Medidata TSDV Risk-Based Monitoring in the Clinical Cloud

Site monitoring costs eat up 30 percent of clinical trial budgets;[1] of that, more than half is spent on source document verification (SDV). Why waste precious time and resources checking all data if you only want to verify critical data?

Medidata TSDV (targeted source document verification) is a unified, electronic data capture (EDC)-based tool that allows life science companies to efficiently and compliantly reduce the amount of SDV conducted. Its configurable, statistical algorithm lets you control your level of SDV coverage—without sacrificing regulatory compliance or your data quality strategies.

It's Simple

Medidata TSDV simplifies the data verification process for members of both the clinical operations and data management teams. The tool allows clinical research associates (CRAs) to perform, record and track partial SDV activities with the same processes and tools they use for 100 percent SDV. Data managers may preset Medidata TSDV at the beginning of the study to recognize when certain variables (e.g., serious adverse events) appear abnormal, triggering the tool to automatically adjust SDV coverage on individual patients as the study runs. Medidata TSDV even gives instant access to SDV work required at the study, site and subject level.

It's Flexible

Medidata TSDV lets study teams configure study-specific and site-specific SDV plans—all the way down to the data field, form and patient visit levels. The embedded statistical algorithm automatically assigns patients to pre-configured SDV regimens as they are enrolled, enabling the study team to achieve desired coverage levels. As the trial progresses, the team can make modifications at any level, without disrupting existing monitoring processes.

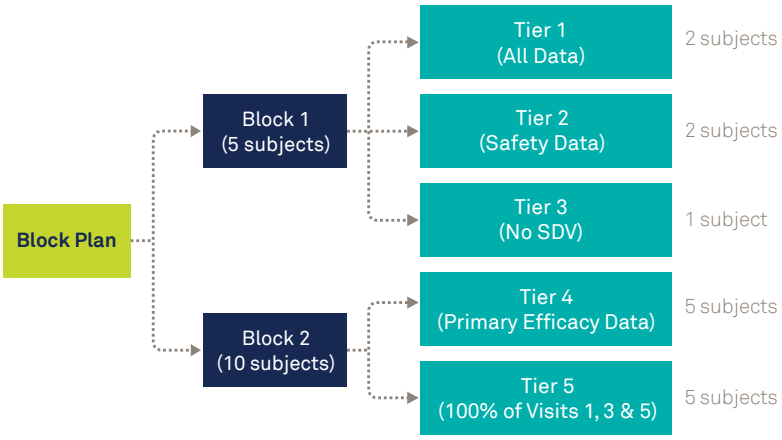
It's Compliant

As part of the Medidata Clinical Cloud™ platform, Medidata TSDV harnesses the robust audit trail capabilities within Medidata Rave®, giving users instant access to change controls and management for complete auditability. Sponsors and contract research organizations (CROs) can easily apply controls to align their monitoring activities with their regulatory strategies. And because all subject SDV assignments and activities are logged in Rave EDC, study managers have full visibility into initial subject SDV assignments, SDV progress and any modifications made mid-trial.

Risk-Based Monitoring Directives

- The FDA draft guidance issued in 2011 (revised in 2013) and the EMA reflection paper issued in 2011 encourage a risk-based monitoring approach.
- The Clinical Trials Transformation Initiative (CTTI) advocates that the clinical research industry builds Quality by Design (QbD) into clinical trials, recommending a monitoring approach that rapidly detects and corrects issues while the study is ongoing with a goal of fit-for-purpose data, not "error-free" data.[2]
- Robust data analytics from the Medidata Clinical Cloud, aggregated from thousands of clinical trials across the globe over the past five years, show that less than 3 percent of all CRF data is actually changed due to post-data capture monitoring and cleaning.[3]
- TransCelerate's 2013 position paper on risk-based monitoring methodologies observed that the "rate of SDV-only discrepancies in Critical Data was 2.4%, suggesting that SDV has a negligible effect on data quality."[2]

An Example of a Configured, Partial SDV Plan



It's Informative

Determining when and where monitoring resources are needed has been a critical challenge in clinical research, until now. Medidata SQM (site quality management) works alongside Medidata TSDV to provide up-to-date information on site quality levels so you know when and where adjustments need to be made to the SDV plan. Medidata SQM's intuitive, color-coded dashboards alert the team to quality deviations using advanced industry analytics that scan data from each site in your study. This gives study teams a birds-eye view of the ongoing quality of sites across the globe, providing the information needed to make mid-trial adjustments to the study's SDV plan.

Medidata Support for Success

Medidata Strategic Consulting Services is ready to help your life science organization realize the full potential of Medidata TSDV. We offer industry-leading expertise in aligning business processes with technology while optimizing risk-based monitoring programs. To learn more, email us at **MedidataConsulting@mdsol.com**

medidata TSDV

[1] E. Eisenstein, P. Lemons II, B. Tardiff, K. Schulman, M. Jolly, R. Califf, "Reducing the costs of phase III cardiovascular clinical trials," *American Heart Journal* 149, 3 (2005): 482-8.

[2] *Position Paper: Risk-Based Monitoring Methodology* (TransCelerate Biopharma Inc.: 2013), 2-3.

[3] Young, Stephen et. Al, "Is Risk-based Monitoring an Appropriate Methodology for Clinical Trials in Emerging Regions?" *Journal for Clinical Studies* 6, 2 (2014): 26-8.

Medidata Clinical Cloud™

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk

Robust Support for Your Risk-Based Monitoring Program

Leverage Medidata TSDV to design, configure and execute any reduced SDV strategy with confidence.

- Configure the study's SDV plan to assign enrolled subjects to specific coverage levels using a robust, EDC-based statistical algorithm.
- Modify SDV coverage mid-trial in three ways:
  - Pre-set mid-trial adjustments that will automatically raise or lower SDV coverage on individual patients in real time.
  - Override SDV plan at the subject and data field level, as needed.
  - Change SDV plan at the site and study level, as needed.
- Access instant view of SDV work required at the study, site and subject level.
- Access change controls and management for complete auditability.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

info@mdsol.com | mdsol.com
+1 866 515 6044