DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of HealthNational Institute of Allergy And Infectious Diseases
5601 Fishers Lane, MD 20852

MEMORANDUM

DATE: December 20, 2021

FROM: Manizhe Payton, Director DAIDS, Office of Clinical Site Oversight (OCSO)
Bariatu Smith, Acting Branch Chief, DAIDS Monitoring Operations Branch (MOB), OCSO

Manizhe E. Payton -S Digitally signed by Manizhe E. Payton -S Date: 2021.12.20 14:43:11 -05'00'

Smith, Bariatu (NIH/NIAID) [E] Digitally signed by Smith, Bariatu (NIH/NIAID) [E] Date: 2021.12.20 16:23:59 -05'00'

TO: NIAID/DAIDS Clinical Trial Unit (CTU) Principal Investigators, Clinical Research Site (CRS) Leaders, CTU Coordinators, CRS Coordinators, Data Management Center (DMC) Directors

SUBJECT: ***Monitoring Update: Expansion of Medidata Remote Source Review (Medidata RSR) to Facilitate Remote Source Document Review***

The Division of AIDS (DAIDS) greatly appreciates the efforts of all sites to facilitate remote Source Document Verification (rSDV) for ongoing clinical trials leveraging various 21 CFR Part 11 compliant platforms. Through your hard work and dedication, we have completed approximately 168 remote monitoring visits as of the end of 3Q2021. We thank you and your staff for your tremendous efforts facilitating monitoring of source documents remotely.

The purpose of this memo is to provide information on the status, plans, and expectations for remote monitoring of studies configured in Medidata Remote Source Review (RSR) and provide guidance on the use of this platform for all DAIDS sponsored studies (ongoing and new studies). Medidata RSR is a secure, 21 CRF Part 11 and HIPAA compliant module of Medidata which will enable sites to upload source documents for monitors to perform rSDV.

In the Expansion of rSDV memo to sites dated January 13, 2021, DAIDS requested that you select an additional rSDV platform <u>other</u> than Medidata RSR for ongoing studies. At that time, DAIDS had configured only a limited number of protocols in Medidata RSR. However, we have since added many more ongoing studies to Medidata RSR and will add all new studies to Medidata RSR as they are opened. Currently, there are 42 protocols configured within the Medidata RSR platform:

ACTG	**IMPAACT**	**HVTN/Co-sponsored**	**HPTN**	**MTN**
A5300B	P1108	HVTN 115 - Part B/C	HPTN 083	MTN-043

A5354	P1112	HVTN 137	HPTN 084	MTN-034
A5355	P1115	HVTN 804/HPTN 095	HPTN 091	MTN-042 - Cohort 1/2
A5357	P1093	HVTN 805/HPTN 093	HPTN 094	
A5359	I2005	HVTN 140/HPTN 101		
A5362	I2008			
A5366	I2009			
A5368	I2010			
A5371	I2014			
A5372	I2017			
A5377	I2019			
A5379	I2021			
A5380	I2026			
A5386	I2032			
A5391	I2300B			
A5404				

In addition to the inherent advantage of using a familiar system, sites currently using Medidata RSR have also indicated a positive user experience. Some of the benefits of using Medidata RSR include, but are not limited to:

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

We expect all ongoing DAIDS studies (excluding A5312 and A5332) to have transitioned to Medidata RSR by March 2022. If your site is not already using Medidata RSR, based on the above-referenced advantages and the availability of many more ongoing studies in Medidata RSR, we are strongly recommending that sites use the Medidata RSR platform to facilitate rSDV for all DAIDS studies. We acknowledge that this pivot to Medidata RSR must be compliant with your site's policies and procedures. Please note that you are not required to obtain IRB/IEC approval for the Medidata RSR platform if your site has previously obtained IRB/IEC approval to allow rSDV.

Additional details are below:

Ongoing studies in Medidata RSR

For sites using an rSDV platform other than Medidata RSR for any of the DAIDS sponsored studies configured within Medidata RSR (listed above), we strongly recommend you switch to Medidata RSR

for all remote monitoring visits by April 1, 2022. If switching to the Medidata RSR platform is not feasible at your site, monitoring will continue through your existing rSDV platform; however, you should inform your OCSO Program Officer (PO) of your site's constraints.

New studies in Medidata RSR

All new DAIDS sponsored studies will be configured in Medidata RSR. The Data Management Centers (DMCs) will notify you as new studies go live in Medidata RSR. For all new DAIDS studies, we request you use Medidata RSR.

Key Points:

- For A5312 and A5332 your site will continue to use the platform already in place to facilitate rSDV.
- Most ongoing DAIDS sponsored protocols have already been configured in Medidata RSR, all remaining ongoing protocols should be configured by March 2022.
- All new DAIDS sponsored protocols will be configured in Medidata RSR.
- By April 1, 2022, we strongly recommend that sites use Medidata RSR for all DAIDS studies.
- If institutional policies or other constraints prevent your site from switching to Medidata RSR please notify your OCSO PO or PPD monitor to discuss these constraints.
- 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.

We understand that using Medidata RSR for new and ongoing studies may require significant changes to your existing systems and processes. In the long term, a centralized operation for rSDV using a single rSDV platform for DAIDS sponsored studies across all sites will be more efficient.

Once again, we sincerely appreciate the tremendous efforts and the flexibility demonstrated by your site staff as we work towards implementing an efficient rSDV framework to meet monitoring goals and address the ongoing disruptions from the COVID-19 public health emergency. Please do not hesitate to contact your OCSO PO and PPD monitor with questions or concerns regarding the expectation for the use of Medidata RSR.