Confidential Audit Report

Dated:

|  |  |
| --- | --- |
| Audit title: |  |
| Study R&D P0 number: If applicable |  |
| REC reference number: If applicable |  |
| ISRCTN number: |  |
| Sponsor name: |  |
| CI/PI: |  |
| 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 Other.*

*Critical findings were noted in the following areas:*

* *Finding summary*

*Major findings were noted in the following areas:*

*• Finding summary*

*Other findings were noted in the following areas:*

*• Finding summary*

Audit Scope

The audit included a detailed review of the following:

*Bullet points.*

Audit Standards

The audit was conducted with reference to the following documents:

*Bullet points.*

**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:

1. where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:

* the rights, safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and /or
* the clinical trial data are unreliable and/or
* There are a number of Major non-compliances across area of responsibility, indicating a systematic quality assurance failure, and/or

1. Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances.
2. Where provision of the TMF does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the Regulations.

Major:

d) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or

e) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

Other

f) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.

**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 |
| **Finding categorisation:** |  |
| **Area:** |  |
| Finding: |  |
| Corrective action: |  |
| Preventive action: |  |
| Suggested Respondent(s): |  |
| Response: |  |
| Date for completion: |  |

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