Data Capture Methods

Module 10 Topic 4

Definition of Clinical Data Capture

Collection of clinically significant data by the Investigator/s for clinical trials on behalf of the Sponsor in a sequential manner (per protocol) to process the same and generate reports at a later stage for submissions to regulatory authorities for various purposes

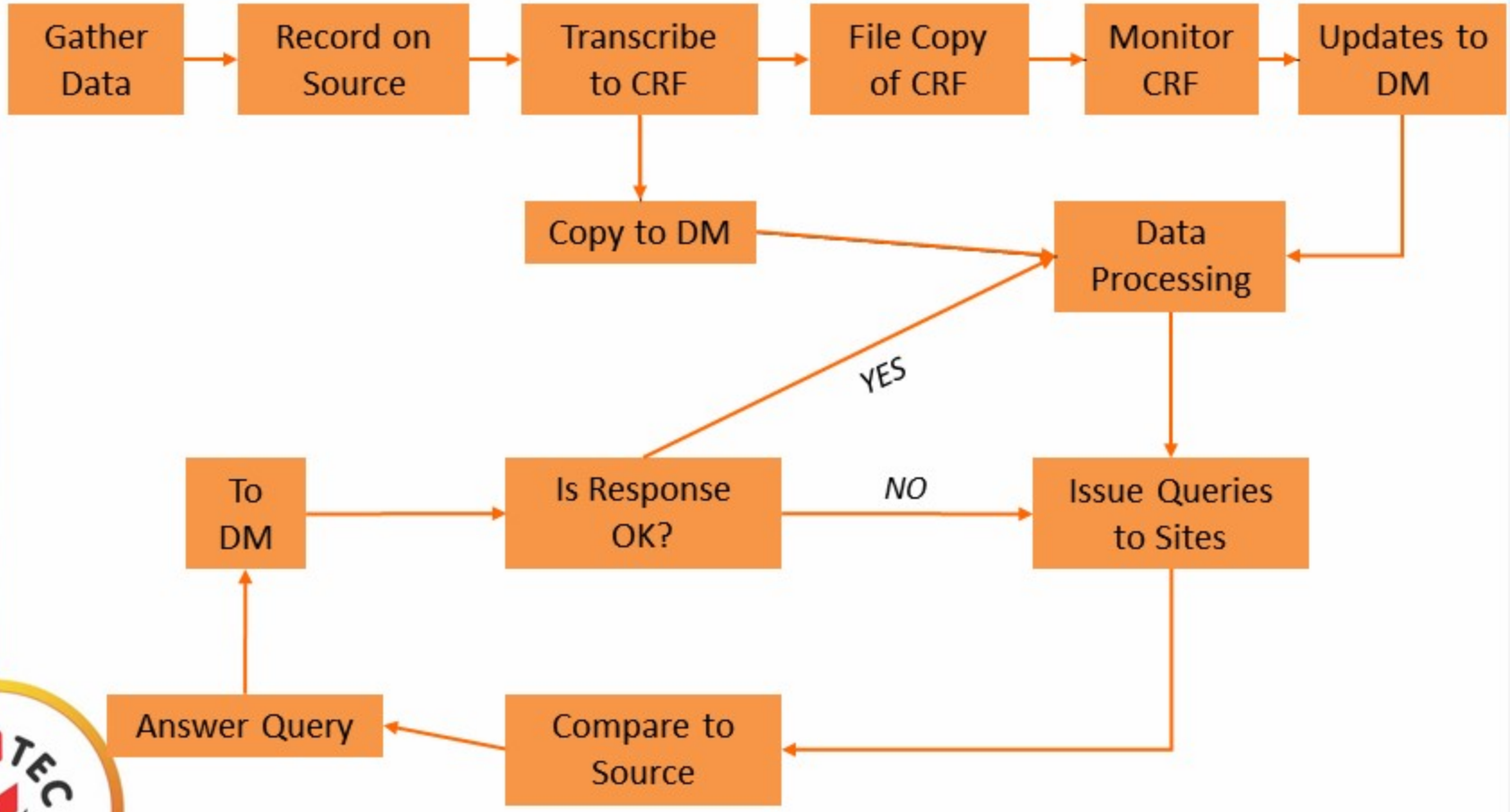
Clinical Data Capture

- Procedures for gathering and recording data from or related to subjects in the study
- Paper based OR Electronic Data Capture (EDC)
- Promise of increased efficiency has led to increasing movement toward implementation of the electronic medical record and to computerised automation in general

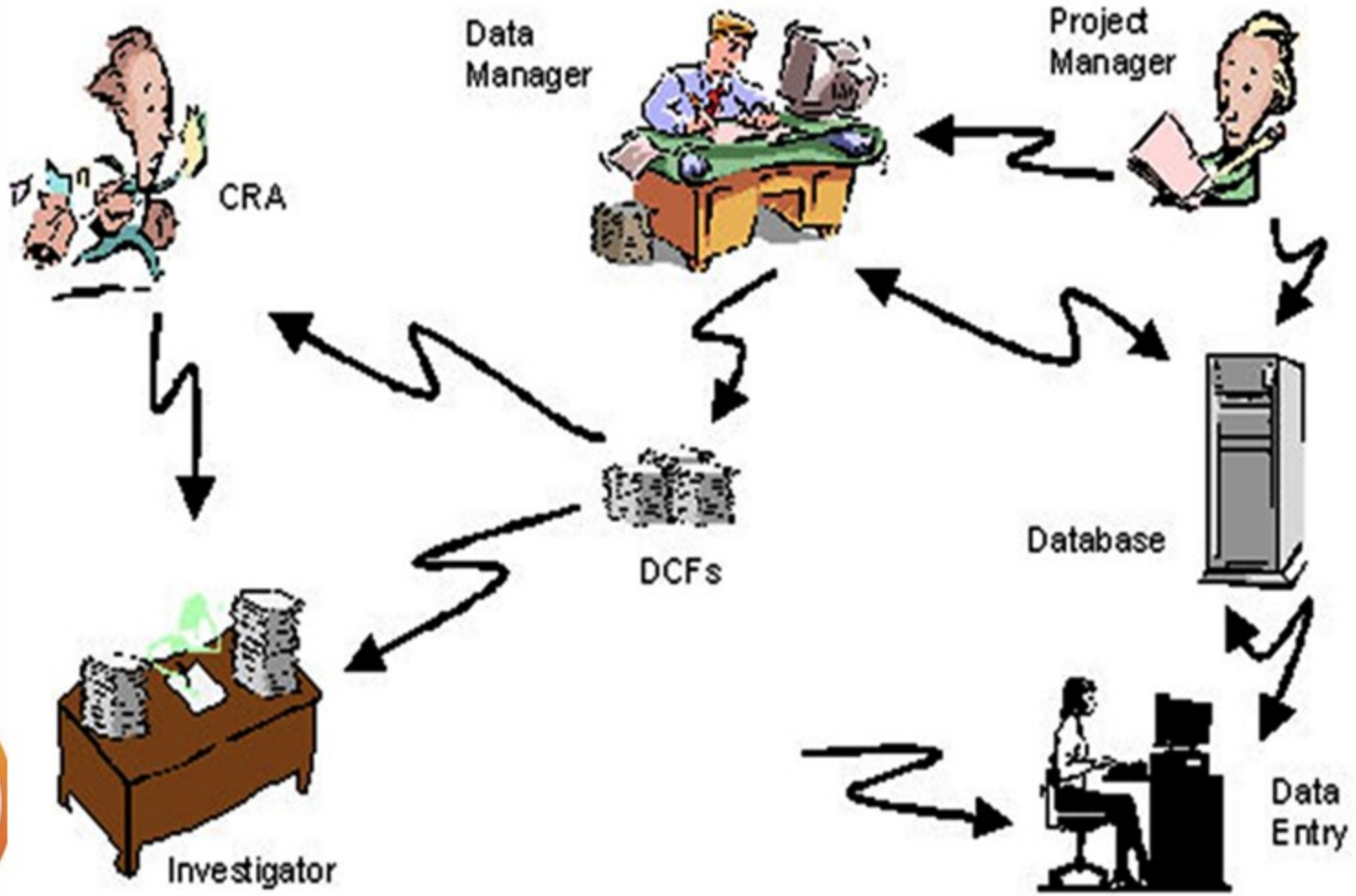
Paper Based Data Capture

- Most widely used form of data capture
- Traditional paper Case Report Forms (CRFs)
  - Manual entry by site personnel on three-part NCR paper CRFs
  - 1 copy retained at investigator site, 2 copies sent to Sponsor or CRO's Data Management department
- Easy to enter data
- Requires simple training
- Logistically patient's bedside may not be the right place for a computer to enter data

Paper CRF Process



Data Flow In A Traditional Paper-based Clinical Trial:



Draw Backs of Paper CRF

- Storage problem
- Time consuming
- Cost of printing and distribution/ Imaging
- Lack of real-time reporting
- Increasing pressure on sponsors to get drugs into market faster
- Confidentiality and Security

Electronic Data Capture (EDC)

- Capability to collect data electronically
- Also known as Remote Data Entry (RDE)
- Online and offline
- Becoming more common than paper technology

Definition of EDC by the Clinical Data Interchange Standards Consortium (CDISC):

- "Collecting or acquiring data as a permanent electronic record with or without a human interface (eg., using data collection systems or applications that are modem-based, web-based, optical mark/character recognition, or involve audio text, interactive voice response, graphical interfaces, clinical laboratory interfaces, or touch screens).

Note: 'Permanent' in the context of these definitions implies that any changes made to the electronic data are recorded via an audit trail."

EDC Tools

- Internet
- Interactive Voice Response (IVR)
- Pen Tablet
- Personal Digital Assistant
- Fax
- Image Recognition Technology (OCR & OMR)
- eCRF

Internet

- Programs and databases located on centralized website
- Data keyed in with access to a browser
- Online
- Real-time reporting possible
- Good solution for small providers who cannot afford software costs

Interactive Voice Response (IVR)

- Interactive speech or touch-pad menu-driven system that takes the caller through a series of prompts
- Responses entered through a telephone keypad
- Real-time reports generated
- Almost maintenance free
- Limited interface
- Typically used in select areas such as patient randomization, adverse event reporting, drug supply management, tracking visit milestones, assisting with study startup or collecting subject diary information

Pen Tablet

- Reduce paper costs by allowing full-size form filling, signature, and simultaneous form inking Ex: ClipGem Pen Tablet
- Users affix a paper form under the clip and sign each individual signature field
- User's signature and biometric data captured, software binds it to the electronic copy of the document in real time, and the inking tip of the pen makes a paper record
- Powered by computer's serial or USB port, hence no batteries or bulky wall transformers needed

Personal Digital Assistant (PDA)

- Replace paper-based subject diaries
- Stores data until transfer to study database
- Hotsyncing to a computer where the data is downloaded and stored
  - Typically operates in offline mode
  - Eliminates data entry

Fax

- Software scans faxed patient forms and faxes back a report, eliminating the need for data entry at the clinic level

- Limitations:
  - Confidentiality
  - Maintenance and monitoring
  - Availability of clerical staff to verify submissions
  - Slow turn around time

Image Recognition Technology

- Image-recognition systems, including optical character recognition and optical mark recognition, provide a means of capturing data from printed sources
- Data on paper chart → Scan → OMR/OCR software →EMR

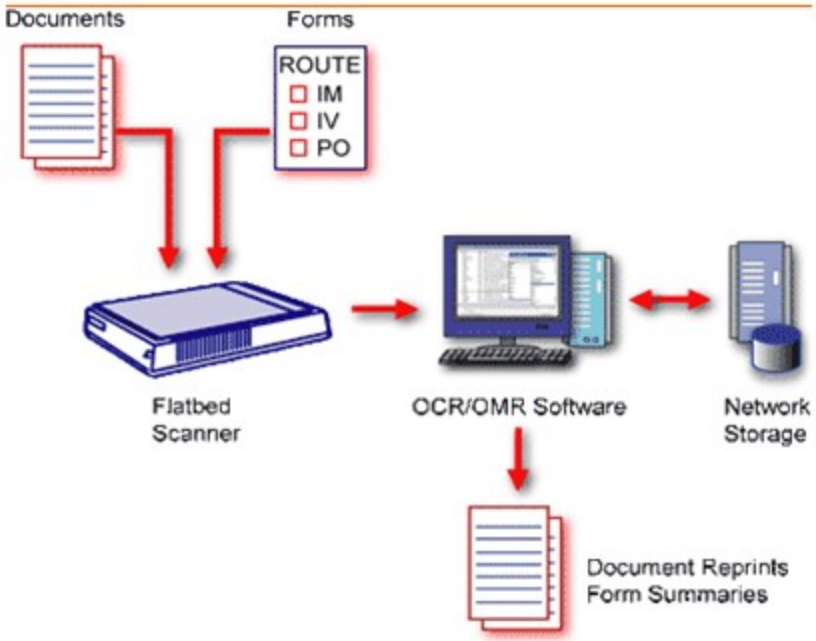
Optical Character Recognition (OCR) technology

- Often used to incorporate legacy information into EMR
- Translation of printed text on each page to electronic text documents
- OCR software converts scanned image to machine-readable and editable text
- Equivalent to keying in text by hand
- Less costly and faster compared to manual keying in

Optical Mark Recognition (OMR) technology

- Scanning preprinted paper forms to convert marks in checkboxes, text printed in block form, and barcodes into machine readable text
- Questionnaire format commonly used in post-marketing trials
- Fast and time saving

Representation of process of using a flatbed scanner and OMR or OCR software. A flatbed scanner with a sheet feeder is the rate-limiting step in the conversion of printed documents and forms to machine-readable data.



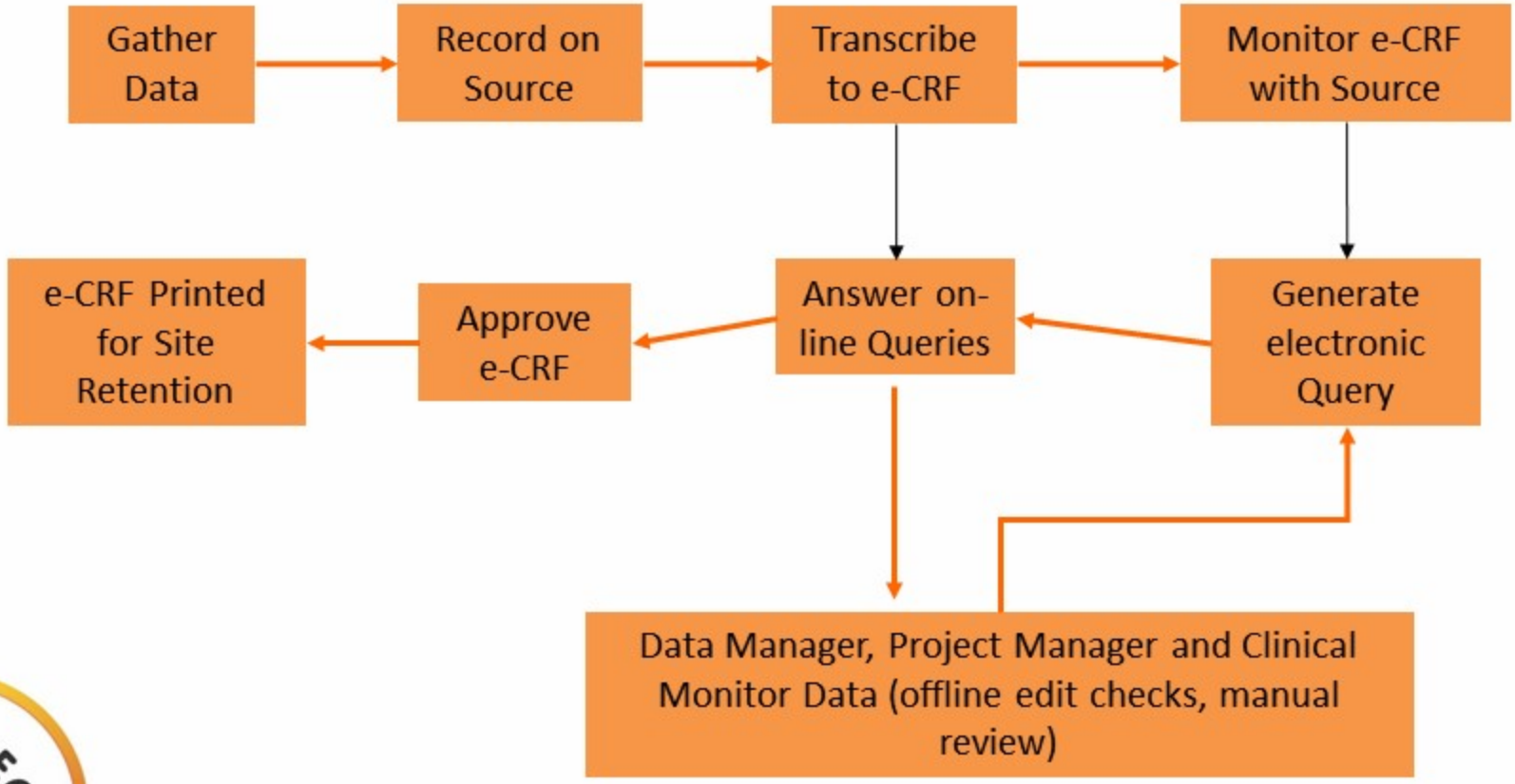
eCRF

- Direct entry into eCRFs that have some form of in-built real-time data validation checks. **Updates to data done electronically**
- **Transmission of data to sponsor accelerated**
- Faster and more active management of the data gathering and processing workflow
- Ensures “cleaner data faster”

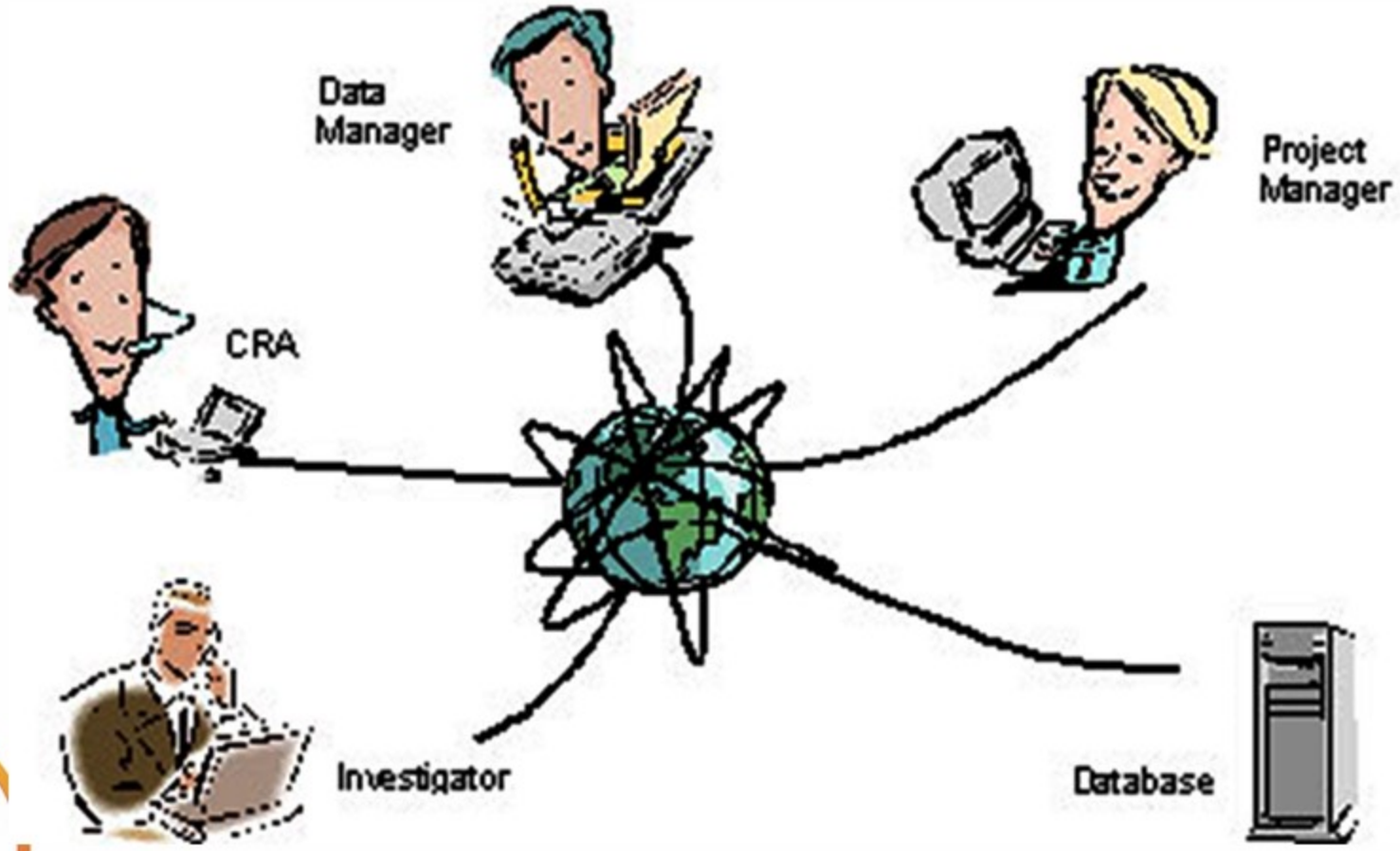
eCRF (contd)

- User interface to be designed with user characteristics in mind
- Validation inputs to be taken into account during initial designing
- Integration of EDC with other corporate systems to be included in designs from the start, as well as information messaging and workflows

eCRF (contd)


Gather Data
Record on Source
Transcribe to e-CRF
Monitor e-CRF with Source
e-CRF Printed for Site Retention
Approve e-CRF
Answer on-line Queries
Generate electronic Query
Data Manager, Project Manager and Clinical Monitor Data (offline edit checks, manual review)

Data flow in an eCRF EDC clinical trial



Advantages of eCRF Over Paper CRF

- Automated data edit checks alert the site to possible errors in data entry
- Faster correction of issues and immediate site education. Hence cost saving
- Immediate viewing by sponsor to review and analyse the data and provide online feedback to the site.
- Shortens time between ‘last patient last visit’ and ‘database lock’

Advantages of eCRF

- Project Manager: access to real-time project metrics
- Clinical Monitoring Staff: less time spent in site visits
- Investigator Sites: less query resolution and less storage issue
- Data Management: eradication of double data entry and faster turn around

Limitations of eCRF

- Resistance to change
- Integration of multiple systems and groups
- Indecision and fear among Sponsors

eSource

- Data directly entered into eCRF without paper source
- Eliminates errors and delays that occur in transcription from source to CRF
- Single data entry

eSource Data

- Definition per ICH
  (International Conference on Harmonization):

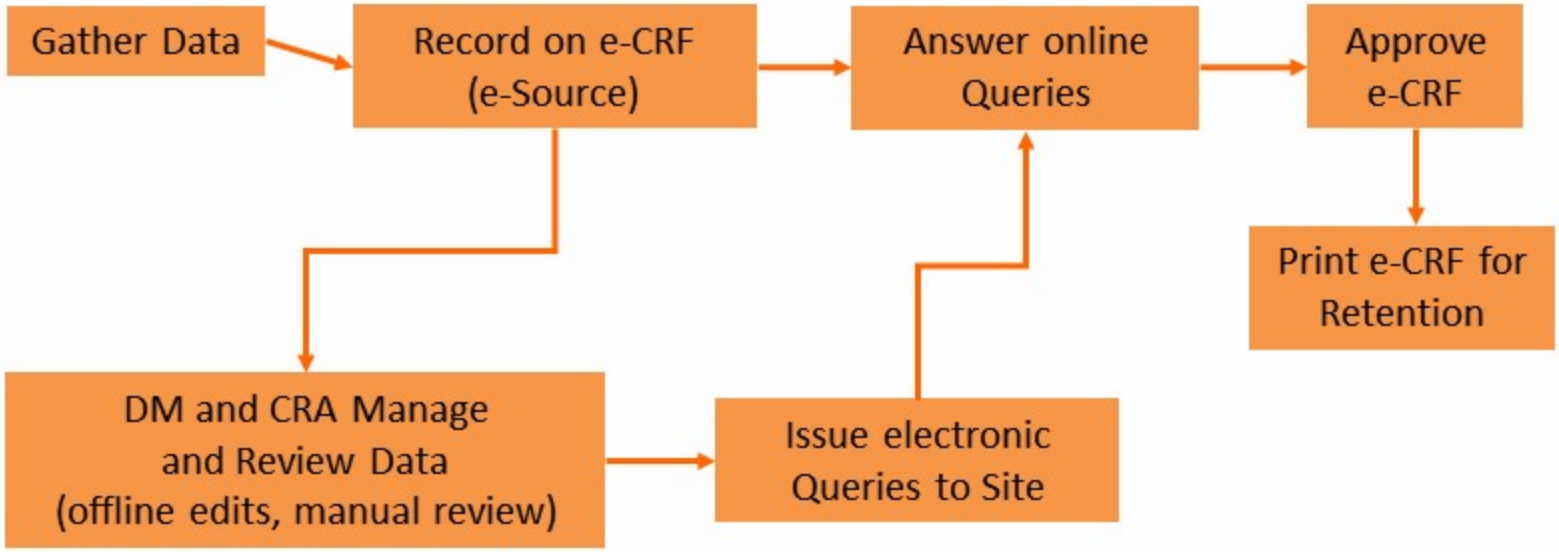
  "Source data captured initially into a permanent electronic record. Note: 'Permanent' in the context of this definition implies that any changes made to the electronic data are recorded via an audit trail."

Source Data

- Definition per ICH
  (International Conference on Harmonization):

  "All information in original records, certified records, and certified copies of original records of clinical findings; observations; or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."

eSource


Gather Data
Record on e-CRF (e-Source)
Answer online Queries
Approve e-CRF
Print e-CRF for Retention
DM and CRA Manage and Review Data (offline edits, manual review)
Issue electronic Queries to Site