EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Quality and Safety of Medicines Department

Work plan 2020 of the Good Clinical Practice Inspectors' Working Group

Due to the COVID-19 pandemic and the recent relocation of the Agency, the activities outlined in the work plan for 2020 may be subject to further review and reprioritisation in accordance with the business continuity plans of the Agency and the Member States.

1. Introduction

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.

The group activities for the period 2020 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).

2. Meetings scheduled for 2020

The following GCP IWG meetings are planned to take place:

- 12 March 2020 (virtual meeting)

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- 23-24 June 2020
- 21-23 September 2020
- 10 - 11 December 2020

The EU GCP Inspectors' Working Group 2020 workshop was planned to take place in Seeheim-Jugenheim (Frankfurt area, Germany), organised by Paul-Ehrlich Institute (PEI) with participation of EU/EFTA[1]/EEA[2] and third country inspectors. This event has been subsequently postponed to 2021 due to the travel restrictions imposed during the COVID-19 pandemic.

3. Inspections conducted in support of the centralised procedure

- Implementing the GCP inspections programme for 2020, 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/ Contract Research Organisations (CROs)/vendors, including IT vendors, type of studies and sites and that a range of different scenarios 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/ Clinical Trial Facility (CTF) and tasks and the general trends to be followed in the period 2020,
  - to ensure that diverse geographical regions are selected for inspection including third countries from which a substantial amount of clinical trial data in marketing authorisation application (MAA) derives from;

- To publish the document 'Classification and analysis of the GCP inspection findings of GCP inspections conducted at the request of the CHMP (Inspection reports to EMA 2000-2016)'.
- To ensure participation in the conduct of routine and 'for cause' GCP inspections in the context of the centralised procedure. Through the EMA-FDA[3]-PMDA[4] GCP initiative (refer to section 8.1, 1st bullet point) as well as the EMA-EU MSs[5]-FDA- WHO 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.
- Promote timely and accurate entry of information on national GCP inspections in the EudraCT database.

[1] The European Free Trade Association
[2] The European Economic Area
[3] US Food and Drug Administration
[4] Japanese Pharmaceuticals and Medical Devices Agency
[5] Member States

4. Harmonisation topics

4.1. Procedures and guidance documents

- To contribute to the revision of the following EMA GCP inspection procedures and guidance documents in order to be aligned with the requirements of the Clinical Trials Regulation (EU) No 536/2014:
  - Guidance for the conduct of Good Clinical Practice Inspections - Annex V Phase I Units.
  - Guidance for the conduct of Good Clinical Practice Inspections - Annex III Computer Systems.
- To continue working on the development of the following document:
  - Guidance for the managing of serious breaches by the EEA Member States, including their assessment and the appointment of a lead Member State.
- To address, in a document, the need to revise the current Data Monitoring Committee (DMC) guidance and initiate work on the revision of the DMC guidance.
- To address the comments raised during the 2017 public consultation and finalise the following document:
  - Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol.
- To publish for public consultation the following guideline:
  - Guideline on Electronic Systems and Electronic Data in Clinical Trials.

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.
- To perform bioequivalence (BE) inspections of CROs of EU interest under national programmes.

4.3. Training and development

- To provide input in the organisation of the 17th GCP IWG Workshop in 2020.
- To contribute to the revision of the on-line GCP and BE inspectors' basic training course in order to be aligned with the requirements of the Clinical Trials Regulation (EU) No 536/2014.
- To contribute to the organisation of the 2020 on-line GCP inspectors' basic training course with webinars for EU and non-EU inspectors.
- To contribute to the organisation of the 2020 on-line BE GCP inspectors' basic training course with webinars for EU and non-EU inspectors.
- To contribute to the organisation, upon demand, of face to face training or webinars of EU/EEA inspectors on specialised topics of interest such as inspection of IT systems and data management tools.

- To continue developing capacity building opportunities for inspectors from countries outside the EU/EEA 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 World Health Organization (WHO) 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:
  - Q&A on inspectors' access to patients' medical records/data when the access of EEA inspectors to medical information is not clearly stated in the Informed Consent Form (ICF).
  - Q&A on sponsor oversight of activities subcontracted to third parties.
  - Q&A on expectations for provision of written information to clinical trial subjects in relation to new information requiring re-consent.
  - Q&A on confidentiality undertaking of EU/EEA inspectors.

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 testing of the inspection module of the Clinical Trial Information System (CTIS);
  - contribute to the finalisation, after consideration from the public consultation, of the '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'.

7. Liaison with other EU groups

7.1. Good Manufacturing and Distribution Practice Inspectors Working Group (GMP/GDP IWG)

- To maintain a dialogue with the GMP/GDP IWG on areas of common interest.
- To finalise 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 6).

7.2. Pharmacovigilance Inspectors Working Group (PHV IWG)

- 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. Clinical Trials Facilitation Group (CTFG)

- To 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.

7.4. Co-ordination group for Mutual Recognition and Decentralised Procedures (human) (CMDh)

- To maintain a dialogue with CMDh, in particular through the GCP IWG CMDh Working Party, on areas of common interest and in particular concerning bioequivalence/bioavailability studies.
- To prepare the 2020 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. 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.

7.6. Committee for Medicinal Products for Human Use (CHMP)

- 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.

7.7. Liaison with other groups

- Collaboration regarding paediatric regulation, advanced therapies, orphan drugs, pharmacovigilance and scientific advice:
  - To 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.

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 guideline E19 on Optimisation of Safety Data collection.
- To contribute to the renovation of ICH E8 General Considerations for Clinical Trials.
- To contribute to the renovation of ICH E6(R2) Good Clinical Practice.
- To contribute to the development of the new ICH guideline M11 Clinical electronic Structured Harmonized Protocol (CeSHarP).
- To maintain the existing links with the Pharmaceutical Inspection Cooperation Scheme (PIC/S), 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 establish links with other projects and initiatives in relation to GCP matters and inspections.
- To contribute to the joint international sustainable training project for India and China in the area of GCP.