Site-specific, Patient-centered and Whip-smart: Enrollment Assistants Adapt to a Shifting Landscape

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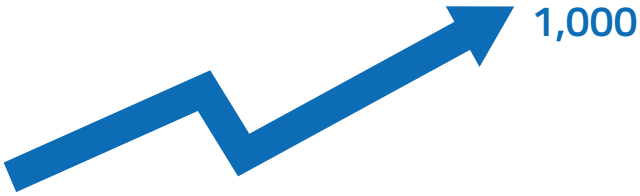
Increasingly complex clinical trials place a tremendous burden on study sites, exacerbating already-troubling recruitment and enrollment issues. Overwhelmed, many sites may not be up to the task or have the appropriate infrastructure, creating costly delays that keep new therapies from patients. However, strategically placed Enrollment Assistants can ease that burden, streamlining enrollment, making sites more agile and offering patients personalized attention that leads to conversion and retention.

For many sponsors and CROs, embedding an Enrollment Assistant™ (EA) at select study sites has become the norm. It's how they get the job done. But in fact, explains Seth Nelson, VP of Operations, WCG-ThreeWire, it's a relatively recent innovation.

"When I started in 2013, we had a handful of Enrollment Assistants. Now we have close to 1,000 active EAs at any given time."



As the numbers grew, the concept evolved. "Initially, the idea was the Enrollment Assistant would go in to a study site, conduct the chart review, deliver the qualified patients and leave. It would be a roughly 40-hour placement."

That's because back then, the EA was the solution.

NO LONGER:

"Now we create many solutions around the Enrollment Assistant. Today, the EA isn't the solution. The EA executes an array of site-specific solutions."

WCG-ThreeWire deploys EAs to clinical research sites around the world to recruit and screen potential volunteers, conduct patient chart reviews, field and evaluate referrals, conduct community outreach, describe trial protocols to patients, explain consent and guide qualified candidates to enrollment.

EAs continue to live up to the trust put in them, Nelson says. "ThreeWire has provided hundreds of Enrollment Assistants at sites all over the globe, and we've never had a compliance issue. We've never had a data issue. We've never had a single regulatory issue. I'd expect no less."

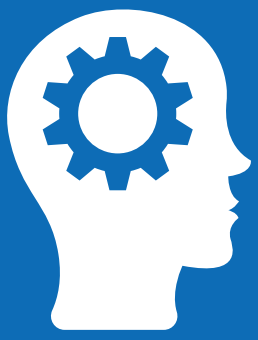
The EA program has expanded exponentially under Nelson's leadership. Now, as part of WCG's end-to-end patient recruitment solution, ThreeWire EAs help clients save two months in patient recruitment and screening time.[1] In one instance, EAs helped enroll 4.9 patients a month at a single site, compared to 0.8 patients a month at a site without EAs.[2]

Each Site is Different

Over the past five years working with sites and EAs, Nelson says he has learned several important lessons. Among the most important: Each site is unique. That may sound obvious, Nelson acknowledges, but obviously it's not, given that many sponsors and vendors still take a one-size-fits-all approach to enrollment.

CONSIDER A STUDY WITH 100 SITES:

Each will have a different set of enrollment challenges, as well as a myriad of other challenges associated with getting a trial off the ground. "There's no single enrollment solution that will work for every--or even most--sites. That's why ThreeWire trains and deploys EAs based on each site's unique needs," he explains. As those needs change, so can the EA's responsibilities.

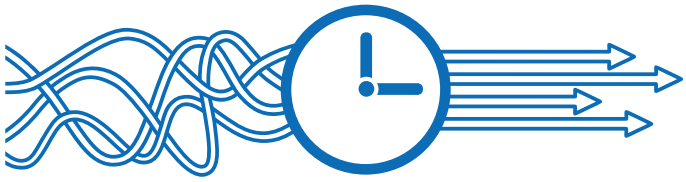


Too Many Recruits, too Little Time

As trials become more complex, it becomes harder for sites to find, screen, educate and enroll study participants.

Neither the Principal Investigator, nor the coordinator, nor the site staff have the bandwidth to work individually with all the screened volunteers. At the same time, the move toward smaller, more precise studies makes the need for one-on-one engagement more acute.

"The more precise you get, the more education you need to provide," he says. Many investigators and coordinators lack the time to develop a complete knowledge of all protocols they are responsible for in order to provide the education required for truly informed consent.



EAs do have the necessary skills, time and knowledge. "We can provide sites with a professional who has that ability and who understands recruitment, screening and enrollment--that's a truly patient-centric solution that serves sites, sponsors and patients," he says.

RECRUITING: NOT THE MAIN PROBLEM

Much of the "too many recruits, too little time" predicament arises out of a misplaced emphasis, Nelson explains. Sites--and the vendors who market "solutions" to them--too often focus on making the phone ring. But that's not the hard part.

"One of the interesting things we've learned is that sites have patients to screen; they just can't find enough time to actually screen them." Sometimes, a third of referrals are never processed, and fewer than one percent of respondents actually enroll.[3]

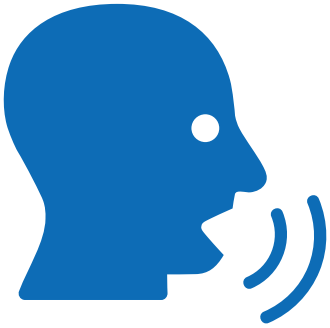
Nelson sees so many sponsors and sites pour resources into the recruitment side while letting the enrollment side languish. That may explain why low conversion rates are common, regardless of the effectiveness of the recruitment campaign.[4] It's costly for sponsors, of course, but it's also frustrating for investigators and ultimately leads to burnout. It's one reason for the increasingly high rates of investigator turnover--turnover that poses a significant risk to medical progress.[5]

Sometimes, the problem is recruiting. In those situations, ThreeWire's relationship with WCG means EAs can tap other resources to identify patients, including Inspire and InformedDNA. EAs are also equipped to do focused community outreach. They understand the local community and the protocol, so they can find potential volunteers more quickly.

And by doing so, they make a personal connection with patients--something busy sites lack the resources to do.

The Human Voice

EAs allow sites to take a more patient-centered approach.



As Nelson says, "Patient centricity is a funny thing because it doesn't really have a definition, right? So, everyone has their own thoughts on what 'patient centricity' is. For WCG--and for me in particular--clinical research is something that's very personal to the patient. It's intimate. You're working on finding a solution for something that will have a profound impact on either the quality or quantity of the person's life. That's what patient-centric means."

Many patients fear becoming a human lab rat, he says. That's a hard perception to get past, and even the most sophisticated interactive voice response (IVR) technology won't be much help.

Technology has transformed the process of identifying and enrolling patients but, warns Nelson, it's unwise to rely on it for personal interactions. "Everyone wants to Google, everyone wants to text--everyone wants all that, except when it comes down to making a decision. Then, you need a voice. You need a trusted voice."

As medically trained professionals who know the study protocol and are familiar with patient concerns, EAs can talk with patients one-on-one, answer questions and relieve anxieties. This is about an individual's health and their personal struggles. No algorithm yet developed can meet those needs.

Many sites still rely on IVR technology; this baffles Nelson. Even credit card companies boast about having a live human at the other end of the line. "If a personal encounter is important for a credit card company, it's certainly going to be important for someone who is considering participation in research study."

A Study Team Member, Not a Temp

Because the EA is part of the study team, when they call a patient they're not saying, "Hey, I'm a ThreeWire Enrollment Assistant." They're saying, "I'm with Dr. Smith. I'm calling about protocol this, this, this."

It sounds like a small thing, but it's not, Nelson says. "That one aspect has proven so important for a study's success." Because WCG enters into a specialized

agreement with each site, EAs can access patient records and site portals, and work directly with patients.

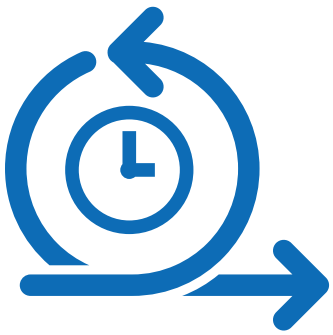
Enrollment Assistants work under the direction of the Principal Investigator on the delegation of authority log. They're an integral part of the study team.

All that becomes clear once the EA is onsite. However, Nelson finds that sites and sponsors who have never worked with an embedded EA sometimes don't grasp what that entails.

All About Agility

An EA provides value precisely because they are not merely a warm body. Enrollment Assistants, under the guidance of the PI, offer fresh perspectives; they can solve problems independently. They have the luxury of being flexible. That dovetails into another lesson Nelson has learned over the years.

"Many of the challenges sites face can't be anticipated, and they need to be able to pivot quickly," he says. EAs have the skills and tools to help them do this.



Nelson related an illustrative story. ThreeWire was supporting a multi-site clinical trial in Texas when Hurricane Harvey struck in 2017. In the aftermath, transportation to the research sites became difficult; many patients cancelled appointments, and those who didn't struggled to make the trip. Immediately, on-site Enrollment Assistants worked with ride-sharing companies to arrange transportation for the patients.

This quick response allowed the sponsor to provide personalized services to volunteers and keep the study on schedule.

That's just one small example, of course. But it illustrates not only the EAs' agility, but their focus on the patient and their commitment to remaining on schedule.

"That's the beauty of Enrollment Assistants: It's not high tech vs. high touch, or timelines vs. engagement, or speed vs. quality. It's all of those, and more," he says. "Enrollment Assistants aren't bound by such artificial choices, because they have the time, technology and practical know-how to get the job done."

About the Authors

Seth Nelson is the Vice President of Operations at WCG ThreeWire.

References

[1] WCG proprietary Knowledge Base

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

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[5] "CTTI recommendations for strengthening the investigator site community," **Clinical Trials Transformation Initiative** Oct. 2017

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