MOB Report

Office Of Clinical Site Oversight (OCSO)

National Institute of Allergy and Infectious Diseases (NIAID)

ORGANIZATION INFO

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THE FEDS

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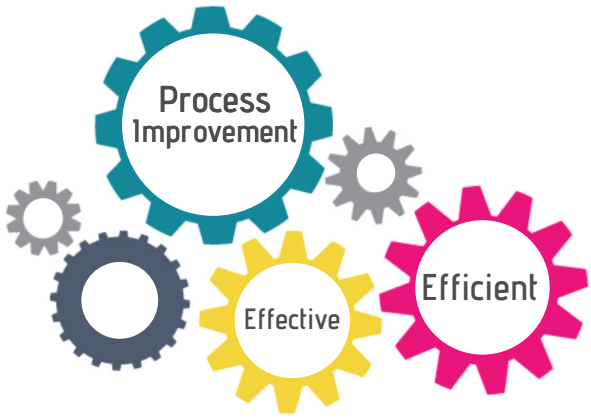
MOB Initiatives

In focusing on process improvements, the Monitoring Operations Branch introduced several new initiatives to increase efficiencies, particularly in monitoring. These improvements included format changes to the Work Order template, process change regarding site staff signatures on the Full Work Order (FWO), and discontinuing the need to retain a copy of the signed FWO on-site.

With the FWO being accessible through the NCRMS CSM by both site staff and the monitoring team, this change allows efficient use of the system and decreases duplication in documentation. Additionally, as the data management centers migrated protocols and now initiate all new protocols in the Medidata Rave database, the listing of Participant Identification numbers (PIDs) for protocols on the Announced Work Order (AWO) was also discontinued. With the implementation of the electronic data capture system, Medidata Rave, site staff can directly access the database to view eCRFs pending data entry, with nonconformant data, and to address queries. Furthermore, this change allows for AWOs now generated in the CSM to more accurately reflect what a monitor will review while on site, focusing on ongoing protocols at the site.



Another initiative is the change to the Record Review Tool (RRT) Part B process. The RRT Part B is the document monitors use to note record review-related findings during the monitoring visit. The process where this document was prepared and finalized by the monitor during the monitoring visit, signed by site staff at the conclusion of the visit and copies of each RRT left on site has been discontinued. This change streamlined the documentation process for observations noted during monitoring visits, which are captured in the Record Review Summary of the monitoring reports. With this process change, monitors can spend more time on site to review records and address site questions. It also reduces the burden on sites participating in multiple networks and protocols to maintain these additional records, in addition to the monitoring reports. The monitors will still review significant observations in detail with site staff at the debrief meeting(s) during the visit.

With process improvement in mind, we enter the second half of the year hopeful to continue this momentum of process review to maintain a high level of efficiency and effectiveness.

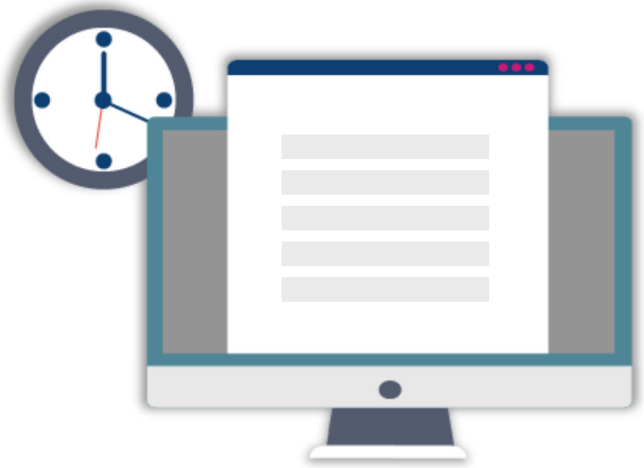
New PPD Monitors

You may start to see some new faces at your site. Due to the increased work volume at Clinical Research Sites (CRSs) participating in DAIDS trials, the NIAID Clinical Site Monitoring (NCSM) contract added several more mointors as of February 2019. We've highlighted three of these new employees in the spotlight section of this Newsletter (page 5).

Policy Updates of DAIDS Policies and Related Documents Recently Presented at the Annual Network Meetings

- Requirements for Clinical Quality Management Plans (CQMP) Policy
  The revised CQMP policy is now final. Sites will receive a memo noting the due date for the submission of the next Clinical Research Site Quality Assurance Summary Report (CRS QA Summary Report) using the new template. A Frequently Asked Questions document is being finalized and will also be posted upon completion.
- 45 CFR 46 Subpart A-Basic HHS Policy for Protection of Human Research Subjects - the Revised Common Rule
- Delegation of Duty (DoD) Log Policy: Released 4 March 2019. DAIDS DoD Log Frequently Asked Questions (FAQs) released 14 June 2019.
- Informed Consent Process Policy

For Policy related questions contact NIAIDOPCROProPEP@mail.nih.gov



Reminder: Timelines for Site Monitoring Report Release & Resolution of Findings

1. Observations made by the DAIDS PPD (contract) monitors during a site monitoring visit are documented in the NIAID CRMS Clinical Site Monitoring (CSM) system. The CSM provides tools for DAIDS staff and collaborators to identify and track monitoring schedules and assignments, review monitoring reports, and identify and facilitate communication with sites for issue resolution of monitoring findings entered into the CSM by the OCSO Program Officer (PO).

2. Per contract requirements, Site Monitoring Reports (SMRs) are released to DAIDS and the site via the CSM no later than 15 business days following the last day of the site visit.

3. The OCSO PO will review, acknowledge receipt of SMRs, and initiate resolution of significant findings (including trends in minor findings) in the DAIDS CSM System within approximately 3-4 weeks of report distribution.

4. The site is expected to provide resolution and corrective action after receipt of notification from the OCSO PO, as soon as possible and preferably prior to the next scheduled monitoring visit.

   The site may upload additional documentation (i.e. IRB/EC correspondence) in the CSM to provide clarification for issue resolution.

5. *When all* significant findings have been resolved, the SMR will be considered closed within the DAIDS CSM System. Under most circumstances, a SMR should be closed out prior to the next monitoring visit.

Monitoring Metrics

Year to Date Monitoring Metrics

February, March	1Q
April, May, June	2Q
July, August, September	3Q
October, November, December, January	4Q
To be determined	TBD

Monitoring Visits

	2018	2019
1Q	141	128
2Q	182	187
3Q	165	TBD
4Q	205	TBD
Total	**693**	**315**

Monitoring Visits: Any time a monitor travels to a site to conduct monitoring.

Monitoring Trips

	2018	2019
1Q	255	232
2Q	317	409
3Q	290	TBD
4Q	364	TBD
Total	**1226**	**641**

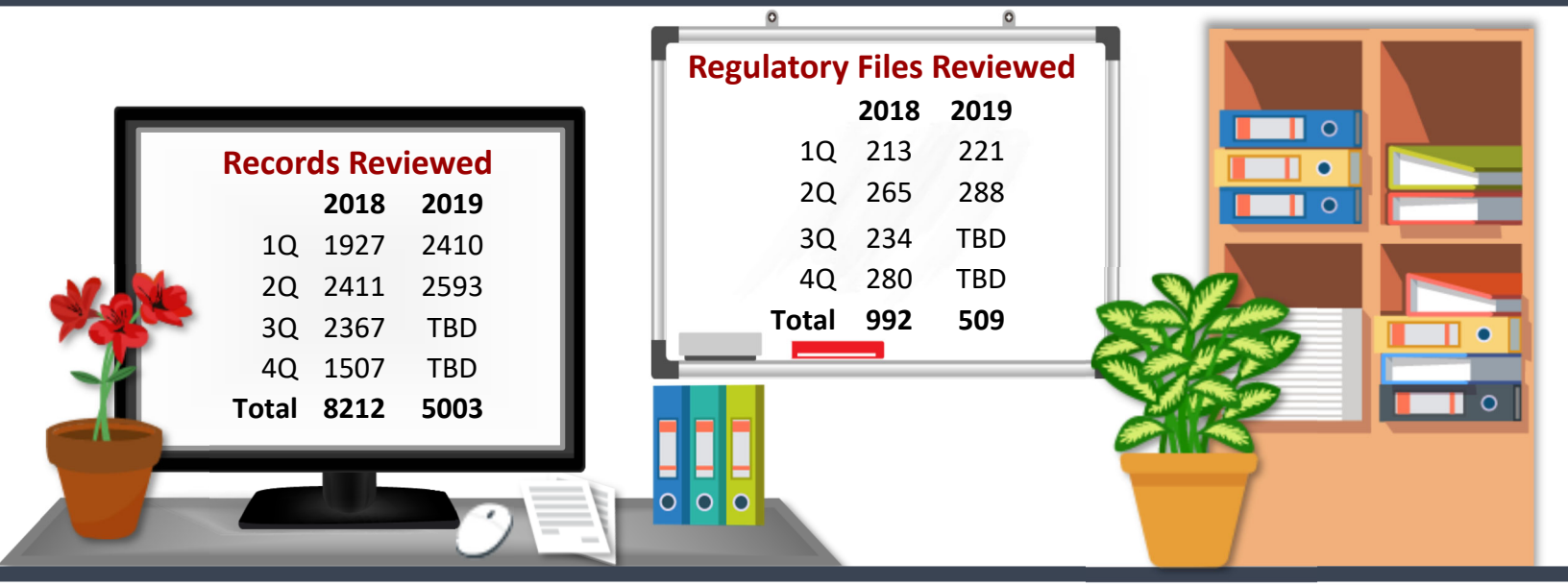
Monitoring Trips: Includes the total number of monitors traveling to a site to conduct a site monitoring visit.

Records Reviewed

	2018	2019
1Q	1927	2410
2Q	2411	2593
3Q	2367	TBD
4Q	1507	TBD
Total	**8212**	**5003**

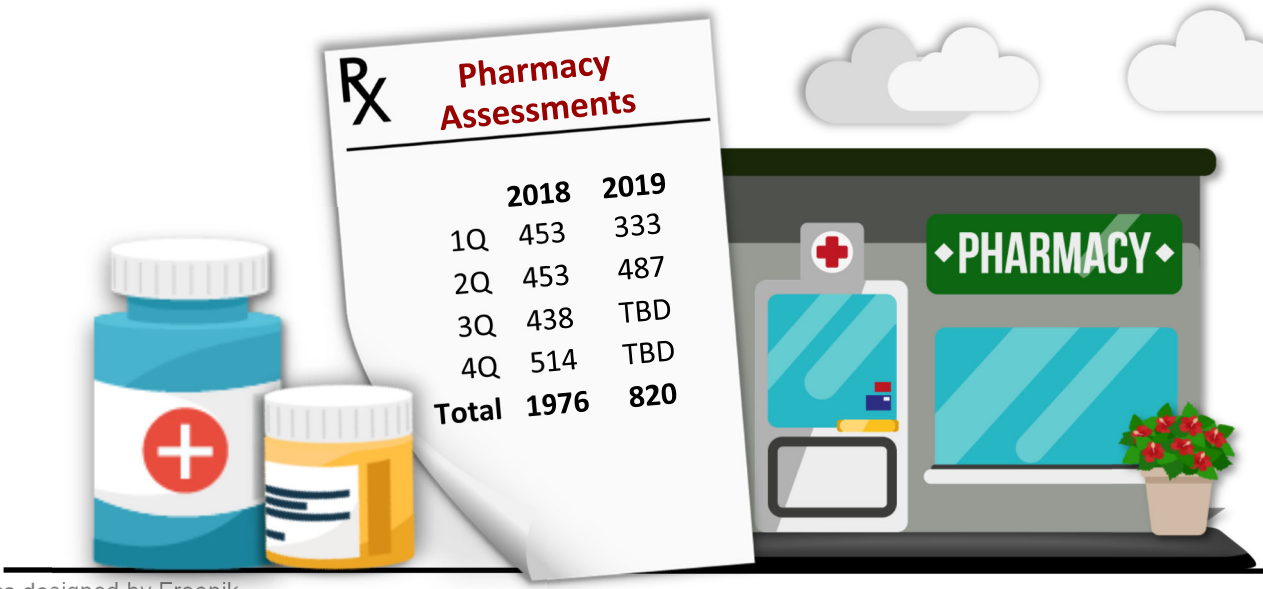
Regulatory Files Reviewed

	2018	2019
1Q	213	221
2Q	265	288
3Q	234	TBD
4Q	280	TBD
Total	**992**	**509**



Pharmacy Assessments

	2018	2019
1Q	453	333
2Q	453	487
3Q	438	TBD
4Q	514	TBD
Total	**1976**	**820**



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Monitor and Manager Spotlight

Taylor Ludman graduated with a Bachelor's in psychology from Dickinson College. During her time at Dickinson College, she worked as a research assistant in a cognitive/ sensory perception neuroscience laboratory and was a teaching assistant for a research methods/biostatistics course. Both experiences, plus working directly with many people in the community diagnosed with chronic health conditions, influenced her to pursue a career in clinical research post-graduation. Prior to joining PPD January 2019, Taylor worked as a research assistant for an inpatient psychiatric facility, research coordinator for pain analgesia/neuroscience studies, and as a clinical research associate (CRA) for infectious disease clinical trials. Currently for the DAIDS NCSM contract, she works as a North American CRA II and the lead monitor for Washington D.C. metro area clinical research sites. Taylor recently bought her first home in Frederick, Maryland and has been enjoying exploring the area and settling into her new home. She's also very passionate about spending time with her kitties and family, playing the piano, experiencing new places, and running/hiking. Welcome to the team Taylor!

Also new to the NCSM contract, **Chelsea Fuller** is a CRA working out of South Africa. Chelsea graduated with a BSc in Genetics and Human Physiology from the University of Cape Town (UCT). Following her time at UCT, she graduated with a Post Graduate Diploma in Management, specializing in Sports Management. A fun fact about Chelsea is her first job was to manage the University of Cape Town Rugby Club. In fact, she was the first team manager and was involved in player recruitment and welfare. She worked for the club for three seasons. Her interest in Clinical Research started when she decided to get back into the science field and came across a job at the UCT Lung Institute as a study coordinator and it is there where she worked on Asthma and COPD trials. Outside of work, Chelsea loves to mountain bike and trail running with her partner and her dogs. In fact, Chelsea stated, "I really enjoy rugby and love my dogs more than anything!" Welcome to the team Chelsea!

While not new to the NCSM contract, **Cheryl Schmitt** is indeed new to her role as Clinical Team Manager (CTM) and she is loving the new role! Cheryl earned her LPN from Wayne County Career Center in Ohio and her RN from Regents College in New York. Prior to her careers within the nursing field and in clinical research, Cheryl worked in the banking industry for five years. Her interest in clinical research started while she was working in a Long-Term Care Facility in North Carolina doing Medicare and Medicaid Assessments and Supervising Nurses. Since being assigned to the DAIDS NCSM contract, Cheryl worked hard as a North American CRA from 2005 to 2012. Cheryl then returned to the contract as a PCRA in 2018 and quickly moved to CTM role early in 2019. Outside of work, Cheryl loves to camp in her motorhome, spend time with her grandchildren, and play piano. Lastly, a fun fact about Cheryl is she grew up in a small Amish town in Ohio with only 600 people. She states, "My favorite memory growing up in this small town was also my worst nightmare! Everyone knew everyone else, and everyone's parents kept track of everyone's kids. We couldn't get away with anything!"