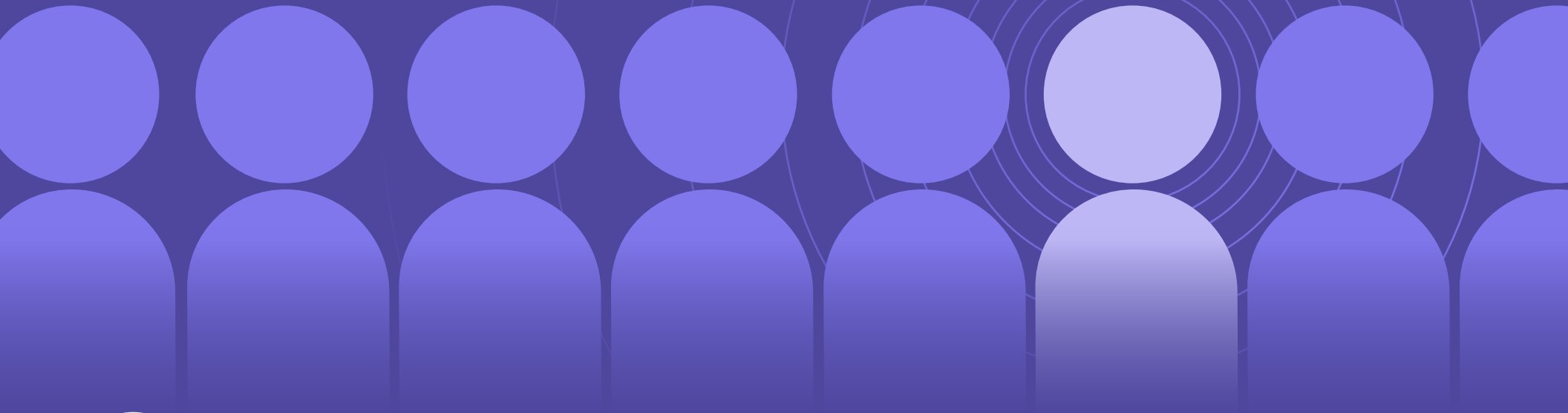
A Centralized Approach to Clinical Trial Recruitment and Retention

ENABLING FASTER, MORE TRANSPARENT ENROLLMENT WITH A SPONSOR-GUIDED GAME PLAN



INTRODUCTION

In clinical research, the protocol outlines the inclusion/exclusion criteria stating who is and isn't eligible for the trial, what procedures will be performed, the timing and frequency of visits, the endpoints being measured, and other details necessary to assess the study. The protocol needs to be prescriptive to uniformly manage and assess the science behind the study. However, there is often no corresponding guidance standardizing and centralizing the process for the recruitment and retention of participants.

Should there always be a "recruitment protocol"?
Just as centralizing data from enrolled study participants enhances analytics and provides deeper insights into key study endpoints, a centralized recruitment strategy similarly enables consistent data collection across sites and recruitment tactics.

Study enrollment is often structured around site policies and practices for natural reasons. Consequently, in a study with 100 sites, for example, a study might have 100 enrollment strategies tracking tactics in 100 ways. If every site does recruitment and retention autonomously, that site-by-site variation limits the ability to provide meaningful study interventions.

"When efforts are managed independently at each study site, enrollment activities become a black box, where sponsors have limited visibility into what is done at the site," said Kari Lotsberg, vice president, Operations, WCG. "Not only do most studies lack a centralized recruitment approach, but most also lack a centralized recruitment tracking and oversight system. And it's all because there isn't a recruitment protocol to fall back on."

In this piece, we'll hear more from Lotsberg and explore the benefits of a centralized recruitment and retention strategy — and what sponsors should consider as they design their own. You'll learn:

- The risks of decentralized site recruitment and retention, and the opportunities of a more centralized approach.
- Best practices when designing a centralized recruitment and retention strategy.
- How to balance site autonomy with centralized sponsor support.

What Is a Centralized Approach?

A centralized approach to clinical trial recruitment and retention involves additional support and guidance provided by the sponsor to accelerate the study. A centralized approach doesn't mean that the sponsor takes over a site's operational structure or existing responsibilities. Rather, the sponsor works with the participating sites to remove variabilities with the enrollment process, allowing for more efficient and transparent enrollment. With this important distinction, centralization **mitigates the risks associated with decentralized recruitment and retention.**

As is widely reported, enrollment is a systemic challenge that delays study timelines and increases costs. According to the National Library of Medicine, 80% of trials fail to enroll on time, and retaining enrolled participants is an additional hurdle. What isn't as widely reported is the fact that the localized site-based approach to recruitment and retention can be a major contributor to those enrollment delays, explains Lotsberg.

"Study inefficiency often occurs between patient recruitment and retention efforts when they're managed independently at each study site," she said. "When each site operates under its own set of processes, these local efforts aren't centrally tracked and coordinated. This prevents sponsors and CROs from having real-time visibility to recognize challenges and leverage successful strategies across the entire study."

Study results can be inherently inconsistent when recruitment activities are individualized to the site. Version control and a lack of efficient tracking are common when using spreadsheets to manage enrollment. This decentralization of information contributes to this "black box," preventing timely information exchange.

"What this means then is that interventions can't be quickly applied if sites are struggling, nor can high-performing strategies be then expanded to all sites," Lotsberg added. "As a result, challenges may persist longer than necessary on a study. Successful tactics can then remain isolated, and overall enrollment timelines are often delayed."

This doesn't mean that sites are doing anything wrong. They know their own participant populations the best and are right to focus on them. That focus can create inconsistency at the study level, where the sponsor is trying to enroll the study. Consider that research sites are often overextended and managing numerous demands — requesting additional status reports places further burden on teams already coping with labor shortages and budget constraints.

Centralizing recruitment and retention activities addresses those needs while giving sponsors more control and transparency into enrollment progress. But it's important to remember that this support should enhance and not replace site processes, Lotsberg adds.

Three Factors of a Successful Centralization Implementation

When sponsors and sites alike approach recruitment and retention from a centralized, study-first framework — as is the case with the WCG recruitment and retention model — there are three factors to consider.

"The study is the focus, but the site and participant should be top-of-mind at all times," Lotsberg said. "Looking at recruitment and retention through that lens is critical for more efficient and effective enrollment."

Here are the top considerations to keep in mind:

1 Identify inside, then look outside.

Maximizing recruitment potential should start with **internal** referrals through a **prescreening of existing patient charts.** These include patients known to the study site who can be identified through the site's existing data. These individuals are typically the fastest to access and recruit for most studies.

Sometimes, however, a site does not have enough of these individuals to fulfill its enrollment targets. In that case, Lotsberg explains, it's **time to look externally**, beyond the site's four walls. "These tactics can include building networks of physicians, community outreach, and media outreach to expand the study's reach beyond the site."

"The targeted approach helps ensure efficient recruitment of high-quality participants while also providing valuable insight into the site's current patient or potential participant pools," she said. "Going back to the value of centralization, understanding the volume of available internal referrals informs which external tactics, if any, are needed to fulfill the study's enrollment target."

2 Apply efforts to appropriate external sources.

Core recruitment and retention opportunities are protocol-driven. When determining which external resources might be necessary and where, when, and how to deploy them, Lotsberg advises that organizations focus on four dimensions of the recruitment process: identification, enrollment, retention, and documentation.

Take an obesity study as an example, she adds:

"**Identification** for that study likely won't be a challenge because the individuals can self-identify and are motivated," Lotsberg said. "But **enrollment** might be. The challenge there is to maintain enough momentum and reach aggressive enrollment timelines with the often high-volume of individuals identified."

Retaining those participants might also be challenging, especially in a placebo-controlled study where participants' motivations to continue in the trial may lessen if there is no observable change. Lastly, **documenting** the high volume of data generated from participants in a competitive landscape that requires fast and clean data turnarounds might be an additional barrier.

HOW THE GAME PLAN CHANGES FROM STUDY TO STUDY

WCG offers a **centralized recruitment and retention playbook** for sponsors that is refined based on multiple factors, from the indication and population characteristics to timelines and goals. The implementation of that playbook at a particular site level is tailored based on the site's unique resources and population — confirming what the site has already done, how it was done, and how to support what remains to be done.

"Every study, site, and participant will be different, and a centralized approach can acknowledge and work within those differences," Lotsberg added. "A successful strategy will reflect the known opportunities while simultaneously addressing the unforeseen challenges with the right support, strategy, and resources."

3 Incorporate study-wide data consistency early to support informed decision-making.

Lotsberg notes that the ability to consistently manage recruitment across sites involves the centralized tracking of recruitment tactics to view current activity and inform future decisions. This can be set up early in the feasibility process to connect expectations during site selection with recruitment and retention.

"Feasibility comes first in that everyone involved — whether at the sponsor, CRO, or site level — shares that common goal that **the study is the primary objective** and focus, advancing the study success for the benefit of the patients," she said. "Another need for consistency is in expectation setting, specifically in offering clear communication channels," she added. "Establishing those regular open lines of communications to discuss challenges, share relevant success stories, and gather feedback keeps all parties aligned and focused on moving this study forward for participants."

Having a centralized recruitment and retention strategy is important. It's similarly important to unify those functions into a single data-powered solution for better data transparency and continuity of trial functions.

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Balancing Site Autonomy with Sponsor-Guided Support

In any centralization effort for recruitment and retention, a balance must be struck between a site's autonomy and a sponsor's guided support for enrollment success.

"The site has the autonomy to utilize whatever options they have available for the study," Lotsberg said. "They also have the autonomy to do that on their timeline…it is beyond the reach of a site to centralize their information without the sponsor. It's at the sponsor level to determine and provide an effective recruitment plan, for example, and to implement and make available a centralized tracking system and to monitor that and make informed decisions based upon the reporting functionality that sites don't have."

Going about that balance comes down to aligning goals and supporting those goals with realistic expectations. This helps avoid surprises. "It's important to focus on connecting feasibility from those early discussions with sites to the overall intended recruitment and retention strategy for a particular study," Lotsberg said, adding that integration with the feasibility strategy is a kind of two-way feedback loop.

"Stakeholders can use what's known from the feasibility survey to inform the recruitment strategy, but also use the desired recruitment strategy to inform the feasibility survey so that sites and sponsors align on expectations and roles and responsibilities at the outset," she said. "This informs which

tactics will be engaged at a centralized level across the study and made available to sites, and what is also expected of sites through that recruitment and retention strategy."

Importantly, the path to success may include provisions of resources as support, not replacement. For sponsors, this involves clarifying that centralized strategies are designed to enhance—not replace—study site teams and processes. The intent is to bolster site capabilities with shared tools, data, and support, rather than dictate operations. A collaborative approach helps ensure **there are no villains.** The study is the focus from start to end, and all stakeholders (sponsors, CROs, site staff, investigators, and participants themselves) share that journey, together.

Centralized Recruitment Is a Study-First Framework

As prescriptive as clinical trial protocols are for assessing the science, they're unfortunately **not prescriptive enough** for recruitment and retention. Sites and sponsors have long struggled with enrollment challenges and delays stemming from the current structure. It's time for a **centralized** approach.

A centralized recruitment strategy focused on collaboration with sponsors, sites, and participants streamlines recruitment and retention activities and information sharing while allowing site autonomy. As we've learned, this strategy can support efficiency, improve data consistency, and preempt many of the enrollment hurdles that have historically challenged the research and development community.

If you're looking to jumpstart your own enrollment activities with a customized and centralized strategy, learn how WCG's recruitment and retention strategies can help.

Learn more →

WCG is at the forefront of accelerating clinical research worldwide, serving as the trusted and preferred partner to biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and site partners. Offering a unique combination of expertise, next-generation data and insights, and tech-enabled solutions, WCG reduces complexity and optimizes study operations and outcomes while maintaining the highest standards of human participant protection. For more than 55 years, WCG has maintained a relentless commitment to efficiency, safety, and impact, empowering clinical trials to deliver life-improving therapies swiftly.

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