

# **Enhancing Clinical Research through Community Engagement: A Vital Step Towards Diversity and Inclusion**

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## **Bridging the Gap: The Power of Community Engagement in Clinical Research**

In the world of clinical research, the role of community engagement has emerged as a critical factor in ensuring the success of clinical trials. In 2020, a pivotal moment unfolded with the release of transformative guidance by the Food and Drug Administration (FDA), shedding light on a more inclusive direction for clinical trials. Throughout history, clinical trials have often unintentionally marginalized the perspectives and experiences of minority groups, resulting in a substantial gap in our comprehension of how potential treatments impact diverse populations. However, a glimmer of hope has emerged in the form of community engagement, charting a course toward a future where inclusivity takes center stage. But what does community engagement truly mean, and how can it be effectively integrated into the research process? This article will focus on community engagement and introduce the Transtheoretical Model of Community Engagement, a robust framework that can transform how we approach clinical research.

## **Defining Community and Engagement**

First, let's establish a foundation by defining the two core elements of "community engagement."

*Community* refers to individuals bound by shared characteristics, interests, or geographical proximity. In the context of clinical research, the community encompasses not only potential trial participants but also healthcare workers, research staff, and community leaders.

*Engagement* involves creating meaningful connections and interactions within this community. It's about cultivating relationships, communication, and shared responsibility in pursuing common goals, particularly advancing medical knowledge and improving healthcare outcomes.

## **The Transtheoretical Model of Community Engagement**

The Transtheoretical Model of Community Engagement is a robust framework designed to facilitate community engagement in clinical research. Developed by Laquita Gilbert, Director of Diversity Education and Outreach at TOTAL Diversity, this model aligns community engagement with the stages of behavior change, thus providing a structured and comprehensive approach to the process.

1. **Precontemplation:** At this stage, communities may be unaware of clinical trials or have misconceptions. The community engagement strategy should focus on raising awareness about clinical trials, using activities such as informational materials and community education sessions.
2. **Contemplation:** Communities may consider participation but have concerns or doubts. The engagement plan should address these concerns by providing accurate and accessible information about the clinical trial process.
3. **Preparation:** Communities seek information to prepare for enrollment. This stage should involve collaborating with local healthcare providers and organizations to establish referral networks and offer guidance on navigating the enrollment process.
4. **Action:** Community members actively participate in clinical trials. The plan in this stage should include strategies to ensure ongoing support, engagement, and retention of participants.
5. **Maintenance:** The focus is on supporting participants to stay engaged throughout the clinical trial. Regular check-ins, newsletters, and celebratory events help maintain motivation.
6. **Termination:** The final stage aims to facilitate participants' transition from the clinical trial and maintain their connection with the research site.

Incorporating the Transtheoretical Model of Community Engagement into clinical research provides a structured path to diverse participation. It signifies the commitment to fostering lasting connections between communities and the research process.

### **Real-Life Example: Bridging Communities and Research**

To understand the power of the Transtheoretical Model of Community Engagement, consider the hypothetical scenario involving a research site working on a groundbreaking clinical trial for a rare disease. The site initiated a comprehensive community engagement plan, addressing each stage of behavior change.

Engaging local healthcare providers raised awareness and dispelled myths about the trial (precontemplation). They organized town hall meetings to address questions and concerns (Contemplation) and provided resources to help prospective participants prepare for enrollment (Preparation). During the Action phase, they established support groups and maintained regular communication to foster participant engagement (Action). As the trial progressed, they celebrated milestones and expressed gratitude to maintain motivation (Maintenance). Finally, after the trial's completion, they discussed future opportunities, keeping the connection with participants alive (Termination).

This approach led to high enrollment and retention rates and built a strong sense of community around the research site. The community engagement efforts transformed participants into advocates, willing to participate in future studies and contribute to the broader goal of advancing medical knowledge.

In conclusion, community engagement is an indispensable component of successful clinical research. The Transtheoretical Model of Community Engagement offers a structured approach that aligns with the stages of behavior change, making it a powerful tool to bridge

the gap between research sites, healthcare providers, community leaders, and participants. By embracing this approach, the clinical research industry can strengthen its ties with communities, advance medical knowledge, and ultimately improve healthcare outcomes for all. Through meaningful community engagement, we can truly transform the clinical research landscape.

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Laquita is an exceptional professional with a profound commitment to community outreach and education. Her expertise lies in health promotion and developing and implementing comprehensive outreach programs that address the unique needs of diverse communities. Her passion for creating positive change shines through her ability to build strong relationships and engage with individuals from all backgrounds. With a deep understanding of the challenges face by marginalized populations, Laquita utilizes her expertise to create effective strategies that empower research sites and communities.



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Dr. Diana Foster is a renowned expert in site management and strategic marketing, led DAC Patient Recruitment Services, transforming it into a premier patient recruitment organization. She has extensive experience in site operations and is the Vice President of Strategy and Development at the Society for Clinical Research Sites. Diana has a global presence, having spoken on five continents, authored five industry books, and received numerous accolades, including recognition by the Global EXEC Women's International Council and PharmaVOICE. She is dedicated to advancing international clinical trials and serves on the boards of various organizations, including the Center for Information & Study on Clinical Research Participation.