



Your Well-being, Our Priority.

FDA GCP INSPECTIONS

2021

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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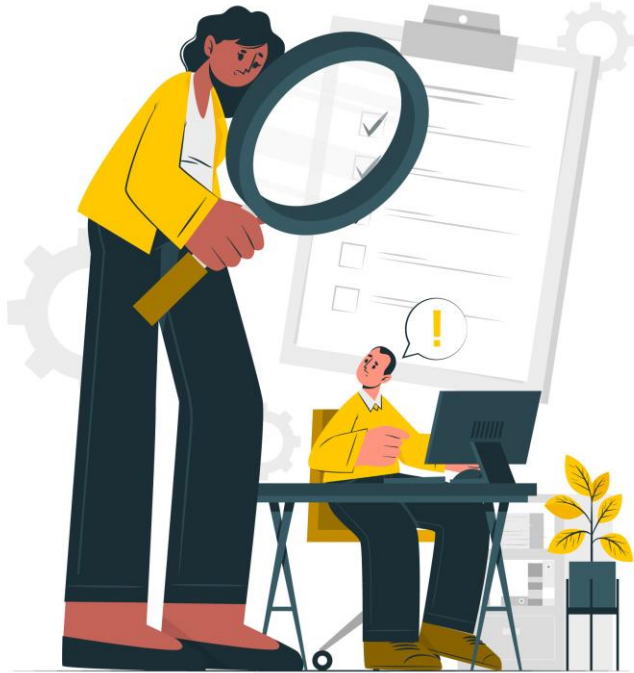


GCP Inspections

- **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

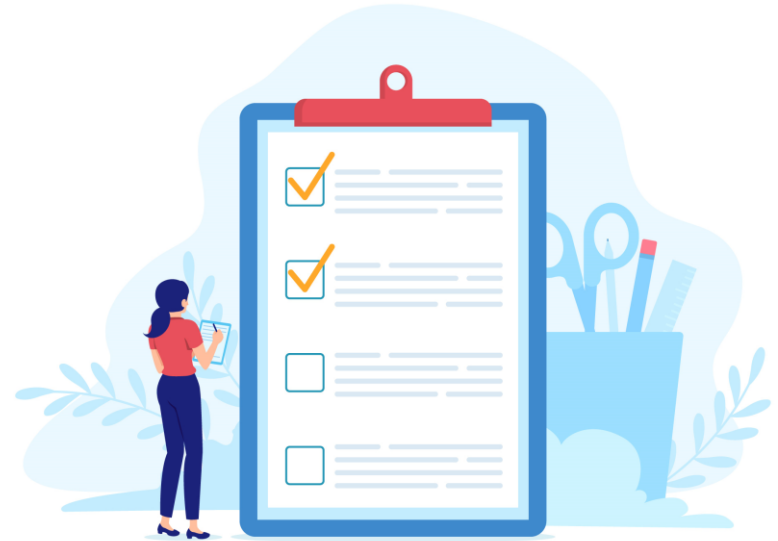
Nature of the investigational product

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.

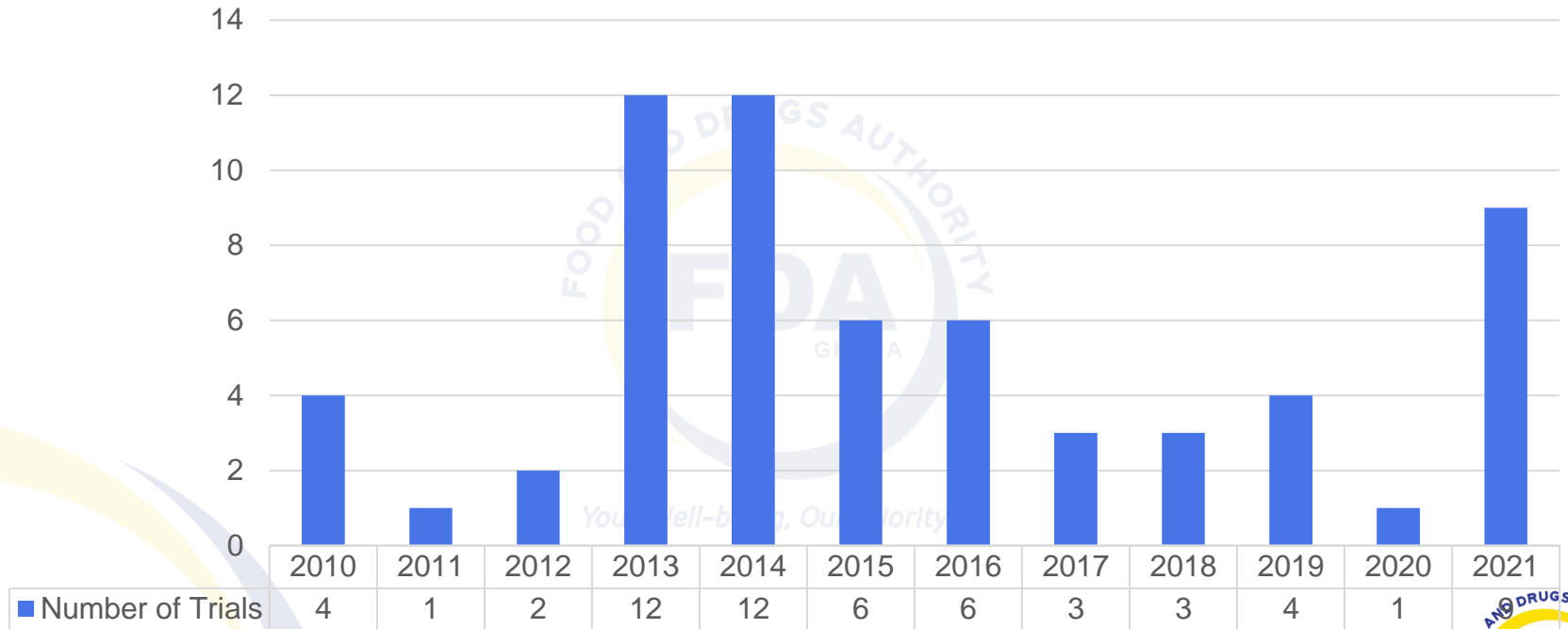


- Opening meeting (Introduction and discussion of inspection plan)
- Inspection
- Closing/ Exit meeting (Discussion of inspection findings)



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

GCP INSPECTIONS (2010-2021)

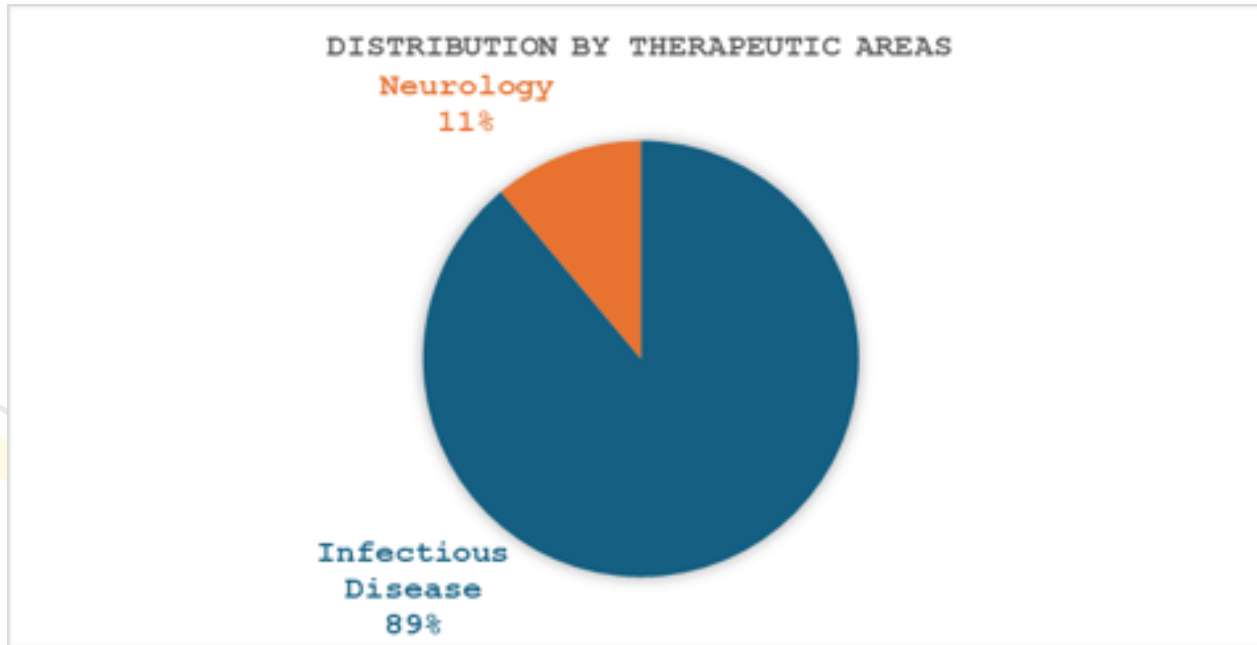


■ Number of Trials



GCP Inspection Distribution (2021)

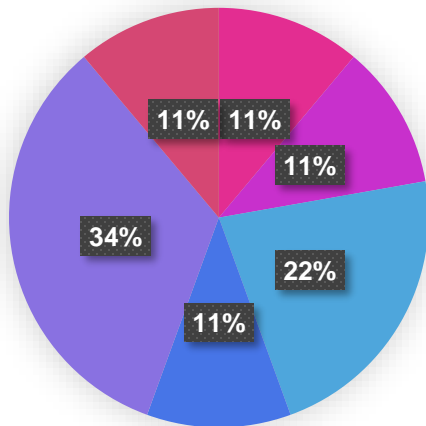
Distribution by Therapeutic Area



GCP Inspection Distribution (2021)

Distribution by Phase of Clinical Trial

Study Phases

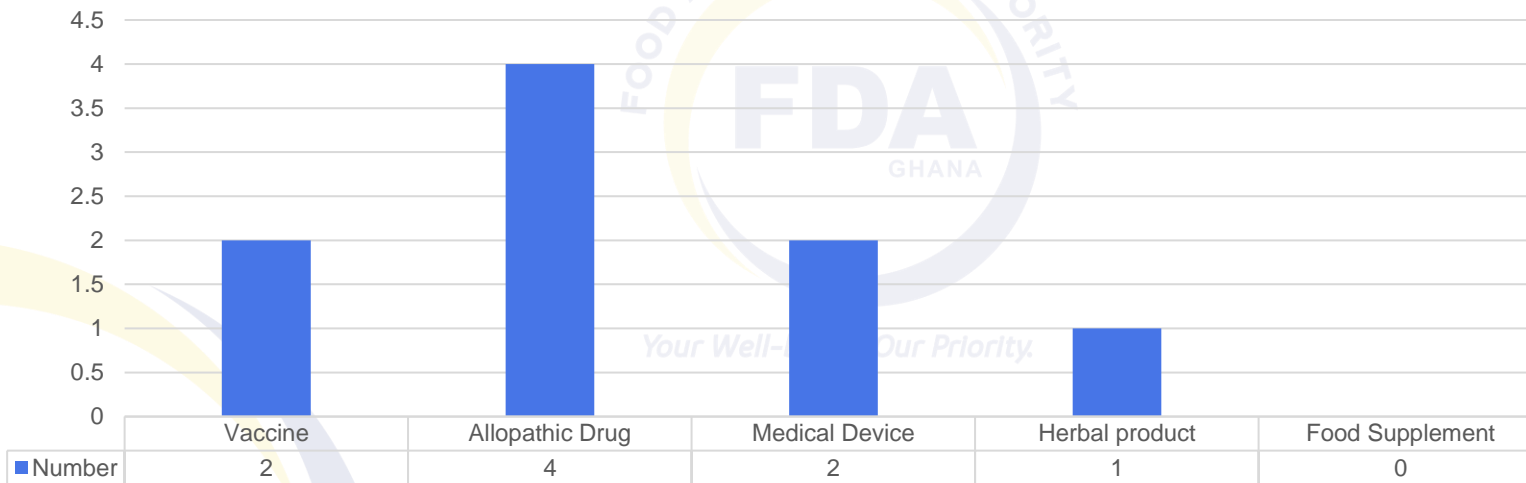


■ Pilot ■ Phase 1b ■ Phase 2 ■ Phase 2b ■ Phase 3 ■ Phase 4

GCP Inspection Distribution (2021)

Distribution by Nature of Investigational Product

NATURE OF INVESTIGATIONAL PRODUCT (2021)



Classification of GCP Inspection Findings

CRITICAL

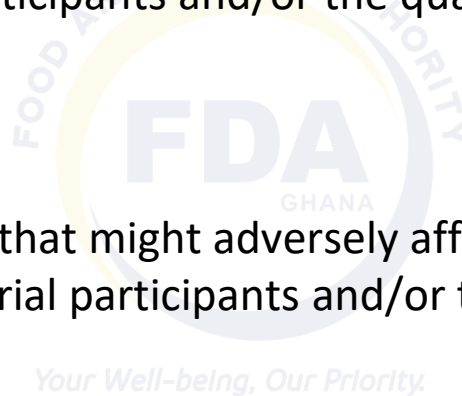
Conditions, practices or processes that adversely affect the rights, safety or well-being of the trial participants and/or the quality and integrity of data.

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.

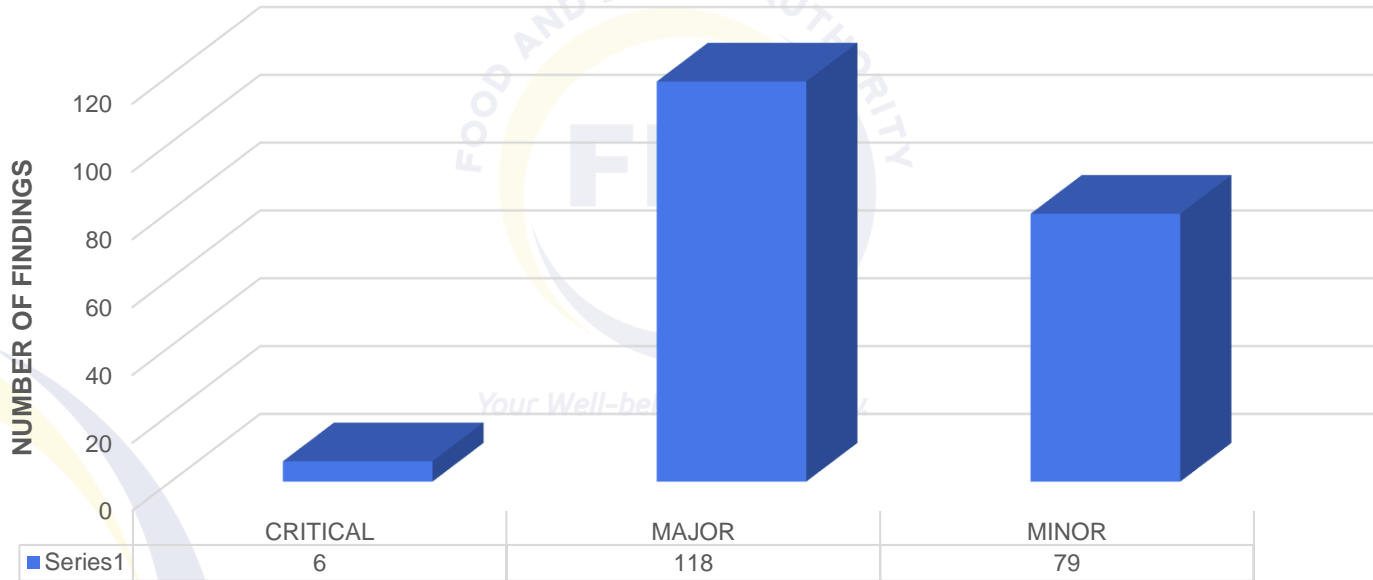
MINOR

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.



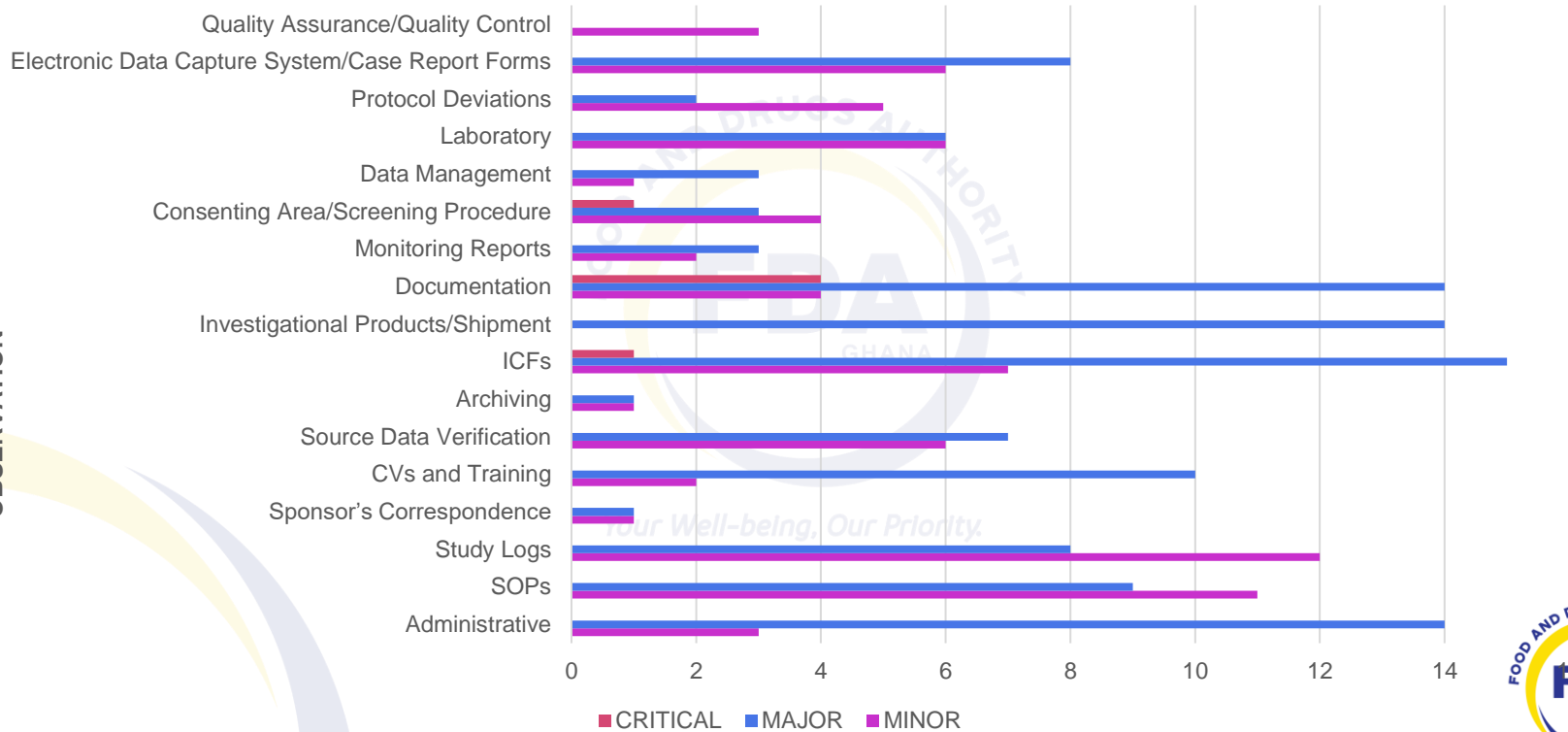
Classification of GCP Inspection Findings CNTD.

2021 GCP INSPECTION FINDINGS



GCP Inspection Observations

OBSERVATION



Study Termination / Suspension

➤ Study termination

None of the clinical trials were terminated through GCP Inspections.

➤ Study suspension

None of the studies were suspended however there were some recommendations to resolve the findings during the inspection to improve the site's compliance with GCP as per the FDA's guidelines and ICH E6 R2 guidelines.

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GCP Inspection Sites (2021)

The inspection took place at the following sites:

1. Komfo Anokye Teaching Hospital
2. Kumasi Centre for Collaborative Research in Tropical Medicine
3. Kintampo Health Research Centre
4. University for Development Tamale Teaching Hospital studies
5. Salaga District Hospital
6. Noguchi Memorial Institute for Medical Research
7. Kwame Nkrumah University of Science and Technology (KNUST)
8. Saint Francis Xavier Hospital
9. Agogo Trial Center
10. KNUST-IVI Collaborating Center
11. Madina Polyclinic – Kekele



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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