



Your Well-being, Our Priority.

FDA GCP INSPECTIONS

2022

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.

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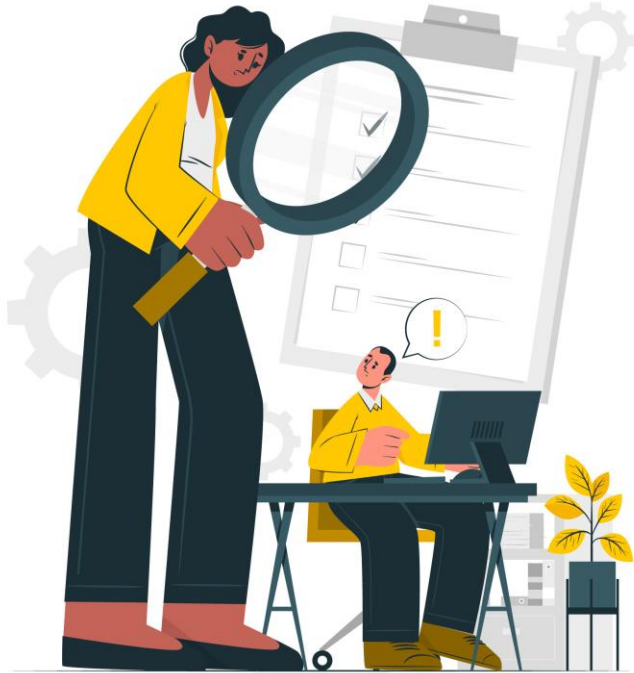


GCP Inspections

- **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.



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.

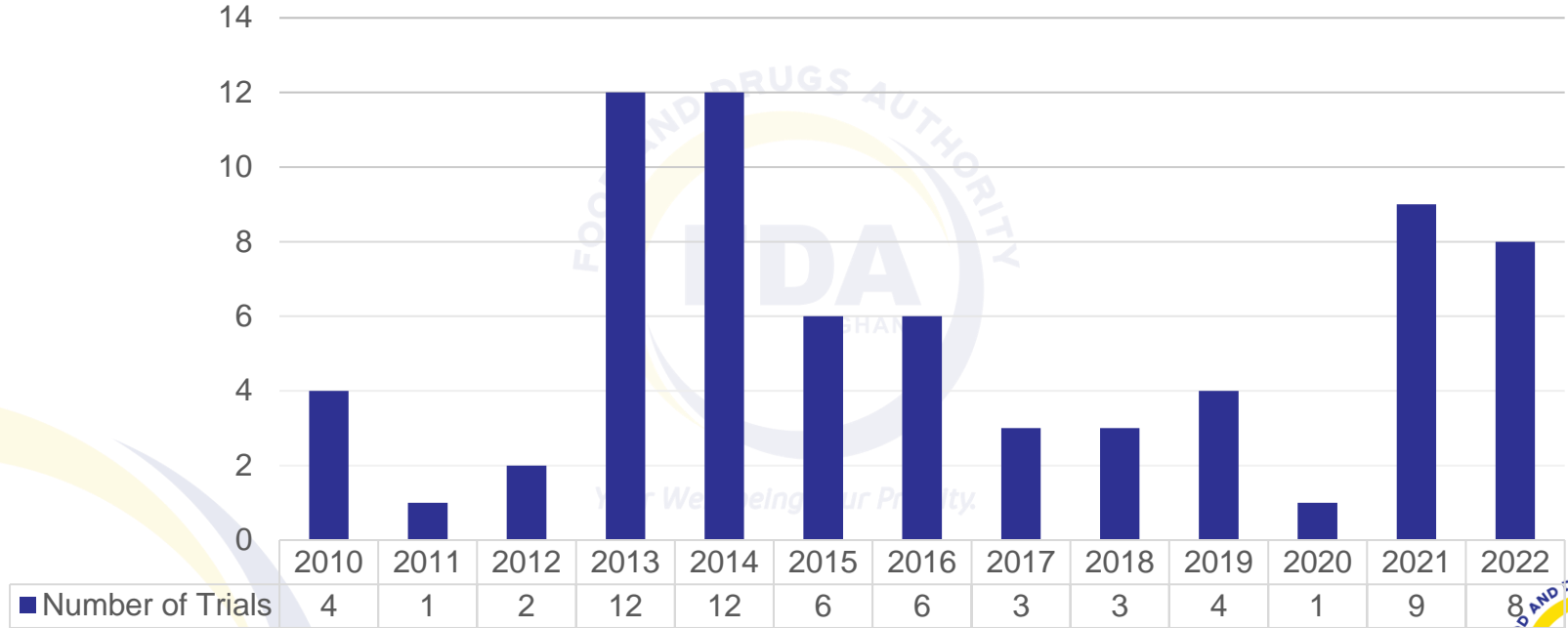


- Opening meeting (Introduction and discussion of inspection plan)
- Inspection
- Closing/ Exit meeting (Discussion of inspection findings)



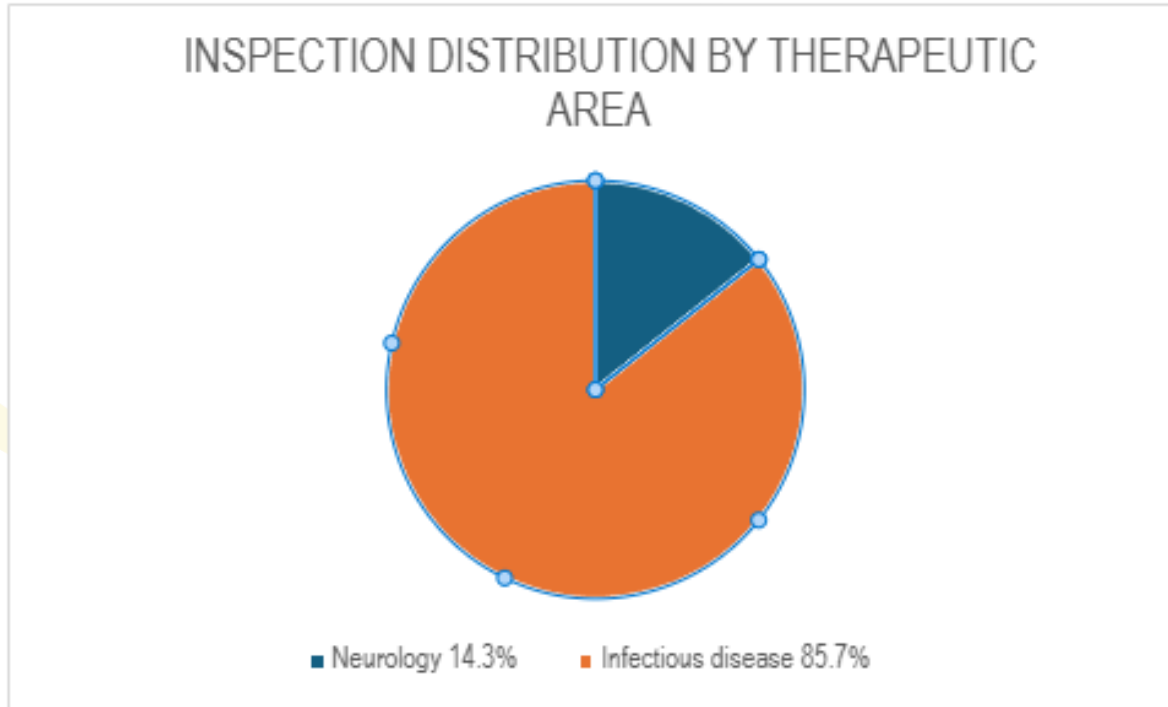
- Send report (prepared & feedback given within 21 working days)
- Timeline given for implementation of recommendations and / or regulatory sanctions and penalties

GCP INSPECTIONS (2010-2022)



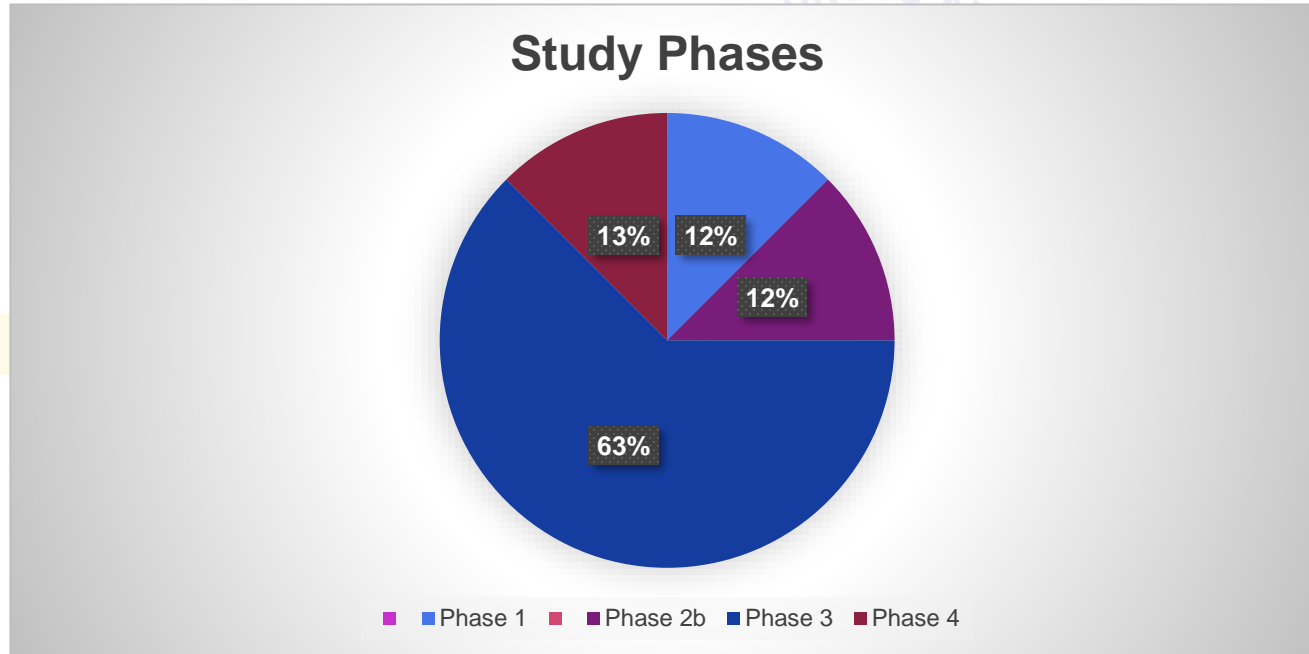
GCP Inspections (2022)

Distribution by Therapeutic Area



GCP Inspections (2024)

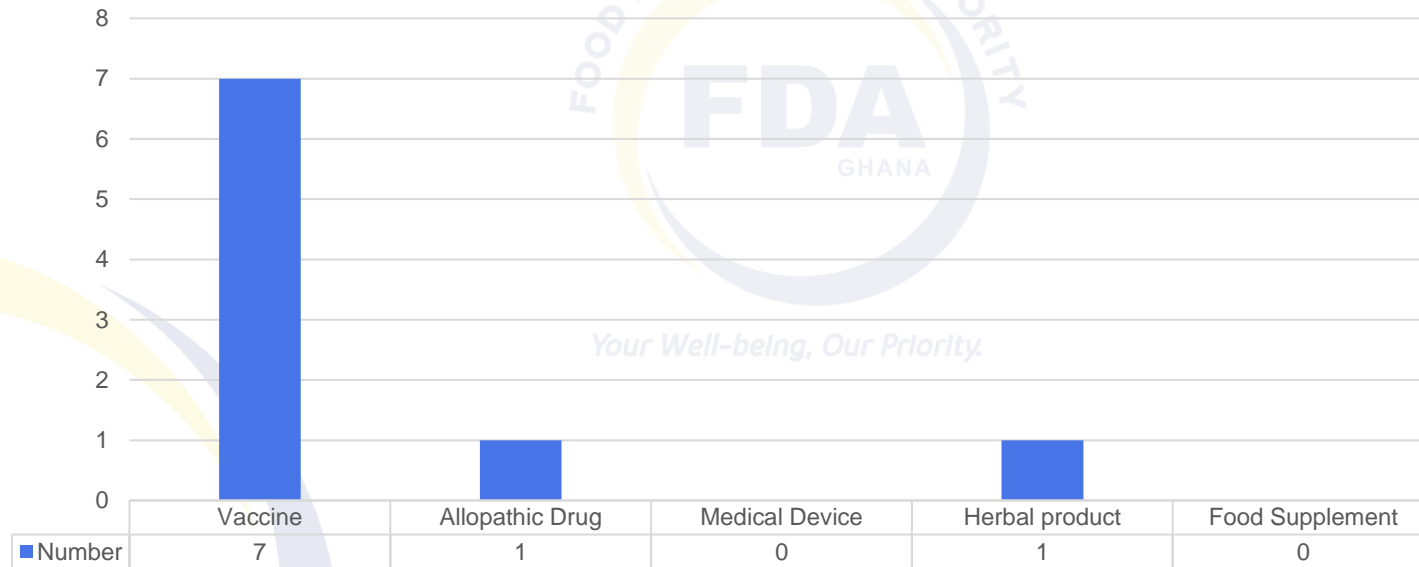
Distribution by Phase of Clinical Trial



GCP Inspections (2022)

Distribution by Nature of investigational Product

NATURE OF INVESTIGATIONAL PRODUCT (2022)



Classification of GCP Inspection Findings

CRITICAL

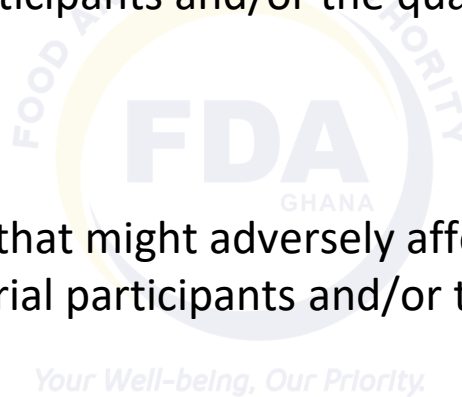
Conditions, practices or processes that adversely affect the rights, safety or well-being of the trial participants and/or the quality and integrity of data.

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.

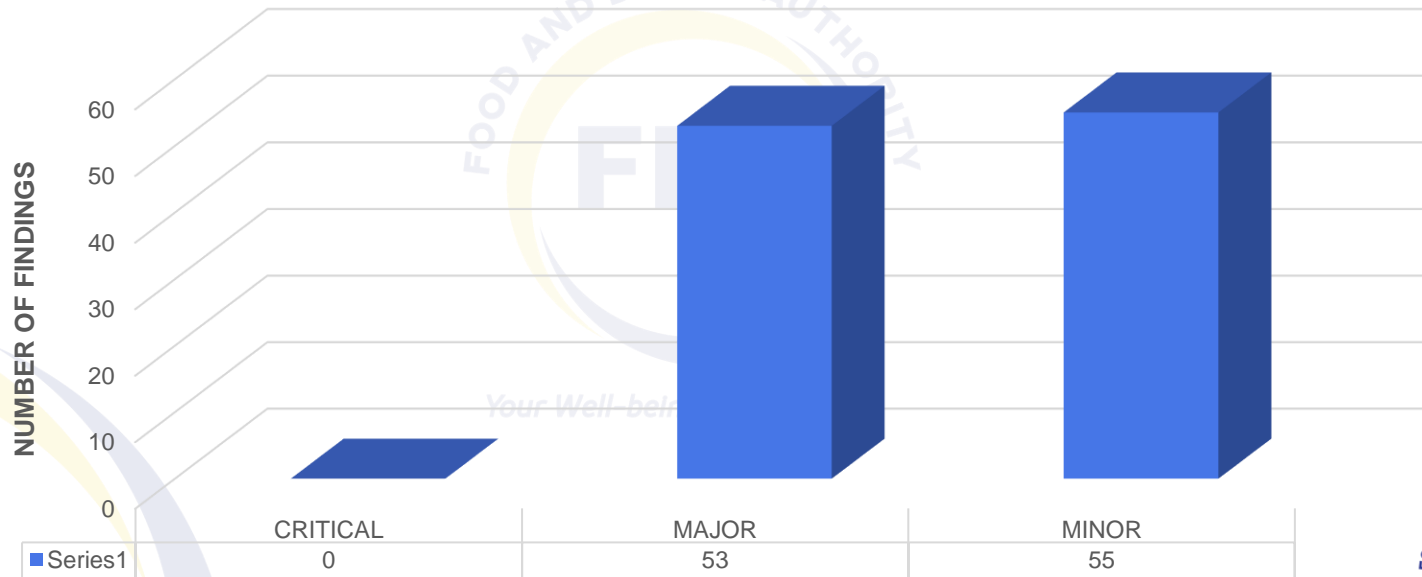
MINOR

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.



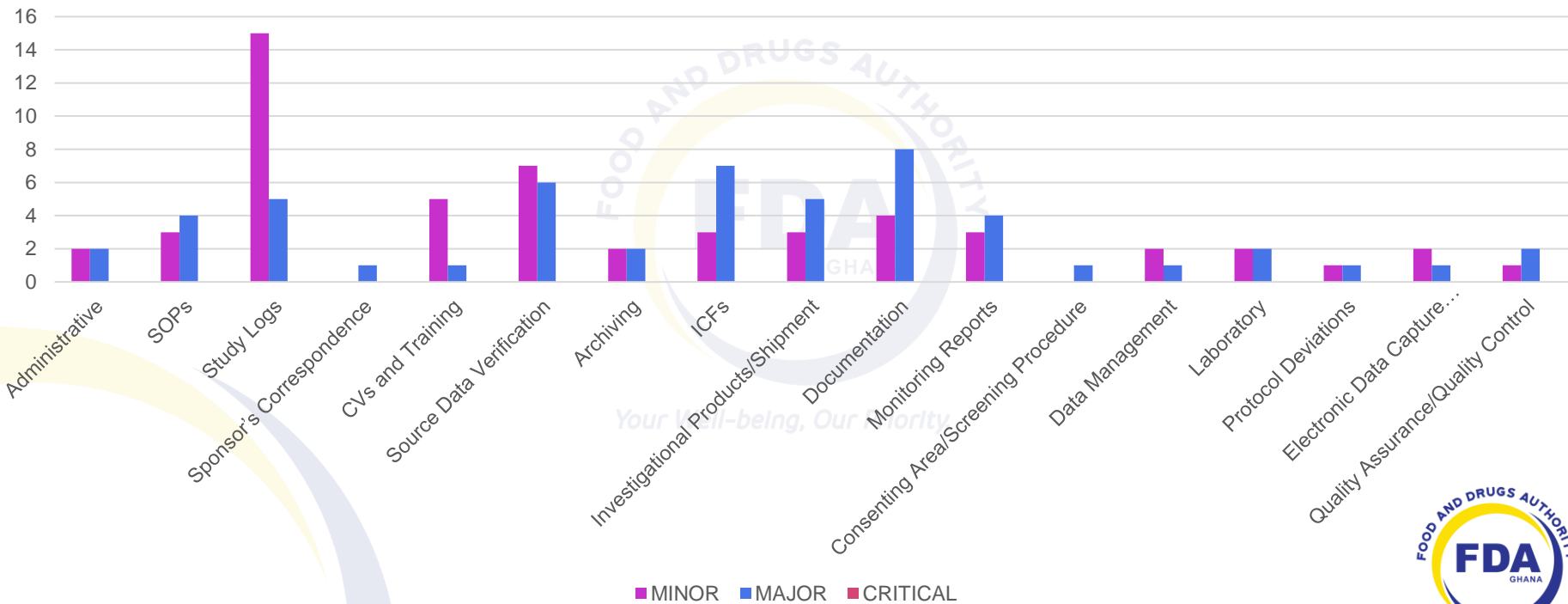
Classification of GCP Inspection Findings CNTD.

2022 GCP INSPECTION FINDINGS



GCP Inspection Observations

2022 Observation Findings



Study Termination / Suspension

➤ Study termination

None of the clinical trials were terminated through GCP Inspections.

➤ Study suspension

None of the studies were suspended. However, it was recommended that the Sponsor and the PIs take immediate steps to resolve all findings made during the inspection to improve the study's compliance as per the FDA's Guidelines and ICH E6R1 Guidelines at the time of the inspection.



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GCP Inspection Sites (2022)

The inspection took place at the following sites:

1. Kintampo Health Research Centre
2. Navrongo Health Research Centre
3. Kumasi South Hospital
4. Kwame Nkrumah University of Science and Technology
5. Komfo Anokye Teaching Hospital
6. Dodowa Health Research Centre



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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