Uploading REDCap Source Data to DataFax

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Who we are

NIH

NIAID

National Institute of Allergy and Infectious Diseases
(1 of 27 National Health Institutes)

OCICB

Office of Cyber Infrastructure and Computational Biology

IBRSP

International Biomedical Research Support Program
FDA definition of electronic record

Any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.
Electronic Source Data Collection

- Source and CRF data should be separate.
- Prevalence has increased.

- **Benefits:**
  - Facilitate collection of accurate, complete data
  - Enter source data during study visit
  - Eliminate transcription of source data
  - Reduce instances of transcription errors
  - Eliminate unnecessary duplication of data
  - Promote real-time access for data review
  - Facilitate remote monitoring of data
  - Provide monitors with the ability to compare source to eCRF
Data Collection

DATA COLLECTION

SOURCE

CDMS

DATA LOSS

Mistakes entering data

Mistakes transcribing to CRF

TRANSCRIPTION OF SOURCE TO CRF

Mistakes entering from CRF to CDMS
Our solution – V1.0

- Host country/PI owns source data → Source data must reside in-country
- mSource was developed and it enabled:
  - Electronic Source Data collection in-country
  - Export of pipe delimited files → Imported into DataFax
  - Data management using array of tools/reports within DataFax
- All user/programmed activity was captured in an audit log.
- Increase in Electronic Source Data collection across multiple studies and sites
Our solution – V1.0 (cont.)

Data entered on mobile devices (encrypted)

Data uploaded to in-country SQL server

Pipe-delimited files created

Management of study data performed in DataFax

DFimport.rpc imports latest data into DataFax

Rsync copies files to directory on DataFax server

* Audit trail logging
The Limitations of V1.0

- mSource licensing model was complicated and restrictive.
- Integration was labor/time intensive with limited functionality.
- Forms development required specialized, higher level skills.
- Did not have the many of the features and awareness that DataFax did.
Proposed V2.0 solution

- Must address V1.0 limitations.
- Is there a tool currently in use that can be considered?
  - Yes ➔ REDCap
Proposed V2.0 solution – cont.

Data entered into REDCap Mobile App

Data uploaded to REDCap server via WiFi or Cellular network

Data exported to SAS, pipe-delimited files exported

Management of study data performed in DataFax

DFimport.rpc imports latest data into DataFax database

Rsync copies files to directory on DataFax server
**Proposed V2.0 solution – cont.**

<table>
<thead>
<tr>
<th>Benefits – V2.0 (REDCap)</th>
<th>Limitations – V2.0</th>
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<tbody>
<tr>
<td>More flexibility</td>
<td>Mobile device management</td>
</tr>
<tr>
<td>Built-in features</td>
<td>User accounts (device + app, changes)</td>
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<tr>
<td>Better integration</td>
<td>Encryption of data &amp; transfers</td>
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<tr>
<td>Licensing model</td>
<td>Non-approved apps</td>
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<tr>
<td>Server can be in-country</td>
<td>Database update synchronization</td>
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Must address V1.0 & V2.0 limitations/issuses:

- Central mobile device management
  - Accounts
  - Security
  - Encryption
- Synchronizing CRF updates with central database/mobile device
- Preserve Host country/PI ownership of data → Data must reside in-country
Acknowledgements

- OCICB
- df/net → We need dfcollect ASAP!
- Project REDCap