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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DM-504 |
| **Title**  **CRF FILLING** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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**Document History**

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

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1. **Introduction**

CRFs are the official documentation of the study for both sponsors and regulatory authorities, and together with the source documents and the Trial Master File/Investigator Site File, will be closely examined during monitoring, audits and inspections. The data collected on the CRF is therefore used directly as the basis for the study report and any publications, as well as making up part of the data for regulatory approval of a new drug. Prior to study initiation, it is the responsibility of a designated member of staff to ensure there is an adequate supply of CRFs at the research site to conduct the trial. CRFs will be kept in a secure location during the course of the trial. Once the trial has closed the CRFs will then be archived with all other essential documentation. Correct filling of the CRFs are important for data security, easy retrieval and physical protection of study documents.

1. **Objectives**

This SOP describes the process for filing of Case Report Forms (CRF).

1. **Responsibility**

The Data Manager or Designee

1. **Procedure**
2. Following data entry or database correction, the data manager or designee will file all CRFs in the appropriate CRF binder.
3. The data manager will train and supervise all other staff including volunteers who assist with the filing process including training in this policy and procedure.
4. All CRFs for a particular visit will be filed and arranged in order according to study visit date.
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**

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