



# Quality Management of a Research Project

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CSA 2020NOE-3102





# INTRODUCTION

- What is Quality Management

This is the overall process of establishing and ensuring the quality of processes, data and proper documentation associated with clinical research activities

This encompasses both quality control (QC) and quality assurance(QA)



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# Objectives of Quality Management

- Quality Management includes BOTH processes aimed at prevention of errors as well as those associated with detection and correction of errors
- QM also ensures that every time a process is performed same information, methods, skills and controls are used and applied in a consistent manner
- Maintaining quality and process performance at consistent levels is the most basic goal of any QMS



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# Quality Control (QC)

- This is a set of operational activities intended to ensure the quality requirements are being met
- It is the ongoing review of data collection forms and other records for completeness and logic e.g.
- Clinical study staff ensure checklists are completed for the intended study procedures e.g. IC process

Conducting systemic data verification

Review of Essential document binder (ISF)



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## What is Quality Assurance (QA)

- A set of activities intended to establish quality requirements and procedures
- QA ensures those requirements are being met and procedures are being followed
- QA verifies that quality is being maintained and this includes generation of procedural documents e.g. SOPs



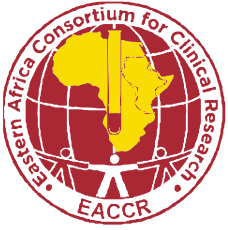
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# Difference Between QA and QC

## Definition:

- QA- A set of activities intended to establish quality requirements and procedures.
- QA- Ensures those requirements are being met and procedures are being followed
- QC-A set of activities for ensuring quality in products. The activities focus on identifying and fixing defects
- QA- These are methods put in place to manage quality in our work
- QC-These are methods used to verify activities performed



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## Why errors occur at any stage of a clinical research

- Training of study team not done prior to the study start and inadequate training offered
- Written procedures not followed i.e. protocol, SOPs, checklists etc..
- Lack of ongoing checks to help identify errors in real time
- Individual roles and responsibilities are unclear or undefined



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- How to ensure QC & QA??



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# Through monitoring....

GCP Definition of Monitoring:

The act of overseeing the Progress of a clinical trial, and of ensuring that It is conducted, recorded, and reported in accordance with the;

- ✓ ICH Protocol
- ✓ Standard Operating Procedures (SOPs)
- ✓ GCP, and the applicable regulatory requirements (E6 1.38).

All studies involving human participants should be monitored as per GCP requirements



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# PURPOSE OF MONITORING

## To verify that:

- ❖ The rights and well-being of human participants are protected
- ❖ The reported study data is accurate, complete, and verifiable from source documents
- ❖ The conduct of the study is in compliance with the currently approved protocol/amendments, with GCP, SOPs and applicable regulatory requirements



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# TYPES OF MONITORING VISIT

The most common types of monitoring visit:

- Pre-site assessment visit
- Site Initiation visit
- Interim Monitoring visit
- Close-out monitoring visit



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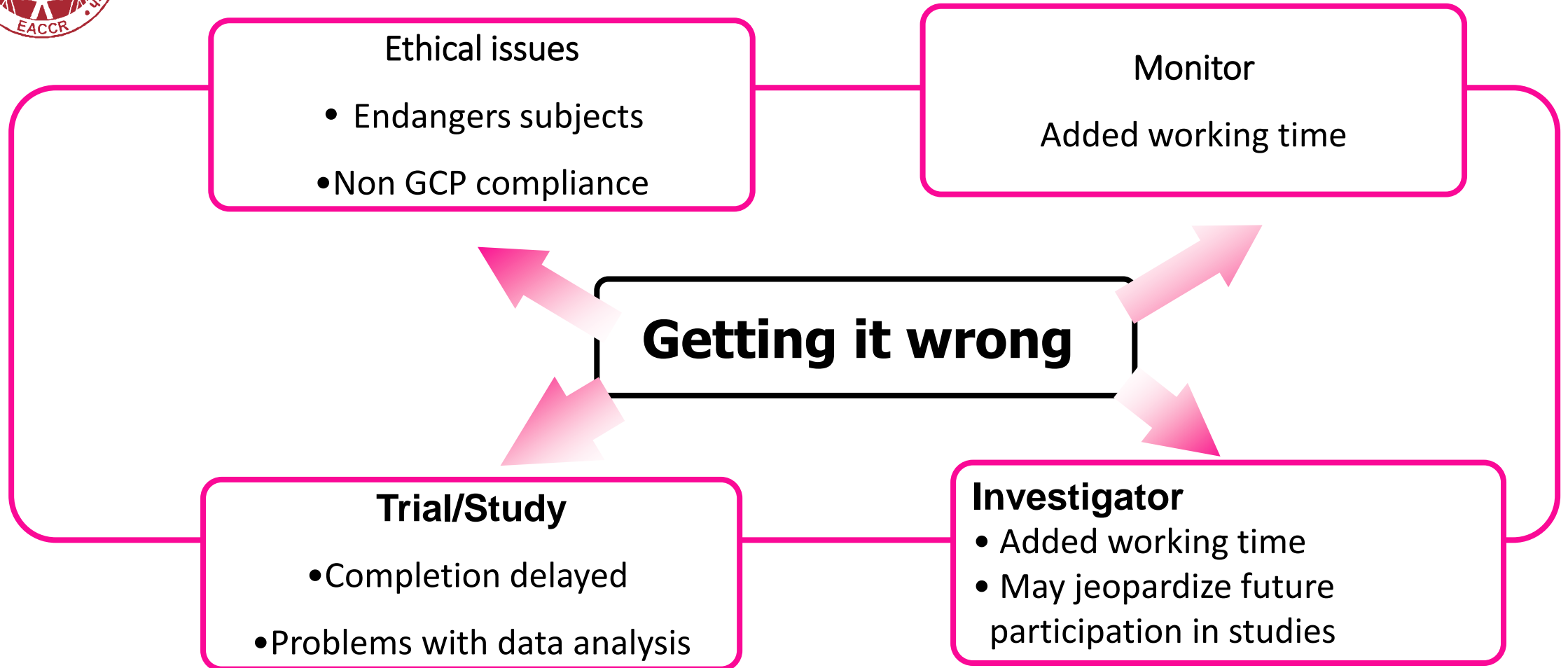


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# Consequences of getting it wrong



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# STUDY EXPECTATIONS

- Study Approval by the regulatory authorities
- Protocol amendments if any, to have it on file
- Investigator Master File (IMF)/Investigator Site File (ISF) with all the essential documents
- Approved Case Report Forms (CRFs)
- Effective communication



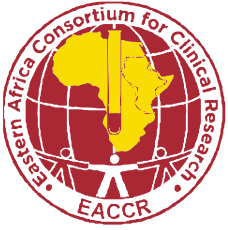
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# INVESTIGATOR SITE FILE

- An Investigator Site File (ISF) contains essential documents which shows that the clinical trial site and Investigator are following the regulatory requirements set out by the ICH GCP guidelines.
- According to the International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines, essential documents are defined as “documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced.”
- The ICH GCP 4.9.4 guideline states that “the Investigator and Institution should maintain the trial documents as specified in the ‘Essential Documents for the Conduct of a Clinical Trial’ guidelines



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