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OFFICE OF CLINICAL SITE OVERSIGHT

MOB *Report*

Medidata Remote Source Review (Medidata RSR) Expansion



We are approaching the first anniversary of Remote Source Document Verification (rSDV) expansion to all DAIDS sponsored studies to facilitate timely data review, and the estimated number of remote/hybrid visits performed at the end of 3Q 2021 was 168. The Monitoring Operations Branch (MOB) would like to express our appreciation for your dedication and flexibility in assisting us with meeting our monitoring oversight responsibilities during the ongoing public health emergency.

When the rSDV expansion memo dated January 13, 2021 was issued, OCSO required that each site should select a compliant Remote Source Review (RSR) platform of their choice, in conjunction with Medidata RSR due to the limited number of studies (8 priority protocols) configured within Medidata RSR at that time. The COVID-19 public health emergency initially declared in March 2020 is still in effect, without a definitive end and unknown resumption of routine business practices. Recognizing the continuing need for rSDV to supplement onsite visits, over the last few months, DAIDS has been working with the Data Management Centers (DMCs) to ensure that all ongoing and new TSDV studies are configured in Medidata RSR. Once a study is configured in Medidata RSR, the DMC sends an email notification to sites.

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Medidata Remote Source Review (Medidata RSR) Expansion *Continued*



To date, the following 42 studies have been added to Medidata RSR platform:

ACTG	
A5300B	A5371
A5354	A5372
A5355	A5377
A5357	A5379
A5359	A5380
A5362	A5386
A5366	A5391
A5368	A5404

IMPAACT	
P1108	I2014
P1112	I2017
P1115	I2019
P1093	I2021
I2005	I2026
I2008	I2032
I2009	I2300B
I2010	

HVTN
HVTN 115 - Part B/C
HVTN 137
HVTN 804/HPTN 095
HVTN 805/HPTN 093
HVTN 140/HPTN 101

HPTN	
HPTN 083	HPTN 084
HPTN 091	HPTN 094

MTN	
MTN-043	MTN-042 - Cohort 1/2
MTN-034	

Based on our review of the Medidata RSR utilization data, only a handful of sites are currently using this platform for rSDV. We strongly encourage sites to use this platform for all the above-listed studies and upcoming new studies. Apart from being provided at no cost to sites, there are many advantages to sites in using the Medidata RSR, some of which include:

- One login for both Medidata Rave EDC and RSR
- No separate site user agreement for initial use or upgrades
- Study specific visit folders pre-configured according to the protocol
- Automatic creation of subject ID from Medidata Rave EDC
- Built in redaction functionality to decrease errors and increase productivity
- Pharmacy folder preconfigured to meet specific study requirements

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Medidata Remote Source Review (Medidata RSR) Expansion *Continued*



The recommendation to use Medidata RSR for all DAIDS studies may pose specific challenges for some sites. However, it is anticipated that in the long run, this approach will enhance the operational effectiveness of rSDV for sites and DAIDS. Further directives will be provided in DAIDS communications. Please reach out to your OCSO Program Officer (PO) and PPD monitor if you need any assistance to initiate or transition to Medidata RSR for your studies.



For questions related to technical use of Medidata RSR, please contact SCHARP Clinical Data Management at sc.medidata.rsr@scharp.org or Frontier Science at usersprt@fstrf.org

Navigating Remote Regulatory Assessments

With the easing of COVID-19 public health and travel restrictions in some regions, the Food and Drug Administration (FDA) has resumed on-site inspections. Where on-site inspection visits are not possible, FDA is leveraging remote tools to ensure continuity of regulatory oversight by conducting Remote Regulatory Assessments (RRAs). RRAs are voluntary and informal assessments being implemented by the FDA to support their regulatory decisions and oversight of facilities, including data reliability and human subject protections.

Recent experience of RRAs conducted at our DAIDS sites can serve as guidance for site inspection readiness and navigating these remote assessments. RRAs may be similar to on-site inspections in terms of scope. However, they do not replace a legally binding inspection: no Form FDA 482 Notice of Inspection will be issued to announce the assessment, nor will observations be presented formally at its conclusion via the FDA Form 483.

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Navigating Remote Regulatory Assessments *Continued*

The FDA personnel assigned to the RRA will reach out to the site to discuss the logistics of the planned assessment. Generally, they will propose a 2-week period for the record review, as agreed upon with the site personnel. As this is a document-based process, the FDA will request documents for review via Cloud File Share. In the recent RRAs, Box.com was used, which securely transfers and stores uploaded documents. During the assessment, the FDA may request daily calls, which may include document requests. During these

calls, they will review their findings, ask questions and interview staff as needed.

Documentation the FDA may request during a remote regulatory assessment is similar to those reviewed during an inspection. An initial list of documents requested for upload may include the following:

- ▶ Participant Case books (investigator signed off eCRF casebook data in PDF)
- ▶ Regulatory tracker (listing all versions of the protocol, Letters of Amendment, Clarifying Memos, consent forms)
- ▶ Form 1572 versions
- ▶ Principal Investigator (PI)'s curriculum vitae
- ▶ Protocol signature pages
- ▶ Clinical Trial Agreement
- ▶ Financial Disclosures
- ▶ List of all studies the PIs have participated in the past five years
- ▶ List of discontinued participants
- ▶ List of EAEs and SAEs
- ▶ Site floor plan
- ▶ IP accountability logs and dispensing documents
- ▶ Safety laboratory records

Uploading requested participant-specific source records or pharmacy dispensing records may take more time, especially for sites using paper sources that may first require scanning to electronic format. Having a team of site staff delegated to document preparation (scan, label, QC, upload) is advised. The daily check-ins with FDA allow for site staff to provide updates on upload progress, clarify document requests or relay any technical difficulties.

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Navigating Remote Regulatory Assessments *Continued*

Areas of focus by FDA during recent RRAs:



Depending on the study, participant records of interest may include terminated participants, seroconverters, participants with protocol deviations or IP administration errors.



Adverse Event reporting: work with the DMC to obtain AE listing to verify reported events in the database against source documentation.



Details of EDC system: consult with the DMC to obtain requested information (e.g. current version of platform in use).



Financial Disclosure of study staff: ensure these are completed for all study team members (see DAIDS policy: <https://www.niaid.nih.gov/sites/default/files/sCollectionFinancialDisclosure.pdf>)

Your Program Officer and personnel from the Network, DMC and LOC will be available as resources to assist with data/document requests, clarifications, or to guide you through appropriate responses.

Outcomes of an RRA

At the conclusion of the assessment, a closing meeting is conducted to review findings, but no formal communication of observations is issued. If significant concerns are found during the RRA, an on-site inspection could be considered by the agency. FDA will rescind site access to the Box.com folders following the assessment, so the site staff should be sure to keep a record of all documents uploaded. Further guidance



from the FDA on remote evaluations can be found here: <https://www.fda.gov/media/147582/download>

Remote practices will likely continue to be used as a tool beyond the pandemic period, whether at sites using RSR platforms or with regulatory agency oversight to reach more sites. Adopting and utilizing remote modalities across the spectrum of clinical research activities results in cost and resource savings and overall efficiencies.

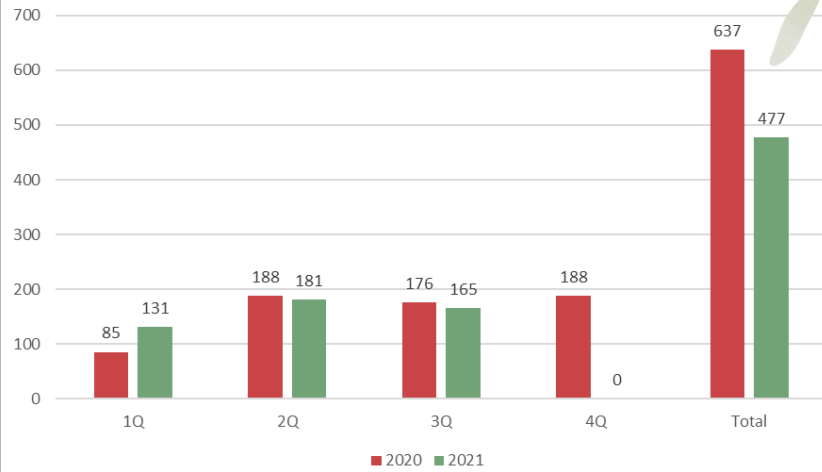
Monitoring Metrics

Year to Date Monitoring Metrics

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

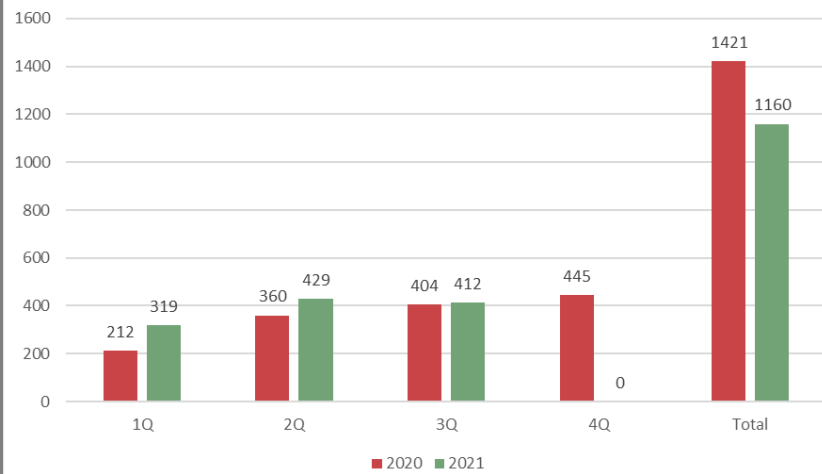
Monitoring Visits

Any time monitoring is conducted during a site visit.



Monitoring Trips

Includes the total number of monitors conducting monitoring during a site visit.



Records Reviewed



Monitoring Metrics

Year to Date Monitoring Metrics

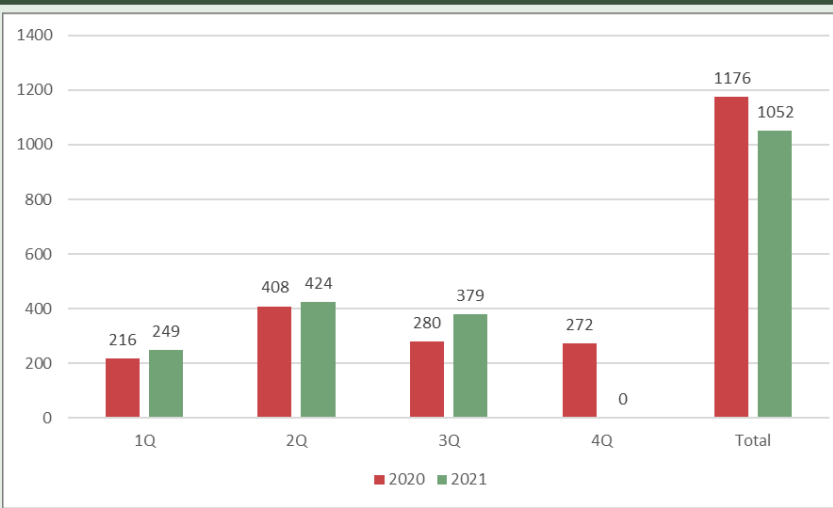
February, March 1Q

April, May, June 2Q

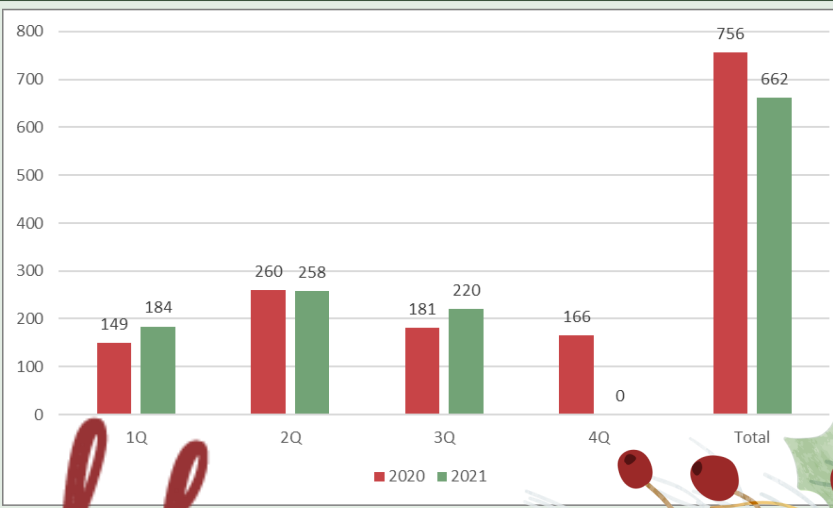
July, August, September 3Q

October, November, December, January 4Q

Pharmacy Assessments



Regulatory Files



happy holidays

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