ROUNDTABLE SUMMARY

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Community Connections: Leveraging Localized Patient Access In Clinical Trials For Better Representation, Improved Retention, And Higher Quality Data

Presenters:

Jeff Huntsman, Chief Commercial Officer, EmVenio Clinical Research
Zhanna Jumadilova, Clinical Lead, Pragmatic Clinical Trials, Pfizer
Matthew Kratz, Principal Lead, Patient Strategy and Insights, Parexel
Melissa Penn, Director of Patient Engagement R&D, Bayer Pharmaceuticals
Meenakshi Valadi, Director of Engagement, Clinical Research Justice League
Thad Wolfram, Chief Strategy Officer, EmVenio Clinical Research

Moderator:

Derrick Gingery, Executive Editor at *Pink Sheet*, Citeline (Moderator)

KEY THEMES

- Ensuring trial diversity starts with going where diverse patient populations are—in the communities.
- Practical strategies for community-based research must meet the needs of both site staff and patients.
- Engaging patients in community research improves the quality and relevance of trial data.
- Measuring ROI for adopting community research requires starting with the end goal in mind.

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OVERVIEW

Two of the pharmaceutical industry's most important priorities are improving patient access to clinical trials and improving the diversity of patients who participate in trials. To make progress on these priorities, trial sponsors have attempted different patient recruitment and retention strategies with varying degrees of success.

Making better use of community-based clinical research sites can help pharma companies achieve both goals while also shortening trial timelines, reducing costs, and ensuring regulatory compliance—which is an optimal scenario for all stakeholders involved.

CONTEXT

The panelists discussed how tapping into community-based research approaches can improve enrollment of the right patient populations, enhance dataset quality, strengthen study relevance, support patient engagement, reduce costs, and incorporate regulatory compliance from the onset.

KEY TAKEAWAYS

Ensuring trial diversity starts with going where diverse patient populations are—in the communities.

Clinical research models are evolving from the traditional approach, where a handful of trial sites—often situated in large academic medical centers—would serve as sponsors' go-to patient recruitment locations, regardless of the target patient profiles or socioeconomic backgrounds of potential trial participants.

In the quest to enroll diverse patient populations into clinical trials, pharma companies are increasingly complementing the traditional approach with community-based models. The reason: the traditional, limited enrollment approach was not as efficient or effective as pharma companies once thought.

> "To allow broader patient access to trials, you have to go where the patients are—and patients are in the community setting because that's where they get care delivered. So it makes sense, from both business and medical perspectives, to reach patients where they are."
>
> *– Zhanna Jumadilova, Pfizer*

But with sponsors broadening their horizons in terms of where to look for more diverse and targeted patient populations, they need to update their recruitment and retention methodology.

> "Traditional sites have been engaging the same patient population in the same way for decades. In going out into the community, you have to completely rethink how you're going to engage, recruit, and retain this broader patient population, which is both the biggest challenge and the biggest opportunity."
>
> *– Thad Wolfram, EmVenio Clinical Research*

For example, in community settings, improving retention is mainly a result of earning trial participants' trust. In traditional research settings, on the other hand, high retention rates may be more a function of trial protocol or optimizing logistics.

> "At Clinical Research Justice League, we believe that improving patient access [through retention] follows trust. We are focused on earning community trust through engagement, education, and collaboration with sites, sponsors, and CROs."
>
> – *Meenakshi Valadi, Clinical Research Justice League*

To build this trust, pharma companies would benefit by considering ways to become more involved in communities beyond just conducting trials; for example, by hiring locally or giving back to the community in various ways.

> "Sponsors should be able to do something for building the communities rather than just extracting data from sites. It's about being present, staying present, and building true, ongoing partnerships with communities."
>
> – *Meenakshi Valadi, Clinical Research Justice League*

> "You have to be a part of the community first before you start talking to people about clinical trials. Adding value to a community that doesn't have anything to do with clinical trials is a really good way to help earn trust."
>
> – *Thad Wolfram, EmVenio Clinical Research*

> "We need to make medicines with the community, not for the community."
>
> – *Melissa Penn, Bayer Pharmaceuticals*

In addition, improving trust in communities in order to recruit new patients into clinical trials requires new forms of outreach. Patients don't just need more information about a trial or their condition—they need guidance conveyed in plain language.

> "We have the internet, and we have information, but we don't have guidance. We don't have, 'What's best for me? What's focused on me?' [Patients] can google their condition and get a million hits, but that doesn't really help them. They need information that's actionable, that takes them to a site, and that [connects them with] a community group with fellow patients who are dealing with the same issue and are knowledgeable."
>
> – *Matthew Kratz, Parexel*

Once participants are recruited into a trial, improving retention also depends on how supported they feel throughout the trial, Meenakshi Valadi, director of engagement, Clinical Research Justice League, added.

> "If patients don't feel supported or if they are not given the right kind of attention when they participate in trials, there will be a lot of dropouts, and retention will become a real challenge. Inclusive research = higher retention, better data, and global relevance."
>
> – *Meenakshi Valadi, Clinical Research Justice League*

Practical strategies for community-based research must meet the needs of both site staff and patients.

To incorporate community-based research into clinical operations, sponsors must consider the unique training needs of community sites, which often lack the expansive resources, capabilities, and know-how of larger academic medical centers with extensive research experience.

> "It's about listening to what the needs of principal investigators and research staff are and giving them support, not just telling them what to do, so they can go within their communities and broaden the reach of the trials. That requires a long-term investment."
>
> – *Matthew Kratz, Parexel*

To bring community-based investigators into its clinical research network, who in turn can bring new patient populations into trials, Parexel has a site scholarship program and an emerging site network. "Building these networks, training them up, and giving them the support that they need is a long-term investment," Matthew Kratz, senior patient recruitment lead, Parexel, said.

Another practical strategy for facilitating community-based research is simplifying trial protocols so that participating in trials does not place excessive burden on patients' time and effort. To achieve this, it is critical that sponsors seek patient input into protocol design early on to ensure that trial requirements are reasonable and that trial endpoints align with patients' functional health objectives.

Equally important as making sure trial protocols are simplified and aligned with patients' needs is ensuring that they also work for sites. "The protocols that we build have to be fit for purpose and manageable by sites in community settings," Zhanna Jumadilova, clinical lead for pragmatic clinical trials at Pfizer, said.

> "In academic centers, many of our protocols' schedule of activities and eligibility criteria go up to 50 bullet points. There are blood draws after blood draws every two weeks . . . so it's hard not only for research staff to administer that protocol, but also for patients to be part of the trial long term."
>
> – *Zhanna Jumadilova, Pfizer*

Melissa Penn, director of patient engagement R&D at Bayer Pharmaceuticals, emphasized the criticality of co-creating trial protocols and outcome measures with patients—an approach she summed up as "nothing about us without us." That approach improves the chances of patients enrolling and staying in a trial.

> "Nothing about us without us."
>
> – *Melissa Penn, Bayer Pharmaceuticals*

To bring further flexibility to sometimes burdensome trial protocols, pharma companies should also consider whether trial visits can be timed and aligned with patients' normal clinical visits. "It's not applicable in every situation, but in situations where it is, we need to try to do that," Jumadilova said.

> "It's a cultural shift for pharma companies because we are built to do science, so with every opportunity, we're trying to get more data through every protocol. But we have to be able to sit back and think, 'For this particular research product, do I need patients to come to the site every two weeks?'"
>
> – *Zhanna Jumadilova, Pfizer*

Not approaching community-based research from the perspective of making it easy for patients to participate in trials would inevitably clash with reality. "In the communities, it's a whole different ball game because [people are dealing with] transportation challenges, food challenges, whether or not they have childcare," Jeff Huntsman, chief commercial officer at EmVenio Clinical Research, said.

> "The industry is very good at using big buzzwords such as 'patient centricity' without really saying, 'What does that actually mean?' As the industry evolves, we have to [start asking the question of] how do we make it easy for people to participate in trials and what's the benefit for them."
>
> – *Jeff Huntsman, EmVenio Clinical Research*

In a similar vein, Thad Wolfram, chief strategy officer, EmVenio Clinical Research, highlighted another contradiction in the pharma industry when it comes to partnering with community-based sites. "You hear so much about, 'We want [to work with] new PIs, we want new sites. But when a study comes up, it's, 'I want a PI with lots of experience.' So immediately these sites get filtered out very quickly."

Engaging patients in community research improves the quality and relevance of trial data.

The key data advantage of conducting community-based research is that as the swath of trial participants broadens, sponsors obtain more representative data of the target patient population that will eventually use the drug.

For sponsors to benefit from this data advantage, though, they have to believe that trial data captured in community settings is of equal quality to data captured in large academic medical centers. This is an assumption the industry often still refuses to fully accept.

> "We have research units that look like mobile homes, whose advantage is that you can embed them next to a YMCA or in a Home Depot parking lot because that is the central point in a community. It's a clinical research site, but because it's not in a hospital setting, you have to spend all this time justifying that you run clinical research the exact same way that is done in a brick-and-mortar site."
>
> – *Jeff Huntsman, EmVenio Clinical Research*

In fact, there is a view by some in the industry that research data captured in community settings can be of even *higher quality* than data obtained in the tightly controlled environments of academically supervised research. This is because community-captured data is real-world data whose importance is continuously being highlighted by regulators, industry, and patient advocacy groups.

> "When you're able to be more flexible with where data is being captured, that's more real-world capture of data than when somebody has to go into an academic medical center. . . So data quality can be better in that [community] scenario."
>
> – *Jeff Huntsman, EmVenio Clinical Research*

> "Not every situation will allow for that, but there are many instances where the use of real-world data to generate real-world evidence should be enhanced and driven by sponsors."
>
> – *Zhanna Jumadilova, Pfizer*

One aspect that should alleviate concerns about the quality of community-based data collection is that much of the relevant real-world data for researchers is already being captured in community clinics' electronic health record (EHR) systems. Thus, the main issue is not one of data availability or data capture, but of the technology necessary to transfer that data from the EHR to research databases.

"There is EHR-to-ADC technology that exists to do that, but it's not utilized enough, and there's technical complexity to it. So the technology still needs to be worked out, but I think that's the future," Jumadilova said, referring to automatic data capture (ADC) technology.

Measuring ROI for adopting community research requires starting with the end goal in mind.

To measure return on investment (ROI) in community-based research, sponsors need to compare it to the ROI from conducting studies in traditional research sites, such as academic medical centers.

Companies also need to employ different financial models to accurately capture the ROI on localized research. Under conventional financial modeling, operators assess ROI through the prism of cost per line item as the study progresses rather than by looking backward from the desired outcome and assessing whether that outcome has been achieved and at what cost.

"There has to be this desire to start looking backward from the endpoint back to the study design," Huntsman said. In traditional modeling, he noted, "Nobody worries about a 18% dropout rate" due to suboptimal study design, yet such high levels of patient loss can significantly delay trials or even lead to trial cancellation—a negative ROI.

> "The real return on investment is, Was that asset able to move faster? Was the trial able to get more patients enrolled sooner or more patients retained? And were we able to do a health authority submission sooner?"
>
> – *Jeff Huntsman, EmVenio Clinical Research*

> "Return on investment . . . we believe in return on community trust, rather than looking at something in the form of dollars. We track that through community referrals across studies, repeat participation, and retention-based strategies that are not relevant to just one protocol, but across studies."
>
> – *Meenakshi Valadi, Clinical Research Justice League*

CONCLUSION

The benefits of community-based research for patients, trial sponsors, and healthcare at large are undeniable. However, to make such research a standard part of pharma companies' trial design strategies—in essence, a must-have and not just a nice-to-have component—sponsors need to have a long-term commitment to community-based research and must make long-term investments.

"You have to build trust and engagement in the community and that takes time. It takes multiple studies, not just, 'We're going to use you for this one study and then we're going to forget about you tomorrow.' It has to be ingrained in what you do and how you approach every study."

– *Matthew Kratz, Parexel*

"Once we have a more general understanding that the greatest value is right in front of us—in the community and with the community—the business value [of long-term commitment and investment] will become foundational."

– *Zhanna Jumadilova, Pfizer*

"Partnering with communities to reduce the burdens and raise awareness of clinical study participation is fundamental to building trust, achieving representation, facilitating comprehensive recruitment, and ultimately ensuring that scientific advancements are accessible and impactful in real-world settings."

– *Melissa Penn, Bayer Pharmaceuticals*

BIOGRAPHIES

Jeff Huntsman

Chief Commercial Officer
EmVenio Clinical Research

Jeff Huntsman is the Chief Commercial Officer, responsible for commercial strategy and revenue. Mr. Huntsman joined EmVenio Clinical Research in 2024 with over 30 years of experience guiding global commercial teams in clinical development and regulatory spaces.

Mr. Huntsman previously led a consulting firm and held Chief Commercial Officer roles at Parexel, Citeline, ConnectiveRx, and LIQUENT, in addition to serving in executive leadership positions at several other organizations. Mr. Huntsman earned a B.S. in Marketing and Political Science from Ball State University in Muncie, Indiana.

Zhanna Jumadilova

Clinical Lead, Pragmatic Clinical Trials
Pfizer

Zhanna Jumadilova is a physician scientist and a pharmaceutical executive with extensive experience in the industry in Clinical Development, Medical Affairs, HEOR and General Management functions in "big" pharma and mid-size biotech companies. In her roles as a senior leader, she has led numerous programs for small molecules and biologics across multiple therapeutic areas. In her current role she leads Pfizer efforts on integrating pragmatic clinical trials in medical evidence generation strategies across the company's portfolio of assets.

Her broad industry experience includes:

- Leading the design and execution of complex phase 2-4 development programs including major efficacy/safety clinical trials, pragmatic and observational/real world studies, pediatric clinical trials to support product development, approval, market preparation, launch and growth.
- Leading the development and implementation of strategic plans and research projects to support value drivers of market access strategies.
- Building and leading a new development organization for a small to mid-sized pharmaceutical company.
- Leading the development and implementation of internal policies and standard operating procedures for large and small companies in compliance with internal and external regulatory requirements.

She has been extensively published on relevant topics on clinical development, patient reported outcomes research, health economics and others in medical literature and an active member of TransCelerate BioPharma, a non-profit organization with focus on advancing innovation in clinical research.

Matthew Kratz
Principal Lead, Patient Strategy and Insights
Parexel

Matthew Kratz has over 25 years of healthcare communications and clinical trial experience with a broad range of experience across different phases of clinical research, and within multiple therapeutic areas. He is currently a Principal Strategy Lead in Parexel's Patient Strategy & Insights group focused on providing effective patient and site engagement pre-award solutions. Kratz has worked in clinical research for years at Parexel, United BioSource (UBC), and MMG. He also has experience across healthcare environments including public relations agencies, associations, and industry at Bayer Diagnostics.

Kratz holds a bachelor's degree in political science from Wake Forest University.

Melissa Penn
Director of Patient Engagement R&D
Bayer Pharmaceuticals

Melissa Penn, Director of Patient Engagement R&D within Bayer Pharmaceuticals' Patient Partnership and Stakeholder Engagement global team, leverages her expertise in patient engagement to advance health and health outcomes for both pediatric and adult populations. She leads initiatives for early, meaningful, and consistent patient involvement in research and development, with a focus on enhancing diversity in clinical trials and fostering a patient-first mindset throughout the organization and treatment lifecycle. Her strategic planning also supports Bayer's objectives in early research and cell and gene therapy, driving innovation and patient focused studies.

Before joining Bayer, Penn was the first administrator of the world's largest cord blood stem cell program, making significant strides in advancing stem cell research and treatment. She founded and led the New York City Hemophilia Chapter, a not-for-profit organization dedicated to improving the health and quality of life for newly diagnosed families and previously isolated individuals with rare bleeding disorders. Additionally, Penn founded the Hemophilia Walk in New York City, playing a pivotal role in uniting and galvanizing the national bleeding disorders community. As a sought-after collaborator, partner, and mentor, Penn is recognized for her ability to build and foster relationships with diverse stakeholders and patient communities. She holds a JD from Rutgers University School of Law and an MPH from Columbia University School of Public Health.

Meenakshi Valadi
Director of Engagement
Clinical Research Justice League

Meenakshi Valadi is the Director of Engagement at the Clinical Research Justice League (CRJL), where she leads strategic partnerships with sites, sponsors, and volunteers to advance justice-centered clinical research. With a background in microbiology, a Research Coordinator by profession, and a deep commitment to inclusive care, her work bridges underrepresented communities with research opportunities that foster trust and representation.

Thad Wolfram
Chief Strategy Officer
EmVenio Clinical Research

Thad Wolfman is the Chief Strategy Officer at EmVenio Clinical Research, bringing over 20 years of experience in clinical trials, healthcare, and the pharmaceutical industry. He has held leadership roles at PPD, EY, and PA Consulting Group, where he led initiatives in corporate strategy, development, and scientific research. Wolfram is passionate about driving innovation and shaping the future of clinical trials.

Derrick Gingery (Moderator)
Executive Editor at *Pink Sheet*
Citeline

Derrick Gingery focuses on the US FDA user fee programs, regulations and policy for new and generic drugs, biologics and biosimilars, advisory committee and other agency activities, as well as federal legislation and budget matters on Capitol Hill. He also hosts Pink Sheet's Pharma Regulatory Podcast. An award-winning journalist, Gingery has been a reporter for several community newspapers and a business journal. When not following FDA, Gingery is keeping close tabs on Indiana University basketball.