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
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

- **Unlocking** the database
  - Authorized changes

[Database Lock Checklist]
[Database Lock Approval]
[Database Unlock Approval]