Site initiation Visit

Venue: AiBST Chitungwiza Clinical Trial Unit

Monitor Clinical trial specialist: Gift Chareka

Date: 28 Mar 2019

Time: 10:00 -15:15

Chair: Gift Chareka

Opening Remarks

1. Introductions and signing of the attendance register.
2. Overview of the Day
    a. Inspection of
        i. Regulatory binder
        ii. ICF process
        iii. Study team qualifications and CVs
            1. Practicing certificates
            2. GCP
            3. Ethics certificate
        iv. Delegation of duties and delegation log
        v. Site SOPs and Study specific SOPs
        vi. Premises
    b. Debrief and closing remarks

Inspection Comments:

1. MCAZ approval letter protocol version 1.0 instead of 1.10
2. Personnel filling
    a. Delegation good but need to revise it to write names in order of seniority
    b. To make sure documents are valid and each staff has the necessary documents
    c. Ethics training a requirement for all the study staff
    d. Staff documents should be filed in order of seniority
    e. Clinical trial manager documents not in file
3. Study Binder
    a. Explore if there is need for RCZ approval based on being partially funded by Novartis
4. Study files
    a. A guidelines file should be there at the study Site, with
        i. MCAZ GCP guideline

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African Institute of Biomedical Science & Technology

AiBST

ii. ICH GCP R2 (Nov 2016)
iii. USA FDA copy
iv. Research act of Zimbabwe

5. SOPs
   To provide all study staff copies of SOPs
   Signing of SOP log
6. Prepare a model binder for participants
7. Premises are good for the phase one clinical trial study based on the following being ideal:
   a. Reception and waiting space
   b. Examination room
   c. Counselling room
   d. Pharmacy
   e. Admission area

Closing Discussion

1. Protocol training all key aspects covered
2. Overall a lot of things in place gaps need to be addressed
   a. Gaps: Missing ethics certificate to be put in place

3. Accountability and responsibility
   - Everyone is accountable team work is key
   - Consenting a key process: Ethics and protocol adherence key in the process
   - The clinical trial manager responsible for all correspondence and to make sure that all documents up to date
   - Study coordinator to work under the supervision of the clinical trial manager
   - Make sure when you sign on logs the name and surname present is the same as the one on the practicing certificate.