EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 March 2025
EMA/INS/GCP/329215/2023 Rev.1.
Inspections Office
Quality and Safety of Medicines Department

3-year work plan for the GCP IWG

First year review – March 2025

Work plan period: January 2024 – December 2026 (with a first review point after one year)

The GCP Inspectors' Working Group (GCP IWG) was established by the European Medicines Agency (EMA) in 1997, within the scope of Article 57(1)(i) of Regulation (EC) No 726/2004.

This group focuses on harmonisation and coordination of GCP related activities at a European level.

A three-year rolling workplan is presented taking into account the current activities of the GCP IWG and the role of the group towards the goals and recommendations of the European Medicines Regulatory Network (EMRN) strategy to 2025. The network has started work on reviewing the scope of the Network Strategy and the EMA RSS to cover the network's goals and objectives up to 2028 (EMANS2028). It is possible that these strategic goals may be amended and updated following publication of EMANS 2028.

A review of the workplan will take place every year to reflect on experience and to optimise the plan, as required. In each section activities/objectives appear in order of priority (high to low and short/medium to long term objectives).

1. Strategic goals:

The GCP IWG 3-year workplan is developed with a focus on the EMA Regulatory Science Strategy (RSS) goals, with a particular emphasis on fostering (innovative) clinical trials in the EU and modernising GCP inspections.

- Harmonisation and coordination of GCP inspection related activities at EU level and beyond. *RSS Goal 2: Driving collaborative evidence generation —improving the scientific quality of evaluations.*

- Continue to strengthen the link with clinical assessors, diversify and integrate the inspection process and compliance management along the product lifecycle. *RSS Goal 2: Driving collaborative evidence generation —improving the scientific quality of evaluations.*
- Develop capacity building opportunities for inspectors from EU/EEA as well as countries outside the EU/EEA and contribute to information-sharing international initiatives. *RSS Section 5: Working together: international regulatory science cooperation.*
- Strengthen the understanding of, and regulatory response to new technologies and materials in pharmaceuticals and integrate in the GCP inspection process. *RSS Goal 1: Catalysing the integration of science and technology in medicines development.*
- Support the coordination of the provision of GCP advice and maintain a dialogue with other groups such as CHMP, CVMP, CAT, CMDh, PhV IWG, GMP/GDP IWG, SAWP, CTCG, CTAG, MedEthicsEU etc. in areas of common interest. *Goal 2: Driving collaborative evidence generation —improving the scientific quality of evaluations*
- Develop external engagement and communications to promote trust and confidence in the EU regulatory system and compliance monitoring. *RSS Goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems*
- Disseminate and exchange knowledge, expertise, and innovation across the network and to its stakeholders. *RSS Goal 4: Enabling and leveraging research and innovation in regulatory science*

2. Tactical goals: activities/projects to deliver the strategic goals

- Prepare and implement the biennial GCP inspections programme for inspections in the context of the centralised procedure.
- Support a harmonised approach for compliance with the requirements of the Clinical Trial Regulation (EU) No 536/2014, including use of the Clinical Trials Information System (CTIS).
- Engage with stakeholders on topics such as electronic data systems, data integrity, data protection and the use of AI in clinical trials and innovative trials.
- Contribute to the raw data pilot on the selection of procedures and sites exploiting the individual patient data listings.
- Cooperate with regulators outside the EU network and build capacity internationally by providing training and networking opportunities organised by the GCP IWG.
- Develop new and review existing EMA GCP inspection procedures and guidelines, as necessary.
- Contribute to ACT EU activities requiring GCP IWG input.
- Build capacity across the EU GCP inspectors' network by initiating a project on understanding capacity building challenges and proposing solutions including, but not limited to, the design and delivery of (on-line) training courses (See section 2.2 on training).

2.1. Guideline activities:

- Contribute to the revision or development and implementation of the following ICH guidelines:
  - Renovation of ICH E6(R2) Good Clinical Practice: ICH E6(R3) including contribution to an impact analysis and implementation of this guideline

  - Development of the new ICH guideline M11 Clinical electronic Structured Harmonized Protocol (CeSHarP).
- Contribute — through the creation of dedicated subgroups — to EMA guidance documents to be in alignment with the requirements of the Clinical Trials Regulation (EU) No 536/2014 and ICH E6(R3).

2.2. Training activities:

- Organise and conduct the GCP Workshop/BE Forum for EU/EEA and global inspectors' network on specific topics of interest.
- Plan for the review of the basic GCP and BE inspections on-line training courses.
- Develop an EMA coordinated GCP inspections online training course for new inspectors involved in EMA coordinated inspections and with a focus on EMA inspection procedures and inspector roles and responsibilities.
- Develop a training module for clinical assessors with GCP inspection aspects of relevance to their role.
- Contribute to the training of inspectors on emerging technologies, including the use of AI in clinical trials, and new concepts by organising appropriate regular and ad-hoc training events.
- Coordinate with ACT EU PA4 to organise training for inspectors on inspecting against ICH E6(R3).
- Develop a mentorship initiative for junior inspectors for EU inspection capacity building.
- Conduct joint/observational GCP inspections to enhance EU inspection capacity building.
- Maintain close communication with assessors and facilitate training and workshops of inspectors and assessors.
- Follow up on the proposals for training within the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) Working Group(s) (WGs) on good clinical practice and pharmacovigilance (GVP) in accordance with the agreed mandate.

2.3. Communication and stakeholder activities:

- Organise joint meetings with external parties on topics of common interests.
- Publish Q&As on GCP interpretation.
- Respond to GCP related queries received by EMA.
- Publish the GCP IWG annual report to increase transparency and to provide information about areas of focus to improve the quality and GCP compliance of clinical trials.
- Explore options for the sharing of inspection information to promote compliance among stakeholders in an efficient manner.

2.4. Cross-domain activities:

2.4.1. Collaboration with the European Commission

Provide expert support to the European Commission on GCP related matters and inspections in relation to the implementation of the Clinical Trials Regulation (EU) No 536/2014. Collaborate with the European Commission on the development of clinical trial legislation and related guidance documents, including documents in Eudralex Volume X, as needed.

2.4.2. Work with the following groups:

- **Good Manufacturing and Distribution Practice Inspectors' Working Group (GMDP IWG)**
  - Maintain a dialogue with the GMDP IWG on areas of common interest.
- **Good Laboratory Practice Inspectors' Working Group (GLP IWG)**
  - Maintain a dialogue with the GLP IWG on areas of common interest.
- **Pharmacovigilance Inspectors' Working Group (PhV IWG)**
  - Maintain a dialogue with the PhV IWG on areas of common interest and, in particular concerning pharmacovigilance in relation to clinical trials.
- **Clinical Trials Coordination and Advisory Group (CTAG)**
  - Maintain a dialogue with the CTAG on areas of common interest.
- **Medical Ethics European Union (MedEthicsEU)**
  - Maintain a dialogue with the MedEthicsEU group on areas of common interest.
- **Clinical Trials Coordination Group (CTCG)**
  - Collaborate on areas of mutual interest in the area of the supervision of clinical trials conducted in the EU/EEA.
- **Coordination group for Mutual Recognition and Decentralised Procedures (human) (CMDh)**
  - Maintain a dialogue with CMDh, through the GCP IWG CMDh Working Party, on areas of common interest and in particular concerning bioequivalence/bioavailability studies.
  - Prepare the annual programme of coordinated routine inspections of contract research organisations used in the conduct of bioequivalence trials included in MAAs for generic products in the mutual recognition and decentralised procedures.
  - Continue the training and development of inspectors in the area of BE inspections.
  - Promote continuing collaboration and interactions between assessors and BE inspectors.
  - Equip EU inspectors and assessors with the skills, training, and relevant tools to facilitate their review of electronic source and raw data at EU level, including the verification of data integrity of BE trials.
  - Promote global cooperation with non-EU Regulators (US FDA, WHO, etc.), in the area of BE inspections through a harmonised approach and the sharing of data, subject to confidentiality agreements in place.
- **Heads of Medicines Agencies (HMA)**

- When requested, to collaborate on HMA initiatives in GCP related areas, in particular in the area of the supervision of clinical trials conducted in the EU/EEA and in relation to inspections in countries outside the EU/EEA.

- **Committee for Medicinal Products for Human Use (CHMP)**
  - Maintain an open dialogue between GCP inspectors and CHMP members/clinical assessors on GCP inspections and related matters, and compliance issues by establishing joint workshops and training events and attending the CHMP (PROM) meetings, as considered necessary.

- **Liaison with other groups**
  - Collaboration regarding paediatric regulation, advanced therapies, orphan drugs, pharmacovigilance, and scientific advice:
    - Continue the communication on inspection issues with the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Pharmacovigilance Risk Assessment Committee (PRAC), the Scientific Advice Working Party (SAWP), Methodology Working Party (MWP) and the Emergency Task Force (ETF), as relevant.

3. Operational goals: medicinal product-specific activities

3.1. Pre-authorisation activities

- Discuss GCP inspections, triggers, processes, and inspection follow-up between GCP IWG and CHMP/CAT, as necessary.
- Provide scientific advice on GCP related issues, when required/necessary (see section 2.4).
- Contribute and provide relevant input to CTCG discussions on GCP related issues, as necessary (see section 2.4).
- Maintain a strong communication link between GCP inspectors and clinical assessors (see section 2.4).

3.2. Evaluation and supervision activities

- Implement the biennial GCP inspections programme.
- Modernise the conduct of GCP inspections by providing training to GCP inspectors on inspecting against ICH E6(R3) (see section 2.2)
- Review EMA inspections procedures and work closer with CHMP/CAT/Assessors to enhance the role and understanding of GCP inspections in the B/R assessment (see section 2.4).
- Strengthen the harmonisation of the conduct and reporting of GCP inspections across the EU through training activities (see section 2.2).
- Discuss specific GCP inspection/product related issues and agree on a common approach.
- Enhance GCP interpretation across the EU by:
  - harmonising the interpretation of existing guidelines and their proportionate application;
  - developing GCP related guidelines on specific topics of need;
  - developing GCP related Q&As.

- Participate in information sharing initiatives with international regulators:
  - Continue with the operational phase of the EMA-FDA-PMDA GCP initiative.
  - Continue with the operational phase of the EMA-EU MSs-FDA-WHO initiative on generic products.

4. Expertise required

Nominations to the group are made in accordance with the mandate of the GCP IWG:

https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-gcp-inspectors-working-group-gcp-iwg_en.pdf

Additional staff of the authorities may attend with the chairman's agreement, in particular where their participation is needed for a specific topic. Experts will be identified depending on the topic of interest. Members of the GCP IWG appointing a subgroup member for their NCA may select any subject matter expert from their NCA, taking into account the relevant expertise required, and the availability of the nominee. Such appointed members should be registered in EMA's Experts' Management Tool.

5. Work modalities/architecture

The GCP IWG shall meet at least four times per year, either face-to-face or by video conference according to the proposed plan. The dates of the meetings shall be communicated to the members in advance. Some meetings or parts of the meetings may involve joint activities with other working groups, workshops, and training in order to make best use of time and resources. Additional meetings may be held when planned for specific reasons such as training. The group will agree on the priorities and adjust this yearly.

Drafting groups will conduct the majority of their business by correspondence and teleconference but upon reasoned request meetings will be organised by EMA usually within the margins of the plenary meeting of the GCP IWG.

Part of training sessions or workshops may be recorded for reuse upon agreement of the speakers and committee members organising the workshop/training so that they can become available to non-members/a broader audience, however, certain parts of training and workshops will be limited to participants only.