EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Oversight of Clinical Trials in the EU-EMA perspective

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1. Scientific Advice – pre submission stage

Scientific Advice

- Companies can **request** scientific advice from the EMA **at any stage of development** of a medicine
- May be **requested for all medicinal products** for use in humans
- Advice on the **design of studies and trials** to support quality, safety and efficacy of a medicinal product at all stages of the product lifecycle
- Given by Committee for Medicinal Products for Human Use (**CHMP**) on the **recommendations of the SAWP**

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2. GCP Validation of a MAA dossier – submission stage

Why do we do a GCP validation? (1/2)

- Check whether the GCP and ethical requirements were fulfilled;

  *All **clinical trials** (conducted within/without the EU) **included in a MAA** must **comply with the requirements/equivalents of Dir. 2001/20/EC**.* (written statement to confirm this)

- Whether there were ethical/GCP problems;

- Where the pivotal trials were conducted/patients recruited;

Why do we do a GCP validation? (2/2)

- Whether the trials have been inspected or audited;
- To collect information:
  - For deciding a routine inspection;
  - Preparation of the inspection request for a triggered or routine inspection.

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3. EMA GCP Inspections – Evaluation Stage

EMA Inspection Process

- CHMP requests GCP inspections of clinical trials related to Centralised Marketing Authorisation Applications.
- EMA GCP inspections *coordinated* by the EMA.

Types of GCP Inspections

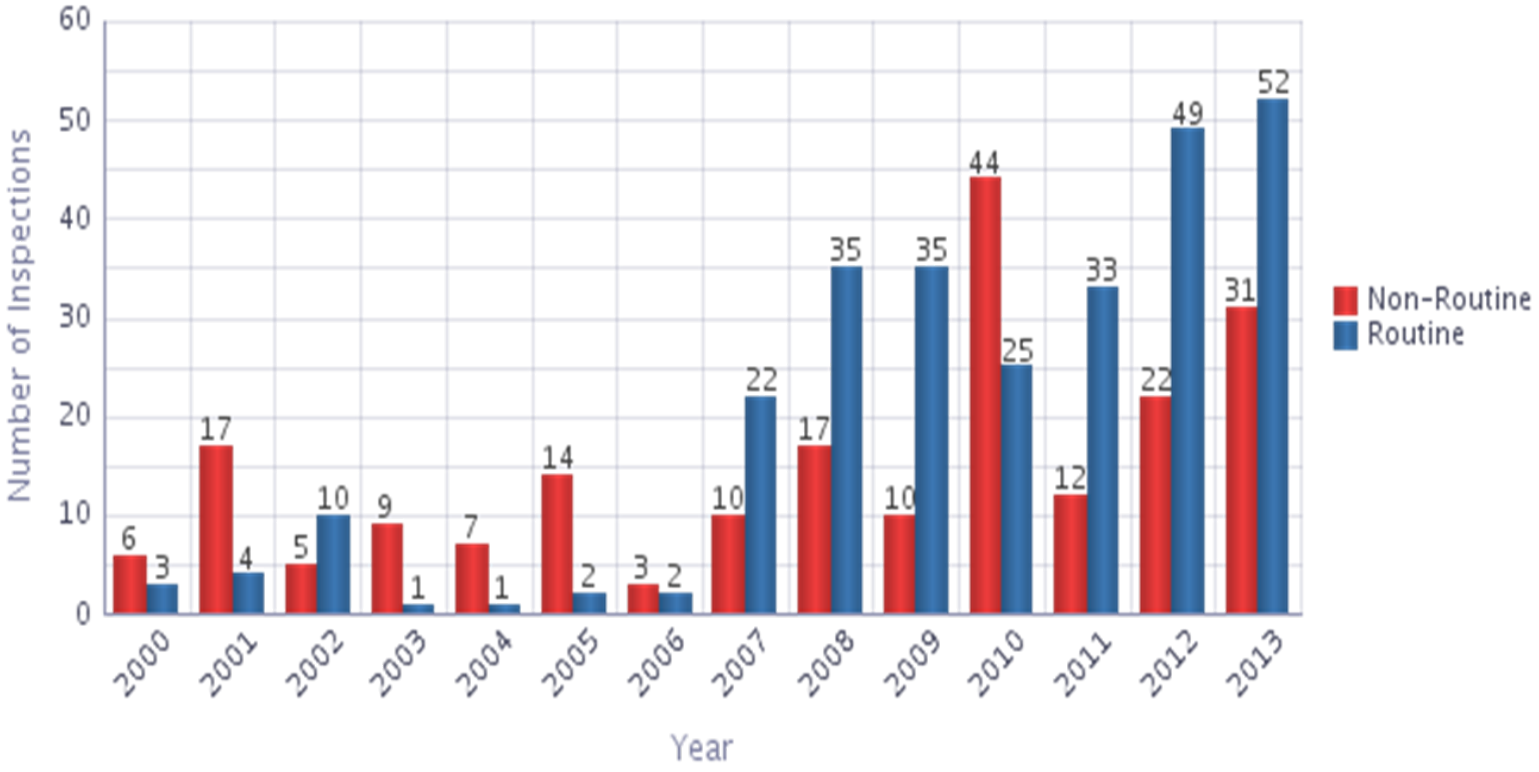
Routine inspections:

- ensure a **routine surveillance of GCP compliance**, in the absence of a specific trigger or concern;
- predefined criteria.

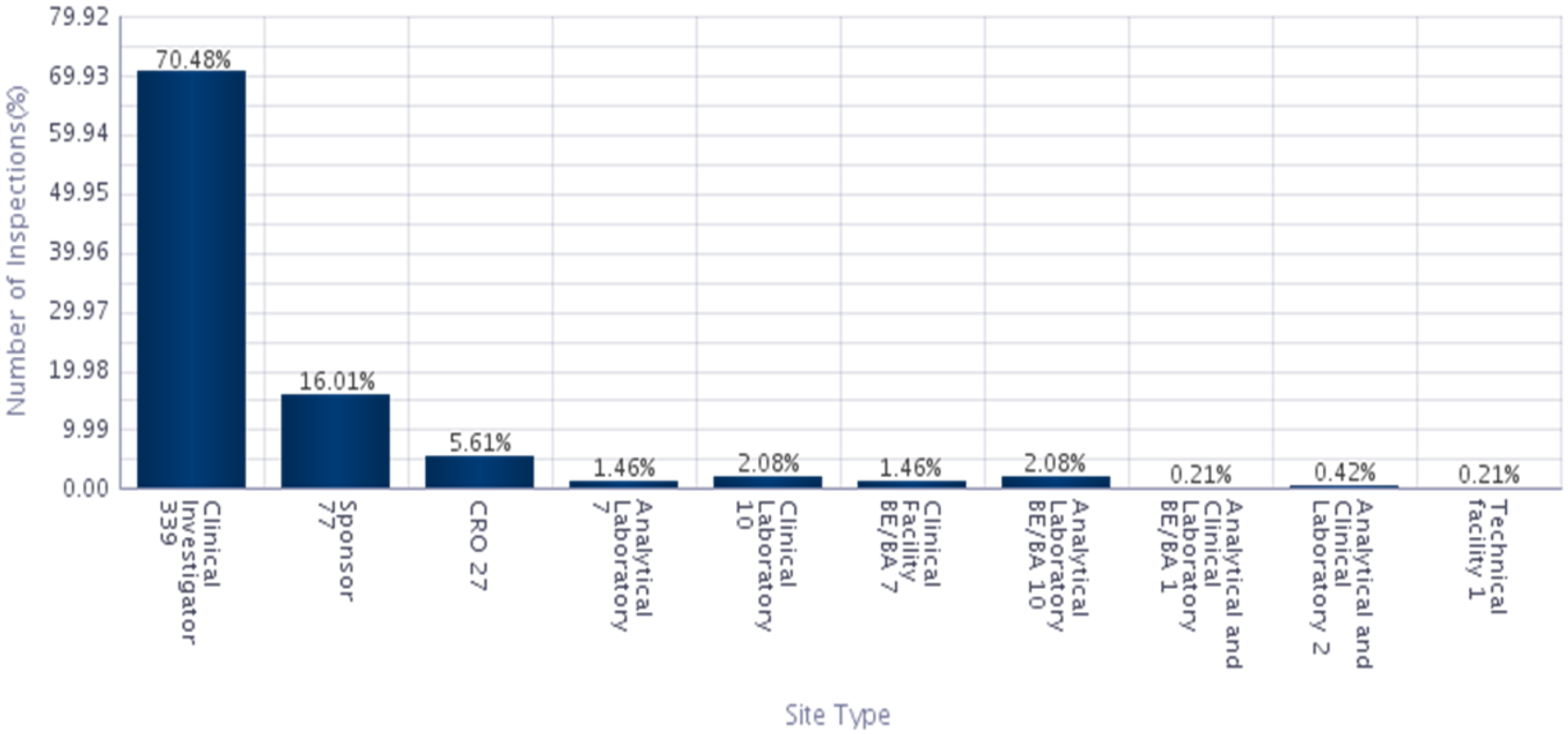
Triggered inspections:

- requested by clinical assessors due to a **concern about a deviation from GCP** in relation to the overall trial conduct or to the conduct at a particular site.

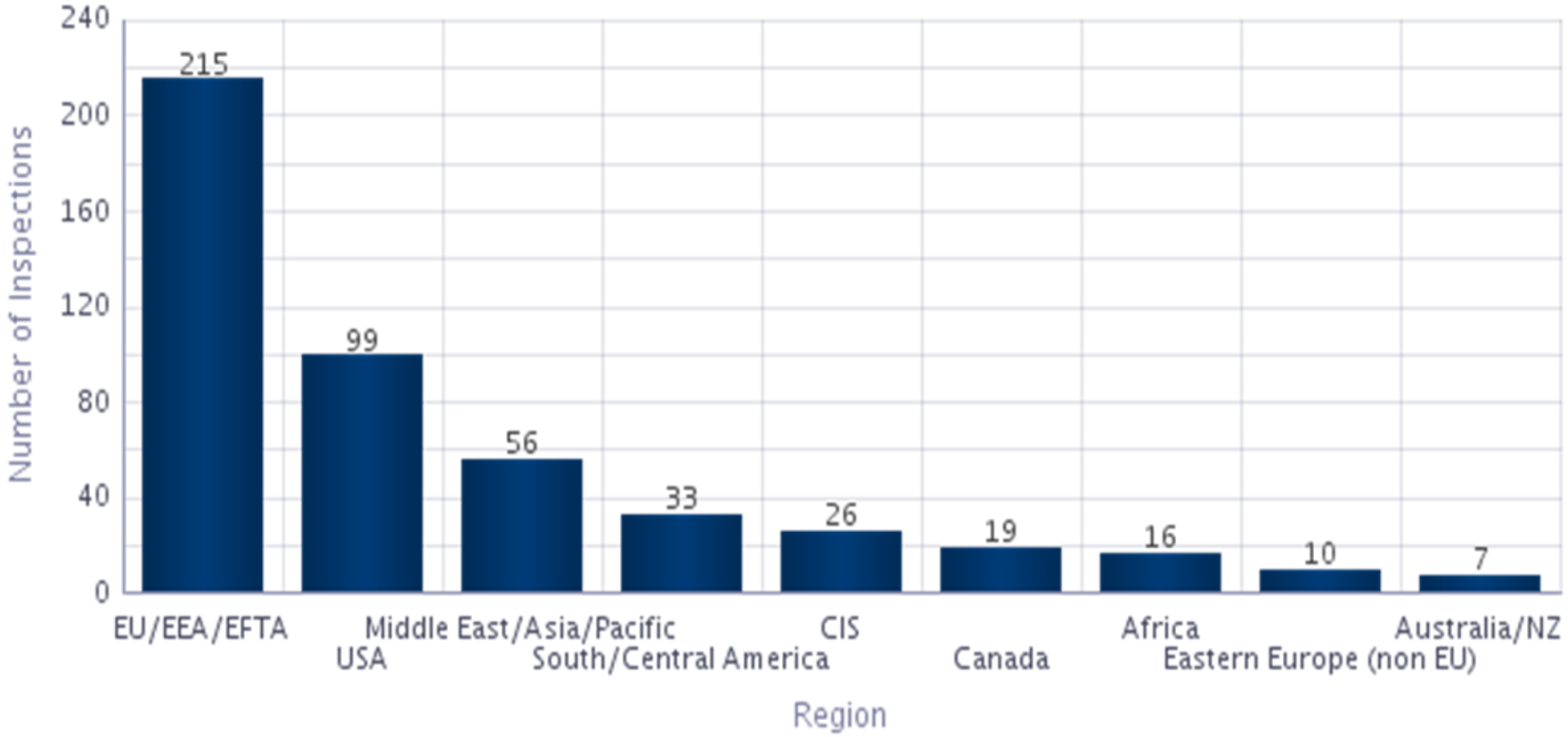
Number of EMA conducted inspections by type of inspection and year, 2000-2013, N=481



Number of EMA conducted inspections by type of inspection site, 2000-2013



Number of EMA inspections conducted by region, 2000-2013



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4. EMA and Harmonisation of GCP related activity

EMA and harmonisation (1/5)

The European Medicines Agency plays an important role in the **harmonisation and co-ordination** of GCP-related activity.

EMA is involved in:

- **co-ordinating GCP inspections** for the centralised procedure;
- chairing and providing scientific secretarial support to the **GCP Inspectors Working Group**;

EMA and harmonisation (2/5)

GCP Inspectors Working Group

EMA and harmonisation (3/5)

- co-ordinating advice on the **interpretation of EU GCP requirements** and related technical issues;
- **developing EU-wide guidelines** on GCP inspections and related procedures for the centralised procedure.

EMA and harmonisation (4/5)

EMA and harmonisation (5/5)

Supporting **training activities** for GCP inspectors:

- Annual GCP inspectors workshop;
- On-line basic GCP inspectors training course.

THANK YOU!