|  |  |  |
| --- | --- | --- |
| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DM-505 |
| **Title**  **CRF QUALITY ASSURANCE** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

|  |  |  |
| --- | --- | --- |
| **Review date** | **Revision Date** | **Signature** |
|  |  |  |
|  |  |  |

**Document History**

|  |  |  |
| --- | --- | --- |
| **Version number** | **Reason for change** | **Date** |
| 1.0 | Initial release | 28th March 2015 |
|  |  |  |
|  |  |  |

**Distribution List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Location** | **No of copies** | **Name/Location** | **No of copies** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Introduction**

CRF quality assurance is the process of profiling the data in the CRF to discover inconsistencies and other anomalies in the data, as well as performing data cleansing activities. Quality data is only possible if the CRF containing them is quality assured.

**Objectives**

This SOP describes the process for quality assurance of CRF prior to data entry. **Responsibility**

The Data Manager

1. **Procedure**
2. The data manager will receive completed CRFs from study personnel along with copies of applicable source documentation
3. The data manager will proof all completed CRFs as follows:
   1. All information transferred from provided source documentation to CRFs will be proofed for accuracy.
   2. All toxicity grading will be verified for accuracy.
   3. All CRFs will be proofed for accuracy, completeness, logic, and conformance to CRF completion instructions.
4. Errors found on CRFs will be returned to the appropriate study personnel and corrected as follows:
   1. All errors will be corrected on the CRFs by drawing a line through the incorrect data, writing the correct information, and initialling and dating the change.
   2. The appropriate study personnel will be notified of any errors that also require correction of the source documentation.
   3. If an error or suspected error is found which requires clinical judgement, the appropriate study personnel will be consulted for correction.
5. The data manager will read and understand the pertinent definitions listed in this policy and procedure.

**Definitions**

**Confidentiality**: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

**This SOP has been read and understood by**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Date** | **Name** | **Date** |
|  |  | 8. |  |
|  |  | 9. |  |
|  |  | 10. |  |
|  |  | 11. |  |
|  |  | 12. |  |
|  |  | 13. |  |
|  |  | 14. |  |