

Accelerating Transformative Therapies: Navigating Complexity and Enhancing Enrollment

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The momentum of progress in transformative therapies is accelerating. Breakthroughs in medicine are unfolding at an unprecedented rate in human history. For the first time, individuals afflicted with certain diseases that once had little hope for effective treatment are now glimpsing the potential for substantial change. Whether it is rare diseases, oncology, cardiology, dermatology, or another therapeutic area, continuous advancements are enhancing the quality of life for people worldwide.

Although the pace of advancement in transformative therapies is gaining momentum, navigating through the clinical study approval process remains a steep challenge. It is becoming evident that there is a growing need for innovation in trial setup and execution. Achieving tomorrow's results cannot be achieved with yesterday's methods. This holds true for all aspects of trial design, including enrollment and retention of study participants.

REMAINING AGILE, NIMBLE AND RESPONSIVE

With the increasing complexity of studies, the importance of having a consultative, flexible, and readily available partner becomes pivotal. Sponsors are aware that each study site visit adheres to the established protocol and schedule. However, ensuring a dependable and predictable approach for reaching those visits and managing follow-ups is often lacking.

It becomes crucial to understand that each site, study team, participant population, and protocol combination possess its own unique characteristics. Additionally, no two studies will share identical requirements, and the interactions at different sites will vary.

Recognizing these unique demands of the study will help to consultatively evaluate how to best assist each of the selected sites accordingly.

ACCELERATING RECRUITMENT AND INCREASING ENGAGEMENT

To bring new therapies to market, studies need participants. Traditional methods of identifying potential participants, including chart reviews, building provider networks, study advertising, and community outreach, are now enhanced with technological advancements that enable swift querying of electronic medical records (EMRs) and the application of artificial intelligence (AI) to analyze records.


While these advancements have the potential to accelerate participant identification, we must remember that the most successful recruitment approach remains fundamentally simple: ensuring the efficient follow-up of each potential participant. This is paramount to meeting enrollment milestones, regardless of what identification tactics are used.

At WCG, we believe that a successful enrollment strategy must include diligently corresponding with, and tracking, each person through to either enrollment or disqualification. Our dedicated support teams are highly trained to manage tasks related to both identification and enrollment, ensuring participant outreach within a 24-hour timeframe. This support coupled with our web-accessed recruitment management portal, My Patient®, provides visibility and control throughout the entire recruitment journey.

While it may not be feasible to anticipate every question in advance, ensuring that every participant

receives fundamental information, presented consistently, is vital for fostering engagement. Accordingly, our support teams work with the sponsor to understand each participant population and the demands of the study. This distinctive role within the trial process allows us to ensure that participants promptly and clearly receive updates on the study, including any timeline adjustments and protocol amendments.

Participants are making a significant choice when deciding whether to join a study or not. When an individual has the courage to volunteer, it is essential to express appreciation and recognition. Participants not only deserve prompt response times but also require access to accurate information, essential resources, and sufficient support. These elements are not only crucial for retaining participants in the study but also serve as a meaningful way to acknowledge their valuable contributions.



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PROPER RETENTION INCLUDES MANAGING DATA ENTRY AND QUERY RESOLUTION

A common misunderstanding is that achieving recruitment success is solely about identifying and enrolling participants. However, this marks just the initial phase of the process. To ensure the study's success, it is imperative that enrolled participants not only join but also remain engaged throughout the study, providing the essential data required by the sponsor during their study visits. Consequently, participant retention emerges as a pivotal stage in the participant journey, with equal importance placed on both retaining participants and ensuring the accurate and timely collection of necessary participant data.

Study teams that excel at enrolling participants may not be as strong with other retention tasks. A misconception about data entry is that it primarily involves individuals physically inputting data into a system. However, this represents only a fraction of the entire process. A more accurate perspective on data entry is to view it as a process aimed at ensuring data completeness before any input occurs. This process may entail various steps, such as engaging in straightforward conversations with a Principal Investigator (PI) nearby or tracking down a PI or Sub PI to verify missing variables.

Ensuring that your study teams are well-prepared to interpret source documents and proficiently navigate established procedures and workflows is a crucial factor in achieving successful enrollment. The accurate entry of all data and the timely resolution of queries within the sponsor's specified

timeframes can be quite challenging. Additionally, this delicate balance can impact enrollment, as time allocated to retention may compete with time devoted to recruitment, and vice versa, as it often involves the same team.

The growing complexity of studies has led to a greater volume of data points, more stringent deadlines, and an increased likelihood of encountering queries. Nonetheless, it is entirely possible to effectively manage this complexity, conduct visits with precision, and adhere to the specified data entry timeline. The challenges posed by complex studies in the ever-evolving field of medicine don't need to lead to sponsors enduring unnecessary delays in obtaining their data or sites having to make a choice between timely data entry and surpassing their recruitment goals.



WHAT'S NEXT FOR THE CLINICAL RESEARCH INDUSTRY?

The industry shows no signs of slowing down, and the future of new therapies entering the market looks promising. Within this momentum, the ongoing challenge of navigating clinical studies is evident. This innovation in trial setup and execution is crucial to keep up with the rapid progress in therapeutic interventions.

When you review your studies to see if your recruitment and retention are currently constrained know that WCG is available to provide dedicated assistance and function as the vital link that connects study teams, sponsors, and participants. Whether your study requires support with Identification, Enrollment, Retention, or Documentation, we provide solutions to help meet your recruitment and retention goals more efficiently.

Contact WCG today to start accelerating your study.

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