Duke Office of Clinical Research

We don’t do the research you do…… we make the research you do easier.”

Jeff Hawley
Rick Sloane
Joan Wilson
Today’s Presentation

- Duke Office of Clinical Research (DOCR)
- Vision - organizational overview
  - What we do, our growth, & how we can help
- GME work examples
- Partnering with statisticians
- Project examples
- Q & A
Vision

- Our core values are quality, collaboration, flexibility, integrity, creativity, service
- Integral to our work model is our people
- We share a common vision of excellent customer service, imaginative problem solving skills, and collaborative partnerships with research teams
- We strive to provide cost effective research solutions for investigator-initiated research at Duke
Institutional Support

- Duke University School of Medicine
- Duke Translational Medicine Institute

DOCR Oversight
- Assessment
- Budgeting
- Evaluation
- Staffing
- Training
- Grant Budget Justifications

IT Support

Data Core
- Data Capture
- Data Cleaning
- Database Design & Documentation
- Statistical Plans & Analysis

Percent Effort Cost

Project Core
- Data Entry
- Intervention
- Interviewing
- IRB
- Recruitment
- Study Coordination
How we can help...

- Data collection/entry/cleaning
- Data mining - DEDUCE
- Database design
- Data management and troubleshooting
- Statistical consultation
- Research design
- Project management
- IRB submission
- Subject interviewing/tracking
- Online module creation
- Chart abstraction
- Research mailings
• Two components:
  – REDCap (Research Electronic Data Capture)
  – REDCap Survey
• Licensed from Vanderbilt University at no charge
• Web-based
• Development through collaborative effort of Consortium
  – Includes over 300 institutional partners from CTSA, GCRC and RCMI funded organizations
• Suitable for research projects with low to medium-low complexity data collection requirements
• Targeting researchers currently using Excel spreadsheets or MS Access to store data
• Ideal resource for data collection as primary function
REDCap Survey

- FREE – Easy set up or % effort cost for RMT to set up
- Designed to collect study participant self-report outcomes
- Survey results can be exported to MS Excel or a variety of statistical analysis packages
- Links to a survey may be distributed via e-mail or posted to a web page
- Responses may be kept anonymous or tracked by individual
Pros

- Auto-validation
- Branching logic
- Calculated fields
- Easily create new databases from previous versions
- Export data to common data analysis packages
  - Raw data and syntax files for SAS, Stata, R, and SPSS
- Univariate graphical views and descriptive statistics
- Ability to import and export data
- Specify deidentified exports
- Ability to set up simple reports to query specific variables

Cons

- Monthly releases (updates include patches)
- No one-to-many relationships – db is a flat file
- Limit to complexity
- Limited querying/reports (very simple SELECT-type queries supported)
- Not an EDC 21 CFR part 11 compliant system (FDA) – can be adapted to meet part 11 via SOPs with written documentation
- Not FISMA compliant (VA data must be deidentified)
Online Course Design and Administration

- Using Adobe Captivate, DOCR transforms presentations into multimedia, interactive, web-based courses.

- Courses are complete with testing, data collection and administrative services.
Medical Training

- Focuses on analyzing and treating individual patients
- Does not routinely focus on diagnosing and treating illness in health care systems
WHY? Improved data management = better data outcomes

• Reduces researcher burden
  – Meet with statisticians, research team up front to set up data collection/capture
• Makes data security and backups easier
• Gets data to publication more quickly
<table>
<thead>
<tr>
<th>What did investigators think about DOCR</th>
<th>Somewhat to Very Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>92%</td>
</tr>
<tr>
<td>Benefit</td>
<td>93%</td>
</tr>
<tr>
<td>Getting an estimate for project</td>
<td>95%</td>
</tr>
<tr>
<td>Data Integrity, Compliance &amp; Security</td>
<td>98%</td>
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</tbody>
</table>
Regular communication among the entire team
  – Increases efficiency
  – Maximizes scientific output
  – Facilitates innovative scientific work
  – Increases statistical power (via decreasing data mistakes and errors)
Statistical Support

.......begins at the beginning
Basics.....

• Identifying research question(s)
• Specific aims
  • Hypothesis testing?
  • Exploratory?
• Measurement issues
• Analysis approaches
• Presentation of results
Project Management

• Where DOCR comes in
• Matching data collection with analysis aims
  – Mapping to analytic variables
• Foundation issue: quality data
  – Excel=history
• Pilot testing
Examples of Projects

A Controlled Trial of a Short Course to Improve Residents' Communication With Patients at the End of Life.

Alexander, Stewart C. PhD; Keitz, Sheri A. MD, PhD; Sloane, Richard MPH; Tulsky, James A. MD. Academic Medicine: November 2006 - Volume 81 - Issue 11 - pp 1008-1012

- Knowledge and skills tests pre and post short course
- Standardized patients encounters recorded and scored
  - validity
  - reliability
Examples of Projects

Education Project Plan Rubric
- MD Fellows workshop to learn how to develop teaching plans
- How do faculty evaluate the quality of these plans?
  – criteria
  – wording

Convened expert panel to develop a consensus. What is “consensus”?
Examples of Projects

To Match or Not: What Factors Influence a Resident's Choice of GME Program.
Alisa Nagler JD, EdD, Kathryn Andolsek MD, MPH, Joanne Schlueter BA, John Weinerth MD

The agony and the ecstasy: The challenges and opportunities of ACGME required Internal Reviews.
Kathryn Andolsek MD, MPH, Alisa Nagler JD EdD, Leslie Dodd MD, John Weinerth MD