Research Data Capture

An Exploration with REDCap

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January 28, 2014
AAMC Group on Information Resources (GIR)

Security Work Group

www.aamc.org/gir
Research data environment

Considerations:

▪ Avoid errors
▪ Identify the owner
▪ Define, store and handle the data to ensure data integrity, provenance and security
▪ Appropriately handle data with regulated identifiers

Education and Support:

▪ Design & architecture
▪ Assess database needs
▪ Identify ‘end user’ and their needs
▪ Adopt best practice – data elements, coding, audit trail
▪ Testing & backup
▪ Role based security
Considerations for Choosing a Data Management System

- **Spreadsheets**
- **Databases**
  - REDCap, MS Access, SQL Server, Oracle, etc.
- **Specialty Clinical Data Management**
  - Oracle Clinical, Clintrial, InForm, etc
- **Statistical Analysis Packages**

There are trade-offs based on type, tools, resources, and time.

*It’s like building a deck.*
Data management & security at Duke – featuring REDCap implementation

Denise Snyder
Group on Information Resources (GIR)
Security Work Group
January 28, 2014 | webinar
How it all started...

So I called this meeting today because the developers say they need our marketing data for their software. Unfortunately, all the data is stuck in an Access database, and I don’t know how to use Access, so we have to figure something out. Any ideas?
Research Management Team (RMT) – Who were we? How did it work? A shared effort pool

• Consultation and estimate are free
• Work is based on percent effort + fringe for a specific employee
• All database design, construction, implementation and documentation follow SOPs
• Investigator pays only for the actual cost of database build, management (not overhead)
• Project-based work also available
What were some of the issues that RMT uncovered?

• Researchers required to self-navigate the clinical research landscape

• Fragmentation of support resulted in redundant activity by researchers across the enterprise

• Inequitable access to data management, statistics and clinical research resources

• No cost efficient and compliant tools for moderately funded projects

• Issues related to data provenance

• Data security challenges
What came next?

- RMT meeting with Duke Translational Medicine Institute (CTSA funding)
- Agreed to support overhead for SOM funded projects
- There was a caveat....
The REDCap Consortium is composed of 914 active institutional partners from CTSA, GCRC, RMI and other institutions in 74 countries. The consortium supports a secure web application (REDCap) designed exclusively to support data capture for research studies.

The REDCap application allows users to build and manage online surveys and databases quickly and securely, and is currently in production use or development build-status for more than 92,000 projects with over 121,000 users spanning numerous research focus areas across the consortium. To find out if your institution is already running REDCap, you will find contact information on the Consortium Partners page. Learn more about REDCap by watching a brief summary video (4 min).

Map of REDCap Consortium Partners

View full screen map

Recent publications using REDCap:


View all 852 articles
How did we implement?

▪ Emphasis on security
  ▫ All data encrypted in transit
  ▫ Collected data stored behind PHI firewall
  ▫ Limited and centralized administrative access
  ▫ Full data backup and retention
▪ Involved Duke Information Security Office (ISO) and Duke Internal Audit (IA)
▪ Validated for HIPAA compliance
REDCap Infrastructure Setup

- Internet
- DMZ Firewall
- Proxy Server
- DMZ
- PHI Firewall
- PHI Zone
- REDCap Application Server
- REDCap Database Server
- Internet User
A perfect storm

▪ Questions were raised about the veracity of the data and the quality of the analyses from one of our laboratories.

▪ These laboratory findings were rapidly translated into decision support instruments for use in human clinical trials.

▪ The work of our investigators was flawed and thus did not demonstrate that personalized genomic predictors could be used for creating “tailored” cancer care.

▪ Problems with data provenance, unexplained errors related to data management, and implausible data combinations that escaped detection at two different levels of independent peer review nullified the work and led to the trials being closed.
Goal:
To ensure the scientific quality and integrity of research that lays the foundation for human studies.

Guiding principles:
Scientific Culture and Accountability
Data Provenance
Quantitative Expertise
Scientific and Conflict of Interest Review

Leadership Team:
Dean
Vice Chancellor
Vice Deans (5)
Chief Information Officer
Chief Research and Academic Information Officer
Director, DCRI
Governance Structures Overview

External Advisors
- External Advisory Committee (EAC)

Industry Advisory Committee

Duke Medicine
- Duke Medicine Clinical and Translational Research Executive Council

DTMI/CTSA Internal
- DTMI Executive Committee
- CTSA PIs, Chief Administrators
- DTMI Leadership Group
- CTSA Education Oversight Committee

DTMI-wide Thematic Initiatives
Supports all faculty, staff, and students by developing the “navigation, tools, and training” for the conduct of clinical research in which Duke serves as an investigative site.
Managing Our Instance

• Validation
  • REDCap 4.13.18 has been validated
  • REDCap 5.0 is being validated (longitudinal surveys)

• User Management
  • Review users yearly on a project basis
    • Reason for access
    • Roles in database
    • Remove users that no longer need access

• Limited Service Agreement
  • Researcher Responsibilities
    • Project build, data dictionary, database testing
  • DOCR Responsibilities
    • Create project, maintain user rights, review project before production, approve post-production changes
REDCap Services@Duke

- Office hours (first and third Tuesdays of each month)
- One-on-one REDCap demonstrations with PIs, study teams
- REDCap training and policy development
- Server maintenance
# REDCap – where we are today at Duke

<table>
<thead>
<tr>
<th>Project Type</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td><strong>REDCap Database</strong></td>
<td>543</td>
</tr>
<tr>
<td>--Development</td>
<td>182</td>
</tr>
<tr>
<td>--Production</td>
<td>287</td>
</tr>
<tr>
<td>--Inactive</td>
<td>10</td>
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<tr>
<td>--Archive</td>
<td>64</td>
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<tr>
<td><strong>REDCap Survey + Database Projects</strong></td>
<td>60</td>
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<tr>
<td>--Development</td>
<td>30</td>
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<tr>
<td>--Production</td>
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<tr>
<td>--Archive</td>
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<tr>
<td><strong>REDCap Survey</strong></td>
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<tr>
<td>--Development</td>
<td>403</td>
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<td>--Production</td>
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<td>--Inactive</td>
<td>67</td>
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<tr>
<td>--Archive</td>
<td>91</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Users Accounts</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Users</td>
<td>1822</td>
</tr>
<tr>
<td>Unique Email Addresses</td>
<td>1753</td>
</tr>
<tr>
<td>Visited at least once</td>
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DATABASE SIZE: 11.00 GB
Duke University School of Medicine

This effort is partially supported by Grant Number 2UL1-TR000436-06A1 from the National Center for Advancing Translational Sciences (NCATS)

Thank you!
Enterprise-wide Launch and Support of REDCap for Data Management

Terri Shkuda
The Pennsylvania State University

Security Work Group Webinar
Group for Information Resources (GIR)
Association of American Medical Colleges (AAMC)
January 28, 2014
Why REDCap?

• CTSA grant, awarded in June 2011, funded a 1.0 FTE REDCap support position and identified REDCap as the best tool for investigators to:
  ▫ Protect confidential data
  ▫ Enjoy the integrity of their data
  ▫ Reach the goal of CTSA to predict, prevent and treat human disease

• PSU internal review
  ▫ Desire to improve security around human subjects data management
  ▫ Data Security and Integrity Policy
  ▫ Data Management Plan

• Compliant with the Data Security and Integrity Policy
• Provides a environment capable for researchers wishing to be compliant with 21 CFR Part 11
• REDCap Consortium provides resources for performing a system validation required for Part 11 compliance
REDCap Governance

- Research Informatics (IT) and CTSI leadership developed governance model and determined the scope of expertise needed, then invited key stakeholders from those areas.
- The REDCap Advisory Group was formed to ensure:
  - Researcher buy-in
  - Compliance with Quality Assurance
  - Representation from main campus
  - Representation from cross-functional areas of subject matter experts
- Group now meets monthly to decide on:
  - Data Management Policies and Procedures
  - REDCap feature implementation decisions
  - Monitoring REDCap resources
REDCap Project Purpose

- REDCap is a CTSA funded application and its primary purpose is **Research**
- Optional use cases fall within **Quality Improvement**, **Operational**, **Educational**
- Specifically **NOT** intended for clinical use for treatment and diagnosing patients
REDCap System Validation

- Validation Scope
  - System Installation
  - Operating Environment Objectives
  - System Life Cycle
- Validation Maintenance
- REDCap Governance
- Risk Management
- Decommissioning
REDCap Support & Funding

- REDCap employs a separation of duties to prevent fraud and error. Key team members are:
  - Information Owner (CTSI)
    - Approves upgrades to REDCap
  - REDCap Administrator (Research Informatics)
    - Primary analyst (training, maintenance, office hours, consortium representative)
  - Systems Administrator (Research Informatics)
    - Performs support software patching (OS, MySQL, Apache) and REDCap upgrades
  - Account Management Analysts (IT Accts Mgmt)
    - Provisions accounts approved by Information Owner

- REDCap is provided to researchers at no charge and is funded by CTSA grant and institutional funding for:
  - Application
  - Support (training, consults, maintenance)
  - Storage
  - Biostats
Training Model

- All users must be trained.
- Three-prong approach to training:
  1. Advanced in-person training:
     - full access users
     - decision makers
  2. Tutorials:
     - external users
     - data entry
  3. Peer training:
     - limited access such data post-processing
It takes a village ...
Growth Rate

- REDCap in production for 2.5 years
- Growth has been steady at approximately 30 new users per month

PSU Growth Rate
Pivotal Points

• IRB Data Security & Integrity Policy
  ▫ REDCap = EZ Pass for IRB submittal
• Continued quality delivery
  ▫ Regular upgrades
  ▫ Thoroughly tested with each release
  ▫ Responsiveness to questions and concerns
  ▫ Stable-secure server environment (validated system)
Lessons Learned

- **Steady growth:**
  - Ensures consistent level of service
  - Supportable for 1.0 FTE
  - Allows for planning of resources

- **REDCap support readily accessible and FREE:**
  - Open Office Hours
  - User Group meetings
  - Consultations
Thank you!

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Questions?

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