

The Basics Aren't So Basic: Successful Participant Recruitment Requires Dedicated Time, Better Relationships, and Adequate Site Support

Author: Shelby Ward, Manager, Site Services, WCG



Recruitment – connecting the right person to the right trial at the right time has become increasingly challenging for clinical research sites. In fact, nearly half (48%) of respondents to WCG’s 2023 Site Challenges Survey Report identified trial enrollment as a significant concern.

Given that most sites fail to meet enrollment targets, this should come as no surprise. The hurdles they face are well documented. But with targeted support and adequate resources, sites can turn patients into participants.

From leveraging internal databases to embracing sophisticated digital media strategies, trial sites have an array of tools with which to identify and recruit the right participants. What follows is a basic overview of site recruitment tactics.

INTERNAL RECRUITMENT: QUERY THE PATIENT RECORDS

This stage involves identifying potential participants from within the existing patient database of the study site, matching individuals against specific protocol criteria.

EMR system query: Use primary study eligibility criteria to identify the appropriate ICD 10 codes. Next, run the codes against the EMR database to pull a list of study candidates. When done properly, this is one of the most efficient ways to find potential participants for a study.

Chart review: The expected time required to conduct a thorough chart review by comparing the patients’ medical history to the protocol inclusion/exclusion criteria, can vary. Some indications will require just a few minutes to review a chart for more simplistic criteria, while others may require extensive review to ensure the patient is an appropriate match for a more intricate protocol design.

Paper Chart review: It’s important to understand that not all sites are fully electronic. If a study site has paper records, the review of potential participants will likely require more time due to the absence of filtering capabilities.

When recruiting participants for episodic or acute conditions, like eczema and migraines, retroactive chart review may not be adequate. Prospective chart review, which continuously monitors current patients for new symptoms, can identify candidates in near-real time. To be successful, this requires a dedicated point to review the incoming patient appointments and/or contacting patients to check-in on their health status.



EXTERNAL RECRUITMENT: COMMUNITY AND CLINICIAN OUTREACH

When a site has exhausted its enrollment potential within its database, the next step is to identify external participants.

Effective community outreach focuses on building strong relationships within the local community surrounding the research site. This is essential to build pathways that allow patients to be educated on the research opportunity through medical professionals, mentors, or community leaders they trust, via collaboration with the study team, before they are referred to the research site.

Community outreach can include a variety of tactics and they will look different for each site due to differences in community landscape and demographic. Some examples of community outreach include attending or hosting community events and basic grassroots outreach. As these activities often require extensive planning and relationship-building, it should be expected that

they are time intensive. Sites need a dedicated and qualified team member who has the time and networking capacity that is necessary to connect with the community utilizing strategies that will resonate with the patient population and their trusted networks.

It begins with a carefully executed community outreach plan. At a minimum, it should focus on identifying opportunities, include a tactful outreach strategy, and sufficient time for follow-up.

Grassroots efforts require putting yourself in the participant's shoes. Where will your participant population be? Look at support groups, local libraries, colleges, festivals, etc. Figure out where your potential participants spend their time, then meet them where they are.

Hosting or attending local events requires careful planning.

- Identify public events that provide opportunities to promote and share study education.

- Coordinate the study team strategy. Confirm any logistical requirements (e.g., securing a booth, obtaining sponsor-provisioned study materials, etc.).
- Create a follow-up plan to engage those who express interest.

The community approach takes time and requires strong interpersonal skills. Don't be discouraged by initial rejections; just focus on building relationships.

Referral provider networking with local healthcare providers is another beneficial method to establish referral pathways. To be successful, it is imperative to tailor each provider referral strategy to the different types of practitioners. For example, general practitioners might be more inclined to readily refer patients needing treatment that would otherwise require a specialized practitioner. However, specialists may require more nuanced approaches to generate referrals. In both cases, meaningfully invest time to cultivate the relationship and build trust, provide study education, and emphasize the opportunity the study provides to patients seeking expanded treatment options.

Regardless of the approach, the most successful outreach pathways are those that are the result of long-term relationship building and mutual collaboration. Once you have been able to establish a meaningful relationship to a community resource, these relationships not only benefit your current study, but can likely provide a source of enrollment in the future as well.



EXTERNAL RECRUITMENT: MEDIA OUTREACH

Media outreach, such as print, radio, TV and digital/social advertisement, remains a primary tactic to identify trial candidates. These are excellent ways to reach patients who understand their own conditions and can advocate for themselves.

Determining the most effective media strategy depends on various factors. Digital media offers quick adaptability and precise tracking. This level of detail, from click-through rates to engagement metrics, makes it a medium of choice.

However, traditional media outreach is still important, especially when targeting patient populations who are less active online.

A successful media strategy must align with a site's capacity. The goal is to increase traffic, so it's crucial to ensure that your media strategy accounts for this. You don't want to overwhelm the trial site and impair its ability to process referrals.

PRE-SCREENING: GETTING ENROLLMENT ROLLING

A critical aspect of the enrollment process is pre-screening. It can be time-consuming, depending on the potential participant's health status and the specifics of the trial. Sites should be recruiting to retain and this stage is crucial as it sets the patient's first impression of the study.

It is essential that sites spell everything out:

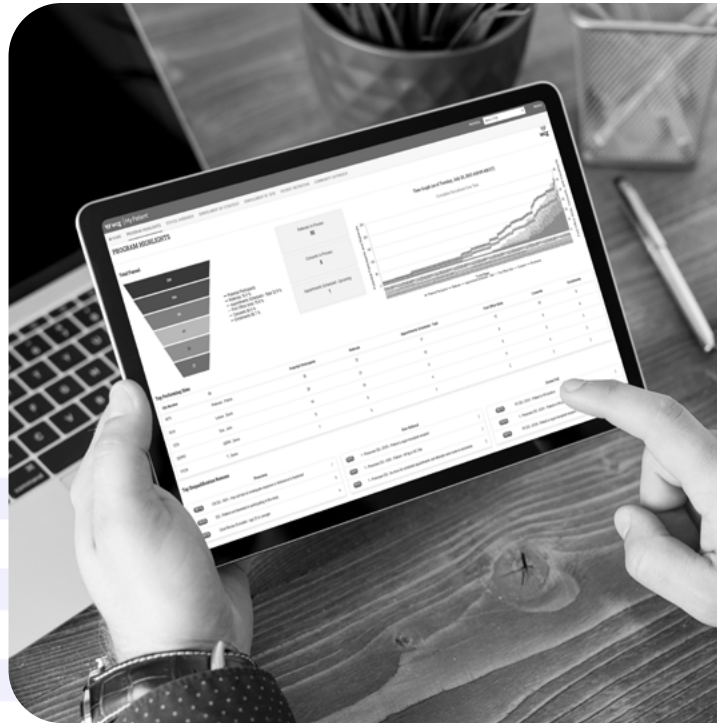
- **Explain the study's purpose and relevance** to the potential participant, ensuring they understand why it may be beneficial for them.
- **Reviewing secondary protocol criteria** to confirm the potential participant's suitability for the study.
- **Answer questions to help** potential participants understand all aspects of the study.
- **Clarifying next steps** to give potential participants a clear picture of what to expect.
- **Complete any remaining steps**, such as retrieving additional medical records, to finalize eligibility.

Don't underestimate the time that proper pre-screening can take. Sponsors and CROs need to ensure sites have the resources to spend adequate time with each potential participant.

DON'T LOSE TRACK

All approaches to recruitment require centralized tracking. Excel has many uses; a database is not one of them. Tracking and evaluating the success of different outreach strategies is crucial. For example, WCG's proprietary My Patient® recruitment and retention platform monitors each step of the progress.

Knowing the status and process of each individual's pathway through the study informs recruitment efforts and can identify methods that yield the best results; this helps ensure efficient and effective recruitment. Knowing where each candidate and participant is in the pipeline enables the support that keeps them engaged throughout the study.



Effective participant engagement starts at the beginning of recruitment but must be maintained throughout the study, in some cases for several years. This level of commitment demands a substantial investment of time and resources, especially as protocols grow more complex.

PARTICIPANT-CENTERED, GOAL-ORIENTED

Focusing on the participant's perspective improves enrollment, supports retention, and increases the likelihood of a successful trial. **Engaged participants are retained participants.**

WCG has guided thousands of sites and sponsors, providing them with the resources and expertise they need to identify, enroll, nurture and retain study participants. Contact WCG to develop a custom strategy that will connect your study to the right participants.





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