Your host:
Ebony Boulware, MD, MPH
Contact PI, Duke CTSA
Welcome

Click here to see Participants and Chat Function

Click on the microphone by your name to mute or unmute your phone. (You are muted on entry.)

Use Chat Function to ask questions or add comments
A quarterly WebEx conversation with the opportunity to...

- Learn about what the CTSA offers
- Meet the people who are providing services and resources
- Learn how to access these resources
- Ask questions of CTSA leadership
How it Works

Each quarter, a different resource will be highlighted

Presentations from those providing the resource

Real world examples from investigators who have used the resource

Time to ask questions about the resource
Today’s Agenda

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• Loren Del Mar Pena, MD, PhD (Pediatrics) |
| Q&A | • Everyone |
| Upcoming Opportunities | • Ebony Boulware |
Where We Are on the CTSA Timetable

- **CTSA 1.0**
- **Bridge Funding**
- **CTSA 2.0**

- Competing Renewal Due May 2017
Priorities for the future

Leveraging Technology

Improving Population Health & Community Engagement

Team Science & Workforce Development

Collaborations – within and outside of Duke
Leveraging Technology

MyResearchHome

Maestro Care Research Optimization

Making “Big Data” Useful
Improving Population Health & Community Engagement

Engaging other CTSAs

• Workforce development
• Assisting our communities in “research readiness”
• Community liaisons
• PCORI Grant

Building on Success of MURDOCK, SEDI, etc.

• Extension of the MURDOCK Study (serial sampling, projects involving local investigators, representative sampling in conjunction with Arts and Sciences faculty)

New Duke-Margolis Health Policy Center

• Director – Mark McClellan
Team Science and Workforce Development

National Priority

Culture Change

- Strengthening ties between schools (Medicine and Pratt School of Engineering)
- Continuing DTRI Pilot Programs to encourage investigators from different departments/fields/schools to collaborate

Building on Current Efforts

- DOCR / HR competencies for Clinical Research Coordinator
- Mentoring Programs
- Non-Academic Careers for PhDs
- Continued reaching out to underrepresented minorities
Collaborations

On Campus Collaborations for Team Science
- Coulter Awards / MedX
- DTRI Pilot Awards

Regional Collaborations Share Expertise
- Duke/UNC Research Collaborations (Basic Science)
- Carolinas Collaborative (IT)
- Regulatory Science Collaborations
Future Collaborations

- Proposing a Trial Innovation Center (TIC)
- Proposing a Recruitment Innovation Center (RIC)
- Encouraging X02 Grant Submissions
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Over to Denise Snyder & DOCR
CTSA Town Hall

Duke Office of Clinical Research
Research Management Team (RMT) Services
Why do we do what we do?
Clinical Research@Duke

- 2013 Industry funded research $177m
- 2015 research expenditures- $678m (direct & indirect)
- 2014 NIH funding $293.2m
- 1462 investigators, 400 coordinators in site based research + another 200 research professionals
- 2100 open enrolling IRB studies during FY15
- 300 NEW clinical trial studies/year open at Duke University Hospital
- 7% of patients enrolled in clinical studies (nearly 18,000 unique patients enrolled in clinical research)
SOM Research Support Mission

Improve patient care through outstanding clinical research that is supported by sustainable business processes and a well-trained clinical research workforce.
SERVICES

Research Management Team

• Programmers and analysts available for:
  • Database design and programming (REDCap)
  • Data management, coding/cleaning
  • DEDUCE queries and data import
  • Training (GME, one-on-one, office hours)

• Coordinators available for
  • Project coordination
  • Data entry/abstraction
  • Regulatory assistance
  • Recruitment/consent/enrollment
Needs of the Community - CRC

- RMT - available effort sold (maxed to capacity)
- Effort sold + unmet requests (possible funded)
- Presumed new requests
Long Term Goals

• Strategically recruit a new workforce of research professionals
• Create a stable and well-trained workforce for the Duke research community
• Provide temporary coordinator services for the Duke research community
• Harmonize movement/progression through career path
Needs of the Community - Data
REDCap is a mature, secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support data capture for research studies. The REDCap Consortium is composed of 1,609 active institutional partners in 92 countries who utilize and support REDCap in various ways.

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 197,000 projects with over 272,000 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) or overview (14 min).

Map of REDCap Consortium Partners

Recent publications using REDCap:


- Geriatric Assessment-Guided Care Processes for Older Adults: A Delphi Consensus of Geriatric Oncology Experts [J Natl Compr Canc Netw. 2015 Sep;13(9):1120-30]


- Critically Ill Children Have Low Vitamin D Binding Protein, Influencing Bioavailability of Vitamin D [Ann Am Thorac Soc. 2015 Sep 10]

- Hospital Incidence and Outcomes of ARDS Using the Kigali Modification of the Berlin Definition [Am J Respir Crit Care Med. 2015 Sep 9]

- Endoscopic factors influencing fecal calprotectin value in Crohn’s disease [J Crohns Colitis. 2015 Sep 7. pii: gr190]
REDCap at Duke

- **Research Electronic Data Capture**
- Licensed from Vanderbilt for free
- Data export to statistical packages (SAS, SPSS)
- Data dictionary
- **HIPAA-compliant, secure alternative to Excel**
- Upgrade validation services, server support and maintenance
- Oversight of project creation, user rights, post-production changes
- Training and demonstrations
- **Office hours: Tuesdays 11:00a, Hock 9047**
My experience with RMT services

• Who am I?
  – Assistant professor
  – Dept of Pediatrics, Division of Medical Genetics
  – Principal investigator for clinical trials in rare disorders
    • Phase 1-4
    • Open label
    • Randomized, placebo controlled
How have I used RMT’s services?

1. Database build
   – RedCap
   – Over 500 data elements on initial build
     • Free text
     • Numerical
     • Multiple choice
     • Branching logic
   – Ongoing maintenance
How have I used RMT’s services?

2. Research involving Epic
   – Building MyChart functionality
   – Data mining
   – DEDUCE queries
How have I used RMT’s services?

3. Project coordination: federal grants, corporate sponsors, investigator-initiated
   – Initial IRB submissions
   – Continuing reviews
   – Amendments
   – Recruitment
   – Scheduling and coordinating study visits
   – Data entry
Why do I prefer RMT?

• Range of services
  – Data entry
  – Database build
  – EMR build
  – Regulatory
  – Study coordination
Why do I prefer RMT?

• FLEXIBILITY
  – Able to provide partial FTE for set periods of time (a little or a lot, for a short or a long period of time)
  – Takes pressure off junior investigator with unpredictable funding

• Knowledge
  – DOCR trains and sets the expectations for skills
    → I know I am partnering with someone who has the right skills set for the project
Why do I prefer RMT?

• Accountability
  – Formal contract with FTE and projects specified
    → everything is spelled out
  – Ability to add additional projects depending on workflow
Why do I prefer RMT?

• Ease of use
  – Submit request and expect to hear back quickly.
  – Requests can be made from the DOCR website under the big orange button “More Information About DOCR Services”
My experience with RMT

Corrine Voils, PhD
Division of General Internal Medicine
Experience with RMT

- Foundation career development award to mentee (Gellad 2010-2012)
- AHRQ-funded grant (Maciejewski; 2010-2012)
- K23 to mentee (McVay; 2015-2020)
- R34 (Voils; 2015-2018)
- Duke Cancer Center pilot (Voils; 2015-2016)
RMT role

• Review of protocol with suggested edits
• Part-time personnel
  – Recruiting, conducting assessments, entering data, maintaining study binder
• Survey programming in REDCap
  – Language for protocol
• DEDUCE data pulls
Benefits of using RMT

• Not needing to hire full-time employees
  – Effort can change from month to month in response to study needs
• Accountability
• Accurate cost estimates
• Timely response
• All-around outstanding customer service
Thank you!

This effort is partially supported by Grant Number UL1TR001117 from the National Center for Advancing Translational Sciences (NCATS)

Duke Office of Clinical Research
Duke University, School of Medicine
Hock Plaza, 9th floor
docr.help@dm.duke.edu
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Upcoming Opportunities

**FUNDING**
- KL2 Scholars Program Offers 3 Years of Protected Research Time – Application Deadline Nov. 20, 2015.
- DTRI Supplemental Awards of up to $25,000 – Application Cycle Opens Nov. 16
- DTRI Translational Research Pilot Offers up to $100,000 – Deadline Oct. 30

**EVENTS**
- IND Best Practices Workshop – Monday, November 9
- Center for Nursing Research and Translational Science Scholarly Series: Transferring Presentation to Publications – Wed., Nov. 11
- Health Informatics Seminar - "Using Real-world Data for Outcomes Research and Comparative Effectiveness Studies“ – Wed., Nov. 11
- IDE Best Practices Workshop - Friday, Nov. 13
- SBIR/STTR Symposium in Cary: "Cultivating Collaborations“ – Wed., Nov. 18
NEXT CTSA VIRTUAL TOWN HALL

JANUARY 12, 2016
11 A.M. - NOON