

Medidata Remote Source Review

Drive Efficiencies and Speed with Secure Remote Monitoring

Remote site monitoring is no longer a “nice-to-have.” Continued success in clinical trial operations now requires a dedicated remote site access and monitoring strategy. Imagine reducing the need for on-site document review, while reviewing documents faster, mitigating risk AND reducing site burden.

Medidata Remote Source Review (RSR) is a cloud-based solution that **rapidly and remotely** enables monitors to acquire critical documents, automates document workflows to the right monitor for the right study and site, and allows them to review documents to support Source Data Verification (SDV) and Source Document Review (SDR). This allows for **real-time assessment of subject safety AND data quality** compared to traditional onsite monitoring efforts. Sites simply upload source documents via a secure browser that has robust built-in Personally Identifiable Information (PII) and Protected Health Information (PHI) blinding capabilities, which removes the need to use error-prone, manual redaction techniques.

The system supports automated workflows to route the documents to the right monitor for remote SDV/SDR. Off-site/remote monitoring not only reduces sponsors monitoring costs, but accelerates data capture and time to review, while improving compliance and quality. Medidata Remote Source Review assists sponsors and CROs when studies have critical timelines and there is no secure option to get monitors on-site for document review.

Medidata Remote Source Review

Remote Source Review provides secure, remote monitoring of critical source documents to help keep your trials running smoothly and:

- Is easy and quick to implement - configured for standardized study set-up 2 weeks after receipt of all startup requirements
- Acquires documents, via secure browser-based uploads
- Supports FDA and other global regulatory guidelines for remote monitoring*
- Allows users to perform redaction of PHI/PII using a built-in, web-based tool
- Enables automatic distribution of documents
- Leverages iMedidata for a single-sign on to reduce site burden
- Automatically creates subjects from Rave EDC resulting in less data reconciliation
- Provides standard reports for task management and status updates

Remote Source Review offers:



Recorded training is available for sites and monitors to help them get started quickly.

*Applicability of the solution needs regulatory consideration in each country where use is intended
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19K+

ACTIVE SITES USING TECHNOLOGY

90%

TRIAL CONFIGURED IN 2 WEEKS OR LESS

<6

AVG DAYS TO COMPLETE REMOTE SOURCE REVIEW (COMPARED TO AN AVG 90 DAYS ON-SITE MONITORING FREQUENCY)

ZERO

FOOTPRINT SOFTWARE

Why Medidata Remote Source Review?

Save Costs in Monitoring Visits

Remote Monitoring of critical source documents reduces the costs of monitors prepping for and going on-site for SDV/SDR, eliminating site travel and per diem costs for those visits.

Reduce Site Burden and Improve Satisfaction

With simple upload and redaction tools and automated workflow/task management, the time sites need to spend preparing for monitoring visits for SDV/SDR is greatly reduced. Remote Source Review is connected to Rave EDC, if applicable, to automatically create study subjects, reducing time spent entering data.

Improve Efficiency and Speed

Off-site/remote monitoring removes travel time allowing for improved speed to review documents and expedites time to first data review. Accelerated data capture and time to read improves efficiency in the management of trials.

Ensure Data Quality and Compliance

Medidata Remote Source Review is a 21 CFR Part 11 compliant system and protects PII and PHI with built-in redaction functionality that helps reduce errors. Intelligent workflows and flexible permissions enable automatic distribution of source documents to the right monitors for their assigned sites. A full audit log and documentation helps track and re-verify data, reducing the risk of failing an audit.

Gain Oversight, Control, and Visibility

Remote Source Review provides a series of standard reports for task management and status updates and improves oversight with a full audit trail that captures all activities. Electronic documents are available for review immediately upon upload.

Simplify Review Process

Single sign on through iMedidata makes it easy for sites. A prespecified workflow to support critical document management and SDR activities simplifies the process and documents can be reviewed in the Cloud without the need for software installation.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,600 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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