

Comments by the European Forum for Good Clinical Practice

on the *FDA Proposed Rule Modifying 21 CFR, Part 312 on Human Subjects Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application*



The European Forum for Good Clinical Practice (EFGCP) wishes to thank the services of Dr. David Lepad at the Office of Science, Health, and Coordination at the Food & Drug Administration (FDA), United States Department of Health & Human Services (DHHS) for the opportunity to comment on the FDA Proposed Rule Modifying 21 CFR, Part 312.120 on Human Subjects Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application. The EFGCP has studied the Proposed Rule as presented in the *Federal Register* (Vol. 69, No. 112, pp. 32467-32475; June 10, 2004), and we have had an opportunity to discuss the Proposed Rule at international meetings in Europe, Asia, and Latin America as well as consult with African & Eastern European partners. The EFGCP has also consulted informally with the World Medical Association (WMA) on the proposed modifications.

The EFGCP finds that the FDA's proposed modifications are, in principle, appropriate measures to improve public assurance of the quality of the science and ethics supporting data for Non-IND studies. The FDA has put forward two fundamental principles as the basis for its proposal:

1. 'Good Clinical Practice is a process that makes all parties to a study responsible for patient safety and study quality.'
2. Data from non-IND foreign clinical studies should be accepted provided the studies 'are well-designed, well-conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community.'

The insistence on an international standard that requires all parties involved in clinical studies supporting non-IND data be responsible for science and ethics is to be commended.

The particular importance given to ethics committees (IECs/IRBs), study monitoring, and GCP inspections in the outline discussion for a Proposed Rule is valuable. In drafting the Proposed Rule, attention should be given to the current development of international standards for the ethical review of clinical studies, including the work done by the Office for Human Research Protections (OHRP DHHS USA), the European Forum for Good Clinical Practice (EFGCP), the World Health Organization (WHO/TDR), and the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). Attention should also be given to the development of national and regional (e.g., European – EMEA) GCP inspections outside the United States and the role they might play in providing public assurance for the quality of the data and the protection of human subjects.

The need for 'ethical principles acceptable to the world community' should remain the core value in international research alongside the articulation and acceptance of well-defined responsibilities. In lieu of a specific reference to the *Declaration of Helsinki*, the Proposed Rule should indicate the Good Clinical Practice standard provided by the international community and adopted by the FDA through the Rule. Imposing a US standard 'consistent with' an international standard would seem insufficient.

*Comments presented on behalf of the EFGCP by
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