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Compliance and Inspections

Work plan for GCP Inspectors Working Group for 2017

Chairperson: Ana Rodriguez

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 provide expert support to the European Commission on GCP related matters and inspections in relation to the implementation of the new Clinical Trials Regulation (refer to section 6, 1st bullet point);
- to develop new, and revise existing document such as EMA GCP inspection procedures and guidelines in relation to the implementation of the new Clinical Trials Regulation (refer to section 4.1, 1st bullet point);
- to provide training and support for EU inspectors with a focus on inspection of bioequivalence trials;
- to continue to engage with stakeholders on topics such as electronic data systems, data integrity, data protection and quality risk management in clinical trials.

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[2] European Medicines Agency (EMA)

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2. Meetings scheduled for 2017

- 28 February -02 March 2017.
- 12-14 June 2017.
- 12-14 September 2017.
- 27-29 November 2017.

The following joint meetings may take place:

- joint meeting with interested parties considering also a specific meeting on the topic of BE trials/inspections;
- joint meeting with CHMP clinical assessors.

A number of subgroup meetings to discuss specific topics and draft documents will be organised to coincide with the plenary meetings when possible, but if needed a number of additional telephone conferences will be scheduled (see section 7).

In 2017 the EU GCP Inspectors' Working Group workshop is planned to take place in Hungary with EU/EFTA/EEA and third country inspectors.

3. Inspections conducted in support of the centralised procedure

- Implementing the GCP inspections programme for 2017, which has the following objectives:
  - to define in advance the number of GCP inspections to be requested in 2017;
  - to ensure a broad coverage of product types, therapeutic areas/indication, target population, sponsors/CROs/vendors, studies and sites;
  - 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 2017-2018;
  - 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 that GCP inspector's resources are allocated for the conduct of routine and 'for cause' GCP inspections in the context of the centralised procedure. In order to save resources, duplication of inspections should be avoided and increased inspection coverage will be ensured for MAA submitted to both, the Agency and the US FDA[4], through the EMA-FDA 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)[6].
- Timely entry of information on GCP inspections in the EudraCT database.

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

4. Harmonisation topics

4.1. Procedures and guidance documents

To contribute to the revision of all EMA GCP inspection procedures and guidance documents in order to be aligned with the requirements of the new Clinical Trials Regulation. In particular:

- To develop the following new documents:
  - Guidance for EU MSs on the redaction of Inspection reports to protect personal data 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 launch for public consultation the following new documents already drafted:
  - Guidance for the appointment of a lead Member State for the managing of serious breaches.
  - Guidance for clinical trial sponsors on what it is expected to be reported as a serious breach.
  - 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 finalise the revision of the following existing guidelines:
  - Detailed guidelines on good clinical practice specific to advanced therapy medicinal products.
  - Recommendations on the qualifications of inspectors verifying compliance in clinical trials with the provisions of good clinical practice.

4.2. Inspection cooperation in the EU

- To perform joint inspections 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” (see section 7.3), when the need arises.

4.3. Training and development

- To provide input in the organisation of the 15th GCP IWG Workshop.
- To run the on-line GCP inspectors’ basic training course with one webinar for EU and one for non-EU inspectors.
- To provide training opportunities regarding inspections of BE[7] trials and in particular to implement an on-line BE inspections module.
- To develop capacity building opportunities for inspectors from countries outside the EU/EEA[8]:
  - to continue to invite them to participate in the above mentioned GCP IWG workshop;

[7] Bioequivalence
[8] The European Economic Area

- to join EU inspections taking place in their countries as observers;
- to invite them to join national EU inspections as observers;
- to provide mentorship upon request and though participation in training courses organised in countries outside EU/EEA;
- to invite them to follow the on-line basic training courses;
- to liaise with WHO[9] in this context.

5. Topics of interest

- To continue working on the preparation of a guidance document on the use of electronic systems and data capture systems in clinical trials.
- To prepare Q&A documents, as required, to clarify the inspectors' expectations with respect to certain processes and procedures, with particular focus on data protection.

6. Collaboration with European Commission

- To continue with the expert support, as required, on the implementation of the new Clinical Trials Regulation, 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 document, considering comments from the public consultation:

  - guidance on risk proportionate approaches in clinical trials;
  - guidance to cover the aspect of shipping (distribution) of IMPs and the second step of the two-step release procedure to address interfaces between the manufacturer and the sponsor of clinical trial.
- EU enlargement:
  - to assist the candidate countries: Albania, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia, and Turkey and potential candidates: Bosnia and Herzegovina and Kosovo (under UNSC Resolution 1244/99), in development of their GCP inspection roles;
  - to invite these countries to observe meetings of the GCP IWG;
  - to contribute to workshops in candidate countries on GCP matters.

[9] World Health Organization

7. Liaison with other EU groups

7.1. GMP/GDP IWG[10]

- To maintain a dialogue with the GMP/GDP IWG on areas of common interest.
- To establish a subgroup of GCP and GMP inspectors to develop a guidance to cover the aspect of shipping (distribution) of IMPs and the second step of the two-step release procedure to address interfaces between the manufacturer and the sponsor of clinical trial.

7.2. PHV IWG[11]

- 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[12]

- Collaboration on areas of mutual concern in the area of supervision of clinical trials conducted in the Community and continue with the implementation of 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[13]

- 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 2017 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[14]

- 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[15] Assessors

- To maintain an open dialogue between GCP inspectors and CHMP clinical assessors' on GCP inspections related matters and compliance issues. This might include also organisation of face to face meetings in 2017.

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

7.7. Liaison with other groups

- To continue the communication on inspection issues with the PDCO[16], COMP[17], the PRAC[18] and the SAWP[19], as requested.

8. Liaison with international partners

8.1. Regulatory agencies from outside the EEA

- To continue with the operational phase of the EMA-FDA GCP initiative.
- To continue with the operational phase of the FDA on the EMA-EU MSs-FDA initiative on generic products.
- To progress with the EMA-FDA GCP initiative including collaboration with PMDA, Japan.
- To encourage observed, joint inspections and complementary inspection programmes with national regulatory authorities in third countries.

8.2. International initiatives

- To maintain the existing links with the PIC/S[20], also through the participation to the Joint Visit Programme (JVP) for GCP inspections, and to participate in the 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[21]/ASEAN[22]/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[23] 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.

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