18 February 2021
EMA/INS/GCP/452875/2020
Inspections Office
Quality and Safety of Medicines Department

3-year work plan for the GCP IWG

Due to the COVID-19 pandemic and in accordance with the business continuity plans of the Agency and the Member States, this work plan may be subject to further review and the activities outlined here may be reprioritised.

Name of Working Party:	**Good Clinical Practice Inspectors Working Group (GCP IWG)**
Chairperson:	Jane Moseley

Work plan period: January 2021 – December 2023 (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. A review of the workplan will take place after the first 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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Strategic goals:

The GCP IWG 3-year workplan is developed with a focus on the EMA Regulatory Scientific Strategy (RSS) goals, with a particular emphasis on fostering (innovative) clinical trials in the EU, and future proofing of 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.*
- 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 an 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.*
- 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.*
- 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, including the publication of inspection reports. *RSS Goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems 3.3.8 Further develop external engagement and communications to promote trust and confidence in the regulatory system.*
- 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, etc. in areas of common interest. *RSS Goal 1: Catalysing the integration of science and technology in medicines development.*
- 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 202x GCP inspections programme for inspections in the context of the centralised procedure.
- Create a GCP IWG subgroup to work on the future proofing of GCP inspections by reviewing EMA inspections procedures and working closer with CHMP/CAT/assessors to enhance the role and understanding of GCP inspections on the B/R assessment.

- Contribute to the ICH E6 (GCP) renovation/modernise GCP oversight to adapt to the updated ICH E6 (GCP).
- Engage with stakeholders on topics such as electronic data systems, data integrity, data protection in clinical trials and innovative trials, complex and decentralised trials. Create dedicated GCP IWG subgroups to focus on the aforementioned topics.
- 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 in relation to the implementation of the Clinical Trials Regulation (EU) No 536/2014 and transparency of inspections.
- Provide input to a future platform to foster (innovative) clinical research in the EU.

2.1. Guideline activities:

- Contribute to the revision of the following ICH guidelines:
  - Development of the new ICH guideline E19 on Optimisation of Safety Data collection.
  - Renovation of ICH E8 General Considerations for Clinical Trials.
  - Renovation of ICH E6(R2) Good Clinical Practice.
  - Development of the new ICH guideline M11 Clinical electronic Structured Harmonized Protocol (CeSHarP).
- Contribute, through the creation of dedicated subgroups, to the following EMA guidance documents in order to be aligned with the requirements of the Clinical Trials Regulation (EU) No 536/2014:
  - Overarching guideline on the redaction of documents uploaded in the CTIS specifically to the chapter on the redaction of inspection reports.
  - Guidance for clinical trial sponsors on serious breaches reporting.
  - Guidance for managing serious breaches by EEA member states including their assessment and the appointment of a lead member state.
- Continue working on the GCP IWG guideline on electronic systems and electronic data in clinical trials through the GCP IWG subgroup.

2.2. Training activities:

- Contribute to the training of inspectors on emerging technologies and new concepts by organising appropriate regular and ad-hoc training events.
- Organise and conduct the annual GCP workshop/BE forum for EU/EEA and global inspectors' network on specific topics of interest.
- Organise the annual basic on-line GCP and BE training courses for EU/EEA and non-EU/EEA inspectors.
- Conduct joint/observational GCP inspections to enhance capacity building.
- Develop a mentorship initiative for junior inspectors for capacity building.
- Maintain close communication with assessors and facilitate training and workshops of inspectors and assessors, including ad hoc attendance of assessors at GCP IWG meetings.

- 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 & 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.

Create dedicated GCP IWG subgroups to work on the above tasks.

2.4. Cross-domain activities:

Work with the following groups:

- **Good Manufacturing and Distribution Practice Inspectors Working Group (GMP/GDP IWG)**
  - Maintain a dialogue with the GMP/GDP 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 Facilitation Group (CTFG)**
  - Collaborate on areas of mutual interest in the area of supervision of clinical trials conducted in the Community and implement the following procedure, when the opportunity arises:
    - Procedure for the voluntary coordination and conduct of GCP inspections of EEA interest outside the context of a marketing authorisation procedure.
- **Coordination group for Mutual Recognition and Decentralised Procedures (human) (CMDh)**
  - To maintain a dialogue with CMDh, through the GCP IWG CMDh Working Party, on areas of common interest and in particular concerning bioequivalence/bioavailability studies.
  - To prepare the 202X programme of coordinated routine inspections of contract research organisations used in the conduct of bioequivalence trials included in MAA for generic products in the mutual recognition and decentralised procedures.
  - To continue the training and development of inspectors in the area of BE inspections.
  - To promote continuing collaboration and interactions between assessors and BE inspectors.
  - To equip EU inspectors and assessors with the skills, training and relevant tools in order to facilitate their review of electronic source and raw data at EU level, including verification of data integrity of BE trials.

- To promote global cooperation with non-EU Regulators (US FDA, WHO, etc.), in the area of BE inspections by having a harmonised approach and through 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 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)**
  - Create a GCP IWG subgroup to work together with (clinical) assessors/CHMP/CAT on the future proofing of GCP inspections:
    - Review EMA inspections procedures and work closer with CHMP/CAT to enhance the role and understanding of GCP inspections on the B/R assessment.
    - Modernise the conduct of GCP inspections to adapt to the revised ICH E6 guideline.
    - Strengthen the harmonisation of the conduct and reporting of GCP inspections across the EU.
  - Maintain an open dialogue between GCP inspectors and CHMP/CAT members/clinical assessors on GCP inspections related matters and compliance issues. This might include also the organisation of face-to-face meetings.

- **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) and the Scientific Advice Working Party (SAWP), 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.
- Provide scientific advice on GCP related issues, when required/necessary (see section 2.4).
- Contribute and provide relevant input to CTFG discussions on GCP related issues, as necessary (see section 2.4).
- Contribute to the future pilot GCP IWG/CTFG/CTEG/SAWP product platform to input on specific trials.

3.2. Evaluation and supervision activities

- Implement the 202x GCP inspections programme.

- 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).
- Modernise the conduct of GCP inspections (see section 2.4).
- Strengthen the harmonisation of the conduct and reporting of GCP inspections across the EU (see section 2.4).
- Discuss specific GCP inspection/product related issues and agree on a common approach.
- Enhance GCP interpretation across the EU by developing:
  - GCP related guidelines on specific topics of need;
  - 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

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' Database.

5. Work modalities/architecture

The GCP IWG shall meet at least four times per year, preferably face-to-face, and by video conference if necessary. 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/broader audience, however, certain parts of training and workshops will be limited to participants only.