MOB Report

Office of Clinical Site Oversight Monitoring Operations Branch

Edition 23, December 2024

Update on Medidata Rave User Access Request

There has been a significant change regarding role assignments in Medidata Rave for CRS Leaders involved in ACTG and IMPAACT studies.

Previous Process:
The user support department at FSTRF previously confirmed the required study-level roles for designated staff personnel within Medidata Rave with the CRS leadership at each site via email. CRS Leaders were automatically assigned the "Investigator" role, which allowed them to provide electronic signatures for eCRFs, perform data entry, make data modifications, and respond to queries.

New Process:
The role confirmation process has been updated, and CRS Leaders are no longer automatically assigned the "Investigator" role in Medidata Rave. CRS Leaders who are not authorized to sign off on eCRFs in the Delegation of Duties log now have the option to request "read-only access" in Medidata Rave. Upon receiving a role confirmation email from FSTRF, sites must specify the role access for each site staff member, including CRS Leaders, based on the following three available roles:

In This Issue

Organization

NIAID, DIVISION OF AIDS,
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The Feds

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(* contractor)

National Institute of Allergy and Infectious Diseases

Update on Medidata Rave User Access Request (cont'd)

1) **Clinical Research Coordinator (CRC):**
   - Responsibilities: Performing data entry, making data modifications, and receiving and responding to queries.
     - Examples: Data Managers, Study Coordinators, and QA/QC staff.
2) **Read-Only:**
   - Responsibilities: Viewing data within RAVE without performing data entry, making data modifications, or receiving and responding to queries.
     - Example: Internal staff monitors.
3) **Investigator:**
   - Responsibilities: Providing electronic signatures for eCRFs, performing data entry, making data modifications, and receiving and responding to queries.
     - Note: This role is for Investigators of Record (IoR) listed on the FDA Form 1572. If the Investigator role is requested for a designee other than the CRS Leader or the study IoR as listed in NIAID CRMS, approval from the CRS Leader is required.

Please contact user.support@fstrf.org with any additional questions.

Focus on Informed Consent Violations

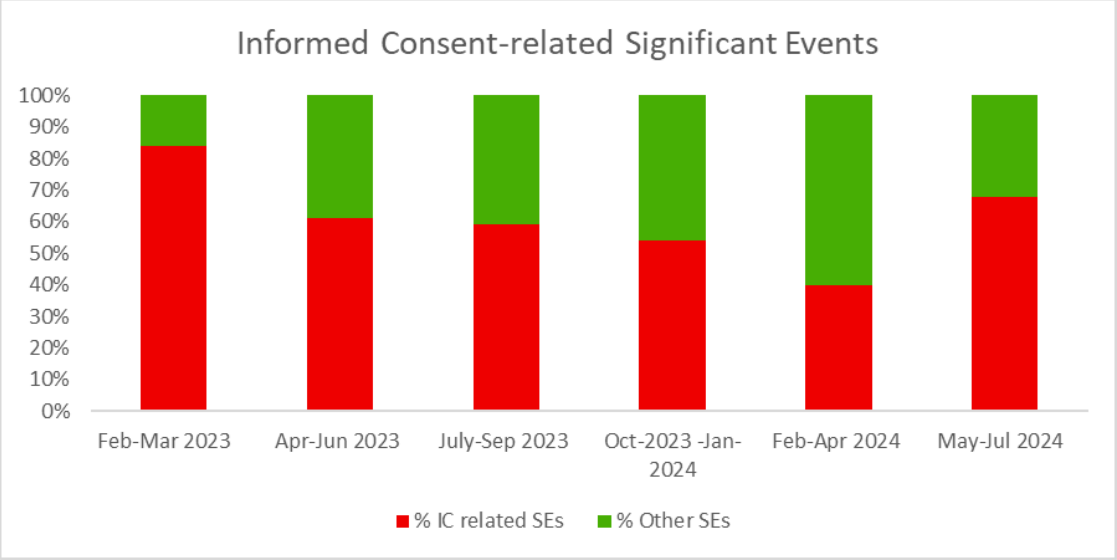
Significant events for DAIDS studies are any unanticipated study-related incident that is likely to cause or increase the risk of harm to participants or others or has a significant adverse impact on study outcomes or integrity. Significant Event (SE) categories include consenting violations, enrollment violations, IRB/EC lapses, safety findings, pharmacy findings and other, related to participant safety or site procedures that impact data integrity. A single incident determined to be a Significant Event may represent more than one category of Significant Event. During monitoring visits from Feb 2023-July 2024, 377 SEs were reported, and 253 of the SEs were related to informed consent violations (Table 1).

Table 1: Reported Significant Events (SEs)

Reporting Period	Total Number of SEs	Number of reported consenting SEs
Feb-Mar 2023	**146**	123
Apr-Jun 2023	**54**	33
July-Sep 2023	**63**	37
Oct2023 - Jan2024	**24**	13
Feb-Apr 2024	**50**	20
May-Jul 2024	**40**	27
Total	**377**	253

Trending over time, informed consent violations comprise a substantial portion of reported Significant Events. See Figure 1 below for informed consent violations as a percentage of the total Significant Events for the last six reporting periods of monitoring.

Figure 1



Focus on Informed Consent Violations (Cont'd)

In the monitoring reports, sites will see these informed consent violations delineated by the categories Level 1, Level 2, and Subsequent Consent Violations. The definitions of these categories are listed below along with examples from recently reported consent-related Significant Events.

- **Level 1 Finding** – A significant monitoring finding that constitutes increased risk by compromising participant safety, rights and welfare, and/or data integrity.
  - Failure to obtain informed consent.
  - Participant signed an expired version of ICF.
  - One or more pages missing from signed original, executed consent form.
  - Protocol-specific (not standard of care) evaluations conducted prior to obtaining informed consent.
  - Participants not consented according to applicable regulatory requirements.

- **Level 2 Finding** – A significant monitoring finding that compromises data integrity and constitutes noncompliance with DAIDS policies, ICH/GCP guidelines or applicable regulations, but unlikely to compromise participant safety.
  - Missing original, signed and dated ICF (only a photocopy available).
  - Informed consent process is not adequately documented in the source documentation.
  - Inappropriate documentation of informed consent including, but not limited to:
    - Signatures and/or dates of investigator, witness or other parties not included (if lines are provided for individuals on IRB/IEC approved ICF).
    - Unable to verify that participant was offered a copy of the ICF.
    - The IRB approved consent requires participants initial each page of the document; however, the participant fails to initial one page of the consent document.

- **Subsequent Consent Reviewed (Violations Noted)** – Any violations noted on informed consent documents subsequently signed by the participant after the initial consent was signed. These violation descriptions are annotated in the monitoring reports with level 1 or 2 categorization, depending on severity.

Focus on Informed Consent Violations (Cont'd)

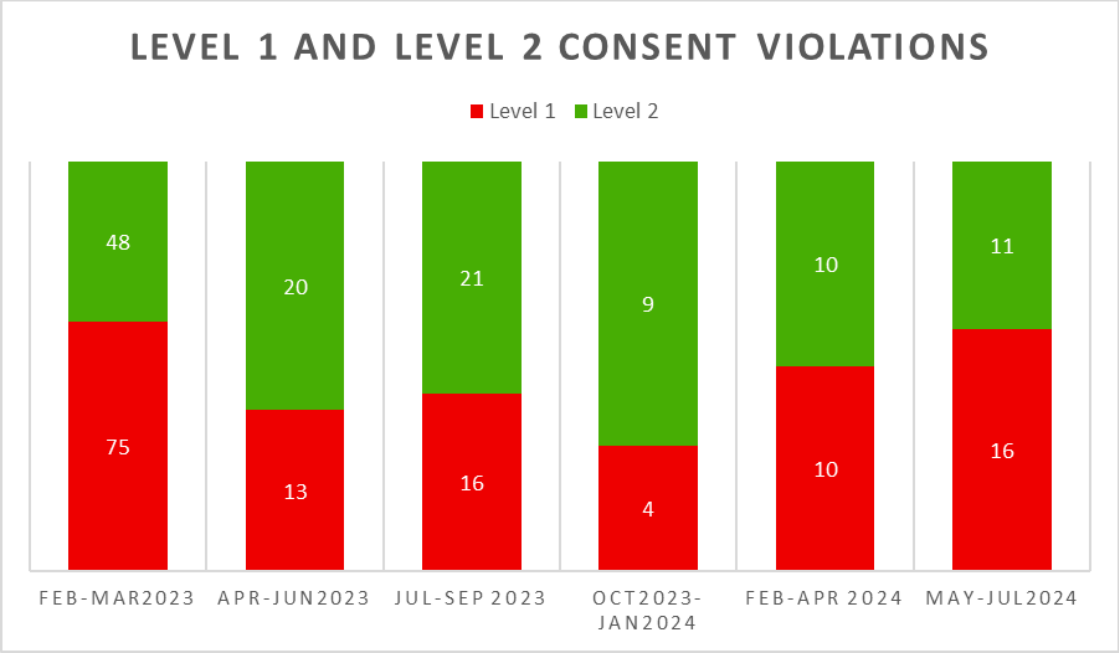
- The site did not consent the participant with the most recent subsequent consent at the last visit.
- Participant was not consented with the most current subsequent ICF at the first participant visit after IRB approval or ICF implementation.
    - Subsequent IC process was inadequately documented.
    - Failure to obtain subsequent ICF.
    - Participant missed to provide the response to the question on subsequent ICF.
    - One page missing from signed original subsequent ICF.

The breakdown of Level 1 and Level 2 consenting violations (inclusive of initial and subsequent consents) are presented in Table 2 and Figure 2, for the last six reporting periods of monitoring.

Table 2: Level 1 & Level 2 Consent Violations

Reporting Period	Total Number of Informed Consent SEs	# Level 1 Findings	# Level 2 Findings
Feb-Mar-2023	123	75	48
Apr-Jun 2023	33	13	20
July-Sep 2023	37	16	21
Oct-2023 -Jan-2024	13	4	9
Feb-Apr 2024	20	10	10
May-Jul 2024	27	16	11
Total	253	134	119

Figure 2



Focus on Informed Consent Violations (Cont'd)

The level 1 findings may indicate a major training gap or resourcing issue. Investigating and analyzing the root cause will identify the immediate causes of the problem, as well as any underlying systemic issues leading to these consenting violations.

Many of the level 2 findings reflect deficiencies in documentation of the ICF document that could be caught by having a second staff person check the entirety of the consent before the participant leaves the clinic. As well, a checklist as a QC measure can be used to ensure all elements are present and complete to prevent and/or decrease errors during informed consent administration.

Subsequent consent violations have comprised similar deficiencies as noted above for the initial consent forms. In addition, it is important to ensure timely administration of a revised consent when reconsenting is required, as determined by your IRB/EC.

DAIDS Monitoring Operations Branch (MOB) announced the annual requirement for one remote monitoring visit per site this time a year ago. Since then, over 70 annual remote visits have been conducted. To ascertain challenges and benefits, a short survey was sent via the HANC to study coordinators to provide feedback on your site's experience with implementing the annual requirement. Your feedback is valuable in evaluating implementation challenges and sharing best practices. For several sites with their remote visit planned in 2025 that cannot complete the survey, we welcome feedback via email to OCSOmob@nih.gov. MOB has also sent survey questions to the monitors, so that we can gain perspectives on this initiative from all parties.

Your continuing efforts and support as MOB integrates remote monitoring visits is appreciated. We look forward to sharing the results in 2025!

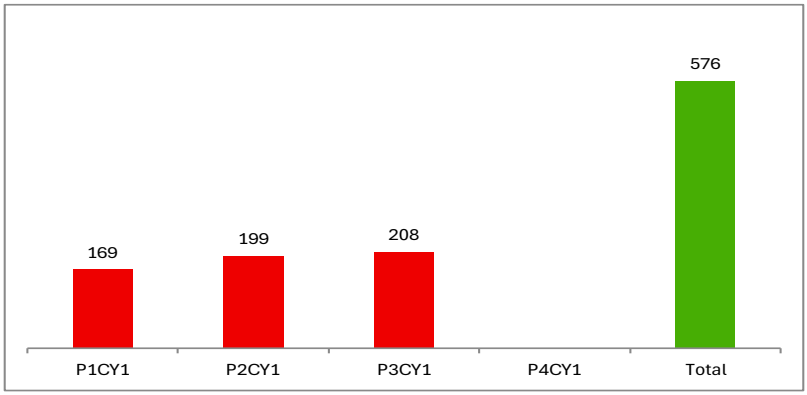
Monitoring Metrics

Year to Date Monitoring Metrics

February, March, April	P1
May, June, July	P2
August, September, October	P3
November, December, January	P4

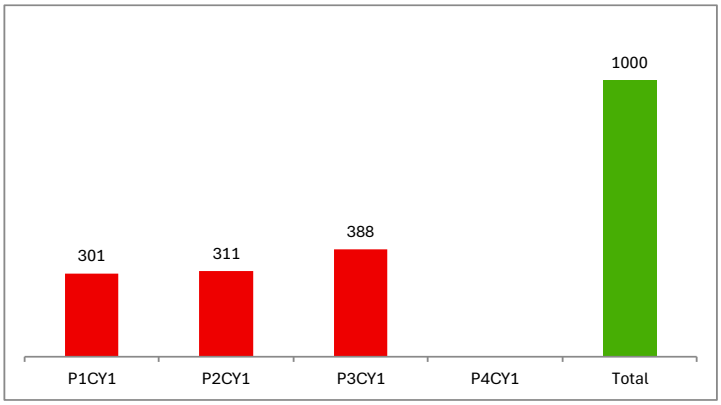
Monitoring Visits

Any time monitoring is conducted during a site visit.



Monitoring Trips

The total number of monitors conducting monitoring during a site visit.



Monitoring Metrics

February, March, April	P1
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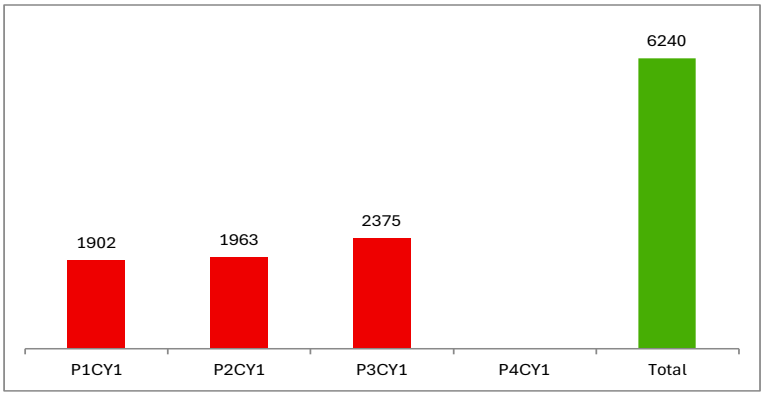
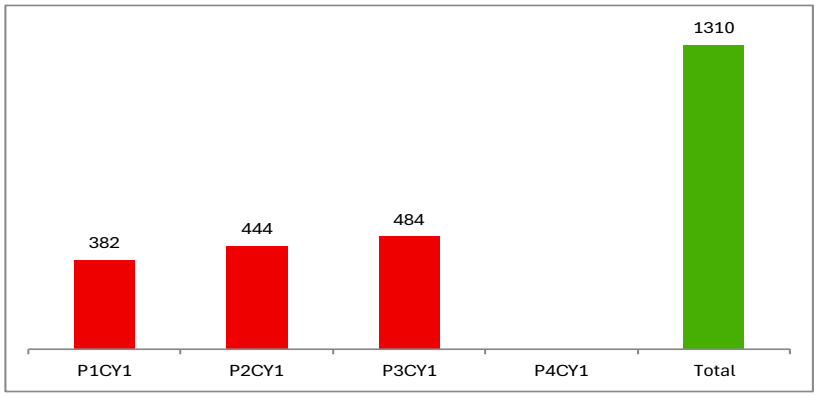
Year to Date Monitoring Metrics

Records Reviewed



Pharmacy Assessments



Regulatory Files Reviewed