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Quality and Safety of Medicines Department

Annual Report of the Good Clinical Practice (GCP) Inspectors' Working Group (IWG) 2024

Adopted by the GCP IWG on 15 December 2025

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List of Abbreviations

AE	Adverse Event
BE	Bioequivalence
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CRF	Case Report Form
CRO	Clinical/Contract Research Organisation
CSR	Clinical Study Report
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
eCRF	electronic Case Report Form
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EWG	Expert Working Group
FDA	(United States) Food and Drug Administration
GCP	Good Clinical Practice
GMDP	Good Manufacturing Practice/Good Distribution Practice
HMA	Heads of Medicines Agencies
IC	Informed Consent
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IEC	Independent Ethics Committee
IIR	Integrated Inspection Report
IMP	Investigational Medicinal Product
IRB	Institutional Review Board
IWG	Inspectors Working Group
MS	Member State
MRP	Mutual Recognition Procedure
PDCO	Paediatric Committee
PhV	Pharmacovigilance
PMDA	Pharmaceuticals and Medical Devices Agency (Japanese competent authority)
Q&A	Question & Answer
ROW	Rest of the World
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SDV	Source Data Verification
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
UK	United Kingdom
US(A)	United States (of America)
WHO	World Health Organisation

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1. Introduction

This document is the seventeenth Annual Report of the GCP IWG. This group was established in 1997 under the scope of Article 51(e) of Council Regulation (EEC) No. 2309/93, subsequently amended as Article 57(1)(i) of Regulation EC5 No. 726/2004.

The GCP IWG focuses on the harmonisation and coordination of GCP related activities at European Union (EU)/European Economic Area (EEA) level. The group's role and activities are described in more detail in its mandate, which was revised in 2013, its current Work Plan and also in Volume 10, chapter IV of the publication "The rules governing medicinal products in the European Union".

The group supports the coordination of the provision of GCP advice and maintains a dialogue with other groups, such as the Committee for Medicinal Products for Human Use (CHMP), the Committee for Medicinal Products for Veterinary Use (CVMP), the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh), the Pharmacovigilance (PhV) IWG, the Good Manufacturing Practice/Good Distribution Practice (GMDP) IWG, and other groups, as needed, in areas of common interest.

This Annual Report has been drawn up in line with the format and objectives of the 2024 – 2026 Work Plan.

2. Meetings

Four regular GCP IWG plenary meetings took place in 2024:

- 5-6 March 2024 (virtual).
- 11-12 June 2024 (hybrid).
- 24-25 September 2024 (virtual).
- 26-27 November 2024 (hybrid).

During 2024 the following GCP inspectors' subgroups/working parties were involved in the discussion of specific topics and the drafting of documents:

- GCP IWG/CMDh working party (refer to section 5.5).
- GCP IWG subgroup on serious breaches submitted and assessed according to the Clinical Trials Regulation 536/2014 (CTR) (refer to section 4.6).
- GCP IWG subgroup on drafting a Q&A about the considerations when direct remote access of identifiable personal and health data is required in a clinical trial (former Subgroup on remote source data verification).
- GCP IWG subgroup on selection of sites for routine GCP inspection, through analysis of individual patient data listings (EMA raw data pilot)).
- GCP-GMDP IWG subgroup on the Recommendation paper on travel advice (refer to section 5.1).
- GCP-GMDP IWG subgroup on drafting a Q&A on which operations fall under re-labelling and re-packaging of IMPs in accordance with article 61(5).

3. Inspections conducted in support of the centralised procedure

3.1. CHMP requested inspections

3.1.1. General overview

a) Foreword

The data in this report relates to inspections carried out in 2024.

Clinical trials were inspected for GCP compliance at 67 sites including 52 routine and 15 for-cause inspections that were requested by CHMP and carried out by the inspectorates of the EU/EEA Member States (MSs) in 2024. It should be noted that several inspections requested in 2023 were conducted in 2024, which are therefore included in this report. In addition, several inspections requested in 2024 were carried out in 2025, which are therefore not included in this report.

The figures cited above reflect the number of inspections performed at a given site. If several clinical trials were inspected at the same time at the same site, it was counted once for the purpose of this report. It should be noted that different methods for counting inspections coordinated by the European Medicines Agency (EMA) can be used in other reports, for instance when the indicator is the number of fees invoiced for distinct inspections, as defined in the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures.

b) Geographical distribution

Similarly to the 2023 annual report, this report distinguishes the following regions:

- EU/EEA.
- North America:
  - United States of America (USA).
  - Canada.
- Rest of the World (ROW):
  - Africa.
  - Asia.
  - Eastern Europe, non-EU (Belarus, Bosnia, the Republic of North Macedonia, Moldova, Russia, Serbia, Ukraine, Georgia).
  - Western Europe, non-EU (Switzerland, United Kingdom [UK]).
  - Latin America and the Caribbean.
  - Oceania.

c) Inspection figures

In Figure 1 and Table 1, the number of inspections conducted in 2024 is shown by region and type of inspection. Most inspections were carried out in Asia (32.8%) followed by North America (25.4%) and the EU/EEA (22.4%).

Table 1: Number of inspections conducted per region and type of inspection

Region	Routine	Non-Routine	Total	%
North America	17	0	**17**	**25.4%**
EU/EEA	15	0	**15**	**22.4%**
Asia	8	14	**22**	**32.8%**
Western Europe (non-EU)	6	0	**6**	**9.0%**
Latin America and the Caribbean	3	0	**3**	**4.5%**
Eastern Europe (non-EU)	2	1	**3**	**4.5%**
Oceania	1	0	**1**	**1.5%**
Grand Total	**52**	**15**	**67**	**100.0%**

Figure 1: Number of inspections by inspection type conducted per region

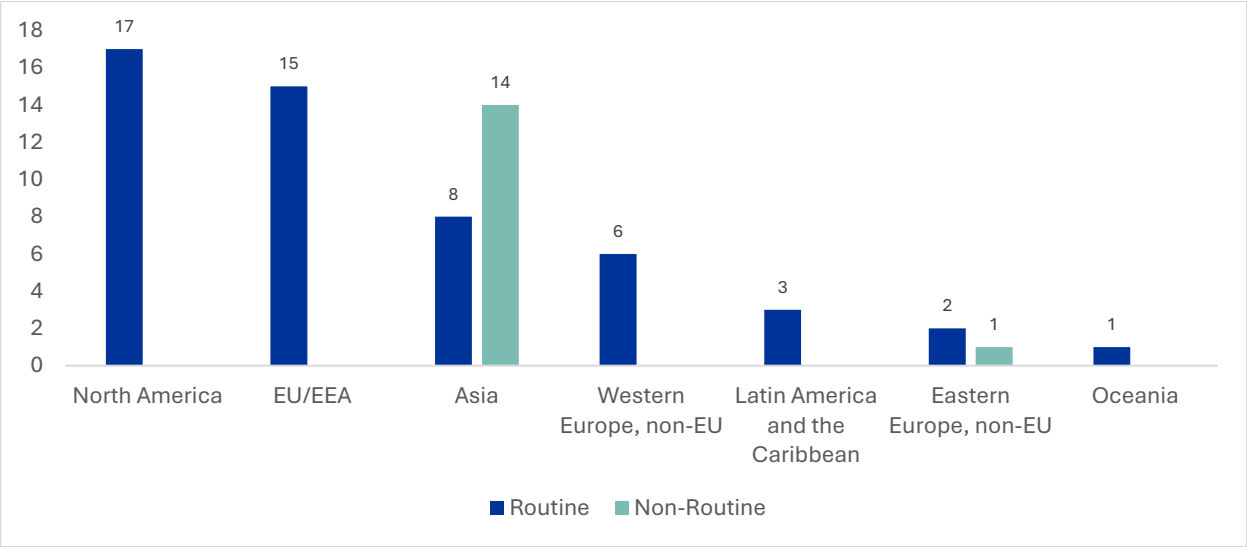
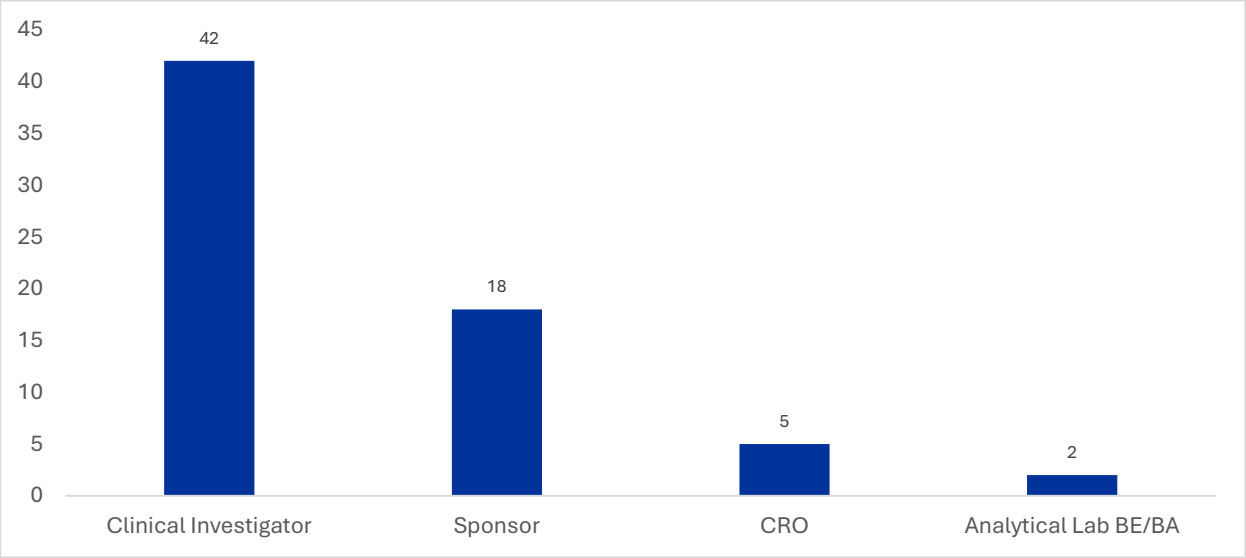


Table 2 and Figure 2 represent the number of inspections conducted in 2024 per type of site. Most of the inspections were conducted at clinical investigator sites, followed by sponsor and CRO sites.

Table 2: Number of inspections conducted per type of site

Inspection Site Type	# Inspected Sites	% Inspected Sites
Clinical Investigator	42	62.7%
Sponsor	18	26.9%
CRO	5	7.5%
Analytical Lab BE/BA	2	3.0%
Grand Total	**67**	**100.0%**

Figure 2: Number of inspections conducted per type of site

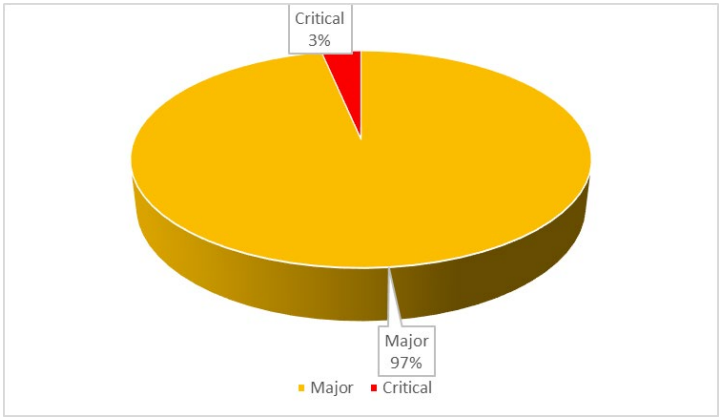


3.1.2. Categorisation of findings

a) General overview

As agreed at the March 2025 plenary meeting of the GCP IWG, in order to focus annual report statistics on the most relevant deficiencies and to align with the reporting requirements in the Clinical Trials Information System (CTIS), minor findings have not been included in this report. While this report only presents statistics on major and critical findings raised during CHMP-requested GCP inspections, minor findings continue to be reported in EMA inspection reports. A total of 335 major and critical deficiencies, comprising 11 critical and 324 major findings were recorded for the 67 CHMP requested inspections conducted in 2024 (Figure 3).

Figure 3: Percentage of findings by grading category: critical and major



Grade	# Deficiencies	% Inspected deficiencies
Major	324	96.72%
Critical	11	3.28%
Total	**335**	**100.00%**

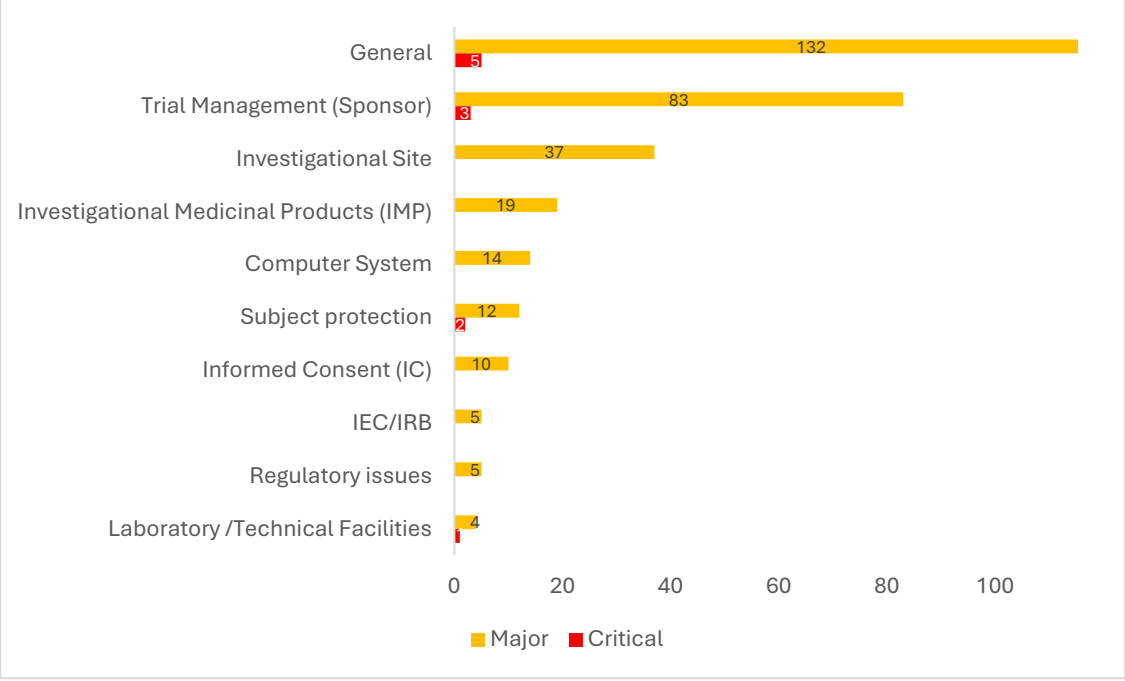
b) Distribution by categories and sub-categories

The main findings raised during inspections in 2024 are detailed below in Table 3, in accordance with the categorisation of findings agreed by the GCP IWG.

Table 3: Number of critical and major findings by main category

Main category	Major	Critical	Total
General	132	5	**137**
Trial Management (Sponsor)	83	3	**86**
Investigational Site	37	0	**37**
Investigational Medicinal Products (IMP)	19	0	**19**
Computer System	14	0	**14**
Subject protection	12	2	**14**
Informed Consent (IC)	10	0	**10**
IEC/IRB	5	0	**5**
Regulatory issues	5	0	**5**
Laboratory /Technical Facilities	4	1	**5**
Others	3	0	**3**
Grand total	**324**	**11**	**335**

Figure 4: Number of findings by main category and grading category: critical and major



Findings are further sub-divided below for the top three most frequently cited categories: General, Trial Management, and Investigational Site.

Table 4: Number of findings per sub-category of the top 3 main categories (General, Trial Management and Investigational Site) graded as critical and major

Category	Sub-category	Major	Critical	Total
General	Contracts/Agreements	5	0	**5**
	Direct Access to Data	3	1	**4**
	Essential Documents	39	2	**41**
	Facilities and Equipment	9	0	**9**
	Organisation and Personnel	4	0	**4**
	Qualification/Training	10	0	**10**
	Randomisation/Blinding/Codes IMP	4	0	**4**
	SOPs	22	0	**22**
	Source Documentation	36	2	**38**
General Total		**132**	**5**	**137**
Trial Management	Audit	3	0	**3**
	Clinical Study Report (CSR)	4	1	**5**
	Data Management	26	1	**27**
	Document Control	4	0	**4**
	Monitoring	35	0	**35**
	Protocol/ Case Report Form (CRF)/ Diary/ Questionnaires design	4	1	**5**
	Statistical Analysis	7	0	**7**
Trial Management Total		**83**	**3**	**86**
Investigational Site	Protocol Compliance (Others)	9	0	**9**
	Protocol Compliance (Assessment of Efficacy)	2	0	**2**
	Protocol Compliance (Safety Reporting)	12	0	**12**
	Protocol Compliance (Selection Criteria)	5	0	**5**
	Reporting in CRF/Diary	9	0	**9**
Investigational Site Total		**37**	**0**	**37**

Examples of common areas of critical and major findings in the subcategories of the three main categories "General", "Trial Management", and "Investigational Site" are listed below.

General

Contracts/agreements:

- Lack of explicit GCP compliance clauses in contracts/agreements
- Insufficient direct access to trial documentation
- Inadequate documentation of third party/vendor qualification and oversight
- Missing or delayed formalisation of contracts/agreements
- Retention and archiving requirements not established in contracts/agreements between sponsors and clinical investigators

Essential documents and direct access to data:

- Lack of access at the trial site to trial-relevant electronic systems containing essential documents/data for monitors and inspectors.
- Trial Master File/Investigator Site File issues including incomplete or poorly maintained files
- Lack of version control and document management: missing version control of worksheets, informed consent forms, inconsistencies between protocol and investigator brochure; no formally documented process for TMF quality control.
- Inadequate certification and quality of copies: Process for certification of copies not established; source data verification/review only based on review of uncertified copies of electronic medical records.
- Lack of inspection readiness at clinical sites.

Facilities and equipment:

- Inadequate archiving and storage facilities.
- Equipment qualification, maintenance, and documentation deficiencies: Lack of equipment calibration, diagnostic equipment lacking proper documentation, equipment maintenance certificates not available.
- Lack of or insufficient assessment of the suitability of facilities for trial procedures.
- Lack of documentation on temporary storage location and the conditions of storage of biological samples.

Organisation and personnel:

- Deficiencies in delegation of trial related tasks:
  - Tasks performed outside of the delegation period.
  - Discrepancies between documented delegation of trial related tasks and actual activities performed.
  - Inadequate delegation log template provided by the sponsor/CRO

Qualification/training:

- Missing or incomplete training documentation (e.g. qualifications, training records, GCP training certificates, etc.) evidencing site personnel training in GCP and trial relevant documents.
- Delayed or untimely training of site personnel (training completed after site activation, training completed after protocol implementation).

Randomisation/blinding/codes IMP:

- Inadequate or missing blinding-related documentation and/or inappropriate communication of changes to randomisation/blinding.

Standard Operating Procedures (SOPs):

- Missing or delayed SOPs for critical trial processes and trial documents.
- Incomplete or inadequate SOP content
- Lack of version control and change management.
- Deficient process to select, review, and approve SOPs for critical trial related processes.
- SOPs not aligned with regulatory requirements and practices.

Source documentation:

- Incomplete, inaccurate, or non-contemporaneous source data
- Discrepancies between source data and case report forms
- Inadequate documentation of key trial processes
- Inadequate documentation of sample handling and clinical procedures

Trial management

Audit:

- Absence or delay of Audit SOPs and processes
- Inadequate documentation and oversight of audits.
- Deficiencies in the performance of routine quality assurance activities:
  - No audits conducted of partners/vendors engaged in activities on behalf of the sponsor.
  - No audits conducted of any sponsor processes/activities.
  - No audits conducted of investigator sites.

CSR:

- Deficient quality control of the CSR
- Incomplete or inaccurate reporting of protocol deviations and key data in the CSR
- Delays and gaps in data inclusion and analysis: Insufficient data cleaning resulting in data changes detected only after primary analysis.

Data management:

- Lack of data management plans, procedures, and oversight

- Inadequate data migration and system validation
- Delays and gaps in data entry, cleaning, and freezing
- Inadequate documentation and traceability of data handling: Use of excel for sensitive data collection; insufficient process for identifying and reporting protocol deviations
- Inadequate version control and date-time stamping of data sets and analysis outcomes
- Inadequate data security: Pseudonymised and unblinded data sent without password protection or encryption.

Document control:

- Lack of formal processes for document review and control
- Incomplete or inconsistent documentation of key decisions in the clinical trial

Monitoring:

- Inadequate or delayed monitoring visits and documentation
- Monitoring not based on an appropriate monitoring plan
- Inadequate detection and escalation of issues: delays in SAE reporting, missing ISF documents, protocol deviations, missing laboratory values not detected.
- Insufficient access to source data for monitors: CRAs did not have direct access to EHRs/EMRs, limiting their ability to perform monitoring tasks; not all available source data used for monitoring.

Protocol/ CRF/ diary/ questionnaire design:

- Errors and ambiguities in protocol and associated documents: editorial errors, misleading table titles, no instructions in the protocol for unscheduled visits.
- Delays and gaps in documenting protocol amendments
- Inadequate design and implementation of CRFs and diaries
- Incomplete or inconsistent documentation of inclusion and exclusion criteria and patient data

Statistical analysis:

- Inadequate handling and storage of final analysis data sets
- Delays and gaps in data cleaning and analysis
- Incomplete or inaccurate statistical reporting
- Lack of documentation of rationale for changes in statistical analysis procedures

Investigational site

Protocol compliance (others)

- Undetected and unreported protocol deviations:
  - Protocol deviations related to the timing of IMP administration.
  - Late detection and documentation of protocol deviations.
- Protocol deviations relevant to participant safety:

  - Eligibility assessment was not completed before the randomisation of participants.
- Protocol deviations related to improper management of clinical samples
- Protocol deviations and changes to trial conduct without a protocol amendment

Protocol compliance (assessment of efficacy):

- Failure to perform or properly document all efficacy assessments required in the study protocol: Missing laboratory tests, failure to conduct all clinical evaluations, not following the protocol-specific order for assessments and questionnaires

Protocol compliance (safety reporting)

- Deficiencies in the safety reporting process at the site leading to under- or incomplete reporting of AEs and SAEs.
- Lack of investigator oversight of SAE reporting: Lack of evidence of principal investigator review and sign-off on SAEs
- Inadequate training and procedures related to safety event reporting at the investigational site

Protocol compliance (selection criteria)

- Inclusion of ineligible participants by the principal investigator
- Failure to complete or document eligibility assessments required by the study protocol
- Delayed or missing documentation on eligibility decisions
- Protocol deviations related to the re-screening for eligibility of study participants

Reporting in CRF/diary:

- Incomplete, missing or delayed data entry in eCRF
- Discrepancies between source data and eCRF
- Lack of principal investigator oversight and/or sign-off
- Errors in data collection and reporting

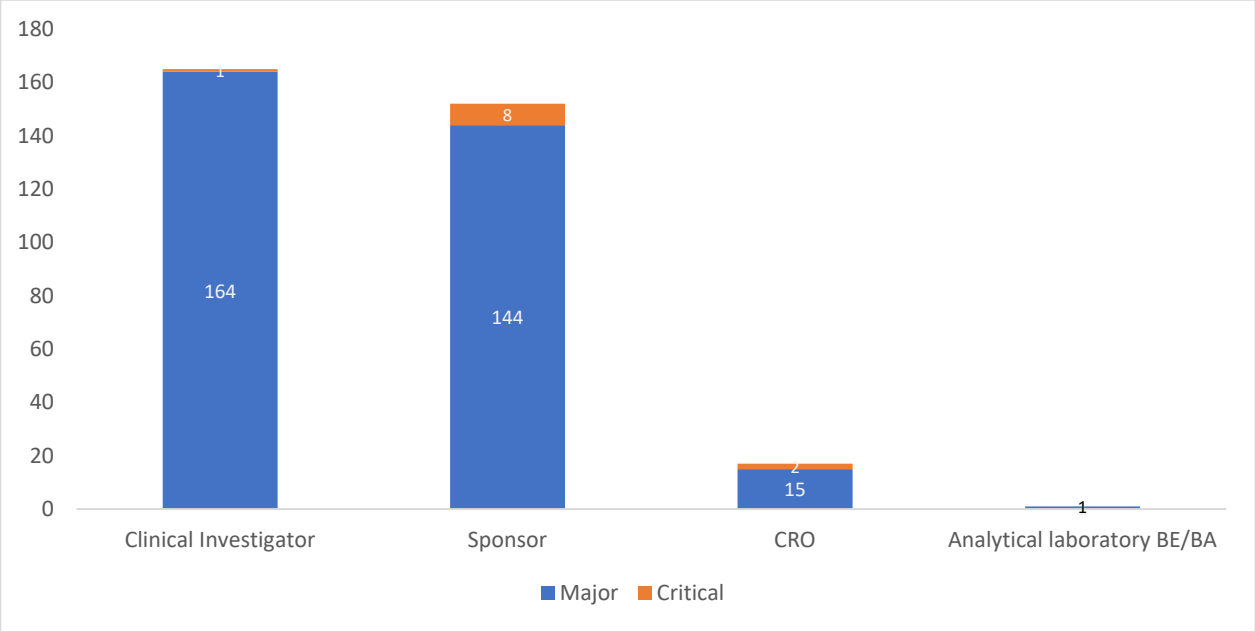
c) Distribution of findings by type of site inspected

The main findings raised during inspections in 2024 grouped by site type are detailed below in Table 5.

Table 5. Number of findings graded as critical and major per site type

Inspection site type	Major	Critical	Findings
Clinical Investigator	164	1	**165**
Sponsor	144	8	**152**
CRO	15	2	**17**
Analytical Lab BE/BA	1	0	**1**
Total	**324**	**11**	**335**

Figure 5: Number of findings graded as critical and major per site type



The figures below show the categories of findings at the following types of sites: clinical investigators, sponsors, and CROs.

Table 6. Number and categorisation of critical and major findings at clinical investigator sites.

Main category	Major	Critical	Total
General	70	1	71
Investigational Site	33	0	33
Trial Management (Sponsor)	19	0	19
Investigational Medicinal Products (IMP)	14	0	14
Subject protection	8	0	8
Informed Consent (IC)	7	0	7
Regulatory Issues	5	0	5
IEC/IRB	3	0	3
Laboratory /Technical Facilities	3	0	3
Computer System	2	0	2
Total	**164**	**1**	**165**

Figure 6: Number and categorisation of critical and major findings at clinical investigator sites.

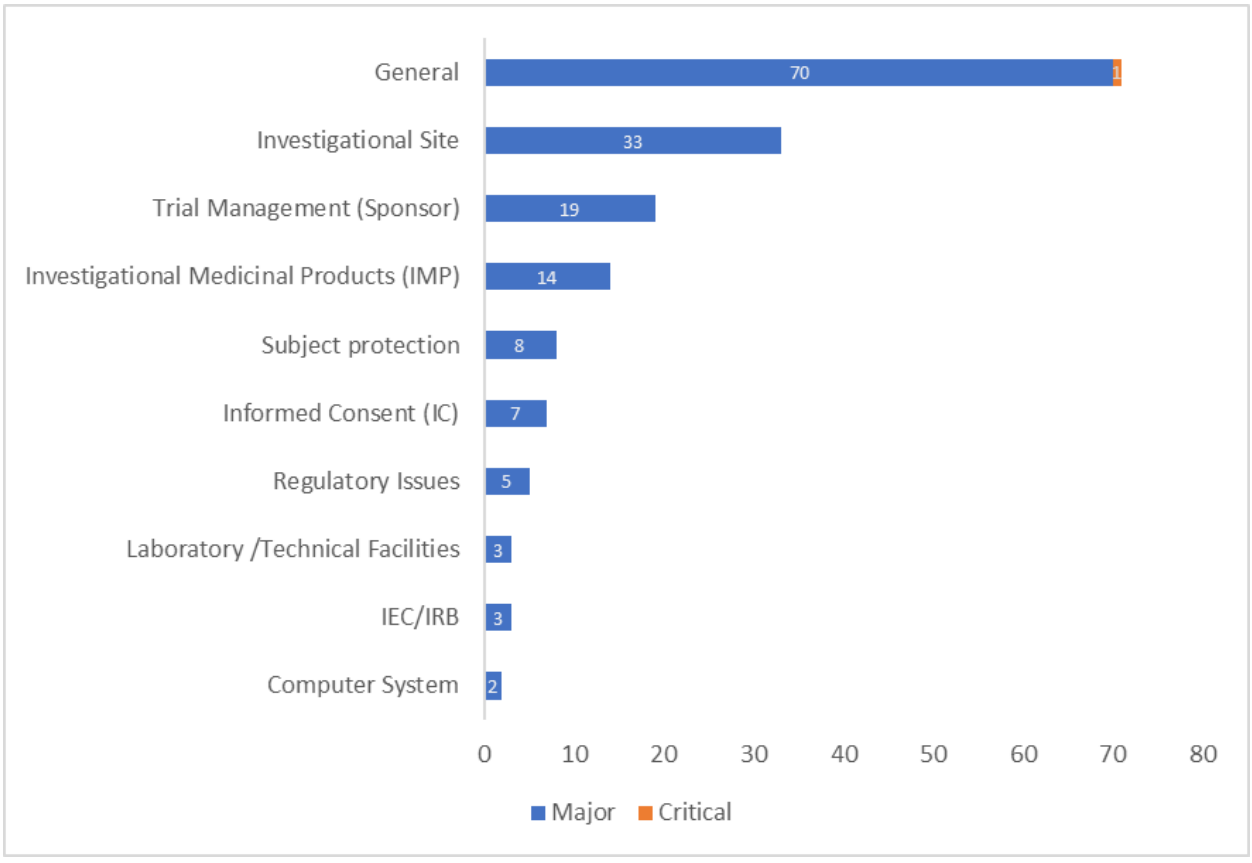


Table 7. Number and categorisation of findings at sponsor sites.

Main category	Major	Critical	Total
Trial Management (Sponsor)	58	2	60
General	57	4	61
Computer System	12	0	12
Investigational Medicinal Products (IMP)	4	0	4
Informed Consent (IC)	3	0	3
Subject protection	3	2	5
IEC/IRB	2	0	2
Investigational Site	2	0	2
Others	2	0	2
Laboratory /Technical Facilities	1	0	1
Total	**144**	**8**	**152**

Figure 7: Number and categorisation of findings at sponsor sites.

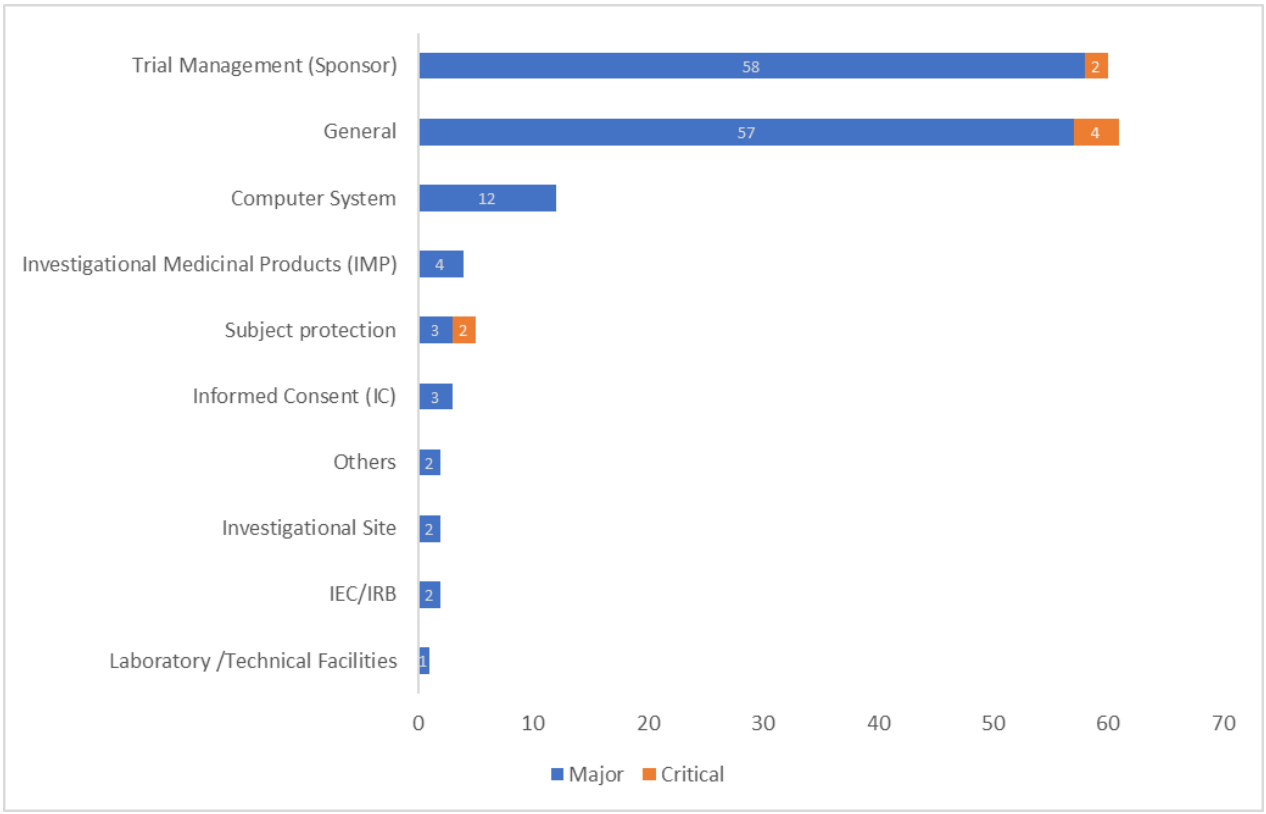
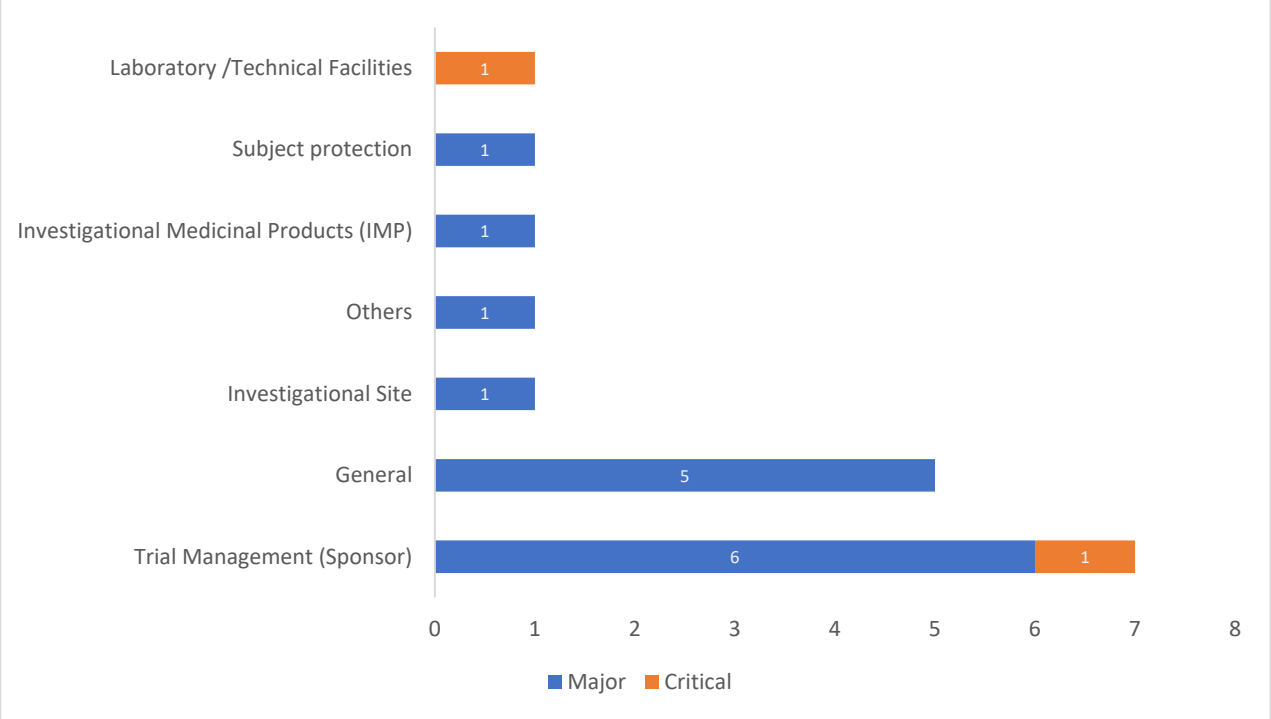


Table 8. Number and categorisation of findings at CRO sites.

Main category	Major	Critical	Total
Trial Management (Sponsor)	6	1	7
General	5	0	5
Investigational Site	1	0	1
Others	1	0	1
Investigational Medicinal Products (IMP)	1	0	1
Subject protection	1	0	1
Laboratory /Technical Facilities	0	1	1
Total	**15**	**2**	**17**

Figure 8: Number and categorisation of findings at CRO sites.



d) Distribution by responsible party

Finally, Table 9 shows the distribution of responsibilities for each grading of finding.

Table 9. Responsibility for findings across all inspected sites

Responsibility	Major	% Major	Critical	% Critical	Total	% Total
Sponsor	168	51.9%	9	81.8%	**177**	**52.8%**
Multiple Responsibility	80	24.7%	2	18.2%	**82**	**24.5%**
Investigator	71	21.9%	0	0.0%	**71**	**21.2%**
IEC/IRB	0	0.0%	0	0.0%	**0**	**0.0%**
CRO	5	1.5%	0	0.0%	**5**	**1.5%**
Total	**324**	**100.0%**	**11**	**100.0%**	**335**	**100.0%**

It is important to mention that the GCP inspections requested by the CHMP, as outlined here, make up only a small fraction of all inspections carried out by EU/EEA inspectors. Many additional inspections occur under their national programmes in the following contexts:

- Oversight of the conduct of clinical trials in Europe.
- Marketing authorisation applications (MRP, DCP or national procedures).

4. Harmonisation topics

4.1. Procedures and guidance documents

The GCP inspectors adopted the following document in 2024:

- Guidance on remote GCP inspections during public health threats emergencies and crisis situations

This document replaces the "Guidance on remote inspections during COVID-19 pandemic" published on 10 June 2020.

The GCP Q&A B.19 was updated on the EMA website Q&A: Good clinical practice (GCP) | European Medicines Agency (EMA):

- B.19: What are the expectations for distribution of updated Investigator's Brochures (IBs) and updated Informed Consent Forms (ICFs) to clinical sites/investigators?

The contribution of the GCP IWG to the third revision of the ICH GCP guideline (E6 R3) is described in section 4.5.

4.2. Inspection cooperation

- Cooperation between the EU/EEA MSs:

All the inspections conducted in 2024 were joint inspections involving inspectors from at least two MSs.

- Cooperation with third countries:

Observers from countries outside the EU/EEA were invited in 2024 to observe the EU/EEA GCP inspections performed in those countries in the context of the centralised procedure.

4.3. GCP training and development

- A project on building capacity in the area of GCP/BE inspections was carried out in 2024. GCP/BE inspection resources across the network were mapped, gaps were identified, and recommendations were collected on how to further strengthen GCP/BE inspection capacity in the EU/EEA. The expansion of training opportunities (both online and on-the-job) was identified as a key area of focus.
- The EMA Inspections Office together with the GCP IWG worked on the design of a new EMA coordinated GCP and BE Inspections Online Training Course, published on the EU Network Training Centre (EUNTC). It consists of the following modules:
  - EMA-coordinated GCP inspections: overview of EMA inspection coordination process.
  - EMA-coordinated GCP inspections: preparation and conduct of investigator site inspections, sponsor site inspections, and BE inspections.
  - EMA-coordinated GCP inspections: reporting inspections – writing of Inspection Report and Integrated Inspection Report.
- 2024 European Union Good Clinical Practice Inspectors Working Group Workshop

The hybrid 2024 EU GCP IWG Workshop took place on 22-24 October 2024 in Larnaca, Cyprus. Participants included 190 inspectors from the EU/EEA/EFTA and third countries.

The 2024 workshop covered the following topics in the form of presentations and breakout sessions:

- Inspecting against ICH E6(R3) with a focus on data governance and data integrity.
- New technologies such as the use of Artificial Intelligence in clinical trials.
- Harmonisation of grading and writing of inspection findings.
- Reviewing the Clinical Study Report.
- Cultural considerations in international inspections.
- Guest presentations from non-EU countries.

- The 2024 Bioequivalence (BE) Inspectors Forum took place in a hybrid setting on 21 October 2024 in Larnaca, Cyprus. GCP inspectors from the EU/EEA and non-EU countries (FDA, WHO, MHRA, Health Canada, Swissmedic) were present. The BE Forum lasted one day, and topics covered in the form of presentations and case studies included:
  - Bioequivalence Studies – A PK BE assessors' perspective.
  - Discussion on case/document from past inspections.
  - Data Integrity Violations in BA/BE Studies.
  - Tools to identify data anomalies.
  - Insights into investigating data integrity in BE inspections.
  - Analytical Inspections for Bioavailability/Bioequivalence Studies.
  - FDA Guidance on Data Integrity for Bioavailability and Bioequivalence Studies.
  - Experience in contacting participants.

- A further one-day training event was organised on data analytics to identify compliance issues of BE studies.

4.4. GCP IWG meetings and topics of interest

4.4.1. GCP IWG meetings

- During the plenary meetings of the GCP IWG held on 5-6 March 2024, 11-12 June 2024, 24-25 September 2024 and 26-27 November 2024, the following topics were discussed:
  - Regulation (EU) No 536/2014 (Clinical Trials Regulation) implementation, CTIS and Union controls.
  - New Fee Regulation (Regulation (EU) 2024/568).
  - Accelerating Clinical Trials in the EU (ACT EU) initiative and relevant priority actions.
  - Guidelines, Q&As and procedures under development.
  - Update on ICH E6(R3) and new ICH M11.
  - Updates on ongoing inspections of interest.
  - Updates from subgroups on their activities.
  - GCP compliance interpretation matters and ethical issues; response to queries received from third parties.
  - Coordination and observation of EMA inspections, and the GCP inspection programme.
  - National inspections.
  - Training activities.
  - International collaboration activities.

4.4.2 GCP IWG joint meeting with CHMP/clinical assessors

- During the GCP IWG-clinical assessors' joint meeting, held virtually on 6 June 2024, a combination of presentations and breakout sessions were used to cover the following topics:
  - EMA coordinated GCP inspection programme.
  - Selection of trials and sites for EMA coordinated GCP inspections.
  - EMA coordinated GCP inspections - scope of triggered and routine inspections.
  - How the outcomes of inspections are taken into consideration for the final CHMP opinion.

4.5. Clinical trial legislation and related guidance documents

The appointed EU experts to the ICH E6(R3) Expert working group (EWG; ICH Official web site: ICH) and the head of the Inspections Office at EMA as the Regulatory Chair of this EWG worked closely on the draft ICH E6 (R3) document during 2024. The Principles and Annex 1 of ICH E6 (R3) were adopted by the CHMP in Dec 2024 (ICH E6 (R3) Guideline on good clinical practice (GCP) Step 5).

4.6. Clinical Trials Information System (CTIS)

GCP IWG members were kept up to date during GCP IWG plenary meetings on CTIS related topics, e.g. on serious breaches, inspections modules and implementation of the revised CTIS transparency rules. The topic of harmonisation between MSs on the assessment of serious breaches submitted through CTIS was also discussed in the meetings of the GCP IWG and the related sub-group.

4.7. EU enlargement

In 2024, representatives from the EU enlargement countries of Albania, Kosovo, Montenegro, North Macedonia, Serbia, Türkiye, Georgia, and Ukraine were invited to the meetings of the GCP IWG as observers.

5. Liaison with other EU groups

5.1. GMDP IWG

The GCP IWG maintained a dialogue with the GMDP IWG on areas of common interest. In 2024, the two IWGs collaborated in particular on the Recommendation paper on travel advice. This paper aims to assist GxP inspectors who are travelling to certain third countries outside EU/EEA where the context would add risk to inspectors' safety and where special attention to specific practicalities is emphasised.

5.2. PhV IWG

The GCP IWG maintained a dialogue with the PhV IWG on areas of common interest and in particular concerning PhV issues observed in relation to GCP inspections.

5.3. HMA/ CTCG

The GCP IWG maintained a collaboration with the Heads of Medicines Agencies (HMA) and the Clinical Trials Coordination Group (CTCG) on areas of mutual concern in the supervision of clinical trials conducted in the EU/EEA. In 2024, representative members of the GCP IWG observed CTCG meetings.

5.4. CHMP

The GCP IWG maintained a dialogue with the CHMP on areas of common interest and in particular on matters related to GCP inspections. The GCP IWG organised in 2024 a joint inspectors-CHMP/assessors joint, virtual meeting (see section 4.4.2).

5.5. CMDh

The GCP IWG and the CMDh, mainly through the GCP/CMDh Working Party, which met 4 times in 2024, have contributed to the following topics:

- CROs of interest and the CRO inspection programme.
- CRO inspections planned, conducted, outcomes and subsequent actions.
- Referral procedures.
- BE inspection resources.
- BE inspectors' curriculum and training including EU NTC modules.

- Training on a tool used for the detection of data manipulation.
- Annual Bioequivalence inspectors' Forum.
- International collaboration, working group, and clusters in the BE area.

5.6. Paediatric Committee (PDCO)

Communication on inspection issues with the PDCO continued in 2024 with the exchange of information on inspections of clinical trials with a paediatric population.

6. Liaison with international partners

6.1. Regulatory agencies from outside the EEA

- EMA and FDA have had a collaboration initiative in place since 2009 in the area of GCP[1]. This collaboration was extended in 2013 to BE, together with some of the EU/EEA MSs[2].
  - During 2024 there were 5 regular teleconferences of the EMA-FDA GCP collaboration and 4 teleconferences as part of the EMA-FDA-WHO-MSs BE collaboration.
  - In addition, the EMA Inspections Office attended the EMA - FDA – MHRA – Health Canada – Swissmedic – Israeli MoH generics cluster, where data integrity issues were discussed.
  - As part of the EMA-FDA GCP initiative the FDA observed two EMA inspections, and there were two joint EMA/FDA inspections. In addition, in 2024, the French inspectorate observed one FDA inspection in its territory.
  - Several FDA representatives also attended the GCP IWG Workshop and BE Forum.
- Pharmaceuticals and Medical Devices Agency (PMDA, Japan):
  - PMDA joined the FDA-EMA initiative as an observer in June 2017 for an 18-month pilot phase. Based on the outcomes of this pilot initiative, EMA and FDA agreed to add PMDA as an official member of the GCP initiative and to continue the activity.
  - Regular exchanges of information occurred during EMA and PMDA meetings.
  - PMDA participated in all regular teleconferences with EMA and FDA as part of the GCP collaboration.
- WHO:
  - Since 2018, WHO has been an observer of the GCP IWG under the EMA, European Commission and WHO confidentiality arrangement.
  - WHO participated in all regular teleconferences with EMA and FDA as part of the BE collaboration.
  - EMA, WHO and the EU/EEA MSs that perform the highest number of BE inspections had 4 teleconferences to pursue the existing collaboration and exchange BE inspection information.

[1] Announcement of the EMA-FDA GCP Initiative
[2] Announcement of the generic medicines application inspections initiative

- Swissmedic:
  - The Swiss Agency for Therapeutic Products (Swissmedic) is an observer of the GCP IWG under the European Commission, EMA, Swiss Federal Department of Home Affairs and Swissmedic confidentiality arrangement, in place since 2015.
  - In 2024, Swissmedic observed one inspection requested by the CHMP.
- Other regulatory agencies:
  - As noted in section 4.2, non-EU regulators observed GCP inspections requested by the CHMP and, as noted in section 4.3 also attended the GCP IWG Workshop
  - Collaboration is being strengthened with additional regulatory agencies. Regular exchange of information occurs with the regulatory authorities with which EMA has confidentiality arrangements in place.

6.2. International initiatives

- Inspection information was exchanged with the regulatory authorities in Argentina, Brazil, Canada, Chile, Georgia, India, South Korea, Malaysia, Mexico, Moldova, New Zealand, Singapore and Thailand.

For details on the activities of the GCP IWG for the period 2024-2026, please see the Work Plan for 2024-2026.