

## 1. PURPOSE

The purpose of this guideline is to elucidate methods, which should be followed in order to avoid loss of the archive materials, due to any reason, of clinical trials handled by investigator, sponsor or contracted research organization, to ensure that they are retained under necessary conditions and to sort and dispose the material that is considered unnecessary to retain. The guideline regulates the way to retain documents related to the clinical trials and explains details of implementing the relevant current legislation.

## 2. DEFINITIONS

**2.1. Archive:** Documentations retained according to the regulations on clinical trials and places where such documentation is retained.

**2.2. Archive Material:** Materials including any and all type of file and documentation which should be retained pursuant to regulations on clinical trials after the trial is completed.

**2.3. Inspection:** Inspection activities performed by the Ministry, the sites where clinical trials are conducted, sites of sponsor or contracted research organization, the documents and records of the trial, the quality assurance regulations, and other agencies, institutions, organizations including Ethics Committees related to the trial, in terms of compatibility to Regulation on Clinical Trials and other relevant legislation.

**2.4. Sponsor:** It refers to an individual, institution or organization which is responsible for the initiation or financing of a clinical trial

**2.5. File:** Group of written material containing same issue.

**2.6. Filing:** It is the process of recording and processing all type of resultant files and storing them in a particular order in order to re-apply in the future.

**2.7. Documentation:** It refers to all documents in any form including written, electronic, magnetic records and scans, x-rays and electrocardiograms that describe and record the method, conduct, or results of a clinical trial, the factors affecting a trial, and the actions taken.

**2.8. Essential Documents:** Documents which individually and collectively permit evaluation of conduction of a study and the quality of the data produced.

**2.9. Confidentiality:** Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a volunteer's identity..

**2.10. Good Clinical Practices:** Rules including the regulations on the design, conduct, monitoring, budgeting, assessment and reporting of the clinical trial, protection of the rights, and body integrity of trial volunteers, and confidentiality and reliability of trial data to ensure conduction of the trial as per international scientific and ethical standards, which are required to be observed by the participants.

**2.11. Principal Investigator:** A physician or dentist responsible for conduction of the trial, who is a specialist or has doctorate degree on the expertise related with the trial.

**2.12. Contract Research Organization (CRO):** An independent organization contracted by the sponsor to perform one or more of a sponsor's trial-related duties and authorizations in accordance with principles of Good Clinical Practices.

**2.13. Standard Operating Procedures (SOPs):** Detailed, written instructions to provide complementary guidance and support to the relevant regulations and Good Clinical Practices.

**2.14. Audit :** An independent and systematic examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures, Good Clinical Practice, and other related regulation.

## 3. RESPONSIBILITY TO PROTECT

**3.1.** Principal investigator, sponsor or CRO are responsible for protecting possessed documentation and archive material of clinical drug trial against any and all hazardous influences and factor and for assorting and retaining in current original order.

**3.2.** The principal investigator, sponsor or CRO should ensure following conditions in relation with retaining archive material.

- 3.2.1. All necessary measures should be taken against damages caused by fire, theft, humidity, flood, dust and any and all animals and insects.
- 3.2.2. The fire-extinguishers should be always operable against fire in accordance with fire instructions,
- 3.2.3. Using hygrometers in suitable locations, the humidity level should be kept between 50 % and 60 % at all parts of the archive,
- 3.2.4. Dehumidifier devices and chemical materials should be used in order to avoid excess humidity.
- 3.2.5. Archive depots should be disinfected at least once a year as a protective measure against micro-organisms.
- 3.2.6. Light and ventilation installations should be appropriately arranged,
- 3.2.7. Heat should be as stable as possible.

#### **4. CONFIDENTIALITY OF ARCHIVE MATERIAL**

- 4.1. The archive material possessed by principal investigator, sponsor or CRO and regarded as confidential throughout the trial period shall be also confidential after it is transferred to the archive.
- 4.2. Measures should be taken in order to ensure that archive can be accessed only by authorized subjects and access by other subjects is limited.

#### **5. USE OF THIRD PARTY ARCHIVE FIELDS**

- 5.1. If adequate space is not available in the trial site or premises of sponsor or CRO, support of a locally operating archive company localized out of the trial organization or institution which is approved by the General Directorate of Pharmaceuticals and Pharmacy can be obtained.
- 5.2. If archive support is outsourced, it should be notified and submitted to the General Directorate of Pharmaceuticals and Pharmacy with all justifications and approval should be obtained for the transfer.
- 5.3. Principal investigator or sponsor or CRO should check if provisions specified in this guideline are satisfied in the field provided by the archive company.
- 5.4. There should be no facilities such as storage facilities of explosive or flammable industrial and chemical substances, paint or plastic factories as well as fuel oil filling and storage facilities and heavy industrial facilities around the premises where archive support is outsourced.
- 5.5. Maintenance and controls of all systems equipped in the facility, where archive support is outsourced, should be regularly performed and relevant documents should be available upon request.
- 5.6. If more than one sponsor or CRO provide service from same archive unit, it is necessary that provisions specified in this guideline should be separately fulfilled and documents of each company should be stored in separate divisions and confidentiality principles should be observed.
- 5.7. When the storage period, as specified in relevant legislation, expires archive materials can be sent abroad.
- 5.8. If the Sponsor has a validated electronic archive system in order to submit the originals of the archive materials upon request from the relevant authority, the Sponsor may also send abroad the financial statement documents, curricula vitae of the investigators (the originals of which are submitted to the Institution), trial budget and protocol/protocol amendment signature pages, confidentiality documents and monitoring reports before the retention period specified in the legislation runs out.

## **6. PREPARING AND TRANSFERRING ARCHIVE MATERIAL**

- 6.1.** All documentation is revised after clinical trial is completed. Essential documents are reserved, which should be retained by principal investigator or sponsor or CRO according to relevant legislation.
- 6.2.** The archive material is recorded to the “Archive Registry Form” and thus, it is transferred.
- 6.3.** The sponsor or CRO should define the filing and archiving methods with a “Standard Operating Procedure” compatible with relevant legislation.
- 6.4.** There should be “Archive Officer” of the sponsor and/or CRO and all archive records should be retained in a particular place.

## **7. RETRIEVING MATERIAL FROM THE ARCHIVE**

- 7.1.** The sponsor or CRO should define a method for retrieving material from the archive in such cases. It may be required to retrieve the material, which was transferred to the archive, for audit, inspection and other reasons.

## **8. DISPOSAL OF ARCHIVE MATERIAL**

- 8.1.** The sponsor should inform, in writing, the sponsor and archive officer the disposal of clinical trial related documents at the end of archiving period.

## **9. APPLICATION AND APPROVAL**

- 9.1.** The approval required for the institutions and organizations intending to be in service for the purpose of storage of documents related to the clinical trials is given by the Turkey Pharmaceuticals and Medical Devices Agency.
- 9.2.** Institutions or organizations intending to take a permission should apply to the Turkey Pharmaceuticals and Medical Devices Agency with the application form published on the website of the Turkey Pharmaceuticals and Medical Devices Agency.
- 9.3.** Audit for institutions or organizations whose application is approved should be performed within 45 days at the latest. After the permission is given by the Turkey Pharmaceuticals and Medical Devices Agency, audit should be performed at least once a year.

## **9. SUPERSEDED REGULATIONS**

The Guideline for Archiving Principles in Clinical Drug Trials, effective with the Authority Consent dated 28.01.2011 and numbered 843, has been superseded.

## **10. EFFECTIVE DATE**

This Guideline is effective as of date of approval.