How Can Frontiers Biomedical Informatics, REDCap and HERON Help Your Research?

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December 14, 2011

This project has been supported in part by NIH grant UL1 RR033179-0
Outline for Today’s Presentation

- **Warning:** my talk is KUMC biased
  - REDCap available to you as Frontiers Investigator
  - HERON requires KUMC sponsorship and collaborators

- Informatics CTSA Aims: focus on storing and getting
  - Tools for storing information: REDCap
  - Tool for viewing/getting information: HERON/i2b2
    - Oversight Process
    - Milestones

- Upcoming Clinical Data in HERON

- Future Functionality and Integration
  - 1.6 release versus current 1.4: visits and modifiers
National Clinical and Translational Science Award (CTSA) Objectives:

The purpose of this initiative is to assist institutions to forge a uniquely transformative, novel, and integrative academic home for Clinical and Translational Science that has the consolidated resources to:

1) captivate, advance, and nurture a cadre of well-trained multi- and inter-disciplinary investigators and research teams;

2) create an incubator for innovative research tools and information technologies; and

3) synergize multi-disciplinary and inter-disciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care.
Frontiers Biomedical Informatics Aims

1. Provide a portal for investigators to access clinical and translational research resources, track usage and outcomes, and provide informatics consultative services. [http://frontiersresearch.org](http://frontiersresearch.org)

2. Create a platform, HERON (Healthcare Enterprise Repository for Ontological Narration), to integrate clinical and biomedical data for translational research.

3. Advance medical innovation by linking biological tissues to clinical phenotype and the pharmacokinetic and pharmacodynamic data generated by research cores in phase I and II clinical trials (addressing T1 translational research).

4. Leverage an active, engaged statewide telemedicine and Health Information Exchange (HIE) effort to enable community based translational research (addressing T2 translational research).
REDCap: Research Electronic Data Capture

- Secure web application for building online surveys and databases
- Data dictionaries managed as Excel compatible files
- Export data to Excel, SAS, SPSS, R, STATA
- Features: logging, branching logic, field validation, & more
- Technology: PHP and MySQL
- KUMC instance maintained by Medical Informatics and Information Resources

The REDCap Consortium is comprised of 307 active institutional partners from CTSA, GCRC, RCMI and other institutions, and it 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 25,770 studies with over 36,880 end-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.

Map of REDCap Consortium Partners
REDCap: Research Electronic Data Capture

- **https://redcap.kumc.edu**
  - You and other users need to request an affiliate account through Frontiers.
    - **https://redcap.kumc.edu/surveys/?s=bKaC6s**
  - Check out the training materials under videos
  - Case Report Forms and Surveys

- For consultation and to move project to production:
  Register your project with us so we can make keep track of your request.
  - [http://biostatistics.kumc.edu/projectReg.aspx](http://biostatistics.kumc.edu/projectReg.aspx)
  - After you register your project, a team member, will get in touch with you.

- Check out other institutions using REDCap and possibly borrow from the master library.
  - [http://www.project-redcap.org/](http://www.project-redcap.org/)
REDCap Disclaimer

- For clinical trials, CRIS/Velos may be a better fit
  - Multiple years of experience, AE reporting capabilities
  - CRIS team builds for you with biostats review
  - Budget for CRIS team and biostats explicitly
- "Investigator driven" REDCap works if PI takes responsibility for data
  - Scalability: informatics provides consultation and responsibility for technical integrity; *not your dictionary.*
  - Underwritten by CTSA right now
- Or middle model where informatics can build for you in REDCap.
  - Again, you budget for our team’s time
REDCap Case Report Form Example

University of Kansas Medical Center
University of Kansas Medical Center

KU-ADC

C Case ID 1 (John Doe, RED_1)

ADC Subject ID

NOTE: This form is to be completed by intake interview per ADC scheduling records, subject interview, medical records, and proxy informant report (as needed). For additional clarification and examples, see UDS Coding Guidebook for Initial Visit Packet, Form A1. Check only one box per question.

Enrolled in NACC MDS

- Yes
- No

Primary Reason for coming to ADC

- Participate in research study
- Clinical evaluation
- Other
- Unknown

specify

Principal Referral source

- Clinician

Presumed disease Status at enrollment

- Control/normal

Presumed Participation

- Initial Evaluation only

ADC enrollment type

Subject's month of birth

Subject's year of birth

Subject's sex

- Male
- Female

Does the subject report being Hispanic/Latino ethnicity (i.e., having origins from a mainly Spanish-speaking Latin American country), regardless of race?

- Yes
- No
- Unknown

What does subject report as his/her primary race

What additional race does subject report?

What additional race beyond what is indicated above in questions, does subject report?

Subject's primary language

Informant's years of education (report achieved level using the codes below; if an attempted level is not completed, enter the number of years attended). High school/GED = 12; Bachelors degree = 16; Master's degree = 18; Doctorate = 20 years:

The REDCap Consortium | Osher REDCap | University of Kansas Medical Center
**REDCap Survey Example**

**Question:**

Vexed by a complicated protocol in a vulnerable population?

Want to go beyond compliance hurdles to sleeping well at night?

**Frontiers CTSA brings you an exciting opportunity to obtain thoughtful ethics consults to further your research.**

Please take a minute to fill out your request so we can direct the best ethicist to work with you on your urgent moral quandary.

**First name:**
* must provide value

**Last Name:**
* must provide value

**Email:**
* must provide value

**Where are you?**
* must provide value
- UMKC
- Children’s Mercy
- KCUMB
- KUMC-CC
- KUMC-W
- KH-L
- Lukes
- KC VA
- Other

**Role:**
* must provide value
- Principal investigator
- Co-investigator
- Study Coordinator
- IRB member
- Other

**Is your question regarding any of the common ethics topics:**
- Informed Consent
- Inclusion/Exclusion criteria
- Recruitment
- Vulnerable populations

**Add any additional notes or comments here**

**Upload your IRB protocol or a copy of your credit card here**

Submit
Aim #2: Create a data “fishing” platform: HERON, https://heron.kumc.edu

- Develop business agreements, policies, data use agreements and oversight.

- Implement open source NIH funded (i.e. i2b2) initiatives for accessing data.

- Transform data into information using the NLM UMLS Metathesaurus as our vocabulary source.

- Link clinical data sources to enhance their research utility.
You’re that fisherman: wanting to land data to answer your research hypothesis

Bennett Spring Trout Park, Lebanon Missouri
http://mdc.mo.gov/regions/southwest/bennett-spring
The Fish: Diagnoses, Demographics, Observations, Treatments
Why so many fish? Medical Informatics.

**Current Goal:** Build Hatchery, Manage the Fishery
Big, well sorted, healthy trout
Second Goal: If you need help fishing, hire a guide from Medical Informatics.

Photo Credit: HuntFishGuide.com
http://www.flickr.com/photos/huntfishguide/5883317106/
Prepare and Analyze data with Biostatistics

Photo Credit: S. Klashill
http://www.flickr.com/photos/sklathill/505464990/
The goal: a tasty publication

Photo Credit: Steve Velo
http://www.flickr.com/photos/juniorvelo/259888572/
Develop business agreements, policies, data use agreements and oversight.

- September 2010 the hospital, clinics and university signed a master data sharing agreement to create the repository.
  - Executive Committee – decides organization/systems expansion
  - Data Request Oversight Committee – guides implementation and approves/monitors use.

- Use Cases:
  - After signing a system access agreement, cohort identification queries and view-only access is allowed but logged and audited
  - Requests for de-identified patient data, while not deemed human subjects research, are reviewed.
  - Identified data requests require approval by the Institutional Review Board prior to data request review.
  - Contact information from the Frontiers Participant Registry have their study request and contact letters reviewed by the Participant and Clinical Interactions Resources Program
Current Functionality

• Single sign-on KUMC authentication system
  • Non-KUMC personnel must be sponsored by a KUMC faculty member and request an affiliate account: https://redcap.kumc.edu/surveys/?s=bKaC6s

• Must be on campus or use VPN
• Real-time check for current human subjects training
• System Access Agreements, Data Use Agreements and Review Processes implemented in HERON with web pages for monitoring system use
• Check http://informatics.kumc.edu for latest status
Implement NIH funded (i.e. i2b2) initiatives for accessing data.
i2b2: Count Cohorts
i2b2: Ask for Patient Sets
i2b2: Analyze Demographics Plugin
i2b2: View Timeline
HERON De-identification Decisions

- HIPAA Safe Harbor De-identification
  - Remove 18 identifiers and date shifting by 365 days back
  - Resulting in non-human subjects research data but treated as a limited data set from a system access perspective. System users and data recipients agree to treat as a limited data set (acknowledging re-identification risk)

- To be addressed:
  - For now, we won’t add free text such as progress notes with text scrubbers (DeID, MITRE Identification Scrubber toolkit)
Developing a Rich Description of our Population: Existing and Planned Data Sources for HERON. Existing sources shown in solid lines and planned in dashed, new sources this Fall/Winter in green.
Biospecimen Shared Resource Integration
Adding Social Security Death Master File

- Have Death status on approximately 90 million people.
  - Contains Social Security Number, Name, Date of Birth, Date of Death, Place of Death
  - Monthly update file from ntis; will sync with releases
- Released Friday, September 23, 2011
  - Matching on SSN plus DOB
  - 177,706 of our 1.8 million people noted as deceased according to Social Security Administration versus 23,850 from hospital systems.
KUH Tumor Registry

- Validated Outcomes and Observations
  - Tumors, Nodes, Metastasis (TNM) on complete cases
  - Untapped investment: 7 cancer registrars (Tim Metcalf)
  - ~60,000 cases, data since 1950s

- North American Association of Central Cancer Registries (NAACCR) file format
  - Will build on work at other NCI designated i2b2 users
    (Group Health Cooperative in Seattle, Kimmel Cancer Center in Philadelphia have shared their code/metadata with us)
  - John Keighley providing invaluable expertise

- Later, supplement with additional treatment information not in NAACCR file

**Draft released Tuesday, November 22, 2011**
Upgrading to i2b2 version 1.6: What do Visits and Modifiers Offer?

**Visits:**
- I want to know the patient had the lab and the medication in the same episode of care.
- Conceptually, i2b2 has had a table for the visit dimension, but the software never exploited the data.

**Modifiers:**
- Is it a billing diagnosis or from the problem list? Is it a primary or secondary?
- How do I represent all parts of a medication order (dose, route, frequency)?
Constrain observations to the same visit

Murphy SN et al, https://www.i2b2.org/events/slides/i2b2_OpeningTalk_20110628_Murphy.pdf
i2b2 Modifiers in the User Interface

Murphy SN et al, https://www.i2b2.org/events/slides/i2b2_OpeningTalk_20110628_Murphy.pdf
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