EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspection

Work plan for GCP Inspectors Working Group for 2013

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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 finalise and publish guidance of community interest that has been developed by the group related to:
  - the risk based approach to clinical trials;
  - interactive response technologies.

  (refer to section 5, 1st bullet point)
- To update and finalise inspection procedures of GCP inspections conducted in the context of the centralised procedure and in particular the procedures on:
  - coordination of GCP inspections conducted in the context of the CAP (refer to section 4.1,1st bullet point);
  - reporting GCP inspections conducted in the context of the CAP including the follow up to the inspection for both trial/application related findings and systems related findings as well as the interaction between the GCP inspectors and clinical assessors/CHMP (refer to section 4.1, 2nd bullet point).
- To revise the GCP inspection policy in relation to the procedure undertaken for the selection of marketing authorisation application (MAA) and clinical trial sites to be inspected;
- 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;

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

2. Meetings scheduled for 2013

- 05-07 March 2013.
- 11-12 June 2013.
- 11-12 September 2013.
- 02-04 December 2013.

The following joint meetings will take place:

- joint meeting with interested parties;
- joint meeting with CHMP[1] 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-CMD(h)[2] subgroup;
- GCP-CTFG[3] Quality risk management in clinical trials subgroup.

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 triggered GCP inspections in the context of the centralized procedure.
- To ensure entry of information on GCP inspections in the EudraCT database.

4. Harmonisation topics

4.1. Procedures and guidance documents

- To revise the existing " Procedure for coordinating GCP inspections requested by the EMA ".
- To finalise and publish the "GCP inspection procedure on Reporting GCP inspections conducted in the context of the centralised procedure", prepared by the GCP IWG–CHMP clinical assessors subgroup within the framework of the CHMP Work programme 2011-2013.
- To implement the procedures described in the 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:

[1] The Committee for Medicinal Products for Human Use
[2] The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
[3] Clinical Trials Facilitation Group

- "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";
- "Points to consider on GCP inspection findings and the benefit-risk balance".

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 authorization procedure, and to be performed under national programmes" (see section 7.3), when the opportunity arises.

4.3. Training and development

- To conduct the 11th GCP IWG Workshop.
- To develop opportunities for inspectors from countries outside Europe:
  - 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[4] in this context.

5. Topics of interest

- To finalise the following reflection papers together with the responses to the comments from the public consultations and progress their publication:
  - "Reflection paper on quality risk management in clinical trials";
  - "Reflection paper on the use of interactive response technologies (interactive voice/web response systems) in clinical trials".
- To publish for public consultation the "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 GCP related matters and inspections and in particular in its revision of the Clinical Trials legislation.
- EU enlargement:
  - Accession country: Croatia.
  - To assist the accession country: Croatia; 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.

[4] World Health Organization

  - To invite these countries to observe meetings of the GCP IWG.
  - To contribute to workshops in candidate countries on GCP matters.
- ATIMPs[5] in clinical trials of Regulation on Advanced Therapies:
  - To monitor the implementation of GCP guidelines on advanced therapies in collaboration with CTFG and CAT[6].
- Paediatric Regulation and orphan drugs:
  - To develop procedures for inspections arising from issues raised by PDCO[7] or COMP[8].

7. Liaison with other EU groups

7.1. GMDP[9] IWG

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

7.2. PHV[10] 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[11] interest outside the context of a marketing authorization procedure.

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.
- To prepare the 2013 programme of the contract research organisations most often used in the conduct of bioequivalence trials included in marketing authorisation applications for generic products in the mutual recognition and decentralised procedures.

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

[5] Advanced Therapy IMPs
[6] Committee for Advanced Therapies
[7] Paediatric Committee
[8] The Committee for Orphan Medicinal Products
[9] Good Manufacturing and Distribution Practice Inspectors Working Group
[10] Pharmacovigilance Inspectors Working Group
[11] The European Economic Area

8. Liaison with international partners

8.1. Regulatory agencies from outside the EEA

- To continue with the operational phase of the European Medicines Agency-FDA GCP initiative and to work closely with the FDA to implement a similar pilot programme for generics.
- 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[12] 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[13]/ ASEAN[14]/ EMA/ WHO initiative on the "Roadmap to promote GCP Inspection" and implement any follow-up actions arising from this initiative.
- To establish a network for international cooperation on GCP matters and inspections by sharing and maintaining a list of relevant contact points for the organisation, authorities and initiatives (international, regional, national etc.) in the area of GCP inspections.
- To establish links, with other projects and initiatives in relation to GCP matters and inspections.

[12] The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co- operation Scheme
[13] Asia-Pacific Economic Cooperation
[14] Association of Southeast Asian Nations