INDEPENDENT RESEARCH SITES: THREE KEY PERFORMANCE METRICS TO HELP YOU INCREASE YOUR STUDY PIPELINE

By: Jonathan Zung, WCG

Independent clinical trial sites capture lots of data but don't necessarily track the operational metrics that matter most, especially to sponsors and clinical research organizations (CROs) who use these sites to conduct their clinical trials. Many sites don't know which metrics to track or how to use those metrics to their advantage. In the absence of quality performance data and industry benchmarks, sites often struggle to attract new trials and grow their clinical trial business. This article provides practical solutions for overcoming some of the biggest challenges that independent clinical research sites face and highlights three key metrics that will help sites improve performance and drive success.

Why are site performance and data quality so critical for independent sites? Biopharmaceutical companies and CROs use site performance data from prior clinical trials to help inform which sites to consider (and ultimately select) for participation in upcoming trials. A site's ability to attract new studies, which is essential to its viability as a business, is dependent upon its relationships and past performance, i.e., how efficiently and effectively the site has conducted past trials.

Data quality is an equally important factor for research sponsors to consider. The collection of high-quality data is the central goal of any trial and the responsibility of every site. Small, independent sites often don't need to create sophisticated programs and complex infrastructure, but they must be capable of substantiating data quality and ensuring patient safety and be able to demonstrate that the systems they have in place are appropriate. This is essential in order to remain competitive when being considered to participate in future trials.

Independent clinical trial sites face many of the same challenges, which include:

Increased Study Complexity – Over the last decade, clinical studies have become increasingly complex. In the past, patients had to meet a limited number of inclusion criteria; however, now, it's not uncommon for patients to have to meet multiple layers of criteria in order to be considered. This is problematic for sites because every added layer of criteria reduces the pool of eligible patients from which they can choose. This has resulted in a more burdensome screening process that reduces the likelihood of finding qualified patients.

Participating in complex studies also requires more intensive operational management on the part of the site. In the past, study coordinators might have successfully managed six to eight ongoing studies. Now, the complexity of studies and the length of corresponding patient visits — sometimes in excess of 6 hours — have maxed out the bandwidth of study teams. Additionally, the copious data generated from in-depth visits and complex protocols require analysis by competent re-

search professionals. Site directors must retain highly trained staff, and more of them, in order to adequately conduct clinical trials today.

The Unpredictable Pipeline of Clinical Trials – Successful sites maintain a robust pipeline of studies, often extending six to 12 months into the future. Without a clear picture of the study pipeline, sites may not have adequate staff to conduct the number of trials in which they've been chosen to participate. PRN staff (pro re nata or "as the situation demands") is virtually unattainable and difficult to train on short notice. Understaffing or inconsistent staffing of clinical trials is a high-risk proposition, which can lead to problems with long-term staff retention, data collection, and patient safety.

Since it is difficult to predict how many studies a site will qualify to participate in, and when those studies may begin enrollment, it is essential for sites to attract as many studies as are appropriate to their practice. When sites track their operational data and diversify their therapeutic areas, they give sponsors a better idea of their capabilities and performance level, which makes the site more competitive for additional upcoming trials.

Although independent sites have a clinical mandate, offering alternative options to their patients who may not be responding to, or even have the option of, standard of care treatments, it is important to remember that they are also businesses and must meet their business obligations in order to remain viable. With considerations including staffing and payroll, rent and other overhead, equipment costs, maintenance expenses, etc., the only way independent clinical research sites can meet both their clinical and operational goals is by effectively and efficiently enrolling patients in studies.

Working in Technology Silos – Another contributor to the overextension of the research staff is the number of siloed technology platforms required to conduct a clinical trial. These platforms, many of which are meant to be used in concert, are often not interoperable. These include platforms for electronic data capture (EDC), clinical trial management (CTMS), and electronic patient reported outcomes (ePRO). Making the situation more complicated is the fact that sites work with multiple sponsors at a time, each with different technological preferences and processes. An independent clinical research site conducting 10 studies could end up operating in over a dozen different technology solutions at any given time.

WHICH DATA MATTER?

There is no shortage of metrics to measure; however, there are three key metrics that every site should capture and benchmark in order to understand their performance. They are:

1. *Speed* – Independent sites have an advantage over academic medical centers (AMCs) and hospitals since they lack the extensive infrastructure that is commonly found within these larger, and often siloed, organizations. Independent sites can execute confidential disclosure agreements (CDAs) and complete contracts, budgets, and IRB submissions more quickly than their AMC counterparts. In order to demonstrate the speed advantage to sponsors, it is essential for sites to track all startup activities from beginning to end, with a focus on turnaround time for each milestone.

Site initiation visits (SIVs) demonstrate a site's readiness and ability to screen and enroll patients quickly. By tracking SIVs, a site can demonstrate its preparedness to conduct a study, assuring the study's sponsor that the patient population has been properly vetted, there is a pool of potential patients for the study, and that its staff is ready to begin enrolling immediately. This not only helps sites to strengthen relationships with their sponsors but also adds to their reputation of professionalism and efficiency.

2. *Quality* – Quality metrics give sponsors confidence in the quality of data they can expect to receive from a site. Enrolling patients whose data will eventually have to be discarded is a significant waste of both time and money, so a keen eye toward data quality signals to the sponsor that a site understands the importance of this metric and devotes resources to ensuring quality is a priority and part of everything they do.

To demonstrate commitment to quality, protocol deviations are a good metric to track. How many protocol deviations occurred? Were patients lost to follow-up? If so, how many? The site should also track metrics on patient inclusion/exclusion, the criteria for both, and the accuracy of them being met. Does the site have a quality program? Although many sites do, few have a bona fide system to track it.

3. *Enrollment* – It is no surprise that sponsors prefer to work with sites that have a track record of meeting enrollment targets, as opposed to those whose performance has been inconsistent or unquantified. A critical element of site sustainability is having both site-specific and study-specific strategies for meeting enrollment targets. If a site can demonstrate its ability to accurately predict and achieve its enrollment targets (i.e., it does what it promises to do), that gives it a significant advantage over peers who do not track this metric, or whose data shows inconsistent target achievement. Tracking the time it takes to enroll the first subject after being "green lighted," enrollment by week, along with overall enrollment per commitment in a trial will allow a sponsor to objectively assess a site's enrollment performance. It will also allow the site to understand where they can become more efficient in future trials.

SOLUTIONS FOR CAPTURING DATA AND CREATING BENCHMARKS

Capturing quality metrics does not need to be a manual process. Most clinical trial management systems (CTMS) simplify reporting on a few quality measures, but when it comes to good clinical practice compliance, financial issues, and other variable clinical measures, the study coordinator typically resorts to manual tracking. There is no argument that enrolling patients into studies is a top priority, and using spreadsheets and other non-automated solutions is quite inefficient.

A quality CTMS will track nearly 80 percent of the data that a small, independent site needs in order to succeed. Small, independent sites often believe they cannot afford a CTMS; however, this is no longer the case with CTMS systems that are designed for the independent site.

ADDITIONAL INSIGHTS – DON'T FORGET THE BASICS

Capturing the right data and maintaining performance metrics to demonstrate a site's commitment to conducting efficient and effective trials can go a long way toward attracting new studies and increasing patient enrollment. To position your clinical research site for success, don't forget the basics:

Ongoing Marketing Efforts – While medical centers and academic institutions have well-established brands that attract sponsors and patients, the same is not true for small, independent sites. Like any small business, independent sites must promote themselves through ongoing marketing activities in order to become and remain relevant. These efforts should include your metrics in the message.

Managing Relationships – Engage with clinical operations staff at sponsors and CROs since they are critical in selecting sites. Forge relationships with medical science liaisons (MSLs) at sponsors since they are often able to give sites visibility into sponsors' drug development pipelines and can provide insights on how to work with the sponsor. Being part of a research site network can provide access to a pipeline of studies.

A High-Quality Facility – It may sound obvious, but investing in the brick-and-mortar footprint of the research site can pay dividends in attracting studies and improving patient enrollment. Biopharmaceutical companies will consider the look and feel of your site during the feasibility process. Having a professional, up-to-date office with modern amenities and equipment can only work in the site's favor, creating a pleasant, welcoming environment for trial participants and instilling confidence in the level of care they will ultimately receive.

While it's true that independent clinical research sites don't have the resources of their larger counterparts, by capturing the right performance data and translating them into legitimate marketing messages, independent sites can differentiate themselves to attract a robust pipeline of research studies and the patient population to support them.

ABOUT THE AUTHOR

Jonathan Zung, Ph.D., is executive vice president, WCG. He has more than 25 years of drug development experience, having led clinical operations organizations in large- and mid-size biopharma, as well as leading the clinical business of a CRO.

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