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Guideline for GCP Inspections of Clinical Trials

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Guideline for GCP Inspections of Clinical Trials

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Acknowledgement

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1 Introduction (background)

1.1. Clinical Trials (CTs) of any investigational product (IP) in humans must conform to the requirements of Good Clinical Practice (GCP) as provided under the International Council for Harmonisation (ICH) Guideline for Good Clinical Practice E6 (R3) and the WHO guidelines for Good Clinical Practice for trials on pharmaceutical products.

1.2. GCP compliance is to ensure that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trial are reliable.

1.3. The Medicines Control Agency (MCA) may conduct an official review of documents, facilities, records, and any other resources that are deemed by the Agency to be related to the clinical trial and that may be located at the site of the conduct of the trial, at the sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the MCA.

1.4. Such inspections can cover all aspects, as appropriate, for a clinical trial and include but are not limited to, data and information relating to regulatory approvals, ethics review, protocols, case report forms, clinical trial reports, participants and participants data, sponsors, investigators and personnel involved in the trial, and laboratory data.

2 Legal basis

2.1. Part VII, section 45 of the Medicines and Related Products Act, 2014 stipulates that the Agency shall monitor a clinical trial from the beginning to the end in order to ensure that the specific and general conditions subject to which the trial was authorised are being strictly observed by the person conducting the trial and that the trial will achieve its aims and objectives.

2.2. The Medicines and Related Products Regulations, 2020 requires in section 79 that the Agency shall inspect a clinical trial to ensure adequate protection of the general public is provided against the risks or adverse effects from the clinical trial of a medicine, and that the trial is conducted in accordance with the Act and the specific and general conditions of the Regulations.

3 Scope

3.1. This guideline covers GCP inspection of clinical trials including bio-equivalence studies.

3.2. It provides guidance for the preparation and conduct of GCP inspections carried out by MCA and is applicable to all stakeholders involved in clinical trials.

3.3. A GCP inspection can be undertaken before, during or after the conduct of clinical trials and be initiated by the Agency or on request by other medicines regulatory authorities or stakeholders.

3.4. GCP inspections can be part of the verification of applications for marketing authorisation of a medical product or as a follow-up to the granting of a marketing authorisation.

3.5. The Agency selects clinical trials for inspection based on a risk assessment considering a series of different risks, e.g. risks inherent in the trial design, of the investigational product itself, the knowledge of the sponsor, contractors and trial site, including previous inspection outcomes, etc.

Note: If not indicated otherwise in the text, time in days means calendar days.

4 Types and Objectives of GCP Inspections

4.1 Types of Inspection and Inspectees

4.1.1. Inspections can either be routine, triggered in response to a request, complain or application, a re-inspection or as a follow-up. They can be conducted before, during or after completion of the trial and can be announced or unannounced.

4.1.2. **Routine** inspections, which can be conducted more than one time, are announced. They apply usually to ongoing clinical trials, but can also be done before or after completion of the trial.

4.1.3. **Triggered** inspections may be a result of suspected violations of the GCP standards and regulatory requirements. Such types of inspections may be done unannounced without sending a notice and apply usually to ongoing or completed clinical trials.

4.1.4. **Re-Inspections** are conducted following a previous inspection where corrections of deficiencies could not be addressed and the whole inspection needs to be repeated.

4.1.5. **Follow-up** inspections are conducted to verify the implementation of corrective and preventive actions or recommendations.

4.1.6. The **inspectees** are the parties to be inspected and are mainly the Principal Investigator and team and/or the Sponsor and/or a Contract Research Organisation (CTO), but can also be manufacturer of investigational products (IPs), hospital pharmacy, laboratory or a supplier of computerised systems.

4.2 Inspection Objectives

4.2.1. GCP Inspections may either be protocol-specific or of systems. System inspections could have a particular focus like e.g. informed consent, investigational products, pharmacovigilance, biological samples, monitoring, etc.

4.2.2. Objectives of **protocol-specific** inspections are:

- To safeguard the rights, safety and well-being of trial participants;
- To verify the quality and integrity of the clinical trial data submitted to the Regulatory Authorities;
- To assess compliance to the protocol, applicable regulations, guidelines and standard operating procedures.

4.2.3. Objectives of **systems** inspections are:

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

4.3 Inspection team and duration

4.3.1. An inspection needs to be conducted by a team of at least two inspectors who have appropriate qualifications and experience in inspecting clinical trials. The Agency is responsible for the appointment of the inspection team.

4.3.2. The team will have a lead inspector responsible for coordinating the inspection, collating the information from team members, and finalising the inspection report.

4.3.3. External experts or inspectors from other medicines regulatory authorities may also be asked to assist during an inspection if needed or requested for. They will be accompanied by an MCA appointed inspector and may also ask questions, access documents and data, and provide input for inspection reports.

4.3.4. An inspection usually takes place over three (3) to five (5) days, but sometimes not as long and sometimes longer, depending on the trial and system inspected.

4.3.5. During an inspection, the inspectors will verify that the trial is initiated, managed and conducted in compliance with the granted authorisation, the approved trial protocol, governing law and good clinical practice (GCP). For the application and authorisation of clinical trials to be conducted in The Gambia, import of investigational products and reporting requirements refer to the MCA *Guideline for Clinical Trials in Humans*.

4.3.6. In accordance with the MCA Reliance Policy, the Agency accepts GCP inspection reports from other national medicines control authorities for consideration and, where applicable, regulatory actions.

5 GCP Inspection Preparation

5.1 Notice of Routine GCP Inspection

5.1.1. The Agency will usually send a notice in writing within 30 days but not later than 14 days prior to the proposed start date of the GCP Inspection.

5.1.2. Depending on the cause and scope, the inspection could also happen unannounced or at very short notice.

5.1.3. The Agency will send the notice and an agenda to the sponsor or sponsor's representative and the parties to be inspected (inspectees). Sometimes the date will be agreed in advance with the sponsor, principal investigator or CRO representative, as applicable.

5.1.4. The letter of notification will detail

- the time and place of the inspection;
- planned areas for inspection;
- rooms and facilities needed; and
- list of documentation and data given access to.

6 Conduct of GCP Inspection

6.1 Opening Meeting

6.1.1. An inspection usually starts with an opening meeting, where the parties are introduced and the inspectors will describe the methods, procedures and references for the inspection.

6.1.2. The inspectors will confirm the agenda and that the resources, essential documents and facilities required for the GCP Inspection are available.

6.1.3. The inspectee would be required to present a general overview of the clinical trial and provide information pertaining to e.g. trial participant recruitment, informed consent process, investigational product management, safety reporting, biological sample handling, etc.

6.1.4. Inspections will usually comprise interviews, a review of rooms and facilities, and a review of data and documentation either on paper or electronic formats.

6.2 Interviews with Inspectees

6.2.1. Inspectors will interview sponsor and/or study staff to determine how the clinical trial is initiated, managed and/or conducted.

6.2.2. At the clinical trial site, questions relating to organisation and study staff, Ethics Committee, MCA and other medicines regulatory authorities (if applicable), participant recruitment, informed consent, source documentation and case report forms, pharmacy services (if applicable) and investigational product management, biological samples handling, record keeping and reporting of data including safety reporting, monitoring, etc. may be asked.

6.2.3. At the sponsor site, questions relating to the insurance for participants, quality management, data management, statistical analysis, public information, etc may be asked.

6.3 Visit to Site Facilities

6.3.1. The Inspectors will visit facilities used to conduct the clinical trial being inspected and assess them against the trial records.

6.3.2. Depending on the activities undertaken by the site, areas such as a clinic or other health facility, pharmacy (if applicable) and laboratories should be available. It is expected that they have the required number of beds (if applicable), appropriate equipment and instruments, adequate location for handling and storage of investigational products (IPs) with controlled access, adequate space for the informed consent procedures, sufficient and adequate space for maintenance of participant records and essential documents, adequate facilities for sample management and storage, appropriate laboratory (if applicable), and other services as appropriate.

6.3.3. At the sponsor's site inspectors will visit the electronic hard and soft ware for data management and statistical analysis, laboratory, archives, etc.

6.4 Document Review

6.4.1. The inspectors will review the maintenance and quality of the essential documents required by GCP guidelines and verify against the documents submitted to the Agency.

6.4.2. They may collect randomly records from enrolled participants and verify the CRF entries against the source documents.

6.4.3. At the sponsor site inspectors will review the essential documents including monitoring and audit documentation, safety documentation, master randomisation list, communication between sponsor and site(s), etc.

6.5 Closing Meeting

6.5.1. The inspection is completed by a closing meeting at which the inspectors go through their observations to ensure that results of the GCP Inspection are clearly understood.

6.5.2. The inspectors will present a Summary Inspection Report indicating the findings and grading and recommended actions, to be signed by an inspectee and an inspector. These summary report and observations are preliminary and serve as the basis for the inspection report.

6.5.3. The GCP inspection findings will be graded as critical, major or minor as follows:

Critical:
Conditions, practices or processes that adversely affect the rights, safety or wellbeing of the participants and/or the quality and integrity of data. Critical findings are considered totally unacceptable with the possible consequences of rejection of data and/or requirement of legal action.

Observations 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:
Conditions, practices or processes that might adversely affect the rights, safety or well-being of the participants and/or the quality and integrity of data. Major findings are direct violations of GCP principles with the possible consequences that data may be rejected and/or legal action may be required.

Observations classified as major, may include a pattern of deviations and/or numerous minor observations.

Minor:
Conditions, practices or processes that would not be expected to adversely affect the right, safety or well-being of the subjects and/or the quality and integrity of data, but indicate the need for improvement of conditions, practices and processes.

Many minor observations might indicate a bad quality and the sum might be equal to a major finding with its consequences.

6.5.4. The inspector will inform the inspectee that the inspection report and where applicable, a plan for corrective and preventive actions (CAPA), can be expected usually within 20-30 days from the last inspection day, depending on the gravity of the observations.

7 Inspection Report and Closure

7.1. Once the GCP Inspection has been completed, the Agency will send an inspection report and where applicable, a plan for corrective and preventive actions

(CAPA) to the sponsor or sponsor's representative and inspected parties usually within 20-30 days from the date of the last GCP inspection day.

7.2. The content of the report will detail the time and place of the inspection, describe observations and summarise deviations from appliable law, guidelines, trial protocols and own procedures, classified as 'critical', 'major' or 'minor' (see above).

7.3. Deviations will be classified based on the specific circumstances during the individual inspection and will be evaluated relative to the risk the deviations pose to the safety and integrity of the trial participants and the quality of the data.

7.4. The assessment of the gravity of the deviations is reflected in the report's conclusion.

7.5. For deviations classified as major or critical, a corrective and preventive actions (CAPA) plan will be provided that contains entries by the inspectors and requests the inspectee to include information about the likely root cause of the deviation, the corrective and preventive actions and timelines for implementation of these CAPA.

7.6. The response and, where applicable, CAPA plan are usually expected to be sent to the Agency within 30 days from submission date of report and plan.

7.7. The inspectors will review the CAPA plan, where applicable, and assess if it can be accepted. If the inspectors do not accept the plan, communication will continue until an acceptable plan is reached.

7.8. If the plan is accepted, the inspection is closed, and the implementation can be verified at a future follow-up inspection.

7.9. The Agency will send a GCP inspection closing letter within 40 days from date of receipt of the response including the CAPA plan. It is important to note that the letter should not be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection.

7.10. In case of serious breaches regulatory actions can be taken immediately such as imposing a fine, the revocation or suspension of the authorisation to conduct the clinical trial or rejection of data submitted with the application for a marketing authorisation of the product.

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: www.mca.gm.

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

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, analysed and accurately reported according to the protocol,

sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Contract Research Organisation (CRO)
A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial- related duties and functions.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance, that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of trial subjects are protected.

Inspection
The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial that may be located at the site of the trial, at the sponsor's and/or contract research organisations (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

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 protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

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

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

Further definitions are provided in the ICH-GCP-Guideline.

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