TAMOXIFEN TRIAL SITE INITIATION VISIT REPORT

DETAILED CHECKLIST ITEMS:

A. Confirm information provided to the site	Yes	No	N/A
1. Confidentiality agreement signed by Investigator	☐	☒	☐
2. Protocol received and reviewed by Investigator	☒	☐	
3. Understanding of relevant scientific background information	☒	☐	
4. Study timeline, initiation, subject accrual rate and completion	☒	☐	
5. Roles and responsibilities of all key Investigator personnel	☒	☐	
6. Monitoring schedule, types of visits, agenda and attendees	☒	☐	
7. Investigational product inventory management	☒	☐	☐
8. Reporting and record-keeping requirements	☒	☐	
9. Potential for Investigator's clinical study audit	☒	☐	

B. Clinical study regulatory requirements	Discussed?		
1. *Obligations of Investigator and key study personnel*	Yes	No	
• Conduct study according to written protocol, local regulations, IRB and other applicable regulatory requirements	☒	☐	
• Document all unanticipated events and immediately contact the CTS OR study Monitor for follow-up instructions	☒	☐	
• Accurately report all data and observations of anticipated and unanticipated adverse events/device malfunctions	☒	☐	
• Observe Good Clinical Practice (GCP), and Good Laboratory Practice (GLP)	☒	☐	
2. *Human subject safety and confidentiality*	Yes	No	N/A
• Conduct informed consent process according to regulatory and IRB requirements	☒	☐	
• Participant identifiers will be properly masked and samples will be coded per protocol requirements	☒	☐	☐
• Storage of participant records secure, protects their confidentiality	☒	☐	
3. *Reporting of study results*	Yes	No	N/A
• Results of investigational device use cannot be used for patient diagnosis or management	☒	☐	☐
• Stipulations for scientific publications and presentations at professional meetings	☒	☐	☐

C. Study management and record-keeping requirements	Discussed?		
1. *Data collection, verification and transmission procedures*	Yes	No	N/A
• Timely completion of case report forms (CRF)	☒	☐	☐
• CRF review and verification for accuracy	☒	☐	☐
2. *Contents of Investigator's study file*	Yes	No	
• Investigator's records, e.g., signed study contract, names of site personnel participating in the study and their qualifications	☒	☐	
• Protocol, CRF and amendments, source documents/participant case histories	☒	☐	
• Communication and site visit logs, product inventory logs, copies of relevant correspondence (Investigator, IRB, MRCZ, and MCAZ)	☒	☐	
3. *Investigational product inventory requirements*	Yes	No	N/A
• Research pharmacist available	☒	☐	☐
• Receipt log of all investigational product	☒	☐	☐
• Accurate and current records of investigational product use	☒	☐	☐

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• Verification of investigational product accountability	☐	☐	☒
4. *Record retention and accessibility*	Yes	No	N/A
• Administrative and subject records maintained for at least two years after the study is closed out and/or (as applicable) MCAZ clears/approves the product	☐	☒	
• Requirement for review of records by institutional Monitors, Auditor	☐	☒	
• Requirement for review of records by government officials (MCAZ)	☐	☒	☐

D. Adverse event reporting requirements	Discussed?		
1. Contact CTS, or if applicable Investigator, by telephone to report serious, life-threatening or fatal unanticipated adverse events immediately	Yes ☒	No ☐	
2. File written reports as stipulated by Investigator and IRB (MRCZ)	Yes	No	N/A
• Unanticipated serious, life-threatening or fatal adverse event to Investigator and IRB	☒	☐	
• Unanticipated, non-serious adverse events in required progress reports to Investigator and IRB	☒	☐	
• Anticipated serious adverse events to Investigator	☒	☐	
• Equipment malfunctions immediately to Investigator	☒	☐	☐
3. Other required reports	Yes	No	N/A
• Periodic participant accrual status reports to Investigator	☒	☐	
• Final study report to Investigator and IRB	☒	☐	☐
• Required progress reports to IRB and MCAZ	☒	☐	

E. Reviewed protocol with Investigator and key study personnel	Yes	No	N/A
1. Purpose of the study	☒	☐	
2. Inclusion/exclusion criteria	☒	☐	
3. Dosing regimen for drug studies	☒	☐	☐
4. Specimen collection, storage and processing procedures	☒	☐	☐
5. Required clinical information needed for study	☒	☐	
6. Performance evaluation and interpretation of results	☒	☐	☐
7. Data collection and completion of case report forms	☒	☐	☐
8. Criteria for study completion or termination	☒	☐	
9. Documenting protocol violations (deviations from the protocol)	☒	☐	☐

F. Conducted qualification site visit (personnel and facilities)	Yes	No	N/A
1. Investigator has sufficient time and adequate training and experience to conduct the study.	☒	☐	
2. Investigator has adequate staff, patient population and other resources for timely conduct of study.	☒	☐	
3. A key study contact has been identified	☒	☐	
4. Other personnel will be participating in the study (to review the staff delegation log)	☒	☐	☐
5. Changes are expected to the study team and/or its schedule	☐	☒	
6. Investigator and staff have experience with FDA-regulated human subject research (list number and types of studies in summary section below)	☐	☐	☒
7. Regulatory issues or problems in prior study (list and describe in summary section below)	☐	☒	
8. Facilities appear adequate for the study (space, equipment, etc.)	☒	☐	
9. Storage for participant and study files is adequate and secure	☒	☐	
10. Adequate written standard operating procedures are available	☒	☐	☐
11. Sufficient eligible participants (patients, samples) are available	☒	☐	
12. Secure storage of specimens and source documents is available	☒	☐	

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3. **SITE CONTACT INFORMATION**	
Address:	CHITUNGWIZA CENTRAL HOSPITAL
Phone numbers:	(024) 31138
e-mails:	comfort.kanji.aibst

4. **FACILITIES AND EQUIPMENT**	
Are there adequate facilities and equipment available?	Yes
Comments: The site has adequate and appropriate space with a dedicated participant waiting area, counseling room, examination room and an appropriately equiped admission area.	

5. **INVESTIGATIONAL PRODUCT**	
Please clarify in comment section if the investigational product already has marketing approval in Zimbabwe and who supplies the investigational product for the investigator. If the product is imported to Zimbabwe for research purposes, who is responsible for the import.	
5.1 Name(s) of Investigational Product(s)	TAMOXIFEN 20MG TABLETS
5.2 Who is responsible for the IP Import?	Blessing DZINGIRAI
5.3 Where is the IP stored?	Study Pharmacy located within the CHITUNGWIZA CENTRAL HOSPITAL premises
5.4 Are the dispensing and accountability procedures adequate?	Yes but the pharmacy requires a study pharmacy specific standard operating procedures.
Comments: A valid current premises license was not available on the day of visit.	

6. **STUDY PROCEDURES**	
6.1 Has the informed consent procedure been discussed?	Yes, this was discussed during protocol training but site to share ther slides for verification.
6.2 Have the protocol required procedures been discussed?	Yes, the Co-investigator to develop and share the protocol specific manual of procedures.
6.3 Have the randomisation and unblinding procedures been discussed?	N/A
6.4 Are there any written SOP's available?	Yes, the Co-investigator will develop the protocol specific data management standard operating procedures.
Comments: The study leadership team must clarify the roles and responsibilities of the study coordinator and the clinical trial manager.	

7. ADVERSE EVENT REPORTING	
7.1 Have the protocol requirements for AE-reporting been discussed?	Yes
7.2 Have SAE- and SUSAR-reporting procedures been discussed?	Yes
Comments:	

8. SOURCE DATA AND CRF	
8.1 Have the source data requirements been discussed?	Yes
8.2 Has the completion of CRF's been discussed?	Yes. CRF completion instructions and guidelines were discussed during protocol training.
Comments: I received a copy of the Manual of Procedures (MOP) from Comfort KANJI after the visit, the MOP is detailed but requires a few revisions. Will share a template to use as reference..	

9. INVESTIGATOR'S TRIAL FILE	
9.1 Are the GCP-required essential documents available at the site?	Yes
9.2 Has the filing and archiving of the study documents been discussed?	Yes
Comments: The revised data management plan to incorporate standard operating procedures for filing and archiving of study documents.	

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10. Other CTS Observations

Describe general impressions of Investigator, staff and facilities to elaborate on elements documented on checklist.

The investigator is qualified and experienced to perform the study, the study site has enough space and appropriate facilities for screening and performing the required study procedures. The investigator was advised to pay attention to the following:

1. Redoing the delegation log after correcting the spellings of names and surnames of some of the study personnel with appropriate version control.
2. Getting current practicing certificates for the research nurses.
3. Performing protocol training for the study coordinator Miriam MANGEYA.

11. Discuss Significant Concerns

All significant concerns were discussed with the investigator during the debrief, these included redoing the filing system, creating a dedicated file for clinical research regulatory reference materials and sharing all study related standard operating procedures with all study personnel.

The CTS will share an example template of a data management plan with the principal investigator for use as reference in revising the study data management plan.

12. Summary and Conclusion

The study site is ready for activation once all the issues mentioned in the comments section under each item, in addition to item 10 &11 have been addressed, followed by a subsequent succesfull dry run of a screening and enrolment visit.

Gift Tafadzwa CHAREKA		30 APR 2019
Clinical Trials Specialist's Name (print)	Signature	Date
Comfort Ropafadzo KANJI		30 APR 2019
Investigator's Name (print)	Signature	Date