Confidential Audit Report

Dated:

|  |  |
| --- | --- |
| Study/Audit title: |  |
| Study R&D P0 number: |  |
| REC reference number: |  |
| EudraCT number: |  |
| Sponsor name: |  |
| CI/PI: |  |
| Point of contact for audit: |  |
| Auditor: |  |
| Date of audit: |  |
|  |  |
| Agreed date for action completion:  |  |

|  |  |
| --- | --- |
| Audit report circulated to: |  |
| Date of circulation: |  |

## **Summary**

Date of audit, purpose, and name of auditor:

Brief overview of findings, key messages, recommendations:

*There are x findings arising from this audit. x have been classified as Critical, x have been classified as Major and x have been classified as Minor.*

*Critical findings were noted in the following areas:*

* *Finding summary*

*Major findings were noted in the following areas:*

 *• Finding summary*

*Minor finding were noted in the following areas:*

 *• Finding summary*

Audit Scope

The audit included a detailed review of the following:

*Bullet points. Copy from the Audit Plan: Highlight any deviations from the Audit Plan*

Audit Standards

The audit was conducted with reference to the following documents:

*Bullet points, copy from Audit Plan*

**Instructions For Responding to Findings**

Please respond in writing to the auditor within 10 working days of receipt of this report.

Please respond to all findings, in order to facilitate follow up of corrective actions where necessary. Responses already provided to the auditor have been included in the audit report for completeness.

In order to aid implementation of corrective actions and to reduce undesirable events such as non-compliances associated with audit findings, please identify details of any planned or completed corrective actions, person(s) accountable, and anticipated or actual date of completion. Please do not withhold responses because corrective actions have not been completed.

The completed report will be reviewed and approved by the QA team.

Audit Findings Categorisation

Critical:

An unacceptable departure from GCP guidelines, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines.

Major:

An unacceptable departure from GCP guidelines, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines.

Minor

An unacceptable departure from GCP guidelines, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients

**Recommendations**

These are findings which are not a departure from GCP guidelines, regulations and/or procedures but which are suggestions for an improvement activity.

Audit Findings

|  |  |
| --- | --- |
| **Finding Number:** | 1 |
| **Category:** |  |
| **Area:** |  |
| Finding: |  |
| Corrective action: |  |
| Preventive action: |  |
| Suggested Respondent(s): |  |
| Response: |  |
| Date for completion: |  |

|  |  |
| --- | --- |
| **Finding Number:** | 2 |
| **Category:** |  |
| **Area:** |  |
| Finding: |  |
| Corrective action: |  |
| Preventive action: |  |
| Suggested Respondent(s): |  |
| Response: |  |
| Date for completion: |  |