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GUIDELINE ON ARCHIVING PRINCIPLES FOR EFFICACY AND SAFETY STUDIES AND CLINICAL TRIALS OF COSMETIC PRODUCTS OR RAW MATERIALS KÜD-KLVZ-48

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Purpose

ARTICLE 1- (1) This Guideline has been prepared pursuant to the requirements of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials in order to provide guidance on the retention of documents related to studies or trials, ensuring that archive materials do not suffer loss for any reason, ensuring their protection under the required conditions, as well as on the sorting out and destruction of materials whose retention is not deemed necessary.

Scope

ARTICLE 2- (1) This Guideline has been prepared for the sponsor, contract research organizations to be appointed by the sponsor, and the responsible investigator.

Legal Basis

ARTICLE 3- (1) This Guideline has been prepared on the basis of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials, published in the Official Gazette No. 29481 dated 20/09/2015.

Definitions

ARTICLE 4- (1) In this Guideline; a) Archive: the documents retained in accordance with the legislation in relation to studies or trials, and the premises housing them, b) Archive material: all types of files, documents and their annexes that must be retained in accordance with the legislation after the completion of the study or trial, c) Sponsor: the person, institution or organization responsible for the initiation, conduct or financing of efficacy studies, safety studies or clinical trials of cosmetic products or raw materials, ç) File: a collection of documents containing the same subject matter, d) Filing: the process of recording all types of documents generated, processing them, and retaining them in a certain order for the purpose of referring back to them when necessary once their use is completed, e) Responsible investigator: the person who has completed their education at the level required by the study or trial in the field relevant to the subject of the study or trial, and who is responsible for the conduct of the study or trial, f) Contract research organization (CRO): the independent organization to which the sponsor has transferred all or part of its duties and authorities related to efficacy studies, safety studies or clinical trials of cosmetic products or raw materials by means of a written contract,

express.

Unofficial English translation for information purposes only. In the event of any discrepancy, the Turkish original text (mevzuat.gov.tr) shall prevail.

Responsibility for Protection

ARTICLE 5- (1) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator is responsible for protecting the documents and archive material of the study or trial in their possession from all kinds of harmful effects and elements, and for classifying and retaining them in their original order.

(2) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator shall ensure the following with regard to the protection of archive material: a) Necessary measures shall be taken against factors that may cause loss or damage, such as fire, theft, humidity, flooding, pollution, animals and pests. b) Against fire, fire extinguishing equipment shall be kept permanently in working condition in accordance with fire instructions. c) Humidity shall be maintained at appropriate values by keeping hygrometers in appropriate places in every section of the archive. ç) Appropriate devices or chemical substances shall be used to prevent excessive humidity. d) Archive storage areas shall be disinfected at appropriate intervals as a protective measure against microorganisms. e) Lighting and ventilation installations shall be arranged in a suitable manner. f) Ambient temperature shall be maintained at appropriate values. g) The archive shall have the conditions required by the documents, substances and materials to be retained.

Confidentiality of Archive Material

ARTICLE 6- (1) Archive material that is in the possession of the sponsor, contract research organization to be appointed by the sponsor, or responsible investigator and that is considered confidential during the period in which the study or trial is ongoing shall remain confidential after being transferred to the archive. (2) Measures shall be taken to ensure that only authorized persons can access the archive and to restrict access by persons other than such persons.

Use of Archive Areas Outside the Institution or Organization

ARTICLE 7- (1) Where the institution where the study or trial is conducted, or the sponsor, contract research organization to be appointed by the sponsor, or responsible investigator does not have sufficient space for archiving, an archive area within the country that has the required conditions and is located outside the institution or organization may be used, or support may be obtained from an archiving company.

(2) Where external archive support is obtained, this situation shall be submitted to the Turkish Medicines and Medical Devices Agency (TİTCK) together with its justifications.

(3) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator shall verify that the conditions specified in this Guideline are also met in the space to be provided by the archiving company.

(4) There shall be no facilities in the vicinity of the facility where external archive support is obtained, such as industrial, chemical storage facilities, paint or plastic factories, fuel filling and storage facilities, and heavy industry facilities, that have explosive or flammable properties. (5) Maintenance and controls of all systems in the facility where external archive support is obtained shall be carried out periodically, and the relevant documents shall be kept ready to be submitted. (6) Where more than one sponsor, contract research organization to be appointed by the sponsor, or responsible investigator receives services from the same archive unit, the archive unit shall be required to separately meet the requirements set forth in this Guideline and to comply with the principle of confidentiality by archiving the documents belonging to each study or trial in separate sections so that they do not become intermingled.

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Preparation and Dispatch of Archive Material

ARTICLE 8- (1) After the completion of the studies or trials, all documents and annexes shall be reviewed. The essential documents that must be in the possession of the sponsor, contract research organization to be appointed by the sponsor, or responsible investigator in accordance with the legislation shall be separated. (2) The material to be sent to the archive shall be dispatched after being entered into a record form. (3) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator shall determine the filing and archiving methods by means of a "Standard Operating Procedure". (4) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator shall have an archiving officer and all archive records shall be kept in a designated place.

Retrieval of Material from the Archive

ARTICLE 9- (1) Material sent to the archive may need to be retrieved for inventory checks, audits or other reasons. In such cases, the sponsor, contract research organization to be appointed by the sponsor, or responsible investigator shall have determined the method for how material is to be retrieved from the archive.

Destruction of Archive Material

ARTICLE 10- (1) The sponsor, contract research organization to be appointed by the sponsor, or responsible investigator is responsible for the destruction of the documents pertaining to the study or trial at the end of the archiving period.

Entry into Force

ARTICLE 11- (1) This Guideline enters into force upon the approval of the President of the Turkish Medicines and Medical Devices Agency (TİTCK). Execution

ARTICLE 12- (1) The provisions of this Guideline shall be executed by the President of the Turkish Medicines and Medical Devices Agency (TİTCK).

REVISION HISTORY Revision No Revision Date Justification and Explanations 1 15.11.2022 An update has been made regarding system requirements.

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