European Medicines Agency
Inspections

London, 12 August 2008
EMEA/INS/GCP/546619/2007

WORK PLAN FOR GCP INSPECTORS WORKING GROUP FOR 2008

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STATUS: JUNE 2008

1. MEETINGS SCHEDULED FOR 2008

- 12-13 March 2008
- 18-19 June 2008
- 10-11 September 2008
- 03-04 December 2008

A joint meeting with assessors will take place during the June meeting.

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 organised (see section 7):
- GCP-GMP subgroup
- GCP-CMD(h) subgroup
- GCP-Advanced Therapy subgroup

2. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

Development and co-ordination of GCP inspections relating to centralised products

This is an ongoing activity and includes coordination of re-inspections when needed.

Maintenance of the information on GCP inspections for Centrally Authorised Products.

To enter the information on GCP inspections in the EudraCT database.
To develop a new database to enter the information on GCP inspections for Centrally Authorised Products.

3. HARMONISATION TOPICS

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 finalise the following guidance on GCP Inspection in accordance with article 29 of Directive 2005/28/EC, and Chapter V, Volume 10 of the Rules Governing Medicinal Products in the European Union, and to be published by the Commission:

- Selection of the trials/sites to be inspected
  - context of assessment of applications for marketing authorisation

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- surveillance of clinical trials in Member States

- Coordination / co-operation with other organisations involved in assessing Good Clinical Practice requirements
- Preparation of Good Clinical Practice inspections
- Conduct of Good Clinical Practice inspections
    - *Investigator sites*
    - *Clinical laboratories*
    - *Sponsor site and/or CRO*
    - *Computer Systems*
    - *Phase I Units*
- Preparation of Good Clinical Practice inspection reports
- Record keeping and archiving of documents obtained or resulting from the Good Clinical Practice inspection
- Actions taken after completion of Good Clinical Practice inspection
- Communication on Good Clinical Practice inspections and findings

Joint Inspections

To continue with joint inspections of sites involving inspectorates from more than one Member State.

Training and development

- Develop peer review of case studies,
- Sharing and discussion of inspection reports, including grading of anonymised findings
- Develop and monitor opportunities for joint inspections
- Provision of on the job training and a process for ensuring that all members gain experience through this
- Development of training guidance
- Develop opportunities for lectures/workshops at the time of GCP IWG meetings, on special topics, by members of the group and by invited guests
- Conduct the 6th GCP IWG Training Course to be hosted by a National Competent Authority in the 3rd or 4th quarter of 2008.
- To develop opportunities for inspectors from developing country authorities to participate in GCP IWG training workshops, to join inspections as observers (e.g. in the context of "Article 58" related GCP inspections) or other related opportunities. To liaise with WHO in this context.

4. TOPICS OF INTEREST

To continue support for the routine GCP inspection programme supporting the centralised procedure.

To further develop inspection processes related to inspections of clinical trials conducted in developing countries (ethical and quality considerations) and to support the conduct of inspections in those countries.

To finalize and publish for public consultation the following bioequivalence related guidance documents:

- Draft Q&A on the documentation and traceability of the IMPs used in bioequivalence studies
- Draft Guidance on the conduct of inspections of bioequivalence studies- Clinic & Laboratory.

To review the outcome of the consultation and further finalization of the following reflection papers:

- Reflection paper on expectations for electronic source documents used in clinical trials
- Reflection paper on advice to applicants/sponsors/CROs of bioequivalence studies.

To develop a reflection paper on quality risk management in clinical trials.

To discuss and prepare further guidance on the use of computer systems for clinical trials either as a reflection paper or through preparation of a concept paper.

To prepare a reflection paper or Q and A document on source documentation.

To prepare a reflection paper on the conduct of laboratory analyses for clinical trials.

To prepare a concept paper in conjunction with the Efficacy Working Party on a guideline on validation of bio-analytical methods.

To discuss and prepare, if considered needed, a document with specific triggers for assessors in the context of the ethical conduct of clinical trials in 3rd countries.

To further develop inspection processes in the context of

- large-scale clinical trials.
- statistical analysis and reporting.

5. COLLABORATION WITH EUROPEAN COMMISSION

Expert support on GCP related matters, in particular inspection

Implementation of Directive 2001/20/EC and of Directive 2005/28/EC and related guidance documents

- Develop guidance, additional documents related to this, or provide input and advice on guidance or other texts being prepared by the Commission - as requested by the Commission and in conjunction with other parties as appropriate.
- To advise on the necessary modifications to Directive 2005/28/EC and related GCP guidelines in the context of the Advanced Therapy regulation.
- To advise on the necessary modifications to GCP guidelines in the context of the Paediatric regulation.

EudraCT Database

To advise the EudraCT TIG, when needed, on inspection issues related to further development of the database and in particular in the development of the pediatric module as required by the pediatric regulation.

EU enlargement

To assist Croatia, Former Yugoslav Republic of Macedonia and Turkey to develop their GCP Inspection roles. To further develop contacts and collaboration with Croatia, Former Yugoslav Republic of Macedonia and Turkey in the field of GCP Inspections.
These countries are invited to observe meetings of the GCP Inspectors Working Group.

Regulation on Advanced Therapies

To contribute to the implementation of article 4(2) by providing input in the preparation of the detailed guidelines on good clinical practice specific to advanced therapy medicinal products.

Paediatric Regulation

To establish good working contacts and input with the Paediatric network once it is set up.

Variations Regulation

To contribute as necessary to the development of proposals for improving the regulation of post-authorisation changes in particular where an impact on GCP inspection resources is foreseen.

6. LIAISON WITH OTHER GROUPS

GMDP IWG

To maintain a dialogue with the GMP Inspectors Working Group, in particular through the GCP/GMP subgroup, on areas of common interest at the interface between GMP for investigational medicinal products and GCP.

Ad Hoc PhV IWG

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

CTFG.

Collaboration on areas of mutual interest and in particular in the area of supervision of clinical trials conducted in the Community

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.

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.

To contribute to the development of the benchmarking scheme (BEMA) regarding interactions with GCP processes.

PIC/S

Ongoing collaboration on areas of mutual interest to ensure harmonisation or equivalence in inspection processes and related matters, and an efficient use of Community inspection related resources.

Other Regulatory Agencies

- Development of contacts between EU and 3rd country agencies, on GCP matters.
- To develop inspection processes and contacts in the context of clinical trials conducted in developing countries through liaison with WHO and developing country inspectorates. To co-operate with wider international partners on the sharing of inspection information.