

Event Info Final Electronic ... Teleconference ...

T 01

# Research Data Capture

## An *Exploration with REDCap*

### Presenters:

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Duke University School of Medicine*

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*Systems Analyst in Research Informatics at  
Penn State University*

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**Darcy Pientka**

*Assistant Director of College of Medicine  
Technology Services at the University of Vermont*

## January 28, 2014



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AAMC Group on Information Resources (GIR)

## Security Work Group

[www.aamc.org/gir](http://www.aamc.org/gir)

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T 03: Research data e



# 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

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T 04: Considerations f



# 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

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# 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.*

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## 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?



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T 07: Research Mana



## 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

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08: What were some...

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# 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

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## What came next?

- RMT meeting with Duke Translational Medicine Institute (CTSA funding)
- Agreed to support overhead for SOM funded projects
- There was a caveat....

**Snyder DC et al.. Clin Trans Sci 2012; 5:464-469.**

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Introduction

Software

Consortium Partners

Become a Partner

Video Resources

Citing REDCap

Library

Consortium Wiki (Login Required)

**Upcoming Events:**

- Weekly All-Hands Consortium Meeting - Every Friday, 1-2PM Central

The REDCap Consortium is composed of **914 active institutional partners** from CTSA, GCRC, RCMI 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****Recent publications using REDCap:**

**The Australia and New Zealand Fontan Registry: description and initial results from the first population-based Fontan registry.** *Intern Med J.* 2013 Nov 7. doi: 10.1111/imj.12318. [Epub ahead of print].

**Heterogeneous practice patterns regarding antiplatelet medications for neuroendovascular stenting in the USA: a multicenter survey.** *J Neurointerv Surg.* 2014 Jan 3. doi: 10.1136/neurintsurg-2013-010954. [Epub ahead of print].

**Triggers of Spontaneous Preterm Delivery - Why Today?** *Paediatr Perinat Epidemiol.* 2014 Jan 2. doi: 10.1111/ppe.12105. [Epub ahead of print].

**A healthy diet with and without cereal grains and dairy products in patients with type 2 diabetes: study protocol for a random-order cross-over pilot study - Alimentation and Diabetes in Lanzarote - ADILAN.** *Trials.* 2014 Jan 2;15(1):2. [Epub ahead of print].

**HIV Viremia and T-Cell Activation Differentially Affect the Performance of Glomerular Filtration Rate Equations Based on Creatinine and Cystatin C.** *PLoS One.* 2013 Dec 23;8(12):e82028. doi: 10.1371/journal.pone.0082028.

**Psychological Resilience, Affective Mechanisms and Symptom Burden in a Tertiary-care Sample of Patients with Fibromyalgia.** *Stress Health.* 2013 Dec 26. doi: 10.1002/smj.2555. [Epub ahead of print].

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## Q&amp;A

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## 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

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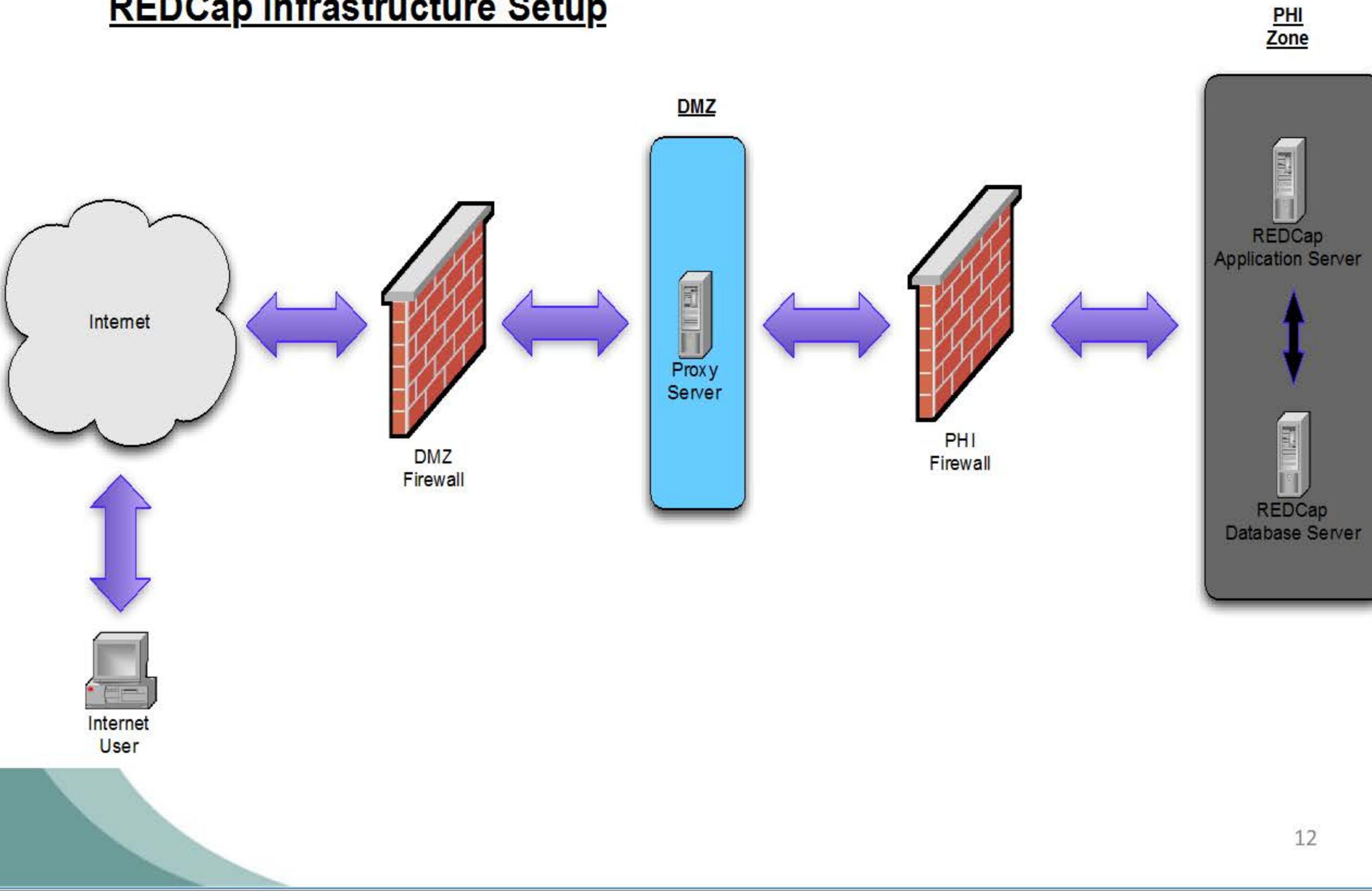
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## REDCap Infrastructure Setup



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## 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.

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# DukeQuEST

Quality and Excellence  
in Scientific Translation

## 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

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# Governance Structures Overview



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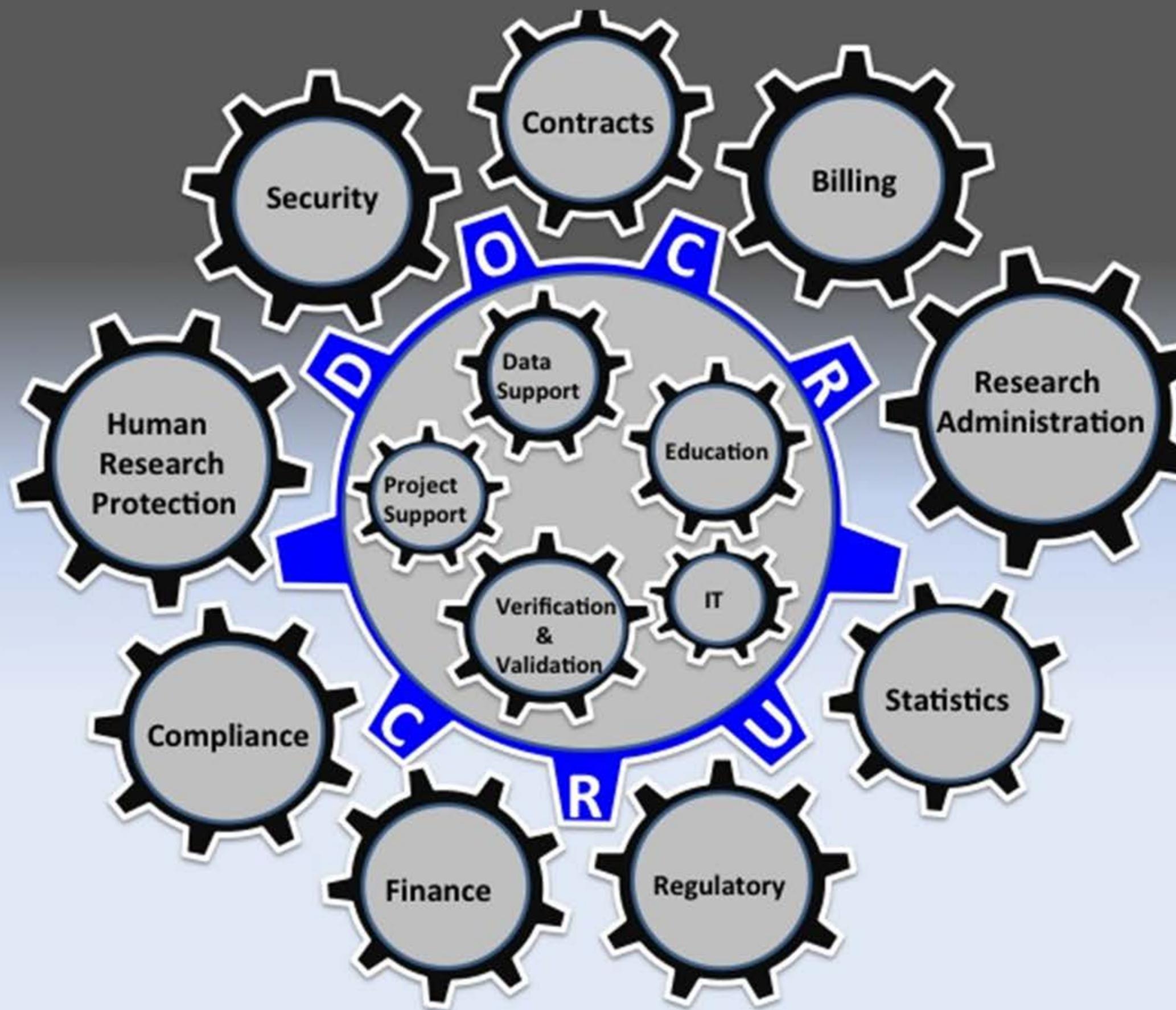
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# Managing Our Instance

- 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

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T 18: REDCap Servic



## 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

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# REDCap – where we are today at Duke

<b>Project Type</b>	<b>Total</b>
<b>REDCap Database</b>	<b>543</b>
--Development	182
--Production	287
--Inactive	10
--Archive	64
<b>REDCap Survey + Database Projects</b>	<b>60</b>
--Development	30
--Production	16
--Archive	14
<b>REDCap Survey</b>	<b>1016</b>
--Development	403
--Production	455
--Inactive	67
--Archive	91

<b>Users Accounts</b>	<b>Total</b>
Total Number of Users	1822
Unique Email Addresses	1753
Visited at least once	1793

DATABASE SIZE: 11.00 GB

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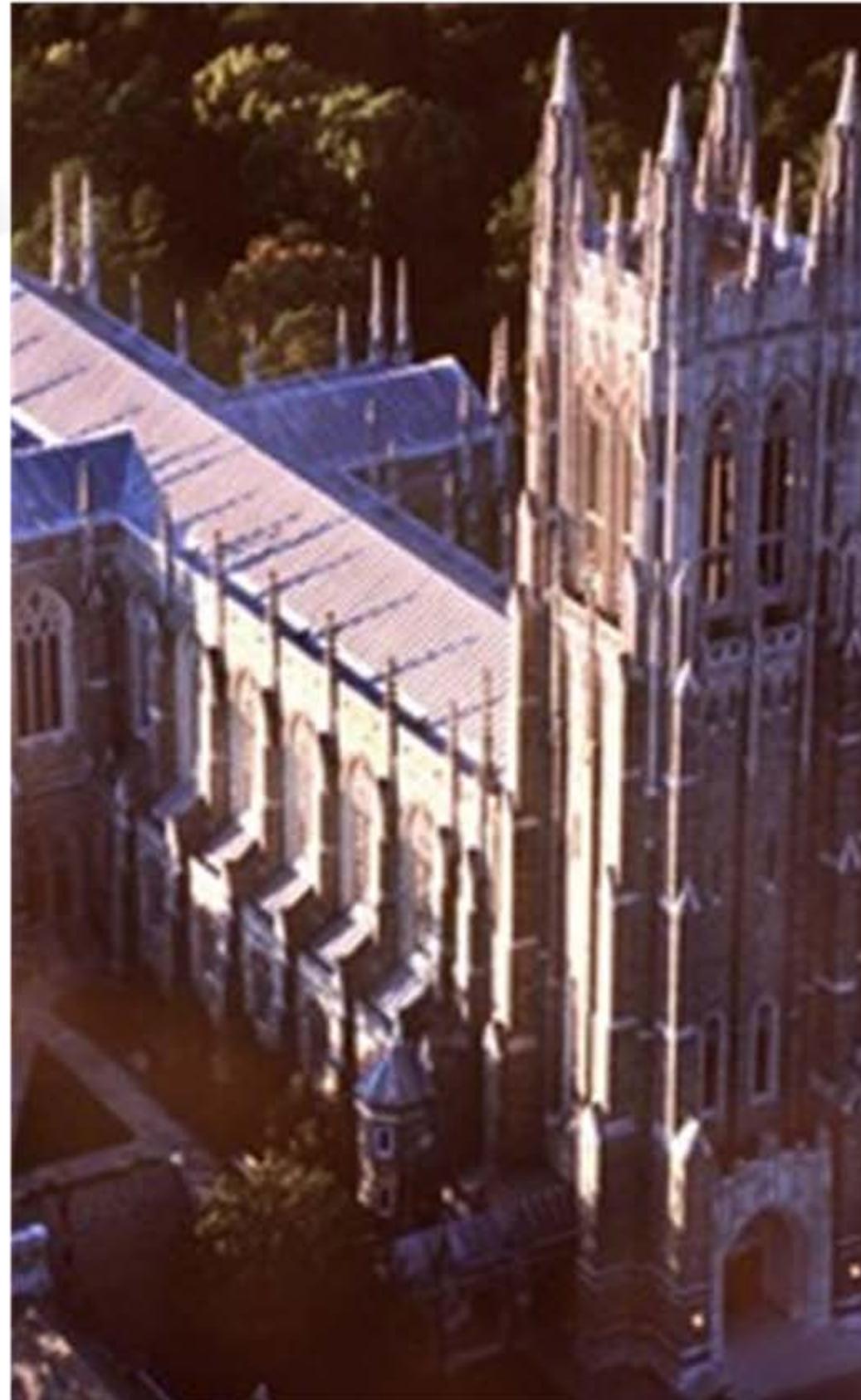


# Thank you!



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22: Why REDCap? ▶

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1855

# 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 an 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

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# 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

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Informatics

REDCap Advisory Group

```
graph TD; RI[Research Informatics] --- PH[Public Health Sciences]; RI --- SSSI[Social Science Research Institute]; RI --- CT[Clinical Trials Office]; RI --- N[Neuroscience Institute]; RQA[Research Quality Assurance] --- M[Marketing & Communications]; CTSI[CTSI] --- N
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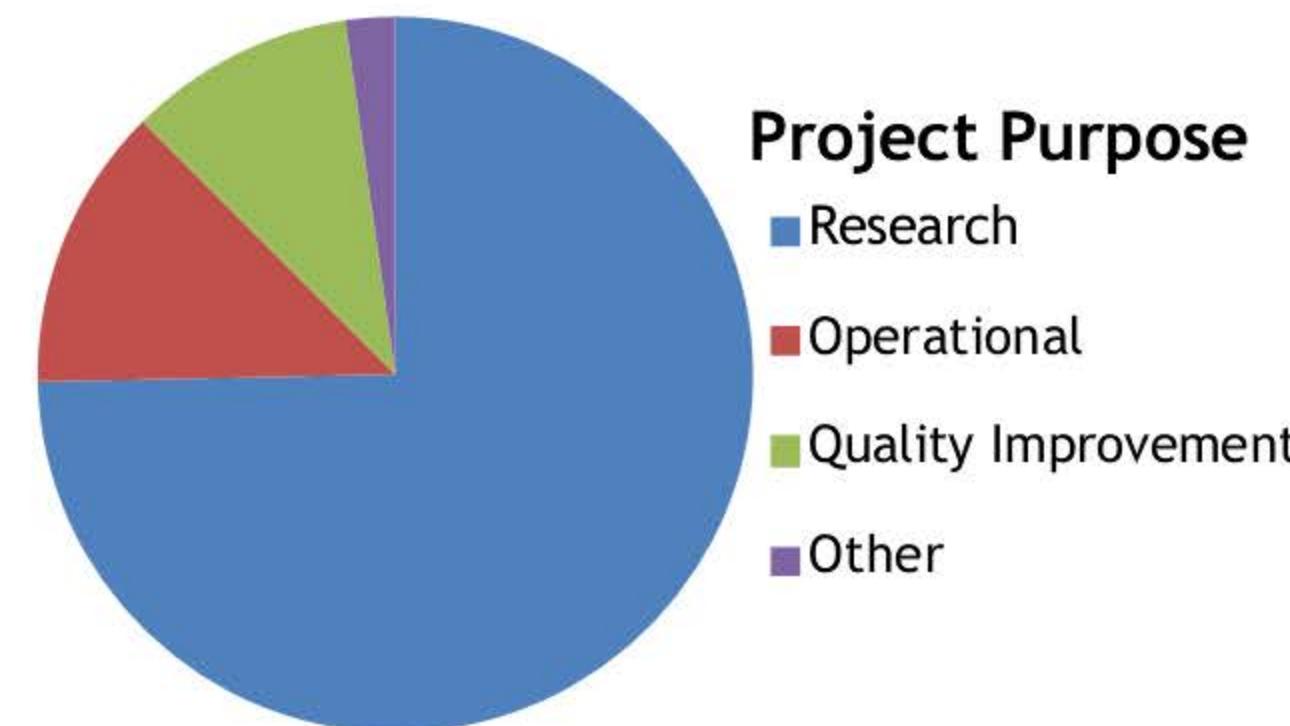
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# REDCap Project Purpose

- 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



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Cisco WebEx Event Center - Electronic Data Capture for Academic Medicine Research: An Exploration with REDCap

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# 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

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T 28: Training Model



# 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

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T 29: It takes a village

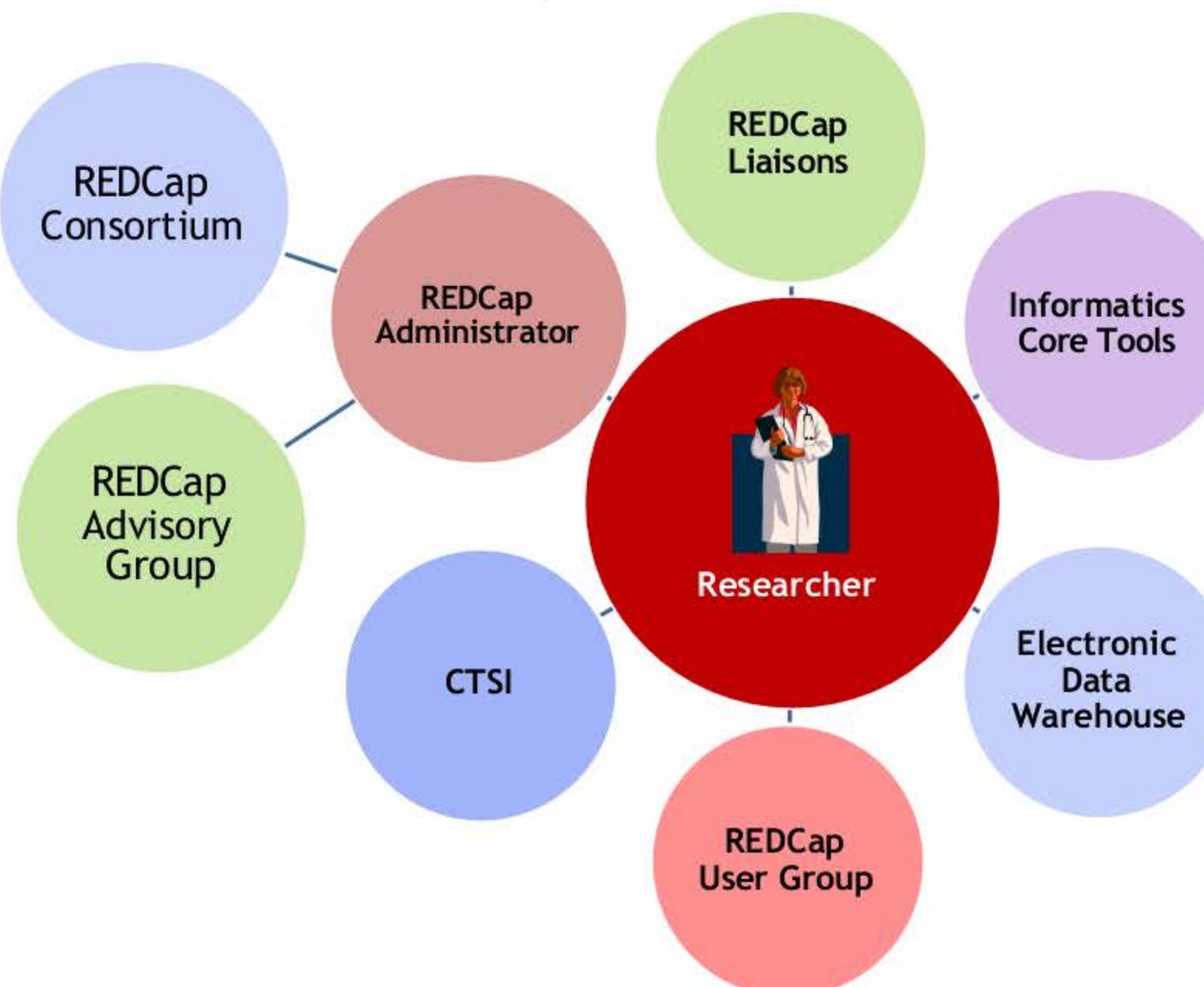
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# It takes a village ...

Technical

Policy



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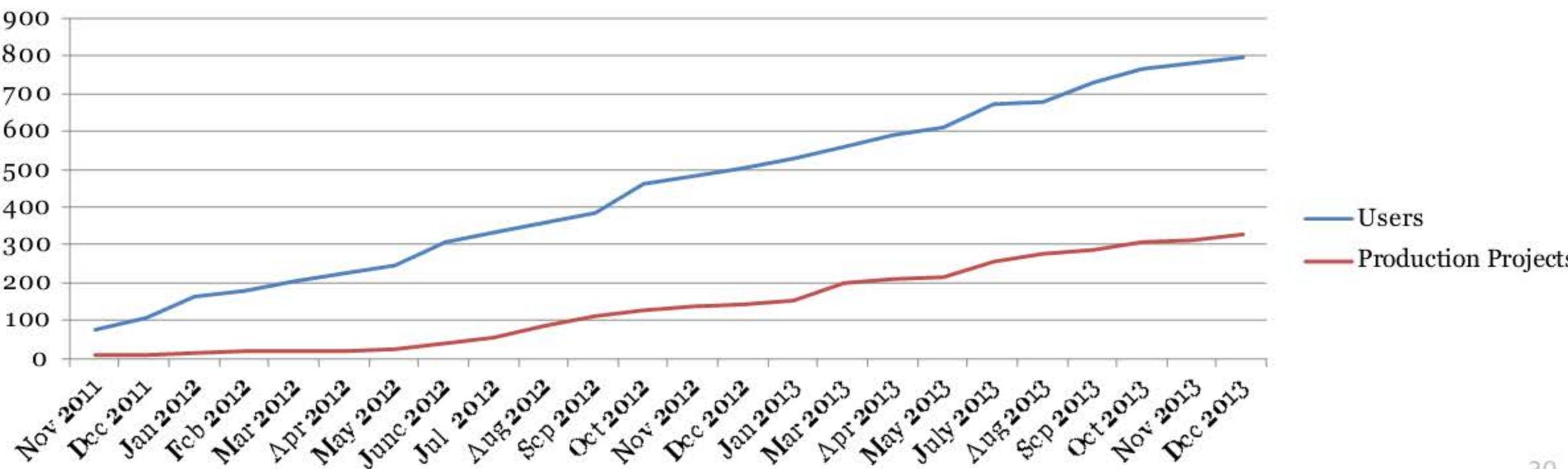
Ask: All Panelists  
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# Growth Rate

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

PSU Growth Rate



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Q&A

All (0)

Ask: All Panelists

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T 31: Pivotal Points



# 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)

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T 32: Lessons Learned



# 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

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T 33: Thank you!

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# Thank you!

The Penn State Clinical & Translational Research Institute, Pennsylvania State University CTSA,  
NIH/NCATS Grant Number UL1 TR000127

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Ask: All Panelists  
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T 34: Questions?

# Questions?

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