



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:

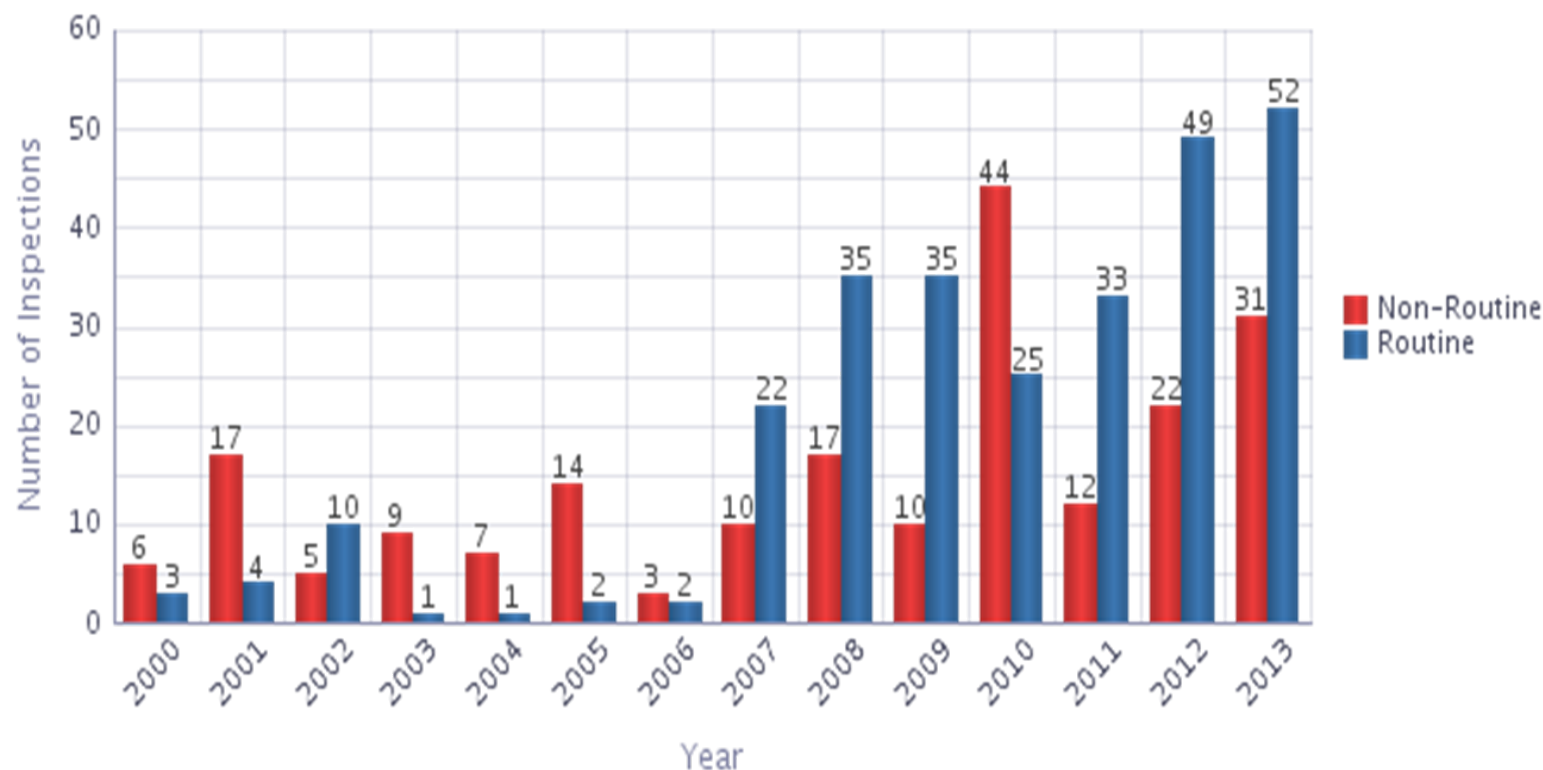
- ensure a **routine surveillance of GCP compliance**, in the absence of a specific trigger or concern;
- predefined criteria.

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.

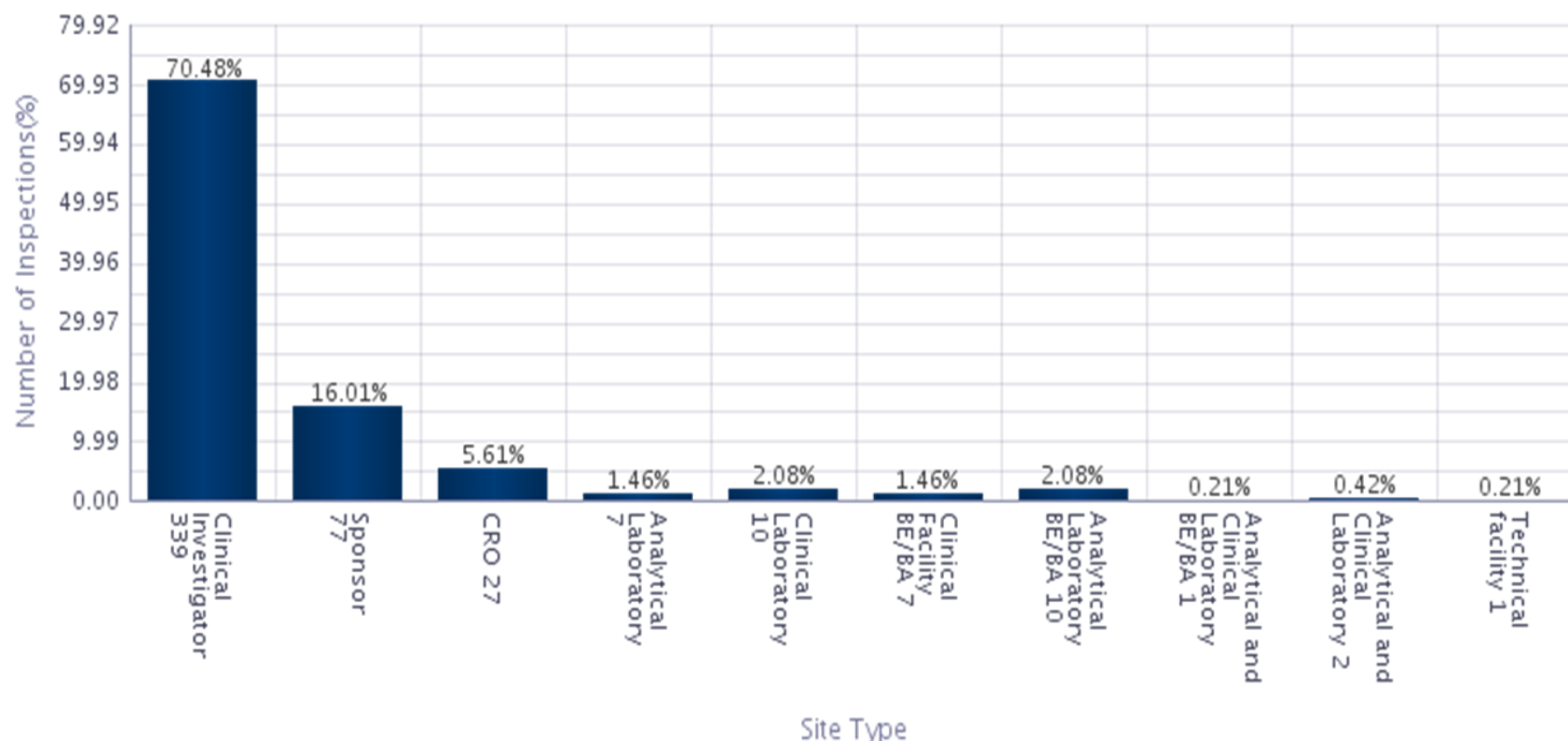


Number of EMA conducted inspections by type of inspection and year, 2000-2013, N=481



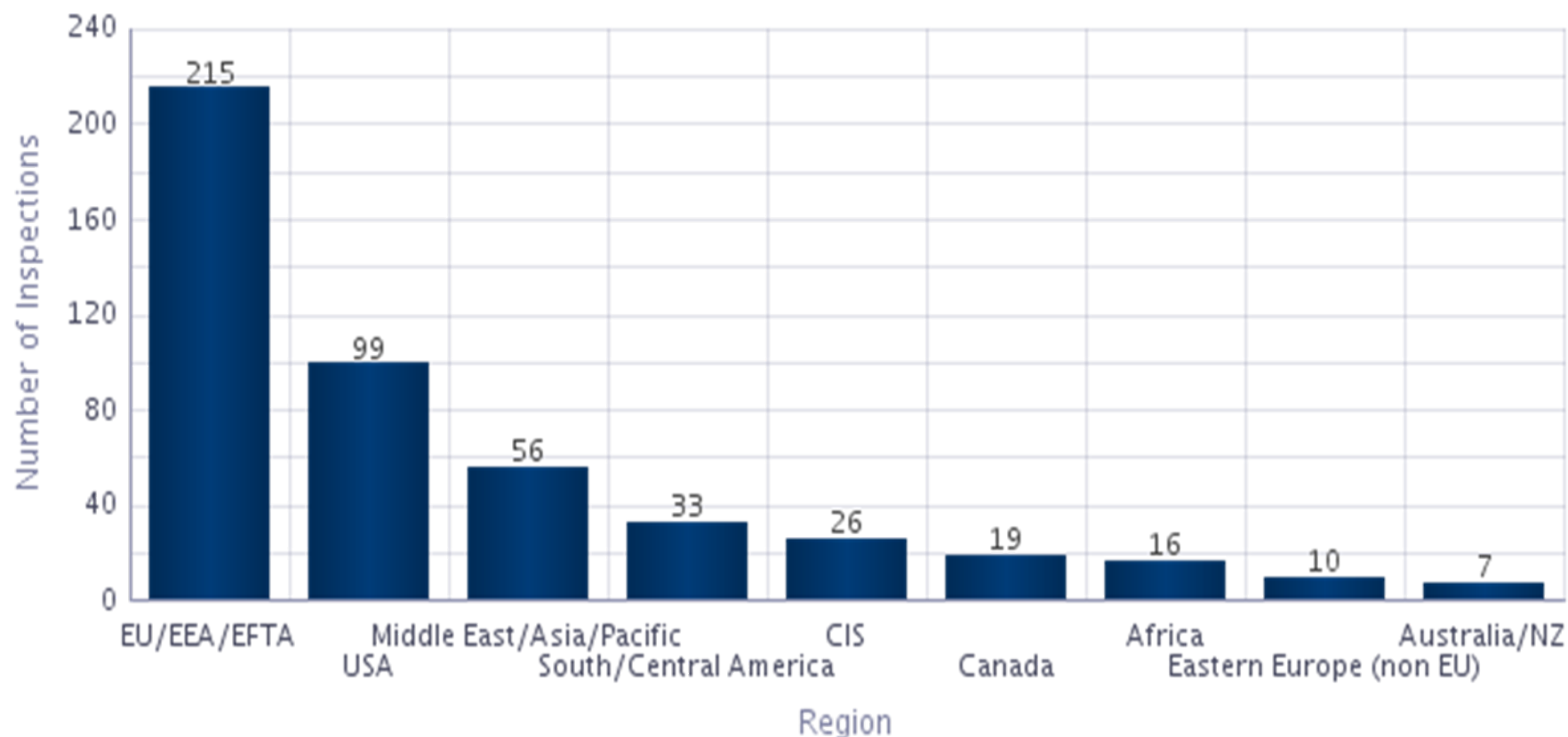


Number of EMA conducted inspections by type of inspection site, 2000-2013





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

The screenshot shows the EMA website in a Windows Internet Explorer browser. The address bar displays the URL: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000136.jsp&mid=WC0b01ac05800296c4. The browser's Favorites bar shows the current page. The website header includes the EMA logo, the text "EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH", and the tagline "An agency of the European Union". A search bar and social media links are also present. The main navigation menu includes: Home, Find medicine, Human regulatory (selected), Veterinary regulatory, Committees, News & events, Partners & networks, and About us. The left sidebar lists various topics: Pre-authorisation, Post-opinion, Post-authorisation, Product information, Scientific advice and protocol assistance, Scientific guidelines, Innovation Task Force, SME office, Paediatric medicine, Geriatric medicine, Orphan designation, and Herbal products. The main content area is titled "GCP Inspectors Working Group" and includes a breadcrumb trail: Home > Human regulatory > Inspections > GCP compliance > Working group. The text describes the group's focus on harmonisation and co-ordination of GCP related activities at Community level. It mentions that the group meets regularly and provides support to the GCP Inspectors Working Group. The text also states that the group maintains a dialogue with GMP Inspectors on areas of common interest. At the bottom, it provides an email address for queries: gcp@ema.europa.eu. The Windows taskbar at the bottom shows the Start button and several open applications: LMS Secure Access, European Medicines, 2014 4th Clin Trials, and Microsoft PowerPoint.



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)

medicines Agency - GCP compliance - GCP Inspectors Working Group - Windows Internet Explorer

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000136.jsp&mid=WC0b01ac05800296c4

Vis Favoritter Funktioner Hjælp

Kurs mod fjerne kyster - Rej... Microsoft Hjemmepakke Carlson Wag Coop Bank DADL Mail PLM OWA-LMS plm Google Maps Sprog Eudralink LPK EudraCT RejsUD mTIME

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Document(s)	Language	Status	First published	Last updated	Effective Date
Work plan for Good Clinical Practice Inspectors Working Group 2014	(English only)	adopted	25/02/2014		
Overview of comments received on 'Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials'	(English only)		21/02/2014		
Minutes of Joint meeting of Good-clinical-practice compliance Inspectors Working Group and eClinical Forum representatives on electronic data capture systems and investigator site eSource readiness	(English only)	adopted	10/01/2014		
Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials, with particular emphasis on the handling of expiry dates	(English only)	adopted	18/12/2013		18/12/2013

Internet

LMS Secure Access - ... European Medicines ... Harmonising Microsoft PowerPoint ...



EMA and harmonisation (5 / 5)

Supporting **training activities** for GCP inspectors:

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



THANK YOU!