EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2015
EMA/INS/GCP/434364/2014
Compliance and Inspections

Work plan for GCP Inspectors Working Group for 2015

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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 facilitate the implementation of the 2015 CHMP[3] work programme in relation to GCP inspections (refer to section 4.1, 1st bullet point);
- to contribute to the development of the ICH[4] E6 addendum (refer to section 8.2, 1st bullet point);
- to continue to provide training and support for EU inspectors;
- to continue to engage with stakeholders to encourage and support the implementation of quality risk management in clinical trials;
- to continue to implement actions arising from the "Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EU Regulatory Authority" and to continue to contribute to the establishment of a network for international cooperation on GCP inspections (refer to sections 4.3 and 8).

[1] Good Clinical Practice Inspectors Working Group
[2] European Medicines Agency (EMA)
[3] Committee for Medicinal Products for Human Use
[4] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

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2. Meetings scheduled for 2015

- 04-05 March 2015.
- 09-11 June 2015.
- 08-10 September 2015.
- 30 November-02 December 2015.

The following joint meetings will take place:

- joint meeting with interested parties;
- 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 main meetings when possible, but if needed a number of additional telephone conferences will be scheduled (see section 7).

3. Inspections conducted in support of the centralised procedure

- To implement the GCP inspections programme for 2015, which has the following objectives:
  - to define in advance the number of GCP inspections to be requested in 2015;
  - 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/central technical facilities and the general trends to be followed in the period 2014-2015;
  - to ensure that diverse geographical regions are selected for inspection including third countries from which a substantial amount of clinical trial data in MAA[5] derives from.
- To ensure the allocation of GCP inspection resources for the conduct of routine and 'for cause' GCP inspections in the context of the centralised procedure. Duplication of inspections will be avoided and increased inspection coverage will continue to be ensured for MAA submitted to both, the Agency and the US FDA[6], through the EMA-FDA GCP initiative (refer to section 8.1, 1st bullet point) as well as the EMA-EU MSs[7]-FDA initiative on inspections for generic applications (refer to section 8.1, 2nd bullet point).
- To ensure timely entry of information on GCP inspections in the EudraCT database.

[5] Marketing Authorisation Application
[6] US Food and Drug Administration
[7] Member States

4. Harmonisation topics

4.1. Procedures and guidance documents

- To contribute to the implementation of the 2015 CHMP work programme in relation to GCP inspections and in particular by:
  - monitoring the impact of GCP inspections on CHMP opinions;
  - identifying needs to revise documents completed in previous CHMP work plans and developed by the GCP IWG–CHMP clinical assessors subgroup, such as the document "Points to consider on GCP inspection findings and the benefit-risk balance" and "Points to consider for assessors, inspectors and EMA inspection coordinators on the identification of triggers for the selection of applications for "routine" and/or "for cause" inspections, their investigation and scope of such inspections". A check list with the criteria used in the selection of GCP inspections is to be developed.
- To publish a revised version of the "GCP inspection procedure on Reporting GCP inspections conducted in the context of the centralised procedure" and/or the inspection report templates, based on the experience gained from the 12 month pilot phase (which ran from Q3 2013-Q3 2014).

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 conduct the 13th GCP IWG Workshop.
- To revise the on-line GCP inspectors' basic training course based on the feedback from the 1st year pilot phase and to organise at least one webinar in 2015.
- To provide training opportunities regarding inspections of BE[8] trials.
- To develop capacity building opportunities for inspectors from countries outside the EU/EEA[9]:
  - to continue to invite them to participate in the above mentioned GCP IWG workshop;
  - to join EU inspections taking place in their countries as observers;
  - to continue to invite them to join national EU inspections as observers;
  - to continue to provide mentorship upon request;
  - to facilitate their use of/access to the online basic training course;
  - to liaise with WHO[10] in this context.

[8] Bioequivalence
[9] The European Economic Area
[10] World Health Organization

5. Topics of interest

- To finalise and publish the following reflection paper together with the responses to the comments from the public consultation:
  - "Reflection paper on trial master files (paper and electronic) for GCP compliance and inspection".
- To prepare Q&A documents, as required, to clarify the inspectors' expectations with respect to certain processes and procedures.

6. Collaboration with European Commission

- To provide expert support 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 particular, to actively contribute in the areas of transparency of inspection reports, the process for managing serious breaches, the development of the Implementing Regulation on GCP and the revision of the current GCP guidelines and GCP inspection procedures, as appropriate.
- EU enlargement:
  - To assist the candidate countries: The Former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey and potential candidates: Albania, Bosnia and Herzegovina, 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.
- ATIMPs[11] in clinical trials of Regulation on Advanced Therapies:
  - To monitor the implementation of GCP guidelines on advanced therapies in collaboration with CTFG[12] and CAT[13].
- Paediatric Regulation, orphan drugs, pharmacovigilance and scientific advice:
  - To increase communication on inspection issues with the PDCO[14], COMP[15], the PRAC[16] and the SAWP[17].

[11] Advanced Therapy IMPs
[12] Clinical Trials Facilitation Group
[13] Committee for Advanced Therapies
[14] The Paediatric Committee
[15] The Committee for Orphan Medicinal Products
[16] Pharmacovigilance Risk Assessment Committee
[17] The Scientific Advice Working Party

7. Liaison with other EU groups

7.1. GMP/GDP[18] IWG

- To maintain a dialogue with the GMP/GDP[19] IWG on areas of common interest.

7.2. PHV[20] 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. CTFG

- Collaboration on areas of mutual concern 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[21]

- 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 2015 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[22]

- 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 and in relation to inspections in countries outside the EU.

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 work closely with the FDA on the EMA-EU MSs-FDA initiative on generic products.
- To encourage observed, joint inspections and complementary inspection programmes with national regulatory authorities in third countries.

[18] Good Manufacturing and Distribution Practice Inspectors Working Group
[19] Good Manufacturing Practice/Good Distribution Practice
[20] Pharmacovigilance Inspectors Working Group
[21] Co-ordination group for Mutual Recognition and Decentralised Procedures (human)
[22] Heads of Medicines Agencies

8.2. International initiatives

- To contribute to the development of an addendum to ICH E6, which is to address risk based quality management, monitoring, electronic tools and TMF[23].
- To maintain the existing links with the PIC/S[24] 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[25]/ASEAN[26]/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[27] 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.

[23] Trial Master File
[24] Pharmaceutical Inspection Cooperation Scheme
[25] Asia-Pacific Economic Cooperation
[26] Association of Southeast Asian Nations
[27] European & Developing Countries Clinical Trials Partnership