Audit Report

Project No.:
Date:
Version: Draft

Sponsor:

1 Audit Team

2 Auditee

3 Location of Audit

The allocation of the CRFs to the clinical trial was checked in the sponsor's OPU in . The data and system audit was performed in the study centre.

4 Date of Audit

Preliminary audit on

Data and system audit

5 Rationale of the Audit

Data verification

Inspection of the study centre and study conditions

6 Audit Objectives

This audit will examine whether all requirements laid down in the study protocol are met and whether the quality activities and related results are suitable for achieving the objectives of the study protocol and are in accordance with the Note for Guidance "Good Clinical Practice for Trials on Medicinal Products in the European Community

7 Scope of the Audit

Random Sample Audit of data

Audit of the quality system

8 Method of the Audit

8.1 Data audit

A random sample of data was checked.

The sample space (lot) is formed by all data entries in the Case Report Forms (CRFs) and the number of patients included in the study. The lot checklist was used to test whether the CRFs are assigned to the lot correctly. The inspection characteristics of the lot checklist were checked in all CRFs (100 % inspection) and compared with the hospital charts. All errors found are listed.

At the sponsor's request even those CRFs were assigned to the lot for which not all characteristics were in compliance with the demands. All data entries should therefore be checked in order to form a general impression of the quality of data sampling by the study centre.

Three sample spaces were formed. For this purpose, all data entries were classified as "Critical Data" (KF), "Major Data" (HF) and "Minor Data" (NF) by the sponsor. From each data class a data sample was drawn according to the operating characteristic curve by the QARS-program (Qualitative Attributes Random Sample) based on the SAS-Software-package SOP AUD/06 to create checklists in clinical trials. In the sampling plan for critical data "KF" p-alpha was set at 1 %, p-beta at 2 %, for major data "HF" the p-alpha was set at 2 % and p-beta at 5 %, for minor data "NF" p-alpha was set at 10 % and p-beta at 20 %. The operating characteristic curve with the probability of acceptance in the presence of the given quality acceptance level, the sample size and the acceptance number are given in the sample plan. The sample plan was generated by .

All data of the three samples were checked in the CRF and crosschecked in the hospital charts.

8.2 System Audit

The system audit was performed by asking the questions listed in the on-site checklist of the audit plan. This checklist was composed in coordination with the sponsor.

9 Basis of the Audit

Note for Guidance "Good Clinical Practice for Trials on Medicinal Products in the European Community"

10 Documents

Study Protocol "X Titel

Case Report Forms (CRFs) X (Doc.No. X)

Notes of the study centre

Sampling Plan X

Classification of data entries according to the sponsor's letter

On-site questionnaire

11 Language of the Audit

The audit was performed in English.

12 Preparation of the Audit

CRFs X of the study centre in X were submitted to audit in the sponsor's OPU in X on , and inspected as described above.

Only the "yellow pages" of the CRF were available. Not all CRFs are completed at the time of the audit. Only data entries up to the documented state of the investigation were considered in the sample space. Deviations from the the characteristics given in the lot checklist are listed below.

13 Audit Schedule

The audit was performed in the study centre on , , starting at a.m. and finishing at p.m.

14 Participants

Auditors Dr. med. U. Paschen

Sponsor

Study Centre

15 Audit Sequence

In a preliminary discussion the aim, scope and method of the audit were explained. The system audit was subsequently performed.

To date audit has been performed at the study centre .

was the investigator responsible for the whole study. No other persons participated.

At first the characteristics given in the lot checklist were cross-checked with the hospital charts, as far as this was feasible.

Afterwards the data entries of the samples were checked in the CRFs and compared with the hospital charts. Since the patients were not informed about the activity of an auditor, the auditors had no direct insight into the charts. The cross-check was therefore performed by the indirect interview technique.

The following nonconformities were found:

General, recurring nonconformities

Nonconformities found in single CRF

Within the limits stated we can conclude from the sample that the data source is within acceptable quality limits.

16 System Audit

The questions in the on-site questionnaire were asked by the auditor and answered by the investigator in a personal interview. Non-compliance was found in the following items:

17 Discussion

This audit was performed to assess the quality level of the study centre and of the realization of the study.

Since the study protocol and the organization of the study were not outlined with a quality audit in mind, some difficulties in quality assurance and some deviations from the standards were expected. But the criticism is of small significance and uncertainties can be cleared up easily.

18 Closing Meeting with Auditee

The auditor will certify this audit according to SOP.

19 Confidentiality

The auditor assures that he and all persons engaged in the preparation and performance of this audit will treat all information and knowledge gained in connection with the audit of this study as strictly confidential. This obligation will continue even in the event of the auditor leaving the McKnight Laboratories GmbH or the outline agreement with the sponsor being terminated.

20 Enclosures

Sampling Plan
Copies of the Lot checklists
Copy of the checklist On Site Audit / /

21 Signatures

Audit Organisation:

Dr. med. U. Paschen - Auditor -

22 Distribution List

2 copies for the sponsor
1 copy for the archive of QM-Beratung