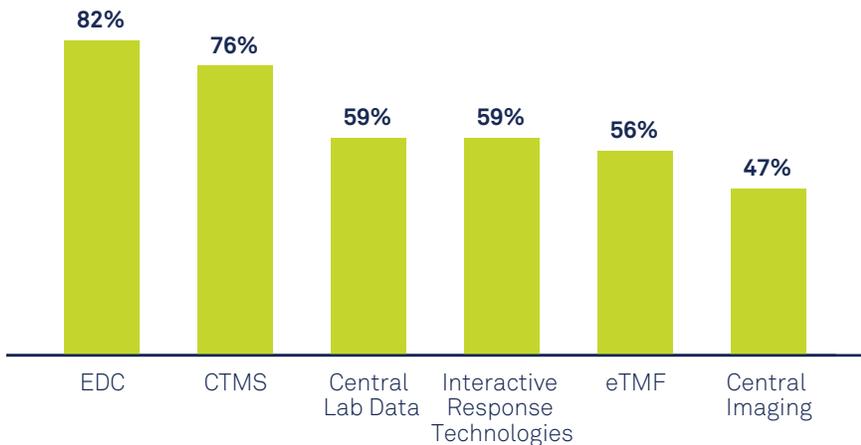


Medidata Rave TSDV (Targeted Source Data Verification)

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 reviewed³ (Figure 1), 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 RAVE 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

RAVE 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 for Tesaro, 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 Rave TSDV

Rave 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.

RAVE 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**.

RAVE 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 Rave 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 Rave 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.

Rave 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 (Figure 2). **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: Rave TSDV user interface showing “verified” fields

The screenshot shows a 'Demographics' form in the Rave TSDV interface. At the top, there are buttons for 'Verify All Fields', 'Inactivate Page', and a settings icon. Below this, a 'Requires Verification' badge is present. The form contains the following fields:

- Date of Informed Consent:** 1 NOV 2017. Status: Verified (green checkmark).
- Date of Birth:** 20 DEC 1965. Status: Verified (green checkmark).
- Gender:** Female. Status: Verified (green checkmark).
- Is the subject of childbearing potential?:** No. Status: Not Verified (grey checkmark).
- Race:** White. Status: Not Verified (grey checkmark).
- Age (YEARS):** 51. Status: Not Verified (grey checkmark).

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

RAVE 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 Rave 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

Rave 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. Rave TSDV enables monitors to engage in high-value activities such as:

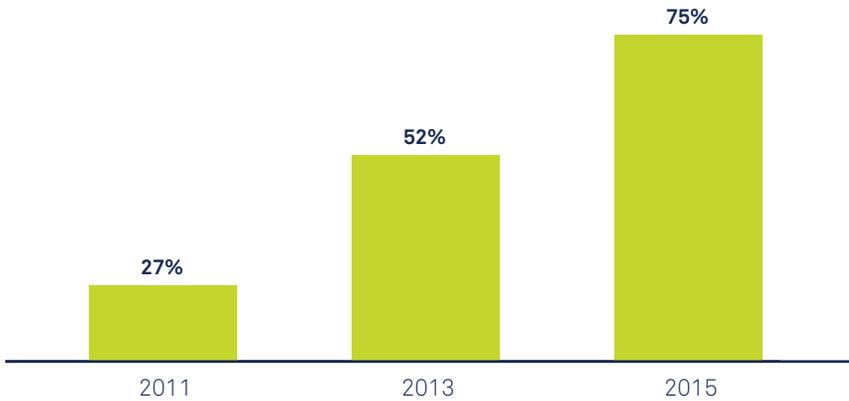
- Ensuring regulatory compliance through ongoing source data review (SDR) of study site processes
- Understanding the implication to data quality when queries are closed incorrectly
- Promoting thorough understanding of protocol to ensure adherence
- Generating discussions around improving recruitment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

Begin your RBM journey with Rave 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 (Fig. 3)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. Rave 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

The Platform of Choice for Clinical Research

The Medidata Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords and excel sheets, you are now on a truly unified platform.

About Medidata

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 the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,200 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life sciences:

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Medidata Rave Clinical Cloud

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