EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Compliance and Inspections

Work plan for GCP Inspectors Working Group for 2016

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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 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 revise the current, and develop new, EMA GCP inspection procedures and guidelines in relation to the implementation of the new Clinical Trials Regulation(refer to section 4.1, 1st bullet point);
- to contribute to the finalisation of the ICH[3] E6 addendum (refer to section 8.2, 1st bullet point);
- to continue to provide training and support for EU inspectors with a focus on inspection of bioequivalence trials;
- to continue to engage with stakeholders on topics such as electronic data systems, cloud solutions, quality risk management in clinical trials and in the area of BE studies.

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

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2. Meetings scheduled for 2016

The plenary meetings for 2016 are scheduled as follows:

- 01-02 March 2016
- 06-08 June 2016
- 06-08 September 2016
- 28-30 November 2016

The following joint meetings will take place:

- joint meetings with interested parties considering also a specific meeting on the topic of BE trials/inspections;
- 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 plenary meetings when possible, but if needed a number of additional telephone conferences will be scheduled (see section 7).

In 2016 the EU GCP Inspectors' Working Group workshop is planned to take place at the Agency on 17-19 October 2016.

3. Inspections conducted in support of the centralised procedure

- To implement the GCP inspections programme for 2016, which has the following objectives:
  - to define in advance the number of GCP inspections to be requested in 2016;
  - 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 2016-2017;
  - to ensure that diverse geographical regions are selected for inspection including third countries from which a substantial amount of clinical trial data in MAA[4] 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. Through the EMA-FDA GCP initiative (refer to section 8.1, 1st bullet point) as well as the EMA-EU MSs[5]-FDA initiative on inspections for generic applications (refer to section 8.1, 2nd bullet point), duplication of inspections should be avoided and increased inspection coverage will continue to be ensured for MAA submitted to both, the Agency and the US FDA[6].
- To ensure timely entry of information on GCP inspections in the EudraCT database.

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

4. Harmonisation topics

4.1. Procedures and guidance documents

- To review all EMA GCP inspection procedures and guidance documents in order to be aligned with the requirements of the new Clinical Trials Regulation. To develop, in this context, the following new document:
  - procedure for EMA coordination of cooperation between MS concerned on inspections conducted in MS, in third countries and inspections conducted in the framework of an application for a marketing authorisation under Regulation (EC) No 726/2004.
- To publish a revised version of the "GCP inspection procedure on Reporting GCP inspections conducted in the context of the centralised procedure" and the inspection report templates for individual inspection report and integrated inspection report, 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 14th GCP IWG Workshop.
- To run the online GCP inspectors' basic training course with one webinar for EU and one for non-EU inspectors.
- To provide training opportunities regarding inspections of BE[7] trials and in particular to develop an online BE inspections module.
- To develop capacity building opportunities for inspectors from countries outside the EU/EEA[8]:
  - 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 invite them to follow the online basic training course;
  - to liaise with WHO[9] in this context.

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

5. Topics of interest

- To begin working on the preparation of a guidance document on the use of electronic data capture systems in clinical trials.
- To prepare Q&A documents, as required, to clarify the inspectors' expectations with respect to certain processes and procedures. In particular, to prepare a Q&A on "contracts with e-vendors".

6. Collaboration with European Commission

- To continue 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 continue to actively contribute in the areas of transparency of inspection reports, the process for managing serious breaches, the development of the Implementing Act on clinical trials inspection procedures including qualifications and training requirements for inspectors and the revision of the current GCP inspection procedures and guidelines published under Eudralex Volume 10, as appropriate. In this context, the GCP IWG will contribute to the development of the following new documents:
  - guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials. This document is to be finalised and published in 2016,
  - guidance on risk proportionate approaches in clinical trials,
  - guidance for clinical trial sponsors on what it is expected to be reported as a serious breach,
  - procedure for the handling of serious breaches including their assessment and the appointment of a lead Member State,
  - guidance on the redaction of GCP inspection reports to remove personal details and commercially confidential information.

  The document "Detailed guidelines on good clinical practice specific to advanced therapy medicinal products" is to be revised.
- EU enlargement:
  - To assist the candidate countries Albania, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey and potential candidates Bosnia and Herzegovina and 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.
- Paediatric Regulation, orphan drugs, pharmacovigilance and scientific advice:
  - To continue the communication on inspection issues with the PDCO[10], COMP[11], the PRAC[12] and the SAWP[13], as requested.

[10] The Paediatric Committee
[11] The Committee for Orphan Medicinal Products
[12] Pharmacovigilance Risk Assessment Committee
[13] The Scientific Advice Working Party

7. Liaison with other EU groups

7.1. GMP/GDP[14] IWG

- To maintain a dialogue with the GMP/GDP IWG on areas of common interest and continue to work on GMP related issues in the new Clinical Trials Regulation.

7.2. PHV IWG[15]

- 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[16]

- 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.
- Collaboration in the development of the following guidance:
  - guidance on risk-proportionate approaches in clinical trials.
- The CTFG will be consulted during the preparation of the two documents below:
  - guidance for clinical trial sponsors on what it is expected to be reported as a serious breach,
  - procedure for the handling of serious breaches including their assessment and the appointment of a lead Member State.

7.4. CMDh[17]

- 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 2016 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[18]

- 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.

[14] Good Manufacturing and Distribution Practice Inspectors Working Group
[15] Pharmacovigilance Inspectors Working Group
[16] Clinical Trials Facilitation Group
[17] Co-ordination group for Mutual Recognition and Decentralised Procedures (human)
[18] Heads of Medicines Agencies

7.6. CHMP[19] assessors

The GCP inspectors/CHMP clinical assessors' subgroup to initiate another project, taking as starting point the results of the analysis performed in 2015 on the impact of GCP inspection findings on CHMP opinions. This project could include further analysis of the work already carried out by the subgroup including details on individual inspection outcomes and their impact on CHMP opinions, and suggestions for improvement in the communication between inspectors and assessors.

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 continue with the operational phase of the FDA on the EMA-EU MSs-FDA initiative on generic products.
- To explore the possibility to expand the EMA-FDA GCP initiative to include collaboration with PMDA[20], Japan.
- To encourage observed, joint inspections and complementary inspection programmes with national regulatory authorities in third countries.

8.2. International initiatives

- To contribute to the finalisation of the addendum to ICH E6, which is to address risk based quality management, monitoring, electronic tools and TMF[21].
- To maintain the existing links with the PIC/S[22], also through the participation to the JVP[23] for GCP inspections, 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[24]/ASEAN[25]/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[26] 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.

[19] Committee for Medicinal Products for Human Use
[20] Pharmaceutical and Medical Devices Agency
[21] Trial Master File
[22] Pharmaceutical Inspection Cooperation Scheme
[23] Joint Visit Programme
[24] Asia-Pacific Economic Cooperation
[25] Association of Southeast Asian Nations
[26] European & Developing Countries Clinical Trials Partnership