Office Of Clinical Site Oversight
National Institute of Allergy and Infectious Diseases (NIAID)

MOB Report

2nd Edition
April 2015


Reviewing charts is a "team" effort.

Welcome...

Welcome to the second edition of the MOB Monitoring Newsletter. The first edition was a pilot, only shared within OCSO. We plan to publish the newsletter on a quarterly basis. The newsletter will include monitoring metrics, regulation and policy updates, monitor spotlight, and an article from a monitor or a site coordinator.

In this issue

Updates, Metrics and Policy

Regulations, Policies & SOPs

Updated HSP and GCP Training Policy

The Division of AIDS has updated the policy on **Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements** to be effective 15 March 2015. It can be accessed online by clicking the hyperlink.

The Division of AIDS has updated the policy on **Requirements for Clinical Quality Management Plans** to be effective 17 April 2015. It can be accessed online by clicking the hyperlink.

Laboratory Specimen Verification (LSV) Assessments

The Monitoring Operations Branch (MOB) in conjunction with PPD are currently piloting an initiative that involves combining LSV assessments for multiple sites in a single visit to a lab. A monitor with laboratory experience visits the lab and conducts LSV assessments not only for the site being visited but also for all other sites supported by this laboratory. This will streamline the LSV process for sites using the same lab.

For example, 6 sites in South Africa are supported by the BARC Lab. During the earliest 1Q 2015 monitoring visit for one of these sites, the LSV assessments for the other 5 sites were also conducted.

DAIDS Clinical Site Clinical Site Monitoring (CSM) System

As of February, the DAIDS CSM Training is available on the DAIDS Learning Management System (LMS). It can be accessed at the following link: **https://www.daidslearningportal.com.**

ORGANIZATION INFO

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THE FEDS

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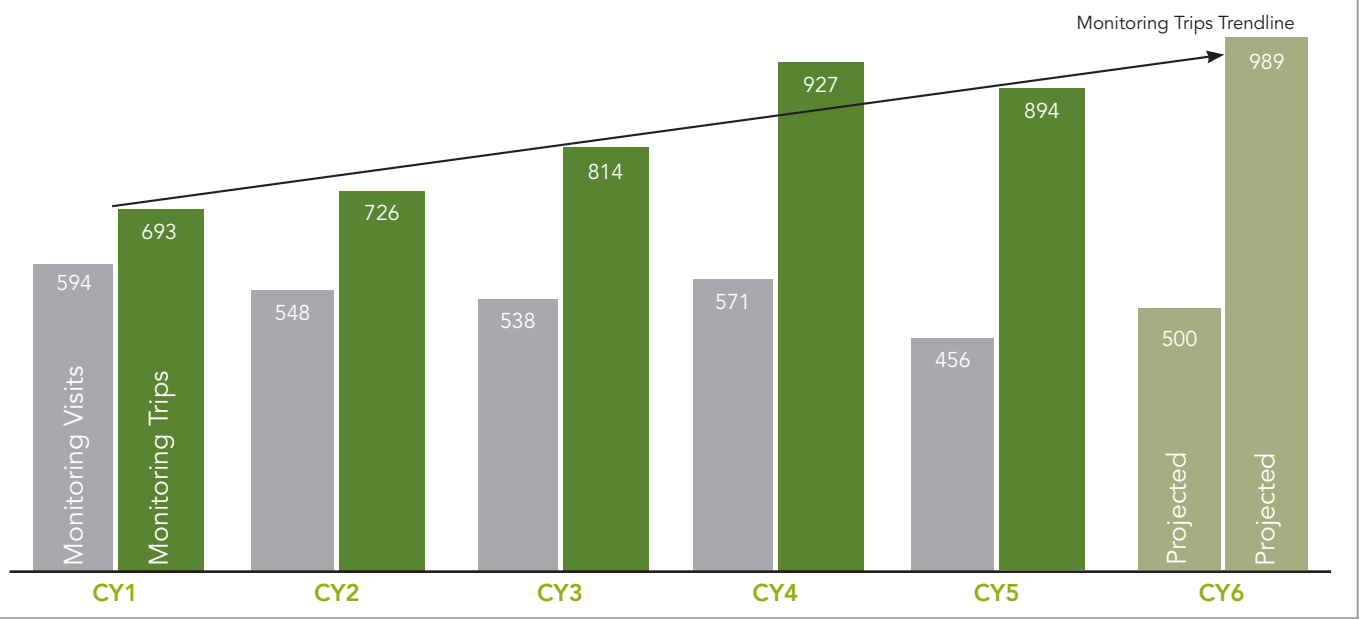
Monitoring Metrics

Overview of Monitoring Visits and Trips to Date

Monitoring Trips and Visits (Contract Year 1 to Contract Year 6)

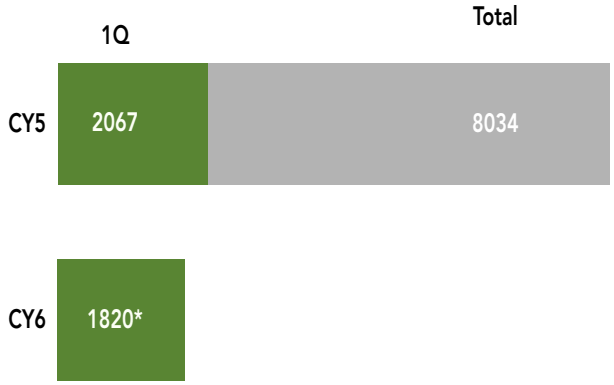
Over the last 5 years, OCSO has conducted a total of 2707 Monitoring Visits and 4054 Monitoring Trips.
Monitoring Trips have increased throughout the past 5 contract years.



Monitoring Visits: Any time a monitor travels to a site to conduct monitoring.
Monitoring Trips: Includes the total number of monitors traveling to a site to conduct a site monitoring visit.

Record Review

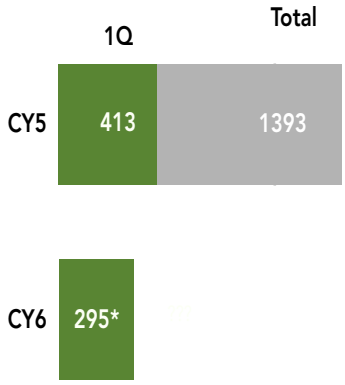
CY5 (2014) and CY6 (2015) Quarter 1 Comparisons



*CY6 1Q data does not include Record Reviews from 25 pending visits.

Pharmacy Assessment

CY5 (2014) and CY6 (2015) Quarter 1 Comparisons



*CY6 1Q data does not include Pharmacy Assessments from 25 pending visits.

Navigating a Monitoring Visit

by Greg Lessing, B.Sc., Principal Clinical Manager

Wherever clinical research ventures, so monitoring follows. Why is this? Justification for monitoring in clinical research is a topic with an extensive, interesting, and in some instances tragic history. Following the happenings in the Nuremburg, Thalidomide, and Tuskegee trials (amongst others), the International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice was adopted by regulatory bodies of the European Union, Japan, and the United States of America (USA). The purpose was to protect human subjects, ensure the collection of accurate, reliable data and most importantly to provide standards and guidelines for the conduct of clinical research. In most countries, ICH guidelines form the basis of national legislation governing the conduct of clinical research and are thus both an ethical and a legal requirement.

If your site is conducting Division of Acquired Immunodeficiency Syndrome (DAIDS)-sponsored protocols that are being monitored, your site will be visited by Pharmaceutical Product Development (PPD) monitors. Usually sites are visited quarterly; however, depending on factors such as number of protocols, protocol risk ranking, enrollment and the pre-determined percentage Participant Identifiers (PIDs) to be monitored, your site may be visited more or less often. While there are instances of more frequent visits to resolve specific issues, the monitoring frequency is seldom adjusted exclusively due to site performance.

At least 21 calendar days prior to a visit, site representatives will receive a Pre-Visit Letter (PVL) and Announced Site Visit Work Order (WO) specifying start and end dates of the monitoring visit, participant charts that will be reviewed, and any audits/assessments due.

More recently, the number of monitors required at sites conducting larger trials has increased dramatically. Occasionally up to 10 monitors attend a monitoring visit; however, this should be approved by the site to ensure that infrastructure exists to support the number of monitors. The Announced Site Visit WO details the primary monitor and the number of co-monitors attending a visit.

During a visit, a monitor conducts record review, regulatory file review, and pharmacy assessments. Biennially and with site relocation a Site Operations Assessment is conducted, which is a detailed review of site operations and facilities.

The following is a step-by-step preparation plan recommended for use by sites in preparation for a visit.

On receipt of the Announced Site Visit WO:

- Review start and stop dates of the visit. Plan for an introductory meeting on the first day and a debriefing meeting on the final day. Attendance of Clinical Trials Unit (CTU) Principal Investigator (PI), CTU and Clinical Research Site (CRS) Coordinator(s), CRS Leader, Pharmacist of Record (PoR), and Network Study Coordinator (when applicable) at debriefings is noted in the Site Monitoring Report (SMR).
- Ensure infrastructure is in place to accommodate the number of monitors attending the visit. Inability or obstacles to monitoring is also recorded in the SMR.
- Provide at least 8 charts listed on the Announced Site Visit WO for monitor review at the start of the visit.
- The Full Site Visit WO accompanying the monitor, details the unannounced PIDs to be monitored, and is available to the site online after midnight on the first day of the visit. The ratio of announced to unannounced PIDs is usually 1:1.
- Where possible, provide Site Standard Operating Procedure (SOP) for Informed Consent and Site Source Document SOP for monitor review from the onset.
- Provide regulatory files for review. Ensure delegation of duties log is up-to-date and corresponds with Food and Drug Administration (FDA) 1572/Investigator of Record Agreement (IoRA). Ensure that all vendors (e.g. Labs) are also recorded as appropriate.
- Provide any trackers to the monitors such as Informed Consent Version trackers.
- Provide access to Curriculum Vitae (CVs), appropriate licenses, and training records of all site staff.
- For pharmacy assessments ensure that pharmacy personnel are available during the visit and ensure temperature monitoring information is up-to-date. Monitors review both primary and secondary temperature monitoring systems.
- Helpful Tip: Check follow-up issues from previous monitoring reports.
- Helpful Tip: Utilize the report templates from previous visits as a tool to determine the points of focus for monitors during a monitoring visit.

It is important to note that the objective of the site, monitor, and sponsor are intended to be collaborative and synchronous, which is a commitment to the conduct of scientifically accurate research while prioritizing the safety and well-being of the human subjects under observation.


John and Nkafwire

Monitor Spotlight

John Chabuka
John joined PPD in August 2014 as a Senior Clinical Research Associate (CRA). Prior to joining PPD, John worked as a Quality Assurance Officer at the University of North Carolina Project, and as a CRA at University of Malawi and ClinTec International. He has 10 years clinical research experience in various therapeutic areas.

He has a bachelor's degree in Statistics from the University of Malawi and a master's degree in Clinical Research from the Medical University of Vienna.

John is married and has a daughter. He spends most of his free time with his family to compensate them for his frequent travels.

Nkafwire Mkandawire
Nkhafwire joined PPD in July 2013 as a Senior CRA, having worked for the University of North Carolina Project as a Quality Assurance and Quality Control Manager, and as a CRA for the Medical Research Council (UK). He has 13 years of clinical trial management and monitoring experience. Nkhafwire is an alumnus of the London School of Hygiene and Tropical Medicine, University of London and holds a Master of Science in Public Health.

He is married and has two sons and spends his free time with family travelling mostly to different beautiful beaches of Lake Malawi.