THE FUTURE OF CLINICAL OPERATIONS EXCELLENCE IS DIGITAL OVERSIGHT

As you optimize your clinical operations strategies, Medidata is moving you forward towards the future of clinical trials, helping you to create an efficient and effective oversight strategy while maintaining patient safety and data quality.

Medidata Digital Oversight is a holistic, innovative digital solution to enable a flexible on-site/off-site approach to study oversight and improved data quality. Leverage our innovative digital technology to support effective trial management and oversight, with increased risk-based monitoring and purpose-driven, intentional interaction with sites.

Digital Oversight

Medidata Risk Management
Identify, document and measure the risk of a study protocol and devise a monitoring plan

Medidata Detect
Automate anomaly detection using a centralized approach for remote monitoring and continuous data review

Rave CTMS
Standardize trial management and monitoring activities at the study, country, and site level

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 risk-based monitoring

We've been preparing for the future of clinical trials for the last 20 years and we don't intend to stop now.

With Medidata Digital Oversight, you can:

Confidently pivot from 100% on-site to risk-based 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.

Q: How does Digital Oversight support decentralized clinical trials (DCTs)?

A: The decentralization, or virtualization, of clinical trials, has transformed from an emerging market trend to an established clinical trial method. At Medidata, our focus is on providing decentralizing technologies which support both sponsors and patients in executing robust DCTs. While patient-level virtualization focuses on patient-facing elements occurring outside a traditional investigator site, sponsor-level virtualization includes remote technologies to enable study teams' workflows offsite. This includes technologies such as Remote Source Review and Medidata Detect, providing CRAs and central monitors remote access to review study-level data anomalies and critical source documents.

Q: What is the value of Digital Oversight? Who benefits from this?

A: Our approach to optimized risk-based monitoring strategy is called Medidata Digital Oversight, a unified, composable set of capabilities 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 empowered with deep analytic capabilities to improve their decision-making.

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 risk-based 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. There is a dramatic reduction in site visits with assessments and oversight being managed remotely in some studies.

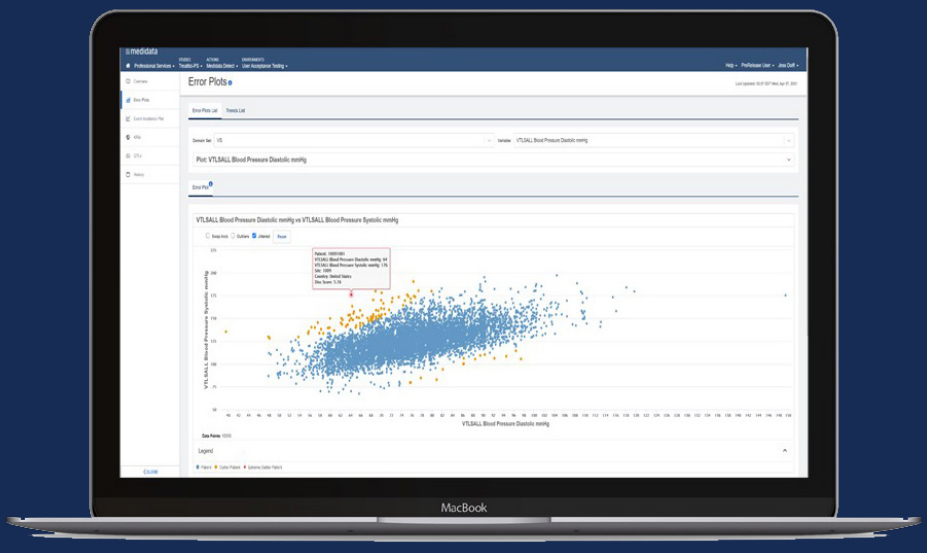
Q: Many new digital healthcare-related technologies are becoming available through varying vendors. Doesn't the use of different tools increase site burden with multiple logins and training?

A: Working with independent point solutions without a unified platform can create significant risk 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 source document review is secure and complies with regulatory and document storage standards?

A: Medidata's 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 the 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 Digital Oversight supports these core activities: **Risk Assessment and Monitoring**, **Centralized Statistical Monitoring**, **On-Site and Remote Monitoring**, **Source Data Verification**, and **Source Document Review**



Learn more about Medidata Digital Oversight here.