MOB Report

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

ORGANIZATION INFO

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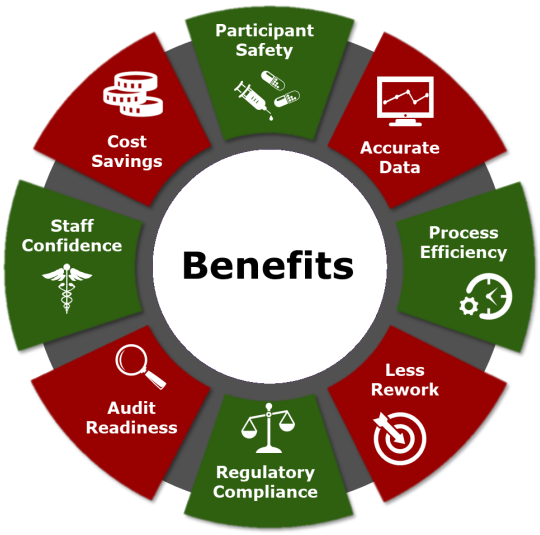
Importance of Quality Management

Inspections by regulatory authorities are conducted to ensure that the rights and safety of participants are protected, and that data collected are accurate and verifiable. As inspection activities can occur at any time, meeting regulatory agency expectations of data integrity and participant protection can be fulfilled by a systematic approach to the entire process of research conducted at your site. As a foundation, sites should develop and implement a Quality Management (QM) program with specific standards for each clinical trial process. Robust quality management programs provide research staff with a formalized proactive process for identifying and resolving protocol implementation and regulatory compliance issues. Quality programs should be reflective of your site's individual processes and include the following elements:

- Training,
- Personnel roles and responsibilities,
- Policies and procedures,
- Quality control and quality assurance,
- Document management, record retention, and reporting,
- Corrective and preventive action (CAPA)

Creating strong yet realistic standards of practice is the foundation for your quality management program. It is essential to have a good set of standards of practice which meet requirements of your institution, Sponsor, protocol and ICH guidelines. Quality management encompasses Quality Control (QC) and Quality Assurance (QA) activities. QC includes the routine site operations, techniques and activities undertaken within the QM system to verify the trial requirements are executed correctly, **at the time the work is being performed.** An example is utilizing a Consent Form checklist to ensure all signatures/dates are present before a participant leaves the clinic. QA activities are systematic and independent examination of all trial-related activities to confirm that all aspects of the protocol were followed, such as periodic participant chart audits and regulatory file review.



For CAPA plans to be effective, there should be in-depth analysis of the root cause of the problem, description of the plan to address the root cause, identification of who will be responsible and details of the required intervention and/or training and education. CAPAs should include realistic timelines, and a method for monitoring your progress and evaluating outcomes.

The goal of quality management is to evaluate the quality of the work performed, and of the data collected, with an eye to continuous quality improvement. When quality management is implemented as part of your site's routine practice, and supported by management at your site, site performance can be improved. These programs can reduce queries and re-work, as errors are identified and corrected, increase efficiencies, and ultimately, help to ensure a constant state of readiness for an inspection.

Are You Ready for an Inspection?

Inspection readiness is not about conducting the perfect study. Rather it is about how your site manages issues throughout, and understanding the story of your study. Inspection readiness is about demonstrating compliance with the protocol, institutional procedures, Sponsor requirements and Good Clinical Practices (GCP).

A part of the story can be told through your Investigator Site File (ISF), which is the Investigator/ Institution portion of the study's Trial Master File (TMF). Ongoing review of the ISF will aid in ensuring relevant, current study documentation is being maintained. This is accomplished through both the site's review and the monitor's review. The monitors conduct initial and subsequent Regulatory File Reviews to confirm the site is obtaining and maintaining applicable protocol-specific essential documents, as required by ICH E6 and country-specific regulations and Sponsor requirements. With implementation of your Clinical Quality Management Plan (CQMP), sites verify adherence to applicable essential documents requirements by completion of the Protocol Regulatory File Review Tool. Adequate record-keeping is a frequent deficiency cited during inspections. To assess if your ISF is complete, sites can ask themselves the following questions:

Did you report to Institutional Review Board (IRB)/ Ethics Committee (EC) as required?	Your site may have specific policies or local regulations that supersede sponsor requirements so ensure you are compliant with your local regulations, institutional policies and organizational procedures.
Do you have documented evidence of training related to the protocol?	Documentation of training has been an observed deficiency noted by regulatory authorities. While initial protocol training may be documented through Network communications, inspectors will also look for training documentation of subsequent protocol versions, letters of amendments, as well as documented training of investigators and other site staff that join the study later. If training is conducted at staff meetings, consider noting the content and attendance of this training in meeting minutes or a file note. Remember to update the Food and Drug Administration (FDA) Form 1572, your training log and Delegation of Duties Log as necessary.
Have you filed your communications?	Relevant communications are those that document any agreements or significant discussions regarding trial administration, protocol deviations/violations, trial conduct, or Adverse Event reporting. These can be in the form of a letter, email, telephone contact, fax or meeting minutes.
Have you resolved action items from monitoring visit follow-ups?	Ensure you have addressed all queries in the Clinical Site Monitoring (CSM) entered by your OCSO Program Officer. Pharmacy/Investigational Product related issues should be resolved by the Pharmacist of Record.

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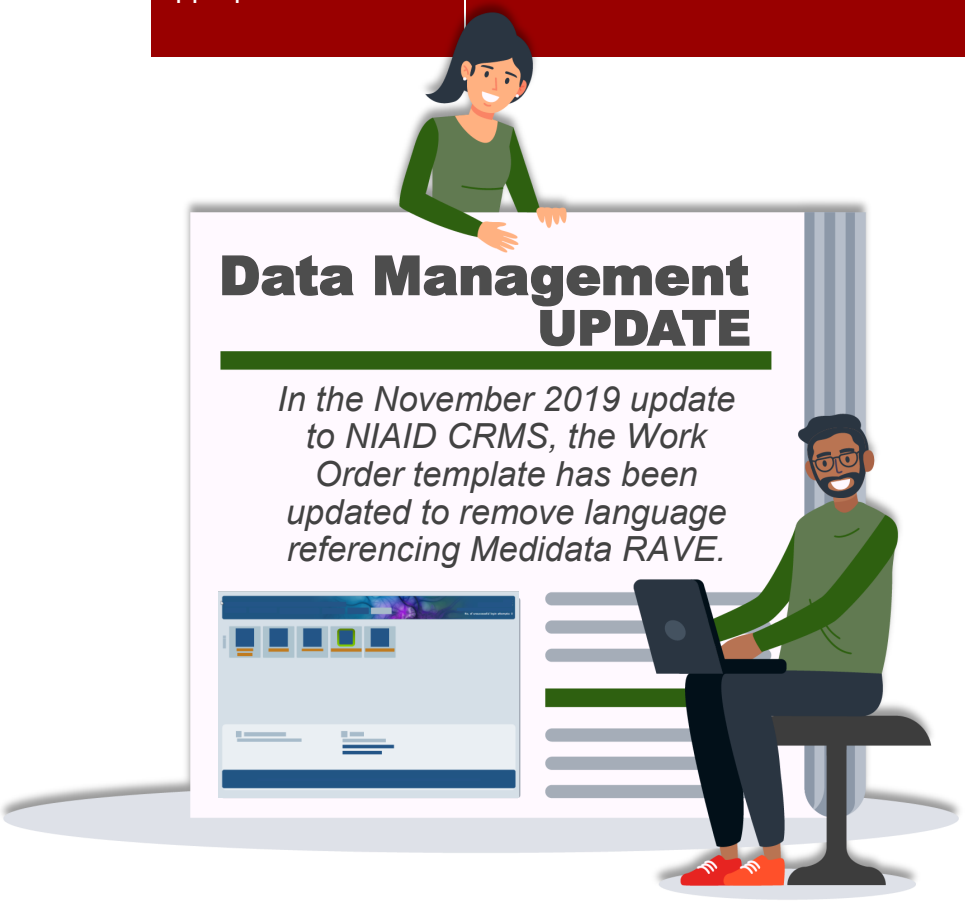
Are You Ready for an Inspection?
Continued

Protocol Deviations are they reported and have you prepared Corrective and Preventive Actions (CAPAs), as appropriate?	Be sure to keep documentation of any problems, particularly those related to the informed consent process, data integrity and protocol procedures. It is important that auditors/inspectors see that issues are addressed in a timely manner and steps taken to mitigate future occurrences. If there are any corrective or preventative actions, be sure that you document all communications and resolution steps.



Should your site be notified of a pending inspection, there are steps you can take to prepare your staff for a successful outcome. Consider holding a training session just prior to inspection. It is good practice to refresh staff on the inspection process before the inspector arrives. This would ensure that everyone is on the same page and has the most updated training. Review the inspection guidelines, such as the FDA's Bioresearch Monitoring Program (BIMO) Compliance Program Guidance Manual which provides uniform guidance and specific instructions for inspections of clinical investigators. You may also refer to the FDA or European Medicines Agency (EMA) Inspections Awareness course on the DAIDS Learning Portal for guidance.

Happy Holidays

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	182
4Q	205	TBD
Total	**693**	**497**

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	442
4Q	364	TBD
Total	**1226**	**1083**

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

Records Reviewed

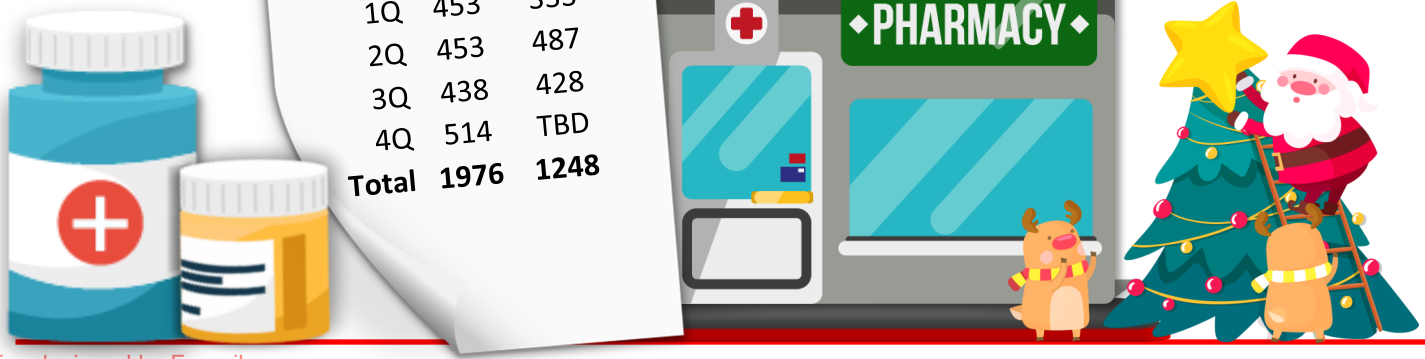
	2018	2019
1Q	1927	2410
2Q	2411	2593
3Q	2367	2930
4Q	1507	TBD
Total	**8212**	**7933**

Regulatory Files Reviewed

	2018	2019
1Q	213	221
2Q	265	288
3Q	234	281
4Q	280	TBD
Total	**992**	**790**

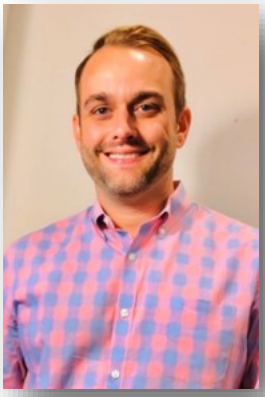
Pharmacy Assessments

	2018	2019
1Q	453	333
2Q	453	487
3Q	438	428
4Q	514	TBD
Total	**1976**	**1248**



Graphics designed by Freepik

Manager and Monitor Spotlight



Michael Wilson, Clinical Team Manager

Michael holds a Bachelor of Science in Public Health from the University of North Carolina at Chapel Hill. He has worked in the clinical research industry for almost two decades, primarily within infectious diseases. The reason he joined PPD seven years ago was primarily due to their vast research experience in HIV/AIDS. He began as a CRA working on industry sponsored projects including HIV treatment and HCV cure trials. In January 2019, he transitioned from the commercial group to work on the monitoring contract with DAIDS as a Clinical Team Manager.

Also, at PPD, he co-leads the newly formed Pride Business Resource Group that promotes LGBTQ visibility, awareness, and advocacy within the company. Through PPD's community outreach program, he enjoys leading volunteer projects for employees. The most recent project consisted of preparing holiday meal packages for clients affected by HIV/AIDS seen at a local AIDS Service Organization.

Outside of work, he is passionate about community service and engagement specifically within the LGBTQ+ community. He created an LGBTQ+ and allies volunteer service organization about six years ago, which holds 1-2 volunteer service projects per month that benefits various social welfare and environmental causes. It feels great to be able to give back locally while creating meaningful connections within the community.

Simon Njuguna, Clinical Research Associate

Simon is a Pharmacist by training and obtained his Bachelor of Pharmacy (BPharm) from the University of Nairobi in 2002. He is currently pursuing a Master of Public Health (MPH) degree in Health Services Management.

He worked for three years as Superintendent District Pharmacist and thirteen years as Pharmacist of Record at a DAIDS site. He just joined PPD as a Clinical Research Associate in October 2019.

He loves music, movies and documentaries, traveling and the great outdoors. He likes engaging in volunteer activities targeting the underprivileged in society. He also takes great interest in global events in politics, economy and the social scene.

A fun fact: He grew up deep in rural Central Kenya, in a village ensconced on the Aberdare Ranges. A pretty cold place for a country that straddles the Equator. His first long journey away from home was when he went to high school, and to the capital Nairobi no less! In his third year, he was picked to join a trio of two students and a teacher that represented the school at the Round Square Conference held at Schule Luisenlund, Germany. Needless to say, during the next holiday, he was a village hero.