DAIDS Monitoring Operations Branch (MOB)

As sponsor, NIAID DAIDS is required to monitor DAIDS sponsored and/or supported clinical trials to ensure protection of human subjects, accurate and complete reporting of trial data, and protocol compliance by Clinical Research Sites (CRSs), in accordance with 21 CFR §312.56 and ICH Good Clinical Practices (GCP) Section 5.18. The Monitoring Operations Branch (MOB) directs the monitoring function for DAIDS-sponsored clinical trials to meet the rigor of all applicable regulations and guidelines.

DAIDS Network studies are being conducted in over 20 countries. The monitoring activities at these Clinical Research Site (CRS) locations are conducted by a Clinical Research Organization (CRO) with a regional presence through a contract mechanism. The current NIAID Clinical Site Monitoring (NCSM) Contractor is Pharmaceutical Product Development (PPD) LP. The MOB develops, executes, and provides oversight of the NCSM monitoring contract.

To monitor the progress of the DAIDS clinical trials and adherence to all applicable regulations and DAIDS policies and procedures, PPD Clinical Research Associates (CRA)s in each region perform routine on-site and remote visits at each CRS. The MOB in conjunction with PPD ensures that the monitors are appropriately trained, as required by ICH/GCP.

MOB uses a “risk-based” approach to monitoring. Each study is assigned a risk level (1-3) based on the phase, magnitude and complexity of the trial. The risk level determines the extent and nature of monitoring. Monitoring visits are generally conducted on a quarterly basis lasting three (3) to four (4) days. The assigned CRA will contact site personnel to schedule the monitoring visit. During these visits, the monitors verify study data against participant medical records (source documents), review the regulatory file documents, perform study product accountability, conduct laboratory specimen verification and conduct clinic and pharmacy facilities operations assessments. All site monitoring visits are concluded with a debrief summary meeting with site to review findings and answer any questions.

The monitoring visit findings are documented in a site monitoring visit report and shared with the site personnel via a computer-based system called the NIAID Clinical Research Management System (NIAID CRMS), Clinical Site Monitoring (CSM) module. Upon completion of training, DAIDS will provide assigned site staff access to the CSM module. The monitors have no role in resolving any findings/deviations noted during a monitoring visit. The assigned DAIDS/OCSO Program Officer (PO) will identify significant findings from the monitoring visit report and request that the site implement corrective and preventive action as necessary. In addition to significant findings identified by POs, sites are expected to address all findings in the Site Monitoring Report. The MOB serves as a resource on operational and regulatory issues that may arise from monitoring visits, and ensures that appropriate clinical research standards, policies, and procedures are adhered to by the CRSs.

DAIDS MOB *continued*

The MOB coordinates with all DAIDS programs to align monitoring resource needs for existing and upcoming trial work. Monitoring visit frequency, length of visit or number of monitors at a visit may be adjusted depending on workload, number of active protocols at the site and enrollment metrics.

To enhance human subject protection and the quality of clinical trial data, MOB monitoring oversight focuses on the most important aspects of study conduct and reporting. The MOB has developed and implemented tools to support risk-based monitoring. We continue to evaluate the efficiency and effectiveness of new monitoring strategies and look forward to working with you on this endeavor.

Click here to see more information about MOB and related trainings on the DAIDS Learning Portal