Uploading REDCap Source Data to DataFax

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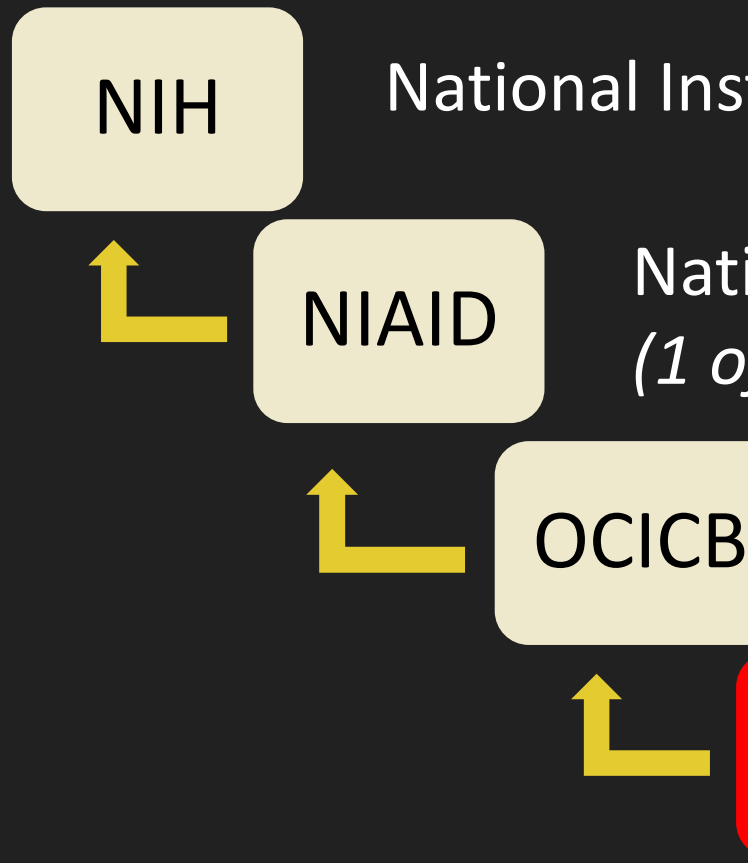
dfnet research

Who we are


NIH
National Institutes of Health
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

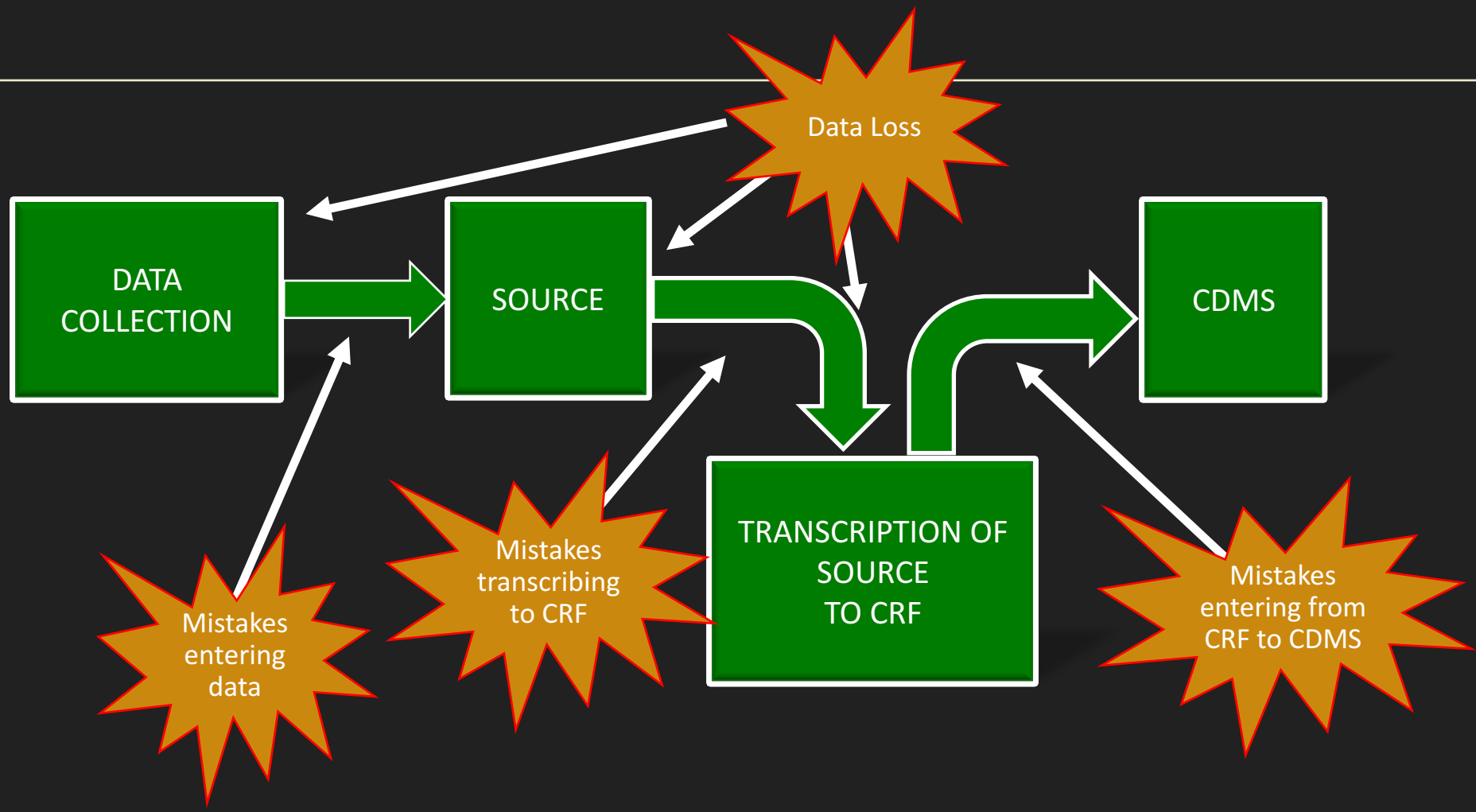
Any combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

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

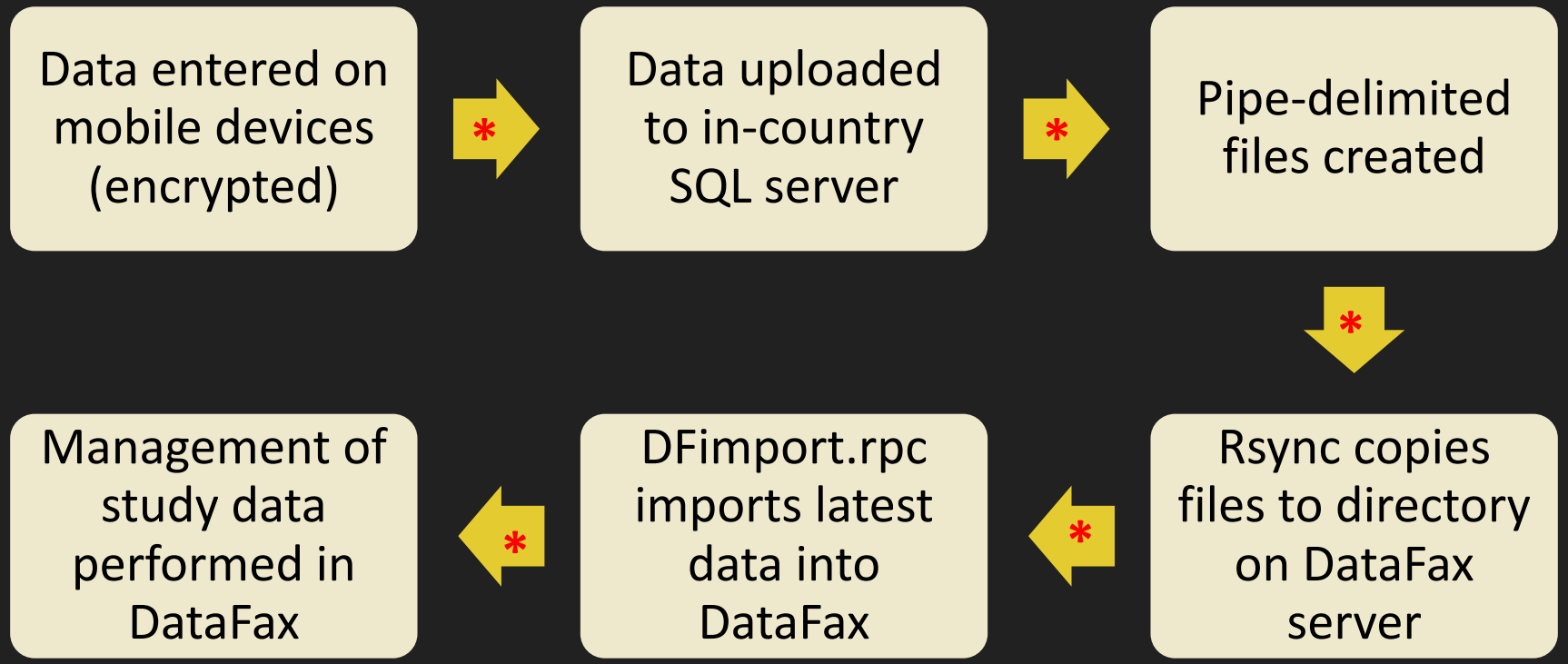
Data Collection



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.)



* Audit trail logging

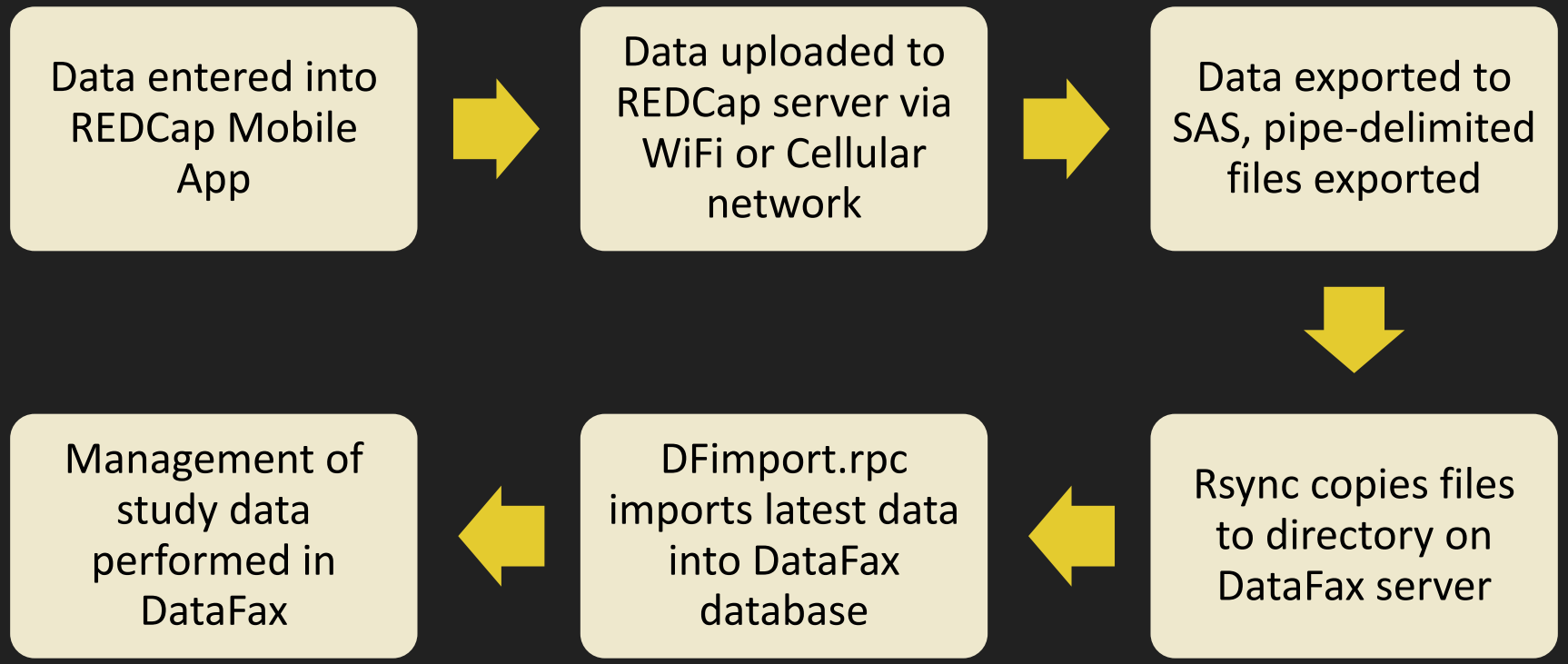
The Limitations of V1.0

- 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.



Proposed V2.0 solution – cont.

Benefits – V2.0 (REDCap)	Limitations – V2.0
More flexibility	Mobile device management
Built-in features	User accounts (device + app, changes)
Better integration	Encryption of data & transfers
Licensing model	Non-approved apps
Server can be in-country	Database update synchronization

Wish list: V3.0 – dfdiscover / dfcollect?

- Must address V1.0 & V2.0 limitations/issues:
  - 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