DAIDS OCSO MOB Presentation: Remote Site Monitoring Q&A

October 23, 2023

1. How far in advance will the work order be provided so sites can prepare for remote monitoring?

   Sites will now receive only one work order (WO) with all assessments announced. This work order will be received 15 business days in advance of the monitoring visit. OCSO MOB is working with the NIAID CRMS team and the monitoring contractor to possibly have the WO released more than 15 business days in advance.

2. In the event monitoring changes from face-to-face to remote, can the site be provided with additional time to prepare?

   At this time we are not offering additional time beyond the 15 business days, though if you need additional time, please reach out to your monitor. OCSO MOB is working with the NIAID CRMS team and the monitoring contractor to possibly have the WO released more than 15 business days in advance.

3. Will we share documents with participants' names/identifiers?

   Since the platform is HIPAA and 21 CFR Part 11 compliant, DAIDS does not require redaction. Our expectation is that documents will be uploaded unredacted, though if they are redacted, then it must be noted as certified copies of the original. Your institution requirements and/or IRB may require redaction. If so, this should be communicated to your monitor.

4. When does the visit start and when does it end? Even with face-to-face visits, monitors occasionally send queries well after the monitoring is completed.

   The monitoring visit starts and ends on the dates noted in the pre-visit letter. In preparing for the monitoring visit, the monitor may begin to review the uploaded documents to ensure adequate quality and completeness. However, queries will only be sent to your site at the beginning of the monitoring visit date as indicated in the pre-visit letter.

   We may still be uploading/changing documents up until the monitoring date. What happens to findings found before the technical start date if the issue is resolved by the time the visit begins?

   In preparing for the monitoring visit, the monitor may begin to review the uploaded documents to ensure adequate quality and completeness. However, queries will only be sent to your site at the beginning of the monitoring visit date. If there are any changes to documents uploaded, please communicate with the monitor to let them know of the updated information.

5. Can the monitor access ICF's, DRA, and REC approval documentation on DAIDS PRO?

   Yes, the monitors have access to documents already available through the DAIDS PRO. Sites are not required to re-upload these documents to Medidata RSR.

6. How do we get access to Medidata RSR for regulatory?

   The access to Medidata RSR is available through the same login for Medidata Rave.

7. Can you confirm that if we already have regulatory eISFs, they can be shared on our platform (as long as the monitor has access 10 days in advance) and don't need to be uploaded to Medidata RSR?
   That is correct.

8. I couldn't figure out how to use the redaction functionality – how can we get more training on this?
   The DMC's have developed a FAQ that walks the sites through the functionality of the system, including the redaction functionality. The FAQ is available on the DMC portal. In addition, your site may reach out to the DMC for technical support using the feature and/or refer to the training video on Medidata.

9. The previous Rave redaction function did not work optimally. Has this been updated?
   Yes, there has been an update to that feature in the recent release of Medidata RSR.

10. How many site staff can get access to Medidata?
    There is no limit to the number of site staff that can have access to Medidata.

11. Would it be possible for site staff to have access to a training platform Rave RSR in which they can train and potentially test all the functionality?
    Unfortunately we do not have a testing environment for sites. Access to Medidata RSR is directly into the live production. If your site encounters issues using the platform, please reach out directly to the DMC for support. Sites are also encouraged to review the Medidata RSR FAQ developed by the DMCs.

12. Could we give the monitor access to Epic and upload some documents in Medidata?
    Yes, though this would need to be communicated to the monitor prior to the visit.

13. Are sites going to receive the pre-visit letter three weeks before the ten business days prior to the actual visit?
    Sites will receive the pre-visit letter 15 business days ahead of the monitoring visit start date. OCSO MOB is working with the NIAID CRMS team and the monitoring contractor to possibly have the WO released more than 15 business days in advance. Sites are asked to ensure that documents are uploaded to Medidata RSR or access to their electronic platform is granted to the monitor, ten business days prior to the start of the monitoring visit.

14. Do CRAs delete records after monitoring is complete, and why?
    No, CRAs do not have access to delete uploaded documents in RSR after completion of monitoring. Records should not be deleted after monitoring is complete. DAIDS and the DMCs have established a process for archiving of documents uploaded on the Medidata RSR once a study has reached final database lock.

15. Can you confirm that monitors have read only access and cannot remove or edit or delete files and folders?
    Monitors only have read-only access to the documents uploaded to the Medidata RSR. The monitor does not access to edit or delete files or folders in RSR.

16. If any changes are made to source documents during or after the monitoring visits (even if not related to the actual monitoring visit, but perhaps related to site QA activities etc.), are these required to be uploaded again?
    We recommend having the most recent and up to date document uploaded to the platform.

17. Do we need to redact participants' names and signatures on the ICFs when uploading?
    Since the Medidata RSR platform is HIPAA and 21 CFR Part 11 compliant, DAIDS does not require redaction. Our expectation is that the ICFs are uploaded unredacted, if they are redacted, then the monitor will reverify during an onsite visit. Your institution requirements and/or IRB may require redaction. If so, this should be communicated to your monitor.

18. Do sites have to request Medidata Rave access (CRC role) from user support for pharmacy and regulatory staff?
    Sites do not have to request access, the DMCs are working to automatically provide each site staff access to the system.

19. Can you clarify that if sites would need to upload documents before the hybrid visits are done, should a monitor start the visit 5 days earlier?
    Sites are recommended to upload documents 10 business days ahead of the full remote or hybrid monitoring visit. Please communicate with your monitor if you encounter issues or challenges.

20. Only half of our active studies are showing up in pharmacy iMedidata RSR. Who do we contact to assist?
    We recommend escalating this issue directly to the DMC to ensure that your site staff are given proper access to the studies. Contact SCHARP at sc.medidata.rsr@scharp.org or Frontier Science at usersprt@fstrf.org

21. If the documents are to be QC'd/finalized and uploaded ten days prior to the monitoring visit week, when will the work order be announced? How long will we have to prepare?
    The work order will be released 15 business days in advance of the monitoring visit. OCSO MOB is working with the NIAID CRMS team and the monitoring contractor to possibly have the WO released more than 15 business days in advance.

22. You mentioned that remote monitors will be asking sites to upload documents prior to the scheduled monitor visit up to 10 days in advance. Will work orders be released to sites 10 days earlier to accommodate?
    OCSO MOB is working with the NIAID CRMS team and the monitoring contractor to possibly have the WO released more than 15 business days in advance following the feedback from the HANC presentation.

23. There is only one audit for laboratories. Do RSMVs not apply to lab, or will face-to-face and RSMVs be alternated each year for lab audits?

The remote monitoring visits are separate from the lab audits. If a scheduled monitoring visit includes a laboratory specimen verification (LSV), this assessment will be completed during the next onsite visit.

24. Will sites have a training with DMC for uploading regulatory documents?

    At this time, a training is not planned. We strongly recommend that sites review the Medidata RSR FAQ from the DMCs which includes step by step instructions for using the regulatory folder.

25. Is it possible to enable in our profile the option to remove an uploaded document if an error occurs?

    Site staff access in Medidata RSR allows removal of documents uploaded to the platform. Please refer to the Medidata RSR FAQ from the DMCs for how to delete a document in RSR.

26. Does Medidata RSR allow for different versions to be uploaded? As logs will have data continually being added so there will be newer updated versions, will it save old versions or does it overwrite the previously uploaded version?

    Medidata RSR allows for different versions to be uploaded. Please refer to the Medidata RSR FAQ from the DMCs for how to upload additional documents to a visit folder.

27. When will the remote monitoring start?

    The remote monitoring visit will start on the date indicated on the pre-visit letter.

28. Where in the RSR do we upload the regulatory documents? Will there be instructions as to how to do so?

    A designated folder has been added to each study in Medidata RSR for regulatory documents. We strongly recommend that sites review the Medidata RSR FAQ from the DMCs which includes step by step instructions for using the regulatory folder.

29. Can remote audits and inspections also be possible?

    While there are situations that may require the use of remote audits and inspections. However, the current remote site monitoring initiative is limited to monitoring visits only.