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Compliance and Inspections

Work plan for GCP Inspectors Working Group for 2014

Chairperson: Ana Rodriguez

1. Introduction

The Good Clinical Practice 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 co-ordination 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 revise the GCP inspection policy in relation to: the procedure undertaken for the selection of MAA[1] and clinical trial sites to be inspected, increasing globalisation of clinical trials, the use of new technology in the conduct of clinical trial and the need for further transparency of inspections and their outcome;
- To work on the development of an on-line GCP inspectors' basic training course (refer to section 4.3, 2nd bullet point);
- To publish a report on GCP findings from CHMP[2] requested inspections (refer to section 5, 2nd bullet point).
- To continue to engage with stakeholders to encourage and support the implementation of quality risk management in clinical trials and to form a subgroup of inspectors who will, together with the EMA, develop a procedure on how inspectors will provide their feedback on risk based assessment/monitoring plans submitted to the SAWP[3].
- 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 contribute to the establishment of a network for international cooperation on GCP inspections;

[1] Marketing Authorisation Applications
[2] The Committee for Medicinal Products for Human Use
[3] Scientific Advice Working Party

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- To provide expert support to the European Commission on GCP related matters and inspections in relation to the revision of the Clinical Trials legislation.

2. Meetings scheduled for 2014

- 04-06 March 2014.
- 03-04 June 2014.
- 02-04 September 2014.
- 02-03 December 2014.

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 teleconferences will be scheduled (see section 7):

- GCP-CMDh[4] subgroup;
- GCP-SAWP.

3. Inspections conducted in support of the centralised procedure

- To increase the number of inspections conducted in countries where there is a rise in the number of clinical trials or patient participation in trials (priority countries).
- To ensure the allocation of GCP inspection resources for the conduct of routine and 'for cause' GCP inspections in the context of the centralized procedure. Duplication of inspections will be avoided and increased inspection coverage will continue to be ensured for MAA submitted to both the EMA and the US FDA[5], through the EMA-FDA GCP initiative (refer to section 8.1, 1st bullet point) as well as the EMA-EU MSs-FDA initiative on inspections for generic applications (refer to section 8.1, 2nd bullet point).
- To ensure entry of information on GCP inspections in the EudraCT database.

4. Harmonisation topics

4.1. Procedures and guidance documents

- To publish the revised version of the existing "Procedure for coordinating GCP inspections requested by the EMA".
- To monitor the implementation of the procedures described in the following documents developed by the GCP IWG–CHMP clinical assessors subgroup within the framework of the CHMP Work programme 2011-2013 and finalised by the GCP IWG and the CHMP:

[4] The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
[5] US Food and Drug Administration

- Revised “GCP inspection procedure on Reporting GCP inspections conducted in the context of the centralised procedure”. A 12 month pilot phase from its publication has been agreed after which the procedure is to be further revised, if considered necessary;
- “Points to consider on GCP inspection findings and the benefit-risk balance”;
- “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.

4.2. Inspection cooperation in the EU

- To perform joint inspections.
- 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 opportunity arises.

4.3. Training and development

- To conduct the 12th GCP IWG Workshop.
- To design and launch an on-line GCP inspectors’ basic training course. This course will be made up of 3 Modules, consisting of presentations given by senior EU inspectors followed by a webinar on each module during which exercises will be discussed and participants will have the opportunity to ask questions.
- To provide training opportunities regarding inspections of BE[6] trials.
- To develop capacity building opportunities for inspectors from countries outside the EU/EEA[7]:
  - to invite them to participate in the above mentioned GCP IWG workshop;
  - to join EU inspections taking place in their countries as observers;
  - to liaise with WHO[8] in this context.

5. Topics of interest

- To 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 publish a report on the ‘Classification and analysis of GCP inspection findings from GCP inspections conducted at the request of the CHMP in the period 2000-2012.’
- To prepare Q&A documents, as required, to clarify the inspectors’ expectations with respect to certain processes and procedures.

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

6. Collaboration with European Commission

- To provide expert support on GCP related matters and inspections in relation to the upcoming clinical trial Regulation..
- EU enlargement:
  - To assist the candidate countries: The Former Yugoslav Republic of Macedonia, Iceland, 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[9] in clinical trials of Regulation on Advanced Therapies:
  - To monitor the implementation of GCP guidelines on advanced therapies in collaboration with CTFG[10] and CAT[11].
- Paediatric Regulation, orphan drugs, pharmacovigilance and scientific advice:
  - To develop procedures for communication on inspections arising from issues raised by the PDCO[12].
  - To increase communication on inspection issues with the COMP[13], the PRAC[14] and the SAWP.

7. Liaison with other EU groups

7.1. GMDP[15] IWG

- To maintain a dialogue with the GMDP IWG on areas of common interest.

7.2. PHV[16] 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.

[9] Advanced Therapy IMPs
[10] Clinical Trials Facilitation Group
[11] Committee for Advanced Therapies
[12] Paediatric Committee
[13] The Committee for Orphan Medicinal Products
[14] Pharmacovigilance Risk Assessment Committee
[15] Good Manufacturing and Distribution Practice Inspectors Working Group
[16] Pharmacovigilance Inspectors Working Group

7.4. CMDh

- To maintain a dialogue with CMDh, in particular through the GCP-CMDh subgroup, on areas of common interest and in particular concerning bioequivalence/bioavailability studies.
- To prepare the 2014 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 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 3rd countries.

8.2. International initiatives

- To maintain the existing links with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) 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[17]/ ASEAN[18]/ EMA/ WHO initiative on the "Roadmap to promote GCP Inspection" and implement any follow-up actions arising from this initiative.
- To establish links with other projects and initiatives in relation to GCP matters and inspections.

[17] Asia-Pacific Economic Cooperation
[18] Association of Southeast Asian Nations