MÉDECINE SORBONNE UNIVERSITÉ

Institut Pierre Louis d'Épidémiologie et de Santé Publique
*Pierre Louis Institute of Epidemiology and Public Health*

Inserm
La science pour la santé
From science to health

# Case Report Form


D Costagliola

Institut Pierre Louis d'épidémiologie et de Santé Publique

Sorbonne Université, INSERM

# Disclosures

- I have received consultancy fees, honoraria, and my team study grants from:
  - Consultancy Innavirvax (2016), Merck Switzerland (2017)
  - Lectures Janssen (2016, 2018), MSD (2017), Gilead (2018)
  - Grants from Janssen (2017-2018, 2019-2021), MSD (2017)

# Definition

- CRF = Case Report Form

- Goal : to collect data that can be verified and used for analysis according to Good Clinical Practice (GCP)

# Designing the CRF

- Should reflect the protocol
- Must be developed and tested in advance
- Must follow a logical order
  - Group the items by domain
- Must be easy to enter in a database
- Can be computerized (eCRF)
- Collect only needed variables depending of the objective of the study
  - Neither too few nor too much
- Provide study schedule, instructions for coding and appendix (Sops, …)

# Designing the CRF

- A good CRF
  - get the right and correct data
  - Neither too few nor too much
  - Simple and easy to read
    - to avoid mistake
      - Clarity, simplicity, neutrality
      - Close-ended question
      - Unambiguous
      - Don’t forget unit
      - Patient identifier on each page
  - Collect data directly as much as possible
      - Raw data (date of birth rather than age)
      - Direct extraction of laboratory data, …

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# Database

# Definitions

- 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
- 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

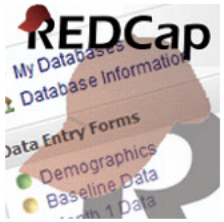
- Definition of data dictionary and relationships between the different data tables
- Centralized data
- Queries
- Will ensure data integrity
- Will allow secure access to data
- Will allow multiple access to data

# 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

- 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

# 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