Six Practices of High Performing Clinical Research Sites

By Rachel Damrow and Lindsay McNair, MD, MPH, MSB

WCG™ WIRB COPERNICUS GROUP®

Clinical research sites have a tough, but critically important, job. We need research sites to help us develop and test new therapies, and to bring new treatments to patients—or to help provide the reliable data that stops the development of unsuccessful projects. It's rigorous and precise work, but essential to the progress of medicine—and important to the patients who want the option to participate in clinical research.

Many medical practices and clinicians explore the possibility of participating in clinical research studies. According to FDA Form 1572 filings, half of the principal investigators who participate in one study never participate in a second one.[1] Meanwhile, other investigators continue to add studies and build successful clinical research teams within their practices. Those active, organized sites are essential to support the conduct of clinical trials. So, what are the things that high-performing clinical research sites do that make sponsors return to them again and again?

1. Invest in infrastructure

While a medical practice that is participating in its first clinical trial may be cautious about how many resources to allocate towards the preparation required to conduct clinical research, it's essential to recognize that clinical research and medical practice are fundamentally different. True preparation for research requires staff training, a realistic assessment of the tasks and associated human resources necessary to conduct research, and the commitment to maintain those resources for the duration of the study. High-performing sites have staff with protected time dedicated to research, which in busier sites means full-time research staff.

2. Hire clinical research coordinators (CRCs) with strong management and interpersonal skills

The clinical research coordinator (CRC) will often make or break a site's performance in a study. The most successful coordinators are those with strong management skills who thrive in a multitasking environment because they will take an active rather than passive role in managing research studies. Few things are more frustrating than a site team that provides updates that say, "We submitted the protocol for review and there's nothing we can do but wait," as weeks go by. Sponsors want to work with sites that take an active role in managing the progress of their studies and control timelines whenever possible. Sites can take active steps to keep studies moving forward, such as insist on the use of a central Institutional Review Board (IRB) for a predictable response time. Strong interpersonal skills are critical to providing research participants with a positive experience during their study participation. Effective communication with study team members, including the sponsor and partners providing additional support and services, will also lead to the constructive collaboration that is a characteristic of all successful sites.

3. Use data and information to support research activities

Too often, when asked how many potential subjects they will see who meet study eligibility criteria, sites will make an educated guess based on thinking about who comes to the practice for treatment. Sponsors have learned that these guesses are rarely accurate. Site teams should work within their institution or practice to determine how they will identify and reach out to patients who may be potential research participants well before the enrollment period starts. Sites can also ask what resources the sponsor can provide to sites, and engage with those resources at study launch to maximize enrollment. Sponsors have the ability, and motivation, to provide sites with a variety of resources (such as dedicated enrollment assistants), that can support the site in:

- using diagnostic codes to search medical records for potential participants (with appropriate HIPAA approvals or waivers, if necessary).
- identifying potential sources of patient referrals within the community.
- engaging with patient advocates and support groups.

4. Be open to collaboration and new ideas

The most frustrating response to suggestions from the sponsor's study team is, "this is the way we've always done it." Some processes and practices are great, and have been honed over time to be efficient and successful. But many practices are ingrained due to habit or ease of use, and it's time to entertain new ideas to improve and accelerate study enrollment. Sponsors are well positioned to support clinical sites with new ideas for study enrollment. For example, many now provide temporary enrollment assistants who add resource support during the peak times of study activity. Sites who are open to new ideas and new collaborations take advantage of the resources offered to them. Experienced sites also ask sponsors for what they need—sponsors are often happy to provide the additional support to keep a study on track.

5. Don't overpromise

Multi-center (and multi-national) clinical trials often involve dozens of research vendors and partners, regulatory agencies and submissions, and oversight committees. When sponsors plan study timelines and resource projections across an entire study, they want to base their project plans on assumptions that are as accurate as possible. At the start of a clinical study, sites are asked to estimate how many subjects they will enroll, and 68% of sites fail to meet their projected enrollment target.[2] If a site estimates that they will screen 35 patients and enroll 25 participants over six

months, that's great- but if that site ends up screening 10 patients and enrolling 7 participants in six months, they're not going to rank high on the list for future studies. It's not solely because sponsors want the highest enrolling sites; it's also because the inaccuracy of the projections impacts the entire study. To get the necessary sample size, another site will have to enroll even more participants, or the study timeline gets pushed out.

Similar considerations are made for meeting important study deadlines. When study data needs to be entered and cleaned due to a database lock for an interim analysis of the study data, one site missing the deadline because the staff doesn't have time to answer data queries holds up the entire study. A sponsor would rather have a site that makes realistic projections about their ability to enroll participants and meet study timelines (or asks for assistance when necessary), than a site that overpromises and doesn't deliver, even if both sites end up with the same enrollment and timing.

6. Recognize that your site is part of a larger team

If you've ever seen the project plan for a multi-center study, you have an idea of the complexities and inter-dependencies of managing a multi-center clinical trial. Although some sponsors facilitate and encourage sites to communicate with each other, it's not uncommon to only have direct communication from the site monitor. This can make it hard to remember that your site is part of the larger effort and part of a giant team that includes study managers, medical monitors, partners who provide study drug and randomization systems, the IRB, and safety monitoring committees—all doing their part to keep things running smoothly and provide answers to the study questions in a scientifically-rigorous and ethical way.

Participating in clinical trials as a research site can be difficult, especially when sites are not prepared for the needs of research studies, research participants, or the ways in which research differs from the practice of clinical medicine. But research participation is also a critically important task which allows medical practices to offer investigational options to current patients while contributing to the development of medications that future generations will rely on as well. Implementing these six practices of successful clinical research sites may seem like more effort for the site team, but it can make the difference for a positive experience and a productive future in clinical research.

References

1. K Getz, C Brown, S Stergiopoulos, C Beltre. Baseline Assessment of a Global Clinical Investigator Landscape Poised for Structural Change. Therapeutic Innovation & Regulatory Science. 51 (5): 575-581.

2. WCG, Data on file.

About the Authors

Rachel Damrow is Manager, Program Management at ThreeWire, a WIRB-Copernicus Group Company

Lindsay McNair, MD, MPH, MSB, is Chief Medical Officer at WIRB-Copernicus Group

WIRB-COPERNICUS GROUP
Ingenuity Lives Here

609.945.0101
www.wcgclinical.com