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: August 27, 2021

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

Manizhe E. Payton -S Digitally signed by Manizhe E. Payton -S Date: 2021.08.30 14:10:40 -04'00'
Ruth P. Ebiasah -S Digitally signed by Ruth P. Ebiasah -S Date: 2021.08.30 12:00:03 -04'00'
Smith, Bariatu (NIH/NIAID) [E] Digitally signed by Smith, Bariatu (NIH/NIAID) [E] Date: 2021.08.29 15:53:55 -04'00'

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, Pharmacists of Record (PoR)

SUBJECT: ***Expansion of PPD Remote Review of Pharmacy Source Documents for all DAIDS supported or sponsored clinical trials monitored by PPD***

We thank you for your efforts to facilitate remote Source Document Verification (rSDV) at your sites and acknowledge the tremendous efforts by your site staff to implement remote monitoring platforms and maintain clinical research operations during the COVID-19 pandemic. Following previous communications distributed in July 2020 and January 2021 regarding DAIDS Remote Monitoring Strategy, we are now expanding remote review of pharmacy source documents to include additional pharmacy documentation.

Previously, remote review of pharmacy documents at your site was very limited in scope. The expansion of remote review of source documents will now include pharmacy source records such as pharmacy accountability logs, prescriptions, randomization files, temperature monitoring logs, shipping documents, etc. To facilitate appropriate monitoring at the site, pharmacy records should be submitted for the remote monitoring visit. As with other monitoring visits, these records will be reviewed separately from the clinic files to ensure the maintenance of the blind.

To enable the expansion of remote review of pharmacy source documents during remote monitoring visits, site pharmacists must utilize the site-identified platform to upload pharmacy source documentation. Earlier this year, DAIDS provided guidance to sites participating in DAIDS supported or sponsored protocols around selecting one or more of the following platforms to facilitate rSDV:

- Veeva SiteVault Platform
- Site Controlled SharePoint or Cloud-Based Portal
- Electronic Medical Record (EMR) System
- Medidata Rave Imaging Solution (Medidata Remote Source Review)
- Any other 21CFR Part 11 and HIPAA compliant rSDV platform

Please refer to the aforementioned memo dated January 13, 2021 for additional details regarding these platform options, as some of these options may be dependent on the protocol in which your site is participating.

When considering a secure platform for uploading of pharmacy source documents and records, the system must have a designated section or folder with the capability to restrict access to only PoRs, Associate Pharmacists and the Monitors. If the system is to be shared with clinic, there must be full functionality for the pharmacy section of the system and there should be no impact to other accounts or permissions associated with the system. The site pharmacist must consider that certain documentation may contain unblinded information, and every effort must be made to maintain the blind.

What should sites expect?

• During the remote monitoring visit, the monitors require access to pharmacy documents which they typically access through on-site visits. Hence sites should provide access to the secure system with remote capability for monitors.

• For studies available in Medidata Rave Imaging Solution (Medidata RSR), a pharmacy folder with access restricted to only PoRs, Associate Pharmacists, and the Monitors will be available for sites using the platform to upload pharmacy documents.

• 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 pharmacy source documents to a secure remote platform. If, prior to a remote monitoring visit your site is unable to upload all available pharmacy source documents, please work directly with your monitor on timelines to complete the upload.

Key Points

- To facilitate remote pharmacy monitoring, the site PoRs should communicate whether the existing rSDV platform selected by your site or if a different platform will be used to DAIDS PAB PEP (daidspabpep@mail.nih.gov) by **September 10, 2021**.

- As a reminder, National/Country (if applicable) and IRB/EC approval is required regardless of the selected option for PPD to proceed with rSDV.

Please contact PAB at NIAIDDAIDSPABMonitoring@mail.nih.gov for pharmacy-related monitoring questions or concerns. Please do not hesitate to contact your OCSO Program Officer with general questions or concerns. We acknowledge the tremendous efforts by site staff to ensure continuity of operations while responding to the COVID-19 pandemic and are committed to working with you to facilitate monitoring of pharmacy source documents through the use of secure remote platforms.