|  |
| --- |
| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** |
| **Study Site:**  | **SOPs Number** : DM-503 |
| **Title****DATA QUERY RESOLUTION** |
| **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**

Data Management is a critical phase in research, which leads to generation of high-quality, reliable, and statistically sound data from clinical study.The quality of data generated plays an important role in the outcome of the study. Data validation is the process of testing the validity of data in accordance with the protocol specifications. Discrepancy is defined as a data point that fails to pass a validation check and may be due to inconsistent data, missing data, range checks, and deviations from the protocol. Discrepancy management includes reviewing discrepancies, investigating the reason, and resolving them with documentary proof or declaring them as irresolvable. Based on the types identified, discrepancies are either flagged to the investigator (data query) for clarification or closed in-house by self-evident corrections.

1. **Objectives**

This SOP describes the process for resolution of data queries received from the Data Managers ` at the Central Data management centre/Unit.

1. **Responsibility**

The Data Manager, study personnel.

1. **Procedure**
2. The data manager and study personnel will be trained to resolve queries in accordance with the following requirements.
* Check daily for posted queries (Email, SMS etc.). All queries must be resolved within 2 weeks unless a specific date of resolution is requested.
* If the query is unclear or if more information is required, the appropriate protocol specific Data Manager at the central data management unit should be contacted.
1. Queries present unique problems that will require the data manager/study personnel to utilize various methods of research. The following list is a sample representation of research methods used by the data manager but is not meant to be comprehensive in nature:
* Verification of data on the CRFs, and/or source documentation.
* Consulting with the appropriate study personnel or clinicians.
* Verification of data with study laboratories.
1. Once the data manager/study personnel has determined the resolution of the query, various methods of correction will be employed.
* Incorrect database information will be changed.
* Incorrect data on CRFs will be changed according to SOP # DM-501 CRF Completion and Correction, and also corrected in the database.
* Missing CRFs will be completed and entered.
* Other communications will be made as directed by the query instructions.
1. Following corrective actions the data manager/study personnel will respond to the query via the route it was received using the Reply All command, and removing the “RE:” (if it is through email) in the subject line. Specific information about how the query was resolved should be included in the response.
2. Once weekly, the data manager/study personnel will check for Unanswered Query, and resolve them promptly.
3. The data manager and study personnel 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. |  |