INC Research Leads the Way for Risk-Based Monitoring Using Medidata Targeted SDV Solution

The Challenge

INC Research, a leading global contract research organization (CRO), Medidata Services Partner and long-time user of the industry-leading Medidata Rave® electronic data capture (EDC) and clinical data management (CDM) system, implemented Rave's targeted source document verification (SDV) solution as part of their larger risk-based monitoring strategy to bring greater efficiencies to clinical trials and sponsors. With some sponsors aiming for SDV rates as low as 25–30 percent along with visibility into site performance – such as protocol deviation rates, time to enter data from patient visit and discrepancy rates – INC Research saw the opportunity for studies to be conducted more cost-effectively, while still focusing on quality.

The Solution

Initially, INC Research focused its use of Rave Targeted SDV on several large, rapidly recruiting Phase III trials across several therapeutic areas. With that experience, INC Research expects up to 30–40 percent of the trials they conduct to be prime candidates for the benefits brought by a targeted SDV approach in conjunction with risk-based monitoring.

Claire Keith-Lucas, senior director of data management for INC Research, explained the key to realizing the benefits of targeted SDV:

"Invest time in creating targeted SDV plans from the beginning in parallel with designing the case report form (CRF). These need to include which data elements are to be verified on which percentage of patients, and also quite detailed rules about how you would then dynamically manage SDV, up or down, in response to pre-determined parameters and thresholds.

Participation from the clinical and monitoring team, biostatistics, data management, safety and any other key stakeholders is needed. The objective is to look at data in a completely new way, not just relying on SDV to ensure data quality, which will also show savings in time and assets."

Best Practices Defined

In piloting risk-based monitoring, INC Research established a typical SDV approach to ensure its success.

SDV tiers per site:

- First two patients at 100 percent SDV
- Next eight patients at very minimal SDV, select CRF pages
- Next eight patients at no SDV

Performance indicators used in risk-based monitoring to dynamically manage SDV level include:

- Missing data from previous SDV
- Site turnover
- Manual query rates

Using Medidata Rave Targeted SDV, an innovative solution within the Medidata Clinical Cloud, the plan can be laid out and implemented by the clinical research associates (CRAs) at the sites. Most importantly, the plan can then be monitored, tracked and amended as needed with the benefit of providing an auditable record for regulatory compliance.

Business Impact

Other current EDC systems are only designed to support 100 percent SDV, limiting the flexibility for adjusting SDV during the conduct of a trial with cost and quality implications. By having a fully integrated EDC-based solution – not just integrated, but actually part of the EDC platform – full or partial SDV plans can be completely implemented within Rave in a scalable manner with the flexibility to handle emergent conditions.

Sites can be grouped to provide variable levels of SDV with no additional system integration in a self-contained solution where the level of SDV can be increased or decreased in response to site data quality, site enrollment and study conduct concerns. Importantly, all of this is implemented in a compliant manner with full audit trail. Implementing the targeted SDV plan through Medidata's solution becomes the easy part, allowing the clinical team to focus on the hard part of writing the plan – all the while reducing monitor visits.

About INC Research

INC Research is a therapeutically focused contract research organization with a reputation for conducting global clinical development programs of the highest integrity. Pharmaceutical and biotechnology companies look to INC Research for a complete range of customized Phase I–IV programs in therapeutic areas of specialty, and in innovative pediatric and women's health trials. The INC Research Trusted Process® methodology and therapeutic foresight lead customers to more confident, better-informed drug and device development decisions.

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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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