

Co-Creating Your Roadmap to Community Engagement in Clinical Research

Community engagement in clinical research is no longer optional. It is foundational to the future of inclusive, representative science. At the 2025 SCRS IncluDE Site Solutions Summit, more than 200 clinical research professionals from across sites, sponsors, CROs, and vendors gathered to explore what meaningful, sustainable engagement really looks like in the Co-Creating Your Roadmap to Community Engagement session.

This work is not only ethically necessary—it's a business imperative. Despite an exponential increase in the number of clinical trials, enrollment rates have not kept pace. A major barrier remains public awareness: many individuals are still unaware that clinical trials exist, what participation entails, or how to get involved. Community engagement addresses this head-on by providing culturally relevant education and outreach, especially to those historically excluded from research.

Every community is different, and there is no one-size-fits-all solution, but the guiding principles are the same: understand your community deeply, build trust before you need it, and measure what truly matters.

Understanding & Defining Community

Every trial, every study participant, every connection happens within a broader human context—the community. Yet too often, the term “community” is used loosely, without a clear understanding of who is being served, what their needs are, or how they define themselves. This ambiguity can lead to misaligned strategies and missed opportunities for meaningful engagement.

The first and most essential step in creating a community engagement roadmap is to intentionally define what “community” means for your site, sponsor, or CRO. That definition cannot be based solely on proximity or convenience. It must be rooted in the lived experiences of the people you serve—geographically, culturally, and socially. For some, community may mean a zip code. For others, it's a rare disease population spread across states or an online support group where trust has already been built.

During the workshop, participants emphasized the importance of intentionally defining your community—not only to strengthen patient recruitment and engagement, but also to open yourself to learning about new perspectives and challenging existing assumptions. They emphasized the importance of mapping influence networks, identifying trusted voices, and recognizing that some of the most powerful community partners may never step foot in the clinic.

Understanding the community's ecosystem isn't about theoretical data—it's about lived realities. What barriers do people face when seeking care? Who do they turn to for health information? Where are the gaps in access, trust, or visibility? Whose voices aren't being heard? What community dynamics are influencing health access, trust, and awareness? These aren't side questions. They are foundational. Only when these questions are addressed can sites begin to create strategies that are both inclusive and effective.

Key Principles

- Community can be geographic, demographic, cultural, digital, or experiential—and often overlaps.
- Different populations may require different approaches, even if demographically similar (e.g., communities in rural vs. urban areas).
- Utilize tools like Community Partner Mapping to understand stakeholders, influencers, and information flow.
- Understanding community means going beyond the data. It requires engaging with the people behind the numbers.
- Sites must look beyond their patient database to understand the broader environment in which those patients live, work, worship, and connect.
- Effective assessment includes both data (e.g., census, SDOH, local reports) and human insight (e.g., trusted messengers, community norms).

Recommendations

- Define your community based on catchment area, therapeutic area, or shared experience.
- Include digital communities in your engagement planning.
- Partner with local institutions like churches, barbershops, schools, advocacy groups, and health departments.
- Create a Community Partner Map that includes institutions, influencers, and local leaders.
- Consider demographics, socioeconomic indicators, trust, access, technology to help frame your population.
- Regularly update your understanding of the community—not just once per study.

“We realized our community isn’t just the patients who walk through our doors, but also the voices we hear online, and the stories shared in local gatherings.” – IncluDE Workshop Participant

Building and Maintaining Relationships

Relationship-building is the backbone of community engagement. Unlike typical outreach, which may be episodic and may make it feel transactional, relationship-driven engagement requires consistency, cultural humility, and transparency. It is built over time, through repeated interactions, mutual benefit, and listening more than speaking.

During the workshop, participants reflected on how their own backgrounds, roles, and organizational cultures influence the way they engage. Many discussed the importance of “reflecting your lens” to identify unconscious assumptions, blind spots, and gaps in representation that may be undermining their efforts before they even begin.

This section explores how clinical research professionals can take meaningful steps to move from awareness to action, starting with themselves and expanding outward into the community. Whether you’re working in a rural health system, a city-based academic site, or supporting trial operations from a sponsor or CRO, the same principle applies: trust is earned, not assumed.

Key Elements of Trust-Building

- Early Engagement: Initiate conversations before there’s an immediate need.

- Consistency: Follow through on commitment; engagement isn't a one-time activity.
- Transparency & Listening: Be clear, admit uncertainties, and remain open to learning.
- Cultural Awareness: Honor community traditions, recognize the impact of historical medical injustices, and validate the lived experiences that shape perceptions of research and care.

Recommendations

- Incorporate staff training on cultural humility and community-specific engagement.
- Invest in long-term partnerships (e.g., local colleges, senior centers, advocacy groups) rather than short-term event sponsorships.
- Be present in the community even when you are not recruiting—visibility builds trust.
- Reflect internally: how does your team's background and identity align (or misalign) with those you're trying to serve?

Engagement vs. Outreach: Know the Difference

In clinical research, the terms “community engagement” and “community outreach” are often used interchangeably, but their meanings and impacts are fundamentally different. Workshop participants repeatedly emphasized the importance of distinguishing between the two when building sustainable relationships with communities.

“Trust isn't built overnight. It's the result of showing up, listening, and being present, even when there's nothing to gain immediately.” – Include Workshop Participant

Engagement is rooted in partnership. Outreach is often event-based or transactional. Both have value, but knowing when—and how—to use each approach is essential for long-term trust and participation.

Key Principles

- Engagement involves mutual trust, consistent communication, and co-created value.
- Outreach is often one-way, centered around disseminating information or executing one-time events.
- Fit-for-purpose strategies mean tailoring your approach to the community's needs, stage of relationship, and communication preferences.

Recommendations

- Include digital communities—social media groups, online health forums, and support networks.
- Evaluate whether your activity is creating a sustained relationship or simply delivering a message.
- Invest in recurring events and consistent communication channels (e.g., monthly health forums).
- Engage before there is a study to promote—not after.
- Clarify internally: are you planning to engage or to inform?

“Outreach tells the community what's happening; engagement asks the community what should happen.”— 2025 IncludE Workshop Participant

Practical Engagement Strategies

Meaningful community engagement does not require large-scale budgets or national campaigns. It requires presence, intentionality, and cultural fluency. During the workshop, participants shared dozens of creative, resourceful ideas that demonstrated how even small actions can have a big impact.

Whether partnering with local businesses, leveraging social media influencers, or hosting informal lunch-and-learns, the strategies that work best are those that are tailored to the local context and created *with*, not just *for*, the community.

Key Principles

- There is no “one-size-fits-all” strategy—every community has different communication preferences, influencers, and needs.
- Effective engagement meets people where they are—literally and culturally.
- Sustainability matters more than scale; long-term presence builds trust.

Recommendations

- Use local institutions like churches, schools, libraries, and grocery stores to spread awareness.
- Identify and support trusted messengers: community doctors, pastors, teachers, and even hair stylists.
- Embrace technology—use social media to highlight your team and demystify research processes.
- Pilot community advisory boards or youth ambassador programs to keep your efforts grounded in lived experiences.

“We hosted a lunch at the local senior center just to answer questions about research. We didn’t pitch a study—we just listened. The impact was enormous.”— 2025 IncluDE Workshop Participant

Securing Resources and Demonstrating Impact

While the pharmaceutical industry increasingly acknowledges the value of sustained engagement, execution still lags. According to the most recent SCRS IncluDE Landscape Survey, over 75% of respondents reported receiving little to no support for community engagement, whether related to specific trials or broader programs. Without intentional investment, these efforts risk becoming one-off gestures rather than a stable part of trial infrastructure.

Participants repeatedly emphasized that sponsors, CROs, and funders want to see outcomes, but those outcomes must go beyond trial enrollment. Community trust, awareness, and relationship-building are measurable and meaningful indicators of success. When sites can demonstrate impact, the pathway to funding becomes clearer and more compelling.

Key Principles

- Engagement initiatives should be resource-aware, not resource-dependent—start with what you have.
- Metrics should reflect the true scope of engagement, including qualitative outcomes and relationship-building efforts.
- Transparency and accountability in reporting outcomes increase credibility with funders and partners.
- Sponsors and CROs must set clearer expectations for trial-related funding opportunities.

Recommendations

- Develop a long-term community engagement strategy and define how it will support and enhance awareness of your clinical trials.
- Track and report community metrics such as:
 - Number of community partnerships formed
 - Types of outreach events conducted
 - Attendee demographics and feedback
 - Materials distributed (flyers, translations, digital impressions)
 - Qualitative stories that show increased awareness or trust
- Use these metrics to advocate for increased engagement budgets during feasibility discussions and trial negotiations.
- Pursue local and private grants, partner with nonprofit organizations, and “just ask”—many participants found that funders are more receptive than assumed.
- Maximize existing resources by:
 - Repurposing staff time toward outreach roles
 - Cross-training team members
 - Collaborating with other sites, FQHCs, or health departments to share the engagement burden
- Clarify return on investment (ROI) with realistic expectations—first-time engagement should not be measured by enrollments, but by trust and awareness.

Closing Reflections: Start Small, Think Big, Stay Committed

The workshop made one thing clear: every site, sponsor, and CRO has a role in shaping what community engagement looks like in practice—and that begins with intentionality. Whether it’s mapping out your local partners, reflecting on your own lens, or funding a grassroots event with limited resources, progress begins with one deliberate step.

“If you only track patient enrollments, you’re missing the story. Our strongest impact has been measured by who shows up to ask questions—and keeps showing up.”— 2025 IncluDE Workshop Participant

Community engagement is not a marketing strategy, public relations effort, a line item or a check the box—it is integral to the scientific and operational success of clinical trials. Without dedicated infrastructure, these efforts remain inconsistent and unsustainable, limiting both representation and the generalizability of research findings. Moreover, sites cannot do this work alone. Industry must provide the support, funding, and flexibility necessary to turn intention into action that supports research reflecting the people it’s meant to serve.

Let this be your charge: take what you’ve learned, commit to one action, and do it well. Share your successes, reflect on your missteps, and above all, stay accountable to the communities you aim to serve. Because when we do this right, community engagement isn’t just good for research. It’s good for people.