CONTINUUM CLINICAL
A SPECTRUM SCIENCE COMPANY

A RECRUITMENT STRATEGY FOR TODAY'S CLINICAL TRIALS

Enrollment is a universal challenge within the clinical trials industry. Countless articles and metrics analyze the same problem: Most clinical trials fail due to inadequate participant recruitment.

The industry's dedication to tackling this issue is reflected by sustained growth in spending on recruitment activities. Some estimates show that the clinical trial participant recruitment market will surpass $5 billion by 2030.[1-3] Despite this surge in investment, enrollment rates steadily move in the opposite direction, declining year over year. A recent study published by WCG revealed a consistent decline in enrollment rates from 2018 through the third quarter of 2022, excluding a temporary spike during the height of the COVID-19 pandemic.[4] This trajectory emphasizes the critical need for a reevaluation of recruitment strategies.

The current landscape of participant recruitment is characterized by turnkey templates and tactics. Often, they are crafted with the aim of casting a wide net within the general disease state, intending to reach a broad audience. This approach can be overly generalized, lacking the necessary precision to engage the target population most likely to be eligible for and interested in participating in the trial — inundating trial sites with ineligible referrals that drain time and resources. The result is a disconnect between recruitment efforts and the individuals who could benefit the most from the clinical trial.

Revamping Clinical Trial Recruitment

It's time to shift toward more nuanced approaches that consider the unique needs, experiences and preferences of potential participants, recognizing that these vary greatly by disease state and protocol. To help stay on time and on target, recruitment strategies require a sharper focus on the target population as well as thoughtful elements of diversity, equity and inclusion.

Clinical trial enrollment will continue to become more competitive, and diverse representation will become even more important in the development of new therapies that improve the health and lives of all those affected by certain diseases.

In June 2024, the Food and Drug Administration published its much anticipated guidance requiring researchers and companies seeking approval for late-stage clinical trials to submit a diversity-focused plan for trial participants. While this guidance is essential to the inclusion of underrepresented racial, ethnic and other demographic populations in clinical trials, Continuum Clinical recognizes the key challenge is the lack of expertise within our industry to make actual change. We need a creative and collaborative approach to help sponsors draft innovative and actionable diversity plans. Only then can we hope to close the health inequity gap in clinical trials. Learn more about how diversity impacts health outcomes.

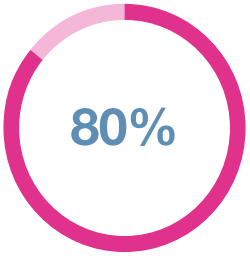
Unleashing the Power of Participant-Driven Strategies

The participant insights-driven approach involves leveraging a deep understanding of potential participants to inform and shape a recruitment strategy. This method goes beyond traditional, one-size-fits-all tactics and embraces a more personalized and empathetic approach by disease state and protocol.

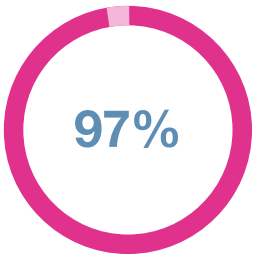
We can truly understand the life of a participant — and caregiver — by elevating their physical and emotional needs above all others. Tapping into their personal experiences can help forge a deep connection and position trial sponsors as trusted leaders that understand their obstacles and aspirations.

Our experience enrolling trials across diverse therapeutic areas in recent years shows that participant insights-driven strategies have played a crucial role in reaching the right audience and achieving enrollment goals.

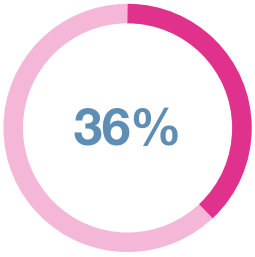
Targeted recruitment campaigns: Out of 20 trials we've enrolled on behalf of a top-20 biopharma sponsor, 80% of trials have enrolled on time or ahead of enrollment.[5]



Patient-insights driven process: In a recent healthy volunteer study, 97% of Continuum generated potential participants randomized into the study compared with 83% of participants generated organically by study sites.[6]



Addressing barriers to participation: In a phase 3 trial, 36% of randomized trial participants were women of color.[7]



Diving Into 5 Key Areas for Clinical Trial Success

Five key areas underpin every clinical trial that we support. At the heart of this methodology is a commitment to deliver innovative, strategy-first and channel-agnostic solutions to sponsors.

We recommend engaging a multidisciplinary group of researchers, scientists, strategists and analytics experts. This team can play a pivotal role in supporting projects throughout the clinical trial continuum — from insights and strategy development to activation and optimization.

1. Deep Human Understanding

"To understand and to be understood makes our happiness on Earth." — German proverb

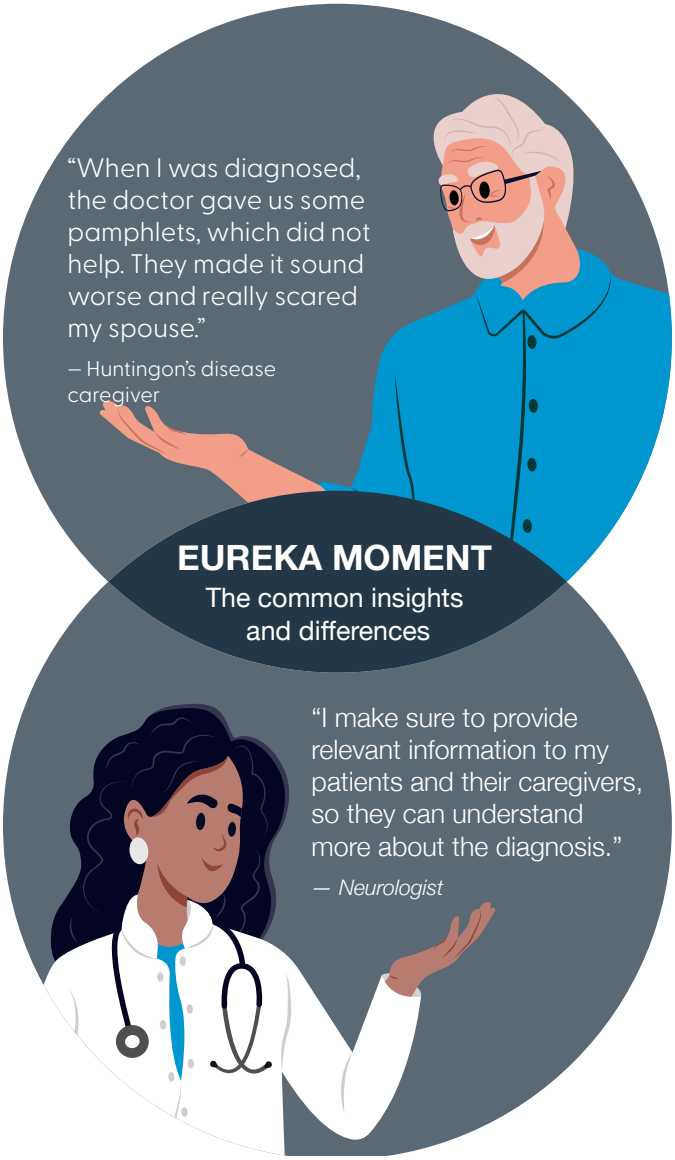
A person who feels completely understood can become a fully engaged participant. To effectively recruit for any clinical trial, you need to understand the participant and caregiver experience. This experience varies considerably depending on the disease state, treatment options currently available and even the clinical trial stage.

To unearth these insights, we use some of the following research methodologies:

- In-depth interviews with potential participants, caregivers and healthcare professionals (HCPs)
- Potential participant and HCP surveys
- Advisory boards and focus groups
- Target population data research and analysis

With this research, we can uncover potential participants' needs, hopes and challenges, and then create bespoke plans that cater to each stakeholder. Incorporating participant insights into trial design, recruitment strategies and overall trial management can help streamline investigative sites and sponsors' efforts.

We often analyze both sides of the treatment experience to guide us to a true insight, which we call our eureka moment.



Thorough research is conducted to make sense of the participant's journey, their experience with the condition and their awareness of clinical trials. This allows us to map out participants' unique motivators and barriers before, during and after clinical trial engagement.

By creating a participant journey map, sponsors gain valuable insights into the participant's perspective as it relates to individual trials. This tool helps tailor participant-focused recruitment strategies and enables organizations to identify the ideal participant profile beyond the protocol's inclusion and exclusion criteria.

In doing so, we can greatly reduce the number of potential participants that need to be engaged at the top of the funnel. Instead, we activate those who are most likely to be both eligible and interested with the right messaging at the right moment. This drives higher rates of conversation and continued consideration at each point in the enrollment process.

Ultimately this leads to more qualified referrals and higher enrollment, saving sites time and energy.

2. Scientific & Clinical Trial Expertise

> **"Research is to see what everybody else has seen, and to think what nobody else has thought." — Albert Szent-Györgyi, Hungarian biochemist**

Understanding a clinical trial from the perspective of every stakeholder is crucial. We need to translate complex scientific topics into actionable messages and consider factors such as competing trials, participant identification challenges and site support needs. What makes the trial exciting? What makes it challenging? What does participation for our target population and sites truly mean?

A myriad of factors influence an individual's decision to participate in a clinical trial. Social, cultural, economic and logistical considerations all contribute to defining the profile of those most likely to participate. Personal values, lifestyle constraints and

the perceived burden of trial participation may significantly impact one's willingness to engage in the trial process.

Acknowledging the impact of these factors is crucial for designing awareness and recruitment strategies that resonate with potential participants. By recognizing that the ideal participant profile is a mix of medical eligibility and broader contextual factors, sponsors can refine their approach to recruitment, enhancing the likelihood of attracting and retaining participants who not only meet the study criteria but also align with the broader goals of the trial.

During a participant-insights project for a vitiligo study, our research identified 3 potential segments of the vitiligo community. All 3 segments would technically be matches for the trial based on the protocol inclusion and exclusion criteria. However, one subset of this population fit the ideal participant profile based on the eligibility requirements and other factors around their needs, personal values and lifestyle considerations.

This research and development of our clinical trial participant personas helped us zero in on the segment of this population who were the most motivated to explore new treatment options. This enabled us to map out the right channels and communication methods for interactions with potential participants.

3. Diversity, Equity and Inclusion in the Forefront

"When everyone is included, everyone wins." — Jesse Jackson, American civil rights activist and former U.S. representative

Understanding the intricacies of the communities we aim to serve is of paramount importance. This includes delving into their cultures, acknowledging their histories and recognizing past experiences that continue to shape their behaviors and perceptions, especially in the context of clinical trials.

> "[Talking about clinical trials] I feel like for older Latinos, they are very weary because of things that happened in the past, with using them as guinea pigs and not being told what was being done to them. I think my grandma and mom, they go to smaller clinics that are in their neighborhood, and they have more trust within those clinics and have a good relationship with those doctors."
>
> *– Hispanic participant, Gen Z*

Diversity must never be an afterthought, it must be in every thought. True representation is achieved by integrating diversity considerations from the first planning meeting through trial completion. Whether it's in protocol design, site selection or social media outreach, a diversity-fueled mindset will deliver more inclusive trials.

EACH COMMUNITY HAS ITS OWN UNIQUE CHALLENGES AND CONCERNS

Blacks and African Americans

- Healthcare system fails to present active research opportunities[8]
- Perceived low compensation[9]
- Participants' inability to have a trial partner, especially for elderly African Americans[9]
- History of mistreatment in clinical research, such as Tuskegee[10]
- Social norms in the community around not trusting doctors and not participating in research[11]
- Lack of awareness[10]

Asian Americans and Pacific Islanders

- Rich diversity of heritages — difficult to find culturally and linguistically accessible information about trials[12]
- Lack of research about Asian Americans and Pacific Islanders[12]
- Some have anti-vaccine and anti-science attitudes[13]
- Concerns about legal issues if the trial fails or privacy protection[13]

Hispanics and Latino/a/x

- Hispanic participants tend to be private and may take time to develop trust in their physician[14]
- Being only Spanish-speaking can be a barrier, as translators are often inadequate or unavailable[14]
- Citizenship status (and somewhat relatedly, health insurance)

LGBTQ+

- Lack of appropriate physicians' training and healthcare disparities
- Gaps in coverage for certain groups
- Cost-related hurdles
- Stigma, including poor treatment from healthcare providers

Key Area in Action: Continuum Clinical was asked to generate large-scale awareness of cytomegalovirus (CMV), a largely unknown virus, and drive enrollment for a clinical trial among women of child-bearing age.

Our participant-insights research showed that although CMV is the leading cause of birth defects globally, 91% of women had never heard of it.[15] Moreover, the diverse populations that were needed for the trial were typically not represented in recruitment campaigns and were distrustful of trials in general.

We leveraged these findings to create a compelling campaign that urged viewers to stop the silence around CMV by activating the activist inside each potential participant. The diverse target audience was authentically represented using photography of women from various ethnic groups, enabling viewers to identify with the messaging.

Our 2-phase campaign resulted in:

- **11,000 women** in the U.S. signing up to learn more
- **9,000 referrals** and **360 enrollments** to the trial
- **36%** of enrolled trial participants from the campaign were people of color

This accomplishment supported our belief that adapting to the needs of diverse populations is not only an ethical imperative but a strategic advantage in achieving more representative clinical trials. We should all continue to advocate for equitable access to research opportunities and embrace diversity at every stage of the recruitment process.

Learn more about overcoming enrollment barriers for minority populations.

4. Distinctive Creative Approach

"Without creativity, there would be no progress, and we would be forever repeating the same patterns." — Edward de Bono, Maltese physician and author

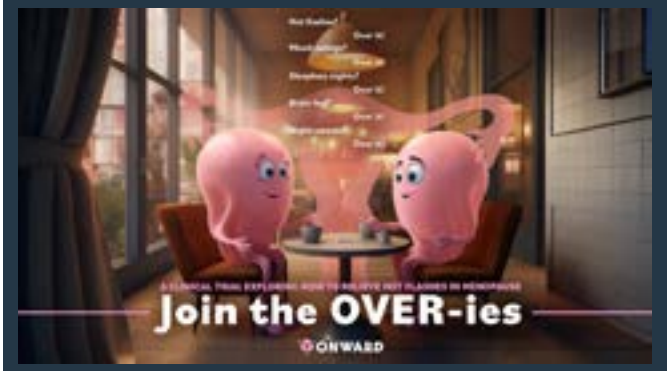
Each clinical trial is unique, each disease state is unique and each participant is unique. Therefore, each clinical trial should have its own unique identity. This is executed by creative branding, informed by strategy and infused with meaning.

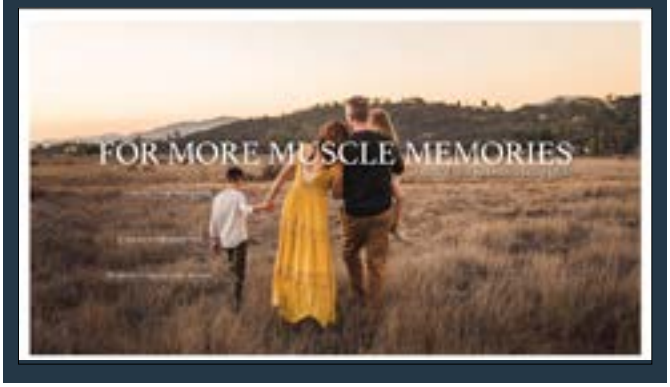
Branding, including a distinctive trial name, logo and visual identity, can inspire patients, caregivers, HCPs and investigators to engage in and support trial efforts. We need to signify to the right participant that this is the clinical trial best suited for their needs. Eye-catching creative branding can maximize the chance for recruitment success.

A trial name could relate to participants' pain points, hopes or experiences with the disease, fitting into either a descriptive, inventive, acronymic, historical, geographic or founder category. Names have the power to capture a potential participant's attention and create differentiation and preference for investigators and sites supporting numerous trials. For multiple-trial portfolios, we recommend a consistent naming convention to ensure creative harmony and a unified story. A color palette and logo also help inform audiences of a clinical trial's mission and help the trial stand out from competitors.

We believe creative concepting is the secret sauce to trial branding. Go beyond stock photos or a simple look-and-feel to explore a wide range of concept ideas, art styles and headlines. Will an illustration style speak to these potential participants more than photography? Should the participant or disease be the focus in the visuals or would a metaphor inspire more action? Weave a story tailored to the eyes of potential participants, and once a concept is chosen, carry it through the tone and supplementary imagery of every recruitment and retention material.

Sample trial branding spec work from Continuum Clinical





Testing the creative branding in research can help ensure it resonates with and drives the desired behaviors of potential participants. Successful branding will encapsulate a true understanding of both the audience and trial. By marrying the two, we can showcase the impact that the trial could have on participants' lives.

5. The MERIS Total Engagement Solution for Clinical Trials

By using MERIS, Sponsors and their partners will have confidence that their clinical trial milestones will be met.

The MERIS™ Total Engagement Solution interacts with participants throughout their clinical trial journey and gives Sponsors the opportunity to proactively identify precise barriers that could impact enrollment and retention.

This insight allows for real-time course corrections and adjustments, which will bring predictability back to clinical trials. Using an innovative set of analytics tools, MERIS improves visibility and removes enrollment and retention blind spots. Real-time aggregated data, coupled with predictive modeling of enrollment projections, provides visibility into when the incoming campaign referrals will turn into appointments, screening visits, and subsequent randomizing. This allows Sponsors to understand the downstream impact of campaigns in near real-time to accurately project the cost and time required to achieve program success.

MERIS helps those accountable for the success of clinical trials achieve and exceed milestones by:

- Eliminating uncertainties for clinical trials by providing streamlined predictability
- Engaging participants at every step of the clinical trial journey
- Providing visibility into all enrollment and retention activities by consolidating data from all sources

Wrapping Up Our Perspective

In an environment where clinical trial recruitment often consists of turnkey templates and tactics, focus on developing customized, strategy-driven solutions to reach, engage, enroll and retain participants. We have experienced firsthand the positive impact this approach has on ensuring our clients meet or accelerate enrollment.

Embrace this innovative, strategy-first approach in 5 key ways:

1. Dive deep into understanding the participant and caregiver experience through research methodologies
2. Define the profile of those most likely to participate and explore factors such as competing trials and site support needs
3. Bring diversity, equity and inclusion into the limelight by instilling it into every facet of the clinical trial
4. Weave participant insights and the clinical trial mission together through creative branding
5. Refine digital and social campaigns with real-time analytics and machine learning

Clinical trials are the cornerstone to advancing treatment for all those in need. Without successful trials, we risk a longer path to protecting people from disease. The solution to clinical trial recruitment and retention is in your hands: prioritize participant-driven insights, inclusivity and creative strategy, backed by science and data.

At Continuum Clinical, we are deeply committed to continuous learning and guiding our clients on their journeys to better serve diverse populations and meet their enrolment targets. To learn more about our capabilities and our differentiated approach to clinical trial recruitment and retention, reach out to us directly at kshore@continuumclinical.com

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