Case Study: Rescuing Troubled Sites

FRENOVA'S SITE MANAGEMENT EXPERTISE GETS SITES — AND STUDIES — BACK ON TRACK

BACKGROUND

The demand for physicians to join clinical research is far greater than what is being supplied, which is why it is encouraging to see increasingly more physicians and other health care professionals recognize clinical research as a viable means to expand one's practice and advance medical knowledge. Whether for altruistic or commercial reasons, the clinical research site industry is growing.

However, newly minted sites are sometimes, by definition, inexperienced in clinical research and may not have achieved a sufficient level of sensitivity to the wealth of regulations involved. When combined with oversight by a clinical research organization (CRO) whose monitors lack experience in renal research and the complexities of dialysis patients and their care, problems can quickly arise.

In this case study, we describe a clinical study managed by another CRO, and how Frenova identified and corrected the consequences of poor monitoring by a procession of inexperienced CRAs.

CHALLENGES

A nephrologist principal investigator (PI) died unexpectedly and the site's lead research coordinator stepped down soon thereafter. The sub-investigator at the site then took over as PI, and Frenova offered to send an interim site coordinator until the site could find its own permanent resource. With the sponsor's approval, Frenova dispatched an experienced coordinator to keep the site on track. This coordinator was also an experienced CRA with an intimate understanding of the renal patient population.

SOLUTION

Immediately upon arriving at the site, Frenova's site coordinator led a thorough review of study documentation and completed a gap analysis. He soon identified many issues that required attention and corrective action that had gone unnoticed by the CRO's changing roster of monitors. The main reason these issues were missed stemmed from the fact that the CRAs lacked experience in the renal patient population and therefore overlooked key data elements of nephrology patient care that were required for the study. In other words, the CRAs didn't know what they didn't know.

The sponsor and the CRO were notified of Frenova's findings and were reminded of how critical a role specific therapeutic area experience plays in renal studies. Frenova provided training to the site staff, including the replacement coordinator, with a specific emphasis on avoiding the consequences of mediocre monitoring by CRAs insufficiently experienced in renal research.

RESULTS

In only a couple of weeks, Frenova's corrective actions put the site on track for success. With training and with more rigorous monitoring and documentation processes put in place, the study continued at the site without incident and the site is still active today.

CONCLUSION

Due to inadequate experience and a lack of understanding and intimacy with this medically complex patient population, the CRO's monitors had been unable to identify critical issues. The Frenova interim site coordinator, with experience caring for the dialysis patient population, was able to quickly identify the issues that had been missed.

By quickly identifying issues and implementing appropriate corrective actions, Frenova's experienced site coordinator was able to protect the study's integrity. The CRO's monitors, due to both turnover and inexperience, could not do the same.

With their depth and breadth of experience in renal research, Frenova's CRAs and other in-house renal research experts have the knowledge and capabilities to help investigators and site staff conduct clinical studies in patients with chronic kidney disease, including end stage renal disease. Frenova provides clinical research services that drive best practices.

ABOUT FRENOVA RENAL RESEARCH

Frenova is the world's only drug and medical device contract clinical development services provider dedicated exclusively to renal research. As a Fresenius Medical Care North America company, Frenova manages a networked system of clinical research assets and resources including over 450 principal investigators at more than 260 sites, representing 160 medical practices and nearly 700 dialysis clinics. Frenova manages clinical trials in kidney disease and its adjacent medical conditions. When you need to conduct a complete renal clinical program, trust the partner that's completely renal ***— Frenova Renal Research.***

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