MOVING YOU FORWARD WITH REMOTE MONITORING

As you make hard pivots to keep your trials running, Medidata is moving you forward, helping you to adapt your monitoring strategy without compromising patient safety or data quality.

Medidata Remote Monitoring is a holistic, innovative digital solution to enable a flexible on-site/off-site approach to study oversight. Leverage our innovative digital technology to support effective trial management and oversight, with increased remote monitoring and purpose-driven, intentional interaction with sites.

Remote Monitoring

Medidata Detect

Automate anomaly detection using a centralized approach for remote monitoring and continual data review

Medidata Remote Source Review

Review critical source documents off-site

Rave TSDV

Design, configure, and execute a highly targeted SDV strategy

Shift from 100% on-site activities, enabling a flexible approach to monitoring

We've been moving you forward for the last 20 years and we don't intend to stop now.

With Medidata Remote Monitoring, you can:

Confidently pivot from 100% on-site to remote monitoring

Leverage our innovative and compliant digital capabilities for source document review and verification. Save time and reduce costs in on-site monitoring visits.

Gain trial oversight, control, and visibility

Capture source data directly in EDC and review remotely. Alert CRAs to data irregularities automatically.

Focus on high-value, meaningful in-person activities

Relieve site burden and improve satisfaction by allowing sites to focus more of their time on patient care. Ensure CRA and site safety by going remote during COVID-19.

Q: What is site-level virtualization? Why now?

A: In the age of COVID-19, where in-person site visits are minimal, trial virtualization has transformed from a once emergent market trend to an established market need. At Medidata, our focus is on virtualizing processes at the patient level and site level. While patient-level virtualization focuses on patient-facing elements occurring outside a traditional investigator site, site-level virtualization includes remote technologies to enable monitors' workflows offsite. This includes technologies such as Medidata Remote Source Review and Medidata Detect, to provide monitors remote access to monitor study-level data and critical source documents.

Q: What is the value of remote monitoring? Who benefits from this?

A: Our approach to study-level virtualization includes Medidata Remote Monitoring, a holistic solution that enables a flexible on-site/off-site approach to site monitoring. Remote monitoring benefits all clinical trial stakeholders, saving time and reducing costs in on-site monitoring visits. Study teams can capture source data directly in EDC and review it remotely. With a more strategic, intentional interaction between sites and CRAs, sites can focus more of their time on delivering quality patient care. CRAs are automatically alerted to data irregularities and are kept safe by going remote during COVID-19.

Q: I'm not looking to go fully remote. Can I still use Medidata technology?

A: Yes–recognizing that trials are rarely 100% virtual, Medidata's Trial Dial framework helps you customize your clinical trial design to reflect the best mix of onsite/virtual touchpoints for your particular study. From a remote monitoring perspective, oversight activities begin with an end-to-end risk assessment to identify critical data and processes, on-site study start-up activities, followed by central statistical data monitoring and data review with virtual remote source review and live-video monitoring visits, and targeted, risk-based, on-site visits. In some studies, there is a dramatic reduction in site visits with assessments and oversight being managed remotely. »

Q: There are many new digital health-care-related technologies becoming available through varying vendors. Doesn't the use of many different tools increase site burden with multiple logins and training?

A: Working with independent point solutions without a unified platform can create significant challenges for sites and sponsors. With multiple logins and the need for device integration, it can become a burden on sites to implement these tools. However, using virtualization tools already built on the EDC being used will mitigate risk and reduce data transcription workload for sites. Medidata virtualization solutions are all unified directly with Rave EDC, enabling direct eSource data capture to provide more information in real-time, with no opportunity for error. With Medidata Remote Monitoring, there is no need to create a new login. Sites log into Rave EDC and access the data in near-real-time for monitoring without the need for data reconciliation.

Q: Data security and compliance are big concerns. How do I make sure remote monitoring is secure and complies with regulatory and document storage standards?

A: Medidata Remote Source Review offers data security and compliance on many different levels. The system is a 21 CFR Part 11 compliant 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.

Medidata Remote Monitoring encompasses three core activities: **Centralized Statistical Monitoring**, **Central Data Monitoring**, and **Off-Site/Remote-Site Monitoring**.

Medidata Detect

Centralized Statistical Monitoring and Central Data Monitoring are supported via Medidata Detect. Driven by machine learning and automated algorithms, Medidata Detect helps unify and ingest study data, identify anomalies, and find risks in your study. Data flows in real time and can be refreshed on demand, supporting the dynamic requirements of safety and quality review.

Medidata Remote Source Review

Mitigate study and site risk with secure, remote monitoring of critical documents to help keep your trials running smoothly. Assist sites and monitors in secure document acquisition, task workflow automation, and Source Document Review (SDR), saving time and costs while ensuring compliance and quality.

Rave TSDV

Rave TSDV gives monitors instant access to SDV work required at the study, site, and subject levels. It also lets study teams configure study-specific and site-specific SDV plans–all the way down to the individual data field level. TSDV harnesses the robust audit trail capabilities within Medidata Rave EDC, giving users complete traceability of change controls and SDV plan.

Learn more about Medidata Remote Monitoring here.