

# SFDA Clinical Trials Oversight Division

Annual Report  
2025





## SFDA Vision

*To be a leading international science-based regulator to protect and promote public health.*

## SFDA Mission

*Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed*



# Scope

This report covers SFDA GCP inspections conducted during the period of **01/01/2025** to **31/12/2025**.

All data in this report has been de-identified to maintain the anonymity of related parties.

All inspections were conducted based on the SFDA Guideline currently implemented at the time of the inspections; "Guideline for Good Clinical Practice (GCP) Version 3.0" *adopted from ICH Guideline for Good Clinical Practice E6(R2)*

## Introduction

### What is Good Clinical Practice (GCP)?

GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

### What is a GCP Inspection?

The act by the SFDA of conducting an official review of documents, facilities, records, and any other resources that are deemed by the SFDA to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the SFDA.

SFDA GCP inspections are conducted with the goal of ensuring patient safety and data reliability by assessing compliance with international GCP standards and local laws and regulations.



The SFDA Clinical Trials Oversight Division GCP Inspection Findings Trend Analysis is an annual report of the findings throughout the pertaining year with the goal of supporting research and innovation.

The analysis of GCP inspection findings aims to foster a culture of continuous improvement and ensure that clinical trials consistently adhere to the highest quality standards.

We hope that through a comprehensive analysis of GCP inspection findings, we can enhance the collective knowledge base by identifying reoccurring issues, leading to implementation of proactive measures to strengthen compliance and integrity in clinical research.

Researchers are encouraged to conduct self-assessments and implement continuous enhancements to uphold the highest standards of Good Clinical Practice (GCP).

### Types of GCP Inspection:

GCP inspections are differentiated based on the sites of inspection which are:

- Investigator Site
- Bioequivalence Center (BE)
- Contract Research Organization (CRO)

GCP inspections are also categorized into **routine** and **triggered** inspections:

- Routine inspections are scheduled throughout the year using a risk-based assessment. The inspection site is given prior notice before conducting this inspection.
- Triggered inspections are done spontaneously without prior notice due to non-compliance with SFDA regulations or due to any whistleblower or anonymous concerns about patient safety or data integrity.



A GCP inspection finding is classified first by a “**Main Finding**”, then a “**Sub-Finding**”, and finally a “**Significance**” of finding.

A “**Main Finding**” is recorded based on the SFDA GCP guideline. It refers to the main issue or responsible party such as:

- Investigator
- Sponsor
- Regulatory Requirement
- Clinical Trial Protocol
- Essential Documents
- The Principles (i.e. SFDA GCP Guideline Principles)
- Investigator’s Brochure

A “**Sub-Finding**” is a more detailed categorization of the issue/responsibility based on the inspector’s observation and judgment. Examples will be shown within the data below.

A “**Significance**” of finding is classified based on the significance of the deficiency as “**Critical**”, “**Major**”, “**Other**”, or “**Comment**”.

For a more detailed definition of each grading:

**Critical:** Conditions, practices or processes that adversely affect the rights, safety or wellbeing of the volunteers and/or the quality and integrity of data. Critical observations are considered totally unacceptable.

**Major:** Conditions, practices or processes that might adversely affect the rights, safety or wellbeing of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of Good Clinical Practice (GCP) principles.

*or*

which indicates a major deviation from GCP;

*or*



which indicates a major deviation from the terms of the sponsor documentation;  
*or*  
a combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such;

**Other:** Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.

**Comments:** The observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

## Metrics

The SFDA Clinical Trials Oversight Division has done a total of 35 inspections throughout the year of 2025.

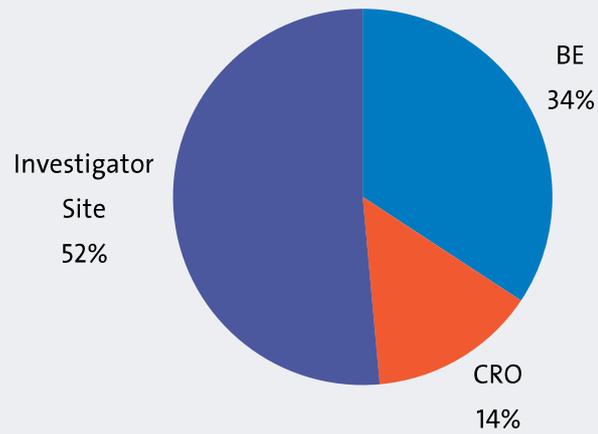
**Types of Inspection:**

Of those 35 inspections:



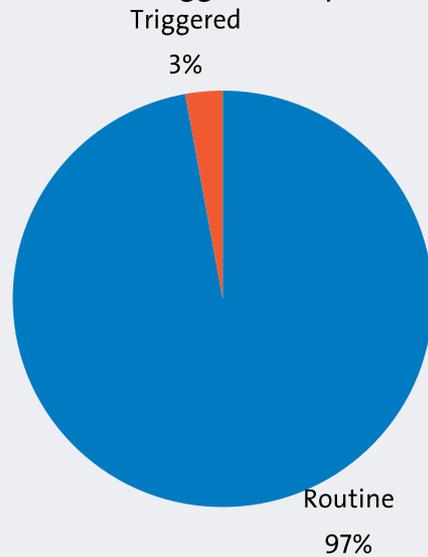
18 inspections were conducted for investigator sites, 12 for bioequivalence centers, and 5 for CROs.

### Types of Facilities Inspected



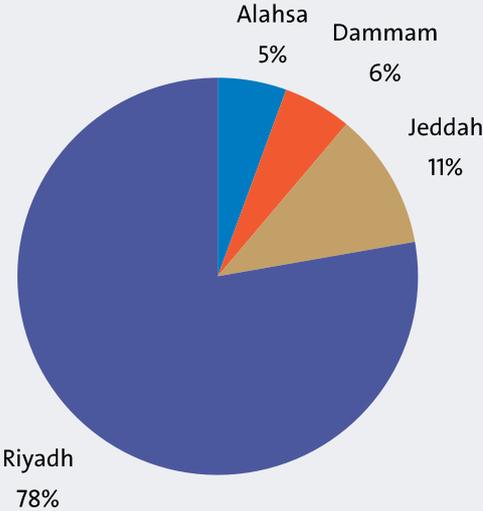
34 were routine inspections, while only 1 was a triggered inspection.

### Routine vs Triggered Inspections



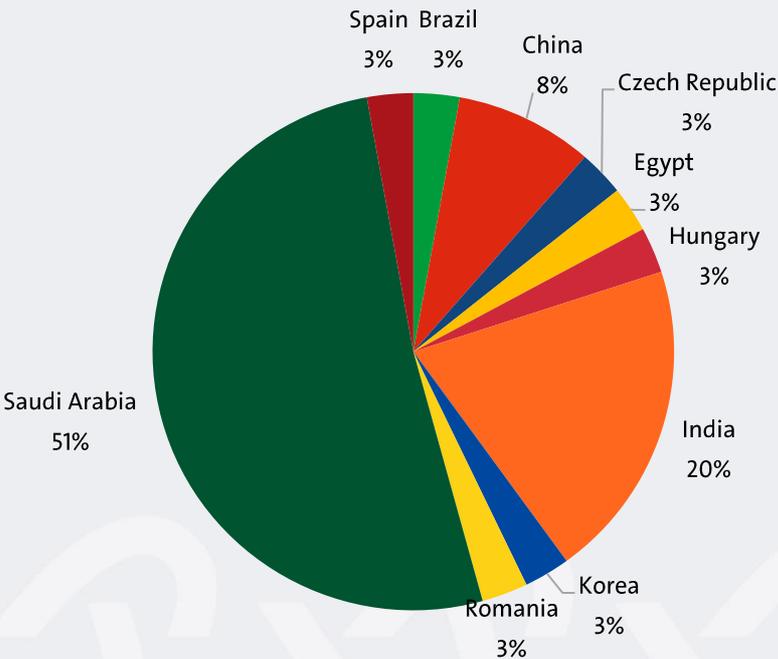
14 were in Riyadh, 2 were in Jeddah, and both Al-Ahsa and Dammam had 1 inspection each, leading to a total of 18 inspections within the Kingdom of Saudi Arabia (KSA).

**Inspections per City (in KSA)**



In addition to the 18 inspections conducted locally within the KSA, internationally, 7 were in India, 3 were in China, while Brazil, Czech Republic, Egypt, Hungary, Korea, Romania, and Spain had 1 inspection each.

**Inspections per Country**

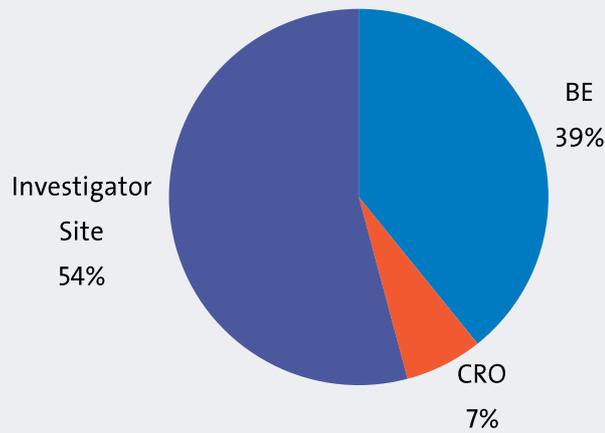




Throughout the 35 inspections, there was a total of 181 findings.  
Of those findings:

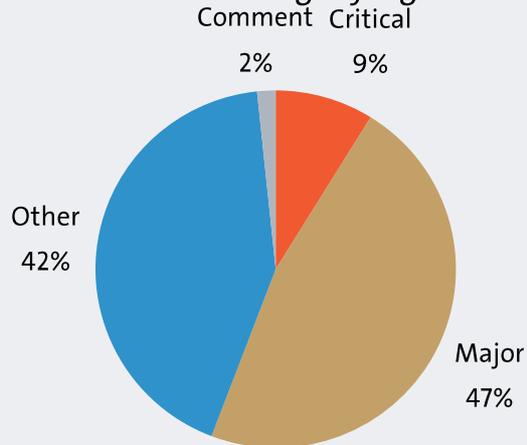
98 were from **Investigator Sites**, 71 were from **BEs**, and 12 were from **CROs**.

**Findings per Facility Type**



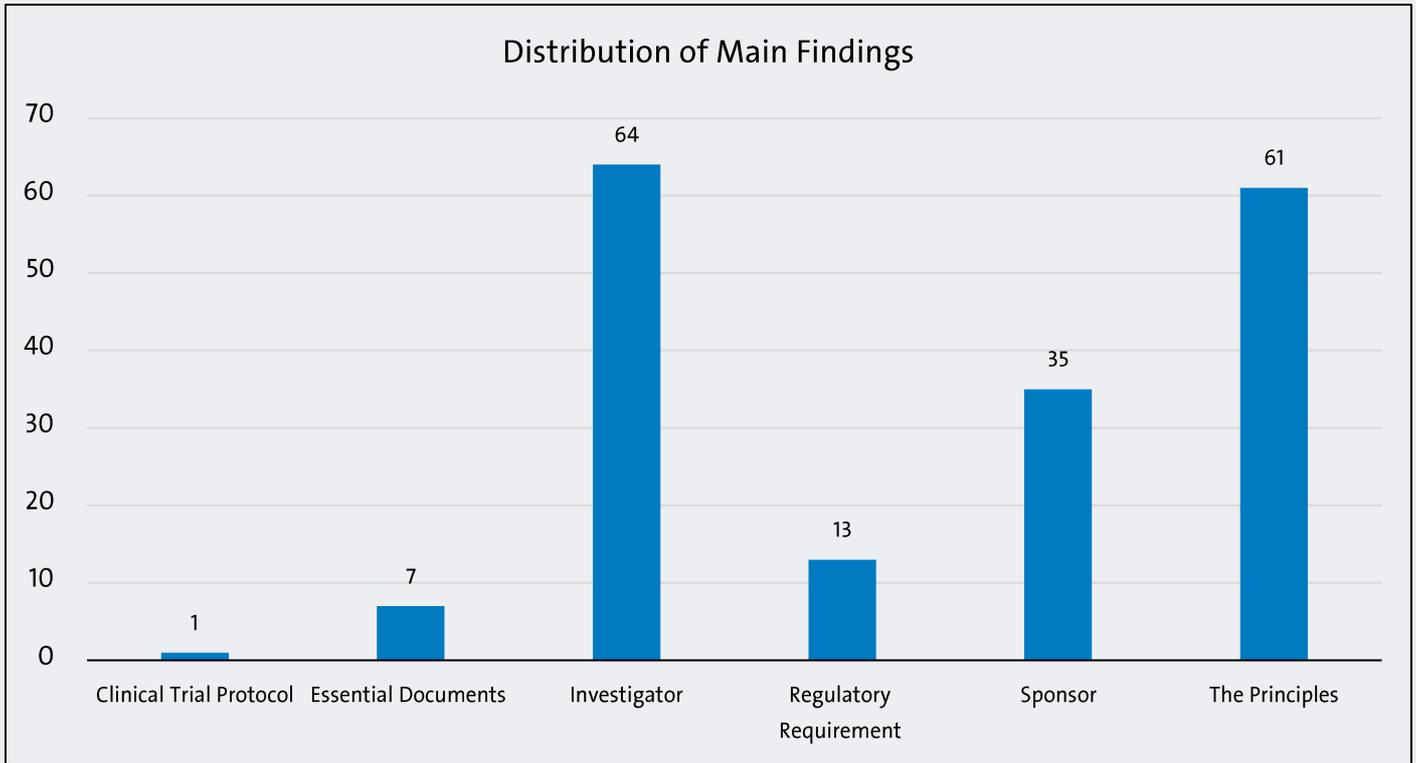
16 were **"Critical"**, 85 were **"Major"**, 77 were **"Other"**, and 3 were **"Comment"**.

**Distribution of Findings by Significance**

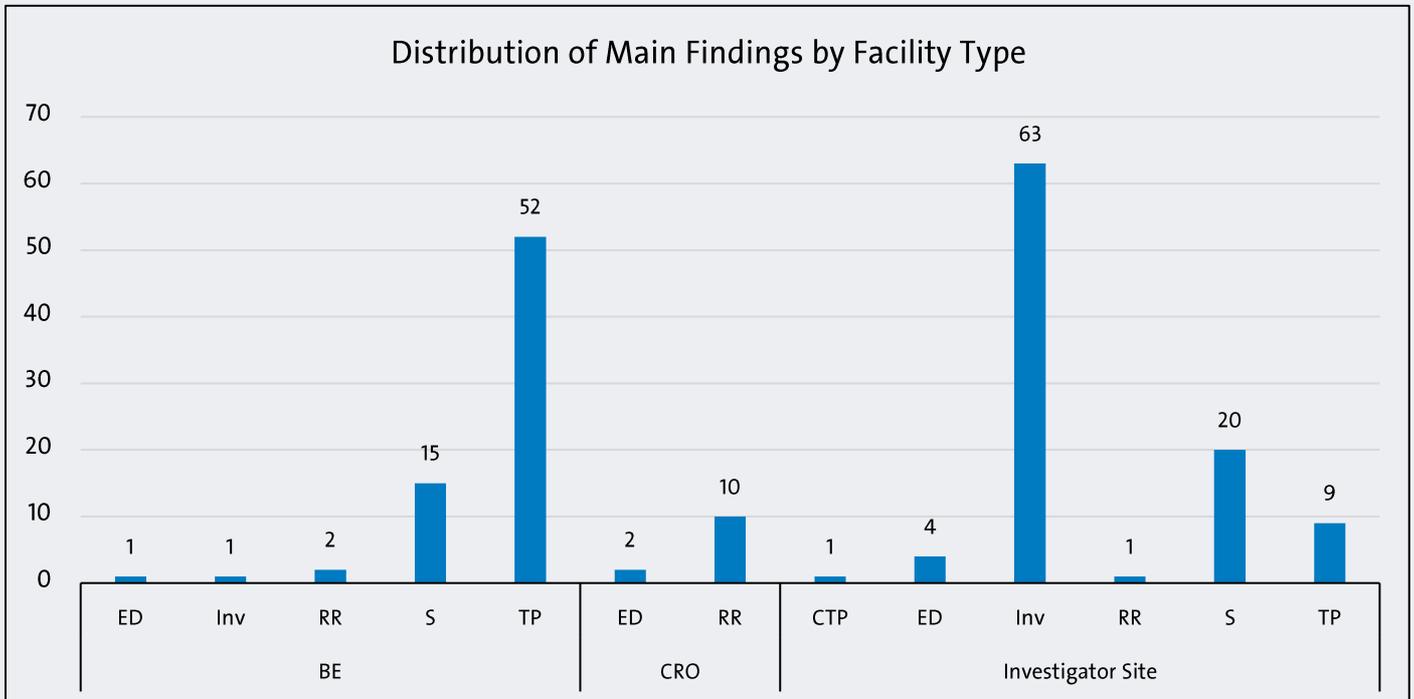


The following section will show the distribution of Main/Sub-findings both in general and by facility type.

General distribution of **Main Findings**:



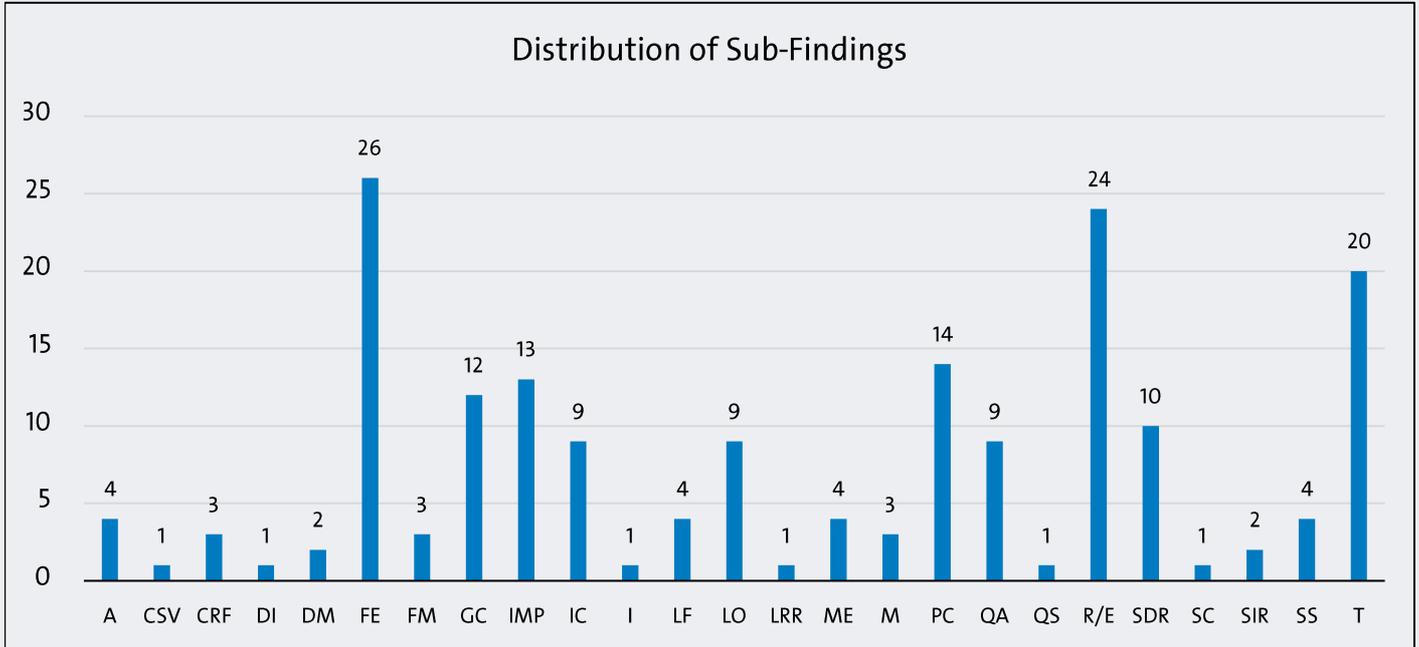
Distribution of Main Findings by type of facility:



CTP = Clinical Trial Protocol, ED = Essential Documents, Inv = Investigator, RR = Regulatory Requirement, S = Sponsor, TP = The Principles



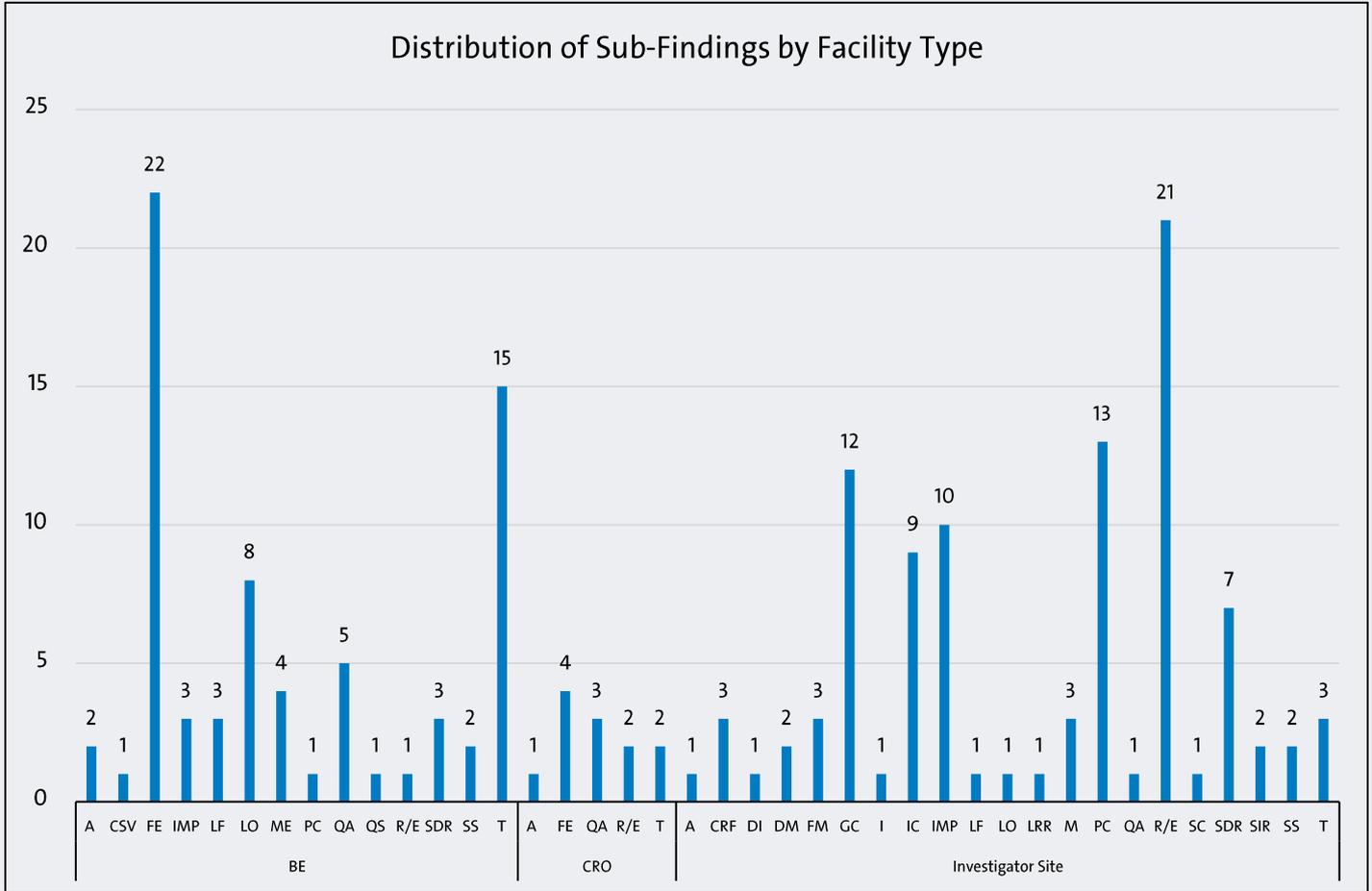
### General distribution of Sub-Finding:



A = Archiving, CSV = Computer System Validation, CRF = Case Report Form Data/Source Data, DI = Data Integrity, DM = Data Management, FE = Facilities and Equipment, FM = False and Misleading, GC = Good Clinical Practice Compliance, IMP = Investigational Medicinal Product Management/Pharmacy, IC = Informed Consent, I = Insurance, LF = Laboratory Facilities, LO = Laboratory Oversight, LRR = Laboratory Results Reporting, ME = Medical Emergencies, M = Monitoring, PC = Protocol Compliance, QA = Quality Assurance, QS = Quality System, R/E = Record Keeping/Essential Documents, SDR = Staff Delegation and Responsibilities, SC = Subject Confidentiality, SIR = Subject Identification and Recruitment, SS = Subject Safety, T = Training



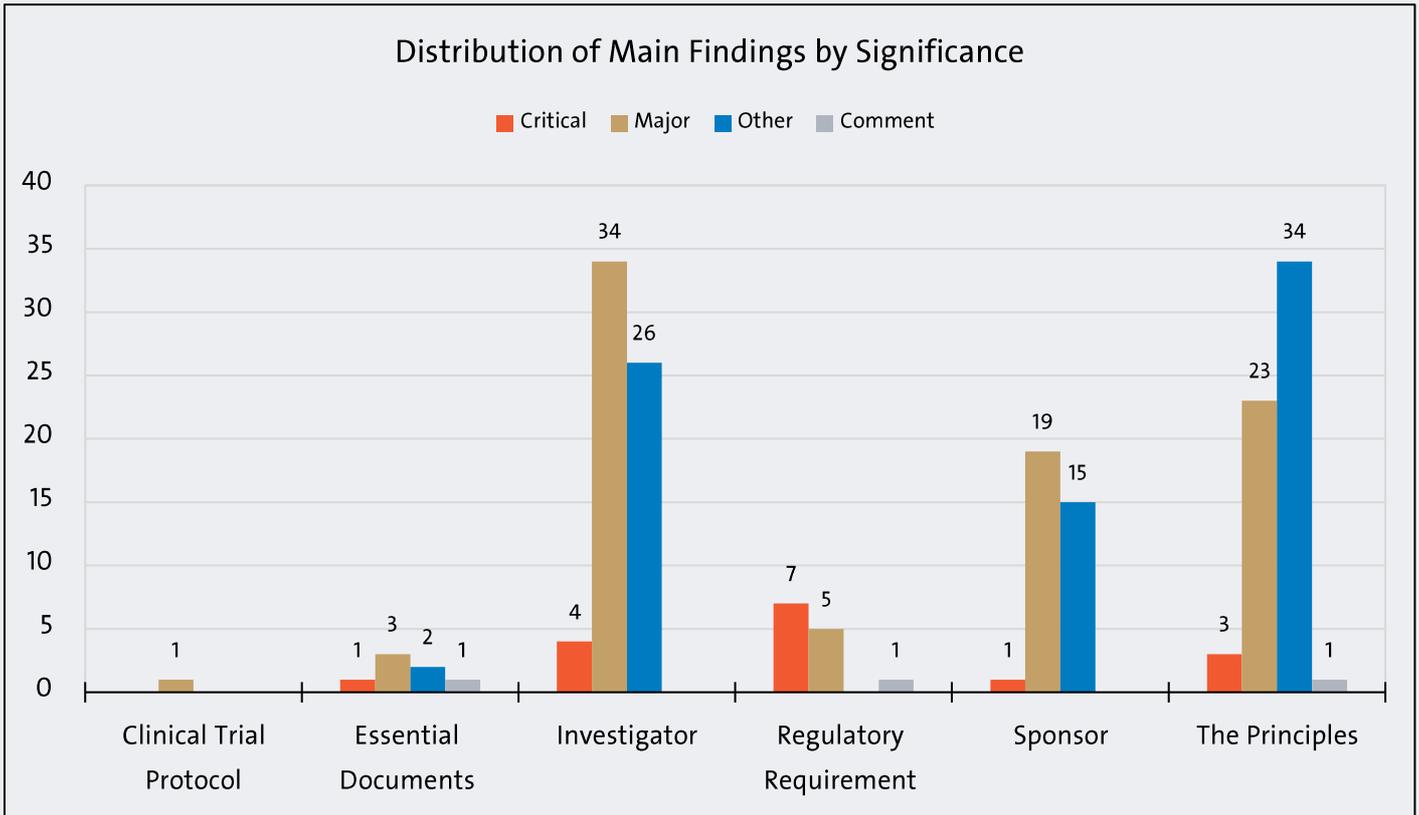
Distribution of Sub-Findings by type of facility:



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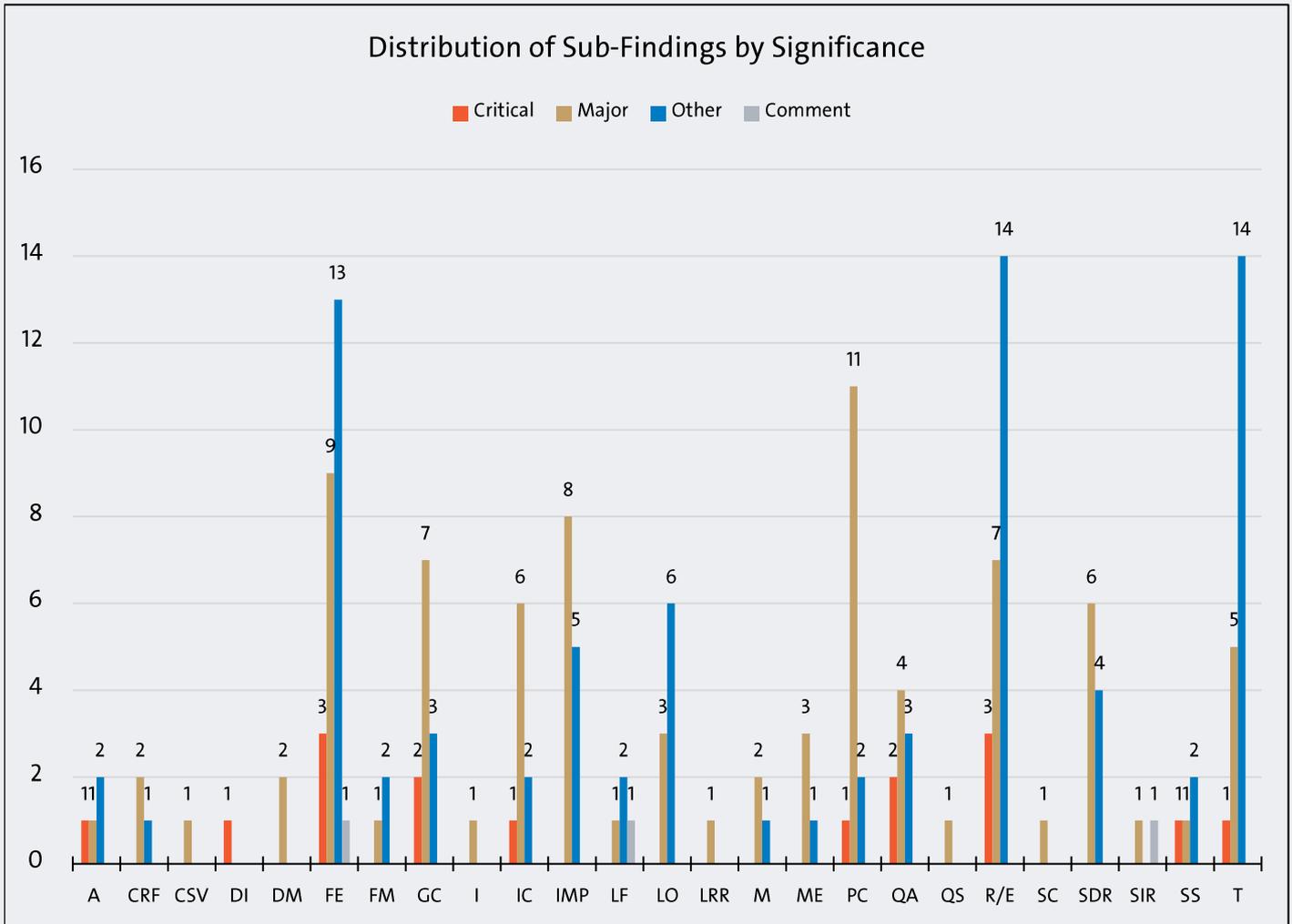
The following section will show the **overall** distribution of Main/Sub-findings based on the significance of each finding.

General distribution of all **Main Findings** based on **Significance** of findings:





General distribution of all Sub-Findings based on Significance of findings:



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