22 March 2018
EMA/87812 /2018
Committees and Inspections

Work plan for GCP Inspectors Working Group for 2018

Chairperson: Ana Rodriguez

The activities outlined in the work plan for 2018 have been agreed in view of preparation for the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency

1. Introduction

The GCP IWG[1] was established by the Agency[2] 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.

The group activities for this year are outlined in this document and the priorities of the group will be:

- to ensure participation in the conduct of routine and 'for cause' GCP inspections in the context of the centralised procedure;
- to continue to engage with stakeholders on topics such as electronic data systems, data integrity, data protection and quality risk management in clinical trials;
- to 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 (refer to section 6, 1st bullet point);
- to 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 (refer to section 4.1, 1st bullet point).

[1] Good Clinical Practice Inspectors Working Group
[2] European Medicines Agency (EMA)

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2. Meetings scheduled for 2018

The following joint meetings will take place:

- 08-09 March 2018
- 05-06 June 2018

When possible in Q2 of 2018 a number of subgroup meetings to discuss specific topics and draft documents will be organised to replace the plenary meetings, and additional telephone conferences will be scheduled as needed.

In 2018 the EU GCP Inspectors' Working Group workshop is planned to take place in Germany with participation of EU/EFTA/EEA and third country inspectors.

3. Inspections conducted in support of the centralised procedure

- Implementing the GCP inspections programme for 2018, which has the following objectives:
  - To plan in advance the minimum number of GCP inspections to be requested per year.
  - To ensure a broad coverage of product types, therapeutic areas/indication, target population, sponsors/CROs/vendors, type of studies and sites and that a range of different situations are included.
  - To pro-actively select the focus areas with respect to indication, population, geographical location of sites, recruitment rates, size of sponsor, size of CRO/CTF and tasks and the general trends to be followed in the period 2018-2019.
  - To ensure that diverse geographical regions are selected for inspection including third countries from which a substantial amount of clinical trial data in MAA[3] derives from.
- To ensure participation in the conduct of routine and 'for cause' GCP inspections in the context of the centralised procedure. Through the EMA-FDA[4] GCP initiative (refer to section 8.1, 1st bullet point) as well as the EMA-EU MSs[5]-FDA initiative on inspections for generic applications (refer to section 8.1, 2nd bullet point), duplication of inspections should be avoided and increased inspection coverage will continue to be ensured for MAA submitted to both, the Agency and the US FDA.
- Ensure timely entry of information on GCP inspections in the EudraCT database.

[3] Marketing Authorisation Application
[4] US Food and Drug Administration
[5] Member States

4. Harmonisation topics

4.1. Procedures and guidance documents

- To contribute to the revision of the EMA GCP inspection procedures and guidance documents in order to be aligned with the requirements of the Clinical Trials Regulation (EU) No 536/2014.
- To continue working on the development of the following documents:
  - Guideline on Electronic Systems and Electronic Data in Clinical Trials.
  - Guidelines on Good Clinical Practice for Advanced Therapy Medicinal Products
  - Procedure for the management of serious breaches by the EEA Member States, including their assessment and the appointment of a lead Member State.
  - Guidance for EU MSs on the redaction of inspection reports to remove personal details and commercially confidential information.
  - Guidance for EMA coordination of cooperation between MS concerned on inspections conducted in MS, in third countries and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No 726/2004.
- To address the comments raised during the 2017 public consultation and finalise the following documents:
  - Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol.
  - Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials.
- To publish for public consultation the following guidance developed in collaboration with the GMDP IWG and European Commission:
  - Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use, in accordance with Good Clinical Practice and Good Manufacturing Practice.

4.2. Inspection cooperation in the EU

- To perform joint inspections in order to facilitate training, mutual understanding and consistency among member states.
- To perform inspections under the "Procedure on the Coordination of GCP inspections of EU interest, outside the context of the marketing authorisation procedure, and to be performed under national programmes", when the need arises.

4.3. Training and development

- To provide input on the organisation of the 16th GCP IWG Workshop.

- To contribute in the organisation of the on-line GCP inspectors' basic training course with webinars for EU and non-EU inspectors.
- To contribute in the organisation of the on-line BE GCP inspectors' basic training course with webinars for EU and non EU inspectors.
- To continue developing capacity building opportunities for inspectors from countries outside the EU/EEA[6] as in preceding years. Some examples are outlined below:
  - to continue to invite them to participate in the above mentioned GCP IWG workshop and on-line GCP inspectors' basic training course;
  - to join EU inspections taking place in their countries as observers;
  - to continue to provide mentorship upon request and though participation in training courses organised in countries outside EU/EEA;
  - to liaise with WHO[7] in this context.

5. Topics of interest

- To prepare new Q&A documents, as required, and finalise already existing Q&As to clarify the inspectors' expectations with respect to certain processes, including, but not limited to:
  - Procedures related to the conduct of the clinical trials performed at subjects' home instead of in a health care establishment (e.g. dispensing IMPs)
  - Contractual arrangements between sponsors and third parties to conduct trial related duties and functions that are clearly responsibility of the investigator.
  - Level of validation/qualification needed to be performed by a sponsor when using an electronic system previously qualified by a provider, and what documentation is required to be available for inspections.

6. Collaboration with European Commission

- To continue to provide expert support on the implementation of the Clinical Trials Regulation (EU) No 536/2014, in relation to matters relating to GCP and the conduct of clinical trials and GCP inspections.

  In this context, the GCP IWG will contribute to the finalisation of the following documents, considering comments from the public consultation:
  - Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use, in accordance with Good Clinical Practice and Good Manufacturing Practice (refer to section 4.1).

[6] The European Economic Area
[7] World Health Organization

7. Liaison with other EU groups

7.1. GMP/GDP IWG[8]

- To maintain a dialogue with the GMP/GDP IWG on areas of common interest.
- To continue the joint development of the 'Guideline on the responsibilities of the sponsor with regards to handling and shipping of investigational medicinal products for human use, in accordance with Good Clinical Practice and Good Manufacturing Practice' (see section 4.1).

7.2. PHV IWG[9]

- To maintain a dialogue with the PhV IWG on areas of common interest and in particular concerning pharmacovigilance in relation to clinical trials.

7.3. CTFG[10]

- Collaboration 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 coordination and conduct of GCP inspections of EEA interest outside the context of a marketing authorisation procedure.

7.4. CMDh[11]

- To maintain a dialogue with CMDh, in particular through the GCP-CMDh working party, on areas of common interest and in particular concerning bioequivalence/bioavailability studies.
- To prepare the 2018 programme of the contract research organisations most often used in the conduct of bioequivalence trials included in MAA for generic products in the mutual recognition and decentralised procedures.

7.5. HMA[12]

- 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.

7.6. CHMP[13]

- To maintain an open dialogue between GCP inspectors and CHMP members/clinical assessors' on GCP inspections related matters and compliance issues. This might include also organisation of face to face meetings in 2018.

7.7 Liaison with other groups

- Collaboration regarding paediatric regulation, orphan drugs, pharmacovigilance and scientific advice:

[8] Good Manufacturing and Distribution Practice Inspectors Working Group
[9] Pharmacovigilance Inspectors Working Group
[10] Clinical Trials Facilitation Group
[11] Co-ordination group for Mutual Recognition and Decentralised Procedures (human)
[12] Heads of Medicines Agencies
[13] Committee for Medicinal Products for Human Use

- To continue the communication on inspection issues with the PDCO[14], COMP[15], the PRAC[16] and the SAWP[17], as relevant.

8. Liaison with international partners

8.1. Regulatory agencies from outside the EEA

- To continue with the operational phase of the EMA-FDA-PMDA GCP initiative.
- To continue with the operational phase of the EMA-EU MSs-FDA initiative on generic products.
- To support the development of the EMA-EU MSs- WHO- Bioequivalence Inspection Collaboration.
- To encourage observed, joint inspections and complementary inspection programmes with national regulatory authorities in third countries.

8.2. International initiatives

- To contribute to the development of the new ICH E19 on Optimisation of Safety Data collection.
- To maintain the existing links with the PIC/S[18], also through the participation to the Joint Visit Programme (JVP) for GCP inspections, and to participate in further training activities to be provided by PIC/S in the field of GCP inspections.
- To maintain the existing links with the WHO on GCP inspection matters.
- To maintain the active participation in the APEC[19]/ASEAN[20]/EMA/WHO initiative on the "Roadmap to promote GCP Inspection" and implement any follow-up actions arising from this initiative.
- To contribute to the EDCTP[21] Fellowship Scheme by providing mentorship to the regulatory fellows, through observed inspections and joint training activities.
- To establish links with other projects and initiatives in relation to GCP matters and inspections.

[14] The Paediatric Committee
[15] The Committee for Orphan Medicinal Products
[16] Pharmacovigilance Risk Assessment Committee
[17] The Scientific Advice Working Party
[18] Pharmaceutical Inspection Cooperation Scheme
[19] Asia-Pacific Economic Cooperation
[20] Association of Southeast Asian Nations
[21] European & Developing Countries Clinical Trials Partnership