SEPTEMBER 30, 2025 ROUNDTABLE SUMMARY

Pharma Ignite | SCRIP Industry News & Insights

Rethinking Trial Access Through Trust-Driven Design and Local Collaboration

Panelists:
Ewa Carrier, MD, Vice President, Clinical Development, Fibrogen
Savine DaCosta, Clinical Trial Access and Representation Site Lead, Biogen
Jeff Huntsman, Chief Commercial Officer, EmVenio Clinical Research
Prakrithi Ramesh, PharmD, RPh, Site Engagement Lead, Sanofi

Moderator:
Nick Patterson, Director, RWD Sales Compliance & Pricing Strategy, Norstella

KEY TAKEAWAYS

- Long-term community engagement is essential to improving trial access and patient retention.
- Designing trials around the patient is a key driver of long-term engagement.
- Inclusive trial designs have benefits for patients, sponsors, and health systems.

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OVERVIEW

Despite growing efforts to improve access and representation in clinical trials, reaching underserved populations remains a challenge. Traditional recruitment models centered around large medical centers often fail to engage patients in community settings. What's needed is a shift toward trust-driven partnerships and trial designs that prioritize patient experience, convenience, and cultural relevance from the start. **EmVenio** is a is a global leader in clinical research with deep roots in community-based research solutions. Its origins trace back to the 1990s, when its parent company, Professional Case Management (PCM), began delivering in-home rehabilitative nursing care to patients. Building on this foundation of mobile, patient-centered service, PCM launched a clinical research division in 2008 focused on expanding trial access through mobile visits and decentralized trial design. In 2025, PCM unified its research efforts under the EmVenio name to lead the industry in globally scalable, community-based clinical trial delivery.

CONTEXT

The panelists discussed how sponsors are rethinking access through community collaboration, culturally relevant trial design, and scalable operational models. The discussion highlighted how aligning trial strategies with the realities of diverse patient populations can help improve enrollment, reduce total trial costs, offload burden on health systems, and strengthen long-term patient retention through sustained engagement and trust.

KEY TAKEAWAYS

Long-term community engagement is essential to improving trial access and patient retention.

Historically, people in underserved communities — including those in rural areas or facing socioeconomic and mobility challenges — have struggled to access and participate in clinical trials. Even when sponsors made efforts to engage these populations, enrollment and retention remained difficult. Building trust with healthcare institutions and tertiary research centers, which is essential for meaningful engagement, has often been a significant barrier. To reverse this trend and improve trial access and patient retention, sponsors need to build long-term community engagement into their clinical trial strategies.

One effective approach is to ensure that clinical research partners, including principal investigators (PIs) and other site personnel, are locally embedded in the communities from which they are looking to recruit patients.

> "It's important that our clinicians are from those communities as well, because it's a big trust factor of where they can see [community members] in the food store or at the park instead of just asking them to come to a site as part of study participation. They understand the multiple bus lines patients might have to take to get to a site, they understand what's going on in the community. . . That's how trust is built up."
>
> – *Jeff Huntsman, EmVenio Clinical Research*

Cultivating long-term community engagement based on trust is also about ensuring PIs have the cultural competency and humility to engage with patients on their level. "The people working at the clinical trial sites should be able to identify with the experiences of the community," Savine DaCosta, clinical trial access and representation site lead at Biogen, said.

> "If you don't necessarily look like someone from the community, you at least need to be able to welcome people from the community into your site in a humanistic way."
>
> – *Savine DaCosta, Biogen*

Designing trials around the patient is a key driver of long-term engagement.

To make long-term community engagement a reality, sponsors need to embed flexibility and cultural relevance into trial protocols. This means trials need to be designed with patients' needs, experiences, and day-to-day challenges in mind—not solely for the convenience of PIs or sites.

> "Patient protocols are typically written as a scientific exercise and what's lacking in the process is having the patient journey in mind."
>
> – *Ewa Carrier, MD, Fibrogen*

Some sponsors recognize that traditional trial protocol designs can hinder patient recruitment, particularly among populations that face barriers to participation. In response, they've begun evolving their processes to better support broader and more inclusive engagement. For example, Sanofi has an entire department dedicated to incorporating the patient voice into protocol design.

"As we write the protocol, we contact patients and hear patient experience narratives. This brings their perspective of how they feel when they have the disease, what their pain points are, and what they are looking for," Prakrithi Ramesh, PharmD, RPh, site engagement lead at Sanofi, said.

> "When you're designing a trial for the working patient, you can't have a very rigorous schedule of activities, crazy endpoints, and a lot of blood draws. It's really inconvenient for the patient."
>
> – *Prakrithi Ramesh, PharmD, RPh, Sanofi*

Incorporating the patient voice goes beyond just calling patients at the outset to get their initial feedback and extends to involving them as consultants throughout the process, where they sit side by side with the clinical study team. "That way, if the team goes out of scope, you have someone who can say, 'Wait a minute, why are we adding this element and how will it impact participants,'" DaCosta said. She noted that the need for bringing in the patient is underscored by the fact that there are still people in the industry who call study participants "subjects"—an outdated, dehumanizing term.

> "It's really about creating optionality by listening to the patient, as opposed to somebody sitting in a room designing a trial protocol that has no idea how it is going to get operationalized. That's the disconnect with the scientists."
>
> – *Jeff Huntsman, EmVenio Clinical Research*

Inclusive trial designs have benefits for patients, sponsors, and health systems.

Inclusive trial design that decentralizes trials by bringing them away from major medical centers and into communities is good not only for patients, who don't have to spend time and money to travel to faraway sites, but it is also good for sponsors, because it increases access and can bring costs down.

For example, EmVenio's trials often take place in community research sites located in parking lots near churches, YMCA centers, or other community hubs. This approach reduces reliance on hospital resources – particularly for assessing secondary endpoints – and can improve retention rates through greater convenience, potentially lowering the total number of patients needed.

Incidentally, this also helps offload pressure from the healthcare system, which is already overwhelmed as demand for care surpasses capacity. Thus, hospitals concerned about losing a revenue stream due to decentralized trials should not perceive community-based trial sites as competition but rather as a "We're here to help" offer, Ewa Carrier, MD, vice president of clinical development at Fibrogen, said.

> "Community-based trial sites can be like satellite clinics."
>
> – *Ewa Carrier, MD, Fibrogen*

CONCLUSION

As the industry continues to expand clinical trial access and foster broader inclusion, leaders must prioritize strategic, sustainable approaches to ensure long-term success. One such approach is committing to intentional and authentic engagement with communities where these patients live; for example, by setting up community-based research sites in familiar locations, liaising with faith-based organizations, or partnering with trusted local leaders. These efforts help sponsors build trust, which is essential not only for initial recruitment but also for long-term retention and repeat participation. Importantly, trial sites themselves should be included as part of this engagement strategy, as they serve as a natural bridge between sponsors and the communities they aim to serve.

> "Community engagement needs to be intentional, not transactional. Sponsors should be engaging with patients not to recruit for one program or one study... but because they want to build trust."
>
> – *Prakrithi Ramesh, PharmD, RPh, Sanofi*

Another method is developing relationships with patient advocacy groups, which often maintain patient registries—including rare and ultra-rare diseases—and can provide hard-to-get insights into disease histories and patient journeys. These groups can be an important ally for sponsors as they frequently organize events with patients, which can serve as a launchpad for unobtrusive yet genuine sponsor involvement with patient communities.

Lastly, sponsors should consider designing trials that can easily be embedded into routine clinical practice, which will naturally expand trial availability in underserved areas.

> "The patient journey is such that when the patient is ill and goes to their doctor, the doctor [should be] able to say, 'Here are your options and clinical research is a part of those options.'"
>
> – *Savine DaCosta, Biogen*

ADDITIONAL INFORMATION

To learn more, visit **EmVenio Clinical Research**

BIOGRAPHIES

Ewa Carrier, MD

Vice President, Clinical Development
Fibrogen, Inc.

Dr. Ewa Carrier is an accomplished oncologist, hematologist, and transplant physician with extensive expertise in clinical development, medical affairs, and preclinical research.

Currently serving as VP of Clinical Development at Fibrogen, Inc., she has led global collaborations with industry leaders such as Genentech and AstraZeneca to advance groundbreaking treatments. Carrier holds a US patent for innovative stem cell technology and has developed FDA-approved first-in-human transplant protocols, pioneered prenatal transplant models, and contributed to the establishment of novel cancer therapies.

Her strategic vision and leadership have driven successful programs in regenerative medicine and oncology globally, including initiatives in India focused on stem cell and transplant programs.

Savine DaCosta

Clinical Trial Access and Representation Site Lead
Biogen

Savine DaCosta is Clinical Trial Inclusion Specialist with over 25 years of industry experience. She is a seasoned expert in sales, marketing, patient engagement, and community engagement in therapeutic areas, including Rare Disease, Respiratory, Infectious Disease, Oncology, Vaccines, and Neurodegenerative. She is passionate about transforming clinical research through inclusive participation and authentic engagement. In her role, DaCosta bridges the gap both internally and externally between research, clinical trial sites, and underrepresented communities. She designs and implements inclusion-focused engagement strategies that drive results. Her mission is to ensure that healthcare innovation reflects and serves all communities. DaCosta thrives at the intersection of strategy, inclusion, and implementation.

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 in 2024 with over 30 years of experience guiding global commercial teams in clinical development and regulatory spaces.

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.

Prakrithi Ramesh, PharmD, RPh

Site Engagement Lead
Sanofi

Driving strategic site partnerships and clinical research excellence, Prakrithi Ramesh specializes in optimizing clinical research operations and fostering strong relationships with research sites. Ramesh is focused on enhancing site engagement strategies and streamlining clinical trial processes to accelerate drug development and improve patient outcomes.

Nick Patterson (Moderator)

Director, RWD Sales Compliance & Pricing Strategy
Norstella

Nick Patterson is an accomplished leader in clinical trial project management, patient recruitment, and clinical trial technology implementation. He combines operational expertise with strategic insight to drive efficiency and compliance across the clinical development lifecycle. With certifications in Project Management and Six Sigma, Patterson applies proven methodologies to optimize trial execution through data, technology, and best practices. He is deeply committed to improving patient access and ensuring each eligible individual has the opportunity to receive the treatments they need.