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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : QA-601 |
| **Title**  **CLINICAL MONITORING VISITS** | | |
| **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**

Monitoring is defined as the act of overseeing the progress of a clinical study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s). The purpose of monitoring is to verify that: **1)** The rights and well-being of the human subjects are protected**; 2)** The reported trial data are accurate, complete and verifiable from source documents**; 3)** The conduct of the trial is in compliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements.

1. **Objectives**

This SOP describes the process for overseeing the progress of the Nigeria PreP study.

1. **Responsibility**

The Sponsor or designee is responsible for complying with procedures necessary to secure the quality of every aspect of the study. He is responsible for determining the level of monitoring and for enabling monitoring activities at the study site. The Study Monitor is responsible for conducting the monitoring visit in accordance with the Monitoring Plan, this SOP (unless otherwise agreed) and regulatory requirements.

1. Procedure

* Upon notification from the Sponsor of scheduling of an upcoming monitoring visit, the site Coordinator will notify all involved study personnel, including Principal Investigator(s), Research Pharmacist, and Research Nurses of the planned dates for the visit.
* Confirm visit dates and availability of key personnel with site personnel and Sponsor (designee).
* A space for the monitoring visit will be reserved.
* The site will receive notice from the Sponsor (or designee) prior to arrival which will confirm the dates and the focus for the monitor visit.
* Prior to the Monitor’s arrival, research binders and source documentation, including progress notes, flow sheets, laboratory or diagnostic reports, consent forms, diary cards or questionnaires, and drug/product accountability logs will be pulled and be placed or ready to go into the reserved space once the monitor arrives.
* Essential documents for the study being monitored will be pulled for review in the centrally reserved room for the monitor.
* Drug product will be assessed in the research pharmacy area and may be moved thereafter to the reserved monitoring room with the Sponsor (designee).
* Reserved space will have a lock or office nearby where all pulled study data may be kept during the night or during times when the monitor is on break.
* At the end of the monitoring period, site personnel will meet for debriefing with the monitor. The Monitor will review findings of the monitoring visit. The site will use findings from the monitoring visit as part of the site specific QM plan.

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

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