National Institute of Allergy and Infectious Diseases

# DAIDS Remote Site Monitoring Visits

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National Institute of Allergy and Infectious Diseases

**HPTN Annual Network Meeting**

June 5, 2023

# Outline

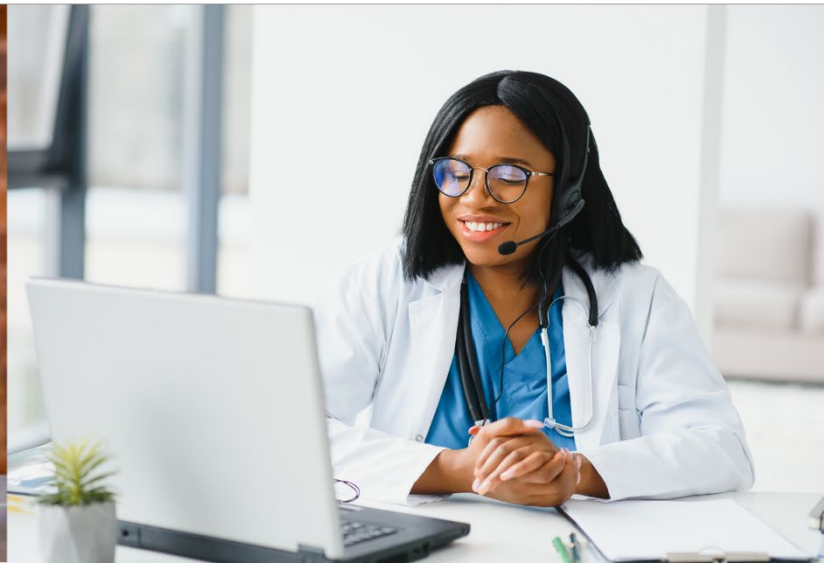
In this presentation we will review:

- What is Remote Site Monitoring?
- Pre-Visit Activities
- What is Remote Source Data Verification (rSDV)?
- What other activities are completed during a Remote Site Monitoring Visit?
- Tips on how to prepare for Remote Site Monitoring Visits
- Medidata Remote Source Review (RSR)
- Challenges of Remote Site Monitoring Visits
- Positive Experiences with Remote Site Monitoring Visits
- Final Takeaways

# Remote Site Monitoring Visits

- Activities conducted during an onsite visit are completed but are completed remotely.

Remote Site Monitoring Visits would not replace onsite monitoring visits instead it will supplement onsite monitoring.



# Remote Site Monitoring Visits

Remote Site Monitoring visits:

- Allow for more flexibility when scheduling
- Reduce the burden of having a monitor onsite; allowing for site staff to focus on daily activities
- Require similar preparation for the visit (in some cases)

# Pre-Visit Activities

- Pre-Visit Activities include:

Review of the planned Work Order (WO)

Monitor collaboration with site staff to provide necessary information in advance of the visit.

Uploading all required source documents for participants and their associated visits to secure platform (i.e., Medidata RSR).

Ensuring site staff are available to meet with the monitor during the visit (i.e., debriefs).

- These are similar to the activities required for an onsite visit.

# Remote Site Monitoring Visit Activities

During the remote review, the monitor performs the following activities:

- Conducts all assessments planned on the Work Order (WO).
- Verifies compliance to ICH-GCP, current protocol/ amendments/LOA, DAIDS policies and procedures, CRS SOPs and other applicable requirements.
- Queries any discrepancies with the CRS team and arranges for corrections of the data, as necessary.

# Remote Site Monitoring Visit Activities

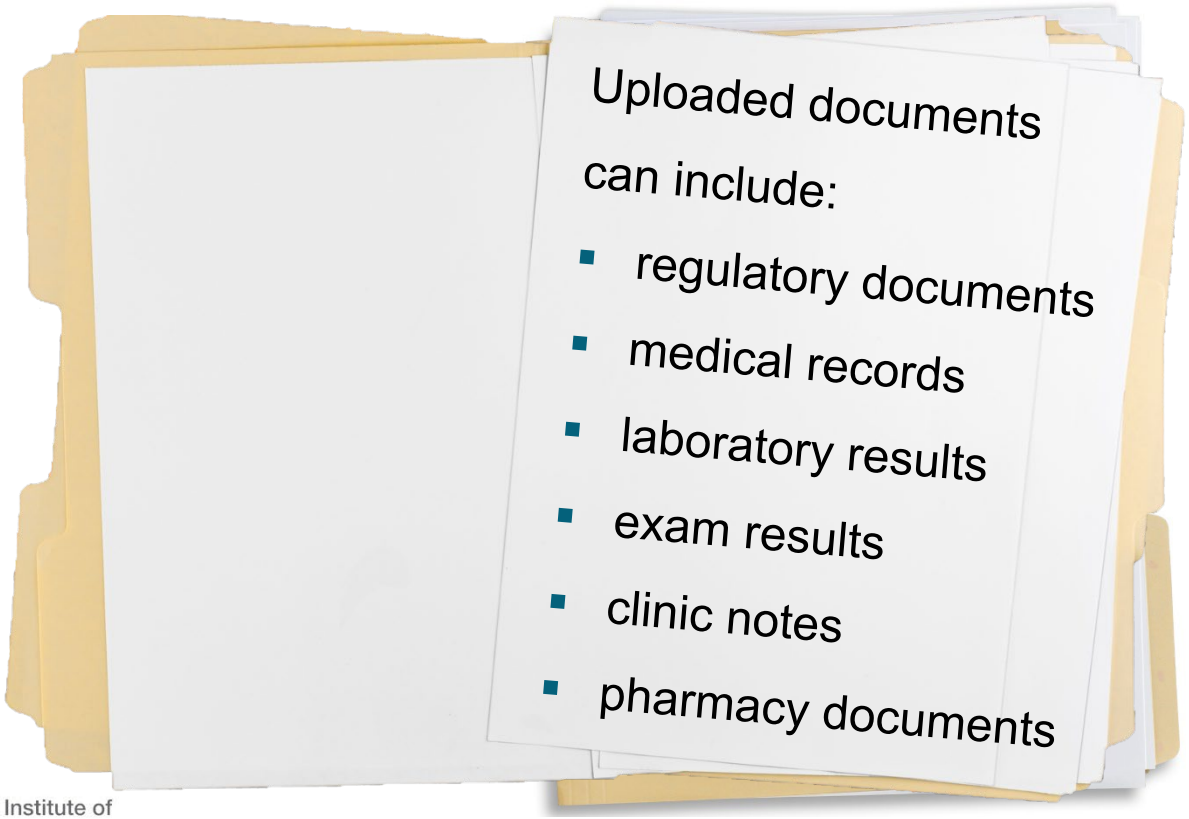
The monitor performs the following activities remotely as well:

- Follows up on issues from previous visits.
- Verifies Investigator of Record (IoR) participation in protocol activities by review of documents.
- Conducts daily debrief of findings identified.

CRS staff should note all findings and attempt to resolve them in an urgent manner, if possible, prior to the end of the visit.

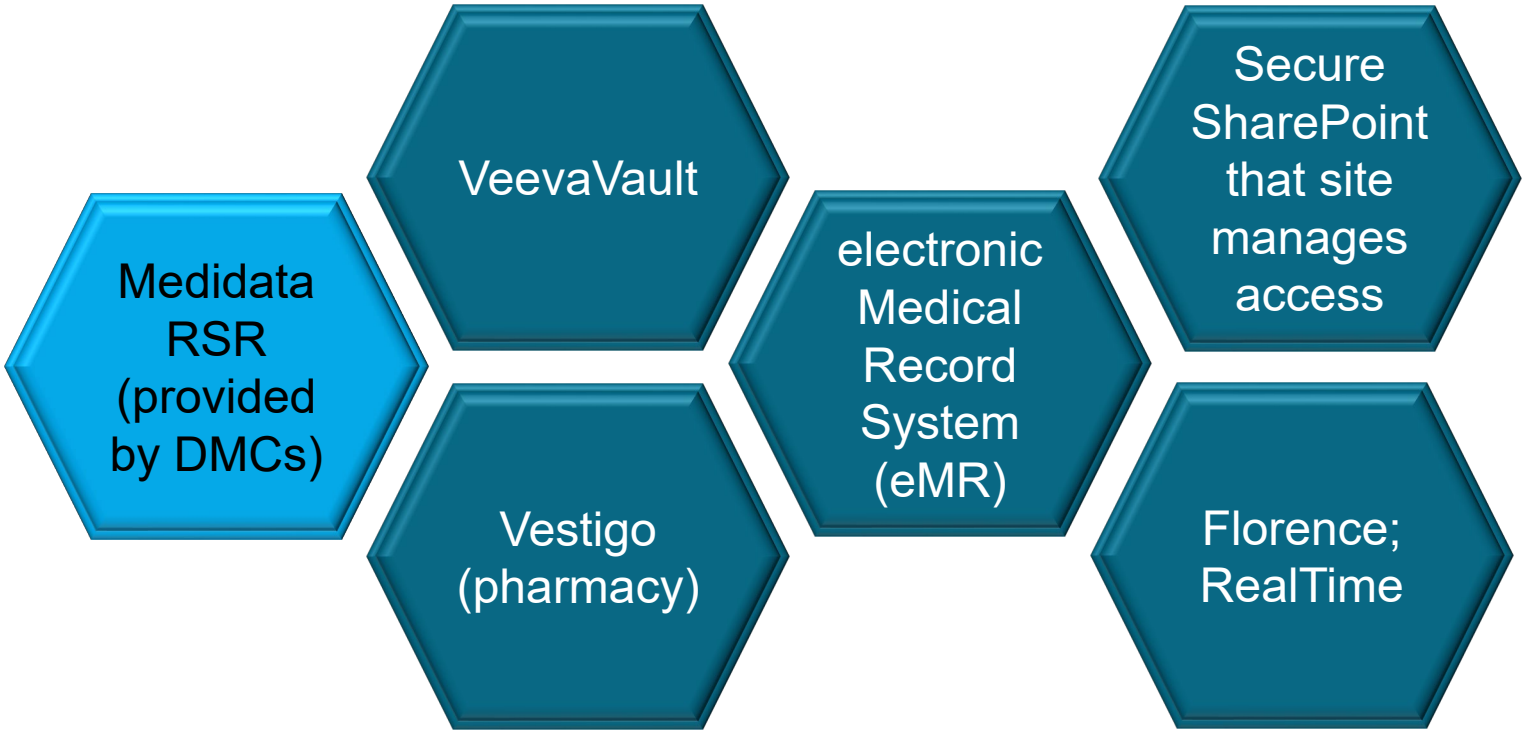
# Remote Source Data Verification (rSDV)

For a remote site monitoring visit, the monitor reviews the uploaded documents and compares to the data entered into the electronic case report form (eCRF). This process is remote source document verification (rSDV).



# Remote Source Data Verification (rSDV)

These documents are uploaded to a secure HIPAA and 21 CFR Part 11 compliant platform for review. Examples of these platforms include:

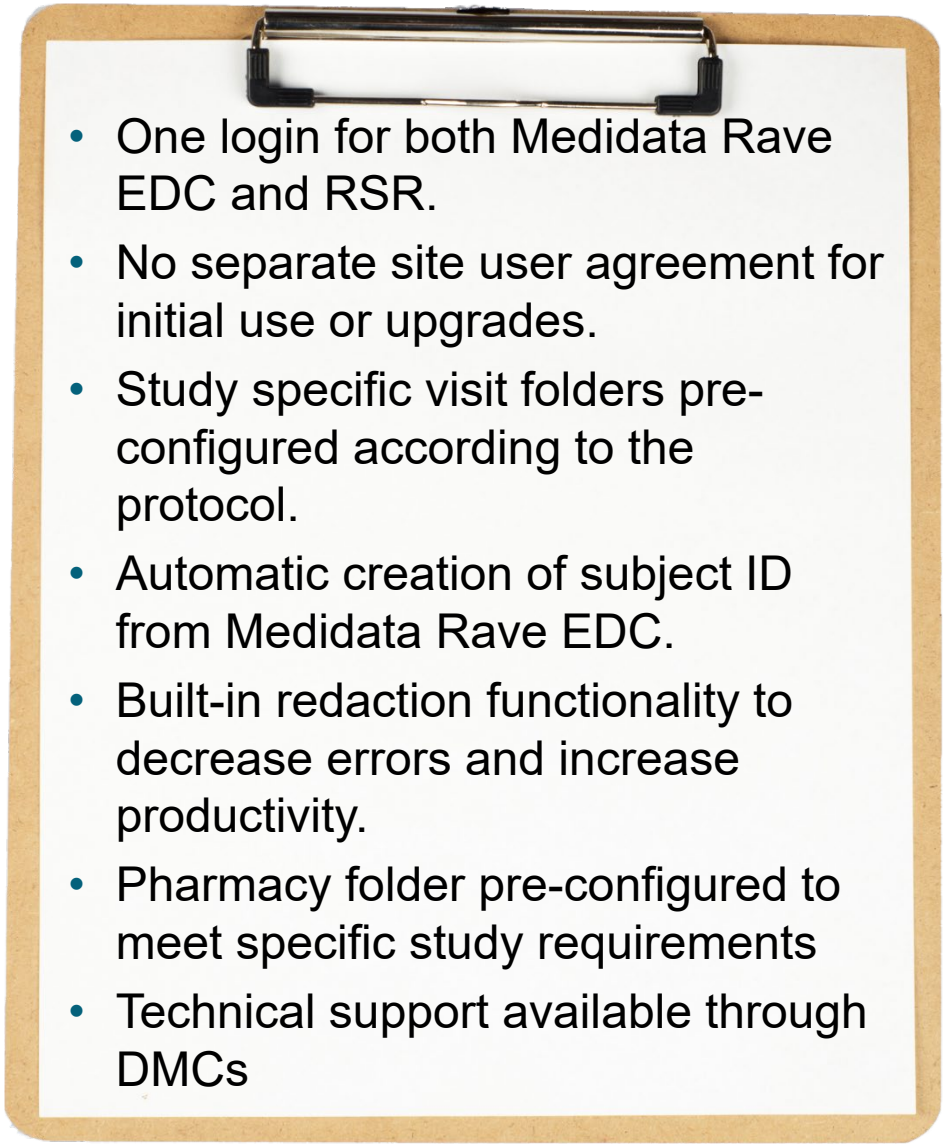



As with onsite SDV, the aim of rSDV is to ensure data accuracy and protecting the integrity of the final study results.

# Medidata Remote Source Review (RSR)

**Medidata RSR platform is available to all DAIDS supported sites for all network protocols.**

Advantages to sites in using Medidata RSR 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 pre-configured to meet specific study requirements
- Technical support available through DMCs

# Tips for Remote Site Monitoring Visits

- Collaborative communication between monitor and site throughout the preparation of the remote SMV.

- Prior to the visit, arrangements should be made for remote meetings that may be needed. These may include touch point meetings with regulatory, data management, and laboratory managers, and debriefing(s) with the IoR, pharmacy staff, and study coordinator.

# Tips for Remote Site Monitoring Visits (Cont.)

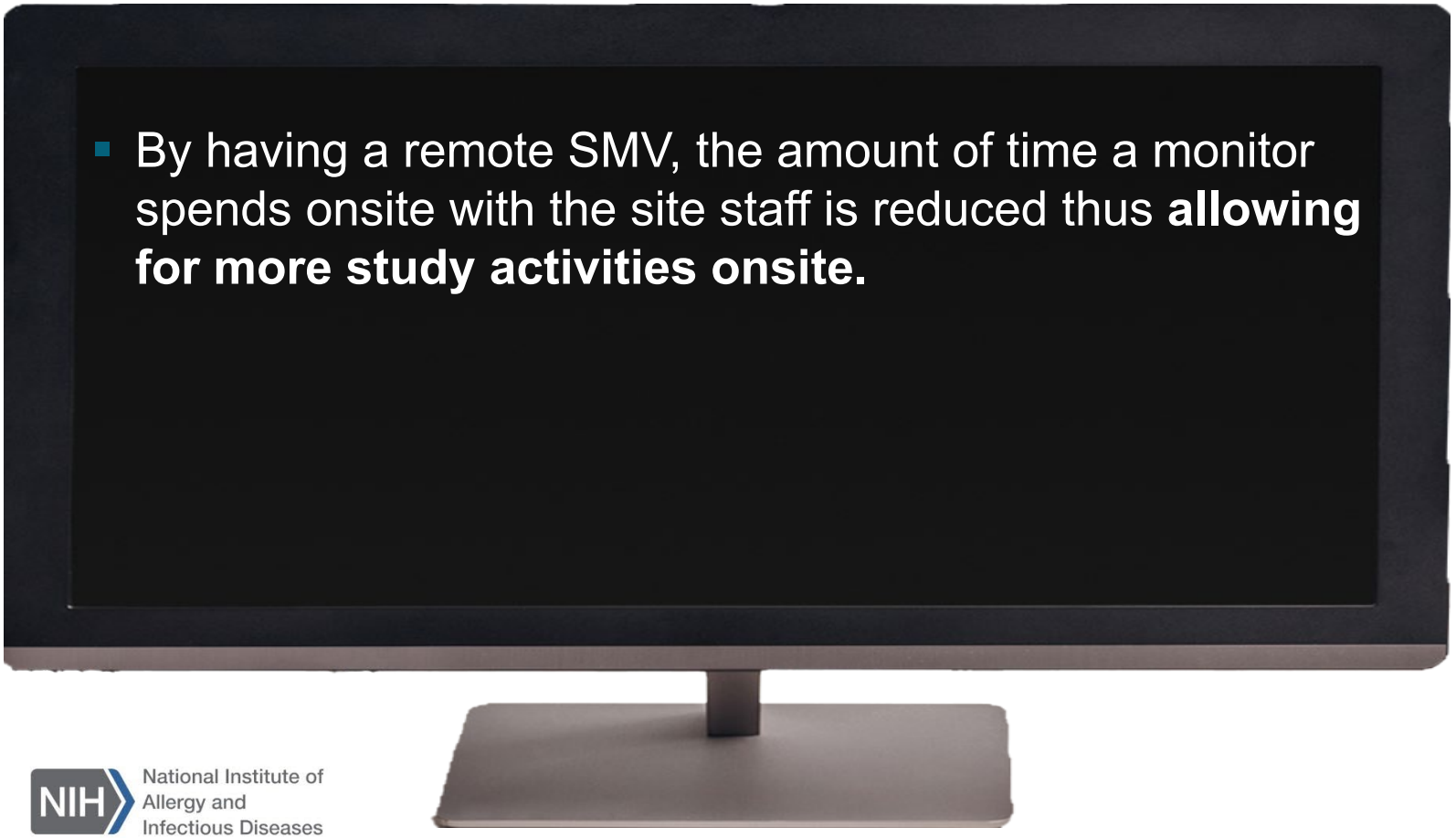
- Ensure your site is prepared by verifying that participants' research records and Investigator Site File documents are available on the remote monitoring platform, as applicable and complete prior to the start date of the visit. For remote SDV, participant records must be uploaded to the platform prior to the visit.

# Tips for Remote Site Monitoring Visits (Cont.)

- Electronic platforms that support remote SMVs may need to be approved at the site level (e.g., institutional IT requirements).
- Communicating the visit plans and monitoring dates to CRS staff including Pharmacy, Laboratory, and Regulatory team.
- Review of follow-up issues from the previous visits

# Challenges of Remote Site Monitoring Visits

**Time involved with uploading documents to the rSDV platform is a burden to sites.**



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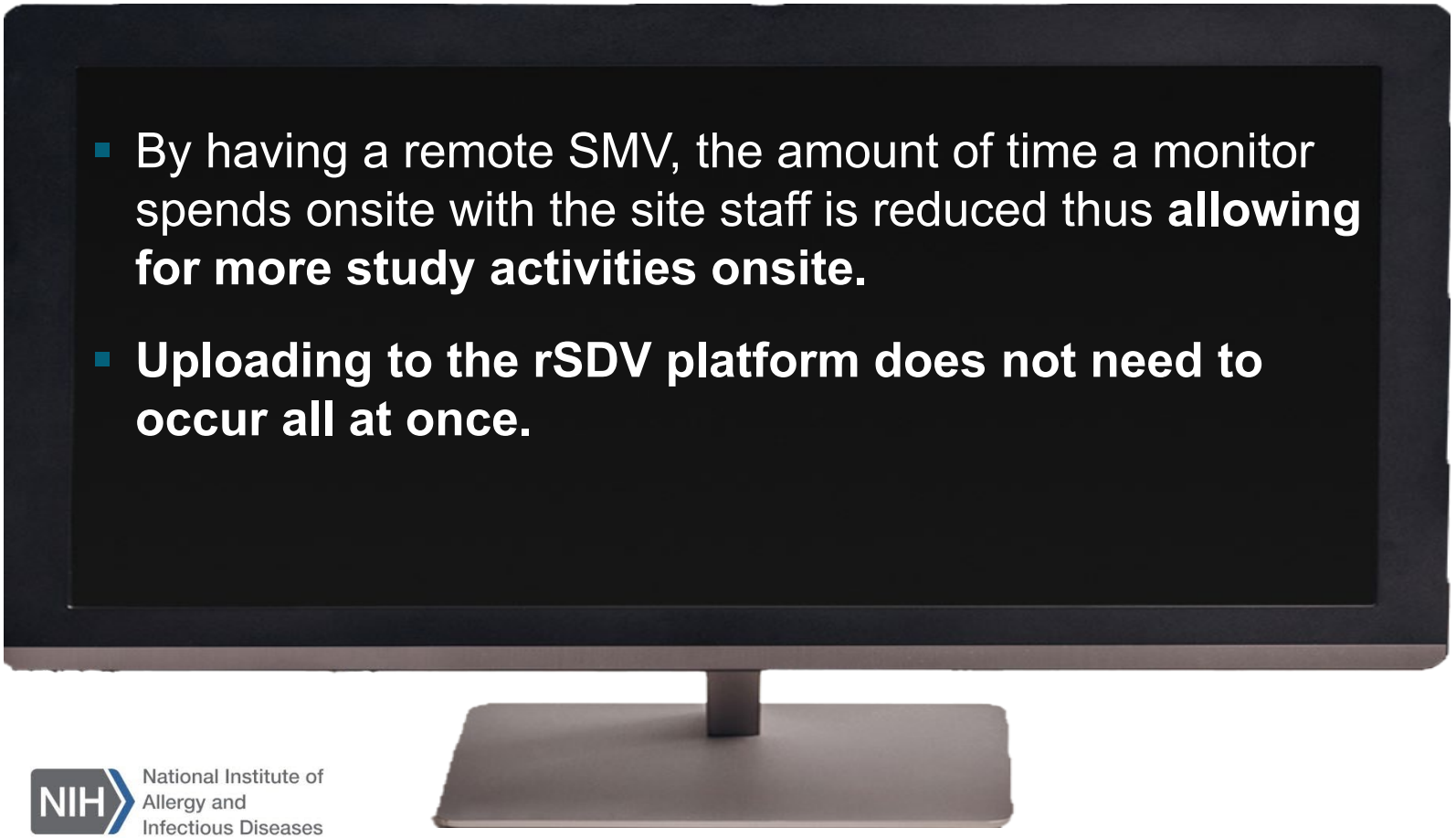

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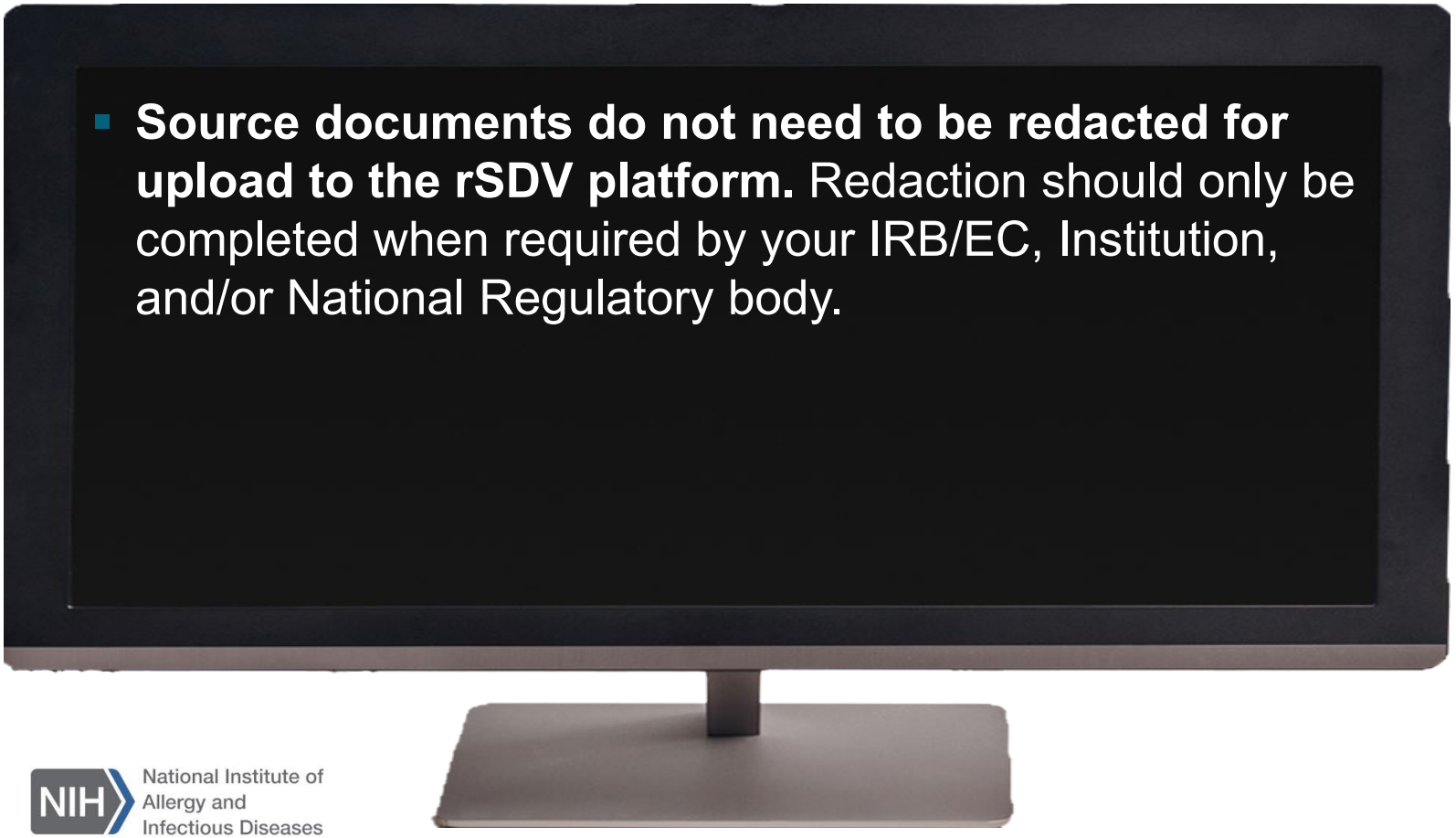

# Positive Experiences with Remote Site Monitoring Visits

- Flexibility with scheduling the site monitoring visit
- Increases efficiency
- Minimizes the impact to daily operations at the site
- Saves both the site and monitor time
- Provides another modality for interacting with the monitor

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# Final Takeaways

- Remote Site Monitoring Visits allow:
  - More flexibility for scheduling and response to queries.
  - More time for site staff to complete daily operations (patient recruitment, follow-up, data entry, etc.)
  - More time for monitors to complete SDV.
- Remote Site Monitoring visit language is included in all active protocols.
- Medidata RSR is configured for all studies and available to all sites through the DMC.
- All site monitoring visits require advanced preparation by the site but Remote Site Monitoring Visits reduce the burden of the monitor being on site.
- Remote Site Monitoring allows for continuity of monitoring operations when situations arise preventing onsite monitoring.

# Questions & Answers