Amendments have been Made to the Guideline on Clinical Research Applications to the Clinical Research Department of the Turkish Medicines and Medical Devices Authority, and to the Guideline on Non-Clinical Evaluation of Animal Immunoglobulins/Immune Serums for Human Use Against Viral and Bacterial Agents

17 Apr 2024

The Guideline on Clinical Trial Applications to the Clinical Trials Department of the Turkish Medicines and Medical Devices Agency ("**Guideline**"), published by the Turkish Medicines and Medical Devices Agency, regulates in detail the Initial Eligibility Application, Amendments to Trials, Notifications, the Agency's Oversight and Supervision of Trials, and Other Provisions.

According to the Guideline, the application file should be prepared before the first application is made. The application file consists of relevant documents, including the cover letter and application form. The cover letter template is available on the Agency's website, and the relevant documents are listed in the Guidelines. Initial applications to the Agency with the prepared application file are made through the Electronic Application and Process Management System (EBS-ESY). It is also possible to revise the initial application and withdraw the research application.

After obtaining research authorization, changes may be permitted in the research. These changes can involve updating existing information and documents or adding new information and documents. Changes to be made in the research can be submitted as a significant change application, a change application, or an information application.

If new situations arise during the conduct of the research or the development of the investigational product that are likely to affect the safety of volunteers, the sponsor or principal investigator may need to take appropriate emergency safety measures to protect volunteers from potential risks. These safety measures may be implemented without approval from the ethics committee and permission from the institution.

If research has not been initiated within 90 days following the date of authorization despite the authorization granted by the Agency, the reason for not initiating it shall be notified to the Agency in accordance with Article 3.3. If this situation continues, the application for notification shall be repeated in every 90-day period. If no subjects have been enrolled in the research in our country within two years from the date on which the research authorization was communicated to the applicant, the authorization granted by the Agency shall be canceled unless an extension is approved upon the request of the applicant. If the research authorization is

revoked, the application may be resubmitted to the Agency as a new research application, but this should be stated in the cover letter. The applicant is responsible for regularly submitting notifications to the Agency.

The date when the first of the research centers in our country opens to receive volunteers (making the initiation visit) marks the start date of the research. This date must be notified to the Agency within 15 days. The notification should include information about which center has been opened. The progress of the trials is monitored through annual notifications, which are made based on the calendar year and must be submitted by 31 January of the following year.

The completion of the research is defined as the date when the research is completed according to the protocol, and all centers in our country are closed. Notification of the completion of the research must be made to the ethics committee and the institution within 15 days. Completion of the research in all countries is defined as the date when it is completed in every country where the research is conducted. Notification of the completion of the research in all countries must be made to the ethics committee and the institution within 30 days.

Within one year after the termination of the research in all centers, the summary of the research result report, along with a version of this summary presented in a manner understandable to volunteers must be reported to the ethics committee and the institution. Summaries of the final report must be prepared in accordance with the format published/accepted by the Agency.

The section on Abnormal Toxicity was removed from the Guideline on Non-Clinical Evaluation of Animal Immunoglobulin / Immune Serums Intended for Human Use Against Viral and Bacterial Agents, in accordance with the Current European Pharmacopoeia.

The full text of the Guideline on Clinical Trial Applications to the Clinical Research Department of the Turkish Medicines and Medical Devices Agency regarding the amendments entered into force on 18 March 2024 can be accessible via this link. (Only available in Turkish)

The full text of the Guideline on the Non-Clinical Evaluation of Animal Immunoglobulin / Immune Serums Intended for Human Use Against Viral and Bacterial Agents can be accessed here. (Only available in Turkish)

Related Practices

- R&D, Licensing and Technology Transactions

Related Attorneys

- A. BAŞAK ACAR, LL.M.
- MERVE ALTINAY ÖZTEKİN