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

MOB Report

1st Edition
December 2014

Welcome ...

Welcome to the pilot edition of the Monitoring Operations Branch (MOB) Monitoring Newsletter. We plan to publish the newsletter on a quarterly basis. In future editions we hope to include monitoring metrics, monitors' corner, or maybe an article from an experienced study coordinator who would have the opportunity to highlight a tool or process that they have successfully implemented at their Clinical Research Site. We also plan to "spotlight" a Monitor or Monitor Manager to allow us to become more familiar with the staff that work on the DAIDS Clinical Site and Study Monitoring (CSSM) Contract.

In this issue

Updates, Metrics and Policy

DAIDS-ES CSM Updates & Info.

Version 2.5 of Clinical Site Monitoring (CSM) Component of the DAIDS Enterprise System
Release Date December 6, 2014

Financial Disclosure Form/Statement

Starting in 1Q 2015 during the Routine Regulatory File review, the monitor will verify the presence of a signed and dated financial disclosure form/statement for each investigator listed on each version of the Form FDA 1572 (staff listed in sections 1 and 6). For more details, see September 25, 2014 memo from Karen Reese, Acting Branch Chief, Monitoring Operations Branch (MOB) in the Office of Clinical Site Oversight (OCSO), Division of AIDS (DAIDS).

Special Assignment

Special Assignment (SA) functionality allows users to track the various special assignment statuses from request through their completion. The different statuses are presented in the form of a bar graph. Clicking on a bar, allows the user to see a listing of SAs within the particular status and access to individual SAs for review or further processing. The SA information can also be exported to an Excel file for further review and analysis.

Scope Report

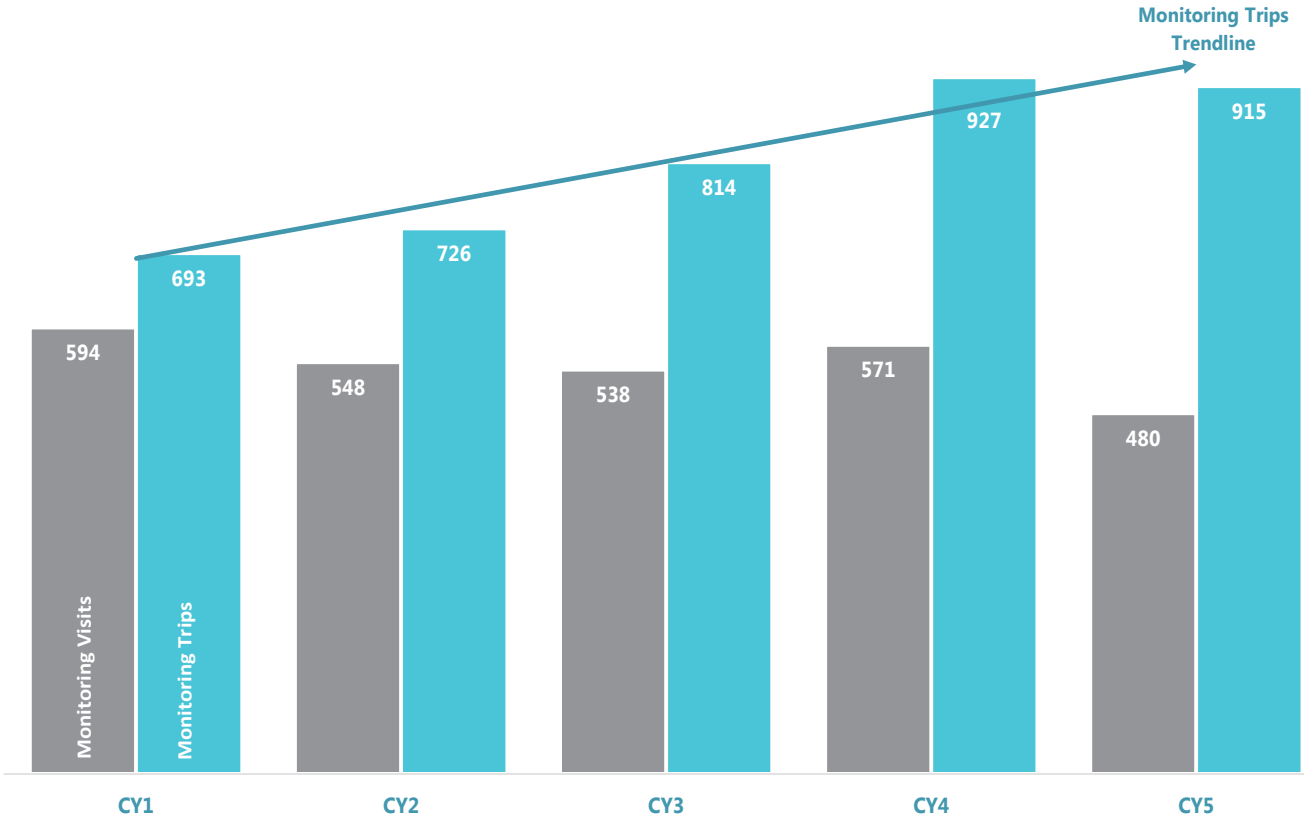
This report enables the user to track the development status of each protocol such as 'in development', 'pending', etc. as well as the monitoring status of each protocol such as 'pending', 'ongoing', etc. Tracking the various protocol development statuses and monitoring statuses supports the analysis of resource allocations for monitoring.

Monitoring Metrics

Overview of Monitoring Visits and Trips to Date

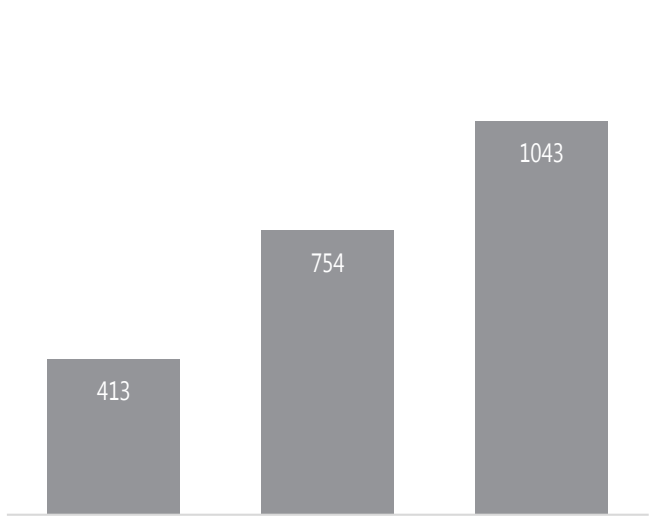
Monitoring Visits and Trips (Contract Year 1 to Contract Year 5)

In the last 5 years, OSCO has conducted a total of 2731 Monitoring Visits and 4075 Monitoring Trips.
Monitoring Trips have increased throughout the past five contract years.

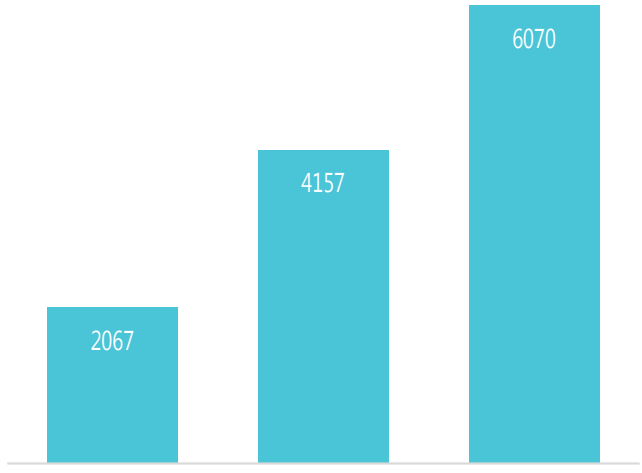


Monitoring Visits: Any time a monitor travels to a site to conduct monitoring.
Monitoring Trips: Includes the total number of monitors traveling to a site to conduct a site monitoring visit (co-monitors).

Running Total of CY5 (2014) Pharmacy Assessment



Running Total of CY5 (2014) Record Review



Regulations, Policies & SOPs

Financial Disclosure

DAIDS will be assessing compliance with the new guidance titled "Process for Collection of Financial Disclosure by Clinical Investigators" per 21CFR 54.4 which became effective July 1, 2014. Beginning with 1Q 2015 monitoring visits, when the monitor conducts the Routine Regulatory File Review, the monitor will verify that staff listed in sections 1 and 6 of all FDA 1572 forms have a signed and dated financial disclosure forms on file for any protocols conducted under Investigational New Drug (IND) Application/ Investigational Device Exemption (IDE). This is applicable only to protocols implemented after July 1, 2014.

Clinical Quality Management Plan (CQMP)

DAIDS Policy titled, "Requirements of Clinical Quality Management Plans" has been updated along with the following tools and appendices:

- Clinical Research Site (CRS) Quality Assurance Summary Report (New)
- Sample Clinical Quality Management Chart Review Tool
- Sample Clinical Quality Management Protocol Review Tool

The major change to the policy includes a requirement for biannual submission of quality assurance findings using the OMB approved template (CRS Quality Assurance Summary Report). Other changes include additional required key quality indicators for review and revised appendices, which include sample tools for chart and regulatory file review.

The New CRS Quality Assurance Summary Report provides the opportunity for all sites to submit Quality Assurance (QA) findings to DAIDS in a standard format while also reporting on the required key quality indicators. This tool captures audited PIDs and protocols, deficient key quality indicators and associated criteria, QA findings and description of corrective action implemented. OCSO Program Officers (POs) will be responsible for reviewing CQMPs and CRS Quality Assurance Reports for their assigned sites.

Assessment of Understanding and Source Documents, Signatures, Initials and Dates are additional key quality indicators captured in the updated policy. They are also reflected in the chart review tool so that specific details can be assessed in relation to the DAIDS Source Documentation Requirements. The chart and protocol regulatory file review tools were revamped by expanding and modifying criteria questions associated with each key indicator. This will provide clarity to the reviewer and specifically tease out gaps in a site's process related to a particular key indicator. Training for OCSO POs is being developed on the new policy and process for review of a site's CQMP. The planned training date will be published once finalized.

OCSO SOP: Oversight of Clinical Site and Study Monitoring

This policy has been updated and has been posted to the OCSO portal for everyone to access. Revisions to the SOP include:

- Mandatory development of a Protocol Specific Monitoring Plan (PSMP) for Risk Level 1 protocols
- Clinical Site and Study Monitoring (CSSM) Contract Monitor Resourcing Proposals consistent with current practice
- Change to current terminology - Contracting Officer's Representative (COR)

Please note that Attachments A, B and C to this SOP can be very useful during the Site Monitoring Report issue resolution process and when planning for a Site Initiation Visit (SIV).

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Monitor Spotlight

Coming Soon