

GUIDELINE ON THE EVALUATION OF CLINICAL TRIALS IN EXCEPTIONAL CIRCUMSTANCES

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1. **PURPOSE** This Guideline has been prepared regarding the evaluation of applications to be made for clinical trials in exceptional circumstances. 2. **SCOPE** In line with the Regulation on Clinical Trials of Medicinal Products for Human Use published in the Official Gazette No. 32203 dated 27/5/2023, it covers matters relating to trials in exceptional circumstances. Clinical trials falling under at least one of the situations described below are considered clinical trials in exceptional circumstances: a) Clinical trials to be conducted with investigational medicinal products (IMP) intended for the treatment, prevention or medical diagnosis of life-threatening or seriously disabling diseases and which will address an unmet medical need, b) Clinical trials to be conducted with investigational medicinal products (IMP) to be used in situations deemed by the World Health Organization or our country to pose a serious threat to public health. 3. **LEGAL BASIS** This Guideline has been prepared for the implementation of Article 16 of the fifth section of the Regulation on Clinical Trials of Medicinal Products for Human Use, which entered into force upon publication in the Official Gazette No. 32203 dated 27/5/2023, and regarding the evaluation of applications to be made for clinical trials in exceptional circumstances. 4. **DEFINITIONS** The definitions specified in the Good Clinical Practice Guideline and the relevant legislation shall apply. 5. **PRE-EVALUATION OF CLINICAL TRIALS IN EXCEPTIONAL CIRCUMSTANCES** With regard to the situations set forth in paragraph (a) of Article 2 of this Guideline; in order to determine whether the trial is a trial in exceptional circumstances, the sponsor or the legal representative of the sponsor shall submit a determination application to the Turkish Medicines and Medical Devices Agency (the Agency). The determination application is made to the Compliance Evaluation Unit of the Department of Clinical Trials. The application, together with a cover letter, must contain the information and documents that will prove that the trial bears the characteristics of a clinical trial in exceptional circumstances. For clinical trial applications to be made with regard to the situations set forth in paragraph (b) of Article 2 of this Guideline, there is no need to submit a determination application to the Agency. Contrary situations will be announced in advance on the Agency's website. The Agency examines determination applications within 3 (three) business days and, where it deems necessary, may request additional explanations and information from the applicant. The requested explanations and information are submitted to the Agency within 3 (three) business days. Together with the additional information and explanations, the application is re-examined by the Agency within 3 (three) business days. As a result of the evaluation of the determination application, the applicant is notified of a positive outcome or a negative outcome together with its justification.

The workflow diagrams relating to the process are provided in Figure-1 and Figure-2. 6. **EVALUATION OF CLINICAL TRIAL APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES** Clinical trial application files to be submitted to the Agency are prepared in accordance with the Guideline on Clinical Trial Applications Made to the Department of Clinical Trials of the Turkish Medicines and Medical Devices Agency, while clinical trial application files to be submitted to the relevant ethics committee are prepared in accordance with the Guideline on Clinical Trial Applications Made to

Ethics Committees. Provided that the applications for the trial are duly made and there are no deficiencies in the information and documents that must be included in the application, it is essential that the application be examined by the ethics committee and the Agency within 7 (seven) business days. During the examination and evaluation of trials, and while exercising its powers, the Agency may make use of relevant decisions issued by official health authorities of other countries and published reports. During the examination and evaluation of trials, and while exercising its powers, the Agency may seek the opinion of scientific advisory committees and their members established pursuant to the Regulation on the Establishment and Duties of Scientific Advisory Committees of the Turkish Medicines and Medical Devices Agency, published in the Official Gazette No. 30849 dated 1/8/2019. For the clinical trials set forth in paragraph (b) of Article 2 of this Guideline, the official letters generated as a result of the initial application evaluation and, if the Agency permits the trial, the initial compliance letter for the trial are signed by the President of the Agency and communicated to the applicant. The workflow diagrams relating to the process are provided in Figure-1 and Figure-2.

7. MEASURES TO BE TAKEN IN CLINICAL TRIALS IN EXCEPTIONAL CIRCUMSTANCES The following situations are considered exceptional circumstances requiring measures to be taken by the Agency. An international pandemic situation declared by the World Health Organization, A national public health emergency declared by Türkiye, Epidemic/disaster and similar situations in Türkiye that may affect the health of the entire population. In exceptional circumstances requiring measures to be taken, participant (volunteer) safety must be considered the foremost priority with regard to trial site visits (volunteer visits). The conduct should be planned in a manner that reduces the burden on the trial sites and the investigator. Measures to be taken by the Agency for clinical trials in exceptional circumstances, based on developing situations and needs, and the related announcements are published on the Agency's website. Additional measures may be published during the process, or measures may be partially or entirely removed.

8. ENTRY INTO FORCE This Guideline enters into force upon the approval of the President of the Agency.

9. EXECUTION The provisions of this Guideline are executed by the President of the Agency.

RATIONALE FOR REVISION

Revision No Revision Date Rationale and Explanations 01 05.02.2024 An update has been made due to the amendment to the Regulation.

FIGURE-1. WORKFLOW DIAGRAM FOR EXCEPTIONAL CIRCUMSTANCE DETERMINATION APPLICATION

FIGURE-2. WORKFLOW DIAGRAM FOR INITIAL COMPLIANCE APPLICATION