REDCap Web-interface
Database System

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What is REDCap?

- **Research Electronic Data Capture (REDCap)**
- “[REDCap] is a novel workflow methodology and software solution designed for rapid development and deployment of electronic data capture tools to support clinical and translational research.” (Harris et al., 2009)
- Among key features:
  - User authentication and role-based security
  - Real-time data validation and entry checks
  - Auditing capabilities
  - Uses MySQL relational database
Selecting REDCap

• KU ADC new in 2011
• Institutional investments
  – Velos eResearch (CRIS) institutional license
  – REDCap growth with the newly-formed Div. of Medical Informatics
• KU ADC needed a system...
  – ...capable of supporting large, multi-site studies, which typically budget informatics personnel to build eCRFs
  – Able to efficiently support smaller scale projects (e.g., KU ADC pilot projects) with small budgets
• KUMC approach to eCRF development
  – CRIS: eCRFs built by personnel in Dept. of Biostatistics
  – REDCap: range of options from investigators developing eCRFs (e.g., model described by Harris et al., 2009) to budgeting for informatics support
Selecting REDCap (cont.)

• Clinical Core’s experience with both programs and preference weighed heavily on our decision

• Strengths of REDCap
  – Cost
  – Web-based user interface supports multi-site studies
  – Facilitates eCRF development by investigators for small budget projects by...
    • ...creating metadata table in Excel for data dictionary
    • ...using the Online Designer via web browser
  – Can facilitate link between study specific data with other data captured by the ADC (e.g., UDS)
  – Sharable form set with other ADCs
    • Opted for “out-of-the-box” REDCap utilization to sharing our database structure with other ADCs
Data Capture and Workflow

• Master patient index for all subjects
  – Clinical Core assigns unique KU ADC ID for each subject
  – KU ADC ID used across all ADC forms

• Links across databases
  – Recruitment
  – UDS and ADC-specific cohort
  – Ability to link pilot study databases
Data Capture and Workflow (cont.)

- ADC ID selected from drop-down list
  - Additional subject information displayed to assist with drop-down selection
## Data Entry: Event Grid

The grid below displays the form-by-form progress of data entered into the project for one particular ADC Subject ID for all defined events. You may click on the colored buttons to access that form for that event. If you wish, you may modify the events below by navigating to the Define My Events page.

### ADC Subject ID test-1234

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>1-NACC UNIFORM DATA SET (UDS) (1)</th>
<th>Follow-up1 (2)</th>
<th>Follow-up2 (3)</th>
<th>Follow-up3 (4)</th>
<th>Follow-up4 (5)</th>
<th>Follow-up5 (6)</th>
<th>MGM-01 (7)</th>
<th>milestone1 (8)</th>
<th>milestone2 (9)</th>
<th>milestone3 (10)</th>
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<tbody>
<tr>
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<td>Demographics KU A1 A2 A3 A5 KUMhx</td>
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<td>Function KU Vitals B7 B5 B6 B1</td>
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<td>Exam KUNeuro B3 B8 B2</td>
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<td>KU Psychometric Battery</td>
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Form A4: Subject Medications

UDS Drug Code Search Tool: NACC DrugID Lookup
For drugs on the NACC Medications List

- Helpful Hints:
  - You can use upper case or lower case letters.
  - You can enter brand name, drug name, or generic name.
  - For aspirins and multivitamins, brand names will produce better search result.
  - No need to enter the complete name. You can enter just the first few letters.

- You can also download the complete list of medications in an Excel spreadsheet or a PDF and search from there:
  - Download Excel File (2.5MB)
  - Download PDF (1MB)

UDS Drug Code Search Tool: Non-NACC DrugID Lookup
For drugs not on the NACC DrugID list

- Helpful Hints:
  - You can use upper case or lower case letters.
  - You can enter brand name or drug name.
  - No need to enter the complete name. You can enter just the first few letters.

Type the name of the drug - optional.

Type a 3rd drug ID, d_ _ _ _ _

Type the name of the drug - optional.
Audit Capabilities

• Creates searchable spreadsheet that captures:
  – User that entered/modified data
  – Date and time
  – Original value
  – New value
  – Reason for change

<table>
<thead>
<tr>
<th>Time / Date</th>
<th>User name</th>
<th>Action</th>
<th>List of Data Changes OR Fields Exported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:45pm 10/01/2012</td>
<td>evidoni</td>
<td>Manage/Design</td>
<td>Delete report</td>
</tr>
</tbody>
</table>
| 2:38pm 10/01/2012 | handerson3  | Updated Record RED_1987 (1-NACC UNIFORM DATA SET (UDS) ) | r_int_think_prob = '0',  
r_int_think_prob2_14f = '1',  
r_int_think_prob_yes = 'attributes to age - word-finding difficulty',  
r_int_trouble_often = '2',  
r_int_10yrs_ago = '3',  
r_int_how_long = '10 years',  
r_int_how_consistent = 'consistent on 5 or 6 things that she has to stop and think',  
r_int_why_are_you = '1',         |
<table>
<thead>
<tr>
<th>Software</th>
<th>Instructions</th>
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<tbody>
<tr>
<td><strong>Microsoft Excel</strong></td>
<td>You may download the survey results in CSV (comma-separated) format, which</td>
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<td>can be opened in Excel. You have the choice of downloading the data either</td>
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<td>with the full headers and answer labels or just with the answer codes</td>
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<td>(i.e. raw data).</td>
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<td><strong>NOTE:</strong> If you are using a version of Microsoft Excel prior to Excel 2007,</td>
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<td>due to limitations the data will only be read to 255 columns when opened.</td>
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<td>**SPSS Statistical</td>
<td>Analysis Software</td>
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<td>Instructions: Download and save all 3 files on the right to a common</td>
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<td>location. First, double-click on the Pathway Mapper (.bat) file, which will</td>
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<td>run quickly and invisibly. (If you are not using a Windows operating system,</td>
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<td>such as Mac or Linux, please see the Additional Instructions.) Now</td>
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<td>double-click on the *.sps file, which will open SPSS. When the file is</td>
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<td>loaded and displayed, choose Run--&gt;All from the top menu options. This</td>
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<td>action will launch the script that will automatically read in all data and</td>
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<td>manipulate data fields with labels, option values, etc.</td>
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<tr>
<td>**SAS Statistical</td>
<td>Software</td>
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<td>Instructions: Download and save all 3 files on the right to a common</td>
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<td>location. First, double-click on the Pathway Mapper (.bat) file, which will</td>
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<td>run quickly and invisibly. (If you are not using a Windows operating system,</td>
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<td>such as Mac or Linux, please see the Additional Instructions.) Now</td>
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<td>double-click on the *.sas file, which will open SAS. When the file is loaded</td>
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<td>and displayed, choose Run (or Run--&gt;Submit) from the top menu options. The</td>
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<td>action will launch the script that will automatically read in all data and</td>
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<td>manipulate data fields with labels, option values, etc.</td>
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<tr>
<td>**R Statistical</td>
<td>Software</td>
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<td>Instructions: Use command read.csv('filename') to read in data file.</td>
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<tr>
<td>**STATA Analysis and</td>
<td>Statistical Software</td>
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<td>Instructions: Download both files to common location and double-click on</td>
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<td>*.do file. This action will launch the script that will automatically read</td>
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<td>in all data and manipulate data fields with labels, option values, etc.</td>
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- **New features can be requested**
  - For example, we requested additional input restriction features, which have now been implemented as “out-of-the-box” features.
- **Better facilitates sharing** (e.g., across ADCs)
Back-up and Security

- REDCap application server
  - Secured from unauthorized access, with access limited to only a few administrators
  - Nightly back-up to different location
  - Uses https to encrypt data transmission
- REDCap database server
  - Secured from unauthorized access, with access limited to only a few administrators
  - Protected by firewall and intrusion detection system maintained by IR
  - Nightly back-up to different location
  - Daily back-up (up to three times/day)
- Utilizes Central Authentication Server
  - Common username and password for KUMC applications
Hosting a REDCap Instance

• Cost of REDCap (http://project-redcap.org/)
  – No cost for REDCap software and support “to institutional partners”
    • ...though not open-source
  – Does have infrastructure requirements (not free like “air”)
    • Hardware needed to host system
    • Personnel to maintain security, implement upgrades, etc.
Citing REDCap

• Recommended citation at http://project-redcap.org/

Study data were collected and managed using REDCap electronic data capture tools hosted at [YOUR INSTITUTION]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Acknowledgements

• DMSC: Cathy Price, Suzanne Hunt, Bhargav Adagarla, Russ Waitman
• Department of Biostatistics: Lexie Brown, Dan Connolly, Kahlia Ford, Mani Nair
• Clinical Core: Jeff Burns, Brad Amstein, Anne Arthur, David Johnson, Eric Vidoni
• MGM Core: Russ Swerdlow
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...and of course...
Study data were collected and managed using REDCap electronic data capture tools (Harris et al., 2009) hosted at The University of Kansas Medical Center. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.
REFERENCES


• http://project-redcap.org/