7 March 2011
EMA/INS/GCP/711390/2010
Compliance and Inspection

Workplan for GCP Inspectors Working Group for 2011

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1. Introduction

The GCP Inspectors Working Group (GCP IWG) was established by the EMEA 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 Community level. The group activities for this year are outlined in this document and the priorities of the group will be:

- To continue the work in the development of a guidance in relation to quality risk management in clinical trials, in particular in relation to monitoring
- To implement actions arising from the "Draft 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 EMA" and in particular to establish a network for international cooperation on GCP inspection
- To prepare a post-inspection follow up guidance document for inspectors and assessors
- To provide expert support to the European Commission on GCP related matters and inspections in its revision of the Clinical Trials legislation
- To develop processes to support cooperation on inspections of ongoing clinical trials in EU and of sites related to them.

2. Meetings scheduled for 2011

- 01 - 02 March 2011
- 14 - 15 June 2011
- 13 – 14 September 2011
- 06 – 07 December 2011

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The following joint meetings will take place:

- Joint meeting with interested parties on 15 June 2011 (pm)
- Joint meeting with CHMP[1] clinical assessors on 05 December 2011

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 limited number of additional meetings or teleconferences will be scheduled (see section 7):

- GCP-GMDP[2] subgroup
- GCP-CMD(h)[3] subgroup
- Quality risk management in clinical trials subgroup

Delegates from this group will be also involved in the Agency's multidisciplinary Working Group on 3rd country clinical trials.

3. Inspections conducted in support of the centralised procedure

- To ensure the allocation of GCP inspections resources for the conduct of routine and triggered GCP inspections in the context of the centralized procedure.
- To ensure the entry of the information on GCP inspections in the EudraCT database.

4. Harmonisation topics

4.1. Procedures and Guidance documents

- To update, as needed, the existing GCP Inspection procedures and guidance for GCP inspections conducted in the context of the Centralised Procedure.
- To prepare a post-inspection follow up guidance document for inspectors and assessors.
- To prepare the following guidance on GCP Inspection in accordance with article 29 of Directive 2005/28/EC, and to publish it in Chapter IV, Volume 10 of the Rules Governing Medicinal Products in the European Union:
  - Actions taken after completion of GCP inspection

4.2. Inspection cooperation in the community

- To set up a process for the coordination of GCP inspections of EU interest, outside the context of the marketing authorization procedure, and to be performed under national programmes.
- To perform joint inspections.

4.3. Training and development

- To conduct the 9th GCP IWG Workshop.
- To conduct the 1st basic GCP IWG Training Course.

[1] Committee for Medicinal Products for Human Use
[2] Good Manufacturing Distribution Practice
[3] The Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

- To develop opportunities for inspectors from countries outside Europe to participate in the basic GCP IWG training course and/or workshop mentioned above, to join EU inspections taking place in their countries as observers or other related opportunities. To liaise with WHO in this context.

5. Topics of interest

- To prepare a reflection paper on the inspector's expectations on TMF.
- To finalize the following reflection papers:
  - Reflection paper on quality risk management in clinical trials.
  - Reflection paper on guidance for GCP laboratories with the comments from the public consultation (end of consultation 28/02/2011).
- To revise the document on triggers for GCP inspection including specific triggers for assessors in the context of the assessment of acceptability of clinical trials from countries outside Europe.
- To provide guidance to the sponsors and service providers on the use of the IVRS/IWRS including the management of the expiry date.
- To contribute to the finalization of the "Draft 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 EMA" after the review of the comments from the public consultation.

6. Collaboration with European Commission

- To provide expert support on GCP related matters and inspections and in particular in its revision of the Clinical Trials legislation.
- EU enlargement:
  - To assist the candidate countries: Croatia, Former Yugoslav Republic of Macedonia and Turkey and the potential candidate countries: Albania, Bosnia and Herzegovina, Montenegro, Serbia and Kosovo (under UNSC Resolution 1244/99), and to develop 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 in clinical trials of Regulation on Advanced Therapies:
  - To monitor the implementation of GCP guidelines on advanced therapies in collaboration with CTFG and CAT.
- Paediatric Regulation and orphan drugs:
  - To develop procedures for inspections arising from issues raised by PDCO or COM.

7. Liaison with other EU groups

7.1. GMDP[4] IWG

- To consult this group in relation to a guidance to be provided to the sponsors and service providers on the use of the IVRS/IWRS including the management of the expiry date.
- To consult this group in relation to the implementation of the advanced therapy legislation in conjunction with the CTFG.

7.2. PhV IWG[5]

- To maintain a dialogue with the Pharmacovigilance Inspectors Working Group on areas of common interest and in particular concerning pharmacovigilance in relation to clinical trials.

7.3. CTFG[6]

- Collaboration on areas of mutual concern in the area of supervision of clinical trials conducted in the Community and in particular to prepare a pilot programme of inspections focused on particular priorities such as central laboratories, CROs, sponsor/legal representatives which may have an impact on many clinical trials.

7.4. CMD(h)

- To maintain a dialogue with CMD(h), in particular through the GCP/CMD subgroup, on areas of common interest and in particular concerning Bioequivalence/Bioavailability studies.
- The review of the outcome of the implementation of the pilot risk based programme of routine GCP inspections of the contract research organisations most often used in the conduct of the bioequivalence trials included in marketing authorisation applications for generic products in the mutual recognition and decentralised and to prepare a programme for 2011.

7.5. Heads of Medicines Agencies

- When requested to collaborate on HMA initiatives in GCP related areas, in particular in the area of supervision of clinical trials conducted in the Community and in relation to inspections in countries outside EU.

7.6. Other bodies

- Develop contact with Ethics Committees, including the preparation of a possible joint meeting.

8. Liaison with international partners

- To operate the pilot programme of the European Medicines Agency-FDA GCP initiative and the future of this programme.
- To develop principles, processes and opportunities for joint inspections with 3rd countries.
- To establish a network for international cooperation on GCP matters and inspections.

[4] Good Manufacturing and Distribution Practice Inspectors Working Group
[5] Pharmacovigilance Inspectors Working Group
[6] Clinical Trials Facilitation Group