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

The Challenge

In 2010, 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® as the best EDC solution to achieve its goals. While exploring Rave, Nordic identified that it could also benefit from Medidata's Targeted SDV solution to streamline its reduced SDV process and enable a true risk-based site monitoring process. Nordic chose Targeted SDV for its ability to:

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

With no process change required, Nordic smoothly implemented Targeted SDV 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 Targeted SDV 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 Targeted SDV, 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 Targeted SDV 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 Targeted SDV. "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 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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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.

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