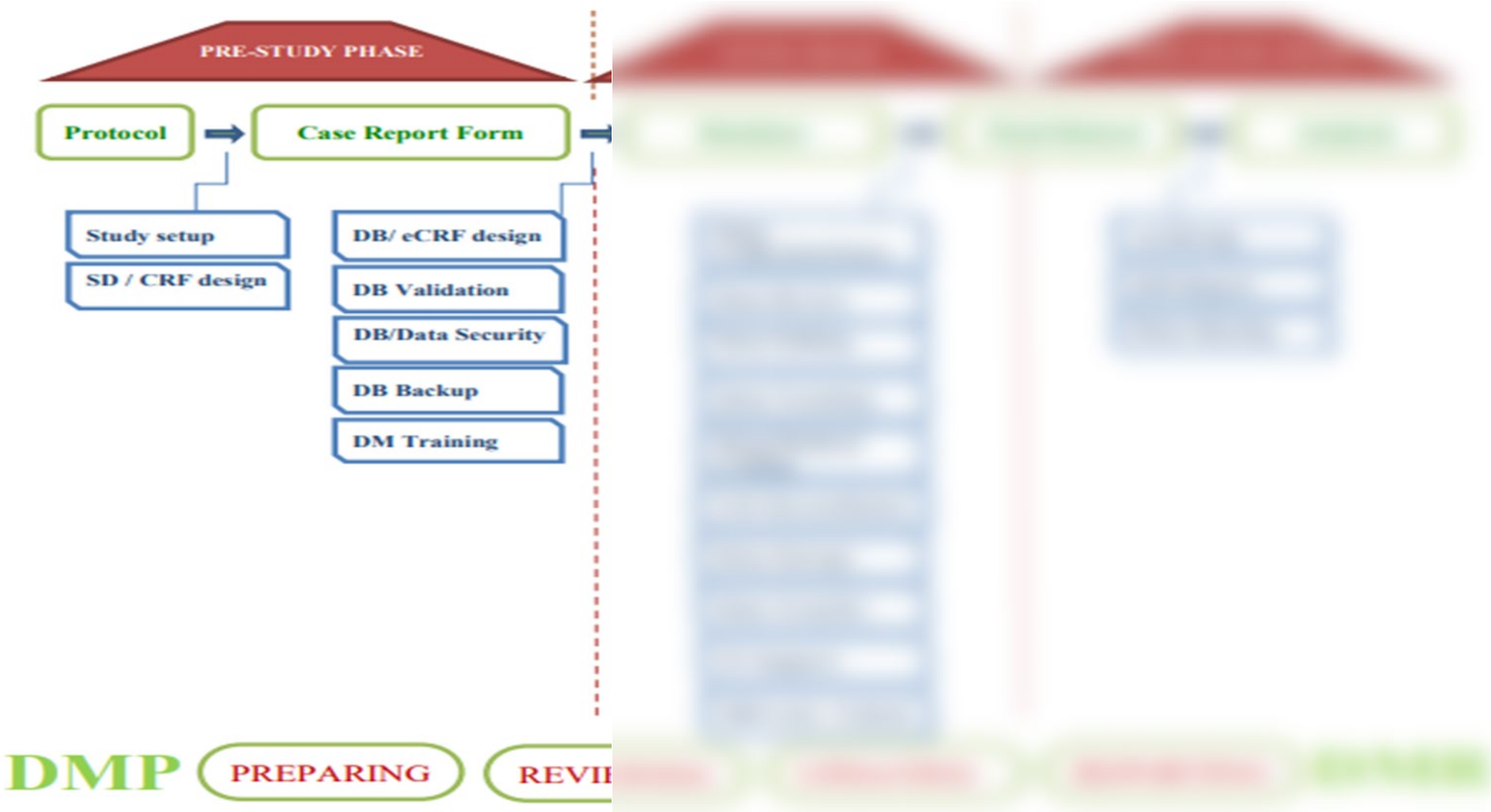
Pre-Study Phase



1. Study setup

1.1 General Data Management Plan information

1.2 Study design

1.3 Communication

1.4 Documentation

1.5 Timelines

1.6 Study roles and responsibilities

1.7 Confidentiality of study participant data

1.1 General Data Management Plan Information

- **Aim** and **purpose**

  - This Data Management plan covers the pre-study, study and post study handling of data in the XXXXX study and is drawn up following the ALERRT Standard Operating Procedure SOP-WP3-04 on a Data Management Plan.
  - Data Management in the XXXXX study will be coordinated by XXXXX at the Institute X in location X.

PS : yellow marked parts to be adapted

1.2 Study design

- **Summary** of the study
- Use:

1.3 Communication

- Who is **focal point** for DM?
  - At sponsor
  - On site
- Regular **meetings**

1.4 Documentation

- **Handling** of DM documents
  - Where

1.5 Timelines

- **DM milestones** (estimated dates)

1.6 Study roles and responsibilities

- **Listing of study roles and responsibilities** (brief description)
- **All involved parties**
  - Sponsor
  - Site
  - External Partners (e.g. lab)

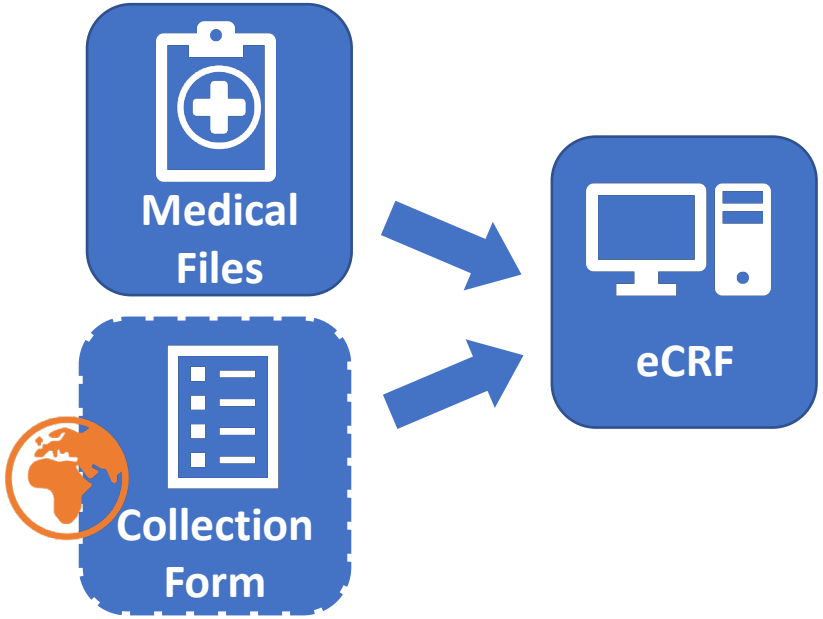
1.7 Confidentiality of study participant data

- **Privacy** and **confidentiality**
  - Participant information
    - Keeping contact details secure and controlled
  - Pseudonymization and Anonymization

2. Data Collection Form/CRF Design

- **Which documents designed:**
  - Data Collection Form (paper CRF or other templates)
  - CRF design (Used for **e**CRF design)

- **CRF design**
  - Standards (e.g. CDASH)
  - User friendliness
  - Meeting needs of protocol
  - Who is involved?
  - Approval!



3. Database/eCRF design

- **Description of database/system (user & regulatory requirements)**
  - Description of **Software (features & functionalities)**
    - Online/Offline
    - Security
    - Audit trail
    - Validation checks
    - Special features
  - Description of **Hardware & System (**tablets, 3G-5G or wifi, server, printer…**)**
- **Data dictionary:** information on variables

4. Database/System Validation

4.1 Validation of CDM software

- Does it work as intended?
- Release Date and Version

Software Validation Protocol

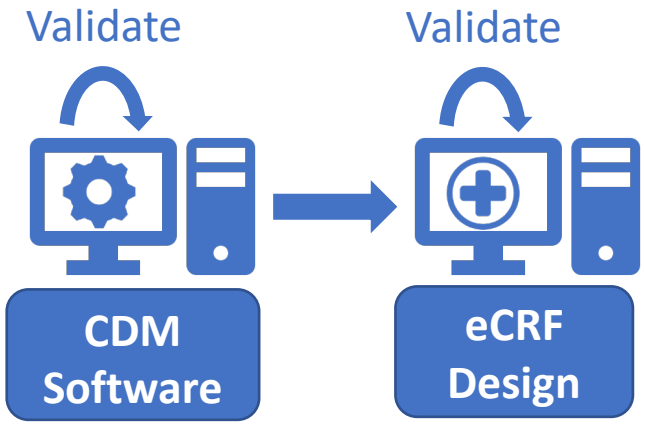
Software Validation Report (approval)

4.2 Validation of Study eCRF

- Does it work as planned?
  - Skipping patterns
  - Edit checks …

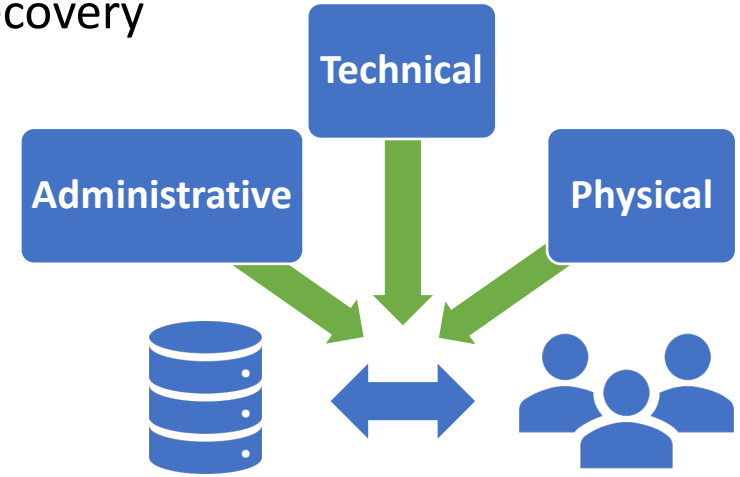
eCRF Validation Protocol

eCRF Validation Report (approval)

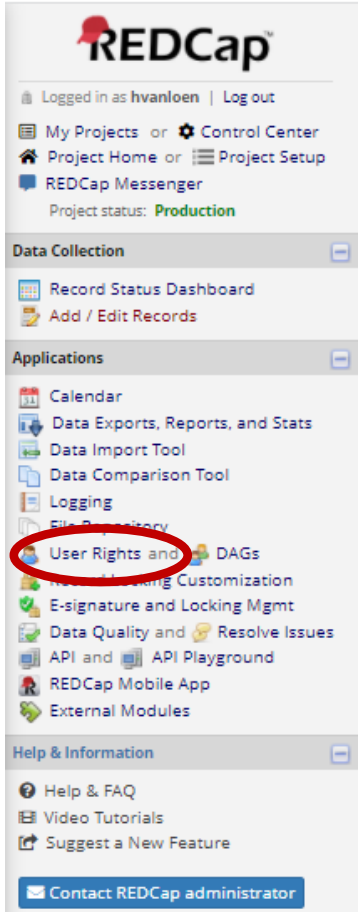


5. Database/Data Security and 6. Database back-up

- **DB, device & server level**
- **Who** has access?
  - Define **user roles**
  - **Access levels/rights**
- **Safeguarding** of the data
  - **Administrative**
    - SOPs on Security, Back-up and Recovery
  - **Technical**
    - Passwords & User roles
    - Encryption
  - **Physical**
    - Locked room
    - Badges



User access log



Role name (click role name to edit role)	Username or users assigned to a role (click username to edit or assign to role)	Expiration (click expiration to edit)	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Calendar	Data Import Tool
—	[redacted]	never	✗	✗	✗	✗	✗	✗	✓	✗
—	[redacted]	never	✓	✓	✓	Full Data Set	✓	✓	✓	✓
DATA MANAGER CRC	[redacted]	never	✗	✗	✗	Full Data Set	✗	✓	✓	✗
DATA MANAGER CTU	[redacted]	never	✓	✓	✓	Full Data Set	✓	✓	✗	✗
ENTRY	[redacted]	never never never never never never	✗	✗	✗	✗	✗	✗	✓	✗
MONITOR	[redacted]	never never	✗	✗	✗	Full Data Set	✗	✓	✗	✗
REVIEW	[redacted]	never	✗	✗	✗	Full Data Set	✗	✓	✗	✗
STATISTICIAN	[redacted]	never never	✗	✗	✗	Full Data Set	✗	✓	✗	✗
VIEW	[redacted]	never	✗	✗	✗	✗	✗	✓	✗	✗

7. DM Training

- Who **receives** training
- Who **gives** training
- **What** is trained

Training Confirmation Form

Periodic Training Plan

Site	Role	System	Trainer	Date and Signature
Site 1 Site 2	Site Investigators Nurses Monitors	Web DE	CDM, monitor(s)	