RADaptor
Duke University’s solution for improved clinical research efficiency

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Duke University Office of Research Informatics
Supported in part by Duke’s CTSA grant (UL1TR001117)
Duke University

- 3 Integrated hospitals using Epic 2015 (16,513 employees)
- Duke School of Medicine Ranked 8\textsuperscript{th} 2016
- 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
The overarching goals for CDISC Healthcare Link are to:

- Make it easier for physicians to conduct clinical research
- Collect data only once in an industry standard format for multiple downstream uses
- Improve data quality and patient safety
Clinical Data Interchange Standards Consortium

Electronic Source Data Interchange (eSDI) Group

Leveraging the CDISC Standards to Facilitate the use of Electronic Source Data within Clinical Trials
**Requirement 1:** An instrument used to capture source data shall ensure that the data are captured as specified within the protocol.

**Requirement 2:** Source data shall be Accurate, Legible, Contemporaneous, Original, Attributable, Complete and Consistent.

**Requirement 3:** An audit trail shall be maintained as part of the source documents for the original creation and subsequent modification of all source data.

**Requirement 4:** The storage of source documents shall provide for their ready retrieval.

**Requirement 5:** The investigator shall maintain the original source document or a certified copy.

**Requirement 6:** Source data shall only be modified with the knowledge or approval of the investigator.

**Requirement 7:** Source documents and data shall be protected from destruction.

**Requirement 8:** The source document shall allow for accurate copies to be made.

**Requirement 9:** Source documents shall be protected against unauthorized access.

**Requirement 10:** The sponsor shall not have exclusive control of a source document.

**Requirement 11:** The location of source documents and the associated source data shall be clearly identified at all points within the capture process.

**Requirement 12:** When source data are copied, the process used shall ensure that the copy is an exact copy preserving all of the data and metadata of the original.
Call for Demonstration Projects

FDA/CDISC eSource Stakeholders Group

(http://www.cdisc.org/CDISC-eSource-Stakeholders-Convene)

An open, inclusive forum that focuses on and coordinates the increasing community of stakeholders interested in realizing the benefits of leveraging eSource in clinical trials and meeting regulatory requirements for eSource data to bring healthcare and clinical research together.
May 2016

Use of Electronic Health Record Data in Clinical Investigations

Guidance for Industry

Draft Guidance

This guidance document is being distributed for comment purposes only.
Research Application Development

Jonathan Parrish
Lori Evans
Chet Corey
Karen Collins
Paula Morrison
April Feickert
Darin London
Matt Gardner
Amy Nordo
(not pictured)
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
Developed Middleware Application (RFD_CCD)
Research Use Case

(1) Request "Baseline" Form

(3) Render Web Form

(2) Populate "Baseline" Form

(4) Receive/Store Form Data

Epic Research (Study/Patient Context)

REDCap

Request Form

Research Coordinator

Save Form

CCD

Populated Form

Form Submission

Last Name: Doe
First Name: John
Date of Birth: 1965/01/01

Save Record
Why Integrate REDCap?

• Significant Duke & CTSA adoption
  • Duke ~1500 active projects; ~3000 users

• Investigator initiated studies – less barriers to adoption

• Integrate Duke enterprise EHR with Duke enterprise EDC

• Duke Office of Clinical Research (DOCR)
  • Enterprise level services, resources, expertise for Duke site-based research
  • Epic for Research @ Duke services
  • REDCap @ Duke services – eCRF design, Data Management, etc.
  • Existing delivery channel for RFD services...
Architecture – How?

- Epic supports the RFD specification – REDCap **DOES NOT** support RFD specification

- Was not on product roadmap for Vanderbilt – feature priority, funding, demand, etc...

- Early “Proof-of-Concept” in collaboration with Epic – confident we could “make it work” with REDCap

- Developed middleware – makes REDCap “RFD aware”
  - Messaging – Brokers RFD messages between Epic & REDCap
  - Data Mapping – CCD data elements to REDCap data elements
  - We call it the “RFD-REDCap Adapter”...
Architecture – Data Mapping...

- Mapping of CCD data elements to eCRF for max utility
  - Build REDCap forms with CCD aware data elements
  - Build generic mapping logic for each standard form
- Expertise in CCD structure/terminology critical
RFD Workflow Demo
Initiate RFD
REDCap Forms Menu
Populated REDCap Form
Populated REDCap Form
Populated REDCap Form
Form Saved to REDCap via RFD
Architecture – Archive Viewer

• Comprehensive audit trail for RFD workflow
  • Track snapshot of CCD
  • Track form state transitions
    • “Retrieved”, “Pre-populated”, “Submitted”, etc.
  • Track parsed CCD data elements
    • eCRF data elements populated/CCD redaction
    • Mapping rules utilized

• Needed insight to the audit trail
  • Archive Viewer Web app – Audit history explorer
  • Immediate use – Facilitates testing verification
  • Down the road – Source document verification
Archive Viewer Demo
### Source Documents

<table>
<thead>
<tr>
<th>CCD ID (click to view CCD)</th>
<th>EHR Protocol</th>
<th>MRN</th>
<th>EDC Subject ID (click to view forms for subject)</th>
<th>Date</th>
<th>Time</th>
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<td>D1002433</td>
<td>18</td>
<td>2015-02-11</td>
<td>16:45:35</td>
</tr>
</tbody>
</table>
### 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>First Name</th>
<th>April</th>
</tr>
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<tbody>
<tr>
<td>Last Name</td>
<td>Showers</td>
</tr>
<tr>
<td>Street Address</td>
<td>123 RFD Way</td>
</tr>
<tr>
<td>Street Address 1</td>
<td>123 RFD Way</td>
</tr>
<tr>
<td>Work Phone</td>
<td>919 555 2222</td>
</tr>
<tr>
<td>Mobile Phone</td>
<td>919 555 3333</td>
</tr>
<tr>
<td>Race Code</td>
<td>W</td>
</tr>
<tr>
<td>Ethnic Group Code</td>
<td>2</td>
</tr>
<tr>
<td>Marital Status Display</td>
<td>Married</td>
</tr>
<tr>
<td>Language Code</td>
<td>English</td>
</tr>
<tr>
<td>City</td>
<td>Durham</td>
</tr>
<tr>
<td>State</td>
<td>NC</td>
</tr>
<tr>
<td>Full Address</td>
<td>123 RFD Way Durham NC 27701</td>
</tr>
<tr>
<td>Gender Code</td>
<td>F</td>
</tr>
<tr>
<td>Gender Display</td>
<td>Female</td>
</tr>
<tr>
<td>Race Display</td>
<td>White or Caucasian</td>
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<tr>
<td>Ethnic Group Display</td>
<td>Hispanic or Latino</td>
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<tr>
<td>Country</td>
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<tr>
<td>Zip</td>
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<tr>
<td>Home Phone</td>
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<td>Email</td>
<td>mailto://aprilshowers@email.com</td>
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### 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="2.16.840.1.113883.10.20.8"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.12"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.11"/>
<id assigningAuthorityName="EPC" root="1.2.840.114350.1.13.324.3.7.8.688883.3562"/>
</ClinicalDocument>
```
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<th>Form Name (click to filter)</th>
<th>Event ID</th>
<th>Status (click to view form)</th>
<th>Date</th>
<th>Time</th>
<th>Creator</th>
<th>CCD ID (click to view CCD)</th>
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<td>Demog</td>
<td>41</td>
<td>Retrieved For Populate</td>
<td>2015-02-18</td>
<td>15:49:04</td>
<td>feick001</td>
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<td>15:49:05</td>
<td>feick001</td>
<td>293</td>
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<td>feick001</td>
<td>293</td>
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</table>

All Source Documents
Effectiveness of RFD for Data Capture
Form populated by Duke RFD Form Manager

### Demog

**Adding new Study ID 32**

| Event Name: Baseline Visit (Arm 1: Arm 1) |
| Study ID | 32 |
| Patient First Name | April |
| Patient Last Name | Showers |
| City | Durham |
| State | NC |
| Zip | 27701 |
| Street Address | 123 RFD Way |
Production December 2015

Duke University School of Medicine

Retrieve Form for Data Capture
Evaluation of the effect of RFD functionality on completion of Clinical Research data collection

Amy Harris Nordo, RN/BSN, CPHQ, LNC, MMCi ¹; Eric L. Eisenstein, DBA ²; Jeffrey Hawley ¹; Sai Vadakkeveedu¹; Melissa Pressley ¹; Jennifer Pennock¹; Iain Sanderson, BM, BCh, MSc¹
Evaluation of the effect of RFD functionality on completion of Clinical Research data collection
Nordo et al

• Hypothesis: eSource data management reduces time and transcription errors, with the implication of savings in study costs, particularly if widely adopted in the most expensive phase of the clinical trials process

• Proof of concept study
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**
Evaluation of the effect of RFD functionality on completion of Clinical Research data collection
Nordo et al

- **Primary study** – PI initiated registry
- **Subjects** - Duke Study team
- **Real patient data**
- **Live work environment**
- **Observed by Industrial engineers augmented by software**

Manual “Swivel Chair” versus eSource
• Set up and break down after every session
• Visually confirm passwords were changed after every session
• Removal of all items within the view of the camera
• Additional security steps
Traditional Data Transcription (non-eSource) Workflow

**Clinician**
- Identifies patient as appropriate for study
  - Gets a pink folder from the clinic workroom
  - Complete Informed Consent
  - Return pink folder to clinic work room

**Patient**
- Complete paper Demographic data collection tool

**CRC**
- Tuesday and Thursday pick up pink folders from clinic workroom
- Enroll patient in study in MC when mother admitted for delivery
- Add patient to "Patient lists" in MC
- Fill out paper CRF
- Hand deliver paper CRF to Data entry personnel
- Corrects Errors on paper CRF

**Data Entry**
- Verify and QC every data point on paper CRF in MC
- Complete form in REDCap
- Notate on front of pink folder completed
- Files pink folder
eSource Workflow

**Clinician**
- Identifies patient as appropriate for study
- Gets a pink folder from the clinic work room
- Complete Informed Consent
- Return pink folder to clinic work room

**Patient**

**CRC**
- Tues and Thurs pick up pink folders from clinic work room
- Enroll patient in study in MC
- Add patient to "Patient lists" in MC
- When mother admitted for delivery
- RFD
- RFD Auto-populates demographic data
- Complete form within MC
- Saves form
- Notate on front of pink folder completed
- Files pink folder

**Data Entry**
Assumptions

• (a) in the initiation period the eSource group would require less time, because two people were logging into the system rather than one
• (b) in the demographic period the eSource group would require less time because some data fields were being pre-populated
• (c) in the supplemental period the times would be similar because even though different individuals were performing the abstraction they all possessed a similar skill level. (Indeed, observing similar times for the supplemental period would provide substantial reassurance in this regard).
# Primary Objective - Efficiency

<table>
<thead>
<tr>
<th>Phase</th>
<th>N=</th>
<th>Non-eSource¹</th>
<th>eSource¹</th>
<th>Difference (95%CI)</th>
<th>p-value²</th>
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</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>21</td>
<td>66.3 (50.5)</td>
<td>21.3 (19.6)</td>
<td>45.0 (19.7, 70.4)</td>
<td>0.001</td>
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<tr>
<td>Demographic</td>
<td>21</td>
<td>212.5 (49.4)</td>
<td>133.5 (38.1)</td>
<td>79.1 (56.7, 101.4)</td>
<td>0.000</td>
</tr>
<tr>
<td>non-e-Sourced</td>
<td>21</td>
<td>1476.1 (406.7)</td>
<td>1447.9 (463.2)</td>
<td>28.2 (-126.6, 183.1)</td>
<td>0.708</td>
</tr>
<tr>
<td>Total Time</td>
<td>21</td>
<td>1755.0 (396.5)</td>
<td>1602.6 (470.0)</td>
<td>152.3 (-1.1, 1305.7)</td>
<td>0.051</td>
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1. Mean (Std. Dev)   2. Paired Samples T-Test
Primary Objective - Efficiency

<table>
<thead>
<tr>
<th>Method</th>
<th>Scroll Button Motion Included</th>
<th>Initiation</th>
<th>Demographic(^2)</th>
<th>Supplemental</th>
<th>Total</th>
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<td>8463</td>
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<td>Manual(^1)</td>
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<td>1695</td>
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<td>11469</td>
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</table>

1. Manual method includes combined effort from CRC and data entry personnel
2. The demographic section contains e-Sourced fields in the database. (This is the only section that contains auto-populated fields).
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
Evaluation of the effect of RFD functionality on completion of Clinical Research data collection

Nordo et al  RESULTS

• The overall average data capture time was reduced with eSource versus non-eSource methods (difference, 151 seconds per case; eSource, 1603 seconds; non-eSource, 1754 seconds; p<0.05)

• The average data capture time for the demographic data was reduced (difference, 79 seconds per case; eSource, 133 seconds; non-eSource, 213 seconds; p< 0.001)

• This represents a 37% time reduction (95% confidence interval 27% to 47%)

• eSourced data field transcription errors were also reduced (eSource, 0%; non-eSource, 9%)
Limitations of the Study

• Small sample size (n=21)
• Single center trial
• Study design: different end users of similar skill using the same cases for each workflow
CONCLUSIONS

• The use of eSource versus traditional data transcription was associated with a significant reduction in data entry time and data quality errors.

• Further studies in other settings are needed to validate these results.
Limitations of the CCD

• Inconsistent implementation across EHRs
  • CCD, CCDA, CDA, C32, etc..
• Limited Data
• XML translation is cumbersome/restrictive
Pivot Technologies

• Single Accepted Standard
• More Data Points
  • Avenue for promotion of new resources
    • ResearchStudy
    • ResearchSubject
• Variety of Formats
  • JSON
  • XML
Add FHIR POC video
Current Work

• Pilot POC with Duke PI initiated Neurosurgery study
• Manuscript submitted: International Journal of Bioinformatics
• Secure additional funding
Next Steps

- EHR agnostic
- EDC agnostic
- Incorporate additional FHIR Resources
  - ResearchStudy
  - ResearchSubject
- Develop remote monitoring functionality
- Share our work
- Conduct multi-center study