Instituts thématiques Inserm
Institut national de la santé et de la recherche médicale

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Database

Definitions 1

- A database consists in one or more tables
  - Row = records (participants)
  - Column = fields (measurements)
- Data dictionary
  - Name, data type, description, range of allowed values for each table
- Data entry system
  - Means by which the data tables are populated
  - Transcription of paper forms
    - Double data entry

Definitions 2

- Electronic data capture
  - On-screen forms of web page
  - Eliminate paper forms
  - A source document can be printed after direct data entry

Spreadsheet and database

- Don’t use excel spreadsheet
  - Data can be changed by error
  - Date can have different formats in the same column or be defined differently on two computers
  - No easy check of the possible values at data entry
  - Data for the same participant may be entered several times
  - Repeated measurement are not easily handled

Use a database management software

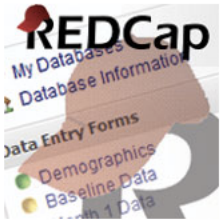
- Definition of data dictionary and relationships between the different data tables
- Centralized data
- Queries
- Will ensure data integrity
- Will allow secure access to data
- Will allow multiple access to data

Which tool ?

- EpiData
  - Free tool from the CDC
  - For small single centre study
- Access (Open office base)
  - More complex study
  - Multiple access to the database
- Easy PHP / Voozanoo/ REDCap
  - Electronic data capture in multicentre studies

Free, web-based electronic data capture tools to support clinical and research studies.

REDCap (Research Electronic Data Capture)



At a glance

Key Features
- Free, web-based, and user-friendly electronic data capture (EDC) tools for research studies
- Databases can be quickly developed and customized for studies' needs

Useful for
- Collecting and tracking information and data from research studies
- Scheduling study events (e.g., patient visits)
- Conducting surveys

Available to
- Investigators at institutions that have adopted REDCap
- All others should contact the Harvard Catalyst EDC Support Staff

REDCap

Beth Israel Deaconess Medical Center
Boston Children's Hospital
Harvard T.H. Chan School of Public Health
Joslin Diabetes Center (accessible only via Joslin Workstation or VPN)
Partners HealthCare

REDCap is a free, secure, web-based application designed to support data capture for research studies. The system was developed by a multi-institutional consortium initiated at Vanderbilt University. Data collection is customized for each study or clinical trial by the research team with guidance from Harvard Catalyst EDC Support Staff. REDCap is designed to comply with HIPAA regulations. REDCap is not 21 CFR Part 11 compliant.

REDCap: Data Management and Survey Tool

Using REDCap's stream-lined process for rapidly developing projects, you may create and design databases and surveys using:

Sponsoring Program

Biomedical Informatics Program

See Also

- HCCRC Protocol Review
- IRB Cede Review Request
- SHRINE

Development 1

- A team work (data manager with investigator, research assistant, statistician, …
- Define the needs
- Analyse the problem
- Conceive the database
- Implement it

Development 2

- Start from the CRF
- Define the data dictionary
- Define the tables and the relationship between the tables
- Define the data check performed when entering the data
  - Ranges, Chronology, ..;
- Define the data entry screens
- Define the queries
- Define the automatic reports
- Test the tool
- Write the documentation

Tracking / Audit trail

- Being able to document data changes
  - Who
  - When
  - What
  - Why
  - Old value
  - New value

Queries

- Sort and filter the data
- Calculate values based on the raw data fields
- Queries are used to
  - Monitor data entry
    - see section data checking
  - Report on study progress
  - Format the results for analysis

Confidentiality/ security

- To protect confidentiality, databases
  - must be stored on secure servers
    - firewall
  - With access restricted and traced
    - Login, passwords
    - Different rights
      - Read
      - Add
      - Change
      - Suppression
      - Change of the structure
  - And audited

Back-up and storage

- Loss of the database must be prevented
  - Regular back-ups
  - Off-site storage
  - Archiving copies for future use

Freezing the database

- To avoid any further change in the data
- When data have been corrected and validated
- In order to perform intermediate or final analysis

Conclusion

- Data management is a critical step for a good quality study