# Quality Management Procedures for a Research Protocol

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# Quality Management System

This is a system used to direct, control and manage quality in clinical trials.

**QM activities allow planning for**

- Effective Protocol Implementation
- Assures compliance with sponsor and applicable regulatory requirements
- Identify areas that are in need of corrective action
- Verify data accuracy
- Assures a constant state of readiness audits and monitoring visits

# Quality Control Vs Quality Assurance

## Quality Control

The **real time**, ongoing day-to-day observation and documentation of a sites work processes to ensure that accepted procedures are being followed

## Quality Assurance

A **periodic**, systematic, objective and comprehensive review of trial-related activities to ensure that the trial is performed and reported in compliance with GCP and any other applicable regulatory requirements

Occurs retrospectively

# Clinical Quality Management Plan

A formal living document that defines the processes and procedures that guide QM activities  in the clinical setting (including QA and QC)

It details, the scope and frequency of QM activities and the responsible persons

QM activities start at after the study ha started and are ongoing thoughout  out the study

It helps to have a Quality Management Unit whose responsibility is to monitor quality

# Key indicators

- Informed Consent Form and Process
- Assessment of Understanding
- Eligibility Criteria
- Protocol required tests
- Visits/missed visits
- Concomitant/prohibited medications
- Study product administration/dosing
- AEs, SAEs

# QC/QA activities

1. **Informed Consent Form and Process**

**QC:** Review ICFs for accuracy, signatures, initials and completion after the IC process

**QA:** Confirm availability/accuracy of ICFs (monthly or quarterly), new versions

2. **Assessment of Understanding (AoU) of IC**

**QC**: completion, scores etc

**QA**: Confirm availability, look at first 10 screened volunteers (monthly)

# QC/QA activities

3. **Eligibility Criteria**

**QC**: Review eligibility using the eligibility checklist, chart notes, lab results etc during screening/enrollment

**QA**: Review the screening/enrollment logs (quarterly)

4. **AE/SAE reporting**

**QC:** Review chart notes/documentation for the AEs (managed, treatment, reported, databse

**QC**: Follow, resolution, reported as SAE, Expedited reporting within timelines…

# CAPA

- Non-compliance issues tend to occur during clinical trials
- A CAPA provides mechanisms to prevent existing problems from reoccurring and eliminate potential causes of future issues

- **C** Corrective
- **A** Action
- **P** Preventive
- **A** Action

**Steps**

Define Problem

Analyze data

Identify solution

Implement CAPA

Evaluate CAPA

# Reporting QC/QA findings

- QC findings to be reported during trial working group (TWG) meetings
- QA findings to be reported on a quarterly basis by the QM coordinator and/or officer.
- Report to provide information on the number of queries issued out, queries resolved and those that are pending. They will also show trends of different events reviewed.
- Significant findings from monitoring visit reports to be reported by the study coordinator during TWG meetings.
- All findings will be discussed and decisions on how to address them will be made. For those that require a CAPA process the SOP for CAPA will be followed.

# Quality Management

Who is responsible for quality management in the organization?

- Each team member plays a vital role (quality mindset)
- Ultimately, PI is responsible for all activities related to the quality of clinical trial activities

# Quality Management

Team work effort!!!!

# When quality is compromised even at a level of 1%


"When we crash, we will crash as a team!!!"

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# Tips

- Recruit qualified staff with experience, training(GCP/HSP)
- Know your Research Protocol and SOPs
- Proper Training of new staff
- Train on Quality Management Plans
- Prepare and train on the Source Documents/CRFs
- Have Dry Runs in all departments
- Do not comprise quality over competitiveness
- Regular meetings especially after monitoring visits
- PROPER DOCUMENTATION

*Thankyou*


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