 **Internal Audit Report**

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| **Audit Number** |  |
| **Audit Title** |  |
| **Date of Audit** |  |
| **Date of Report** |  |
| **Auditor** |  |
| **Auditee** |  |
| **Reported and distributed to** |  |
| **Audit Objective** |  |
| **Supporting documents** |  |
| **Summary of Findings/Observations** |  |
| **Date CAPAs addressed** |  | **Date Audit Closed** |  |

**Findings and Observations**

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| --- | --- |
| **Category** | **Definition** |
| Critical | * The safety, well-being or confidentiality of participants has been jeopardised or has the potential to be jeopardised.
* Reported data are unreliable or absent.
* Inappropriate, insufficient or untimely corrective action has taken place regarding major non-compliance.
* Lack of adequate documentation available to reconstruct the study or failure to maintain an appropriate Investigator Site File (ISF)
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| Major | * Significant and unjustified non-compliance with relevant legislation or the principles of GCP.
* A number of breaches of legislation or the principles of GCP within one area, indicating systematic quality assurance failure.
* A failure to comply with legislative requirements including annual reporting requirements.
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| Minor | * Low risk to participants but requires resolution.
* Any other finding that is neither critical nor major.

GCRF Activity Data Audit sub-categories

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| Category A | Data unreliable/inconsistent/inaccurate/incomplete and must be updated or query answer immediately.  |
| Category B | Minor issues with data which need to be addressed. |

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**Corrective Action and Preventative Action**

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| **1** | **Categorisation of finding:** |
| **Description of finding:** |
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| **Corrective Action:** |
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| **Preventative Action:** |
|  |
| **Actioned By** |  | **Date** |  |