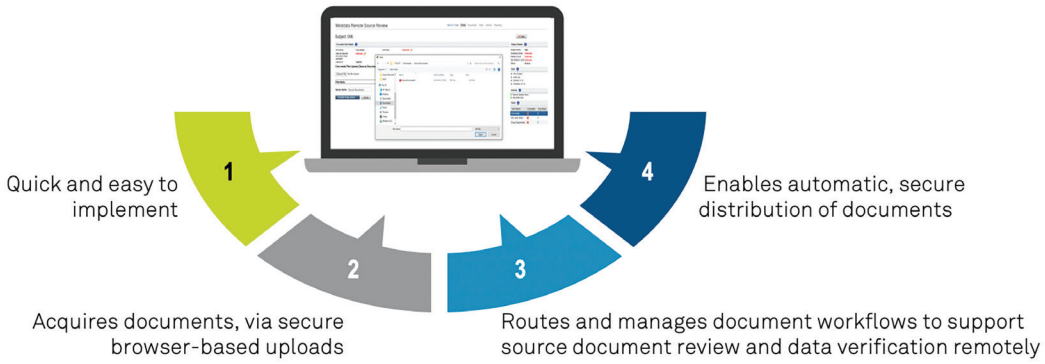
Drive Efficiencies and Speed with Secure, Remote Monitoring



Medidata Remote Source Review 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 him/her to review documents to support SDV and 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 PHI/PII blinding capabilities, which removes the need to use error-prone, manual redaction techniques. Imagine reducing the need for on-site document review, while reviewing documents faster, mitigating risk and reducing site burden.

Remote Source Review Benefits

Remote Source Review provides secure remote monitoring of critical source documents to keep your trials running smoothly.

Improve Efficiency and Speed

- Easy and quick to implement - configured for standardized study set-up 2 weeks after receipt of all startup requirements
- Built-in PDF Viewer and Editor makes it easy to manage documents
- Off-site/remote monitoring removes travel time
- Accelerated data capture and time to read

Ensure Data Quality and Compliance

- Document acquisition, via secure browser-based uploads
- FDA and other global regulatory guidelines for remote monitoring are supported
- Web-based redaction tools for removing PII/PHI
- Monitors only have access to documents for assigned sites

Gain Oversight, Control and Visibility

- Electronic documents available for review immediately upon upload
- Status reports available to sites, monitors and sponsors
- Full audit capabilities that capture all activities

Simplify Review Process

- Single sign-on through iMedidata
- Lower site burden results in higher site satisfaction
- Documents reviewed in the cloud with no software to install

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

Remote Source Review Features

Submission & Review

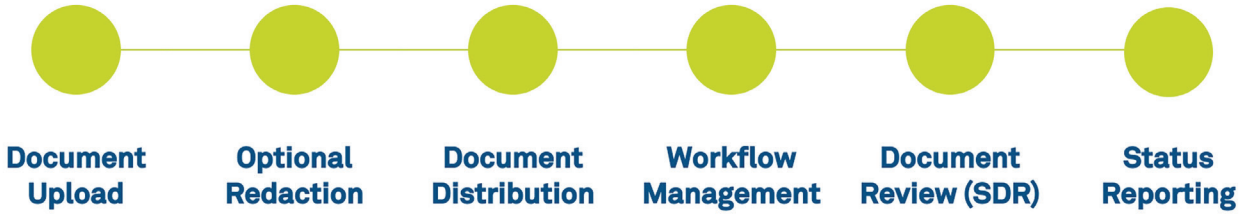
- Structured submission process
- Prespecified workflow to support critical document management and SDR activities
- Minimal manual data entry
- Automated patient entry
- Consistent and seamless user interface
- Preconfigured query text

Workflow Management

- Task management
- Document routing
- Conditional logic
- Standard reports for task management and status updates

Security & Compliance

- Search and find feature for automatic redation
- Tracking of tasks with completed forms
- 21 CFR Part 11 compliant system
- Audit ready - accelerated resolution of audit findings
- Process for systematic permanent document removal



The Medidata Advantage

As sponsors and CROs make hard pivots to keep their trials running, Medidata is helping them adapt their monitoring execution models while still ensuring patient safety and data quality. Medidata offers innovative digital technology to help the shift from 100% on-site monitoring, enabling a flexible on-site/off-site approach to monitoring and study oversite. Remote Source Review is part of a risk-based quality management (RBQM) and remote monitoring solution that help optimize clinical trial operations to deliver high-quality treatments, on-time and efficiently.