Edition 24,
July 2025

MOB Report

Office of Clinical Site Oversight

Baltimore, MD

In this Issue


Bangkok, Thailand

NAVIGATING UNCERTAINTY

Our commitment to Clinical Research Excellence

DAIDS OCSO affirms our unwavering support and commitment to our Clinical Trials Unit and Sites. While external factors may introduce operational challenges, our focus remains on advancing the DAIDS mission and safeguarding the scientific integrity of HIV research in today's dynamic environment.

Our Leadership closely monitors emerging developments and actively collaborates with stakeholders to minimize disruptions of site operations. We are committed to transparent communication, providing timely updates, and offering comprehensive guidance as needed.

We recognize that uncertainty can raise concerns, and we stand ready to support your specific needs. Your expertise and resilience are crucial to advancing life-saving research and improving health outcomes. Together, we will continue to navigate these challenges and deliver innovative solutions.


Lima, Peru

Evolution of DAIDS Remote Monitoring Visit

Over recent years, the Division of AIDS (DAIDS) has transformed its approach to site monitoring visits. It is driven by the necessity to adapt to travel limitations and maintain sponsor oversight of safety and data integrity during public health emergencies. DAIDS now employs a multi-modal monitoring strategy, which includes onsite, hybrid, and remote visits, ensuring effective monitoring of clinical research sites even when travel restrictions are in place. Here's a timeline outlining this progression:

2020

March

OCSO MOB suspended all onsite monitoring visits due to travel and other restrictions from the COVID-19 public health emergency.

April

To meet Sponsor obligations for ongoing clinical trials, DAIDS initiated remote monitoring reviews. Clinical Research Associates (CRAs) began assessing Case Report Forms (CRFs) in the Electronic Data Capture system for inconsistencies and missing data, without verifying source documents.

July

Following the FDA's guidance on conducting clinical trials during the COVID-19 public health emergency, which recommended optimizing centralized and remote monitoring, DAIDS implemented remote source data verification alongside remote CRF reviews for selected priority protocols using Medidata RSR and other secure platforms compliant with HIPAA and 21 CFR Part 11.

Evolution of DAIDS Remote Monitoring Visit
continued

2021

January

OCSO MOB expanded the remote source data verification requirement to include all DAIDS-sponsored protocols.

December

Medidata Remote Source Review (Medidata RSR) was developed for all protocols, with a recommendation for sites to use this platform for remote source document review.

2023

December

DAIDS began annual remote monitoring visits to ensure sites are prepared for future public health emergencies that may restrict onsite visits. This aligns with the "FDA Guidance Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies Guidance for Industry, Investigators, and Institutional Review Boards" issued in September 2023.

2024

December

DAIDS completed its first year of annual remote monitoring visits for each site. Of 469 site monitoring visits, 96 were conducted either as hybrid or fully remote sessions utilizing secure platforms. DAIDS distributed evaluation surveys to all sites to gather feedback, and 105 site responded. The key insights from these surveys were presented during an all-sites call on June 10, 2025. We have included these highlights in this newsletter for the benefit of sites that were unable to attend the call.

Most sites shared positive experiences with remote monitoring, although 30 sites reported otherwise (Figure 1). Approximately half of the sites without positive experience were yet to have remote monitoring visits from DAIDS at the time of the survey.

Sites Positive Experiences with Remote Monitoring

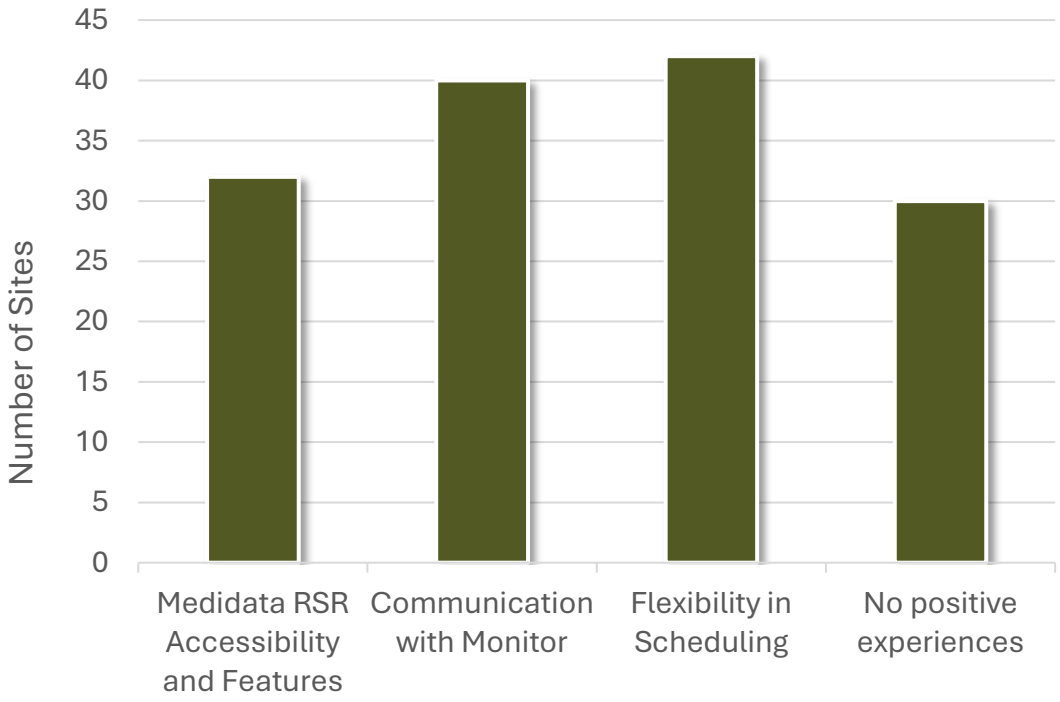


Figure 1

As anticipated, challenges with remote monitoring visits persist, with only 10 sites reporting no significant issues. Notably, 7 of these 10 sites utilized DAIDS Medidata RSR. The top five challenges remain similar to those identified in the baseline survey conducted in 2023, except for the complexity of the remote monitoring platform (Medidata). This concern has diminished as sites have become more familiar with these platforms (Figure 2).

Sites Challenges with Remote Monitoring

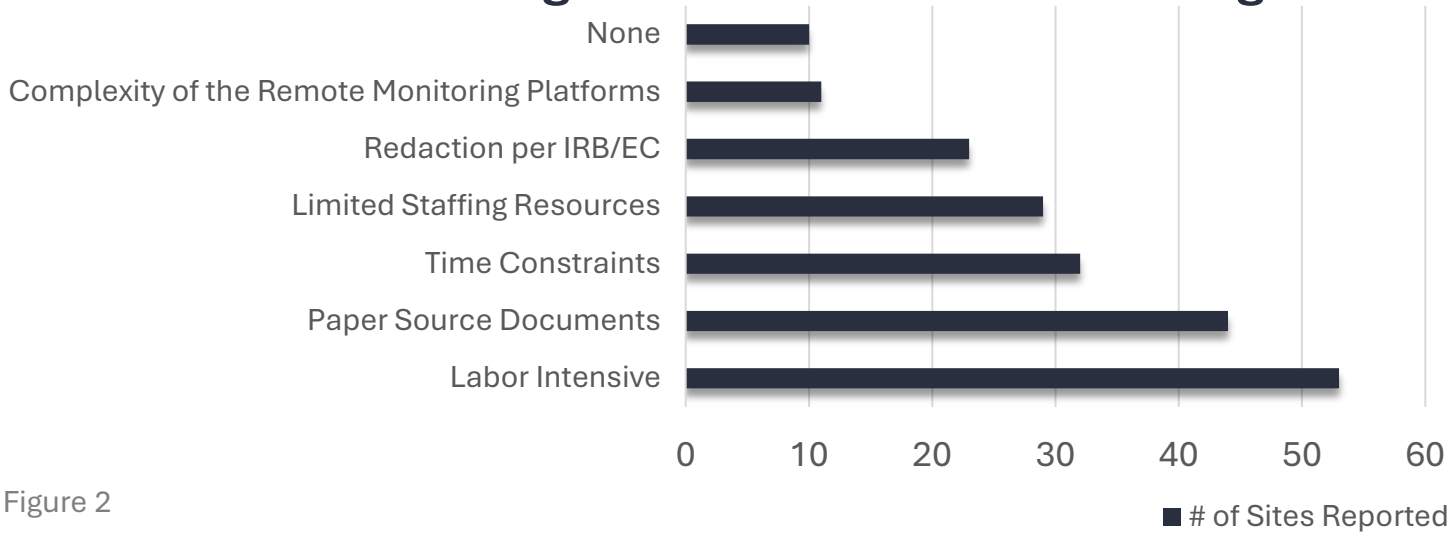


Figure 2

Evolution of DAIDS Remote Monitoring Visit
continued

Sites utilize several platforms for remote monitoring visits, specifically for record reviews, pharmacy assessments, and regulatory file reviews. Medidata RSR is the most frequently used platform (58%), followed by Veeva Site Vault, EMR, and Vestigo (Figure 3). Among the 44 sites that responded "NO," to using Medidata RSR, 17 can use Medidata RSR but have not yet participated in a remote monitoring visit.

Remote Monitoring Platforms

Percentage of Sites Reporting the Use of Medidata RSR

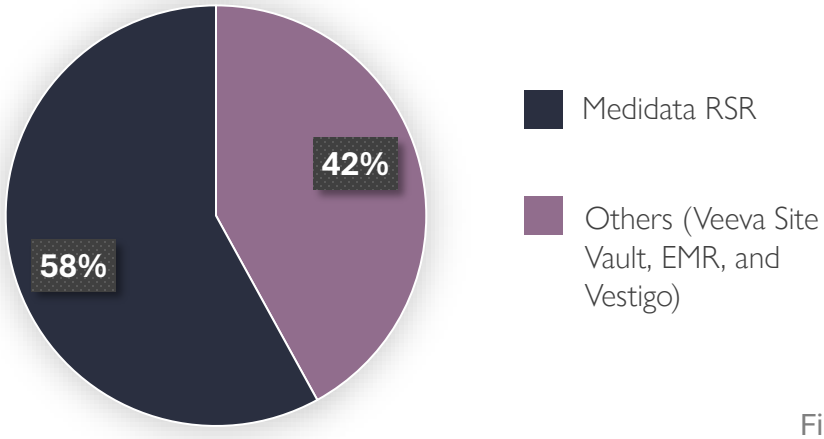


Figure 3

Based on site responses outlining their best practices for remote monitoring visits, three key areas of focus have emerged: Preparation, Communication, and Internal Processes (Figure 4).

Preparation

- Start preparation immediately upon receipt of PVL to organize, review, and scan/upload all required documents
- Ensure there are available staff the week of the remote visit
- Share the duties of scanning among many team members and carving out specific time to complete that task prior to the remote visit

Communication

- Maintain consistent and clear communication with the Monitor prior to the visit
- Meet with the Monitor as a team prior to the start of the visit
- Suggest: Create a MS Teams chat or shared tracker to allow the Monitor to provide findings and the site to provide responses in real time

Internal Processes

- Develop internal Standard Operating Procedure (SOP) for remote visits
- Ensure site is conducting all Quality Assurance and Quality Control activities so that the participant source documents are always ready to be scanned/uploaded
- Train site staff on any new protocols specific to remote visits

Figure 4

Evolution of DAIDS Remote Monitoring Visit
continued

Interestingly, about 25% of the 105 respondent sites stated that they can accommodate more than one remote monitoring visit annually. Please notify your DAIDS PO and PPD monitor if your site falls into this category. DAIDS MOB will determine approval based on site performance, protocol risk levels, data management timelines, and other study-related factors.

Key Take Aways

1. Organized Preparation
2. Clear and Consistent Communication with Monitor
3. Development of Internal Processes
4. Ensure Monitor Access in Advance
5. Teamwork Mentality

thank you!

Thank you for your continuing efforts and support as we integrate remote monitoring into our monitoring visit modality. We will continue to actively seek opportunities to engage with sites and gather additional feedback to further enhance our processes for conducting remote monitoring visits.


Sao Paulo, Brazil

Follow-up Letter

We extend our sincere gratitude to every Clinical Research Site that participated in our post-monitoring visit communication survey. Your insight and candid feedback represent an invaluable contribution as we strive to enhance the quality and effectiveness of post-monitoring visit communication. The insights you have shared provides a critical perspective from the field that will directly inform our approach to developing a streamlined, and more robust process.

Our team is conducting a comprehensive analysis of all survey responses, and will be sharing survey findings, implementation strategy, and proposed timeline about the initiative in the near future. Please stay tuned for further updates.

DAIDS Clinical Site Monitoring (CSM) System

New layout for Site Monitoring Visit reports- Release Date April 7, 2025

As part of MOB's initiative to enhance post-site monitoring visit communication, we have revised the SMR format and structure to streamline tables, eliminate redundant or duplicative information, and highlight action items requiring site follow-up.

Record Review Summary Report tables for enrolled PIDs	Record Review Summary Report tables for screen failures
Summary of Enrolled PIDs	Summary for Screen Failure PIDs
Case Records Reviewed for Enrolled PIDs	Case Records Reviewed for Screen Failure PIDs
Enrolled PIDs with observations – To be followed up by sites and monitoring staff	Screen Failure PIDs with observations – To be followed up by sites and monitoring staff
Enrolled PIDs with observations – To be followed up by sites	Screen Failure PIDs with observations – To be followed up by sites
Enrolled PIDs with observations - Resolved	Screen Failure PIDs with observations – Resolved
Enrolled PIDs with observations – Cannot be fully resolved; no action required	Screen Failure PIDs with observations – Cannot be fully resolved; no action required

The Division of AIDS has updated the policy on Electronic Information Systems (EIS) Requirements, with an effective date of 14 March 2025 and a final implementation date of 25 April 2025.

Sites are no longer required to submit the EIS Evaluation Checklist for review and approval; instead, the EIS Evaluation Checklist will serve as an optional internal tool.

Please note that even though sites will no longer submit the EIS Evaluation Checklist for DAIDS review and approval, sites still must ensure that all electronic information systems as defined under the EIS policy are compliant with 21 CFR Part 11 and supporting documentation is on file.

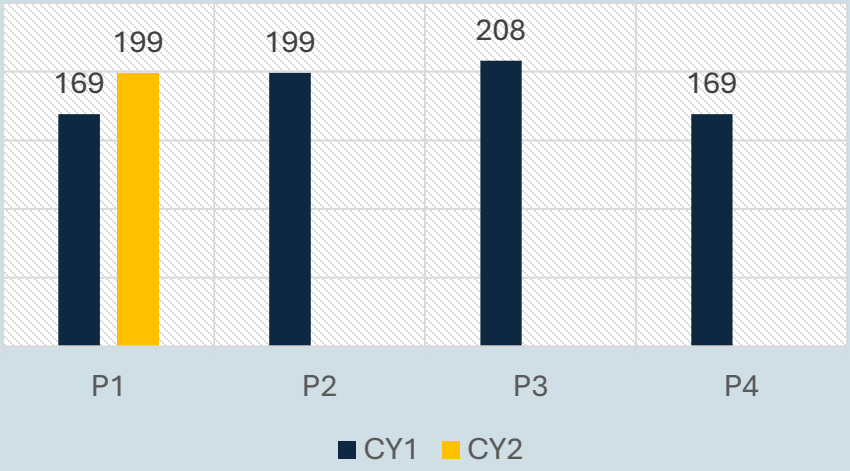
PPD monitors will continue to identify and record platforms used for remote monitoring. Compliance with the EIS policy, ICH E6, 21 CFR Part 11, and other applicable requirements will be verified through routine quality audits conducted by the DAIDS Quality Officer.

Contact your OCSO PO with any questions or clarifications.

YEAR TO DATE MONITORING METRICS

Visits

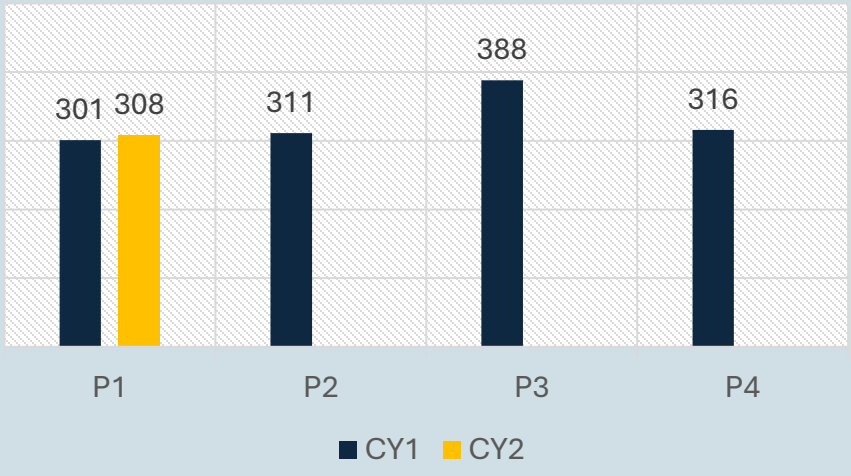
Anytime monitoring is conducted during a site visit



Reporting Periods	
February, March, April	P1
May, June, July	P2
August, September, October	P3
November, December, January	P4
Contract Years	
February 1, 2024- January 31, 2025	CY1
February 1, 2025- January 31, 2026	CY2

Trips

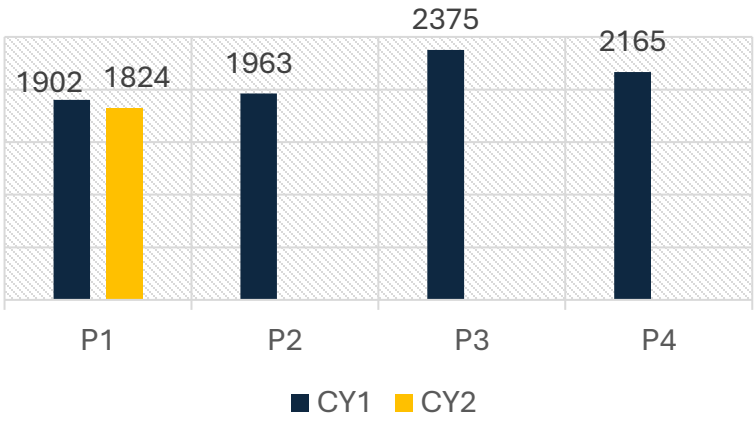
Total number of monitors conducting monitoring during site visit



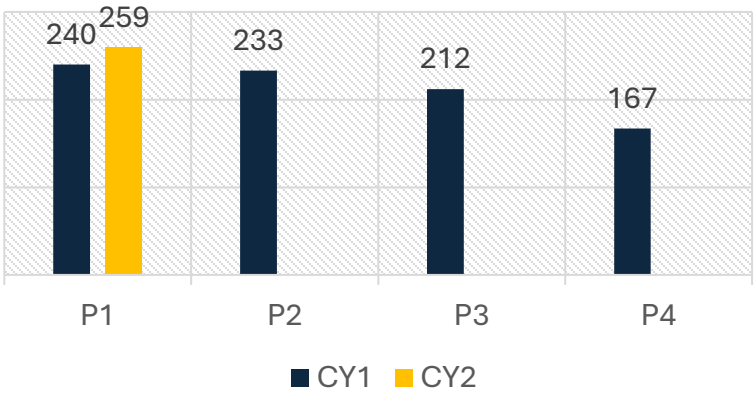
YEAR TO DATE MONITORING METRICS

continued

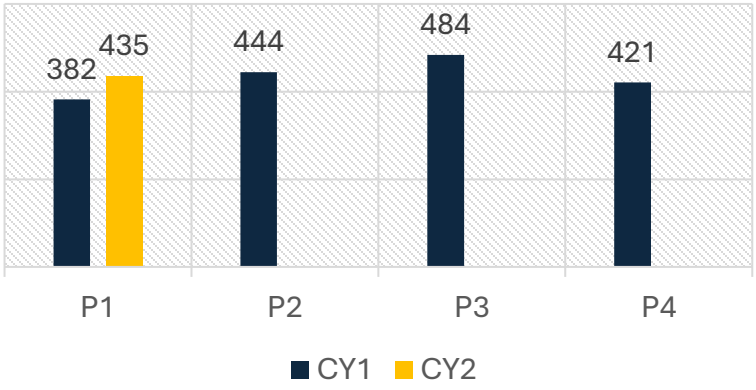
Records Reviewed



Regulatory File Reviews



Pharmacy Assessments



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NIH National Institute of Allergy and Infectious Diseases