Frenova Renal Research

CLINICAL DEVELOPMENT | RENAL SITE NETWORK | BIOINFORMATICS & ANALYTICS

Overcoming Barriers to Enrolling Renal Patients in Clinical Trials: Q&A With Kurt Mussina

Kurt Mussina, general manager of Frenova Renal Research and vice president of Clinical Studies Operations for Fresenius Medical Care North America recently discussed the barriers to enrolling renal patients in clinical trials that are investigating potential new pharmaceuticals and medical devices.

Q: SLOW PATIENT ENROLLMENT IS TYPICALLY THE LEADING REASON WHY MOST CLINICAL TRIALS ARE NOT COMPLETED ON TIME. WHY IS THIS SO CHALLENGING?

A: Patient enrollment accounts for between 35 and 50 percent of a trial's timeline. Study protocols have become quite complex in recent years and often have rather narrow eligibility criteria for who can be included.

While many patients believe research is a good thing, only a small number of people with kidney disease are participating in trials. We have the challenge of making eligible patients aware of the study and then educating them about clinical research and why it's important.

We also work hard to help design trials that reduce any undue burden on our patients. For example, a trial that requires dialysis patients to come in for a study visit on an "off" day is a major concern for a patient who already must attend treatment three days a week.

That's why at Frenova, we look at potential study protocols and help drug and medical device companies better understand the impact of the study on our patient population. We help find the operational weaknesses that would make a study difficult to execute. The research has to be both patient-centric and clinic-centric, working for both our patients as well as the care teams at the dialysis center itself.

Q: HOW DO PATIENTS BENEFIT FROM PARTICIPATING IN CLINICAL TRIALS? WHAT DO PATIENTS TELL YOU ABOUT THEIR EXPERIENCE?

A: There is a level of satisfaction in participating in something that may help both yourself and others. Many patients receive a stipend to cover their travel and time, which can be beneficial for those individuals who may be unable to work full-time because of their disease.

A lot of patients will talk about what they see as an extra level of attention. Not only do patients say they have the clinic staff looking after them, but also close engagement and regular communication with the research team. For some, there may be a real-world benefit to being administered a potentially better therapy, perhaps one that is in oral form versus an injection or a treatment with better safety and efficacy.

Q: CAN YOU PROVIDE AN EXAMPLE OF HOW FRENOVA HELPED ACCELERATE THE APPROVAL OF A NEW DRUG THAT BENEFITED RENAL PATIENTS?

A: Clinical trials are designed to help us understand the safety and efficacy of any new drug or medical device that is undergoing the regulatory approval process on the way to market. Just recently, we managed trials that helped lead to the approval of a new biosimilar drug for anemia. These types of drugs have the potential to improve competition and lower health care costs for everyone. A number of studies underway right now are also looking at whether oral medications for anemia can replace injections.

Q: F1RST UP®, YOUR EXCLUSIVE ALLIANCE OF 24 TRIAL SITES, HAS SHOWN FASTER START UP TIMES FOR NEW TRIALS AND FASTER PATIENT ENROLLMENT. HOW HAVE YOU DONE THAT?

A: The F1RST Up (**F**renova **R**apid **ST**art **U**p) sites have master agreements in place so that for every new study that comes along, we negotiate a much simpler statement of work. This allows us to execute new agreements much more quickly and efficiently.

The sites that are part of F1RST Up also have been selected because they are highly dedicated to research and have an existing infrastructure in place. We work closely with these sites every day, dedicating our own resources to build that relationship. We have a group of site support specialists who we regularly deploy to research sites or clinics to address any issues that may come up during a trial.

Within F1RST Up, Frenova runs its site management organization (SMO) business. We recently added a fifth site to our SMO, and this is an exciting development in helping us directly participate in new clinical trials. These SMO sites are staffed by Frenova employees, which typically leads to improved relationships between the research staff and dialysis center staff, thereby better facilitating research and Frenova's mission to advance the science of renal therapies for our patients.

Q: WHAT CAN FRENOVA DO TO BETTER ENGAGE PATIENTS AND STAFF AT DIALYSIS CENTERS TO EDUCATE THEM ABOUT THE BENEFITS AND IMPORTANCE OF PARTICIPATING IN CLINICAL TRIALS?

A: We have started putting together more patient-focused materials that help educate patients about the benefits of participating in clinical trials. I think we have a tremendous opportunity to do much more around educating all patients about the importance of clinical research so that more people participate in opportunities that can improve the lives of all renal patients.

ABOUT KURT MUSSINA

Chemist, executive and entrepreneur, Kurt Mussina, leads FMCNA's contract clinical research services business, including a world-class network of more than 450 principal investigators across 260 research sites. A former analytical chemist and research and development scientist for Teva and Novartis Pharmaceuticals, he holds a bachelor's degree in chemistry from Montclair State University and an MBA from the Fuqua School of Business at Duke University.

Additional Resources:

Insight:
F1RST Up®: Accelerating Clinical Trial Start-Up

Insight:
Advancing Medicine by Routinely Offering Clinical Research to Patients

Patient Testimonial:

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