Rave
Medidata Clinical Cloud

FACT SHEET

Rave Imaging Critical

Remote Document Review

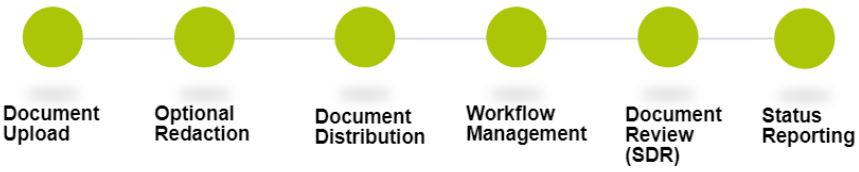
The impact of COVID-19 on clinical trial research has been a catalyst for significant change. As a result of global restrictions, most sponsors and CROs are unable to monitor their active studies on-site, and may not be able to acquire critical documents. Some have turned to less secure, antiquated, 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 tailored its Rave Imaging workflow tool to align with the current situation and 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, is available at no cost for the sites, and can be used as a primary solution or alternative for sites. Rave Imaging Critical:

- 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) PII and PHI
- Connected with Rave EDC which makes it easier for sites and for data reconciliation

Rave Imaging Critical

Rave Imaging Critical 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

Ongoing Workflow Management: 6 month access

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*

15K+

GLOBAL IMAGING SITES

780+

STUDIES

ZERO

FOOTPRINT SOFTWARE

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 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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