GUIDELINE ON INSURANCE COVERAGE TO BE PROVIDED IN CLINICAL TRIALS 13 NOVEMBER 2015

1. PURPOSE This guideline has been prepared for the purpose of establishing the procedures and principles regarding the provision of insurance coverage by the sponsor of the trial, in order to protect the volunteers/patients participating in clinical trials against any damage that may arise from the trial, in accordance with the legislative provisions on good clinical practice and clinical trials. 2. GENERAL PRINCIPLES 2.1. Insurance coverage is provided in the event that volunteers participating in a clinical trial suffer damage or die as a result of the investigational products used during the clinical trial or the procedures applied in the trial. Within this scope, it is required to document that volunteers participating in clinical trials are covered by insurance provided by the sponsor of the trial in accordance with the relevant legislation. 2.2. The insurance policy, or, in cases where the insurance policy cannot be submitted with justification, a certified copy of the insurance policy or insurance certificates clearly specifying the conditions of the policy and referring to the policy, must also be submitted to the ethics committee and the Turkish Medicines and Medical Devices Agency (TİTCK). Within this scope, the insurance policy or insurance certificates to be submitted to the ethics committee and the Turkish Medicines and Medical Devices Agency must: 2.2.1. clearly contain the insurer's first and last name, trade title and domicile, 2.2.2. the first and last name or trade title and domicile of the policyholder (the sponsor or its legal representative), 2.2.3. the first and last name, trade title and domicile of the insured (the sponsor or its legal representative, or the trial site), 2.2.4. the subject matter of the insurance (the explicit name of the clinical trial to be conducted and, if any, the protocol number), 2.2.5. the type of insurance (such as a clinical trials liability policy, third-party financial liability insurance policy), 2.2.6. the risks assumed by the insurer (the scope of the insurance including illness, disability and death, and treatment expenses) and the moments at which they commence and terminate, 2.2.7. the insurance amount (the insurance compensation limit determined per event/person and the total insurance compensation limit), 2.2.8. the amount of the premium and the time and place of payment, 2.2.9. the number of volunteers to be enrolled in the clinical trial (the minimum number of volunteers planned to be enrolled in our country), 2.2.10. all circumstances that serve to determine the true nature of the risks assumed by the insurer, 2.2.11. the duration of the insurance (the period of insurance must, at minimum, cover the start and end dates of the trial), 2.2.12. the date of issuance and wet signature, 2.2.13. the special conditions under which the insurance is to be provided, 2.2.14. the exclusions set forth in the insurance policy, if any, 2.2.15. additional coverages to be provided together with the investigational product, 2.2.16. the countries in which the insurance is valid, 2.2.17. provisions related thereto, if the contract contains a foreign element, 2.2.18. information on exemptions or coinsurance, if any, regarding the insurance taken out, 2.2.19. the inclusion in writing of the general insurance conditions approved by the relevant Ministry and printed in a clear and easily legible manner. 2.3. The insurance policy and certificates must not contain a clause stating that, where the policyholder is additionally covered under another insurance coverage such as professional liability insurance, life insurance or the like, the coverage of such insurances will be sufficient and that the clinical trial insurance coverage will come into effect only in cases where such coverage is insufficient to compensate for the damage arising from the clinical

trial. 2.4. Clinical trial insurances must be arranged independently of other insurance coverage and in such a way as to provide coverage against any damage that may arise from the clinical trial. 2.5. Where the insurance policy or insurance certificates containing all of the above matters are issued by insurance companies established in Turkey and licensed to operate in Turkey in accordance with the relevant legislation, the documents must be drawn up in Turkish; where the insured and the insurance company are foreign, the original or certified copy of the documents drawn up in a language other than Turkish must be submitted together with a Turkish translation (certified by a notary or a sworn translator). 2.6. The acceptance of insurance documents issued by insurance companies established in Turkey is subject to the condition that such companies are

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licensed by the Undersecretariat of Treasury of the Prime Ministry of the Republic of Türkiye. 3. OTHER PROVISIONS 3.1. Explanations regarding insurance requested by the Turkish Medicines and Medical Devices Agency (TİTCK) and the ethics committee must be provided by the relevant insurance company. 3.2. Where the changes in the information and documents contained in the clinical trial application are also present in the insurance-related information and documents, the said changes must also be reflected in these documents. 3.3. The "Exclusions" section of the insurance documents must not contain expressions such as professional liability, medical malpractice, intentional deviation from the trial protocol, procedures performed in accordance with the protocol, product-related damage, or the failure of the placebo to provide a therapeutic effect in trials in which a placebo is used. 4. REPEALED PROVISIONS The "Guideline on Insurance Coverage in Clinical Trials", which was put into effect by the Approval No. 43020 dated 17.04.2013, has been repealed. 5. ENTRY INTO FORCE This guideline enters into force on the date of its approval.

Dates and Issue Numbers of the Publication of Amendments Made to the Guideline

Date Issue No. 1. 10.02.2009 883 2. 20.02.2010 7905 3. 16.06.2011 5258 4. 23.08.2011 7481 5. 17.04.2013 43020

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