



RWANDA FDA
Rwanda Food and Drugs Authority

**GUIDELINES ON GCP INSPECTION OF CLINICAL TRIALS
IN RWANDA**

OCTOBER, 2024

FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) was established by Law N° 003/2018 on 09/02/2018. Rwanda FDA is a regulatory authority that has the mandate of overseeing and inspecting clinical trials, among others, as stipulated in article 8, paragraphs 7 and 12 of the aforementioned Law.

Furthermore, the technical regulations No. FDISM/PVSM/TRG/001 requires Rwanda FDA to oversee the conduct and inspection of clinical trials, specifically outlined in Articles 34 and 38. In this context, Rwanda FDA issues these Guidelines No. DD/PIL/GDL/014 on Good Clinical Practices (GCP) for the inspection of clinical trials in Rwanda.

The purpose of inspecting clinical trials is to ensure that the trials are conducted in accordance with the standards of GCP, which is an international ethical and scientific quality standard for designing, conducting, performing, monitoring, auditing, recording, and reporting clinical trials that involve human participants.

Compliance with these guidelines can ensure public confidence that the rights, safety, and well-being of trial participants are protected, following principles derived from the Declaration of Helsinki. It also assures that the quality, reliability, and integrity of the collected data are maintained.

These guidelines provide details about the steps and processes required during the GCP inspection of clinical trial conduct to ensure the effective protection of trial participants and compliance with requirements as well as the clinical trial protocol.

Strict adherence to these guidelines will facilitate the acceptance of clinical data by international regulatory authorities, especially since these guidelines adopt the basic principles outlined by the International Committee on Harmonization of Good Clinical Practice (ICH-GCP) with some customization to fit the local requirements.

I am confident that the publication of these Guidelines will mark another milestone in our efforts to strengthen clinical research in Rwanda. The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General



DOCUMENT DEVELOPMENT HISTORY

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1	<ol style="list-style-type: none"> 1. The reference number was changed from DIS/GDL/043 to No FDISM/PVSM/GDL/009_1 as per the current SOP on document control. 2. Criteria for designing, conducting, recording, and reporting clinical trials were included in line with the latest version of ICH GCP and AVAREF guidelines; 3. Frequency of trial monitoring based on risk included; 4. Considerations for inspection of multicentre trials were included; 5. A section related to remote GCP inspections was included; 6. Formats and forms were updated to include a section related to the trial administrative formation 7. Necessary editorial changes in line with SOP on document control were included.
2	<ol style="list-style-type: none"> 1. Adoption of new Rwanda FDA organogram for GCP activities from PVCT to PIL Division; 2. The form titled "Grading of Clinical Trial GCP Inspection Findings" has been removed from these guidelines and reclassified as an internal document of the PIL Division; 3. Necessary editorial changes in line with updated SOPs and SOP on document control were included.

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ACRONYMS AND ABBREVIATIONS

ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
AVAREF	African Vaccine Regulatory Forum
CAPA	Corrective Action and Preventive Action
CRF	Case Report Form
CRO	Contract Research Organization
DSMB	Data and Safety Monitoring Board
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICH	International Conference on Harmonization of Technical
IP	Investigational Product
IRB	Institutional Review Board
RNEC	Rwanda National Research Ethics Committee
SAE	Serious Adverse Event
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File

GLOSSARY / DEFINITIONS

In these Guidelines, unless the context otherwise states:

“Applicable Regulatory Requirement(s)” Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

“Authority” Means Rwanda Food and Drugs Authority or its acronym “Rwanda FDA”, established under article 2 of Law N° 003/2018 of 09/02/2018.

“Audit” A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol and applicable standard operating procedures (SOPs), the Authority and ICH-GCP requirement(s).

“Case Report Form” A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each study participant.

“Clinical Trial” Any investigation in human study participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

“Clinical Trial report” A written description of a trial/ study of any therapeutic, prophylactic or diagnostic agent conducted in human study participants in which the clinical and statistical description, presentations and analyses are fully integrated into a single report.

“Contract” A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

“Data and Safety Monitoring Board” An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data and the critical efficacy endpoints and to recommend to the sponsor whether to continue, modify, or stop a trial.

“Documentation” All records, in any form (including, but not limited to written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

“Essential Documents” Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

“Ethical Clearance” An authorization to conduct a clinical trial issued by the Rwanda National Research Ethics Committee (RNEC) based on ethical issues related to trials involving human participants in Rwanda.

“Good Clinical Practice” A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that assure that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial/study participants are protected.

“Informed Consent” A process by which a study participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the study participant's decision to participate. Informed consent is documented using a written, signed and dated informed consent form.

“Inspection” The act of conducting an official review of documents, facilities, records, and any other resources that are deemed by the Authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or CRO's facilities or at other establishments deemed appropriate by the Authority.

“Investigational Product” A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

“Investigator” A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

“Investigator's Brochure” A compilation of the clinical and non-clinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human study participants.

“Monitor” The person responsible for ensuring that the study is performed at the agreed progression and that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP, GLP and the Authority requirement(s).

“Phase I trials” These are the first trials of a new active ingredient or new formulations in man, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamic profile of the active ingredient in humans.

“Phase II trials” These trials are performed with a limited number of study participants and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and to assess the short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships to provide an optimal background for the design of extensive therapeutic trials.

“Phase III trials” Trials in larger (and possibly varied) patient groups to determine the short and long-term safety/efficacy balance of formulation(s) of the active ingredient, and assess its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g., clinically- relevant

investigation of medicinal product interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomized double-blind design, but other designs may be acceptable, e.g. long-term safety studies. Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use.

“Phase IV studies” Studies performed after the marketing of the pharmaceutical product. Trials in phase IV are carried out based on the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials are designed to explore new indications, new methods of administration or new combinations, among others are normally considered as trials for new pharmaceutical products.

“Principal Investigator” A person responsible for the conduct of the clinical trial at a trial site who is a physician, dentist or other qualified person, a resident in Rwanda and a member of good standing of a professional body. If a trial is conducted by a team of individuals at a trial site, the principal investigator is the responsible leader of the team. See also Sub-investigator.

“Protocol” A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The protocol usually also gives the background and rationale for the trial but these could be provided in other protocol-referenced documents.

“Sub-investigator” Any member of a clinical trial team, supervised by the investigator at a trial site and allowed to perform critical trial-related procedures

“Source Data” All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

“Sponsor” An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

“Trial participant” An individual who participates in a clinical trial either as a recipient of the investigational medicinal product(s) or as a control.

“Trial Site” The location(s) where trial-related activities are conducted.

1. INTRODUCTION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, performing, monitoring, auditing, recording, and reporting clinical trials that involve the participation of human subjects.

These guidelines provide a set of harmonized procedures to conduct GCP inspection of clinical trials in all phases including bioequivalence studies. Further objectives include ensuring that there is a basis to ensure the ethical, scientific, and data integrity of clinical trials. It may be used by inspectors from the Authority or in joint GCP inspections with RNEC according to the Joint Institutional Collaboration Framework (MoU) between Rwanda FDA and RNEC. It can support recognition of GCP inspection findings and regulations actions for clinical trials between countries that apply the same standards and procedures of GCP inspection.

The areas for the GCP inspection of a clinical trial conducted in Rwanda include but not limited to the clinical site organization, administrative aspects, protocol compliance, informed consent, safety reporting, Source of data verification (SDV), IP management, Clinical sample management, Trial Master File, Trial Management & Monitoring of related clinical trial data.

These guidelines will help the Authority to establish a conducive environment for clinical trial conduct and oversight to ensure sustainable quality, scientifically sound clinical trials conducted acceptably and ethically. Therefore, inspectors and the inspected team are urged to adhere to the provisions of these guidelines while planning, preparing, conducting, and reporting clinical trial inspections.

1.1 SCOPE

These Guidelines apply to the GCP inspection of all clinical trials approved by the Authority and conducted at investigator site (s), sponsor facility (ies), CROs, and other establishments involved in clinical trials deemed necessary.

The areas of the inspection include but are not limited to data and information relating to regulatory approvals, ethics review committee approval, protocols, consent forms, case report forms, IP management, safety reports (SAEs and SUSARs), clinical trial reports (progress and final reports), participant and participant data, sponsors, investigators and personnel involved in the trial, and laboratory data.

1.2 Objectives of GCP Inspections

The objectives of conducting clinical trial inspections are:

- (a) To safeguard the rights, safety, and well-being of trial participants;
- (b) To verify the quality and integrity of the clinical trial data submitted to the Authority;
- (c) To assess compliance with the protocol and applicable regulations, guidelines, and standard operating procedures;
- (d) To assess whether a clinical trial system is suitably designed, controlled, maintained and documented to fulfil the objectives for which it has been set up;
- (e) To identify areas for quality improvement;

- (f) To investigate a complaint about the conduct of the study at a particular site;
- (g) To verify the implementation of corrective actions and preventive actions.

1.3 GCP Inspection Criteria

Rwanda FDA ensures that the rights, safety and well-being of trial participants are protected and that the results of the clinical trials are accurate and credible.

During GCP inspection, the Authority shall therefore ensure compliance with the following criteria:

- 1.3.1 Approved Protocol and its supplementary documents;
- 1.3.2 Applicable clinical trial regulatory requirements;
- 1.3.3 Applicable Site Standard Operating Procedures (SOPs) for clinical trials;
- 1.3.4 Other applicable requirements are as per the latest version of ICH Good Clinical Practice Guidelines.

2. TYPES OF GCP INSPECTIONS

Rwanda FDA conducts the following three main types of inspection for clinical trials in Rwanda:

- (a) Routine GCP inspection;
- (b) Triggered GCP inspections;
- (c) Follow-up GCP inspection.

The clinical trial sites may be inspected before granting the regulatory approval, while the trial is ongoing, when trial participants are being enrolled in a trial or completed on a routine basis, or sometimes when triggered by a complaint or there is a suspicion of serious non-compliance integrity issues and/or scientific/ethical misconduct. Generally, GCP inspections are announced. However, unannounced inspections may be possible.

2.1 Routine GCP Inspections

Routine inspections are inspections performed regularly to monitor GCP compliance in the absence of specific trigger elements. These inspections are announced in advance and apply to ongoing clinical trials. The duration of the inspection and the number of inspectors will vary depending on the complexity of the clinical trial and the activities taking place at the site. They are typically scheduled for 3-5 days per site.

2.2 Triggered GCP Inspections

Triggered GCP inspections are conducted when there is a suspected concern due to either the actual issues observed or the potential impact of deviations from GCP on the conduct of the study as a whole or at a particular site or when a serious breach of GCP occurred. In addition, products with a major impact factor could be considered to require special attention. This type of inspection may be done announced or unannounced and apply to ongoing or completed clinical trials.

2.3 Follow Up GCP Inspections

A follow-up is also referred to as a re-inspection or re-assessment of the site. It is performed specifically to monitor the result of corrective and preventive actions of the site following previous

inspection(s). Depending on the nature of the observation(s), and the work required the follow-up inspection could be carried out within the agreed timelines after the previous inspection. The follow-up inspection is limited to specified clinical trial non-compliances that have been observed.

3. INSPECTION PROCESS

3.1 GCP Inspection Prioritization

The Authority shall use a risk-based approach to select sites for GCP inspections. The Authorized trials with higher risk are more likely to be inspected. The majority of GCP inspections shall be routine inspections of clinical trials that are ongoing or completed. However, other types of inspections including triggered inspections may also occur. The duration of the GCP inspection shall vary depending on the complexity of the clinical trial, the risk involved, and activities conducted at the site and shall be scheduled for 3-5 days per site.

The selection of trial sites for the GCP inspection includes, but is not limited to the following criteria:

- (a) Nature of intervention or investigation product;
- (b) Clinical trial phase;
- (c) Inclusion of vulnerable populations in the trial;
- (d) Size of the trial (number of trial participants and sites).
- (e) Route of administration of the investigational product;
- (f) Significant or frequent reports of serious adverse events;
- (g) Complaints on the conduct of the trial were reported to the Authority.

3.2 Inspection Team

The GCP inspections of a clinical trial site must be performed by GCP inspectors appointed by the Authority according to the procedures in place. However, the Authority may involve experts in the GCP inspection of the clinical trial whose qualifications and experience correspond to the proposed clinical trial. In addition, the Authority may conduct joint inspections at the clinical trial site to ensure the safety and protection of participants in clinical trials and the integrity of collected data.

The inspection team is constituted considering the phase or type of trial, the investigational product, and other variables considered relevant on a case-by-case basis. The inspectors should be well-qualified and have valid GCP certification obtained within three (3) years as per ICH-GCP guidelines. The team will have a lead GCP inspector responsible for coordinating the inspection, collating the information from team members, and finalizing the inspection report as Shown in **APPENDIX-I**.

3.3 GCP Inspection of Multicentre Trials

Multicentre trials are usually conducted simultaneously by several investigators at different sites implementing the same protocol and its supplementary documents. The trial sites with more participants or frequent serious adverse event reports will be prioritized. However, the non-compliance of the GCP inspection from one clinical trial site can trigger further GCP inspections at other site (s) that were not planned for inspection.

In case of multi-centre clinical trials carried out in more than one country including Rwanda, non-compliance with the GCP inspection performed by other regulatory authorities will trigger further

inspection of the trial site (s) in Rwanda to ensure the protection and well-being of the trial participants in Rwanda.

3.4 Notification of GCP Inspection

The Authority shall contact the inspectee notifying the date(s) of inspection one (1) month prior to the proposed announced inspection dates and ask to confirm the proposed dates. A subsequent reminder by the Authority may be sent within fourteen (14) days in case the inspectee fails to confirm the availability. If the inspectee fails to confirm the proposed inspection date, the Authority shall conduct the triggered GCP inspection.

The notification will specify the clinical trial to be inspected and the proposed sites for the inspection. In the case of triggered or follow-up inspections, the Authority may notify the trial site within a short period. The following information will be requested by the Authority:

- (a) Participant status per trial site (number of randomized, dropout rate, number of SAEs reported per site, among others.) at trial initiation or during the trial;
- (b) Copies of Standards Operating Procedures (SOPs) along with amendments (e.g., monitoring procedures, informed consent procedures, SAEs reporting Procedures, and Pharmacy Management Procedures, among others);
- (c) Trial-specific documents such as Trial Master File (TMF) or Investigator Site File (ISF), a copy of the current protocol and protocol amendment and informed consent form, source data verification guidelines, investigational product management and accountability, product handling instructions, laboratory manual, randomization code, breaking procedure, monitoring plans and reports;
- (d) Updated CV of principal investigator or co-investigators, and members of the DSMB if applicable;
- (e) In the case of a computerized system, the PI or sponsor provides access to the system;
- (f) Any other document deemed necessary by the Authority;
- (g) Any other document deemed necessary by the Authority.

In case the GCP inspection dates are confirmed by both parties, the PI or sponsor shall submit the signed cover letter and aforementioned data to the Authority electronically or in hard copy within fourteen (14) days of the receipt of the notice of GCP inspection to the following address:

The Director General

Rwanda Food and Drugs Authority

P.O. Box 1948 Kigali, Rwanda

E-mail: info@rwandafda.gov.rw

3.5 Preparation for GCP Inspection

The GCP inspection schedule and Guidance for Clinical Trial GCP Inspection Checklist will be shared with the principal investigator within five (5) working days to prepare for the upcoming inspection. Each member of the inspection team should become familiar with all the relevant documents, including the study protocol(s), clinical trial report(s), case report forms, adverse event reports, trial site information, and other related documentation. The inspectee should ensure that access is provided to all trial records, including trial participant medical records, Investigator Site File, Trial Master File, Case Report Forms, and applicable standard operating procedures, where applicable.

4. CONDUCT OF GCP INSPECTIONS

4.1 Opening meeting

The opening meeting between the inspector(s) and the inspectee(s) will:

- (a) Introduce the inspector(s) to the inspectee(s) and identify their roles and responsibilities
- (b) confirm the GCP inspection schedule;
- (c) explain the scope of the inspection and GCP Inspection regulatory framework;
- (d) give a brief overview of the trial site;
- (e) provide a summary of the methods and procedures to be used for the conduct of the inspection; confirm the availability of resources, access to records, and facilities required for the GCP inspection, and clarify matters relating to confidentiality.

4.2 Verification and collection of information during GCP inspection

After the opening meeting, the inspection begins. The inspectors assess the site's compliance with both regulatory requirements and GCP standards. The essential documents to be reviewed during GCP inspection will depend on the stage of the trial as per regulatory requirements and provisions of the latest version of AVAREF and ICH GCP guidelines.

The GCP inspection guide checklist (APPENDIX-II) will be utilized to inform the inspectee about the inspection process. Meanwhile, the inspector will document observations, comments, instances of non-compliance, and recommendations for improvement in the Inspector's notes, adhering to the relevant internal procedures that establish forms and formats for monitoring and evaluating corrective and preventive actions (CAPA). The scope and activities examined during the inspections undertaken by the Authority may include different aspects.

4.2.1 Legal and administrative aspects

During the inspection, the inspection team shall verify whether the site is ready to conduct clinical trials. This includes verification of the authenticity and validity of the documents issued by the Authority and other relevant bodies.

a. Ethical Clearance

During the Inspection, the inspection team shall verify relevant records relating to ethics to ensure the protection of the rights and welfare of participants in clinical trials. This verification shall include but not limited to:

- (i) Validity and authenticity of RNEC ethical clearance and consent forms (reference number, dates, signatures, and stamp, among others);
- (ii) Reports submitted to the RNEC related to the serious adverse events occurring during the trial implementation and follow-up up as well as other relevant communications with RNEC if any;
- (iii) Approval given for any advertisement, recruitment, screening, compensation and payments of trial participants.

b. Regulatory Authority Approvals

The inspection team shall ensure that:

- (i) clinical trial approval certificate was granted to conduct the trial before its initiation;
- (ii) revisions and changes/amendments to the protocol and related documents were granted approval before implementation;
- (iii) serious adverse events (SAEs) and other reports were submitted to the authority according to the timelines of relevant regulations and guidelines.

4.2.2 Organisational aspects

The inspection team will verify the compliance of the procedures and practices carried out by the investigator in line with the protocol and reports submitted to the Authority.

a. Implementation of the trial at the site

The site has to be ready to conduct clinical trials. Depending on the activities undertaken by the site, areas such as a clinic, pharmacy, and laboratories should have enough space with appropriate infrastructure and equipment. The access to the storage of investigational products (IPs) and other services should be controlled as appropriate.

b. Organization and personnel

The investigator is responsible for ensuring that an investigation is conducted according to the approved protocol, the investigational plan, and applicable regulations and guidelines. The contract between the sponsor and the investigator has to clearly define the responsibilities of each party. The inspectors shall verify if:

- (i) the clinical trial agreement (contract, Memorandum of Understanding, etc.) is still valid, i.e., dated, period covering the trial, signatures by all parties;
- (ii) the academic qualification and work experience as stated in the curriculum vitae and training records;
- (iii) the research team complies with the multidisciplinary aspect as per trial requirements;
- (iv) Training records are available and updated by checking certificates of training and training logs or reports;
- (v) the training subjects were relevant to the trial objectives being implemented at the trial site.

c. Facilities and equipment

Each site should be equipped with adequate, calibrated, and maintained equipment depending on the type of clinical trial to be conducted.

d. Implementation of the protocol

The Clinical trial should be conducted in accordance with the provisions of the approved study protocol and/or amendments. During the inspection, inspectors shall verify if:

- (i) the approved protocol is being implemented;

- (ii) all trial participants enrolled met the inclusion and exclusion criteria;
- (iii) dosing, meals (fed and fasting), and sample collection were done as stipulated in the protocol;
- (iv) randomization, product information, reporting of serious adverse events, and preparation of reports are compliant with the requirements;
- (v) there are no deviations from the approved protocol;
- (vi) violations to the protocol were reported;
- (vii) Reporting of results was/being done as required.

e. Management of biological samples

The aim of checking the management of biological samples is to examine conditions and documentation regarding collection, analyzing, storage, and shipping conditions (if applicable) for proper management of biological samples. The laboratory of a Clinical research site should be able to analyze samples as specified in the protocol. In case the testing is outsourced, the contract should define the responsibilities and scope of each party including sample transport, storage, preparation, and methods used as well as reporting of results. The inspectors shall review the contracts and appropriate SOP for sample handling at the time of inspection.

f. Organization of the documentation

The site needs to have archiving facilities with sufficient space to ensure the protection of records from damage, i.e. fire, water, humidity, and deterioration. The site has to have procedures and records to place and retrieve documents and trial data. During the inspection, SOPs and records to archive electronic data and electronic records shall be verified.

g. Monitoring and auditing

The Sponsors generally perform site monitoring of a clinical trial to ensure high-quality trial conduct. The sponsor may perform such monitoring directly or may utilize the services of an outside individual or organization (e.g., contract research organization). The “on-site” monitors review individual case histories to verify adherence to the protocol, ensure the ongoing implementation of appropriate data entry and quality control procedures, and verify adherence to GCP principles.

h. Use of computerized systems

The use of validated computerized systems to generate data should be encouraged. Computer hardware, software, and associated documents (e.g., user manual) that create, modify, maintain, archive, retrieve, or transmit in digital form information related to the conduct of a clinical trial should be validated. During inspection, it is necessary to ascertain their validation status. Computer system features, security, maintenance and controls, back up and data recovery should be inspected to ensure data integrity. The inspection team will ensure the availability of a central computerized system that is protected to ensure the backup or data recovery of clinical trials.

4.2.3 Informed consent of trial participants

The aim is to determine whether informed consent was obtained in accordance with ICH GCP principles. The trial participants have to be informed of the advantages and disadvantages of participating in a trial. This includes information on the IP, possible adverse events, insurance, and other issues. The inspection team will verify and confirm that:

- a. The required information was presented to the participant, verbally and in writing;
- b. If each participant signed the ICF before participating in the trial;
- c. The contact details of the investigator or secretariat were given to trial participant(s).

4.2.4 Review of the trial participant data

The aim of the trial subject data review is to check whether the investigator team conducted the clinical trial according to the approved protocol and its amendments by source data verification. In the source data verification, it will be necessary to evaluate the source records taking into account their organization, completeness and legibility. The description of the source data inspected should be reported by the inspector. It will be necessary to evaluate whether corrections to the data recorded in the CRF were done according to the latest version of the ICH GCP (signed and dated by the authorized person who did it and providing justification, if necessary). For a number of participants that will be determined within the inspection plan, (the sample might include the first and last patient enrolled among others) the following should be checked:

- (a) characteristics of the participant in the clinical trial;
- (b) participant's visits calendar;
- (c) efficacy and safety assessment data;
- (d) concomitant therapy and intercurrent illness;
- (e) safety management and reporting.

4.2.5 Data integrity in clinical trial

During inspections, the Authority shall verify the integrity of data generated in clinical trials and assure the protection of trial participants, in addition to ensuring that clinical trial is conducted according to the applicable regulations and guidelines. An open reporting culture in research sites should be encouraged as fundamental to data integrity promotion throughout the data lifecycle, including processes from generation or recording of data to destruction, if needed, and the intervening processes.

Decisions made, based on the outcome of clinical trials, rely on the integrity of the results and data obtained during the study. The data should be complete, attributable, legible, contemporaneous, original and accurate, commonly referred to as "ALCOA+". This applies to all data and information as reflected in manual records and electronic data from computerized systems.

During the Inspection, the team of inspectors will interview the research team member to determine how the clinical trial is or being conducted. The interview responses may trigger the deep review of essential documents pertaining to the clinical trial being inspected.

4.2.6 Management of the investigational product(s)

The aim is to verify whether all the activities are related to the management of Investigational Products. The aim is to verify whether all the activities related to the management of Investigational

Product(s) have been done according to the protocol and appropriate SOPs at the trial site. Clinical research sites usually have a pharmacy where IPs are stored and dispensed under appropriate conditions. The inspection team during the inspection shall verify and confirm that:

- (a) access is controlled and that access records reflect entry and exit against the clinical trial activities such as dates for receiving and storage of IPs, dispensing, issuing, returns, and disposal;
- (b) SOP content for the various activities including receiving, checking, storage, dispensing, labelling, and reconciliation of IPs. Verify the related records to ensure compliance with the protocol and SOPs;
- (c) SOP and records to monitor the conditions under which the IPs are stored. Verify the labelling requirements against the room storage conditions such as temperature and relative humidity observed from the calibrated devices. If there are values outside the specifications, verify if they were investigated and if any prospective impact on the IPs was assessed;
- (d) records relating to the IP, such as import license, proof of purchase, shipping letter, storage conditions during transport, certificate of analysis, stock card, and dispensing record including dates, quantity and signatures;
- (e) check the suitability of storage conditions and their records (fridge, freezer and controlled substances, among others);
- (f) cross-check the records such as label sheets, randomization, CRFs, and reconciliation records for the IPs;
- (g) whether IP labels contain the correct information such as the study number, “for clinical trial use only”, participant number, period, randomization, dosage form, and route of administration, as appropriate;
- (h) SOP for safe disposal of damaged or expired IPs.

The inspectors should check where required that these documents have been signed and dated by the responsible persons according to the site SOP and/or applicable requirements related to the management of investigation products. If access to any record or copying is denied, or there is any withholding of documents or denial of access to areas to which the inspector has legal access, the refusals should be documented and included in the inspection observations or report.

4.3 Interview with Research Team Members

During the Inspection, the team of inspectors will interview the research team member to determine how the clinical trial is or being conducted. The interview responses may trigger the deep review of essential documents pertaining to the clinical trial being inspected.

4.4 Inspection of trial site facilities, equipment and system

The team of Inspectors shall inspect facilities equipment and system used to conduct the clinical trial being inspected and take appropriate documented evidence to support the inspection report where necessary. The inspection team shall inspect the following units: consultation room, laboratory, pharmacy, data management room, trial equipment and instrument, clinical trial documentation, and other applicable infrastructure covering the trial operations.

4.5 Generating GCP inspection findings

The GCP inspection evidences should be evaluated against the inspection criteria in order to determine inspection findings. These findings can indicate compliance or non-compliance with inspection criteria. The inspection findings should include compliance and good practices along with supporting evidence, opportunities for improvement, and any recommendations to the inspectee. The findings should be well documented in a clear, concise manner using the inspection checklist (APPENDIX -I) adopted from AVAREF and supported by objective evidence.

4.6 Clinical trial inspection closing meeting

At the end of the inspection, a closing meeting to present inspection findings to the inspectee(s) will be held at the clinical trial site. During the closing meeting, on the last day of the inspection, the preliminary findings noted during the inspection will be highlighted. This meeting will help to ensure that the results of the inspection are clearly understood and that there is no misunderstanding by both parties. This is also an opportunity to discuss the findings, request/provide clarifications and supporting documentation, as needed, and also ask questions.

The inspector(s) or the inspectee(s) will also sign the Memorandum Form of GCP findings (APPENDIX- III) listing all the non-compliant findings noted during the clinical trial inspection of which a copy will be left at the investigator's site.

4.7 Remote GCP inspections

During public health emergencies, the Authority may remotely perform GCP inspections where access to the clinical sites is difficult. If a remote inspection reveals issues that require on-site inspection, or the inspection objectives cannot be met remotely, the site shall be physically inspected.

4.8 Grading of clinical trial inspection findings

The grading of findings from GCP inspections of Clinical Trial sites is classified into three risk categories: critical (Risk-1), Major (Risk-2), and Minor (Risk 3).

4.8.1 Critical findings

Critical findings are conditions, practices, or processes that adversely affect the rights, safety or well-being of the participants and/or the quality and integrity of data or that represent a serious violation of regulations and guidelines. They present the situation that results in fatal, life-threatening or unsafe conditions for study participants. The critical findings may include fraud, adulteration, misrepresentation, falsification of records, absence of source documents and falsified data are classified as critical findings.

4.8.2 Major findings

The major findings are conditions, practices or processes that describe a situation where a marked finding, other than a critical one, may result in undue health risks for the clinical trial participants or in other persons and/or could invalidate the data.

4.8.3 Minor findings

Minor findings are conditions, practices or processes that would not be expected to adversely affect the rights, safety or well-being of the participants and/or the quality and integrity of data. The minor finding simply necessitates actions for the improvement of conditions, practices and processes.

4.8.4 Considerations for grading of GCP inspection findings

The GCP inspection findings classification may vary depending on circumstance, the severity of the findings, corrective actions and preventive actions that may be taken and the nature of the investigational product. In some circumstances, major findings may be categorized as critical. However, a finding reported after a previous inspection and not corrected may be given a higher classification.

4.9 Outcome of GCP inspections

The results of a GCP inspection are an inspection report and a close-out letter describing the outcome with the applicable regulations and guideline(s) issued by the Authority. The overall inspection report concludes that the clinical trial site is:

- (a) Compliant- only minor and major observations were reported;
- (b) Non-Compliant- one or many critical observations; or a repetition of major observations reported during a previous inspection and may result in suspension or termination of the trial.

4.9.1 Clinical trial inspection report

Once the inspection has been completed, an inspection report will be written in the format shown in **APPENDIX-V** and issued to the sponsor/investigator within twenty (20) working days from the last days of inspection. The inspectee is required to acknowledge the receipt of the GCP report and propose corrective and preventive actions (CAPAs) to all highlighted findings within fifteen (15) working days.

In case CAPAs are satisfactory, the Authority will issue the Inspection closing letter. However, if CAPAs are not satisfactory, additional actions will be requested by the Authority and when necessary, a follow-up inspection may be conducted for verification. Once the CAPA is deemed acceptable, the Authority will send a GCP inspection close-out letter.

4.9.2 Transparency & confidentiality during GCP inspections

The Authority will conduct GCP inspections of authorized clinical trials transparently from preparation, planning and conduct of inspections in accordance with provisions of regulations, guidelines and standards operations procedures in place. All trial sites will be inspected using the same inspection standards and tools. The rights of trial participants in terms of privacy and confidentiality must be protected and maintained.

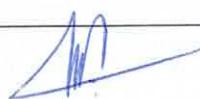
5. REGULATORY ACTIONS DURING GCP INSPECTIONS

Based on the findings of the GCP inspection, the Authority may proceed with administrative regulatory actions if the inspectee fails to address critical and major findings according to the

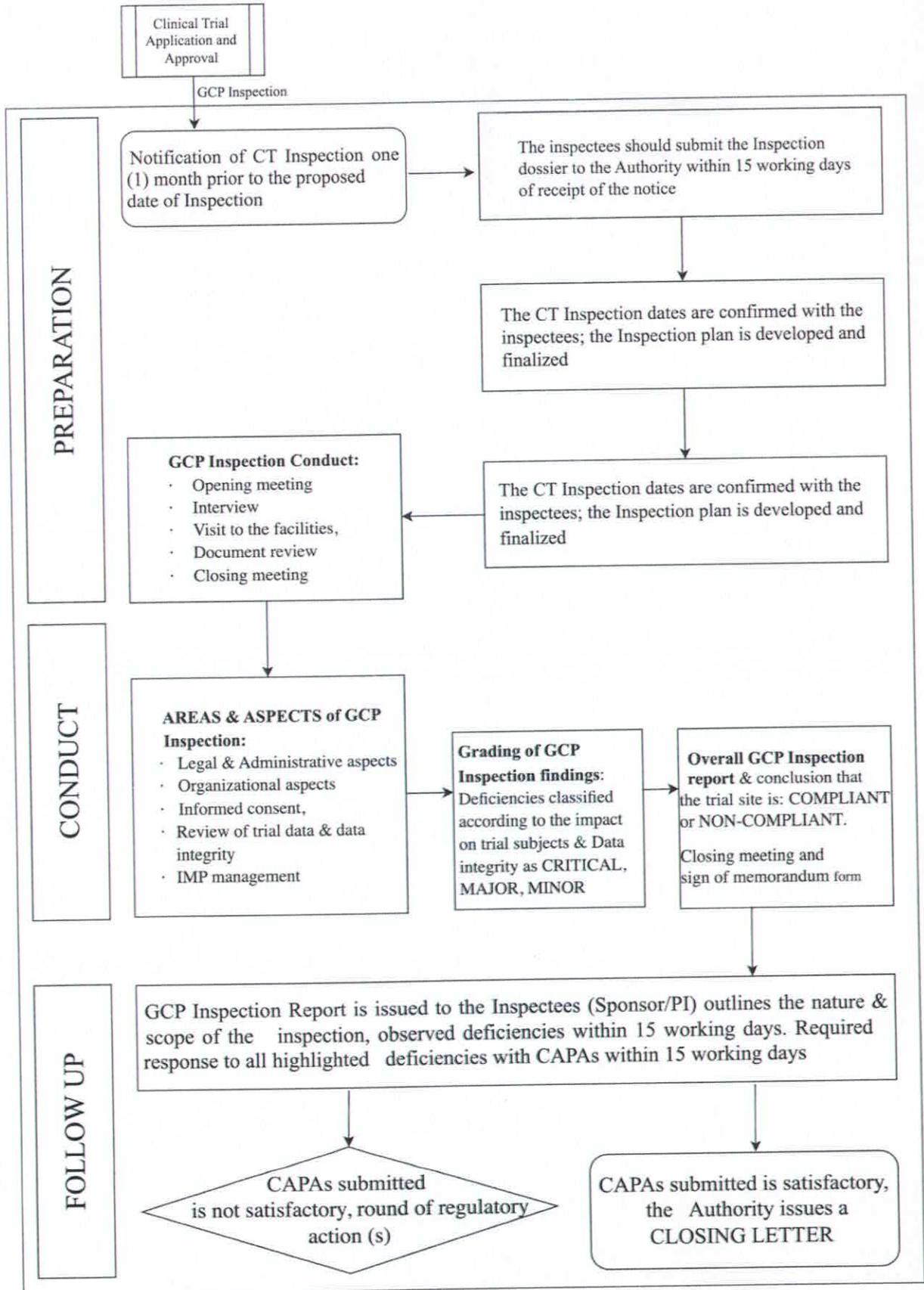
provisions of regulations and laws enforced in Rwanda. However, the Authority may not wait for CAPA to administrative regulatory actions in cases of deliberated misconduct such as fraudulent documentation or continuation of the clinical trial can have an adverse effect on trial participants. The following regulatory actions depending on the GCP inspection findings may be taken:

- (a) Issuance of a warning letter;
- (b) Temporary suspension of the trial;
- (c) Permanently terminate the trial and revocation of clinical trial Approval certificate
- (d) Blacklist the principal investigator or sponsor;
- (e) File case for court proceedings.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	Checked by		Approved by
Title	Division Manager of Pharmaceutical Inspections and Licensing	Head of Drugs Department	For QMS Division Manager	Director General
Names	Dr. Marilyn M. MURINDAHABI	Dr. Védaste HABYALIMANA	Mr. Théogène NDAYAMBAJE	Prof. Emile BIENVENU
Signature				
Date	28/10/2024	28/10/2024	28/10/2024	28/10/2024

APPENDIX-I: GCP INSPECTION PROCESS FLOW CHART



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APPENDIX-II: GUIDE CHECKLIST FOR CLINICAL TRIAL GCP INSPECTION



Doc No: DD/PIL/CKL/061
Version: 2
Effective Date: 29/10/2024

GUIDE CHECKLIST FOR CLINICAL TRIAL GCP INSPECTION

ADMINISTRATIVE INFORMATION OF THE TRIAL	
Date of Inspection	DD/MM/YYYY
Clinical trial(s) names	
Rwanda FDA CTAC number	
Trial protocol title	
Trial site address	
Total number of sites	
Investigational product(s)	
Names and contact of the Principal Investigator	
Name of the site	
Physical Address of the site	
Protocol Number	
Stage of the trial [Tick as appropriate]:	<input type="checkbox"/> Before commencement <input type="checkbox"/> Ongoing <input type="checkbox"/> Completed
Principal Investigator	
Sub/Co-Investigator	1..... 2..... 3..... 4.....
Regulatory Authority approval date Version & Date
Ethical Approval date for informed consent form	1)..... 2).....
Names of Inspectors	1..... 2..... 3..... 4.....
Screening date 1 st Participant	
How many Participants enrolled	
Randomization date of 1 st Participant	

Handwritten signatures and initials in blue ink.

How Many participants withdrew from the study?			
How many participants completed the study			
How many SAEs were reported			
DATA INTEGRITY	YES	NO	NA
There is a written data integrity policy			
There is an SOP describing principles of data integrity ensuring ALCOA+			
Data and results were reviewed and considered to comply with data integrity requirements. (If “no”, complete the comments section below)			
Comments:			
FACILITY INSPECTION			
CONSULTING AREA	YES	NO	NA
1. Is the consulting area where the Clinical trial team evaluates the participants during visits adequate in size?			
2. Are there lock-up cupboards for confidential documents?			
3. Is the trial-specific equipment available in the consulting room?			
4. If not, is the area where procedures are performed adequate and easily accessible?			
COMPLIANCE TO THE TRIAL PROTOCOL			
1. Is the trial being carried out in accordance with the trial protocol provisions?			
2. Are the SOP mentioned in the protocol being implemented? (Note: You can provide a detail of SOP mentioned) 1. 2..... 3.....			
3. Was the dose in the protocol the same as the dose dispensed?			
PROCEDURE ROOM			
1. Are all protocol-specified equipment calibrated and validated?			
2. Are SOPs on how to use equipment available?			
3. Is the blood sampling area kept according to infection control procedures?			
4. Is an SOP on handling biological waste available?			
5. Is an emergency trolley available in the procedure area?			
5.1 Is the trolley locked and are keys available and controlled?			
5.2 Is the emergency trolley frequently checked?			
5.3 Are medicines stored within their expiry dates?			
5.4 Are oxygen and accessories available checked and			

signed?			
5.5 Are investigators ALS trained?			
Comments:			
PHARMACY MANAGEMENT (INVESTIGATIONAL PRODUCTS STORAGE AREA)			
	YES	NO	NA
1. Are the Pharmacy access controlled, temperature and humidity?			
2. Are Investigational products stored as per temperature or humidity?			
3. In the case of vaccines, is a spillage SOP available, and is the study team trained to handle such an incidence?			
4. Are electronic or hand-written logs available?			
5. Is an SOP on how to handle electricity or temperature failure in the pharmacy available?			
6. Are the investigational products for different studies identified and stored in separate lock-up cupboards?			
Comments:			
ARCHIVE			
	YES	NO	NA
1. Is there an agreement between the Sponsor and the Clinical trial site/CRO on archiving of documentation			
2. Was access to the archive facility restricted?			
3. Are records of retrieval of documents from the archive available?			
4. Was the archive storage area fireproof and pest-controlled			
Comments:			
CLINICAL LABORATORY			
	YES	NO	NA
1. Is the clinical laboratory at the same site?			
2. If not, are procedures for handling biological samples documented?			
3. Is the laboratory accredited for the tests to be performed?			
4. Are all testing procedures used in the laboratory validated?			
5. Are all instruments adequate?			
6. Are all instruments and equipment calibrated and maintained/			
7. Are updated signed CVs of analysts available?			
8. Are the frequencies of QC checks for each instrument before analysis documented?			

9. Are there SOPs for receipt, storage of chemicals, and preparation of solution available?			
10. Is an SOP for waste disposal (e.g.: organic and biological waste) available?			
11. Are normal values ranges for medical/laboratory/technical procedures and/or tests and wherever applicable their updates during the trial available?			
Comments:			
STUDY-SPECIFIC INSPECTION			
CONTRACT AND AGREEMENTS	YES	NO	NA
1. Did the contract or the protocol describe any transfer of responsibility between the sponsor and the investigator?			
2. Was a confidentiality agreement signed between the sponsor and the investigator(s)?			
3. Was there a signed and dated financial agreement between the sponsor and the investigator available?			
4. Was an insurance certificate that covers the duration of the study available?			
5. Was there a signed conflict of interest declaration?			
6. Has the final version of the protocol been signed by all appropriate persons?			
Comments:			
REGULATORY APPROVALS	YES	NO	NA
1. Was regulatory approval for the protocol obtained before the start of the study?			
2. Was the version number of protocols used in the study versus the version number of the approved protocol identified?			
3. Were regulatory approvals of any new investigators obtained?			
INVESTIGATOR BROCHURE	YES	NO	NA
1. Was an investigator brochure and updates available on file with the date and version corresponding to that submitted Rwanda FDA			
2. Was an investigator brochure and updates available on file with the date and version corresponding to that submitted Rwanda FDA			
INFORMED CONSENT	YES	NO	NA
1. Was the informed consent form version that was used approved by RNEC?			
2. Was a written SOP used to solicit informed consent?			
3. Did all the subjects sign the consent form before any study-related procedure?			
4. Did all the subjects receive a copy of the signed informed			

consent form?			
5. Did participants receive information regarding insurance?			
6. Was an assessment of understanding of the contents of the informed consent done?			
7. Did the principal investigator or person designed by the principal investigator conduct the informed consent appropriately			
8. Were the participants given sufficient time to decide whether or not to participate in the study?			
Comments:			
RESPONSIBILITIES OF THE INVESTIGATOR	YES	NO	NA
1. Were updated CVs and adequate training certificates available? (check for GCP training)			
2. Did the investigator have sufficient personnel for the conduct of the study?			
3. Was a record of the pre-trial training for all staff available?			
4. Were the signatures of the staff involved in the study recorded?			
5. Was a participant identification log available?			
6. Was a participant enrolment log available?			
7. Were the facilities at the site adequate for the safe and proper conduct of the trial?			
8. Did the investigator have a contingency plan for medical care in case of emergency?			
9. Were significant trial-related duties and functions delegated to qualified persons documented?			
10. Were all the inclusion criteria and none of the exclusion criteria met by participants?			
11. Was the sixth monthly progress report sent to the RNEC?			
12. Was the sixth monthly progress report sent to the Regulatory Authority?			
13. Were treatment compliance documented for all participants?			
14. Were all SAEs/AEs reported within the specified timelines to the Rwanda FDA			
15. Were all SAEs/AEs reported within the specified timelines to the Sponsor?			
Comments:			
INVESTIGATIONAL PRODUCT	YES	NO	NA
1. Were the records of shipping letters of the investigational product(s) (e.g.: dates, batch numbers, quantities, letters) from the Sponsor to the investigator available?			
2. Were all study medications kept in a securely locked, temperature-controlled area accessible only to authorized			

persons?			
3. Were the records of storage conditions e.g.: temperature control log available?			
3. Were records of the products used available in dosage form? Strength, batch number, expiry date, certificate of Analysis, or other coding that identifies the specific characteristic of the product tested?			
4. Were Valid certificates of analysis (CoA) for the study products available? (Check stability and expiry dates)			
5. Were instructions for handling investigational products and trial-related materials available?			
6. Was the dispensing of the investigational product done according to the protocol/SOPs?			
7. Was dispensing done by a registered Pharmacist or by a person with a dispensing license?			
8. Did the labelling of the investigational products reflect clinical research purposes only?			
9. was there a record of reconciliation at the end of the dispensing?			
10. Were retention samples available?			
11. Were there proof that conditions, as stated in the protocol, have been maintained during shipment and storage of products?			
12. Was drug accountability done?			
13. Were decoding procedures (for blinded trials) available?			
14. Was documentation on the disposal of investigational products available?			
Comments:			
RECORD KEEPING AND DATA HANDLING			
	YES	NO	NA
1. Were records of key trial-related procedures e.g.: CRF, source documents			
2. Was a signature sheet reflecting the signatures and initials of all persons We're authorized to make entries and or corrections on CRFs available.			
3. Were corrections to the CRF/eCRF verified during the inspection done in such a way that it leaves an audit trail?			
4. Were the CRFs verified during the inspection signed, initiated, and dated by the investigator?			
5. Did each page of the case report form identify the participant and the study?			
6. Was there an SOP for data entry/corrections in the CRF?			
7. Was the security of data protected in the eCRF?			
8. Were there any discrepancies between Adverse Events recorded in the source documents and those reported in the			

CRF?			
9. Was follow-up to all the adverse events reported satisfactory?			
10. Were concomitant therapies included in the CRF verified during the inspection?			
Comments:			
QUALITY ASSURANCE	YES	NO	NA
1. Did a quality system exist to ensure compliance with GCP/GLP training?			
2. Were records available for training of staff, including proof of GCP training?			
3. Was there a procedure available for internal monitoring of the quality system?			
4. Was an audit certificate available?			
5. Was there documentation on SOP training?			
General Comments:			
#	Print name	Functions	Signature

Cam F [Signature] [Signature]

APPENDIX-III: FORM OF MEMORANDUM OF GCP INSPECTION FINDINGS



Doc No: DD/PIL/FOM/023

Version:3

Effective Date: 29/10/2024

MEMORANDUM OF GCP INSPECTION FINDINGS

#	ADMINISTRATIVE INFORMATION	
	Clinical trial(s) names	
	Rwanda FDA CTAC number	
	Trial protocol title	
	Trial site address	
	Total number of sites	
	Investigational product(s)	
	Names and contact of the Principal Investigator	
	Date of inspection	
	Number of Findings	

#	GCP Findings details	Comments

Cent *E* *AA* *61*

Guidelines for GCP Inspection of Clinical Trials in Rwanda

#	GCP Findings details		Comments
#	Inspectee' names	Functions	Signature
#	Inspectors' names	Functions	Signature

APPENDIX-IV: TEMPLATE FOR CLINICAL TRIAL SITE GCP INSPECTION REPORT



Doc No: DD/PIL/FMT/031

Version:3

Effective Date: 29/10/2024

CLINICAL TRIAL SITE GCP INSPECTION REPORT

GCP INSPECTION Report N°	
Trial Protocol title:	
Inspected Sites and address	
Type of inspection:	<input type="checkbox"/> Routine <input type="checkbox"/> Triggered <input type="checkbox"/> Follow-up [Tick as appropriate]
Status of Trial Implementation	<input type="checkbox"/> Before commencement <input type="checkbox"/> Ongoing <input type="checkbox"/> Completed trial [Tick as appropriate]
Principal Investigator and site address	
CTAC reference number	
Names of lead Inspector(s):	
Names of Inspector(s):	
Other Clinical Trial Sites not inspected:	
Inspection dates:	
Inspection Report date:	
Due date for reply from Inspectee:	
BACKGROUND OF TRIAL	
Brief description of the Trial <Insert comments as appropriate> Reason and scope of the inspection 2.1.1. Opening meeting <Insert comments as appropriate> 2.1.2 Closing Meeting <Insert comments as appropriate> <Attach attendance sheet for the opening and closing meeting was also signed>	
DOCUMENTS REVIEWED	
Study specific documents reviewed in preparation for the GCP inspection: List the documents, version number and date, amending as applicable, for example: <ul style="list-style-type: none"> • Protocol and amendments version xxx • Investigator Brochure version xxx 	

(Handwritten signatures and initials)

- Rwanda National Ethics Committee (RNEC)/ Rwanda FDA

Site initiation report version xxx
 Safety reports/SUSARs
 Monitoring Plan version xxx
 Site personnel interviewed:

ORGANIZATION AND MANAGEMENT

< Insert summary comments as appropriate >

Facility and Equipment

< Insert summary comments as appropriate >

Management of Investigational Product (s)

< Insert comments as appropriate >

Documentation and Trial Master File

< Insert comments as appropriate >

(Contract and agreements, regulatory approvals, compliance to the trial protocol, investigator brochure, informed consent, ethical clearance, Patient information leaflet, safety reporting forms, progress and close-out reports among others.)

Record Keeping and Data Handling

< Insert comments as appropriate >

(Use of computerized systems, Data integrity in clinical trial, Efficacy and safety assessment data Safety management and reporting

Monitoring and Auditing

< Insert comments as appropriate >

Clinical Laboratory (Management of biological samples, among others)

< Insert comments as appropriate >

Quality assurance

< Insert comments as appropriate >

GCP Inspection Report Summary

< Insert summary of the GCP inspection >

After grading the internal technical committee meeting held on, the graded GCP inspection findings made during the inspection are tabulated below:

#	GCP Inspection Findings	Reference (Regulations, ICH GCP, Guidelines, etc.)	Grading of Findings
1			Critical/Major/Minor
2			

Critical observations:

Major observations:

Minor observations:

An appropriate Corrective and Preventive Action (CAPA) for each documented finding must be provided by the principal investigator, together with the name of the person responsible for implementing the CAPA and the planned date for completion.

(Handwritten signatures and initials)

Grading of GCP Inspection findings

The inspection findings are graded per the criteria as detailed below. Several minor (or major) observations may collectively be considered equal to a major (or critical) observation.

Critical	
Definition	Conditions, practices, or processes that adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Critical observations are considered totally unacceptable.
Possible consequences	Rejection of data and/or legal action required.
Remark	Observation classified as critical may include a pattern of deviations classified as major, bad quality of the data, and/or absence of source documents. Manipulation and intentional misrepresentation of data belong to this group.
Major	
Definition	Conditions, practices, or processes that might adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of GCP principles.
Possible consequences	Data may be rejected and/or legal action required.
Remark	Observations classified as major may include a pattern of deviations and/or numerous minor observations.
Minor	
Definition	Conditions, practices, or processes that would not be expected to adversely affect the rights, safety, or well-being of the subjects and/or the quality and integrity of data.
Possible consequences	Observations classified as minor, indicate the need for improvement of conditions, practices, and processes.
Remark	Many minor observations might indicate a bad quality and the sum might be equal to a major finding with its consequences.

Quality of the data, ethical conduct, and GCP compliance

<Insert summary>

Recommendations for the acceptability of the clinical trial data

<Insert summary>

REPORT APPROVALS

	Names	Position	Date	Signature
1				
2				
3				

APPENDIX-V: FORM FOR CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)/CAPA PLAN OF THE GCP INSPECTION FINDINGS



Doc No: DD/PIL/FOM/024
Version:2
Effective Date: 29/10/2024

CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)/CAPA PLAN OF THE GCP INSPECTION FINDINGS

#	ADMINISTRATIVE INFORMATION							
	Clinical trial(s) names							
	Rwanda FDA CTAC number							
	Trial protocol title							
	Trial site address							
	Total number of sites							
	Investigational product(s)							
	Names and contact of Principal Investigator							
	Date of inspection							
	Number of Findings							
No	GCP inspection findings	Grading	Root cause	Corrective action	Preventive action	Responsible	Timeline	Evidence (DOC1, etc.)
1								
2								
3								
4								
5								
6								

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