Better Together:

3 Ways Sites, Sponsors & CROs Can Accelerate Research

The number of clinical trials hit an all-time high of 327,386 in January 2020[1] and continues to soar as drug makers seek a record amount of orphan drug designations from the U.S. Food and Drug Administration (FDA).[2] At the same time, there is intense competition for clinical trial sites, especially in the fields of oncology, neuroscience, and rare disease.

Clinical research sites face significant hurdles in meeting the demands of this new era of drug innovation. The clock is always ticking, even as trial complexity grows. The industry has a significant opportunity to improve collaboration and speed trial execution. Sites have the most to gain, especially in improving productivity and reducing delays.

Recently, leading investigators from a range of sites identified three key opportunities for improvement: communication, information sharing, and streamlining common trial processes.

1. Improve Communication to Drive Productivity

While the ability of sponsors and CROs to meet the needs of sites has progressed in recent years, most sites say there is room to improve communication,[1] especially around their day-to-day responsibilities and workloads that impact timelines.

"Sponsors don't have visibility into the many things on my plate to understand that their timelines are sometimes not achievable," said Katie Seehusen, a Regulatory Specialist with the Iowa Diabetes & Endocrinology Research Center. "I am the only Regulatory Specialist at my site, and we currently have 30 ongoing drug and device studies, with seven new studies coming soon. So it's important that I structure my time to get everything done."

Seehusen has to balance the critical deadlines of various sponsors and CROs and ultimately make difficult judgement calls about which jobs get done first. "Sometimes there just isn't enough time in the day," she said. "Just because we work at high volume, doesn't mean we have a high volume of staff."

The demand on sites to get more done, faster can be overwhelming and is partially hindered by the outsourcing model itself. "There's sometimes a big gap between the sponsor and clinical trial sites with separate companies handling labs, oversight, and so forth," said Dr. Jeff Kingsley, CEO of IACT Health. "If sites and sponsors become more strongly connected, we could better support the tremendous growth happening throughout the industry. Bridging the communication gap is critical to this."

2. Streamline Systems for Faster Information Exchange

One of the most common needs cited by researchers is streamlining information exchange with sponsors and CROs.[2] Currently, sponsors and CROs on average use four different systems to exchange trial data and documents with study partners. With the average site using a minimum of 12 different systems to collect and capture clinical study data, and each sponsor providing their own unique system to sites, the use of technology can become overwhelming.[3]

"We not only work in various systems, but also have different log-ins for the same EDC system. For example, for 10 different studies in the same system, we must manage 10 different user accounts with 10 different passwords that expire and require reset at 10 different times. In addition, our staff uses an average of six different portals that each require study-specific access," said William Chrvala, Managing Director at Mid Hudson Medical Research. "Streamlining the number of systems and how they are accessed would increase efficiency before, during, and after study visits."

Several sites noted that better information sharing could be addressed by newer cloud-based tools.[4] Administrative minutiae and lack of automation are holding sites back but this could be resolved with better technology.

Some sites also said making information sharing more efficient would enable them to focus more time and energy on other important matters, most notably training. "Research is always changing. We have a job where we constantly need to learn about what's new," said Seehusen. "I want more time to train and be better at my job."

Better training is an opportunity to improve clinical trials. Researchers want a roadmap for the right qualifications to do their job – the skills and related competencies they should have. With so many specialized roles, the industry could benefit from giving sites more ways to get credentialed and properly trained for their unique roles.

3. Simplify Operational Processes to Reduce Delays

With more study partners in the mix, trials have become increasingly complex. More people are involved in trial processes, each wanting to review and approve a site's work.

"There are many parties involved these days," said Kingsley. "Innovation can stagnate because of so many in-betweens. CROs typically prefer that all communication be filtered through them, so we often lose the emotional

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connection with sponsors. Sponsors and sites don't have much contact anymore."

Seehusen said she often finds herself dealing with many people who all need the same information. "There can often be a lot of redundant steps that cause delays. Centralizing coordination could save me hours. Multiply that across all the studies happening at any given time, and it could add up to days of improved productivity."

Payment processing is another major point of delay. "Improving speed and visibility into payment details would help eliminate a lot of back-and forth communication so we can reconcile payments more easily," added Chrvala.

Collectively Delivering Innovations to Patients

The pressure to bring specialized therapies to market quickly will only grow as the ecosystem of clinical trial stakeholders expands. Improving efficiency among study partners will enable the entire industry to better support the growing number of trials and, ultimately, speed innovative medicines to patients.

"Our biggest focus is on improving the lives of patients," Seehusen concluded. "So, if we're working at a capacity of 15 studies a year and we can get to 20 because we're working more efficiently, effectively, and collaboratively, then we can see more patients and help more people. That's really our end goal."

References

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Bree Burks
Vice President, Site Strategy
Veeva Systems