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CLINICAL TRIAL INVESTIGATOR MEETING APPLICATION GUIDELINE

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Objective

ARTICLE 1- (1) The objective of this Guideline is to determine the procedures and principles of clinical trial investigator meetings to be organized with the participation of the research team involved in the conduct of clinical trials assessed within the scope of the Regulation on Clinical Trials on Human Medicinal Products published in the Official Gazette No. 32203 dated 27/05/2023, in line with the provisions of the Regulation on Promotional Activities for Human Medicinal Products published in the Official Gazette No. 29405 dated 03/07/2015, as well as the applications for such meetings.

Scope

ARTICLE 2- (1) It covers investigator meetings to be organized with the participation of the research team involved in the conduct of trials falling within the remit of the Department of Clinical Trials.

Legal Basis

ARTICLE 3- (1) This Guideline has been prepared based on the seventh paragraph of Article 7 of the Regulation on Promotional Activities for Human Medicinal Products published in the Official Gazette No. 29405 dated 03/07/2015.

Definitions

ARTICLE 4- (1) In this Guideline: Investigator Meeting: national and international meetings, workshops, symposiums and similar events related to a trial, organized either domestically or abroad, to be attended by the members of the research team, Department: the Department of Clinical Trials affiliated to the Vice Presidency of Pharmaceuticals and Pharmacy, Ethics Committee: independent clinical trial or bioavailability and bioequivalence ethics committees established to provide scientific and ethical opinions on the suitability of the natural or legal persons involved in the clinical trial, the trial sites, the information and documents required to be submitted in the clinical trial application file, as well as the methods and materials to be used in obtaining and documenting informed consent from volunteers, and approved by the Agency, Agency: the Turkish Medicines and Medical Devices Agency (TİTCK), Regulation: the Regulation on Clinical Trials on Human Medicinal Products published in the Official Gazette No. 32203 dated 27/05/2023.

(2) The term "trial" in this document refers to both "trials" and "studies".

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General Principles

ARTICLE 5- (1) For trials without ethics committee approval; an application may be made only for the participation of the coordinator in an investigator meeting planned to be held abroad, and the assessment is carried out by the Department. (2) For trials with ethics committee approval; an application may be made for the participation of the research team in an investigator meeting planned to be held abroad. (3) For all trials with or without ethics committee approval; an application may be made for the participation of the entire research team in an investigator meeting planned to be held domestically or online. For trials without ethics committee approval, the document demonstrating that an application for the trial has been made to the ethics committee or the Department shall be attached to the application. (4) Online investigator meetings shall be recorded in order to be submitted upon request by the Agency. (5) If the content of the meeting covers more than one trial, a single application shall be sufficient. However, in this case, the requirements specified in the first, second and third paragraphs shall be taken into consideration. (6) Separate applications shall be made and separate permits shall be obtained for meetings organized on different dates for the same trial. (7) The applicant may support the registration, accommodation and travel expenses of the members of the research team who will attend domestic and international investigator meetings, provided that these are indicated at the time of application. (8) Persons participating in the meeting may not accept or request any incentive other than the expenses specified in the seventh paragraph from the applicant. (9) No one may participate in any investigator meeting without a permit from the Agency.

Application principles

ARTICLE 6- (1) The application is made using the 'Clinical Trial Investigator Meeting' application form and the sample cover letter available on the Agency's official website. (2) For meetings to be held face-to-face, the application shall be made at least 22 (twenty-two) business days prior to the planned meeting date.

(3) For meetings to be held online, the application shall be made at least 15 (fifteen) business days prior to the planned meeting date. (4) For online meetings, the date and time of the meeting shall be specified in the application file; the meeting participation link and, if any, the participation password shall be submitted to the Agency. (5) Applications made with missing information and documents shall not be taken into assessment, and the applicant shall be notified. (6) The meeting program shall not include organizations such as dinners or cocktails taking place on a separate day.

Administrative sanction

ARTICLE 7- (1) In the event that a meeting is organized in violation of this Guideline or unauthorized participation is detected, the applicant and the persons concerned shall be warned by the Agency by official letter. In the event of recurrence within 1 (one) year from the date of the warning, the applicant may not apply for an investigator meeting for a trial conducted in our country for a period of 6 (six) months.

Entry into force

ARTICLE 8- (1) This Guideline enters into force upon the approval of the President of the Agency.

Execution

ARTICLE 9- (1) The provisions of this Guideline shall be executed by the President of the Agency.

REVISION HISTORY Revision No Revision Date Justification and Explanations 01 01.02.2024 Updated due to an amendment to the Regulation and a review. 02 A recording requirement has been introduced for meetings to be organized online in the fourth paragraph of Article 5. The

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application period for meetings to be organized online has been re-determined in the second paragraph of Article 6. Requirements regarding applications for meetings to be organized online have been determined in the fourth paragraph of Article 6.

A rearrangement has been made in the sixth paragraph of Article 6 regarding organizations such as dinners and cocktails taking place on a separate day. The expressions in all articles have been reviewed and rearranged in a more easily readable and understandable language without any change in meaning.

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