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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** |
| **Study Site:**  | **SOPs Number** : DM-502 |
| **Title****CRF DATA ENTRY** |
| **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**

Data collection tools are among the most important aspects of clinical study. They determine the amount and quality of data gathered during any research endavour. Adequate care should be employed in their design as inadequate data collection has the potential to ruin a well conducted study.

1. **Objectives**

This SOP describes the process for data entry of Nigeria PreP Study Case Record Forms (CRF).

1. **Responsibility**

The Data Manager or Designee.

1. **Procedure**
2. The data manager will receive complete, quality assured, and corrected CRFs as defined by the Nigeria PreP Study CRF Quality Assurance SOP # DM-605.
3. All CRFs will be double data entered by the data manager or Designee within 2 weeks of the study visit utilizing the Software supplied by sponsor (NACA).
4. All data entry will be proofed for accuracy by the data manager using the following methods:
	1. Visual proofing of the CRF with the computer screen post data entry.
	2. Cross-referencing with source documents as appropriate.
	3. Data compare between the two data bases ( acceptable difference = 0.25 % or less)
5. All CRFs data entered will be initialled and dated in the appropriate location on the CRF.
6. Entered data will be saved to the local database once every 4 hours, and backed up onto a disk/CD (3 copies (On site; PI and Data Manager). All data will be uploaded to the central data unit at NACA daily.
7. All completed and verified CRFs will be filed in its appropriate CRF folder.
8. The data manager or designee 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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