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# **FDA GCP INSPECTIONS**

# **2020**

# 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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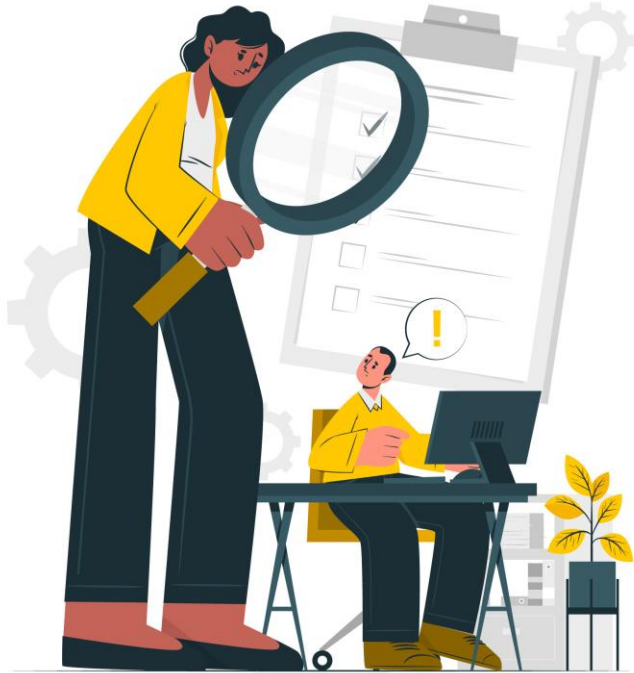


# GCP Inspections

- **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.

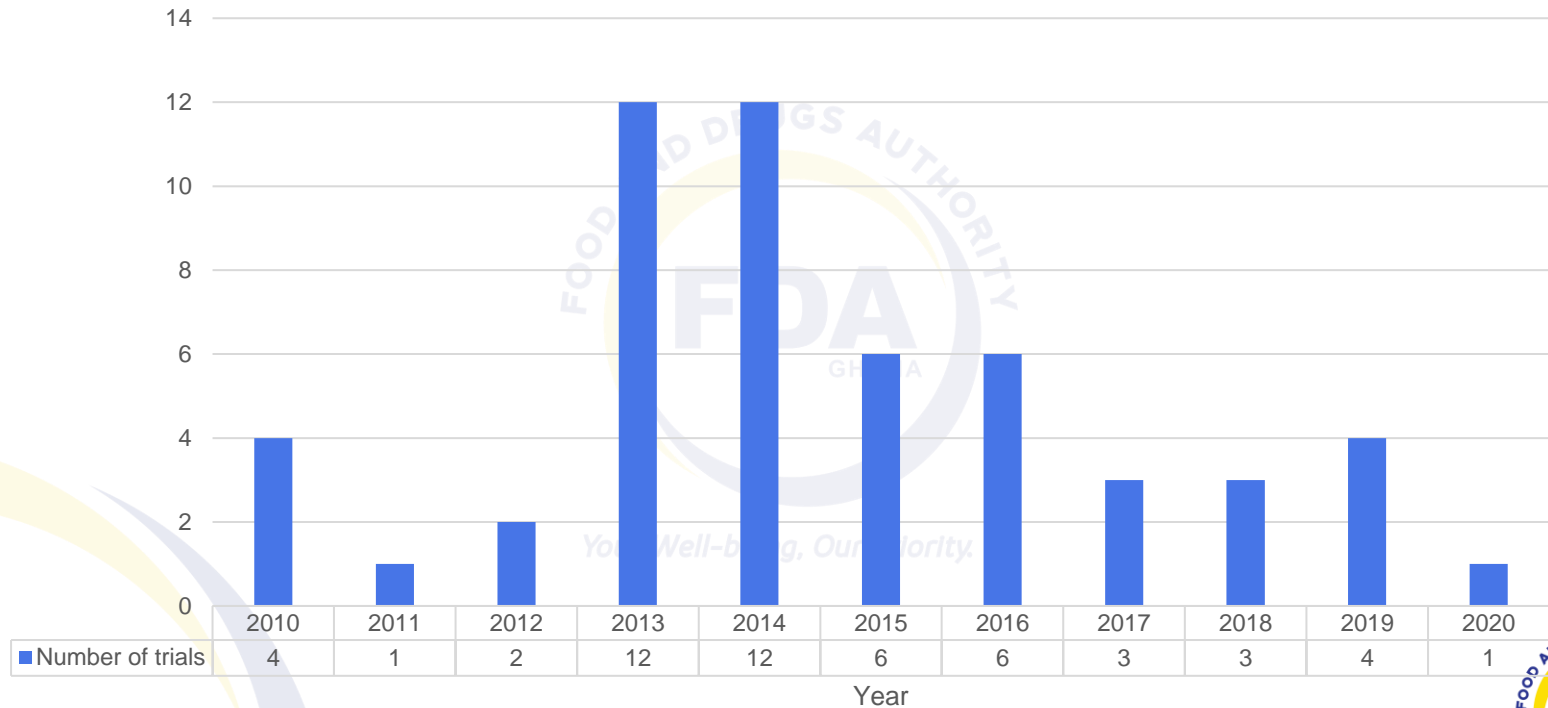


- Opening meeting (Introduction and discussion of inspection plan)
- Inspection
- Closing/ Exit meeting (Discussion of inspection findings)



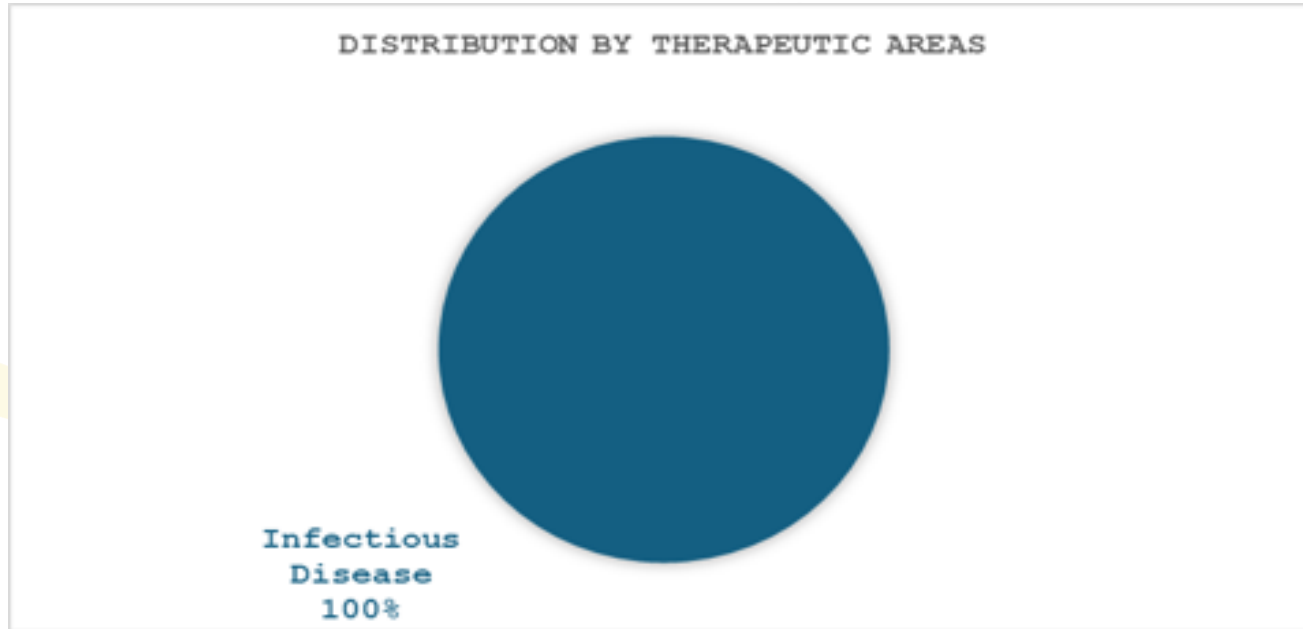
- Send report (prepared & feedback given within 21 working days)
- Timeline given for implementation of recommendations and / or regulatory sanctions and penalties

# GCP INSPECTIONS (2010-2020)



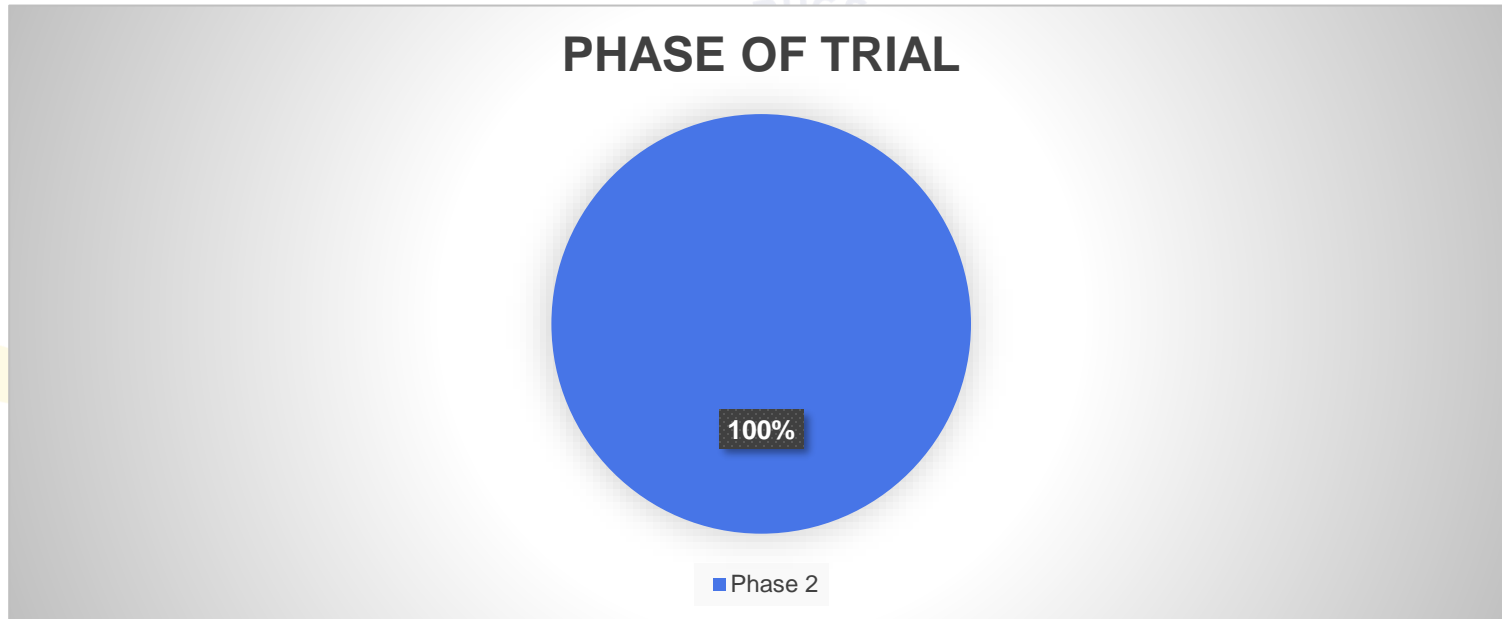
# GCP Inspections (2020)

## Distribution by Therapeutic Area



# GCP Inspections (2020)

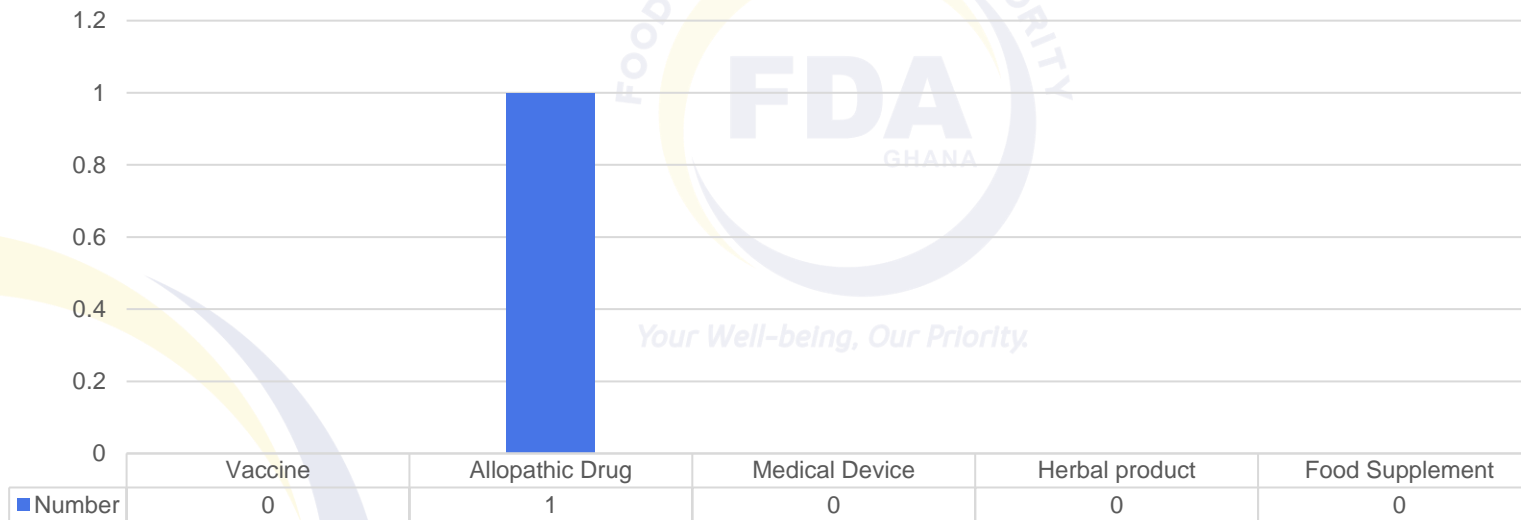
## Distribution by Phase of Clinical Trial



# GCP Inspections (2020)

## Distribution by Nature of Investigational Product

NATURE OF INVESTIGATIONAL PRODUCT (2020)



# 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.



# Classification of GCP Inspection Findings CNTD.

## MINOR

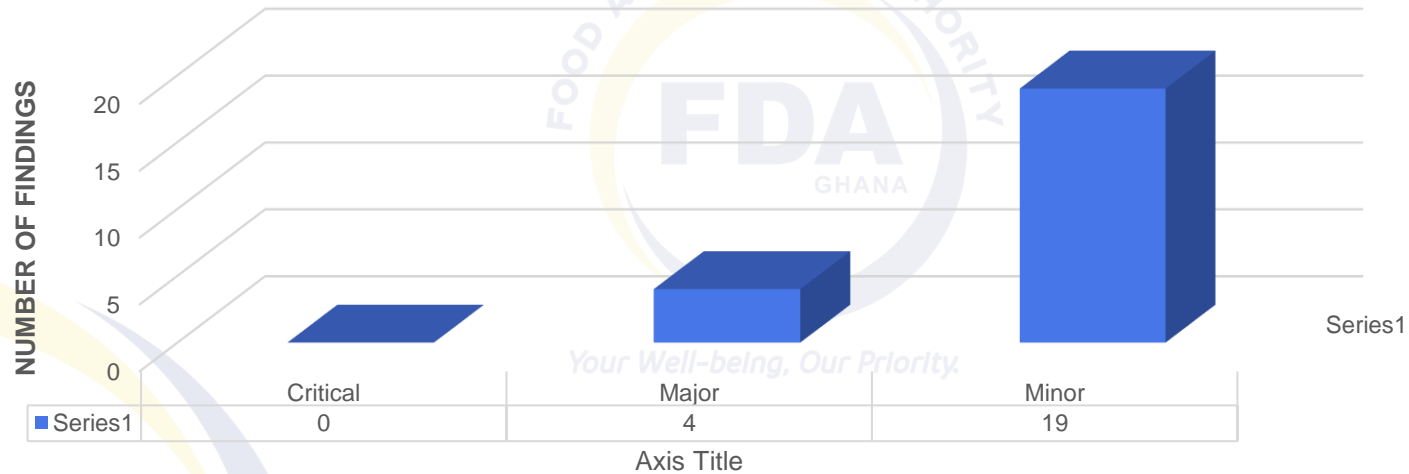
Conditions, practices or processes that would not be expected to adversely affect the rights, safety or well being of the trial participants and/or the quality and integrity of data.

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# Classification of GCP Inspection Findings CNTD.

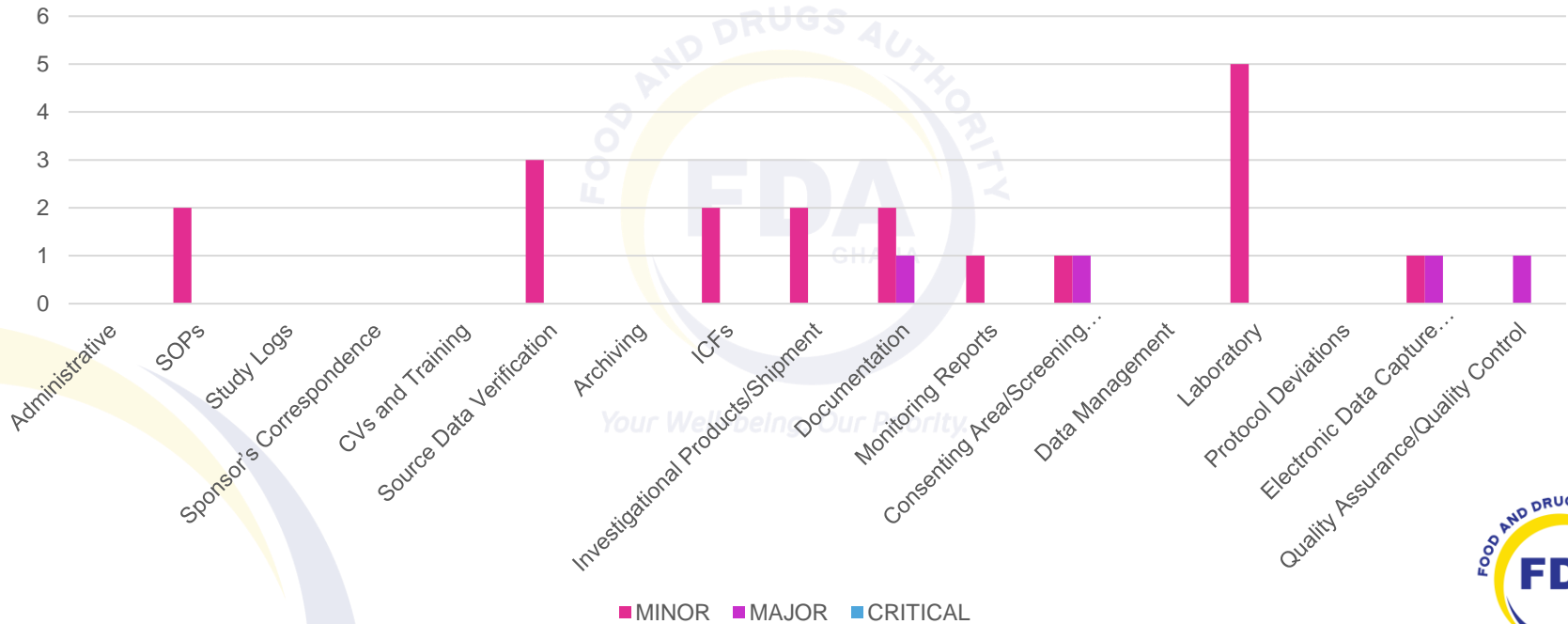
## 2020 GCP INSPECTION FINDINGS





# Classification of GCP Inspection Findings CNTD.

## 2020 OBSERVATION FINDINGS



# Study Termination / Suspension

## ➤ **Study termination**

None of the clinical trials were terminated through GCP Inspections.

## ➤ **Study suspension**

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

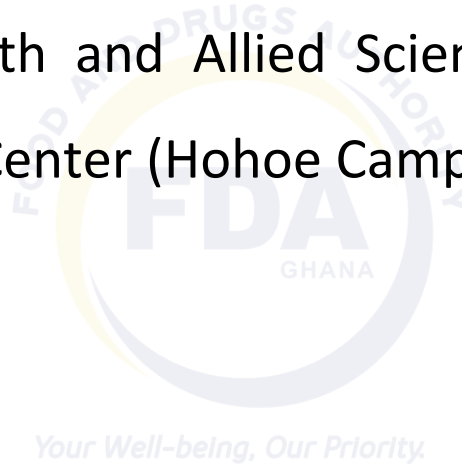
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# GCP Site Inspections (2020)

The inspection took place at the following sites:

1. The University of Health and Allied Sciences of School of Public Health Research Center (Hohoe Campus)



# 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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