Invert to Convert: Rethinking Patient Recruitment and Enrollment Strategies

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Despite all the advances in science, medicine and technology, clinical trials are stuck in a rut: Most have trouble meeting enrollment targets. It's an analog problem in a digital world.

You could find hundreds, maybe thousands, of reasons why a specific study is slow to enroll, but 90 to 95 percent of those reasons come down to one or both of the following two root causes:

Lack of Potential Participants:

The site doesn't have an adequate pool of patients from which to draw. This "top of the funnel" problem is where most sponsors and CROs focus their efforts.

Lack of Site Resources:

The site lacks the resources to handle all the referrals it receives. Thus, many patient referrals remain unprocessed or are processed incorrectly. It may have access to a robust pool of patients but fail to convert them into enrollees.

Looking at it this way, it seems obvious: The current approach-starting at the top of the recruitment funnel-simply doesn't make sense anymore. Perhaps it never did. It's like passing a football with no one downfield; you may have the best arm in the league, but if there's no receiver to catch it, what's the point?

You may find potential enrollees, but if you don't address a site's bandwidth issue, you can't enroll them effectively.

Across study types, low conversion rates are common, regardless of the effectiveness of the recruitment campaign.[1] In fact, the more successfully a campaign generates respondents, the greater stress can be on the site.

The Status Quo is Failing

We've all seen the numbers: Most sites fail to meet their projected enrollment targets, and 20-25 percent of all clinical studies close because they fail to meet enrollment targets.[2] This is one reason why the average time from site identification to study start-up completion is 31.4 weeks-a month longer than 10 years ago.[3] That's no surprise, really: We've long known that deadlines are frequently unmet. Study timelines are frequently extended to nearly twice their original duration to meet enrollment; some take even longer.[4]

It may be easy to fault the sites. But it would be missing the point.

The Plight of Sites

When sponsors start at the top of the funnel, it's often a lose/lose for sites. If the recruitment strategy fails, the site gets no patients. But if it's a smashing success, the site can become overwhelmed with recruits. Sites accustomed to a handful of calls are suddenly deluged with referrals. The accompanying paperwork and processing is more than they can handle. Because of the unmanageable burden, sites often don't get around to screening all the candidates or even recruiting from their own patient database.

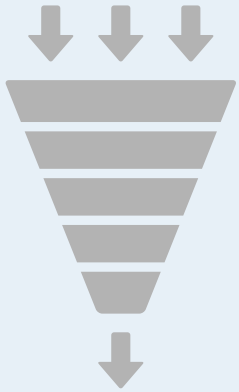
This means the successful-and costly-marketing campaign is wasted.

The number that matters most isn't the number of responses to recruitment efforts, but the number of them converted into enrollees on schedule.

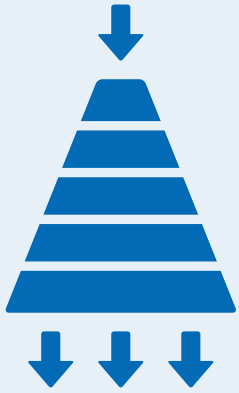
To change this, you must flip the recruitment funnel. But what does "flipping the funnel" actually mean? Address site bandwidth and resource issues before you create a recruitment program. It doesn't make sense to pour people into the top of the funnel if the site isn't able to screen them. Yet, most recruitment firms still start at the top, which in turn strains the site's resources.

The current industry model is to focus patient recruitment efforts at the top of the funnel, when we should flip the funnel to focus on addressing the site resourcing issue and convert recruits into enrollees.

Current Industry Model



Rethinking Patient Recruitment



To Convert, Invert

Starting at the bottom of the funnel requires strategic and tactical planning. It starts with answering questions such as:

- What's the enrollment target?
- When's the deadline?
- What are the recruitment sources?
- Will the site handle prescreening? If not, how will that be managed?
- From what time zones will we be receiving calls? How do we staff accordingly?
- How will potential enrollees contact the site?
- What are the steps of the screening process? How will the site manage it?
- How many appointment slots will we need?
- Who will follow up with each patient to ensure lab work is done, consent forms are signed, etc.?
- Which staff members will be accountable for each task?
- Who will follow up on all of this to make sure it's done-and done correctly?

It's all about capacity. At WCG ThreeWire, we've developed a scalable way for sponsors and CROs to bolster that capacity. We streamline study processes by providing sites and practices the necessary resources for screening, enrolling, treating and retaining patients to meet program goals.

At the heart of that process is the Enrollment Assistant™.

So, What are Enrollment Assistants, Anyway?

Enrollment Assistants (EAs) are on-site resources that fully manages the recruitment and retention process for your study. They work diligently and unobtrusively to support existing site staff--making their jobs easier, freeing them for clinical work, speeding enrollment and nurturing your patients so they continue to the last visit.

Our on-site enrollment assistants have access to the site's portals, process, calls, etc. They review the prescreen responses and work through the calls one by one until all are completed. They also conduct chart reviews to ensure every possible study patient from the site's own database is contacted.

Through My-Patient.com, EAs track patients from initial referral through recruitment and enrollment. EAs access site databases and conduct interviews with patients. They schedule visits, help with patient education and can serve as the primary point of contact for the study.

Through a Business Associate Agreement (BAA), the proprietary contract between the EA and the site allows the EA to access site databases and conduct unscripted interviews with patients.

An engaged site leads to engaged enrollees, and engaged enrollees mean trials move faster, getting important therapies to market sooner.

With EAs in place, sites can focus on the top of the funnel, identifying candidates, starting with the low-hanging fruit--patients with a current or past relationship with the site. EAs scour the entire database of patients at that site, performing a thorough Chart Review™using proprietary software.

Once the known patients are identified and contacted, only then is it time to seek the unknown patients. ThreeWire's relationship with WCG means EAs can tap other resources, including Inspire and Informed DNA. Then, if necessary, it may make sense to build out and launch a digital or traditional media campaign.

A Customized and Targeted Solution

Enrollment Assistants reduce the site's workload, accelerate enrollment and make the entire recruitment process more efficient.

In a perfect world, every study site for every trial would have an EA. But that's not realistic, so we work with sponsors and CROs to identify the sites that most need assistance. Over time, we've figured out that usually, by working with a third to a half of the sites, we can help ensure the study meets its enrollment goals.

Sponsors and CROs select the sites; then we help customize the approach to each site's unique needs.

To get started, we ask each site the following three questions:

1. What tasks do you need help with? (Put another way, what are the skills your EA needs to have?)
2. How many hours per week do you need help?
3. For what duration do you need assistance?

We're then able to train and deploy EAs in a way that best meets their needs. As those needs change, so can the EAs' responsibilities.

This approach works because the EA becomes an extension of the site team. They work under the investigator and they basically become ancillary staff members at that site. Because we enter into a business associate agreement with each site, the whole arrangement is HIPAA compliant, allowing EAs to access patient records and work directly with patients.

Accountability is baked in: Sponsors and CROs have total transparency via My-Patient.com and, based on the data, they are free to change how the EA's efforts are deployed.

All of this accelerates enrollment: On average, by flipping the funnel and making sure sites have the resources they need, ThreeWire helps clients save two months in patient recruitment and screening time.

This means the trials can begin sooner, providing a crucial competitive edge. With every recruited patient processed appropriately, retention improves and sponsors save time and recoup their investment in recruiting efforts.

Overall, the landscape of patient recruitment and enrollment have become highly specialized and data-driven. They demand a specialized, data-driven approach that nurtures potential participants and delivers bottom-line results, quickly and within budget.

About the Authors

Mark Summers is a President, WCG Patient Engagement Services.

References

[1] PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2018/2019

[2] WCG proprietary Knowledge Base

[3] March/April 2017 Tufts CSDD Impact Report

[4] Jan/FEB 2013 Tufts CSDD Impact report

[5] WCG proprietary Knowledge Base

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