Frenova®
Renal Research

Case Study: Maximizing Site Performance

From Problematic to Top Performing: Frenova's Site Strategy for Efficient Clinical Research

Background

Today, the conduct of clinical research can be especially complex for physicians in their day-to-day practice. The transition from providing clinical care to clinical care plus clinical research requires a new set of skills similar to those of running a business.

When conducting clinical research, sites need to be able to navigate and manage contracts, budgets, new software and training, patient recruitment, enrollment and retention, as well as multiple levels of government and private-payer policy to determine which study treatments and services are (and are not) eligible for insurance coverage. The proliferation of multiple technologies is also challenging with a typical site using multiple systems for data collection.

All these factors — combined with increasingly stringent regulatory and administrative requirements — require investigator sites to think differently about clinical study processes. To conduct clinical trials cost-effectively, clinical research organizations can play a unique role in helping investigators transition to research, reducing the time for sites to successfully enroll patients for the study.

Challenges

An investigator site faced numerous challenges managing its studies and experienced ongoing issues with quality, finance, communication and operations. The site staff was overloaded and without standard operating procedures (SOPs), handling every task differently. In addition, the site had undergone several FDA audits within a short period of time, and issues with oversight and data quality were identified.

The lack of formalized procedures extended across all functions at the site. Without dedicated financial personnel, the site failed to collect study revenues. Employees handled office management and patient visit scheduling absent of an overarching management structure. The lack of basic technologies — such as centralized email and voicemail — made effective communications difficult and conveyed an image of unresponsiveness.

The site was committed to the value of clinical research to provide long-term solutions to CKD and ESRD and welcomed guidance to improve its operations. Lacking clearly delineated job responsibilities, the site needed Frenova's help and direction to resolve these issues and improve efficiencies to reestablish its standing as a high-performing clinical research site.

Solutions

Upon request from the site to improve its overall efficiency and functionality, and to gain a clear understanding of site operations, the Frenova team visited the site for several days to observe processes and interactions among the research staff. A financial analyst examined the site's records to determine the extent of uncollected revenue. From these observations, the Frenova team created a corrective action plan for site improvement.

Quality

- Frenova shared its site quality management system to give the site a jump start with a comprehensive and proven set of tools to efficiently conduct research in compliance with GCP.
- Regular quality assurance and best practices reviews were performed to prevent future issues.
- Relevant SOPs were developed to ensure compliance and support operations.

Finance and Trial Logistics

- A clinical trial management system (CTMS) was deployed to track schedules, patient records, visits, financial information, payments and invoices.
- Frenova developed and implemented a plan to improve the site's revenue stream by ensuring that the site received payment for all study activity and invoiceable line items and maintained a consistent pace of enrollment throughout the year for a variety of studies.

Technology

- A synchronized calendar system was implemented that improved patient scheduling.
- Voicemail, out-of-office notifications and forwarding of messages to cell phones facilitated a response within 24 hours and improved responsiveness to sponsors.
- A centralized email system was deployed to improve office staff and office staff-to-sponsor communications.

Staffing

- Frenova helped the site hire an appropriately skilled and experienced research site manager to implement consistent processes, manage the study team and proactively solve any issues that arose.
- Frenova trained all staff and developed a process to ensure training records were maintained and up to date.
- The Ontario Protocol Assessment Level was implemented to help the study team quantify clinical trial activity based on study protocol complexity so the site could objectively and effectively manage staffing.
- Job descriptions were updated to establish hierarchy in titles and responsibilities (such as research assistant 1 or 2 and research coordinator 1, 2 or 3) and clarify roles and responsibilities.

Results

Within six months of collaborating with Frenova and implementing the corrective action plan, the site experienced tangible results. The new research site manager coordinated the study team scheduling and established their priorities and focus in alignment with the site's commitment to clinical research. SOPs were deployed and institutionalized for efficient and consistent processing of patients, documents and communications. The site's new technology implementations improved internal and external communications and workload scheduling. Revenue collection activities also improved significantly. All previous quality issues were addressed and processes were in place to prevent recurrence.

The improved day-to-day operations helped the site rebuild its reputation with patients and sponsors. Overall, the site's efficiency and productivity improved dramatically, allowing it to increase the number and variety of clinical studies conducted and enroll patients faster.

Conclusion

By creating a corrective action plan and formalizing accountability, Frenova helped the site develop a better workflow and improve its long-term productivity. Frenova also employed these best practices at many of the other investigator sites. The practices include creating an infrastructure early (including implementation of a CTMS), developing financial plans for managing the trial, defining job roles and conducting training across all areas such as regulations, research and financials. Serving in a consultative role, Frenova empowers principal investigators and the entire research team to work together to maximize site performance and success.

> **The site discussed in this case study is now a top-performing clinical research site.**

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About Frenova Renal Research

Frenova is a provider of clinical research and site management services with over 20 years of experience centered on renal research and the unique needs of renal patients. Whether you want to conduct a renal-related study, seek guidance on your protocol design or access to patients around the world, Frenova provides the managed investigator sites, patients and data your clinical trial demands.

Frenova, a company of Fresenius Medical Care, manages the world's largest network of renal research assets, including over 550 principal investigators at more than 350 sites around the world. We also offer access to hundreds of thousands of patients with kidney disease including CKD and ESRD. By pairing this extensive network with our clinical development and bioinformatics database and capabilities, Frenova easily determines protocol feasibility, drives patient recruitment/enrollment strategies and identifies the right sites for your study. We develop strategies that shorten your path to study completion no matter the scope of your needs.