DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MEMORANDUM

DATE: January 13, 2021

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

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

SUBJECT: Expansion of Remote Source Document Verification (rSDV) to all DAIDS sponsored clinical trials

The Division of AIDS (DAIDS) would like to wish you a healthy and successful New Year! We thank you for your efforts to facilitate remote Source Document Verification (rSDV) at your site for several high-priority clinical trials. We are reaching out to follow-up on previous communications distributed in July 2020 to all DAIDS CTUs and CRSs and/or sites participating in high-priority protocols (HPTN 083, IMPAACT P1106, IMPAACT 2007, IMPAACT 2014, and IMPAACT 2010) regarding DAIDS Remote Monitoring Strategy and the Implementation of rSDV. Sites participating in any of the high-priority protocols referenced above selected one or more of the following platforms to facilitate rSDV:

Option #1-Veeva SiteVault Platform

- Available through a free subscription from Veeva Systems
- 21CFR Part 11 and HIPAA compliant platform
- Allows site to upload participant source documents to site owned/controlled cloud-based
- system
- Site provides and controls monitor's access to a specified study(ies)
- May require a signed agreement between site and Veeva Systems
- Multiple on demand training resources available through Veeva SiteVault

https://sites.veeva.com/resources/remote-monitoring-for-sites-in-sitevault-free/

Option #2- Site Controlled SharePoint or Cloud-Based Portal

- Site will upload participant source documents to a secure document sharing portal
- Site will provide access to monitor(s) for a specific protocol
- Portal must be 21CRF Part 11 and HIPAA compliant as applicable
- Solution may require approval from an Institution or Site Security Officer, and signed agreements between sites and monitor(s) or designee

Option #3- Electronic Medical Record (EMR) System

- Site provides monitor(s) direct access to their EMR for a limited period
- Access may require approval from an Institution or Site Security Officer and signed agreements between the site and monitor(s) or designee

Option #4- Medidata Rave Imaging Solution (Medidata Imaging)

- Available through the DMCs
- 21CFR Part 11 and HIPAA compliant platform
- Allows sites to upload participant source documents to a Sponsor (DMC) controlled electronic system
- DMCs provides access to monitor for assigned study

There are currently 8 priority protocols configured within the Imaging Solution platform:

A5359	I2014	HPTN 083	P1093
I2017	I2010	HPTN 084	5300B (PHOENIx)

DAIDS continues to experience challenges with conducting traditional onsite monitoring visits as a result of travel restrictions, physical distancing and other limitations from the COVID-19 public health emergency. The U.S. Food and Drug Administration (FDA) issued a guidance document in March 2020 (updated in December 2020) entitled "FDA Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency", which provides the following guidance: "FDA regulations require sponsors to monitor the conduct and progress of their clinical investigations. The regulations are not specific about how sponsors must conduct such monitoring and are therefore compatible with a range of approaches to monitoring that may vary depending on multiple factors".

DAIDS is now expanding the use of rSDV beyond the priority protocols noted above to all sites participating in DAIDS sponsored protocols where feasible and approved by the IRB/EC and national/country regulatory agencies. In this memo, we wish to provide additional guidance regarding expansion of rSDV to all DAIDS sponsored protocols.

For sites participating in one or more of the 8 priority protocols noted above, you may already be using one of the available platforms to facilitate rSDV, and this platform should be expanded to include all DAIDS sponsored protocols. However, if Medidata Imaging was the only platform feasible for implementation at your site, then monitoring at your site is currently limited to the eight priority protocols configured within the Medidata Imaging System. Therefore, your site will need to identify another 21CFR Part 11 and HIPAA compliant rSDV platform for all other protocols.

For sites that are currently using Veeva SiteVault, site-controlled file sharing portal, direct EMR access or any other 21CFR Part 11 and HIPAA compliant platform, rSDV will be conducted by the monitors using this platform for all ongoing DAIDS sponsored studies at your site.

If your site <u>is not</u> participating in any of the 8 priority protocols noted above, based on your site's clinical research operations/ processes we ask that you select one platform from the following options to allow monitors to perform rSDV for all ongoing DAIDS sponsored studies at your site:

1. Veeva SiteVault

2. Direct EMR access

3. Site-controlled file sharing portal

4. Other 21CFR Part 11 and HIPAA compliant rSDV platform

Please note that the option you select is in addition to Medidata Rave Imaging Solution platform which is available to all sites through the DMCs. However, Medidata Rave Imaging Solution is currently limited to the eight priority protocols noted above. Although expansion of Medidata Imaging to other protocols is ongoing, there will be delays in implementation of this platform beyond the 8 priority protocols. Sites will be notified as new DAIDS sponsored studies are configured in Medidata Imaging.

What should all sites expect?

• In addition to rSDV visits, traditional onsite monitoring visits will continue to be scheduled, as feasible to meet the monitoring goals. The modality and frequency of monitoring visits for each site will be determined by the nature of travel and on-site visit restrictions, outstanding volume of data that requires source data verification and upcoming timelines for interim analysis and database freeze or lock.

• To conduct rSDV the monitors require access to participant source documents, which they typically access through on-site visits. Hence sites should provide access to participant source documents through their selected secure system with remote capability for monitors.

• There is additional work required by your site to accommodate remote visits. Specifically, prior to the remote monitoring visit, site staff will need to upload corresponding source documents for specific PIDs, and study visits indicated in the Work Order to the secure remote platform selected by your site. If, prior to a remote monitoring visit your site is unable to upload all available source documents that are pending verification, please work directly with your monitor on timelines to complete the upload.

•National/Country and IRB/EC approval is required regardless of the selected option for PPD to proceed with rSDV.

Key Points

• rSDV monitoring visits will be expanded to all DAIDS sponsored protocols at all sites by **February 8, 2021**.

• Please select a platform to facilitate rSDV and communicate your selection to your DAIDS Program Officer by **January 29, 2021**.

- **NOTE**: If your site is already using rSDV for any of the eight priority protocols configured in the Medidata RAVE Imaging Solution, you must select a different option other than Medidata Imaging to support all other DAIDS sponsored protocols at your site.

We recognize the tremendous efforts by your site staff to continue clinical research operations during the COVID-19 pandemic. Please do not hesitate to contact your OCSO PO with questions or concerns. We want to partner with you to identify solutions to conduct SDV at your site, and truly appreciate your site's efforts as we work to expand rSDV to all ongoing DAIDS sponsored protocols.