Guidance for Industry

Acceptance of Foreign Clinical Studies

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

Clinical Medical

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

Food and Drug Administration (FDA) regulations permit the acceptance of foreign clinical studies in support of an application for marketing approval of a human drug, biological product, or device if certain conditions are met. Foreign studies performed under an investigational new drug application (IND) or investigational device exemption (IDE) must meet the same requirements of 21 CFR Part 312 or 21 CFR Part 812, respectively, that apply to U.S. studies conducted under an IND or IDE.

Under 21 CFR 312.120(c)(1), FDA will accept a foreign clinical study not conducted under an IND only if the study conforms to the ethical principles contained in the Declaration of Helsinki (Declaration), as set out in 21 CFR 312.120(c)(4), incorporating the 1989 version of the Declaration, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects.

FDA issued 21 CFR 814.15(a) and (b), a similar regulation applicable to devices, in 1986, when the 1983 version of the Declaration was in effect.[1] Under 21 CFR 814.15(b), FDA will accept a foreign clinical study involving a medical device that is not subject to an IDE only if the study conforms to the ethical principles contained in the 1983 version of the Declaration or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects.

In October 2000, the World Medical Association revised the Declaration. FDA has not taken action to incorporate those revisions into its regulations. FDA is making available this guidance document to clarify that the action of the World Medical Association did not change FDA regulations.

II. DECLARATION OF HELSINKI

The World Medical Association first adopted the Declaration in 1964 and, subsequently, has revised the document five times.

It is FDA's responsibility to define the conditions under which it will consider foreign clinical studies to be acceptable under the standards imposed by the United States laws and regulations. In carrying out that responsibility, in 1975 FDA incorporated the 1964 Declaration in its regulation governing investigational drug trials conducted in non-U.S. countries. The agency amended the regulation in 1981 to replace the 1964 Declaration with the 1975 version, and again in 1991 to replace the 1975 Declaration with the 1989 version.[1] FDA has repeatedly considered amendments to its regulations governing foreign clinical studies not conducted under an IND. Each time, FDA has incorporated amendments only after carefully considering the impact of the amendment and revising its regulations.[2] FDA has not amended 21 CFR 312.120 or 21 CFR 814.15 to incorporate the 2000 amendments to the Declaration recently issued by the World Medical Association.

FDA is currently reviewing its regulations pertaining to the acceptance of foreign clinical studies, to determine if it should revise those regulations to incorporate new or modified standards or requirements.

[1] 46 Fed Reg. 8942 (January 27, 1981); 56 Fed. Reg. 22113 (May 14, 1991).

[2] FDA has not amended its regulation governing investigational device trials conducted in non-U.S. countries to incorporate a different version of the Declaration.