Medidata Remote Source Review

Remote Document Review
The impact of COVID-19 on clinical trial research has been a catalyst for significant change. As a result of global restrictions, most sponsors and CROs are unable to monitor their active studies on-site, and may not be able to acquire critical documents. Some have turned to less secure, antiquated, risky tools to manage these critical documents such as fax, email, video and file sharing software. Without the ability to easily and compliantly manage these documents, timelines and data integrity are at risk.

Based on the current FDA Guidance*, Medidata has aligned its Rave Imaging workflow tool to enable clients to rapidly and remotely deploy a method to assist monitors in critical document acquisition, workflow, and Source Document Review (SDR). Rave Imaging Critical is a streamlined and quick-to-implement solution that helps fill the gap when studies have critical timelines and no secure option to collect, de-identify, manage, review and verify critical study documents. Easy to get started with no software to download, Remote Source Review is available at no cost for the sites and can be used as a primary solution or alternative for sites. Medidata Remote Source Review:

- Acquires documents, via secure browser-based uploads, routes and manages document workflows to support source document review and verification remotely
- Is a 21 CFR Part 11 compliant system that includes the ability to de-identify and redact Personally Identifiable Information (PII) and Protected Health Information (PHI)
- Connected with Rave EDC which makes it easier for sites and for data reconciliation

Medidata Remote Source Review
Remote Source Review offers:

Quick, Focused Set-Up: Time to Value within 2 weeks
- Medidata configured, standardized study set-up 2 weeks after receipt of all startup requirements
- Standard folders for document upload with additional study-specific folders, as required
- Leverages iMedidata for single sign-on
- Automatic creation of subjects from Rave EDC
- Availability of standard reports for task management and status updates

Virtual Training: Recorded training available for sites and monitors

*FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency