Tailored, Dedicated Support Expedites COVID-19 Vaccine Trial

Proactive Approach to Site Augmentation Helps Enroll Over 30,000 Vaccine Study Participants in Just Over Three Months

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As COVID-19 spread around the world, the accompanying lockdowns and travel restrictions brought many challenges for clinical trials. At the same time, there was an urgent effort to develop and test vaccines and therapeutics. These endeavors required enrolling tens of thousands of trial participants as quickly as possible, creating a huge burden on clinical trial sites that were already trying to figure out how to continue work during a global health emergency.

Despite the challenge of a global pandemic, a top five pharmaceutical company developing a COVID-19 vaccine was able to enroll more than 44,000 patients in a clinical trial in just over three months. This record-breaking achievement was made possible thanks to tailored clinical site augmentation that combined the sponsor's strategy with dedicated, qualified resources focused on what sites needed to recruit, support, and retain patients. More than 30,000 patients came from sites that benefited from tailored clinical site augmentation.

AS SITE COMPETITION GROWS, TRADITIONAL APPROACHES FALL SHORT

Even before the pandemic, the approaches used for patient recruitment and retention weren't providing reliable results. Historically, there have been several reasons for this. For one, sponsors are spending an exorbitant amount of money on media-based recruitment campaigns to reach new patients while sites are recruiting from the same pool of patients for various trials. Also, as more clinical trial sites take on more than one study at once and trials continue to increase in complexity, their time, energy, and resources get split. This leaves most clinical sites without the resources they need to effectively recruit and retain the specific patient population needed for a study.

Compounding the problem is the fact that trial recruitment strategies are often built without direct input from the study sites. These campaigns don't usually account for the level of external referrals study sites can handle. Because sites don't know when referrals are going to start or stop coming in, they can become quickly overwhelmed when trying to handle referral volume. Without the bandwidth

to follow up quickly, and a feedback loop to understand the changing site dynamics, potential study participants may fall through the cracks or lose interest.

For years, the overarching strategy, focus, and funding given to patient recruitment and retention efforts has been lacking at best. However, the critical nature of developing a COVID-19 vaccine – and the accelerated timelines required to get a life-saving vaccine approved – made it clear that custom-built resources, technology, and approaches are needed to prepare for the clinical trials of the future.

A MASSIVE UNDERTAKING DURING A CHALLENGING TIME

The scale and timeline of the COVID-19 clinical trials required completely new strategies that had to be implemented during a time when people were just starting to emerge from lockdowns. To meet these needs, WCG solved problems and responded to site-based recruitment challenges in real time, keeping every level of the study and program moving forward.

When the vaccine trial launched, we were able to place 225 WCG Clinical Research Coordinators (CRCs) at over 100 sites in multiple countries in just six weeks. These coordinators provided an extra set of hands to perform record review, contact patients, schedule office visits, perform data entry, and carry out retention activities. This allowed an unprecedented volume of patients to engage with study sites in a short period of time.

Regulatory approvals require data consistency across every region, site, and patient—both in terms of when data is submitted and its quality. For this study, there was a sponsor-mandated requirement for data to be entered within 24 hours. So, every time a site enrolled a new patient or received information from a patient, the details had to be entered within 24 hours. To meet these requirements, we had CRCs working seven days a week at study sites. There were also multiple individuals at each site who solely focused on preserving data integrity and quality.

ONLY A PROACTIVE STRATEGY WILL HELP SITES AND ENROLL THE RIGHT PATIENTS

We combined site augmentation with a media campaigned designed to spread awareness about the trial and enroll the right patients. Because COVID-19 affects people from all walks of life, the FDA and the study sponsor asked that the study engage a larger breadth of patients than is required for most clinical trials. The only way to meet this need under such tight time constraints was through a proactive yet tailored approach. This involved designing a media campaign that was based on the study strategy but uniquely included the ability to customize efforts to meet the needs of each site and market.

We specifically homed in on patient demographics and the volume of referrals a site could take at a given time. We also implemented approaches that made sure that every eligible, potential participant who was already a patient at each study site was contacted. This effort was supported by our My-Patient.com® platform, which provides real-time tracking for incoming referrals and information on how many referrals the site can process. The flexibility to pause a channel for a certain market while a site catches up on those referrals or to open more channels when needed was key for achieving the type of efficiency necessary to enroll a record number of patients in such a short timeframe.

All referrals were put in contact with a study site as quickly as possible to ensure qualified subjects were promptly scheduled for an office visit. The interconnectivity between the media campaign and the full suite of site augmentation we provided was critical in providing the staffing needed to make sure that participants didn't fall through the cracks or lose interest while waiting for a contact.

Our custom-built, holistic approach to site augmentation, which combines a highly targeted media campaign and state-of-the-art technology infrastructure, is essential to enroll the right patients at just the right time. It's what strongly contributed to the overall success of this trial. No matter the trial's operational challenges or therapeutic area's complexities, we can create a tailored and flexible solution that dedicates time, energy, and resources exactly where the sponsor needs them. From a single set of protocols to a full therapeutic portfolio, we increase pharmaceutical companies' competitive strength by providing long-lasting, strategic site relationships to accelerate clinical trial continuity.

KEEPING PATIENTS ENGAGED

Patient engagement is extremely important for retaining study participants. Our 24/7 call

center allows us to engage patients within 24 hours of entering information into the study website. They then receive support throughout their entire trial experience. Each patient has a guaranteed point of contact who can answer logistical questions about visiting a clinical site or provide information about the study. More conversations and better education for patients helps improve retention at the study sites, which ultimately means better outcomes for any study.

As attention increased on COVID-19 and a potential vaccine, the study website began to receive more volume from different patient channels. We built a website with a programmatic function in advance so that different studies with different cohorts with defining characteristics could all flow through the same website. This meant that when an adult came to the website, they could see that there were multiple studies prescreening patients and could select the options that best fit them and other members of their family. This type of programmatic website can be extremely helpful to enroll participants in long-term clinical trials by building brand recognition over time.

QUICK AND EFFICIENT DEPLOYMENT

Our subject matter and deployment expertise, existing infrastructure, extremely high level of commitment, and sponsor engagement helped the COVID-19 vaccine receive an Emergency Use Authorization (EUA) in only 10 months.

Just under 90% of enrollments in the U.S. and 70% of global enrollments came through clinical sites we supported. Globally, more than 40% of the enrollments were from diverse backgrounds.

This success story shows that, with our approach, it's possible to meet aggressive timelines, even for exceptionally large studies. Our consultative approach is not a one-size-fits-all solution. Everything we do is customized to the therapeutic area, the study, the site, and ultimately to each patient. Our highly engaged team of experts is very adaptable and can quickly respond to challenges as they arise.

In addition, we offer global services that put dedicated teams in each region. These teams not only speak the local language and engage with patients in a meaningful way but are also familiar with local regulatory standards. We are ready to support the next wave of vaccine trials, the vast majority of which will be globally focused.

Partnering with us will give your clinical sites the time, energy, and resources necessary to carry out your clinical trials while increasing the patient-centricity of the study. By combining strategy and technology with our clinical experts, we provide the flexibility of an ongoing tailored service, meeting the needs of the site, the sponsor, and the research participants throughout the life cycle of a clinical trial.

WCG is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. Comprised of two segments, Ethical Review and Clinical Trials Solutions (CTS), WCG enables biopharmaceutical companies, CROs, and institutions to advance the delivery of new treatments and therapies to patients, while maintaining the highest standards of human participant protection.

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