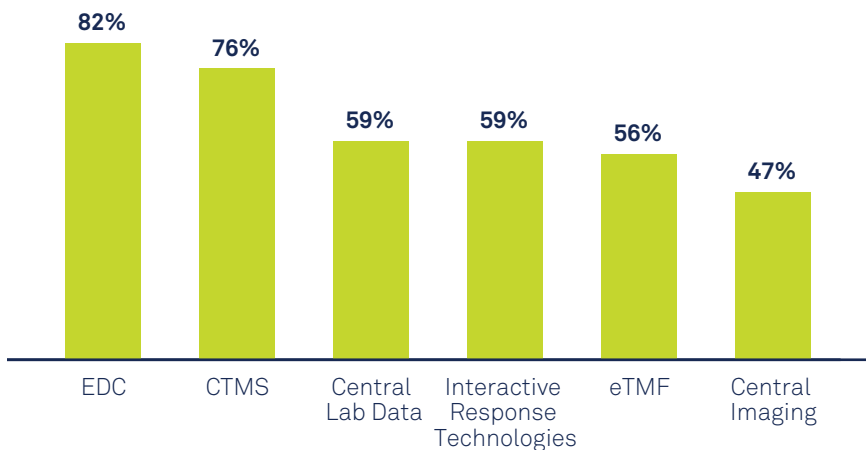


Medidata Edge Targeted SDV: The First Step in a Targeted Monitoring Approach

It is widely known that site monitoring costs make up to 30 percent of clinical trial budgets, of which more than half is spent on source data verification (SDV).¹ Site monitors typically spend one day per month visiting every site in a study and nearly half their time on-site doing SDV.

Electronic data capture (EDC) systems remain the primary source of data to be reviewed,³ but research also suggests that while conducting 100% SDV of this data, less than three percent of all case report forms (CRF) data is actually changed due to post-data capture monitoring and data cleaning.⁴

Figure 1: Top Electronic Data Sources Reviewed During Centralized and Remote Monitoring Review



Source: Metrics Champion Consortium 2016

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.
 3. Metrics Champion Consortium 2016
 4. Young, S. et al., "Is Risk-based Monitoring an Appropriate Methodology for Clinical Trials in Emerging Regions?" *Journal for Clinical Studies*. 2014. Volume 6 Issue 2. 26-28

ACHIEVE ICH GCP E6 (R2) COMPLIANCE WITH MEDIDATA EDGE TSDV

- Study-specific and site-specific SDV plans configuration—all the way down to the data field, form and patient visit levels.
- Complete auditability with instant access to change controls and management
- Centralized management of data and reporting to ensure timeliness around data entry and clean-up

MEDIDATA EDGE TSDV SUCCESS METRIC #1: REDUCED MONITORING COSTS

Taking a **targeted monitoring approach** and reducing SDV coverage by **20 percent** resulted in **247** fewer on-site visits, helping them save more than **\$1 million** in travel costs in 2017.

Checking every box for every data point is not the best use of a site monitor's time on-site. In fact, regulatory bodies are saying that by doing 100% SDV, organizations are likely missing something else that is important⁵. Therefore, conducting 100% SDV is not considered a more detailed, comprehensive approach, but a misuse of valuable resources during their on-site monitoring visits.

Nevertheless, clinical teams continue to rely on 100% SDV to review all data points, not knowing where to look, thereby diverting attention and resources from critical data (e.g. data that focuses on primary and key secondary endpoints, serious adverse event data, and data critical to subject safety) and critical processes (e.g. maintaining compliance and evaluating safety outcomes).

At Medidata, we believe that a more focused approach to SDV is not only possible but can also lead to higher data quality and integrity that sponsors and contract research organizations (CROs) can use to align their monitoring activities with their regulatory strategies.

Design, configure and execute any reduced SDV strategy with Medidata Edge TSDV

Medidata Edge Targeted SDV (TSDV) is a turnkey solution that allows life science companies to reduce the amount of SDV conducted without sacrificing regulatory compliance or data quality strategies. Patients are assigned to pre-configured SDV regimens (focused on critical data) as they are enrolled, enabling study teams to achieve desired coverage levels. As the trial progresses, the team can make modifications at any level, without disrupting existing monitoring processes.

TSDV gives monitors instant access to SDV work required at the study, site, and subject levels. TSDV 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, giving users complete traceability of change controls and SDV plan management.

MEDIDATA EDGE TSDV SUCCESS METRIC #2: FASTER DATA CLEANING CYCLES

In a study where SDV coverage was reduced from 100% to **66%**, the **targeted monitoring approach** resulted in reducing data entry to query closure cycle times by **10 days**.

MEDIDATA EDGE TSDV ENABLES A TARGETED MONITORING APPROACH BY HELPING YOU TO:

- Focus on data elements truly critical to the overall quality of the study
- Optimize site and study team performance that can impact the success of a trial

ROBUST SUPPORT FOR YOUR RBM PROGRAM

Medidata Strategic Consulting Services can work with your organization to help realize the full potential of Medidata Edge TSDV. We offer industry-leading expertise in aligning business processes with technology while optimizing risk-based monitoring programs.

5. <https://www.fda.gov/downloads/Drugs/guidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf>

“By integrating Medidata’s solutions—which have a proven track record in the global market—into our clinical trial practices, we hope to improve the accuracy and quality of our clinical data while increasing the efficiency of new drug development processes.”

Head of Medical, Medytox

With Medidata Edge TSDV, study teams of clinical operations, data management, clinical research associates (CRA) and study managers can experience a simplified data verification process coupled with a centralized way to manage data and reporting.

Medidata Edge TSDV allows **clinical research associates (CRAs)** to perform, record, and track reduced SDV activities with the same processes and tools they use for 100% SDV. **Data managers** may pre-set TSDV at the beginning of the study to recognize when variables meet certain criteria, triggering the tool to automatically adjust SDV coverage on individual patients as the study runs. 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.

Figure 2: Medidata Edge TSDV user interface showing “verified” fields

The screenshot shows a user interface for a demographics form. At the top, there is a header with '10341021' and 'Screening' on the left, and 'Verify All Fields', 'Inactivate Page', and a settings icon on the right. Below the header is a 'Demographics' section with a 'Requires Verification' badge. The form contains several rows of data, each with a 'Verify' button. The first three rows have green checkmarks in the 'Verify' buttons, indicating they are verified. The last three rows have empty 'Verify' buttons, indicating they are not yet verified.

Field Name	Value	Verification Status
Date of Informed Consent	1 NOV 2017	Verified (Green Checkmark)
Date of Birth	20 DEC 1965	Verified (Green Checkmark)
Gender	Female	Verified (Green Checkmark)
Is the subject of childbearing potential?	No	Not Verified (Empty)
Race	White	Not Verified (Empty)
Age (YEARS)	51	Not Verified (Empty)

At the bottom of the form, there are 'Save' and 'Cancel' buttons on the left, and a checkbox labeled 'Move to next task after save' on the right.

MEDIDATA EDGE TSDV SUCCESS METRIC #3: HIGHER SITE ENROLLMENT

An analysis of over 2,000 Phase II/III trials showed that taking a **targeted monitoring approach** (enabled by TSDV) increased site enrollment by **50 percent**.

“By using Medidata Edge TSDV, the teams have seen that the quality has not suffered. They’ve actually seen that it has gotten better because it allows clinical teams to actually focus on what they need to focus on.”

Data Operations, Syneos Health

Medidata Edge TSDV helps you focus on high-value activities

When monitors are not heads down on conducting 100% SDV, their valuable time can instead be used to have more targeted communications with study sites, leading to increased efficiency and performance. Medidata Edge TSDV enables monitors to engage in high-value activities such as:

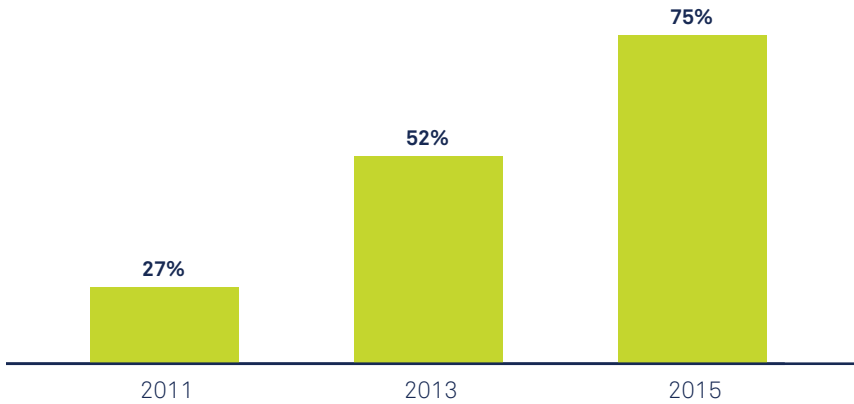
- Ensuring regulatory compliance through ongoing source data review (SDR) of study site processes
- Understanding the implication to data quality when queries are closed incorrectly
- Promoting thorough understanding of protocol to ensure adherence
- Generating discussions around improving recruitment and patient retention

Begin your RBM journey with Medidata Edge TSDV

The percentage of companies that have adopted a risk-based monitoring approach has increased from 27 percent in 2011 to 75 percent in 2015.⁶

Sponsors and CROs who value a quality-driven approach to risk management are in a much better position to make the clinical trial process more meaningful and successful for themselves as well as their study sites. Medidata Edge TSDV takes the first step toward a risk-based monitoring journey, ensuring greater focus on data elements truly critical to the overall quality of the study and ultimately optimizing both study team and site performance.

Figure 3: Tracking the adoption of RBM — Percentage of companies reporting the use of risk-based monitoring approaches



“Medidata is really knowledgeable about RBM. They knew exactly what we needed and exactly where to lead us. They helped us build our risk management plan and develop our KRIs.”

Clinical Trial Manager, TESARO

About Medidata Solutions

Medidata is leading the digital transformation of life sciences with the world’s most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: www.mdsol.com

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