

# SFDA GCP Inspection Finding Data Trend 2024





# Introduction

- Good Clinical Practice (GCP) serves as the cornerstone for safeguarding the rights, safety, and well-being of trial participants while ensuring the credibility and reliability of clinical trial data.
- The Clinical Trials Department is pleased to present a summary of GCP inspection findings conducted between January 2024 and December 2024.
- The analysis of GCP inspection trends aims to foster a culture of continuous improvement and ensure that clinical trials consistently adhere to the highest quality standards.
- By identifying recurring issues and their root causes, we can implement proactive measures to strengthen compliance and integrity in clinical research.
- Through a comprehensive analysis of GCP inspection findings and data trends, the SFDA aims to enhance the collective knowledge base, supporting ongoing efforts to strengthen quality standards and drive continuous improvement in clinical research.
- By sharing inspection findings, researchers are encouraged to conduct self-assessments and implement continuous enhancements to uphold the highest standards of Good Clinical Practice (GCP)..



**A total of 26 GCP inspection visits were conducted in 2024, resulting in 110 inspection findings.**

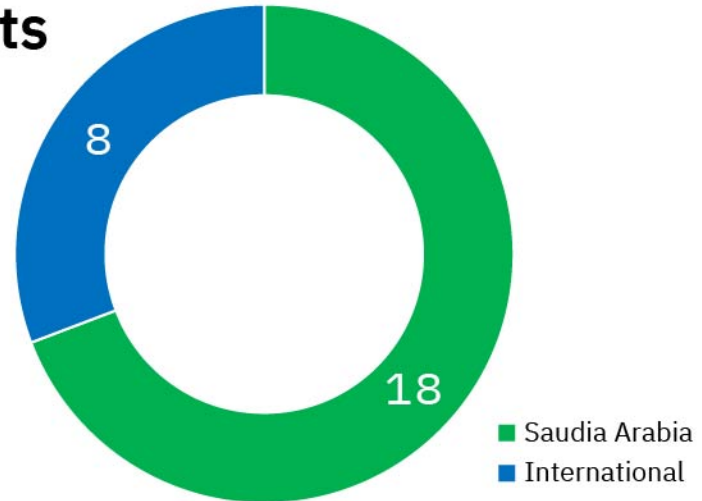
**The most common findings were related to:**

- IMP Management/Pharmacy.
- Facilities and Equipment.
- Archiving.
- Protocol compliance.

## Inspection visit locations

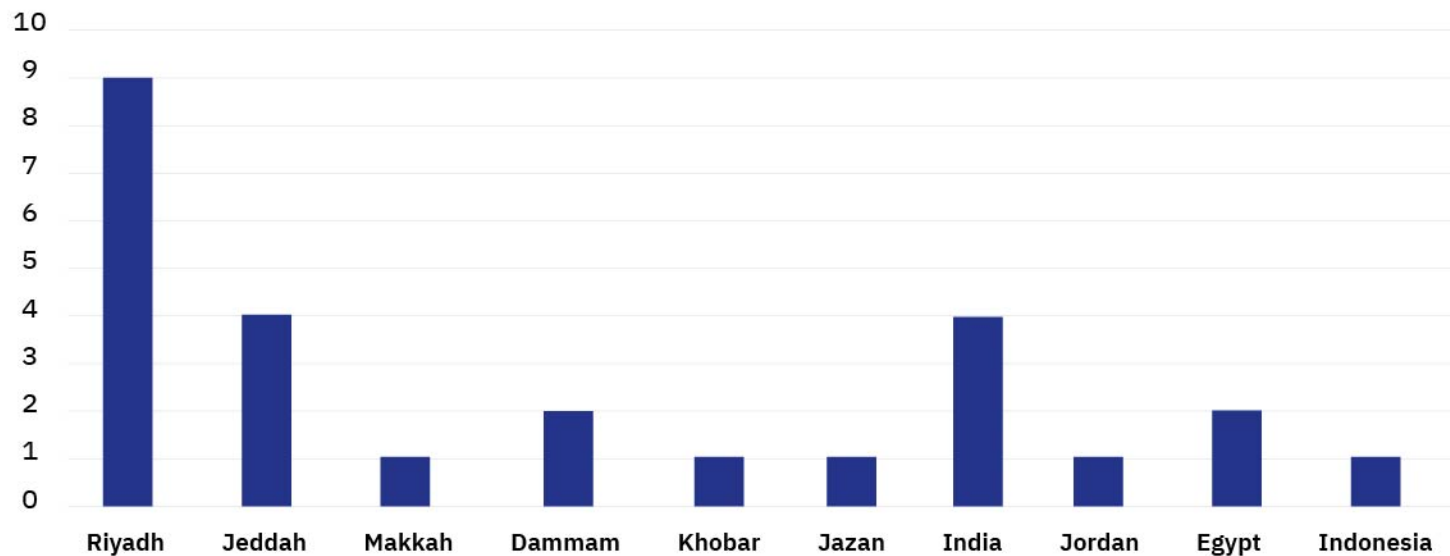
- The inspection visits were conducted in locally and internationally as shown in the figure.

### Visits



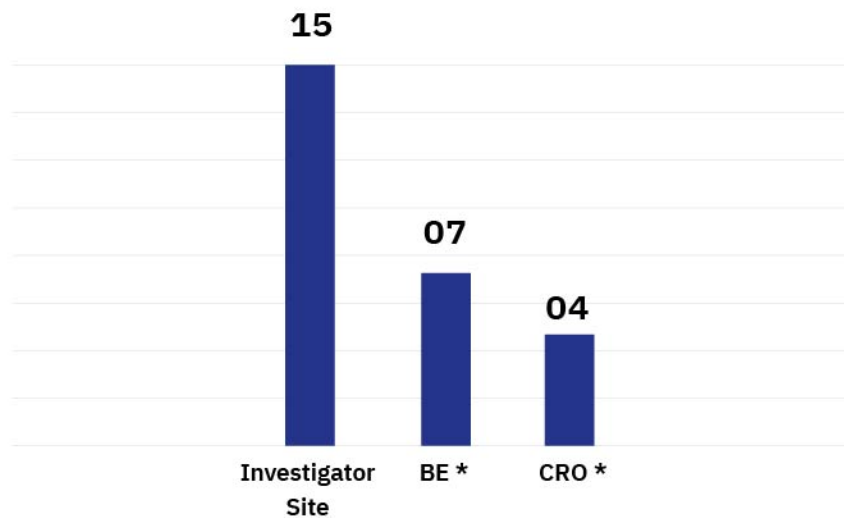


## Inspection Locations



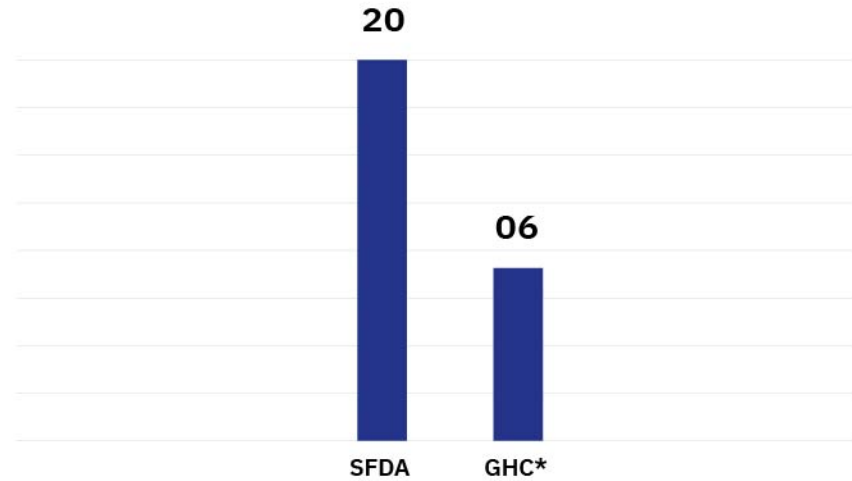


## Type of Inspection



BE = Bioequivalence, CRO = Contract Research Organization

## Type of Inspection



GHC = Gulf Health Council

## Inspections visit classifications

### Critical

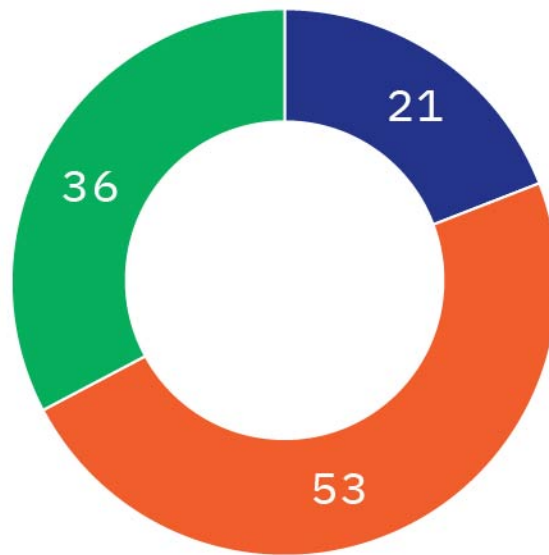
- 21 Critical findings raised
- 19% of all 110 findings are classified as critical

### Major

- 53 Major findings raised
- 48% of all 110 findings are classified as Major

### Other

- 36 Critical findings raised
- 33% of all 110 findings are classified as critical

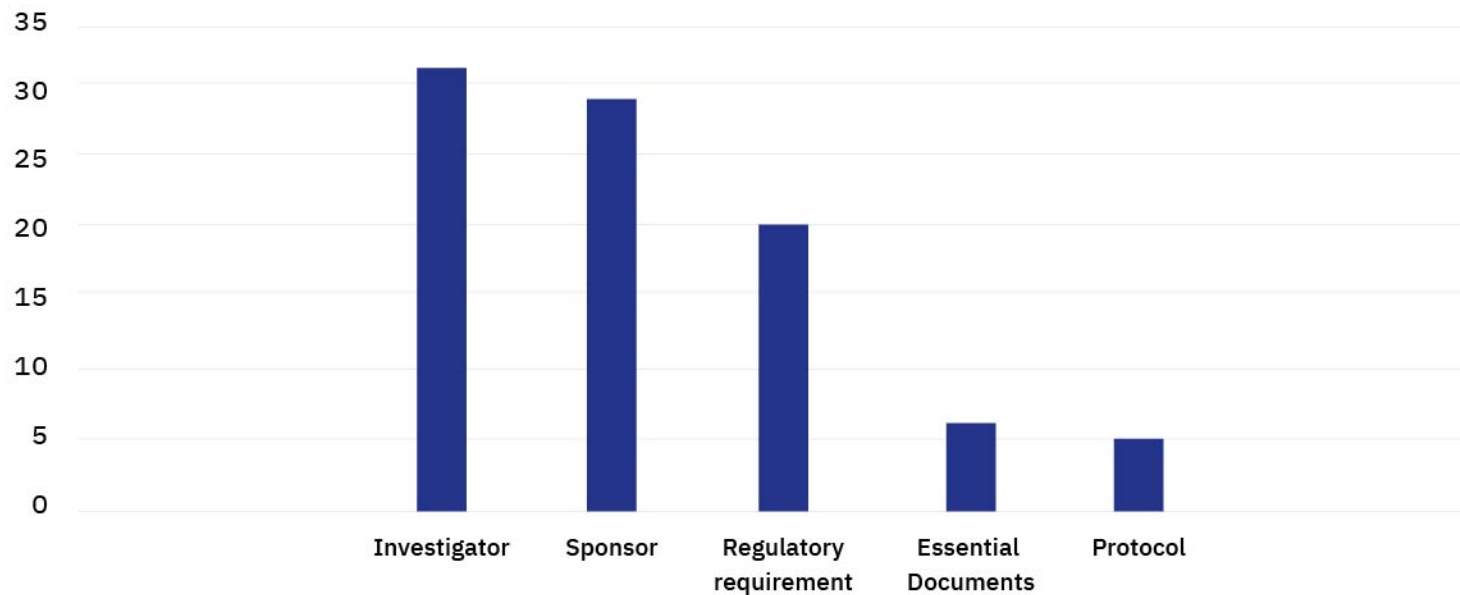


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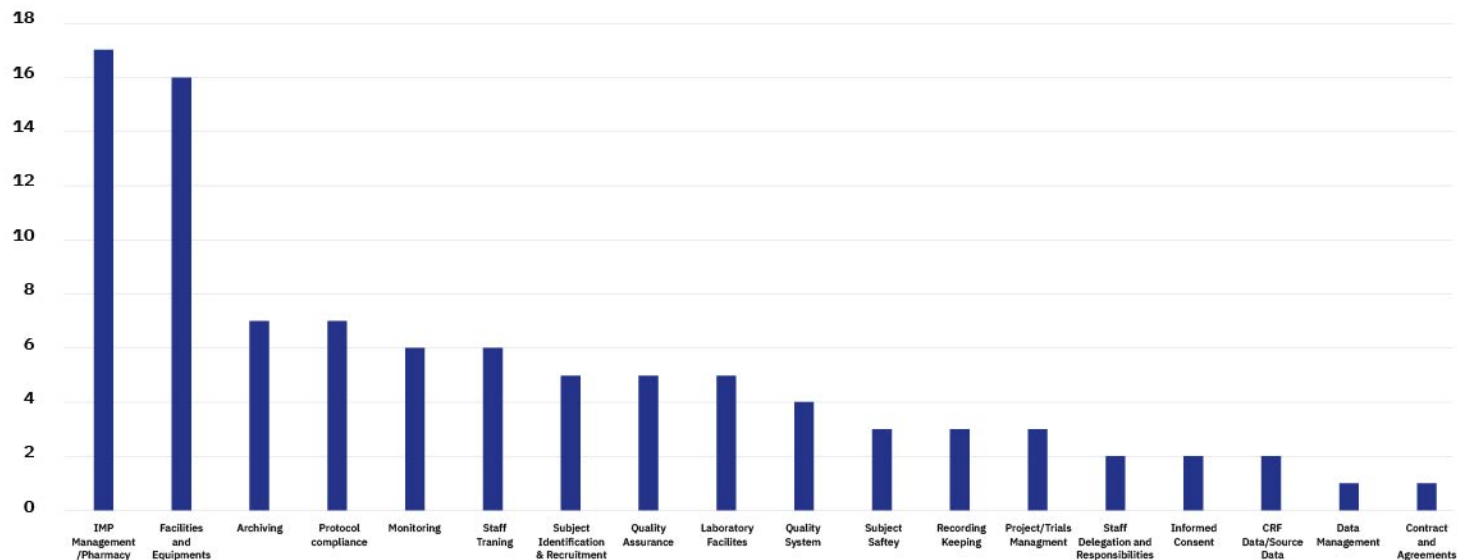


## Most Common findings According to GCP





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# Thank You