Too Much of a Good Thing: Clinical Study Sites Struggle to Manage Responses to Ad Campaigns

By Molly Hair

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An overwhelming response to a media campaign can paralyze a study site. That's because too many potential enrollees can be as bad as too few.

Many sites are ill-equipped to handle the volume of referrals generated by a successful campaign. Referrals don't get processed--or are processed incorrectly. Subjects are lost, and the trial is delayed.

Delays add costs: $1.7 million is lost for every day a study is postponed.[1] Moreover, 68 percent of sites fail to meet their projected enrollment targets.[2] Even worse, 20-25 percent of all clinical studies close because they fail to meet enrollment targets.[3]

It all begins with the ad campaign.

Needles in a Haystack

Sponsors, through large media vendors, blanket a region or country with advertisements via radio, TV, newspaper, social media, etc., casting a wide net for potential participants. When the study involves a common condition, such as osteoarthritis (OA), people respond in droves. Sites that can barely manage 10 calls a day receive more than 100. Coordinators want to throw up their hands in frustration. It's not a failure on the site's part: They simply lack the staffing capacity to act on all those referrals.

To their credit, most sites keep plowing through. And they grow more frustrated. Most individuals they're interviewing at this point won't qualify for a first office visit (FOV). Imagine screening 100 eager patients and finding only five who qualify. Ultimately, the sites fall behind--and some give up altogether, missing out on potential study patients. Sites become even more fatigued, not only by the volume of calls but by the fact so few qualify.

As the pressure mounts prescreening may become sloppy. So now, not only do they miss potential subjects, but they are calling in people for the FOV who never should have made it to that point.

Meanwhile, because they are so busy processing referrals, they don't have time to recruit from their own database—so even more potential subjects are missed.

Future studies may suffer as well if some sites become unwilling to follow up on media-generated leads.

The Open Secret: Poaching

All this pressure has other consequences.
For example, the coordinator could be managing several competing studies.

So occasionally, a candidate who responds to an ad for one trial may be recruited for another. It's not malicious: As the enrollment deadline approaches, the coordinator and staff are under tremendous pressure. And then they are on the phone with a candidate for one study who fits this other one. We all know what happens. It's

an unfortunate by-product of how the system works. But it can be costly for sponsors.

It doesn't have to be this way. There is a solution to both challenges: enrollment assistants.

Not a Call Center

WCG ThreeWire on-site enrollment assistants (EAs) 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.

Sometimes EAs work remotely, still focused on a single study but matching subjects with multiple sites.

Through MyPatient.com, EAs can track patients from initial referral through recruitment and enrollment. And because each EA works on only one study at a time, the sponsor knows the money invested in advertising a particular study yields subjects for that one—not a competitor's.

Making the Connections

EAs can access site databases and conduct interviews with patients. They can schedule visits, help with patient education and serve as the primary point of contact. They connect. Patients need to be engaged as they move throughout the process. They need to feel respected and valued. That's what EAs do best.

No one is going to sign up if they feel uncomfortable—or worse, ignored. That's where EAs shine. An EA can call at any time that's convenient for the patient and educate a partner, caregiver, grown child—even the primary care physician. EAs have the time to do this, something site teams do not. And this high-touch support turns recruits into enrollees. In one instance, EAs helped enroll 4.9 patients a month at a single site, compared to 0.8 patients a month at a site without EAs.[4]

Impact on Site Recruitment Effectiveness:

Without ThreeWire

0.8

Average Patients **a Month**

With ThreeWire

4.9

Average Patients **a Month**

6x increase in enrollment rate

At the same time, it ensures only the most qualified and study-educated patients are scheduled for FOVs. Our 96 percent FOV-to-consent rate in a recent OA trial illustrates our ability to make this happen. And as every coordinator knows, better recruiting means better retention. With an overall 30 percent study dropout rate, it makes clinical and business sense to use every available tool to enhance recruitment and retention.[5]

Reduce the Workload, Don't Add To It

Because the sponsor pays for EAs, sites lose nothing by accepting EA support. And the services can be customized to meet the particular needs of a site and a study.

EAs focus on reducing a site's workload and pressure. That approach yields immediate and downstream benefits. If EAs can take on the work of recruitment the site has more timely data, and it can give its study patients more attention and make them feel more valued, which improves post-consent retention.

Any media referral that doesn't have a vendor resource follow up is more work for the site. In other words, if a vendor does not have the equivalent of an EA, it is creating more work.

That's where WCG comes in. Our end-to-end patient recruitment solution helps sites achieve enrollment milestones, on or ahead of schedule. On average, we help our partners save two months in patient recruitment and screening time.[6]

In fact, we can even manage the direct-to-patient marketing. WCG's comprehensive Media Outreach Services can develop a data driven outreach campaign targeted at historically high-performing sites. Referrals are followed up within 24 hours, and everything is tracked via Mypatient.com.

Conclusion

We work with sites to give them what they and the sponsor want. We tailor our enrollment-support solutions to meet the unique needs of each study site. That's because working with a site coordinator who is enthusiastic about working with EAs is best for everyone—sponsor, site, EAs and the patients.

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

References

[1] WCG case example: Osteoarthritis Pain

[2] WCG proprietary Knowledge Base

[3] WCG proprietary Knowledge Base

[4] WCG ThreeWire On-Site Recruitment Success For Large Pharma Study

[5] National Research Council Panel on Handling Missing Data in Clinical Trials . The Prevention and Treatment of Missing Data in Clinical Trials. Washington, DC: The National Academy Press; 2010. https://www.ncbi.nlm.nih.gov/books/NBK209904/

[6] WCG proprietary Knowledge Base

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