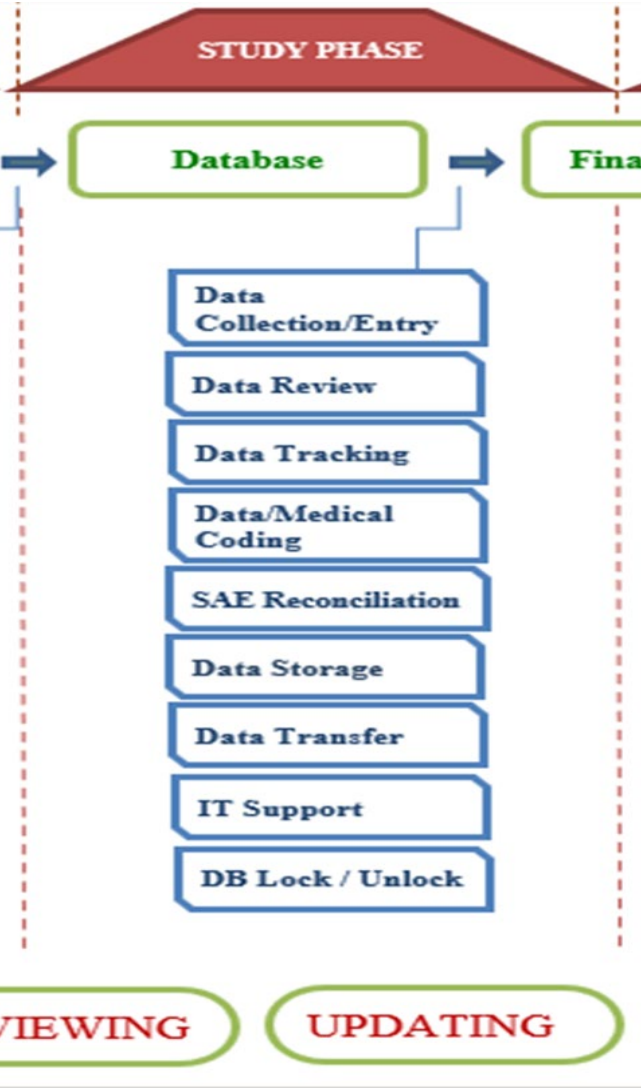
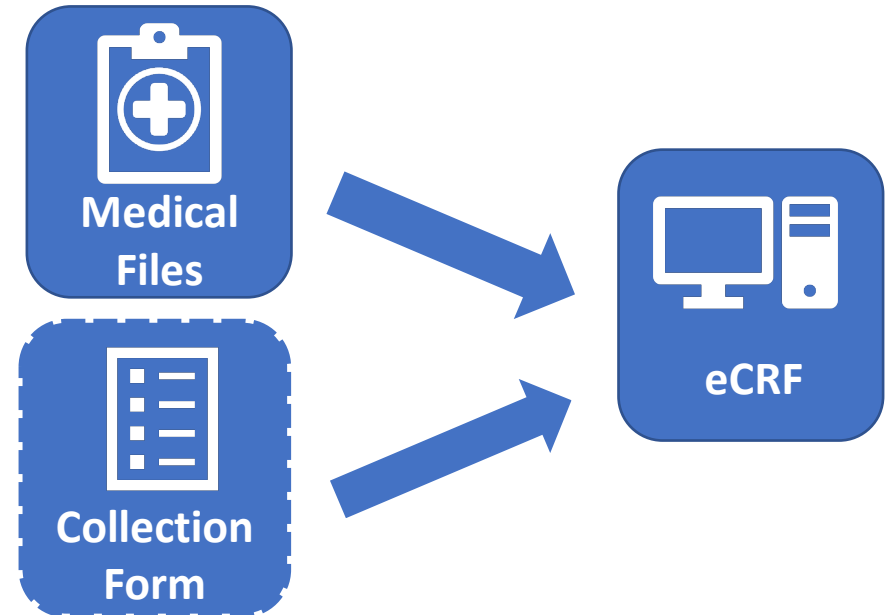


# Study Phase



## 8. Data Collection/Entry

- **Which data**
  - Types of source (Clinical, Lab, ...)
  - Data Collection Forms (medical files, pCRFs, eCRFs...)
- **Quality measures** (manual review, double data entry...)
- **Target times for collection/entry**
- **Randomization**
- **Data Collection/Entry Guidelines**



## 9. Data Review

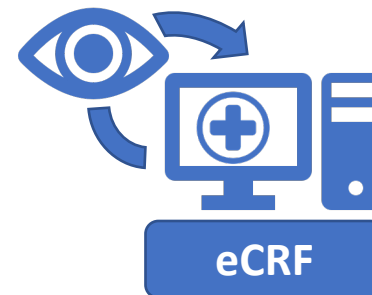
- **Manual review**
  - Discrepancies
  - Responses to warnings (edit checks)
  - Missing fields
  - Prepare for Medical Coding
- **Automatic review**
  - Edit checks, ...
- **Monitoring visits**
- **Discrepancy handling**
- **Timelines**



Data Validation Plan



Monitoring Plan



## 10. Data Tracking

- **Making sure documents and files don't get lost!**
- Paper documents/electronic files
- Sources
  - Laboratory
  - Clinical
- **Data flow**
- Software reports
  - Missing data



## 11. Data/Medical Coding

- **Type of coding**
  - **Data dictionary**
  - **Medical Event Coding**
  - **Drug Coding**
- **Dictionary**
  - Name (MedDRA, WHODrug)
  - Version
  - Language
- **Timelines**
- **Procedures**
- **Roles and responsibilities**



Coding Conventions

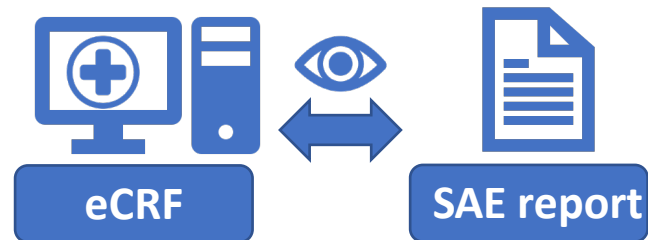


## 12. SAE Reconciliation

- **Procedures and documents**
- **Timelines**
- **Responsible staff**



SAE Reconciliation Checklist



## 13. Data Storage

- **At Site and Sponsor**
- **Electronic files**
  - Formats
  - Saved where?
- **Paper documents**
  - Type of data
  - Place of storage
- Refer to **5. DB/Data Security**



## 14. Data Transfer

- **Confidentiality and appropriate measures**

How will **sensitive data** be transported (if needed)

- Filesender
- Email with encryption
- WinZip encryption
- Be careful w/ **cloud**

→ If needed, refer to **Data Protection Officer or QA officer**

- **Specifying timelines & formats**





## 15. IT Support

- **Support** on Hardware/software
- **Implementing measures , actions or helpdesk** to tackle problems



## 16. Database Lock/Unlock

- **Process description**

- **Data entry** completed
- **Discrepancy** resolution
- **Freezing/locking** data
- DB Lock **meeting**
- **Authorized Intermediate lock**
- **Authorized Final Lock**



Database Lock Checklist



Database Lock Approval

- **Unlocking the database**

- **Authorized** changes



Database Unlock Approval

