FDA GCP INSPECTIONS

2023

Outline

- GCP Inspection Framework
- GCP Inspections Mandate
- Criteria, Type, and Process
- GCP Inspections conducted
- Classification of Findings
- Termination and Findings
- GCP Site Inspections
- Regulatory actions/sanctions

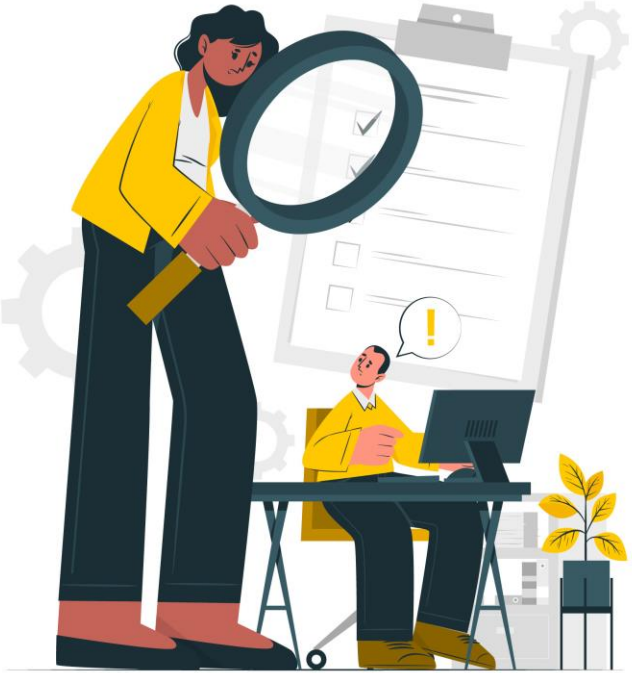
OBJECTIVES OF GCP INSPECTIONS

- Safeguard the rights, safety and well-being of trial participants.
- Verify the quality and integrity of the clinical trial data submitted to the Regulatory Authority.
- Assess compliance to protocol and applicable regulations, guidelines and standard operating procedures for clinical trials.

GCP Inspections

- **GCP inspection by the regulatory authority(ies)** – official review of documents, facilities, records, and any other resources deemed by the authority(ies) to be related to the clinical trial and may be located at the trial site, sponsor's and/or CRO's facilities or at any other establishment deemed appropriate by the regulatory authority(ies).

Scope of GCP Inspections



- Before, during, or after the conduct of clinical trials
- As part of the verification of applications for Market Authorization
- Clinical trials in all phases are inspected by FDA.

Regulatory Actions/Sanctions

Timeline to address infractions

Warning letters

Administrative fines

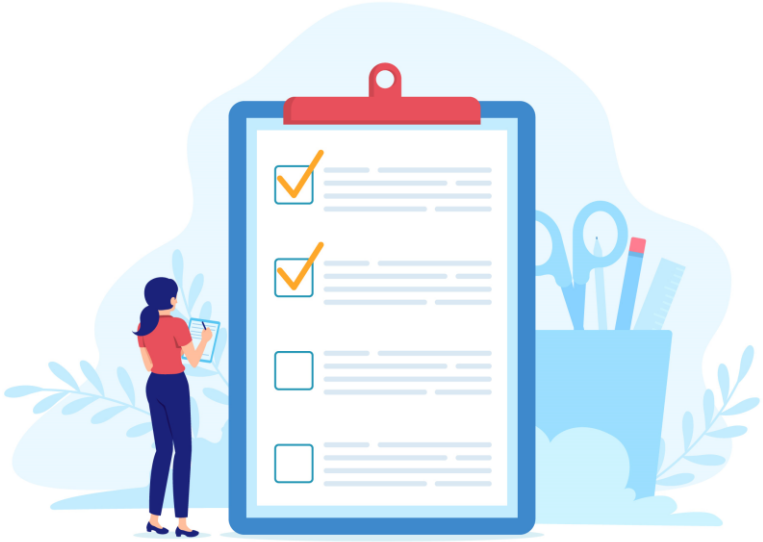
Suspension of study

End study/recall all IPs

Dissociation of study data/results

Criteria For Site Inspections

- Phase of the clinical trial
- Nature of the investigational product
- Population under study
- Market authorization status of the IP
- Capacity of the trial site
- FDA’s experience with Sponsor/Principal Investigator (PI) with respect to compliance with GCP requirements.



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Types of Inspections

Pre-trial	• To ensure/verify the site's capacity to host trial
Routine/Announced	• Conducted during the life cycle of the study to ensure compliance • PI/Sponsor given prior notice to prepare
Unannounced/For-cause	• Conducted when there is suspicion or reason to investigate non-compliances going on in the study • PI/Sponsor not given prior notice
Follow-up/Verification	• Usually to ensure that directives given are being complied with on site/CAPA put in place after an initial inspection

The Inspection Process

- **Preparation**
  - Agree on inspection date with PI (announced/ routine)
  - Request for documents
  - Inspection plan, review of trial related documents such as protocol, IB, progress reports, SAEs, etc.

- Opening meeting (Introduction and discussion of inspection plan)
- Inspection
- Closing/ Exit meeting (Discussion of inspection findings)

Send report (prepared & feedback given within 21 working days)

Timeline given for implementation of recommendations and / or regulatory sanctions and penalties

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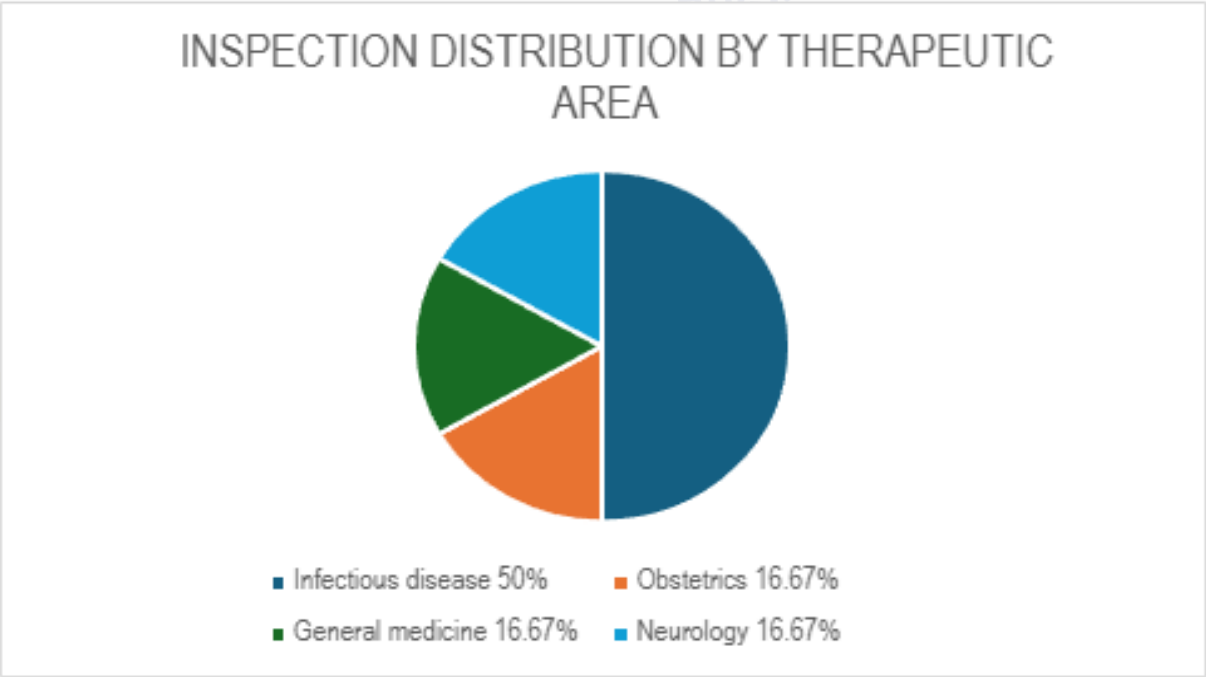
GCP INSPECTIONS (2010-2023)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Number of Trials	4	1	2	12	12	6	6	3	3	4	1	9	8	6

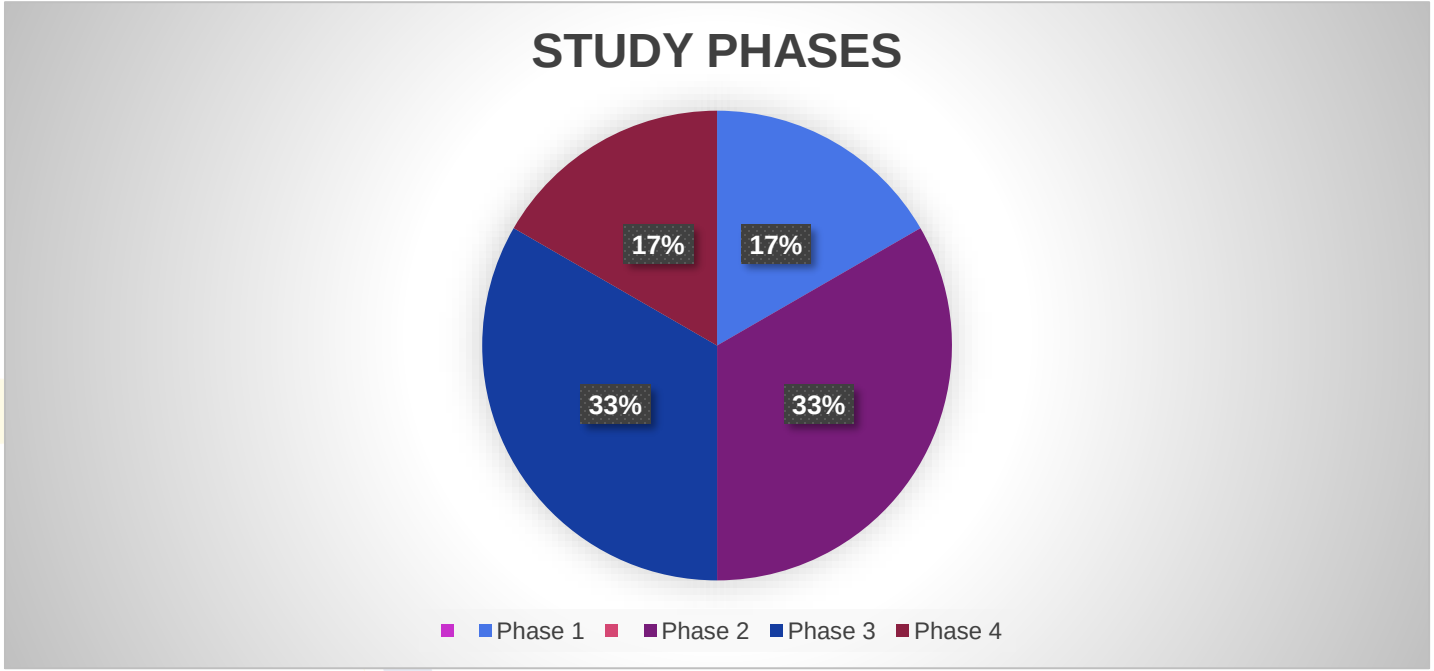
GCP Inspections (2023)

Distribution by Therapeutic Area



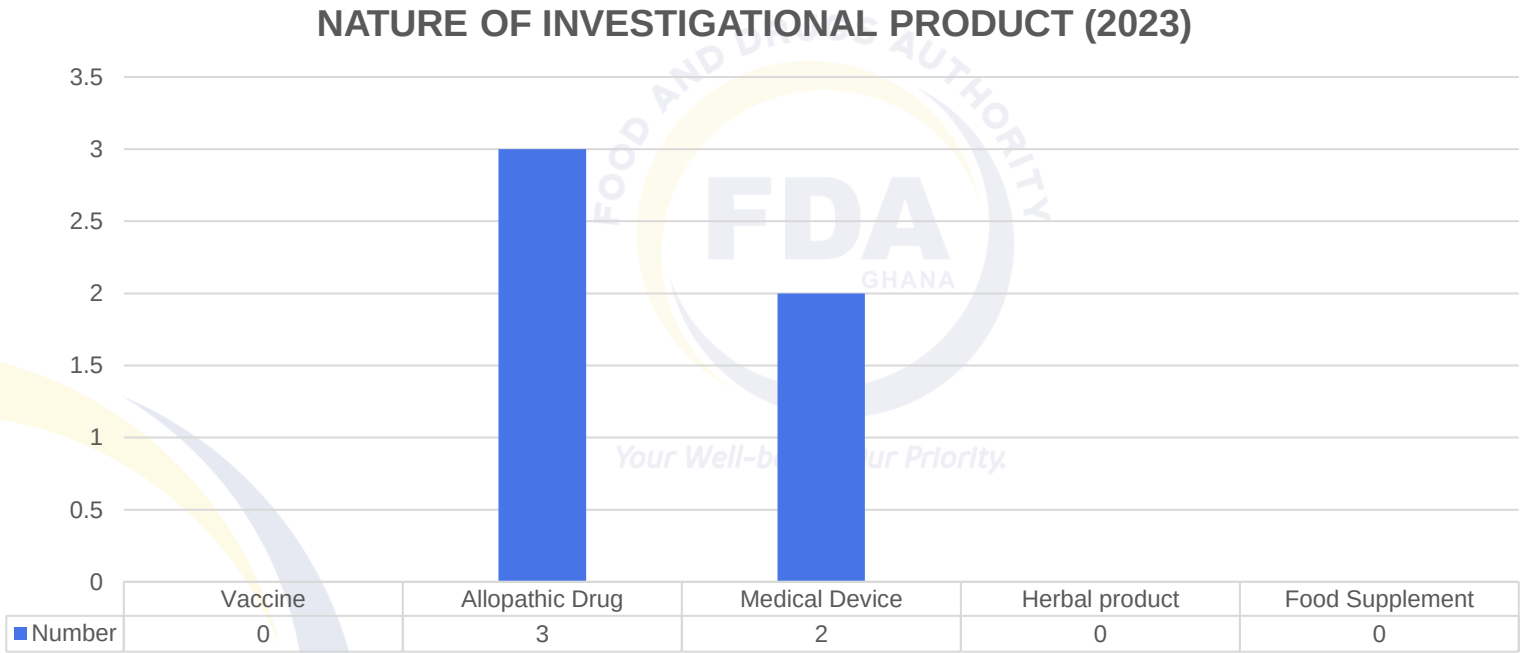
GCP Inspections (2023)

Distribution by Phase of Clinical Trial



GCP Inspections (2023)

Distribution by Type of Investigational Product



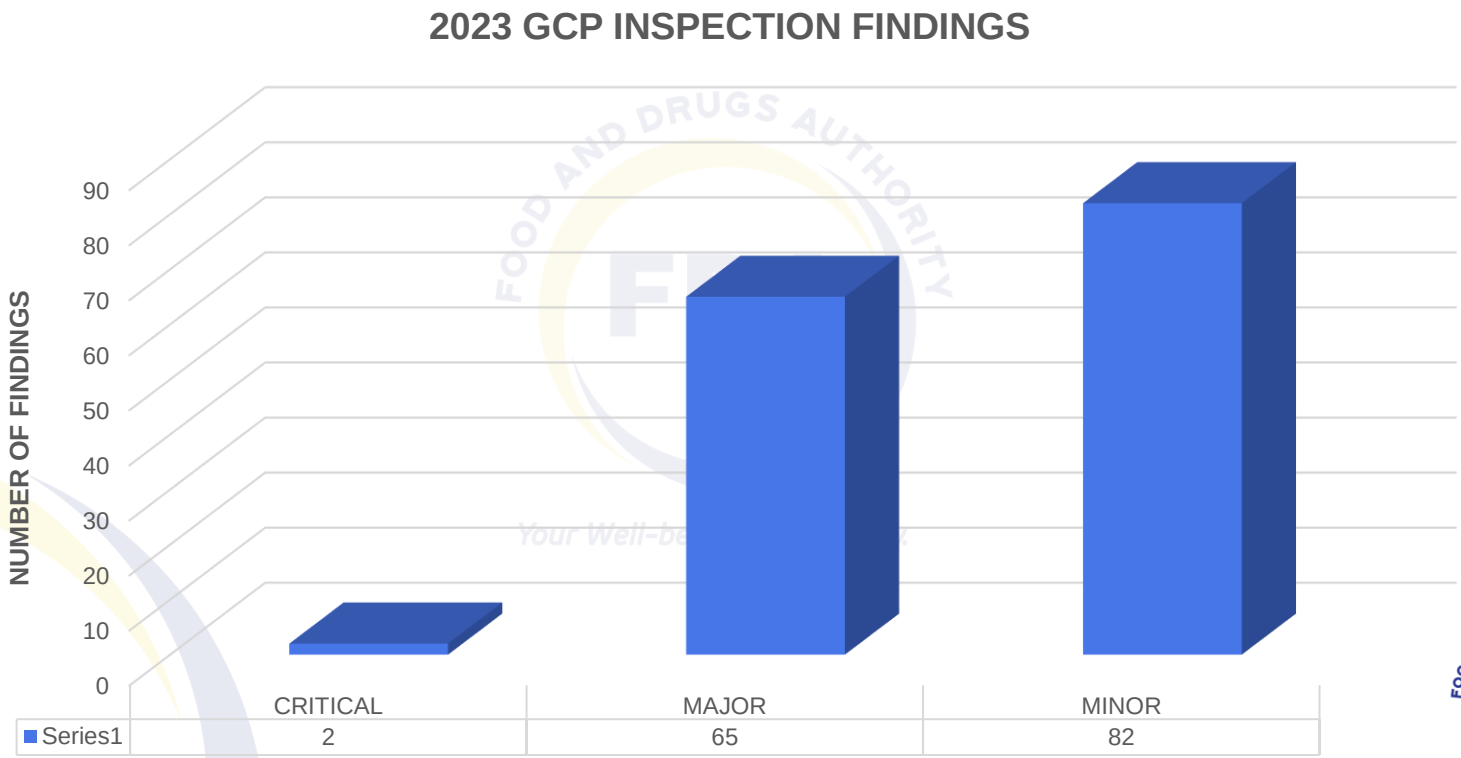
Classification of GCP Inspection Findings

CRITICAL
Conditions, practices or processes that adversely affect the rights, safety or well-being of the trial participants and/or the quality and integrity of data.

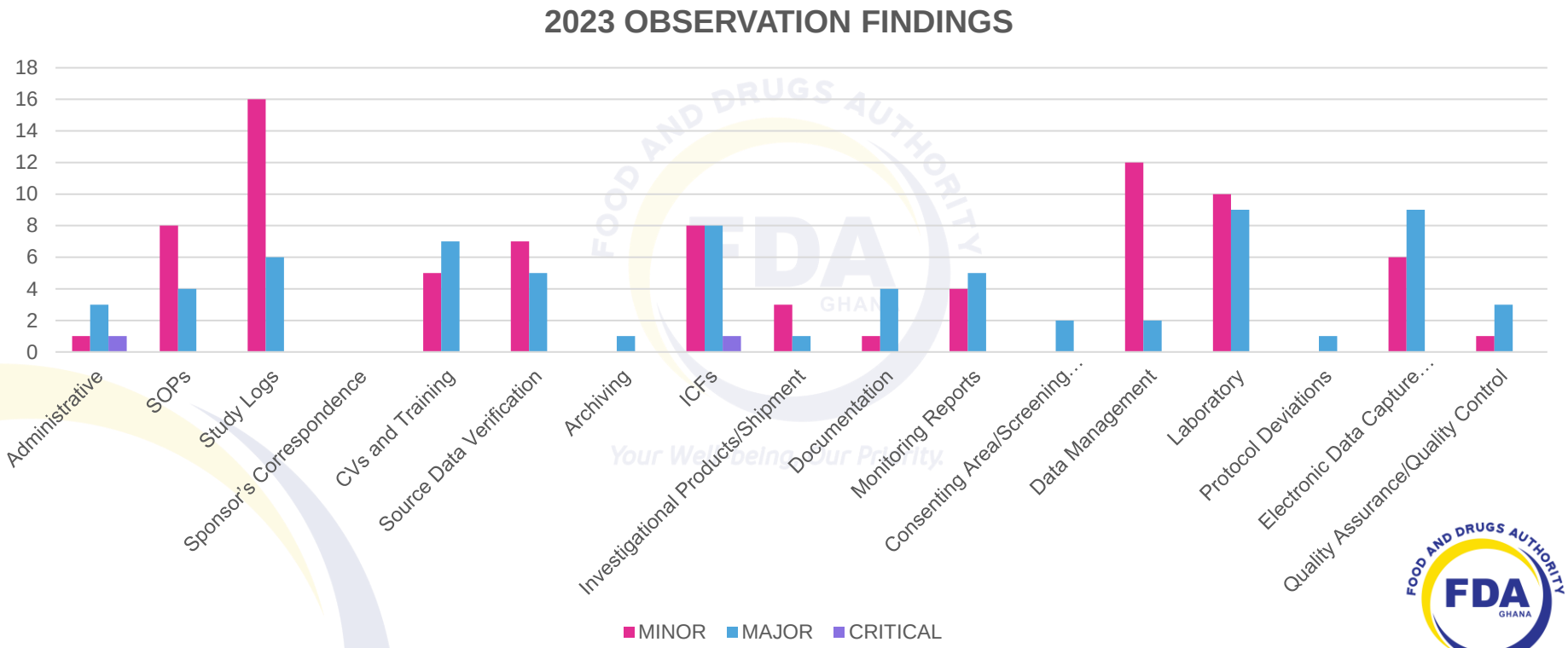
MAJOR
Conditions, practices or processes that might adversely affect the rights, safety or well-being of the trial participants and/or the quality and integrity of data.

MINOR
Conditions, practices or processes that would not be expected to adversely affect the rights, safety or well being of the trial participants and/or the quality and integrity of data.

Classification of GCP Inspection Findings CNTD.



GCP Inspection Observations



Study Termination / Suspension

- **Study termination**

None of the clinical trials were terminated through GCP Inspections.

- **Study suspension**

One of the studies was suspended because it was found not to be in compliance with GCP as per the FDA's Guidelines and ICH E6R1 Guidelines at the time of the inspection.

GCP Site Inspections (2023)

The inspection took place at the following sites:

1. Accra Psychiatric Hospital
2. Mercy Women's Hospital
3. Korle-Bu Teaching Hospital
4. University of Health and Allied Sciences SPH, Hohoe Campus
5. Kumasi Centre for Collaborative Research in Tropical Medicine
6. Agogo Presbyterian Hospital
7. Tepa Government Hospital
8. Dunkwa Government Hospital

Conclusion

- Sponsors and investigators play an important role in maintaining the quality of a clinical trial.
- Implement systems with procedures that assure the quality of every aspect of the clinical trial.
- If it was never documented, it was never done!
- It is always better to prepare, than repair!

THANK YOU

ANY QUESTIONS PLEASE?

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