Using REDCap: Data management in studies linking primary and secondary data

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Acknowledgements

• VIReC REDCap group
• Vanderbilt REDCap
• CTSA
• My collaborators at the VA and elsewhere
Poll #1: About you – research role

• What is your role in research?
  – Research investigator
  – Data manager/analyst
  – Project coordinator
  – Other – please describe via the Q&A function
Poll #2: About you – data experience

How many years of experience do you have working with VA data?

- Less than 1
- 1-2
- 3-6
- 7+
Session Overview

- **Brief introduction to REDCap**
- Examples of REDCap in research
  - Combining primary and secondary derived data
  - Complex studies-Longitudinal
- Reporting and reproducible research
- Other capabilities
Poll #3: REDCap Use

Please choose the category that best describes your familiarity & use of REDCap.

• Heard of REDCap, but know very little about it.
• Somewhat aware of REDCap and how it can be used
• Very aware of REDCap and use it occasionally
• I use REDCap frequently
REDCap Consortium

• Developed as part of Vanderbilt University’s CTSA

• Get **database creation** and data acquisition out of IT and **back to the researcher**

• Make the creation of databases and surveys **technically easy, secure and responsive/nimble** for individual researchers and the general research enterprise

• **NO PROGRAMMING EXPERIENCE NEEDED**
Features: 3 Things REDCap can do

• Handle a wide variety of data types (multiple categories, memo, calculated, branching logic) in an equally wide combination of applications (sample tracking, survey data, combining multiple sources, etc.) with EASE

• Secure access and activity tracking in single and multi-institutional settings

• Reporting capabilities and export with de-identification capacity to most common statistical packages or flat file
Features: Easy modification
Features: Code can be re-used
Features: Access

- Specific invitation with notification by e-mail (individual)
Features: Audit trail
Features: Security

• Definable roles with corresponding access levels
  – Data entry, de-identified download, etc.
• Definable groups with security based on roles
  – A group may only see its own data
  – A role may only manipulate or change data (delete records)
Features: User Rights
Control of access and groups
Features: Report creation and facilitating IRB review

- Pdfs of data collection tools/forms available for review (paper data capture)
- Report creation for internal QA and external review
- Security features that appeal to IRB
  - VINCI firewall
  - Access controls
  - Easy to de-identify archived data?
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Example 1

TREAT Lung Cancer Clinical Predictive Model
Deppen et. al, JTO 2014
Example #1 – Lung Cancer

• Initially a single institution retrospective chart review

• Clinical prediction model of suspicious lung nodules at the time of surgical evaluation

• After publication, multi-center data collection
  – 3 US sites, 1 VA and 1 International
  – Screening population, pulmonary clinic

• Metadata used in varying ways for data collection at each site
Example – Lung Cancer

Imported demographics and basic epidemiological data from enterprise data warehouse
Abstracted imaging, diagnosis, and clinical risk factors from patient medical record.
Example #2

A Meta-analysis
Meta Analysis Study

• Import data from external data source with a common meta-data model, but slight differences – PUBMED & EMBASE

• Data entry for study review abstraction

• Supports systematic data collection (2 reviewers and study adjudication)

• Export data for analysis and reproducible research

Deppen et al, JAMA 2014
PUBMED/EMBASE data - imported

Data imported from PUBMED and imported to both ENDNOTE and REDCap with a common data structure
Systematic Review

QUADAS standardized questions adapted and additional guidance specific to this study
Export for Analysis
Example 3

LONGITUDINAL STUDY
Longitudinal Multi-visit Study
Unique Design/Elements

• One participant can have multiple encounters or the project can have a multi-arm study
  – One form can be used multiple times
  – Multiple forms for one encounter

• Classic epidemiological cohort study or drug trial
  – National Neurosurgical Quality Outcomes Database
  – Right from the Start
  – STS Thoracic Surgical national quality database***
Longitudinal Multi-visit Study

- Chose Longitudinal as part of project setup
- Walks you through the process of setting up data collection and business rules
Longitudinal Multi-visit Study
“Event” Creation

- Temporal design
- Multiple arms
- Multiple events-encounters, adverse events, etc.
Longitudinal Multi-visit Study Form Assignment

Record Status Dashboard – Individual participant view
Longitudinal Multi-visit Study
Record Review-Data entry

Record Status Dashboard (all records)

Displaying below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Displaying: Instrument status only | Lock status only | All status types

<table>
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<th>Study ID</th>
<th>Demographics Enrolment</th>
<th>Contact Info Enrolment</th>
<th>Baseline Data Enrollment</th>
<th>Patient Morale Questionnaire Dose 1 Visit 1</th>
<th>Visit Lab Data Visit 1</th>
<th>Patient Morale Questionnaire Visit 1</th>
<th>Visit Blood Workup Visit 1</th>
<th>Visit Observed Behavior Visit 1</th>
<th>Patient Morale Questionnaire Dose 2 Visit 2</th>
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<th>Completion Data Final visit</th>
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</table>

Record Status Dashboard - All records view
Longitudinal Multi-visit Study Record Review-Data Entry

- Within a record, tags of where you are (event)
- Who you are updating (participant/form)
Longitudinal Multi-visit Study
Record Review - Data entry

Data entry form
Form status
Current form
Forms with current event and form status
Longitudinal Multi-visit Study
Missing Data Reporting

- Default data quality reporting - tabular and graphical
- Ability to filter and subset data within a report
Export to a variety of statistical packages
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Exporting

• Generates code for each statistical package for labels, redefinition of variables and transformation of dates into package specific code for each variable

• 147 lines of code for the TREAT database, mostly label definitions, in STATA export

• Greatly reduces biostatistics time

• Specific exports/reports for data review committees
REDCap Live Run

• Example from Meta-analysis and multicenter trial
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Other capabilities

- Randomization
- Multi-site study
- Dual data entry
- Survey
- Push activity/data collection needs to study coordinator
REDCap in the VA

• **Intranet** Web application
  – Surveys can only be administered to respondents via the VA INTRAnet

• VIReC REDCap **Resources**
  – REDCap Overview Webpage:
    • [http://vaww.virec.research.va.gov/REDCap/Overview.htm](http://vaww.virec.research.va.gov/REDCap/Overview.htm)
  – Resources for New Users:
    • [VA REDCap FAQs](http://vaww.virec.research.va.gov/REDCap/FAQs.htm)
    • [VA REDCap User Guidelines](http://vaww.virec.research.va.gov/REDCap/UserGuidelines.htm)
  – Helpdesk: [VIReC@va.gov](mailto:VIReC@va.gov)
Other REDCap Resources

• [http://project-redcap.org/](http://project-redcap.org/)
  – Survey Library
  – Training Videos
  – Searchable Help and FAQ (for current users)
• Large group of international users and potential collaborators
• Coming soon: API for scripted import of data or transfer to another program – TREAT website example
• Customer support provided by VIReC
Questions?

Thank you for your time.
Contact Information

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References
