# 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"

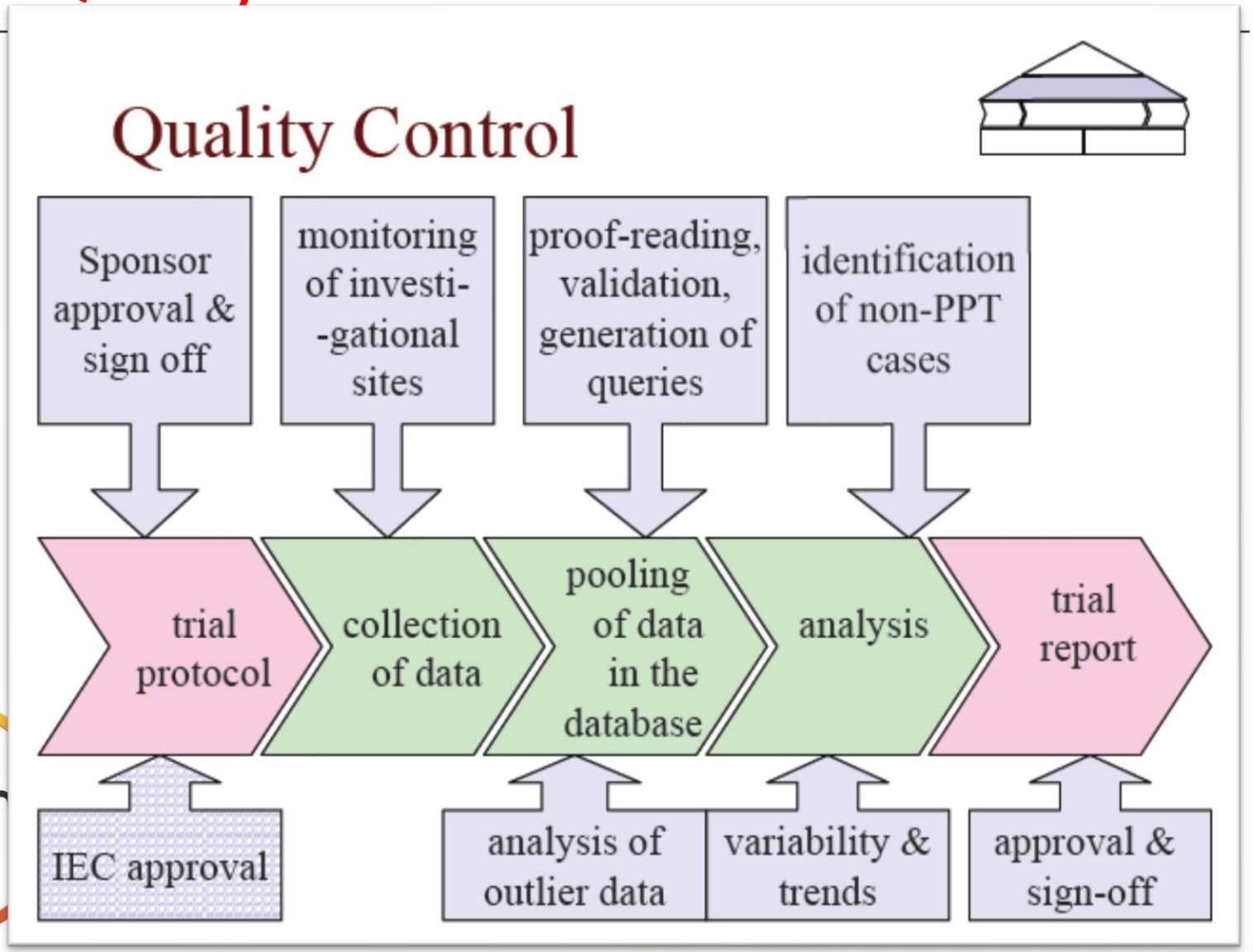
- More studies; more sites; greater volume at each site
- Expansion and fluidity of clinical investigator pool
- "New" players in new roles (CRO's, SMO's)
- New technologies (electronic record-keeping)
- More participation by "vulnerable" subjects
- Global expansion (areas new to GCP)
- Above all, outsourcing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

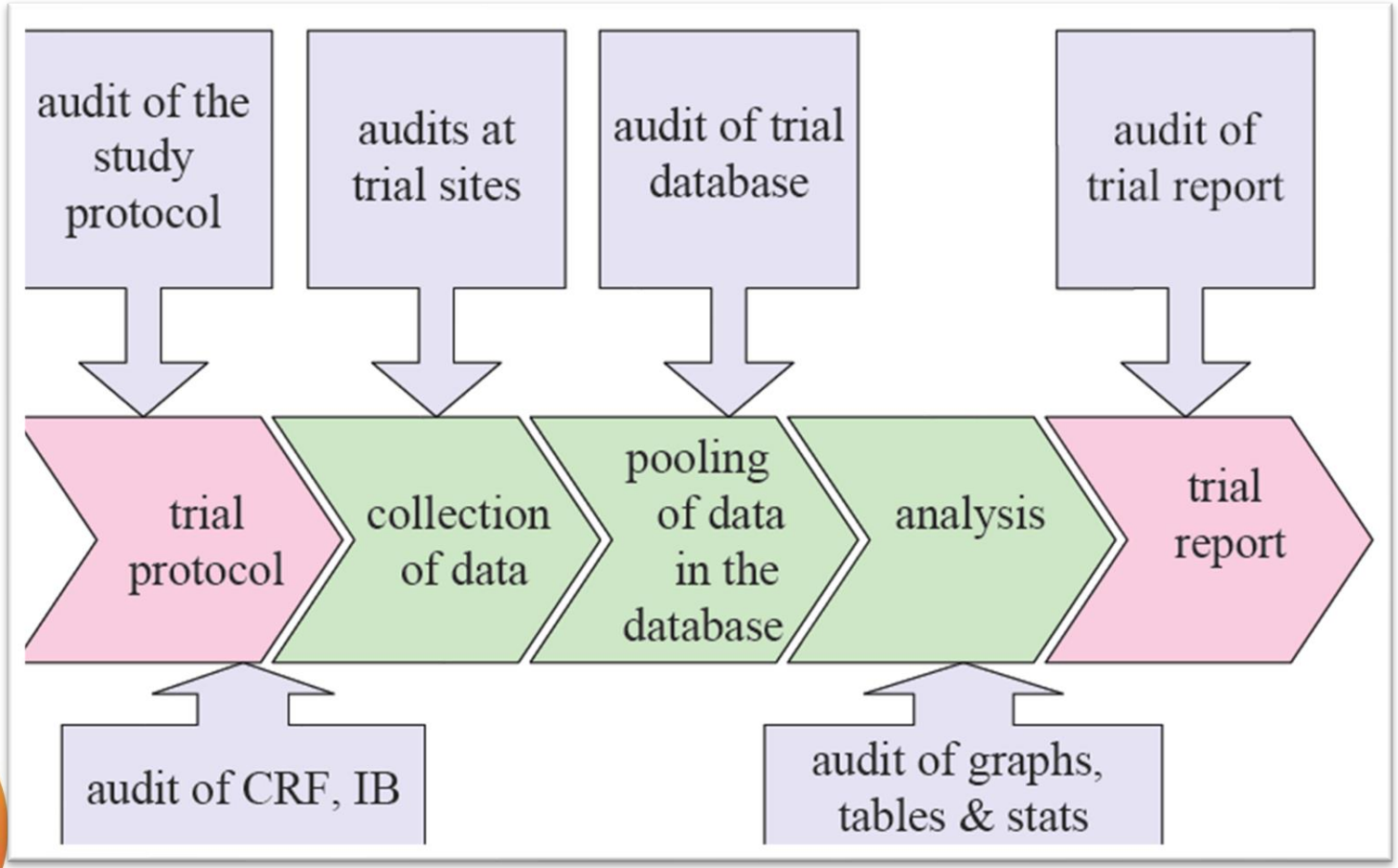
- **Quality Control (QC)**
- Daily, ongoing, “real time” activities
- Usually 100 %
- **Quality Assurance (QA)**
- Systems and processes established to ensure that the trial is performed and the data are generated in compliance with GCP.

# 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)

ICH GCP 1997

# 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**: 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 not only sponsored, but investigator initiated trials also follow international trial guidelines :Implemented through

  - 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)** |

- 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 with 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.