS)

Ethnicity [?]

[Printable Version](#) [Icon Key](#)

CRF Draft 3316 - Page Generated: 01 Mar 2017 11:45:37 Greenwich Standard Time

Save Cancel

- Coverage
- Usability

Subject: **Subject**
Page: **Adverse Events**

| # | AE Number | Adverse Event [?] | Start Date (DD MON YYYY) [?] | Stop Date (DD MON YYYY) [?] | Serious [?] | Relationship [?] | Action Taken [?] | Outcome [?] | Severity [?] | Cancer [?] | Cong. Anom. [?] | Disability | Death [?] | Hospital [?] | Life Threat [?] | Overdose [?] | Other Event [?] | Con. Trt. [?] | Toxicity | Other Action [?] | Category for Adverse Event | AE Subcategory | Time Pattern | Location [?] |
|---|-----------|-------------------|------------------------------|-----------------------------|-------------|------------------|------------------|-------------|--------------|------------|-----------------|------------|-----------|--------------|-----------------|--------------|-----------------|---------------|----------|------------------|----------------------------|----------------|--------------|--------------|
| 1 | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data |

Add a new Log line

Hidden field for adding SAE form

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