Guideline on Assessing Protocols for Clinical Trials and Bioequivalence Studies on Drugs Applying for License Registration/Extension by Food and Drug Administration

This guideline serves as a supplementary document for other national regulations and guidelines for medical research, in order to clarify and facilitate the protocol assessment process for clinical trials and bioequivalence studies that fall under the jurisdiction of the Iranian Food and Drug Administration (FDA), for the purpose of licensing new drugs, or extending licenses for existing drugs as applied by pharmaceutical companies.

١. The clinical trial protocol shall be submitted to FDA's Drugs Directorate General by the applying pharmaceutical company, together with the required documents and attachments as per related guidelines (draft form of informed consent document, patient's data report form, etc.).

٢. After submission of the mentioned documents to the Directorate for Monitoring Clinical Trials of the above Directorate General, and completion of the process for scientific judgment and assessment, the file shall be considered by the Clinical Trials Committee. Once initially approved, and before a Clinical Trial Authorization (CTA) is issued, the final version of the protocol and its related attachments shall be referred by the mentioned Directorate General to the research ethics committee of the medical university conducting the study.

Note ١: FDA's Clinical Trials Committee shall assess the submitted protocols in terms of scientific considerations, methodology, researchers' competence and compliance with ethical standards.

Note ٢: An unlimited number of committee sessions may be dedicated to assessing a protocol until approval, which depends on the protocol quality and decision of the related judges.

Note ٣: A clinical trial subject to this guideline shall be commenced only after receiving a CTA (by the applying company and the executor(s) of the clinical

trial). The clinical trial shall otherwise be legally invalid, and construed as a violation of research regulations.

۳. The research ethics committee of the conducting university shall consider and assess the protocols subject to this guideline with highest priority at its first upcoming session, and submit its related decision to FDA's Clinical Trials Committee, together with a copy of the protocol and its attachments.

Note ۱: After considering and approving the ethical considerations of the related clinical trial, the research ethics committee of the conducting university shall include in its approval statement the sentence "The study shall be commenced only after receiving a CTA from FDA's Drugs Directorate General".

Note ۲: In case of objections by the Clinical Trials Committee to the results or modifications in the protocol, through consideration process of the research ethics committee of the related university, the Secretariat of the National Committee for Ethics in Biomedical Research shall consider the issue and make the final decision, or upon the discretion of the Committee Chairman, consider and decide on the issue in the first upcoming session of the National Committee.

Note ۳: The decisions made by the National Committee on medical studies shall clearly mention that studies for drug licensing or similar purposes shall receive FDA approval only if referred by FDA's Clinical Trials Committee to the related ethics committees.

٤. After approval by the ethics committee, the research executor(s) shall register the protocol with the Iranian Registry of Clinical Trials (at www.irct.ir), and announce the related registration number through the applying pharmaceutical company to the FDA's Drugs Directorate General.

٥. Once the IRCT registration number is received and the registered details are checked for conformity with the final approved protocol, FDA's Drugs Directorate General shall have the applying pharmaceutical company submit the required documents and proceed to issue a CTA.

Note: FDA's Drugs Directorate General shall submit a copy of the final approved protocol and the issued CTA to the Secretariat of the National Committee for Ethics in Biomedical Research, of the Ministry of Health and Medical Education.

٦. Within two weeks after the receipt of the above protocol and CTA, the National Committee shall appoint one competent ethical supervisor for each trial subject to this guideline, and introduce to FDA's Drugs Directorate General.

This guideline in ٦ paragraphs and ٧ notes was approved by the Seventh Session of the National Committee for Ethics in Biomedical Research, on ٢٢ June ٢٠١٥.

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