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GUIDANCE DOCUMENTS CONTAINING THE COMMON PROVISIONS ON THE CONDUCT OF GCP INSPECTIONS BY COMPETENT AUTHORITIES OF THE DIFFERENT MEMBER STATES

Annex VI

TO GUIDANCE FOR THE CONDUCT OF GOOD CLINICAL PRACTICE INSPECTIONS

Record keeping and archiving of documents

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This document forms part of the guidance documents containing the common provisions on the conduct of GCP inspections. Please check for updates in the Volume 10 of the Rules Governing Medicinal Products in the European Union.

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1. INTRODUCTION

The scope of this document is to provide guidance for the record keeping and archiving of documents in relation to all Good Clinical Practice ("GCP") inspections carried out by the competent authorities of Member States of the European Union.

An inspection file is an organized body of records produced or received during the performance of the GCP inspection and which contains all correspondence concerning the inspection, documents submitted by the sponsor and/or applicant and the documents retrieved and copied during the inspection.

The Lead Inspectors ("**LI**") participating in an inspection have to open Local Inspection Files, which content is described in appendix 1.

In the context of the national authorisation procedure, mutual recognition procedure/decentralised procedure ("**MRP**"/"**DCP**") or centralized procedure, a central file should be also kept by the Reporting Inspector, which content is described in appendix 2.

Local Standard Operation Procedures ("**SOP**"s) concerning the management of documents are not affected by this procedure, except where it is more stringent.

2. MANAGEMENT OF THE INSPECTION FILES

2.1. Responsibilities

The LIs and, where applicable, the Reporting Inspector ("**RI**") should establish the Local and the Central Inspection Files, respectively, immediately after appointment. The general layout of these files should be in accordance with the format as described in the appendices to this procedure.

All entries in the files should be made or completed at the time each action is taken and should be added in chronological order within the sections of the appendix.

All ensure that all copies of relevant data/documents are routed to the RI so that the information can be incorporated into the Central Inspection File and archived properly during the conduct of the inspection.

Locally collected information by all participating inspectors (validated copies of relevant data/documents, etc.) is filed into the Local Inspection File(s) according to the procedures of the concerned inspectorates. A copy of all local information that is of a general importance or reflects on the whole of the inspection is sent to the RI, where applicable, to be incorporated into the Central Inspection File, in particular documents which prove conditions, practices or processes that might adversely affect the rights, safety and/or wellbeing of the trial subjects and/or the quality and integrity of data.

2.2. Storage

The Local Inspection Files are preserved by the concerned inspectorates while the Central Inspection File, where applicable, has to be maintained at the Reporting Inspectorate.

It is the responsibility of the involved inspectorates to store the Inspection Files under conditions that prevent accidental or premature destruction of the documents according to national requirements.

The inspection files should be stored safely in a suitable archive for the whole retention period. It is strongly recommended that only authorised personnel have access to the archives.

Documents may be stored electronically, onto human readable media or other new media as changes in technology demand. If documents are to be archived using electronical or optical media, the methods for transferring the data to these media should be validated. A suitable backup-strategy must be implemented to prevent loss or destruction of data. There must be a possibility to generate hardcopies throughout the period of retention.

2.3. Confidentiality and security

Each involved authority is responsible for ensuring the correct application of applicable data protection requirements.

On reasonable request of a Member State inspectorate, the EMEA or the Commission, the documentation could be made available for review. Access will not be provided to parties other than the Commission, the EMEA or the Competent Authorities or the duly appointed experts of these parties, unless otherwise is indicated by legislation[1].

Whenever an authority grants access to the inspection file(s) or parts thereof, this access should be recorded. If copies of documents are required these may be provided, subject to confidentiality, to the parties mentioned above. The parties in receipt of the documents then bear full responsibility for ensuring their continued confidentiality.

2.4. Retention period and destruction

The retention period of the inspection files is determined by national requirements. The inspection files should be preferably maintained for a period at least of 30 years, or for 10 years after the product has been withdrawn from the market, whichever is the longer. After this time, the inspection files could be removed from the archives for destruction. The signature of the person who is responsible for the destruction of the inspection file and the date of the destruction has to be recorded and should be kept in the archives for unlimited time.

[1] Such as national legislation on Freedom of Information.

APPENDIX 1: FORMAT OF A LOCAL INSPECTION FILE

1. Table of contents

2. Communication

with Requesting Party

with the participating inspectors and, where applicable, Reporting Inspector

with assessors

with applicant/sponsor

with inspectees

others

3. Trial related documents[2]

Provided by the applicant/sponsor:

Protocol and amendments

Clinical Study Report

Investigators Brochure

Blank patient informed consent forms

Printout of the Clinical Database

other

4. Inspection related documents

Inspection request

Inspection team composition

Contracts

Time Schedule for the inspection

Inspection Plan

[2] Multiple copies of documents from the applicant/sponsor may be sent to each member of the inspection team. One copy has to be retained in the Local and, where applicable, Central Inspection File as required by Appendix 2 of this Procedure. Therefore the concerned inspectorates could decide on the destruction or the return of those documents. The destruction or return of documents has to be recorded in the Inspection File.

Local Inspection Plan

other

5. Documents retrieved/copied during the inspection

7. Inspection Reports

Inspection Report(s) (that was/were sent to the inspectee(s) for comments)

Response of the inspectees

Inspection Report (final version)

Integrated Inspection Report (final version), where applicable

APPENDIX 2: FORMAT OF THE CENTRAL INSPECTION FILE (ONLY APPLICABLE IN THE CONTEXT OF THE MRP/DCP OR CENTRALIZED PROCEDURE)

1. Table of contents

2. Communication

with Requesting Party

with Lead Inspector(s) and participating inspectors

with assessors

with applicant/sponsor

with inspectees

others

3. Trial related documents

Provided by the applicant/sponsor:

Protocol and amendments

Clinical Study Report

Investigators Brochure

Blank patient informed consent forms

Printout of the Clinical Database

Other

Provided by assessor:

Clinical Study Report (if applicable)

Assessment reports

List of Questions

Response to the List of Questions

Other

4. Inspection related documents

Inspection request

Inspection team composition (central and for each selected site)

Contracts

Time Schedule for the inspection

Inspection Plan

Local Inspection Plans

Other

5. Locally collected information of general importance

Documents retrieved or copied during the inspection

6. Inspection Reports

Inspection Reports (including the responses of the inspectee(s) and evaluation of these)

Integrated Inspection Report (final version)

APPENDIX 3: REFERENCES AND RELATED DOCUMENTS

- Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

- Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such product.

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, as amended.

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

- EUDRALEX Volume 10 - Clinical trials, of the Rules Governing Medicinal Products in the European Union.