Clinical Research on FHIR

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Duke University

• 3 Integrated hospitals using Epic 2015 (16,513 employees)
• Duke School of Medicine Ranked 8th 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
Swivel Chair Approach
eSource Compliance

Diagram:
- EHR
- RADaptor
- Additional Data Added
- Updated Data
- EDC (Sponsor/CRO)
- FDA
- Provenance of Source Document
  - Additions
  - Updates
- CDISC (ADaM)
Development Team

Jonathan Parrish
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(not pictured)
How did we get here?

- 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 – proof it worked!
Cons of the CCD

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

• Single Accepted Standard

• More Data Points
  • Avenue for promotion of new resources
    • ResearchStudy
    • ResearchSubject

• Variety of Formats
  • JSON
  • XML
Launch

<table>
<thead>
<tr>
<th>HyperSpace - Frontend</th>
<th>RADaptor</th>
<th>Epic Maestro Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch RFD_FHIR using the CCD C32 sending POSTing SOAP</td>
<td>Creates Source Document (Record of CCD) Patient (If they don’t already exist)</td>
<td>REDCap</td>
</tr>
<tr>
<td>Patient ID (MRN)</td>
<td>Returns: SOAP Response message with Redirect URL to the RADaptor Transporter with Params Patient ID (De-identified Not MRN) Study ID (De-identified Not Protocol Number) SourceDocument ID</td>
<td>Redirect: Back to URL from SOAP to RADaptor</td>
</tr>
<tr>
<td>Study ID (Protocol Number)</td>
<td>Unauthorized user is redirected to FHIR Auth Server (OpenID, OminAuth)</td>
<td></td>
</tr>
</tbody>
</table>
Authorize

Backend

Auth Server

Login User

New User?

Yes

New users authorizes RADaptor for access

No

Token exchange with RADaptor

Redirect back to RADaptor Transporter with Params from SOAP
Retrieve and Publish Data

1. Make FHIR call(s) from Study Metadata
   - Longitudinal data?
     - Yes
       - Select values from drop down boxes where required
       - Submit REDCap Record
         - Redirect user to newly created or updated REDCap record in iFrame
         - Create EDC_Record in RADaptor DB
         - Login
         - View Record in iFrame
     - No
   - Data Extraction
Research Studies

Add a new study to list

Enrolled (IC obtained-under waiver or signed form)

RFD Testing Two

Study Code: PR000011112

Data Capture Forms: REDcap
Next Steps

- EHR agnostic
- EDC agnostic
- Incorporate additional FHIR Resources
  - ResearchStudy
  - ResearchSubject
- Share our work