Retrieve Form for Data Capture

*Integrating Epic with REDCap @ Duke*

Amy Harris Nordo and Matt Gardner
Duke Office of Research Informatics

Supported in part by Duke’s CTSA grant (UL1TR001117)
Clinical Research at Duke

- 2013 total research revenues - $651m
- 2013 NIH funding $284m - ranked 10th
- 2012 Industry funded research $215m
- Duke Clinical Research Institute is the largest Academic CRO in the world with over 900 employees
- Duke is the Coordinating Center for PCORI, NIH Collaboratory Grants
- Our CTSA was renewed in 2013
- Duke School of Medicine Ranked 8th 2014
- 7,000 simultaneous users of Epic (Epic’s largest big bang go-live)
  - Integrated clinical research management into Epic.
The state of research data capture...

- Data capture for clinical research – paper based

- Numerous stages of transcription: EHR -> Paper Case Report Form -> Study Database (Sponsor EDC)

- Inefficient, time intensive, prone to transcription error

- Data elements are often non-standard

- Data security risk for the enterprise
Perhaps a better process...
Pre-populate Web based case report forms
A standard framework...

Retrieve Form for Data Capture (RFD)
RFD...

- **Retrieve Form for Data Capture**

- Integration profile co-developed by Integrating Health Enterprise (IHE) and CDISC
  - A standard for research data collection from EHRs
  - Allows EHR platform to display Web based data collection form sourced from an EDC platform
  - Pre-populates form with data sourced from **Continuity of Care Document (CCD)**

- Adopted by **EHR** and **EDC** vendors
Web based research database (eCRF) and survey tool

Developed by Vanderbilt University

No charge for consortium partners (not open-source)

Consortium comprised of ~1300 institutions
  Duke is partner with ~1500 projects; ~3000 users
REDCap is ubiquitous data capture tool for Academic Research...

Why not integrate it with Epic using RFD...
The Core Team

- **Champions**
  - Iain Sanderson (Duke ORI), Landen Bain (CDISC)

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

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

- **Duke Office of Research Informatics (ORI)**
  - Matt Gardner (Systems Architect)
  - April Feickert (Business Analysis - Middleware)
  - Karen Collins, Matt Gardner, Darin London (Lead Developers – Middleware)

- **Duke Office of Clinical Research (DOCR)**
  - Jeff Hawley (Lead Analyst/Programmer – REDCap)
  - Nicole Nussbaum (Business Analysis – Epic for Research)
### Research Dashboard for Clinical Research Coordinators

#### Report Listing
- No reports are available for display.
- Refresh

#### Quick Launch to Research Activities
- Patient Research Studies
- Study Administration Records

#### In Basket Glance
- Show only new messages
- My Open Encounters (1)
- My Unsigned Orders (1)
- Refresh as of: 12:32:54 PM

#### Research Links
- **Government Sites**
  - ClinicalTrials.Gov
  - NIH Grants
- **PRMO Sites**
  - Charge Correction Entry
  - PRMO Clinical Trials
- **DOCR Sites**
  - DOCR Wiki
- **Maestro Care**
  - Duke Maestro Care
  - Maestro Care Research Tip Sheets
Yikes the CCD...

**Continuity of Care Document (CCD)...**
- Transition/continuity of care for patient
- Snapshot in time of patient chart

```xml
<patient>
  <name use="L">
    <prefix qualifier="TITL"><nspace prefix="ms" uri="/nspace/nspacePrefixes">Ms.</prefix>
    <given>Jane</given>
    <given>A</given>
    <family>Doe</family>
    <suffix>Jr.</suffix>
  </name>
  <administrativeGenderCode code="F"
    codeSystem="2.16.840.1.113883.5.1"
    codeSystemName="AdministrativeGenderCode" displayValue="Female"/>
  <birthTime value="19900809"/>
  <maritalStatusCode nullFlavor="UNK"/>
  <raceCode codeSystem="2.16.840.1.113883.6.238"
    codeSystemName="CDC Race and Ethnicity" nullFlavor="UNK"/>
  <ethnicGroupCode codeSystem="2.16.840.1.113883.6.238"
    codeSystemName="CDC Race and Ethnicity" nullFlavor="UNK"/>
  <languageCommunication>
    <languageCode code="eng"/>
    <preferenceInd value="true"/>
  </languageCommunication>
</patient>
```
How it works...

1. Request "Baseline" Form

2. Populate "Baseline" Form

3. Render Web Form

4. Receive/Store Form Data

Epic Research (Study/Patient Context)

REDCap

Request Form

Research Coordinator

Save Form

Lost Name: Doe
First Name: John
Date of Birth: 1965/01/01
Architecture - how we did it...

- Epic supports RFD – REDCap **DOES NOT**

- 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

- **Duke developed middleware** – makes REDCap “RFD aware”
  - **Messaging** – Brokers RFD messages between Epic & REDCap
  - **Data Mapping** – Maps CCD data elements to REDCap data elements
  - **Archival** – Archives details of the process from start to finish
  - We call it the “**RFD-REDCap Adapter**”...
Architecture – messaging...

Epic for Research

RFD Form Filler
Request Form for Study Participant and render Form

Request Form (CCD)  Pre-populated Form  Form Submission

RFD Form Manager
Get Form and Pre-populate from CCD

RFD Form Receiver
Relay Form data

RFD-REDCap Adapter
RFD Form Archiver
Archive Messages

Archive Log

RFD Form Archiver
Archive Messages

Form Definition  Form Data

Form Metadata  Participant Data

REDCap
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 is vital*
Architecture – archive viewer...

- Comprehensive audit trail for all 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
    - 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
## 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>
</tr>
</thead>
<tbody>
<tr>
<td>293</td>
<td>99992</td>
<td>D1366461</td>
<td>32</td>
<td>2015-02-18</td>
<td>15:48:03</td>
</tr>
<tr>
<td>292</td>
<td>99992</td>
<td>D1234567</td>
<td>22</td>
<td>2015-02-18</td>
<td>15:39:08</td>
</tr>
<tr>
<td>291</td>
<td>99992</td>
<td>D1234567</td>
<td>22</td>
<td>2015-02-18</td>
<td>15:37:17</td>
</tr>
<tr>
<td>290</td>
<td>99992</td>
<td>D1360579</td>
<td>31</td>
<td>2015-02-18</td>
<td>15:02:35</td>
</tr>
<tr>
<td>289</td>
<td>99992</td>
<td>D1360579</td>
<td>30</td>
<td>2015-02-18</td>
<td>14:58:15</td>
</tr>
<tr>
<td>288</td>
<td>99992</td>
<td>D1360579</td>
<td>29</td>
<td>2015-02-18</td>
<td>14:54:31</td>
</tr>
<tr>
<td>287</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>14:52:55</td>
</tr>
<tr>
<td>286</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>14:34:54</td>
</tr>
<tr>
<td>285</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:54:39</td>
</tr>
<tr>
<td>284</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:52:29</td>
</tr>
<tr>
<td>283</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:51:50</td>
</tr>
<tr>
<td>282</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:30:44</td>
</tr>
<tr>
<td>281</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:25:34</td>
</tr>
<tr>
<td>280</td>
<td>99992</td>
<td>D1362057</td>
<td>23</td>
<td>2015-02-18</td>
<td>13:17:12</td>
</tr>
<tr>
<td>279</td>
<td>99992</td>
<td>D1369596</td>
<td>28</td>
<td>2015-02-18</td>
<td>13:26:20</td>
</tr>
<tr>
<td>278</td>
<td>99992</td>
<td>D1369596</td>
<td>27</td>
<td>2015-02-12</td>
<td>13:24:39</td>
</tr>
<tr>
<td>277</td>
<td>99992</td>
<td>YB8050</td>
<td>25</td>
<td>2015-02-11</td>
<td>16:46:46</td>
</tr>
<tr>
<td>275</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>21</td>
<td>2015-02-11</td>
<td>16:45:36</td>
</tr>
<tr>
<td>276</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>22</td>
<td>2015-02-11</td>
<td>16:45:36</td>
</tr>
<tr>
<td>267</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>13</td>
<td>2015-02-11</td>
<td>16:45:35</td>
</tr>
<tr>
<td>268</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>14</td>
<td>2015-02-11</td>
<td>16:45:35</td>
</tr>
<tr>
<td>269</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>15</td>
<td>2015-02-11</td>
<td>16:45:35</td>
</tr>
<tr>
<td>270</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>16</td>
<td>2015-02-11</td>
<td>16:45:35</td>
</tr>
<tr>
<td>271</td>
<td>PRO00035959</td>
<td>D1002433</td>
<td>17</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>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>April</td>
</tr>
<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>Street Address 2</td>
<td></td>
</tr>
<tr>
<td>Ethnic Group Code</td>
<td>2</td>
</tr>
<tr>
<td>Race Code</td>
<td>W</td>
</tr>
<tr>
<td>Marital Status Code</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>
</tr>
<tr>
<td>Ethnic Group Display</td>
<td>Hispanic or Latino</td>
</tr>
<tr>
<td>Country</td>
<td>USA</td>
</tr>
<tr>
<td>Zip</td>
<td>27701</td>
</tr>
<tr>
<td>Home Phone</td>
<td>919 555 1111</td>
</tr>
<tr>
<td>Dob</td>
<td>2014-06-04</td>
</tr>
<tr>
<td>Marital Status Code</td>
<td>M</td>
</tr>
<tr>
<td>Email</td>
<td>mailto://aprilshowers@email.com</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="1.2.840.114350.1.721.15.1.51693"/>
  <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="1.2.840.114350.1.13.324.3.7.8.688888.3562"/>
</ClinicalDocument>
```
<table>
<thead>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>Demog</td>
<td>41</td>
<td>Retrieved For Populate</td>
<td>2015-02-18</td>
<td>15:49:04</td>
<td>feick001</td>
<td>293</td>
</tr>
<tr>
<td>Demog</td>
<td>41</td>
<td>Populated</td>
<td>2015-02-18</td>
<td>15:49:05</td>
<td>feick001</td>
<td>293</td>
</tr>
<tr>
<td>Demog</td>
<td>41</td>
<td>Submitted</td>
<td>2015-02-18</td>
<td>15:53:19</td>
<td>feick001</td>
<td>293</td>
</tr>
</tbody>
</table>
• **Interconnect** = The Epic interface gateway; brokers all inbound and outbound RFD messages.
• **RFD REDCap Adapter** = Middleware application that brokers all RFD messages between Epic and REDCap. Also serves mashed up REDCap Web forms to the browser contained within the Epic UX.
• **REDCap for RFD** = REDCap application server that is dedicated to serving projects that are RFD enabled.
• **REDCap Proxy** = Proxy server for external access to REDCap RFD instances.
Lessons & Challenges

• The need for Redaction
  – CCD may pass more information than the minimum required for the study, so if you archive the CCD, you need to redact the excess

• The need for a robust archival service
  – Study monitors want this to inspect provenance.

• The need to be able to manage the content of the CCD; eg an ICU study wants data from bedside monitors
  – A unique CCD can be outputted independently in epic, but its not easy.

• REDCap forms – mapping code is tightly coupled to HTML

• Allowing for Study CRF updates… appropriate UX workflow

• Managing user Web session state – Hyperspace, Adapter, REDCap...

• SOAP vs. REST interface – The SOAP interface of the RFD standard is looking a bit old …
The value to Duke and beyond...

- Save CRC **TIME** – reduce data collection burden
- Facilitates data provenance – have an app for viewing this
- Minimizes transcription errors – better data quality
- Secure, single-point registration of participants into REDCap from Epic context... and hopefully other EDC platforms...

**Observational Comparative Effectiveness Study**
What next...

- **Extend data mapping coverage for maximum utility**
  - Exhaust what is in the standard Epic CCD
  - Work with Epic on strategy to extend CCD
  - The RFD source document does **NOT** have to be **CCD**
    - Fast Healthcare Interoperability Resources (**FHIR**)
The RFD dream...

- Multi-site coordinated clinical trials –

- Sites have different EHR platforms – e.g. Epic, Cerner
  - RFD interface and CCD are standard components

- Populate a centralized EDC system/database that supports RFD interface – e.g. Oracle Inform, Medidata

- Open Source
Thank you

Contact information:
Amy Harris Nordo
Product Manager Maestro Care for Research and Retrieve Form Data Capture
amy.nordo@duke.edu