Propelled by Necessity, Anchored by the Status Quo: Sites NOW November Session Dives into the Uncharted Waters of Decentralized Trials

November 2020

Amanda Rangel
Executive Vice President, Virtual Trial Solutions
VirTrial

"Necessity is the mother of invention." When it comes to decentralized trials in 2020 and 2021, this tried-and-true proverb holds fast. While decentralized trials existed prior to 2020, the COVID-19 pandemic converted them from a clinical curiosity and patient luxury into an absolute necessity. A safety-centric industry had to move – fast. In this SCRS Sites NOW session, clinical research leaders compared observations of a trial landscape that had, just like the rest of the world, "gone remote."

Amanda Rangel, MS, CRRC, EVP of Virtual Trial Solutions at VirTrial, discussed the urgent need for decentralized trials, defined by the FDA as studies executed through telemedicine and local or mobile healthcare providers using processes that differ from the traditional healthcare model. According to Rangel, decentralized trials started years ago as a contingency plan, not protocol. They were viewed as increasingly risky due to the inability of the investigators and coordinators to control certain aspects of the study and maintain patient monitoring. The global pandemic made the inverse true: what was once considered threatening to trial success had become one of the only options.

This change is a positive one as the benefits of decentralized trials are numerous. They optimize real-time data collection, improve enrollment by relieving the patient's burden, expand access which increases diversity, and catalyze higher retention. Rangel disclosed that 70 percent of patients live more than two hours away from a clinical research site and there is an average 30 percent dropout rate in phase three of a traditional clinical research trial. Decentralized trials effectively extinguish these barriers to optimal enrollment and study completion.

While the advantages are significant, challenges still remain for sites converting to a decentralized model. For starters, there has been a lack of guidance from federal, state, and local regulators, leaving sites in the dark as to best practices and compromising acceptance of results. There is a lack of experience among investigators and coordinators who are accustomed to the more traditional model. There is also sometimes a deficiency in the ability of patients to engage with technology to provide necessary data. The ideal model, according to Rangel, is a hybrid of the traditional and decentralized models that allows for remote and in-person data capture and monitoring. The hybrid model can keep costs to the site low, promoting profitability, and foster confidence in the accuracy of the

information collected.

Post-session, clinical executives convened in breakout groups to compare experiences and project expectations. It was contemplated: what are the keys to unlocking success in a decentralized trial? “Sites and patients must be flexible and empowered,” averred one clinical executive. Another asserted that “communication must be early and frequent, amongst all stakeholders.” One participant shared that her experience as a patient in a decentralized COVID vaccine trial had given her ideas for best practices but also triggered new questions. She pondered how the site can share critical data with patients; i.e., whether they are vaccinated or not, to promote public health without compromising the study. It was clear that so long as sites can be adaptable and sponsors and service providers attentive to their needs, the potential for bringing drugs and devices to market through decentralized means is infinite.

SCRS is committed to keeping its members on the cutting edge of innovation in clinical research. To learn more, access the SCRS Digital Innovation Initiative, an educational platform where workstreams comprised of industry and site leaders learn to optimize the technology that sharpens and streamlines clinical research.

SCRS Sites NOW is a virtual discussion and content project created in response to the COVID-19 pandemic and focused on the changing landscape clinical research sites and industry partners now face. Each session is centered around a singular topic; in January, the topic was the Evolution of Patient Engagement. Attendees benefit from an opening presentation hosted by an industry leader who provides a unique perspective and meaningful metrics on the topic at hand, then break out into groups for a dynamic discussion guided by relevant queries designed to identify areas of opportunity for participants in the clinical research pipeline.

7250 Parkway Drive, Suite 405
Hanover, MD 21076

Phone: +1 410.696.5080
info@myscrs.org

SCRS
Society for Clinical Research Sites
Our Voice | Our Community | Your Success