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The Data Still Matters. How It's Collected Matters More

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The Data Still Matters. How It's Collected Matters More

Retention, data quality, and execution pressure are forcing sponsors to rethink not just what evidence they generate, but how and where it is produced. Community-based research is no longer peripheral to that conversation.

Clinical trial innovation has long focused on improving data quality through better protocols, monitoring, and analytics. The 2025 Trends in Clinical Trials Survey, conducted by Citeline in partnership with EmVenio Clinical Research, highlight a more practical reality. The ways in which data is collected, and whether patients can realistically participate in the protocol as written, are now becoming just as influential as the scientific methodology itself.

Community-based research has typically been viewed as an access solution, a way to reach patients who struggle to participate in traditional site-centric trials. But findings from last year's survey, alongside emerging operational and technology perspectives, point to something broader. As trials grow more complex and enrollment pressure intensifies, the mechanics of data collection are becoming a limiting factor.

Only 56% of organizations reported actively using community-based models in 2025, despite widespread agreement that these approaches can improve patient retention and shorten study timelines. This disconnect reveals a deeper tension. Sponsors may understand the theoretical value of community-based approaches in principle, but many still stop short of adopting community-based approaches as a core infrastructure, instead treating them as situational add-ons.

Heading into 2026, the science behind trial design remains steady; what's changing are the assumptions about where and how evidence is produced.

Participation Is No Longer A Downstream Concern

One of the clearest signals from the survey is the growing recognition that patient retention has become inseparable from trial performance. Improved retention ranked as the top perceived benefit of community-based research, ahead of faster recruitment and increased diversity.

EmVenio's chief medical officer, Dr. Mark McKenzie, frames the issue in practical terms: "Anything that makes it easier for a patient to participate in a clinical trial and maintain compliance with the protocol can be beneficial to overall study success," he says.

Too often, he notes, qualified patients enroll but later disengage when the demands of repeated site visits clash with work, caregiving responsibilities, or geographic constraints.

"The less we negatively impact the daily life and routine of a study participant, the more likely they are to stay engaged," Dr. McKenzie adds.

This is not a question of convenience for its own sake. Attrition affects timelines and data quality in ways sponsors can no longer afford to ignore – a reality underscored by the 2025 research. Community-based models are emerging as a practical response to longstanding operational weaknesses in traditional trial execution.

From Access Solution To Operating Model

Historically, community-based research has been deployed reactively: when enrollment stalled or diversity targets slipped, sponsors relied on mobile visits or satellite locations as correct measures.

Philip Stanford, vice president of research technology at EmVenio, argues that this perspective is beginning to shift.

"For years, the industry treated community-based research as a bespoke rescue tactic rather than a core strategy," he says. He notes that infrastructure maturity is changing that equation. Sponsors now have access to established, professionalized networks that can be activated quickly, rather than building community-based capabilities from the ground up.

"When a sponsor plugs into a mature community-based network, they're not just getting a location," Stanford explains. "They're getting trained mobile clinical staff, integrated eSource technology, and established community trust."

That distinction matters. Much of the perceived complexity cited by non-adopters reflects the burden of building capabilities internally. As external infrastructure becomes more standardized, the operational barrier to entry begins to fall.

At the same time, traditional sites are approaching a capacity ceiling. Complex protocols, overlapping studies, and staffing constraints continue to strain established academic and hospital-based centers. In this environment, community-based models are less about replacing sites and more about extending the system's overall capacity.

Data Quality Moves From Reassurance To Differentiator

One of the more striking findings in the Citeline research was the shift in perception around data quality. Nearly nine in ten respondents said community-based research produces data that is equivalent to or better than site-based models, and only a small minority believed data quality suffered.

As these models mature, the focus is moving away from theoretical concerns about oversight to practical questions of execution.

Stanford believes 2026 will mark a turning point: "Retention is the fuel of a trial," he says, "but data accuracy, specifically real-time data integrity, will be the defining priority." In distributed settings, the ability to capture data directly into eSource at the point of care, whether in a mobile research unit or a patient's home, functionally shifts how sponsors think about oversight.

"We're reaching the end of duplicate data entry," he adds. "Sponsors want clean, audit-ready data in real time, not a query storm at the end of the study."

Sponsors are redefining what control looks like, placing greater emphasis on system reliability and real-time visibility than the physical location of trial activity. The outcome? Community-based models that demonstrate high retention and immediate, high-integrity data capture will excel, resulting in comparative, rather than defensive, value propositions.

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Regulation As Operating Context, Not Obstacle

Regulatory concerns in the 2025 survey were concentrated among non-adopters. As experience with community-based models grows, those concerns appear to be losing influence.

For Dr. McKenzie, ICH GCP E6(R3) provides a clearer framework for patient-centered trial conduct. "Industry understanding and adaptation of the R3 guidelines can lead to more support for patient-beneficial trial conduct", he notes – a shift he believes will help ease regulatory hesitation as experience accumulates.

By emphasizing proportionality, ICH GCP E6(R3) enables oversight to more accurately reflect trial risk, reducing the administrative friction that has historically kept community-based models on the margins, Stanford adds.

In 2026, diversity is no longer an adjacent consideration in trial planning. The data shows that alignment is already in motion, with community-based approaches emerging as one of the more workable ways sponsors are meeting those expectations.

New Metrics Are Coming Into Focus

Interest alone has not translated into widespread adoption of community-based research. Survey data indicates that decisions continue to hinge on demonstrable evidence, particularly around time and cost efficiencies.

Where sponsors seek that evidence is starting to change.

Rather than relying on static cost-per-patient benchmarks, sponsors are increasingly focused on indicators that expose delay and execution risk.

"Each day of delay costs millions," Stanford notes. Metrics such as time to first dose, site startup velocity, and screen-to-randomization ratios offer a clearer view of where trials stall and why.

These metrics are also prompting a more practical examination of patient burden. Travel requirements, visit schedules, and administrative demands surface quickly when enrollment slows or sites struggle to keep patients engaged. In that context, reducing friction becomes less about patient experience and more about protecting trial continuity and cost control.

From Dr. McKenzie's perspective, the bar has not moved. Sponsors still judge performance on whether trials run safely, remain compliant, and keep patients engaged through completion. Community-based sites earn confidence only when they can consistently deliver on those fundamentals.

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Beyond Early-Fit Therapeutic Areas

Respiratory and infectious disease trials may have led early adoption of community-based models, but suitability is increasingly defined not by indication, but by how well a protocol functions outside traditional sites.

"Any trial that has visits that can be done remotely or in a patient's home appropriately is amenable to a community-based approach," Dr. McKenzie says. Suitability is now determined by protocol logic rather than therapeutic label.

Metabolic and rare disease trials are beginning to expose the limits of site-centric design. Large obesity studies and geographically dispersed rare disease populations impose participation demands that traditional models struggle to meet. In this context, Stanford argues the primary risk is no longer structural complexity, but delay, noting that traditional sites have "hit a capacity ceiling".

From Option To Expectation

Trial participation is exerting growing influence on how studies are designed, shaping protocols more directly than it did even a few years ago.

Patients are now accustomed to local access, remote touchpoints, and flexibility in routine care. That familiarity shapes how they approach clinical research. Designs that require repeated travel to centralized sites are no longer viewed as the default, particularly when viable alternatives exist.

Dr. McKenzie notes that patients "appreciate the options it provides and will continue to ask for more". In practice, that expectation tends to surface when participation becomes difficult to sustain. Interest wanes, visits are missed, and protocols become harder to execute as designed.

According to Stanford, trial models are now being tested against how people already engage with healthcare, with participation pathways that allow certain visits to occur locally or remotely, proving easier to sustain over time.

This shift does not point to a single preferred model, nor does it displace established sites. Instead, it signals a shrinking tolerance for study designs that overlook the practical demands of patient participation.

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