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 signi□cant 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 veri□cation (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 classi□ed as requiring SDV, records were color-coded in spss:eqlsnhyha(eqls moni t)10 opss: ygleqls da(eqlsad t)10 oyvweifyMn adw,(Nor)18 (di fw)5 ac7ed huahIngleqls the moni tecu tdg SDVringyt

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