Clinical Research Through HL7 FHIR® & CDISC

February 22, 2017

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Speaker Introduction

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CDISC
(Clinical Data Interchange Standards Consortium)

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Sr. Exec. 25+ years biopharma clinical research processes, pharmacovigilance, regulatory, standards, technologies.

ASTER: First demonstration of auto-generated adverse events from EHRs to regulators.

The Blind Men & the Elephant...
Founded in 1997 (all volunteers); incorporated in 2000 as a non-profit charitable organization

Today > 400 member organizations of all types

Global Standards Development Organization (SDO) developing global consensus-based standards focusing on Clinical Research

Collaborate with other SDOs (e.g. ISO, HL7, IHE)

CDISC Standards required by U.S. FDA and Japan’s P

CDISC Standards – goals

- Enable innovation
- Support all types of research from protocol through analysis and reporting
- Streamline research processes and enable data sharing/aggregation
- Link healthcare delivery and clinical research through EHRs/eSource

Mission: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare
 HOW STANDARDS PROLIFERATE:
(SEE: A/C CHARGERS, CHARACTER ENCODINGS, INSTANT MESSAGING, ETC)

**SITUATION:**
There are 14 competing standards.

14?! Ridiculous!
We need to develop one universal standard that covers everyone's use cases.

Yeah!

**SOON:**

**SITUATION:**
There are 15 competing standards.

https://imgs.xkcd.com/comics/standards.png
Standards and Interoperability

• What’s the connection?
  – Interoperability amongst providers and patients is an imperative
  – Extending interoperability to clinical research and regulated decision-making...
  – Allows for the creation of the Learning Healthcare System

• The real issue:
  – Large number of stakeholders with (vastly) different economic drivers
  – Historical development (legacy systems)
  – Result: Disparate data models and (vastly) different motivations
Why eSource? …to promote direct entry into eCRFs and No Paper
eSOURCE Stakeholders Group

- Inaugural meeting 18 March 2016
- Diverse set of stakeholders, including: biopharma, CROs, academic medical centers, EHR/EDC vendors, regulators, consultants...
- Focus on collaboration and building a conceptual foundation that allows us to stand up a model that can be examined and improved over time
- Partnering with FDA; sharing information with Transcelerate; exploring European interests; reaching out to other groups
- Projects
  - Duke and registries
  - Hospital Corporation of America (HCA)
  - RESTful Retrieve Form for Data (RFD) / FHIR
  - E2C Assessment tool for clinical data used in regulated decision-making
  - UCB Pharma
eSSG: Groups

- Primer (overview)
- Provenance (Data, process)
- eCRF concept
- System Validation / Privacy
- Economics / Cost vs Benefit
- Scalability requirements (technical, regulatory, political)
- Mobiles / Wearables (to be started)
- “E2C” Mapping CCD to CDASH / FHIR
There's a poem by John Godfrey Saxe about the blind men and the elephant. The first stanza sets up the situation:

"IT was six men of Indostan
To learning much inclined,
Who went to see the Elephant
(Though all of them were blind),
That each by observation
Might satisfy his mind."

But the last stanza really brings home our challenge...

"And so these men of Hindustan
Disputed loud and long,
Each in his own opinion
Exceeding stiff and strong,
Though each was partly in the right
And all were in the wrong."
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Wayne R. Kubick, CTO,
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Speaker Introduction

Wayne R. Kubick, BA, MBA

Chief Technology Officer
Health Level Seven International
@WayneKubick

Sr. Executive with more than 25 years of experience in pharmaceutical clinical research processes, standards and technologies.

Former CTO, CDISC
Standards for Health: www.HL7.org

- Not-for-profit Standards Development Organization, Founded in 1987
- >500 organizational members in >55 countries; >1000 volunteers
- >50 healthcare standards from anatomic pathology to vocabulary
- Major product lines: v2, v3, CDA, FHIR, Conceptual content models, v3 Regulatory standards (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.
The Fundamentals of HL7 FHIR

- A next generation **standards framework & platform**, built on 30 years of HL7 experience, designed for implementation
- Advanced RESTful Services technology platform (used by Facebook, Twitter…)
  - Can Create, Read, Update and Mark Deletion
- Content based on Resources: essential modular information components easily assembled into working systems.
- Flexible outputs: messages, documents, data, services
Principles of FHIR

• Data resides at the **source of truth**
• **APIs** access data: *pull* what you need, instead of taking what’s *pushed*
• Focus on **implementers**
• Include rigorous **semantics**
• Design for the common **80%**; extensions for the rest
• Off-the-shelf **security and authorization**
• **Speed, scalability**
• Human **readable**, ease of understanding
• Open source, **freely** available for all.
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

• A simpler, widely available, common way to make health data eSource reusable for research.
Some Talking Points

• The availability, consistency and quality of digital health data is rapidly improving, accessible under MU 3 through FHIR APIs, and can thus provide significant benefits for Biopharma and research.

• Research would benefit by learning how to use data in its original form, minimizing transformations, terminology conversions and mapping.

• The vast power, potential and widespread acceptance of the FHIR platform standard is creating unprecedented opportunities to align healthcare and research systems, and will catalyze many new opportunities to improve healthcare treatment and outcomes.
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Duke University Office Of Research Informatics
Supported in part by Duke’s CTSA grant (UL1TR001117)
3 Integrated hospitals using Epic 2015 (16,513 employees)
   – Duke University Hospital: 957 beds
   – Duke Raleigh Hospital: 186 beds
   – Duke Regional Hospital: 369 beds
• Duke School of Medicine Ranked 8th 2015

  ▪ 1462 investigators, 400+ coordinators in site based research
  ▪ ~2100 open enrolling IRB studies during FY15
  ▪ ~300 NEW clinical trial studies/year open
  ▪ Duke’s REDCap approximately 4000 projects and 4000 users
Research Use Case

Epic Research (Study/Patient Context)

1. Request "Baseline" Form

3. Render Web Form

Request Form

Research Coordinator

Save Form

REDCap

2. Populate "Baseline" Form

CCD

Populated Form

Form Submission

4. Receive/Store Form Data

< ClinicalDocument xmlns="urn:hl7-org:v3">
  <patient>
    <name>
      <given>John</given>
      <family>Doe</family>
    </name>
    <birthTime value="19650101"/>
  </patient>
</ClinicalDocument>
The Team

**Epic**
- John Stamm, Lindsey Gregor (Integration Engineering)

**Duke Health and Technology Solutions (DHTS)**
- James Stewart (Integration Engineering)

**Duke Office of Research Informatics (ORI)**
- April Feickert (Development Analyst)
- Matt Gardner (System Architect)
- Karen Collins, Darin London (Senior Developers)
- Chet Corey, Jonathon Parish (Developers)
- Paula Morrison, Lori Evans, Iain Sanderson, Steve Woody (Leadership)

**Duke Office of Clinical Research (DOCR)**
- Jeff Hawley (REDCap)
- Nicole Nussbaum (Maestro Care Analyst)
REDCap – Consortium Partners
Both EHR and EDC must be RFD enabled
Mapping of CCD data elements to eCRF

CCD Domains
- Problems
- Procedures
- Meds
- Labs
- Vitals
- etc...

REDCap Forms
- Problems
- Procedures
- Medications
- Labs
- Vitals
- etc...

Demographics
Open Source
RFD: Retrieve Form for Data Capture Open Source Software

Open source software for making electronic health data interoperable between Epic & REDCap

Download on GitHub

This open-source software transfers electronic health data across platforms, reduces data collection time, and prevents manual transcription errors, allowing researchers and their teams to conduct more efficient and high-impact clinical research.

What is it?
Retrieve Form for Data Capture (RFD) is a tool that standardizes research data collection from Electronic Health Records (EHRs). The software works as a bridge between Epic and REDCap, allowing researchers to quickly and accurately transfer EHR data and eliminate transcription errors.

Why use it?
Duke CTSI Github

RFD is a tool that standardizes research data collection from Electronic Health Records (EHRs). The software works as a bridge between Epic and REDcap, allowing researchers to quickly and accurately transfer EHR data. For additional information please see the Duke Clinical Translational Science Institute (CTSI) website.

https://www.ctsi.duke.edu/RFD

cd
retrieve-form-for-data-capture

4 commits
1 branch
0 releases
1 contributor

Branch: master
New pull request
Find file
Clone or download

jonathanparrish committed on GitHub Update README.md

README.md Update README.md

RFD_Classic
Check out the WIKI for our DOCS
For more information:
eSource @duke.edu
Next steps

The RFD use case lives on, but technology needs to evolve...

- FHIR (Fast Healthcare Interoperability Resources)
- Lightweight access to HL7-defined data models
  - Developer friendly RESTful API
  - Patient chart resources represented in JSON or XML format – Patient, Medications, Conditions
- Epic FHIR implementation
- Duke has experience with FHIR
Thank you!

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