Avoid Enrollment Pitfalls: Find Your Best-fit Clinical Trial Sites

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Selecting the right site is the single most crucial decision you'll make about your next clinical trial. And perhaps the single most important consideration in selecting a site is whether it can make its enrollment. Many don't; in fact, 20-25 percent of all clinical studies close because they fail to meet enrollment targets.[1]

The startup process is often more complicated than either sponsors or sites anticipate. Research[2] from March 2018 finds that:

- Average time from site identification to study start-up completion is 31.4 weeks; that's a month longer than 10 years ago.
- On average, 11 percent of investigative sites initiated were never activated; what's more, that figure hasn't changed in 20 years.

For decades, CROs and sponsors have found their "best fit" sites and returned for future studies. But in the era of precision medicine and adaptive trial designs, that may not always be the best course of action. It is becoming increasingly necessary to turn to untapped resources to find potential enrollees. As research increasingly focuses on rare diseases with highly targeted patient sub-populations, the percentage of new sites is expected to increase.[3]

According to Tufts research released in March 2018, sponsors and CROs report that 28 percent of their sites are new relationships with no prior history or familiarity. Those relationships can be tricky. The overall site initiation cycle time is nearly 10 weeks longer for new sites compared to repeat or familiar ones.[4] Moreover, sites with insufficient experience are more likely to violate protocols or have low-quality data, which leads to more on-site visits and more request for clarification—even additional training. And all of that takes time and money.[5]

Finding Your Best Fit

In this environment, how do sponsors determine the best-fit sites for their studies? Much of what constitutes "best fit" is specific to the study, the patient population and similar factors, but we've identified five characteristics that apply more broadly.

A Best-fit Site Has a Strong Record of Success

Unlike what they say about securities, past performance does predict future results. A site that regularly hits its enrollment goals will likely hit them for your study. But how much do you really know about past performance of the site or the investigator?

Most sponsors rely on site-reported data. So Clinicaltrials.gov and Citeline can give you insights into whether a site has participated in studies for, say RA or Alzheimer's, but other than that it doesn't give you much to go on. Not only is the data self-reported, it's often not current.

Without the right partner, it becomes difficult to assess past performance. With the right partner, however, you have access to verified data to help you make an informed decision. For instance, WCG has been able to partner with our clients and give them the data they need. Because we have five IRB companies in our portfolio, we have access to 95 percent of all protocols, allowing us to provide FDA-verified intelligence to support the site-selection process.

A Best-fit Site Has a Strong Community Presence

No matter how diligently they scour their records and recruit their own patients, no site is going to fully enroll a study from its own patient population. A site that's active in the community and has built community relationships is more likely to be successful at enrollment.

Among the signs of a practice engaged in its community:

- Participation in programs such as "lunch and learn," which demonstrate presence in and commitment to the community.
- Relationships with patient-support and condition-specific groups, which engender trust and can provide potential pools of trial participants.
- Established referral pathways: Ideally, physicians are tapping colleagues in other practices as a source of participants.
- A social media presence can, at the very least, keep patients alert to research opportunities and build connections with patient advocacy groups. What's probably more useful is participating on sites such as www.inspire.com/, a social network for patients and caregivers that provides peer support and connects patients to clinical trials.

A Best-fit Site Takes an Integrated Approach

The best-fit sites embrace clinical research as another offering of care to the patient. It's fully integrated into their practice, and they promote clinical research in much the same way they'd promote a fitness class or a smoking-cessation program.

These practices are proactive. The approaches may use include:

- Showing a list of opportunities on a monitor in the waiting room.
- Talking to patients who may be eligible to participate in trials.
- Engaging their colleagues in the practice —including nurses, NPs, PAs, etc.—to help them spread the word.

A recent survey found that 81 percent of people would be very or somewhat likely to participate in a clinical trial if it was recommended by their doctor. Unfortunately, only 9 percent report that their doctor has ever talked to them about the possibility of participating in a clinical trial.[6] Overall, physicians refer less than 0.2 percent of their patients to clinical trials.[7]

These percentages are higher in practices that are clinical trial sites, but you'd be surprised at how many of even those fail to successfully promote their studies to patients.

It comes down to a failure to see clinical research as an integrated part of the medical practice. Not only does that suggest that the practice devotes inadequate resources to the research, but it also suggests a lack of passion. As we've helped clients look for best-fit sites, we've learned that passion counts for a lot. Successful sites have a passion for research. Being a clinical trial site is an added responsibility for someone—and very few people want extra responsibility. A commitment to research is driven by passion more than revenue.

But passion alone isn't enough: The practice has to dedicate the resources.

A Best-fit Site Has a Plan and a Dedicated Clinical Research Team to Execute It

A clinical trial site can't just do a study or two on the side. They need a plan and the right people to execute it. Enrollment is always top of mind for best-fit sites. The coordinator needs to be able to explain how they will identify and connect with potential research participants. Given that 68 percent of sites fail to meet their projected enrollment targets,[8] you'll want your coordinator to be able to explain how it will make up any potential shortfall.

Still, a plan isn't enough, either. Can the team execute? You can get a sense of this before or during the pre-selection visit. Here are some common red flags.

- They are managing too many protocols with too few staff.
- They don't return questionnaires or other material in a timely fashion.
- They can't explain their recruitment strategy to you.
- They seem harried and overworked.

There's one other element that may not be a red flag today, but it will be tomorrow: The site lacks some of the technology tools sophisticated sites use, such as e-consent and a clinical trial management system. In our experience, the more open to technology a site is, the better their enrollment.

A Best-fit Site is Open to Innovation

Small and emerging biopharma companies will always have unique challenges—but there's help available. Small companies are in a great position to adopt new technologies, take advantage of the services that partners can provide, and to leave behind the "that's the way we've always done it" mindset that has prevented the clinical trials operations field from moving forward at the same speed as medical advances.

Finding Your Best Fit

Everything rests on site selection: Pick the wrong site, and your trial could end up in rescue—or worse. Everyone understands that, yet roughly a third of sponsors and CROs say they are unsatisfied with their site initiation processes.[9]

By working with sites that meet the aforementioned criteria, and by availing yourself of the data and other resources available, you can dramatically improve the likelihood that your next clinical trial will succeed.

References

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