Clinical Research on FHIR

Amy Nordo MMCi, BSN, RN, CPHQ, LNC
Duke University

Supported in part by Duke’s CTSA grant (UL1TR001117)
Duke University

- 3 Integrated hospitals using Epic
  - (16,513 employees)
- Duke School of Medicine Ranked 8th
- Research integral part of mission and vision
- 1462 investigators, 400+ coordinators in site based research
- ~2100 open enrolling IRB studies during FY15
- ~300 NEW clinical trial studies/year open
- Academic Clinical Research Organization-Duke Clinical Research Institute
# eSource Discussion Topics

## The Issue
Situation & Complication (Issue & Root Causes)
- Size / Scale

## The Value
Results & Conclusions
- Outputs: what was delivered
- Outcomes: improvement in business performance

## The Approach
Methodology & Solution
- People & organization
- Processes
- Technology & data
- External reviews (Regulatory / Ethics Committees)

## Keys to Success
Specific Challenges & Lessons Learned

## The Future
Gaps & Opportunities
- Unmet Needs
- Remaining Barriers
- Opportunities for Scale

---

For the Roundtable Discussion
The Issue
Development Team

Jonathan Parrish
Lori Evans
Chet Corey
Karen Collins
Paula Morrison
April Feickert
Darin London
Matt Gardner
Amy Nordo
(not pictured)
“INTEROPERABLE DATA FUTURE WITH PATIENTS AT THE CENTER”

- Information security paramount
- Patient perception and engagement of research
- Research personnel can be the same as clinical personnel
- Common data elements collected manually multiple times
- Multiple systems
“INTEROPERABLE DATA FUTURE WITH PATIENTS AT THE CENTER”

EMR
CRMS
IRB
Animal Management EMR
Resource Sharing
Bio-banking
Multiple EDCs
Support software
COI software

Analytical Tools
Data Warehouses
Study tracking systems
CDRNs
Budgeting software
Financial tracking software

• Instantiating an new system is a process
• Every interface needs to be maintained
• Each interface is a potential security risk
• Business Agreements, Data Sharing and Data usage agreements
• Clinical Research Informatics Team?
The Issue

- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - Structural interoperability
  - Semantic interoperability
  - Information security

The Approach

The Value

Keys to Success

The Future

Duke University’s eSource Journey?

- Developed middleware application (RADaptor) to implement the Retrieve From Data standard using the CCD at Duke as part of our CTSA award
- Conducted pilot study (demographics) August 2015
- Transitioned to production use December 2015
- Conducted a Time & Motion study to evaluate error reduction and time savings
Research Use Case
### Source Document

**CCD ID:** 293  
**Record Created:** 2015-02-18 15:48:03

- [See All Source Documents](#)
- [See RFD Forms related to this CCD](#)

#### RFD Aware fields:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Name:</strong></td>
<td>April</td>
</tr>
<tr>
<td><strong>Street Address:</strong></td>
<td>123 RFD Way</td>
</tr>
<tr>
<td><strong>Work Phone:</strong></td>
<td>919 555 2222</td>
</tr>
<tr>
<td><strong>Race Code:</strong></td>
<td>W</td>
</tr>
<tr>
<td><strong>Language Code:</strong></td>
<td>English</td>
</tr>
<tr>
<td><strong>City:</strong></td>
<td>Durham</td>
</tr>
<tr>
<td><strong>Mobile Phone:</strong></td>
<td>919 555 3333</td>
</tr>
<tr>
<td><strong>Ethnic Group Code:</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>State:</strong></td>
<td>NC</td>
</tr>
<tr>
<td><strong>Gender Code:</strong></td>
<td>F</td>
</tr>
<tr>
<td><strong>Gender Display:</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Marital Status Code:</strong></td>
<td>Married</td>
</tr>
<tr>
<td><strong>Country:</strong></td>
<td>USA</td>
</tr>
<tr>
<td><strong>Ethnic Group Display:</strong></td>
<td>Hispanic or Latino</td>
</tr>
<tr>
<td><strong>Race Display:</strong></td>
<td>White or Caucasian</td>
</tr>
<tr>
<td><strong>Full Address:</strong></td>
<td>123 RFD Way Durham NC 27701</td>
</tr>
<tr>
<td><strong>Zip:</strong></td>
<td>27701</td>
</tr>
<tr>
<td><strong>Home Phone:</strong></td>
<td>919 555 1111</td>
</tr>
<tr>
<td><strong>Dob:</strong></td>
<td>2014-06-04</td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td>mailto://aprilshowers@email.com</td>
</tr>
<tr>
<td><strong>Mrn:</strong></td>
<td>D1366461</td>
</tr>
</tbody>
</table>

### Message from Epic:

```xml
<ClinicalDocument>
<realmCode code="US"/>
<typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
<templateId root="1.2.840.114350.1.72.1.51693"/>
<templateId root="2.16.840.1.113883.10" extension="IMPL_CDAR2_LEVEL1"/>
<templateId root="2.16.840.1.113883.10.20.3"/>
<templateId root="2.16.840.1.113883.10.20.1"/>
<templateId root="2.16.840.1.113883.3.88.11.32.1"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.2"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
<id assigningAuthorityName="EPC" root="1.2.840.114350.1.13.324.3.7.8.688883.3562"/>
</ClinicalDocument>
```
The Issue
- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - System interoperability
  - Semantic interoperability
  - Information security

The Approach
Retrieve Form Data Capture pivoted to FHIR
- Internal reviews (IRB, ISO, STRA, CRI...)
- External reviews (FDA)

The Value

Keys to Success

The Future
Gaps & Opportunities
- Unmet Needs
- Remaining Barriers
- Opportunities for Scale

For the Roundtable Discussion
eSource Value Proposition

1. Facilitates Data Provenance
   • Specification dictates archiving/auditing – RFD Form Archiver
   • Archive Viewer Web Application... stay tuned

2. Improve Data Quality
   • Minimize transcription errors

3. Time: More efficient use of Clinical Research Coordinator
   • Provides the opportunity to change workflow process

4. Security
   • Secure, single-point registration of study participant’s data into EDC database from Epic context
Evaluation of the effect of RFD functionality on completion of Clinical Research data collection

Amy Harris Nordo, RN/BSN, CPHQ, LNC, MMCi
Eric L. Eisenstein, DBA
Jeffrey Hawley
Sai Vadakkeveedu
Melissa Pressley
Jennifer Pennock
Iain Sanderson, BM, BCh, MSc
Study Objectives

- Primary study objective: compare the **time** spent completing the eCRF using traditional (non-eSource) and eSource-enabled workflows
- Secondary objective: compare **data quality** associated with these data capture methods
- Secondary objective: **flexibility**
eCRF

RFD Pilot Study

RFD-Populated 1.75%  Unpopulated 98.25%
Observational Comparative Effectiveness Study

Preliminary Findings

↓ 37% Total time

↓ 1 FTE

↓ 65% Total keystrokes
Secondary Objective - **Data Quality**

**Non-eSource**

9% data error

- On critical data elements:
- Patient’s name
- Medical Record Number

**eSource**

% data error for RFD sourced variables
Secondary Objective- Flexibility

• EDC maintains all existing functionality
• Workflow alteration possible
• Potential for remote Study monitoring without direct EHR access
The Issue
- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - Structural interoperability
  - Semantic interoperability
  - Information security

The Value
- Facilitates Data Provenance
- Improves Data Quality
- More Efficient Use of Study Team Time
- Improved Data Security
- Improved workflow with opportunity for concurrent data collection
- Flexibility

The Approach
Retrieve Form Data Capture pivoted to FHIR
- Internal reviews (IRB, ISO, STRA, CRI...)
- External reviews (FDA)

Keys to Success

The Future
Lessons Learned

• Inconsistent implementation across EHRs
  • CCD, CCDA, CDA, C32, etc..
• Limited Data in a CCD
• XML translation is cumbersome/restrictive
• Multiple Standards Organizations
• Semantic Interoperability
• Bandwidth of IT/Informatics Teams
Duke University eSource

**The Issue**
- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - System interoperability
  - Semantic interoperability
  - Information security

**The Value**
- Facilitates Data Provenance
- Improves Data Quality
- More Efficient Use of Study Team Time
- Improved Data Security
- Improved workflow with opportunity for concurrent data collection
- Flexibility

**The Approach**
Retrieve Form Data Capture pivoted to FHIR
- Internal reviews (IRB, ISO, STRA, CRI…)
- External reviews (FDA)

**Keys to Success**
- Structural Interoperability
- Semantic Interoperability
- Single, EMR agnostic tool that connects to multiple end points

**The Future**
Pivot Technology to FHIR

- Single Accepted Standard
- More Data Points
  - Avenue for promotion of new resources
    - ResearchStudy
    - ResearchSubject
- Variety of Formats
  - JSON
  - XML
### Research Studies

<table>
<thead>
<tr>
<th>Study Code</th>
<th>Data Capture Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRO00011112</td>
<td>REDcap</td>
</tr>
</tbody>
</table>

### Enrolled (IC obtained-under waiver or signed form)

- **Study Code**: PRO00011112
- **Data Capture Forms**: REDcap
The Issue

- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - Structural interoperability
  - Semantic interoperability
  - Information security

The Value

- Facilitates Data Provenance
- Improves Data Quality
- More Efficient Use of Study Team Time
- Improved Data Security
- Improved workflow with opportunity for concurrent data collection
- Flexibility

The Approach

Retrieve Form Data Capture pivoted to FHIR
- Internal reviews (IRB, ISO, STRA, CRI...)
- External reviews (FDA)

The Future

- FHIR - Alignment of standards
- Internal RFP

Keys to Success

- Structural Interoperability
- Semantic Interoperability
- Single, EMR agnostic tool that connects to multiple end points

The Issue

- Clinical Research Data Collection OFI
- Cost of clinical research has increased over last 60 years
- Greatest cost increases have occurred in late phase clinical trials where >65% of total costs are site-related (for site management and site trial work)
- Manual duplicate data entry
- Data Sharing constraints:
  - Structural interoperability
  - Semantic interoperability
  - Information security
THANK YOU