

Clinical Quality Assurance and Control



Module 7 Topic 1

Learning Objectives

- What is Quality Control and Assurance?
- What is the difference between the two?
- Importance of QC and QA in Clinical Trials
- What is an Audit?
- Types of Audit?



Need for QC/QA in a Changing Clinical Trial “Landscape”

- More studies; more sites; greater volume at each site
- Expansion and fluidity of clinical investigator pool
- “New” players in new roles (CRO’s, SMO’s)
- New technologies (electronic record-keeping)
- More participation by “vulnerable” subjects
- Global expansion (areas new to GCP)
- Above all, outsourcing boom in India



Quality Control (QC)

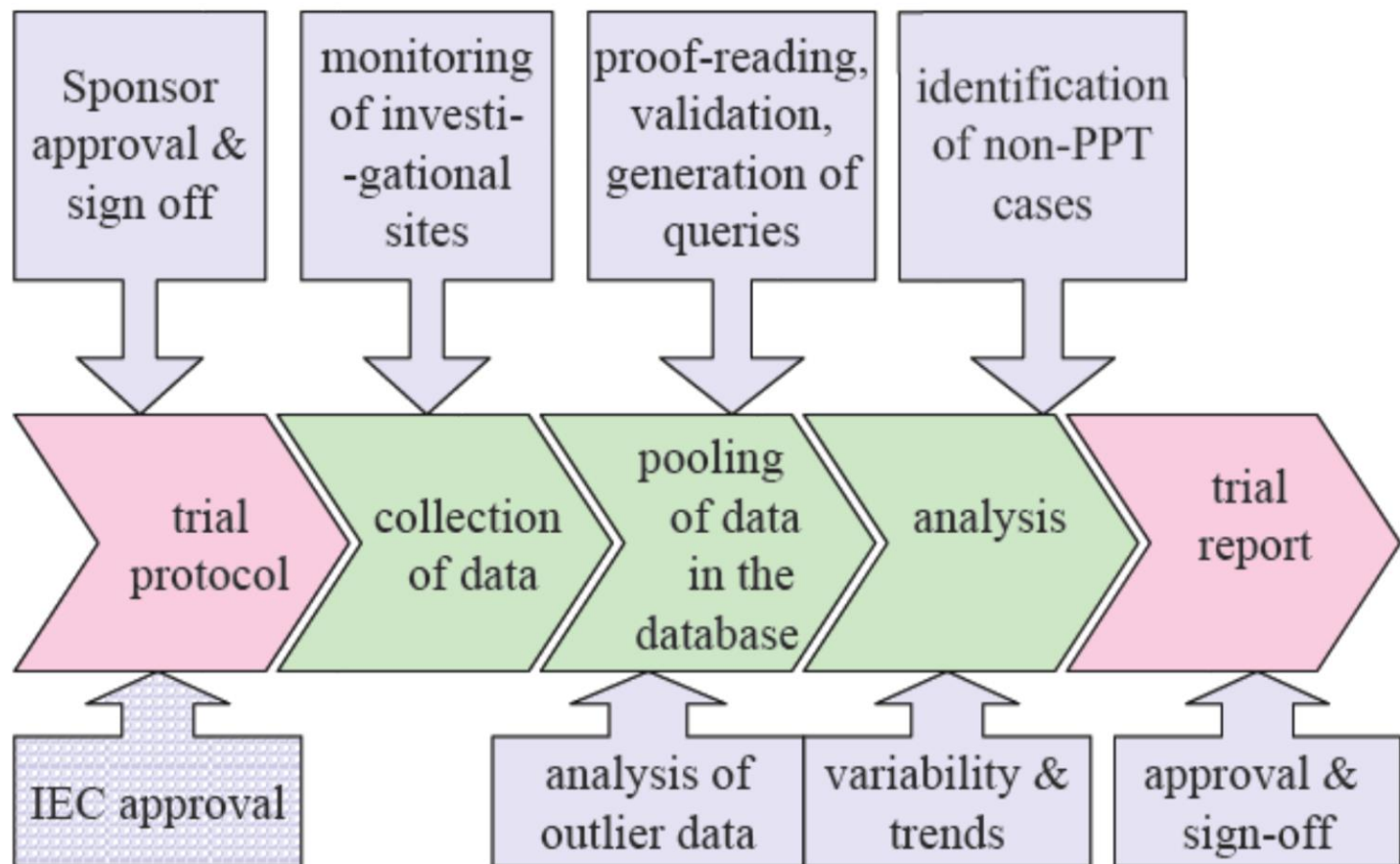
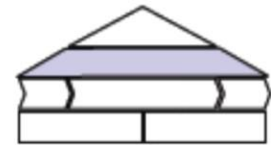
- Periodic functional checks within each functional department to verify that clinical data are generated , collected, handled, analysed and reported according to protocol, SOPs and GCP.

ICH-GCP section 1.47



Quality Control

Quality Control



Quality Control and Quality Assurance

- **Quality Control (QC)**
 - Daily, ongoing, “real time” activities
 - Usually 100 %
- **Quality Assurance (QA)**
 - Systems and processes established to ensure that the trial is performed and the data are generated in compliance with GCP.

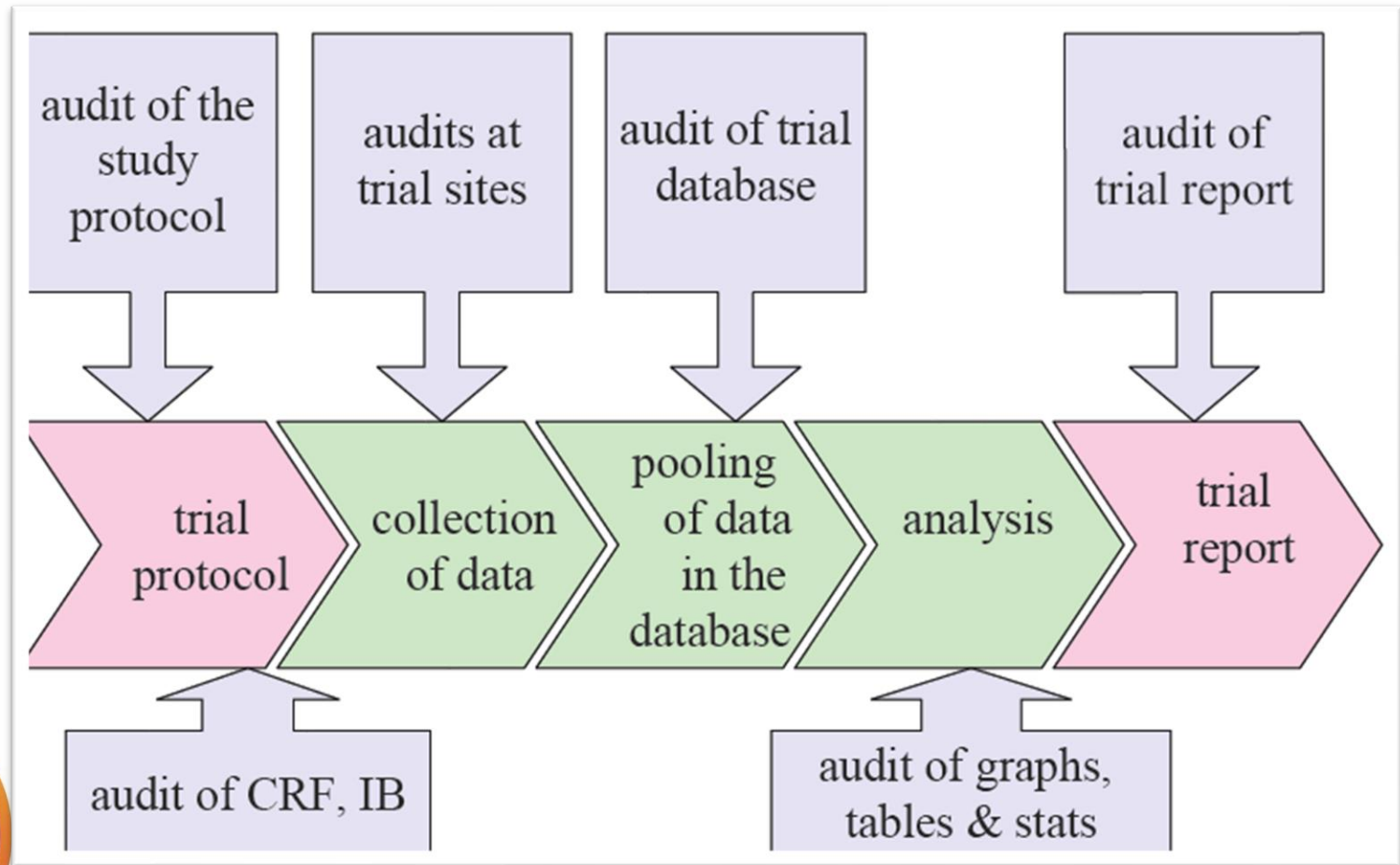


Quality Assurance is mentioned in ICH-GCP

- Chapter 5 : Sponsor
 - Section 5.1 Quality assurance & quality control
 - The sponsor is responsible for implementing & maintaining quality assurance & quality control systems with written SOPs to ensure that trials are conducted & data are generated, documented (recorded) in compliance with protocol, GCP & applicable regulatory requirement(s)



QA, Trial Specific Audits



Types of Audits

Investigator site audit	Off site archiving
Database audit	Laboratory
Clinical study report audit	Clinical supplies
System audit	Clinical Research Organisation (CRO)
Protocol, protocol amend, consent forms, patient/volunteer information leaflet and CRFs	Validation of computer systems
IRB Audit	



Difference b/w QC & QA

QC: Routine checks, an ongoing process.

QA: Periodic checks

QC: Can be carried out by functional personnel

QA: Should be carried out by an independent person/team

QC: Subpart of Quality Assurance System

QC: Reports to the functional Head

QA: Reports to the higher management to avoid Conflict of interest



Audit Process

- Main stages of an audit are as follows:
 - Planning
 - Performing
 - Reporting
 - Follow Up



Auditors- Where do they come from?

- Federal agency that oversees the research
- Sponsor (or their designee)
- In-house (QA)



Audits and Inspections

QA of clinical trials is crucial.

The quality control is made by means of:

Drug Regulatory authority inspections

Sponsor Audits

Institutions with clinical trial activities should also implement a QA programme to ensure that also to ensure that investigator initiate trials follows international trial guidelines:

- Education
- SOPs
- Audits



Difference between Audit and Inspection

In Audit, Inspectors are employees of the company who work for active clinical quality assurance (CQA) function (i.e. Sponsor/CRO)

In Inspection, Inspector are employed by government, through the agency of the regulatory or competent Authority (i.e. FDA/DCGI)



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- Quality control is the responsibility of the people carrying out the work, such as the monitor, investigator or data manager.
 - SOPs are provided to ensure that QC is built into the process.



Synopsis

- A Clinical research set up (Sponsor/ CRO) has many functions which are essential for the smooth flow of activities.
- QA/QC is one of the mandatory functions without which Clinical Research cannot run.
- All Clinical trial Protocol, Clinical Trial Reports shall be treated as Final only when it is QA ed by Quality Assurance Department.



References

- www.pharmanet.com/pdf/whitepapers/QCQA.pdf
- www.ifapp.org
- Spiker B (1991). Guide to Clinical Trials, Raven Press, New York.

