

Nordic Bioscience Targets 20 Percent SDV with Risk-Based Monitoring to Streamline Clinical Trial Execution

Risk-Based Monitoring Implementation

In piloting risk-based monitoring, Nordic identified critical data points that require 100 percent SDV:

- Informed consent
- Inclusion/Exclusion criteria
- Adverse and serious adverse events
- Drug accountability
- Safety
- Primary endpoints
- Efficacy

For other data points, centralized monitoring strategy is employed to identify emerging risks, track key performance indicators (KPIs) and guide SDV level.

The Challenge

Recently, Nordic Bioscience, one of the fastest-growing biotech companies in Europe, realized that it was outgrowing its homegrown electronic data capture (EDC) system. The company determined that maintaining its in-house EDC system would require significant resources that would be better spent serving its mission of being the reliable partner of doctors and pharmacists. Adopting an external EDC solution would enable it to focus its resources on bringing innovative drugs to market.

Nordic was already a pioneer in utilizing reduced source document verification (SDV), routinely applying 50 percent SDV in most of its clinical trials. However, Nordic's teams were burdened by a highly manual process: once subjects were classified as requiring SDV, records were color-coded in spreadsheets that monitors used to manually guide who and what data to verify. In addition, Nordic faced a bigger challenge of ensuring that the monitors executed SDV according to the plan. This burdensome manual process did not support Nordic's aspirations to capitalize on recent regulatory guidance in risk-based monitoring. Moving from reduced monitoring to true risk-based monitoring could enable Nordic to further reduce its SDV to 15–20 percent, which could yield significant cost savings while increasing data quality in compliance with FDA's new guidelines on risk-based monitoring.

The Solution

Nordic chose Medidata Rave EDC as the best EDC solution to achieve its goals. While exploring Rave EDC, Nordic identified that it could also benefit from Medidata Rave TSDV (Targeted Source Data Verification) solution to streamline its reduced SDV process and enable a true risk-based site monitoring process. Nordic chose Rave TSDV for its ability to:

- Execute an auditable and compliant targeted SDV strategy;
- Set up and track targeted SDV within the Rave EDC system; and
- Support different targeted SDV models for individual studies and sites.

With no process change required, Nordic smoothly implemented Rave TSDV to supplement its manual practices. The initial success in streamlining reduced SDV process propelled Nordic to move toward true risk-based monitoring with the goal of further reducing SDV to the 15–20 percent range.

Business Impact

Nordic adopted Rave TSDV to streamline reduced SDV in a global study – over

40 sites spanning Eastern Europe, Asia, Latin America and the United States. Within that study, Nordic piloted a risk-based monitoring approach in Denmark, using a centralized monitoring strategy that identified emerging trends and potential high-risk areas. Powered by the power of Rave TSDV, Nordic could easily make real-time adjustments to SDV requirements, prospectively or retrospectively, at the geography, site or subject level. With positive pilot experience, Nordic has great hopes for its risk-based monitoring:

- **Streamlined SDV Execution, Tracking and Reporting**

“Within one week of having Rave TSDV up and running, we immediately saw the benefits of replacing spreadsheets in our monitoring practices. With that alone, it’s already a big success,” said Jeppe Ragnar Andersen, head of clinical development at Nordic. Eliminating the manual comparison, tracking and reporting in SDV execution not only improved efficiency of both data managers and monitors, but also eliminated the human errors inherent in manual processes.

- **Reduced Monitoring Costs with Risk-based Practice**

Nordic expects to further reduce its SDV coverage from today’s 50 percent to its target of 15–20 percent by fully leveraging risk-based SDV. This has potential to realize millions of dollars in cost savings per study. Nordic can now dynamically adjust SDV requirements mid-study based on identified risks – the heart of risk-based monitoring – which was nearly impossible in its previous spreadsheet-based practices.

- **Improved Data Quality**

Nordic also expects to improve data quality with risk-based monitoring enabled by Rave TSDV. “If you focus on everything, you don’t focus on anything. Monitors want to look at what matters,” said Andersen. Monitors can concentrate on the data elements truly critical to the overall quality of the study. In addition, sparing monitors from time-consuming SDV activities allows them to engage in more value-added on-site activities, such as protocol training. By proactively addressing high-risk areas, Nordic can eliminate potential quality issues well before they happen, improving the overall quality of the study.

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, you are now on a truly unified platform.

About Nordic Bioscience

Nordic Bioscience Clinical Development (NBCD) seeks to achieve excellence and continuously improve performance in clinical trials leading to better drugs, faster to the market and improved patient benefit around the world. Our extensive operational and scientific experience in osteoporosis, osteoarthritis and diabetes provides clients with in-depth know-how and superior management for all levels of the clinical trial process. With a strong commitment to protect and improve patient safety, NBCD works with high-enrolling, dedicated clinical trial centers to deliver rapid and quality recruitment.

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