



European Medicines Agency

US Food and Drug Administration

EMEA-FDA GCP Initiative

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The clinical development of medicines is a global undertaking. In most cases the same clinical trials are used to support Marketing Authorisation Applications (MAAs) to the European Medicines Agency (EMEA), and New Drug Applications (NDAs) and Biologics Licence Applications (BLAs) to the US Food and Drug Administration (FDA).

A substantial number of trial subjects participating in the pivotal clinical trials in these marketing applications have been recruited in Europe and the USA. Regulators in the US and European Union (EU) must ensure that clinical trials, both in their own territories and in other regions of the world, have been conducted in accordance with good clinical practice (GCP) and in an ethical manner, have been carried out in concurrence with the protocol/investigational plan, and that the data have been correctly reported.

The increasing globalization of clinical research, coupled with limited inspection resources, means that only a sample of sites and clinical studies can be inspected. If regulators can work in a collaborative and synergistic manner in carrying out GCP inspections and implement information exchanges, then GCP inspection resources can be used more efficiently. Sponsors can also facilitate this process by informing regulators in the US and the EU of a joint filing which can be coordinated in both regions.

The EMEA and US FDA have agreed to launch an EMEA-FDA GCP Initiative. This initiative will be carried out in the framework of the Confidentiality arrangements established between the European Commission, the EMEA and the US FDA. The EMEA-FDA GCP Initiative will commence with an 18-month pilot phase which will consider only a subset of regulated products; specifically, those regulated by the Center for Drug Evaluation and Research (CDER) in US FDA and by EMEA for the centralized procedure in EU.

The key objectives of the EMEA-FDA GCP Initiative are:

- 1. To Conduct Periodic Information Exchanges on GCP-Related Information
 - a. To streamline the sharing of information relevant to GCP inspection planning so that the selection of studies and sites is well informed, and inspection coverage is improved.

¹ "Extension of Confidentiality Arrangement Between the United States Food and Drug Administration and the European Commission Enterprise and Industry Directorate-General and the European Medicines Agency to Exchange Regulatory Information" signed in September 2005

- b. To exchange GCP-related information contained in applications for scientific advice, orphan medicines designation, paediatric investigational plans, marketing authorization or post-authorization activities of significant public health interest.
- c. To communicate effectively and in a timely manner on inspection outcomes (negative and positive) and their potential impact, where the clinical trials and/or inspected sites/organisations are of common interest.

2. To Conduct Collaborative GCP Inspections

- a. To build mutual understanding of, and confidence in, the GCP inspection processes utilized by the EU/EMEA and FDA through the sharing of information, experience and inspection procedures, and cooperation in the conduct of inspections.
- b. To improve effectiveness of inspections by sharing best-practice knowledge in order to enhance inspection techniques and processes.

3. To Share Information on Interpretation of GCP

- a. To keep each other informed of GCP-related legislation, regulatory guidance documents, position papers, and policy documents that might be in draft or finalized form.
- b. To identify and act on areas where greater convergence could be achieved to the benefit of the clinical research process.

At the conclusion of the pilot phase, a joint assessment will be made by the EMEA and FDA. The process will then be amended and the scope modified as needed. Terms of engagement have been developed. The pilot phase will start on 1 September 2009.

At this moment, the FDA/EMEA are looking to partner with applicants/sponsors who are willing to volunteer during the pilot phase of the initiative to engage in dialogue and planning of joint inspections involving applications that are anticipated to be submitted fairly simultaneously to both regulatory agencies within the next 12 months.