What I will talk about

- Part 1: Brief history of our EDC project journey
- Part 2: Summary of pilot partnership evaluations of three EDC systems from 2008-2010
- Some Terms:
  - CTSA: NIH Clinical and Translational Science Awards, or loosely the national consortium of institutes funded by CTSA
  - EDC: Electronic Data Capture, for managing semi-structured clinical trial data
Our EDC journey

- CTSA funded our Institute of Translational Health Sciences (ITHS) roughly 3 years ago
- We wanted a “Cadillac” Clinical Trials Management System (CTMS) infrastructure, but realistically needed to start small
- Many small-scale investigators lack funds for any EDC, so fall back on paper Case Report Forms (CRFs) transcribed to spreadsheets
CDMS: EDC & Ancillary Systems

- AE & Medication Coding Systems
- Electronic or Paper Data Collection System
- Interactive Web Randomization System
- SAE Tracking System
- Case Report Forms
- Randomization
- AEs, SAEs, & ConMeds
- Clinical Data Management Systems
- Study Drug Distribution Management System
- Electronic or Paper Patient Diary
- Interactive Web Study Drug Distribution Management System
- Patient Reported Outcome Data
- Specimens Blood, Sputum, Swabs
- Overreading
- Specimen Bank
- Specimen Tracking Systems
- Laboratory Data Exchange
- Laboratory 1
- Laboratory 2
- Laboratory 3
What small-scale investigators have
Previous Work

- Foundation from interviews with investigators and survey of other informaticists


- “None of the systems we evaluated provided all functionality”
Part 2: ITHS pilot projects

Electronic Data Capture

electronic data capture
www.real-ediscovery.com/  Free eDiscovery webinars and whitepapers from Guidance Software.

Clinical Trials Software

Electronic data capture - Wikipedia, the free encyclopedia
An Electronic Data Capture (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human ...
en.wikipedia.org/wiki/Electronic_Data_Capture - 25k - Cached - Similar pages - 🔄

Electronic Data Capture - Phase Forward
Electronic Data Capture technology solutions in order to capture data electronically and store and refine data and ultimately being able to quickly report ...
https://www.phaseforward.com/products/clinica/edc/ - 15k - Cached - Similar pages - 🔄

Clinical Trial Software for Electronic Data Capture | OpenClinica
Nov 12, 2007 ... OpenClinica is a free, open source clinical trial software platform for Electronic Data Capture (EDC) clinical data management in clinical ...
www.openclincia.org/section.php?sid=1 - 13k - Cached - Similar pages - 🔄
Narrowing Down

- Requirements:
  - Free, open source, or very low cost
  - Web based to prevent need to install software
  - API for data integration with other systems

- 7 systems met requirements
  - Discarded 2 systems with no recent activity
  - Found that 2 more systems did not include a way for the study team to create their own forms
  - Completed 3 pilot projects
Partnership Approach

- We provided the technical expertise:
  - secure server, including standard OS and database
  - install EDC system
  - SSL website security certificate
  - backups

- Study team configured their own project:
  - set up the system for data collection (with training)
  - performed all data entry
  - provided us with valuable user insights
Importance of Ease of Use

- Initially we assumed that functionality would be paramount (focus of a whitepaper we prepared)
- Study teams were willing to work around limitation since anything is a step up from paper and spreadsheets
- Our qualitative evaluation focused on ease of use of the functionality that was present
## Qualitative evaluation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Catalyst</th>
<th>OpenClinica</th>
<th>REDCap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of training materials and documentation</td>
<td>Good</td>
<td>Fair</td>
<td>Good</td>
</tr>
<tr>
<td>Ease of designing CRFs including edit checks</td>
<td>Good</td>
<td>Poor</td>
<td>Good</td>
</tr>
<tr>
<td>Create a patient visit schedule for data entry</td>
<td>Poor</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>Flexibility of site and user roles and permissions</td>
<td>Fair</td>
<td>Good</td>
<td>Fair</td>
</tr>
<tr>
<td>Effort taken in exporting or importing data</td>
<td>Poor</td>
<td>Poor</td>
<td>Good</td>
</tr>
</tbody>
</table>
Pilot notes: UW Catalyst

- Open source suite including surveys, secure file management, and project workspaces
- General use, not specialized for clinical studies
- Setup requires a lot of manual customization
- Behavior on modification: if you edit wording in data export column is split:
Open source, developed by Akaza Research

Creating CRFs requires learning complex design with over 20 options per item (LEFT_ITEM_TEXT UNITS RIGHT_ITEM_TEXT TEXT SECTION_LABEL etc.)

Potential good fit for centers with dedicated CRF design staff, but not for many small-scale studies.
Pilot notes: REDCap

- Not Open Source, but free for “institutional partners”
- Extensive tutorials and online training materials
- Less functionality than OpenClinica in many areas such as complex CRFs and site management
- In the past few years, REDCap has added features including an online CRF editor, basic scheduling, API, and online surveys sent directly to subjects
Going Forward

- Early 2010 decided on REDCap as EDC system
- Current: local REDCap user group
  - “Power users” can assist others
  - CRF templates to augment REDCap Consortium’s Shared Library for common forms
  - Create website and other documentation with clear support options and steps for investigators to start using REDCap quickly
- Future: contribute to REDCap, for example value sets from OCRe (Ontology of Clinical Research)
Thanks!

- Questions?

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