

Nordic Biotech realized that it was outgrowing its legacy electronic data capture

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

or 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

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