CASE STUDY: FRANCISCAN HEALTH

Re-Imagining the Research Business Model & Adapting to the Evolving Clinical Trial Landscape

The clinical trial industry is seeing an increase in complexity, including study design, basket trials, adaptive design and more administrative work to address protocol amendments. Adapting to the evolving landscape, Kathleen Kioussopoulos and the Franciscan Health team have re-imagined their multi-center research program. They leverage WCG services, including institutional review board (IRB) and institutional biosafety committee (IBC) as well as Study Start-Up services: coverage analysis, budget development, contract redline and negotiation – with the flexibility to add services as needed. Kathy shares her experiences redefining their research business model.

COVID-19 RESEARCH OPPORTUNITIES

"Our oncology research program operates as a hub-and-spoke model," notes Kathy, "with our central oncology research hub based in Indianapolis.
In 2020, I saw an evolution in our organization's understanding of research because of the pandemic. As therapies were introduced under emergency or compassionate use, our system looked to the research staff to make these therapies available. As a non-academic center, we're not usually first in line for trials, but I felt involvement in COVID-19 studies was important. The landscape was quite competitive; however, our relationship with WCG and leveraging their Managed Research Solutions team allowed us access to these trials.

INFRASTRUCTURE & STANDARDIZATION

"Our challenges included establishing a common infrastructure across an extensive health system with legacy departments embedded in historical methods. We created a system-wide program and implemented system-wide standards, partnering with WCG for most of our IRB and institutional biosafety committee (IBC) projects. This approach has created a common standard, meeting our specific requirements as a Catholic health system. Our consent form now looks the same in Northern Indiana, Western Indiana or Indianapolis.
"Over 20 years, I have seen many changes in clinical research. Administrative burdens are being shifted to sites, and trials are increasingly complex in terms of design, number of patient

visits and components. We also face Medicare compliance and billing risks. Ethically, we don't want our patients to experience financial harm from participating in research; we are here to help them obtain treatment access. In response, we pivoted to partner for many of our administrative services, which allow standards and cost containment across our system. We wouldn't have been able to hire the staff needed to conduct the trial volumes we have."

STUDY START-UP & PARALLEL WORKFLOW

"Study initiation is a key pain point for clinical research, with workflow having a significant impact. Our target is 30 days, but many trial components are outside of our control (e.g., third-party involvement), so we use parallel workflows whenever possible. WCG allows us to consistently standardize our approach and offload administrative burden. For example, we don't have to carry the staff costs to negotiate budgets and perform coverage analysis. If we suddenly need surge capacity to look at 15 studies, we send those to WCG, and the work takes place efficiently in parallel. We also have a standard fee schedule as a part of our pricing model."

COVERAGE ANALYSIS, BUDGET DEVELOPMENT, CONTRACT REDLINE & NEGOTIATION

"I have learned over time that it's important to get your costs covered and be adequately budgeted. A coverage analysis should provide enough information to determine if this is the right trial between feasibility and budget review. Having a defined fee schedule allows us to show sponsors the basis for our price. Also, the way trials are budgeted, typically there's an appropriation amount. Just because you have appropriation doesn't mean that you shouldn't itemize as part of an internal discussion. It's vital to have a systematic manner for dividing funds to cover expenses. "Contract negotiation is critical to hitting our trial turnaround time goals. We're seeing a shift in contract terms including EU-based cybersecurity requirements. There are also common negotiation sections in subject injury and indemnification. One of the most significant pain points for sites is the concept of budget holdbacks for meeting study milestones, along with term and termination. Many agreements are one-sided, but WCG helped us to develop a playbook to make the terms bilateral (e.g., confidentiality).

"During negotiation, we also work to understand the patient population and protocol. We see hundreds of patients a day in our clinics. How do we know which patients have which diseases? Is it the right trial for us? Doing our homework upfront by looking at our patient population, diseases and statistics is important, and allows us to reach first patient in faster."

STAFFING AND STRATEGIC PARTNERSHIP

"It takes time to find good people, and they are a valuable resource. Keeping a qualified

coordinator in the clinical research setting is challenging, which is why we are mindful as we take on trials. It's not about quantity; it's about quality and making sure that we have the staff to do proper data entry. These data are vital to sponsors and trial outcomes.

"Our organization has partnered with WCG IRB for many years, and we find that embedded standards are beneficial. We set the standards, and our partners help us implement those standards – raising visibility for research across the organization, gaining leadership buy-in and ensuring that we provide a consistent product to sponsors. When sponsors come to our site, they expect rapid turnaround, and our WCG partnership helps us deliver

Kathleen Kioussopoulos, MBA

Director, Research Administration, Franciscan Alliance

The Franciscan Alliance operates 14 hospitals in Illinois and Indiana as Franciscan Health. Kathy is Director of Research Administration, leading research efforts across 14 hospitals and physician practices. She is an active member of the Association of Clinical Research Professionals and was a charter member of the Clinical Trial Best Practices Study Coordinator Advisory Committee for the Duke Clinical Research Institute.

WCG Managed Research Solutions is a suite of flexible services for research institutions and sites that optimize performance to solve the right challenge at the right time. For more information, visit www.wcgclinical.com/optimize

For more information, please visit www.wcgclinical.com/optimize