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

The Challenge

Nordic Bioscience (Nordic), an innovative biotech company headquartered 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 Rave EDC to achieve its goals. While exploring Rave EDC, Nordic identified that it could also benefit from Rave Targeted Source Data Verification (TSDV) 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 Rave EDC; 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.

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.

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 flexibility 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

About NORDIC BIOSCIENCE

Nordic Bioscience is the leading expert in extracellular matrix (ECM) research with 30+ years of experience in biomarker development, pre-clinical and clinical research. With more than 575 peer reviewed publications, our science-driven approach has been the evolving force behind our decades of success.

Through its Protein Fingerprint technology, Nordic Bioscience identifies fragments of the ECM that are released from affected tissues and develop blood-based biomarker assays to quantify disease activity with the aim of precision medicine.

Nordic Bioscience is headquartered in Herlev, Denmark, with a high-quality standard laboratory, running clinical trials under Good Clinical Laboratory Practice (GCLP) with accreditation by the College of American Pathologists (CAP) and ISO9001 certificate. Nordic Bioscience employs more than 180 people who are dedicated to improving patient management for a broad range of therapeutic areas including Hepatology, Rheumatology, Dermatology, Oncology, Gastroenterology, Respiratory, Neurodegenerative and Cardiovascular diseases.

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